Developing a measure of informed choice in cancer screening

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Declaration

I declare that this thesis is entirely my own work and that it has been submitted only for the degree of PhD.

Abstract

The principle of informed choice has recently become incorporated into cancer screening policy. However, there has been limited empirical or theoretical work on informed choice in this particular context. The main aim of this thesis is to develop an instrument/approach that could be used to measure informed choice in both research and service settings. The principal research question is, 'What are the key domains of informed choice in cancer screening, and how best can they be measured?'

Systematic reviews were undertaken to identify the relevant qualitative and quantitative studies. A qualitative study (nine focus groups and 15 individual interviews) was undertaken with people who had different experiences of screening (for breast, cervical or colorectal cancer). The purpose of the study was to identify the key domains of informed choice. Data from the qualitative study were used to define the items in the questionnaire. The questionnaire was piloted initially by sending it to a sample of 150 screening invitees and 54 replied (36%). It was then further refined and sent to 1292 people who had been invited to participate in one of the three types of screening. Of these, 553 returned a completed questionnaire (43%).

Findings from the systematic reviews suggested that lay people define and conceptualise informed choice differently from researchers and policy makers. These findings were substantiated in the data from the qualitative study. The study also found that information on the disease was as important to people as information on the risks and limitations of screening. However, information may have little part to play in the choices people make. It may have more impact on outcomes such as satisfaction and anxiety. Analysis of the questionnaire data found that people had limited knowledge of the risks and consequences of screening. In addition, perceived informedness was strongly predicted by attitudes rather than the knowledge of the risk and benefits. High levels of knowledge were not a predictor of the level of choice people had.

The main policy reason for promoting informed choice is to enhance autonomy and to prevent people being deceived or coerced. However, this research shows that the provision of evidence-based information alone does not necessarily mean that an informed choice is made. People may not read, want, or understand the information, and, additionally, people may not be able to carry out their intended choice. For example, people may feel that they do not have the choice to refuse screening, even though they might wish to do so. Moreover, there may be personal barriers, such as physical or mental health problems and language, or organisational barriers, such as the availability of the service/intervention and access. This research identifies the complexity of the relationship between information and choice, revealing a number of reasons why the concept of 'informed choice' requires more subtle understanding in the context of cancer screening.

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CHAPTER 1. INTRODUCTION

The principle of informed choice has recently become incorporated into cancer screening policy. However, there has been limited empirical or theoretical work on informed choice in this particular context. The objective of this thesis is to define and measure the core components of informed choice in cancer screening. The principal research question is, *'What are the key domains of informed choice in cancer screening, and how best can they be measured?'* In answering this question, a central part of this thesis was the development of a reliable and valid measure (using a self-completed questionnaire) of informed choice in cancer screening. The purpose of developing such a measure was so that it could be used to evaluate screening policy and practice, used to assess population levels of informed choice, and used as an outcome measure in studies of informed choice interventions.

Before developing the measure of informed choice in cancer screening, several areas needed to be explored and understood. Firstly, the role of cancer screening and its context in the wider health care arena. Secondly, definitions of informed choice, and its relationship to other concepts such as informed consent and patient autonomy. Finally, what informed choice means to people invited for screening. The first two areas were explored using literature reviews while the last area was explored by undertaking qualitative research. Once these three areas were fully explored, a measure of informed choice was developed and validated.

1.1 Structure of the thesis

The first chapter is an overview of the different methodologies (the philosophical or theoretical assumptions underlying the research process) and methods (specific techniques for data collection under those philosophical assumptions) used in the research. It also briefly describes the emergence of the importance of informed choice in cancer screening and why it is an important area of research. The second chapter describes the issues important to cancer screening and informed choice, including risk and autonomy. The third chapter is a systematic review of the literature and includes a review of other relevant measures of informed choice, as well as a review of relevant

qualitative and quantitative research. Chapter 4 describes the methods used to develop and carry out the qualitative and quantitative studies (including the measure of informed choice in cancer screening (MICCS). Chapters 5 and 6 present the results for both the qualitative and quantitative studies. Chapter 7 discusses the results, and concludes with implications for policy and for further research in this area.

Informed choice is a complex concept and its implications and applications have not been widely researched within the context of cancer screening. The aim of this research was to provide a convincing argument on why informed choice is important to measure, what are its principle components and how best it can be measured. To answer these questions, three different methods were employed in this research; systematic reviews, a qualitative study, and a quantitative study.

1.2 Methods

While the specific research methods used in each part of the research will be outlined in more detail in the relevant chapters,[1] they are briefly summarised here.

Systematic reviews

Systematic review methods were used to identify and synthesise three types of studies. The first systematic review evaluated other instruments that measured some aspect of informed choice about healthcare decisions. The main purpose of this systematic review was to identify instruments that could either be used as a gold standard, or used in the theoretical development of the measure of informed choice.

The second review evaluated both qualitative studies and quantitative studies. It was part of a larger Cochrane review which is currently in progress (Broclain et al, 2004). The first part of the review evaluated qualitative studies that aimed to provide data on patients' understanding of informed choice in cancer screening. In this review, the empirical data from the qualitative data were used:

[1] In respect to the methods chosen for this research, I initially applied to the CSO for a training fellowship to develop a measure of informed choice for use in RCTs and to evaluate screening policy. One of the reasons I chose this research question was to receive training in, and gain experience of, both qualitative and quantitative methodologies.

- to provide insights on concepts such as 'informed consent', and 'comprehensive information' in the context of decision-making about screening
- to explore what types of information about screening invitees valued in order to make a decision, and why
- to answer questions about the use, appropriateness, and acceptability of interventions.

This review was followed by a review of quantitative studies. There were two main reasons for having such a systematic review. Firstly, it provided a theoretical and conceptual background for the development of the measure of informed choice. In the intervention trials, it was the underlying constructs and definitions that I was interested in, rather than the effect of the interventions. In other words, I was interested in the definitions of informed choice used in these trials, and the variation in information included in the interventions.

Secondly, it increased my understanding of what informed choice interventions were being developed, and how these interventions were evaluated. One of the reasons for developing this measure of informed choice is so that it could be used as an outcome measure in such trials. I therefore needed to determine whether there were other measures of informed choice in cancer screening, which evaluated outcomes in these trials.

After the two reviews had been undertaken, the results of the qualitative and quantitative reviews were combined. The purpose of this synthesis was to ascertain how members of the public defined informed choice, and their definition related to definitions of researchers and policy makers. These systematic reviews provided me with a good understanding of the significant theoretical, conceptual and developmental work in this area.

Two primary studies were undertaken in this thesis (a qualitative study and a quantitative questionnaire study). All the research was undertaken in Scotland, within three types of screening (breast, cervical and colorectal).

Qualitative study of informed choice in cancer screening

It has been argued that qualitative research is a prerequisite of good quantitative research, particularly in areas that have been subject to little previous investigation (Pope and Mays, 1995). The starting point for research in a new area of health behaviour is an attempt to understand how and why people conceptualise issues, and why they behave as they do when faced with them. With informed choice in cancer screening, therefore, I needed to understand what that concept meant to people participating (or not) in screening, and how the provision of information affected their screening behaviour. Thus, the qualitative study provided insights into the broad concept of informed choice and enabled me to develop a theoretical framework. In addition, it enabled me to evaluate whether there were differences in the information patients wanted in order to feel informed compared to the information policy makers and researchers thought was important.

Quantitative study of informed choice in cancer screening

The main aim of this research was to develop a measure of informed choice. Informed choice is argued to be an important concept for ethical and legal reasons (see later sections). If this argument is accepted, then it is logical to ask, 'Why should it be measured? The response is that measurement may encourage health professionals to be accountable and to know and to explain clearly what they plan to do, and why (Alderson and Goodey, 1998). By having an objective measure of whether a person is making an informed choice or not, may defend them from unwanted interventions or treatment. In addition, it can be used to evaluate the effectiveness of policy and research in this area.

Such an empirical approach assumes that informed choice is something which is measurable. Yet, even if all the constructs of informed choice are not able to be precisely measured, a questionnaire may be useful in other ways; firstly, as a 'checklist' to make sure that all the potentially relevant areas of informed choice have been covered; and secondly, to explore relationships between autonomy and informed choice within the context of public health policy. These relationships have never been assessed before. Measurement of informed choice can also enable comparison of levels of choice, autonomy, coercion and knowledge *between* screening programmes. For example, the way screening programmes are organised may affect the extent to which a person can act

autonomously; a person doing a screening test at home (bowel cancer screening) may be more 'autonomous' than a person who needs to go to their GP for the screening test (cervical screening). In addition, the characteristics of those taking part (such as age and gender) may affect such variables.

The measure of informed choice in cancer screening (MICICS) developed, piloted and validated in this study was a self-administered questionnaire that included items on knowledge, attitudes towards screening and decision making, and socio-demographic factors. Although qualitative methods can help understand and define the key domains of informed choice, a quantitative measure can add to our understanding in several ways. In particular it can aid understanding of the degree to which people use information in their screening choices, and the extent to which it varies amongst different populations (e.g. by age, gender, and screening type). To develop the measure I drew on different paradigms.

1.3 Research paradigms

This section briefly describes different theoretical and philosophical paradigms for assessing the acquisition of knowledge about the concept of informed choice. This study deliberately employed both qualitative and quantitative methods. However, it has been argued that these methods relat to two different and competing inquiry paradigms (or methodologies) (Patton, 2000: 37). Patton describes the two paradigms as: *logical-positivism* which uses quantitative research methods to deductively test out a priori hypotheses; and *constructivism /phenomenology/interpretivism* which uses qualitative methods to inductively understand human experience in context specific setting. The complex nature of informed choice and the political and moral context of cancer screening (see Chapter 2) meant that I had to carefully consider the position of my research within these two paradigms.

Positivism

Positivism is an epistemological position which believes that science can be conducted in a way which is value-free (i.e. objective). It entails elements of both inductive and deductive approaches (Bryman, 2001:12). In research terms, for a positivist there is one

reality outside the researcher that should be discovered by the researcher. Attempting to objectively measure informed choice/consent has been described as taking a positivist approach. It has been argued that positivist concepts of consent sometimes distinguish factual concepts through dichotomies: informed/non-informed; coerced/not coerced; choice/no choice (Alderson and Goodey, 1998). However, informed choice can also be viewed on more of a continuum (e.g. fully informed, partially informed, or uninformed). Positivists would view consent as being real and measurable, as opposed to being constructed. A positivist approach would assume that consent and choice are outcomes, rather than part of a process.

Constructivism

The second paradigm (which some argue to be a competing paradigm) is constructivism (or phenomenology/interpretivism). Constructivism is an ontological position which asserts that social phenomena and categories are in a constant state of revision and socially constructed. It includes the idea that the researcher's own accounts of the world are social constructions, rather than definitive (Bryman, 2001:12). Constructivists argue that objective knowledge of the world is impossible, since all observation is driven by pre-existing theories or values on how objects are constituted and why some objects are selected rather than others (Seale, 1999:23). In relation to choice and consent, social constructivism demonstrates how consent can be a complex, ambiguous process. For example, assessment of adequate information, competence and voluntariness can be seen as social constructs rather than universal standards (Alderson and Goodey, 1998). Social constructivism demonstrates that without numerous social and personal influences, we would not have choices or the ability to choose.

For constructivists/interpretivists there are multiple and socially constructed realities. Proponents of emancipatory paradigms agree with the constructivist/interpretative view and add that these multiple realities are shaped by social, political, cultural, economic, ethnic, gender and disability values (Mertens 1998). Yet, this does not necessarily mean that one construction is more valid than another in explaining the nature of reality or 'truth'. Hence, the researcher's aim is to understand the multiple social constructions of meaning and knowledge (Mertens 1998). Informed choice can be viewed as being largely a social construct; it is neither a medical condition, nor a measurable outcome

like screening uptake. However, it can be argued that paradigms should not be the most important drivers of research into such concepts.

Mixing methodologies and paradigms

It has been argued that allegiance to one paradigm or the other may lead to methodological inflexibility. A more pragmatic approach suggested is the '*paradigm of choices*' (Patton, 2000). Using this approach the primary criterion used for methodological quality is methodological appropriateness rather than methodological orthodoxy. Thus it is the credibility of the research that is important rather than the particular methodological or philosophical position that underpins it.

It has also been contended that connections between research strategy and epistemological and ontological commitments are not deterministic (Bryman, 2001:433). Bryman suggests that it is by no means clear that quantitative and qualitative research methodologies are in fact paradigms. He claims that there are two main versions of the nature of research which have different implications for their combinations. The first, an *epistemological* version, contends that multi-strategy research cannot be undertaken (Bryman, 2001:446). The second, a *technical* version gives greater prominence to the strengths of data collection and data analysis and sees these as being compatible. There is recognition of the different epistemological assumptions, but the connections are not viewed as intractable. Therefore, the technical version is similar to the paradigm of choices described by Patton. Both emphasise the strength and quality of the data rather than strict adherence to a particular paradigm.

The purpose of this research was to develop a measure that was valid and workable within current organisational constraints of screening. I initially approached this research wanting to, and assuming I could, measure informed choice (a positivist stance). However, after discussions with sociologists, and anthropologists, combined with reading about the different paradigms, I realised that this was a narrow and limiting stance to adopt. I therefore drew on both paradigms; using the interpretative/constructivist paradigm enabled me to accept multiple constructions of informed choice. Using a positivist approach enabled me to accept that there was

something about informed choice that was measurable. However, the main reason why I combined methods was from a *technical* perspective, with the primary criteria being methodological appropriateness and quality.

1.4 My personal perspectives

My background is as a health services researcher, who worked for many years undertaking systematic reviews. I embarked on the research with an epidemiological perspective. However, as I began reading, I realised that screening was more than a public health policy aimed at identifying asymptomatic disease. Therefore I broadened my perspective to look at the social, political and historical context of screening and informed choice. From a personal perspective, I approached this as someone who was largely neutral about health screening. I also had an open mind about the concept of informed choice.

1.5 Boundaries to the research

Within cancer screening there are many different screening tests. This research had to be limited in some way to make it meaningful, manageable, and appropriate. I therefore only considered informed choice within the context of national cancer screening programmes (i.e. breast and cervical) or pilot cancer screening programmes (i.e. colorectal). In addition, I only included the standard tests that are used as part of the programmes; mammograms for breast screening, Papanicolau (Pap) smears for cervical screening[2] and faecal occult blood tests (FOBt) for colorectal cancer screening. In this research, I was not evaluating the effectiveness of screening, nor national screening policies that are in place. Rather I was interested in how the process of promoting informed choice in screening is implemented and evaluated. Genetic screening for cancer was not considered, as the issues of informed choice are very different and more complex.

[2] At the time of starting the study, the most common way of taking a cervical sample was using a spatula. However, during the course of the study, some women reported having it taken using liquid based cytology (LBC).

1.6 Screening for disease

This following section provides an overview of screening, and emergence of informed choice in this area. It briefly defines health screening including its benefits, limitations, and consequences. It highlights some of the controversies and debates surrounding screening, and the emergence of informed choice.

Screening stands apart from traditional medicine in that it seeks to detect disease in individuals before they present with symptoms to a health professional. Screening separates apparently well persons who have a disease from those who probably do not (Holland and Stewart, 1990). The purpose of cancer screening is to reduce mortality in people who develop cancer, by detecting it at a stage when treatment is most likely to be effective. Screening not only refers to the tests (i.e. mammograms, cervical smears, and faecal occult blood tests) but the entire screening process (often referred to as a screening programme). The screening process comprises activities such as identifying and inviting people to be screened, the screening test, diagnostic tests when an abnormal result is detected, treatment, and follow-up.

The effectiveness and appropriateness of screening programmes are assessed according to stringent criteria (National Screening Committee, 1998; Wilson and Jungner, 1968) (see 2.8). In screening for a particular condition, a large number of apparently healthy people are tested in order to identify a small number of people who have preclinical disease (i.e. before they present to a clinician with symptoms).

Benefits of screening include improved prognosis for some cases detected by screening; less radical treatment that cures some early cases; resource savings and reassurance for those with negative test results. Unintended adverse effects of screening potentially include longer morbidity for cases whose prognosis is unaltered; over treatment of questionable abnormalities; resource costs; false reassurance for those with false negative results; anxiety and sometimes morbidity for those with false-positive results; and process hazards of screening tests (Chamberlain, 1995). In addition, other non-malignant conditions such as ductal carcinomas in situ may be detected through screening. The identification of such conditions has been described as a subtle but potential harm of screening (Ernster and Barclay, 1997; Schwartz et al, 2000). Each

programme has different benefits, limitations, and consequences (see Chapter 2) which can generate enormous controversy and debate.

In the UK, cancer screening programmes are primarily government initiatives, and fall under the umbrella of public health. There are currently two national cancer screening programmes (breast and cervical cancer) and one pilot screening programme (colorectal cancer).

1.7 Debates over screening

The issue of whether cancer screening is of value has been fiercely, and publicly, debated over the past 25 years (e.g. Barr, 2003; Baum, 2003; Skrabanek, 1988a; Warren, 1988).[3] For example, the controversy surrounding breast cancer screening has been described as, 'a *brawl, stoked by uncertain evidence, differing worldviews and plenty of invective* [4] (Taubes, 1997). Many public and professional bodies support and promote cancer screening, from politicians and clinicians, to the media and lay pressure groups. There are also many critics, but opposition comes primarily from clinicians, epidemiologists, and those who have been involved in screening programmes. Proponents of screening argue that the benefits for the populations being screened are great and the harms are likely to be minimal, or acceptably low in view of health gains. Critics argue from various standpoints; from its lack of proven effectiveness to the lack of focus on primary prevention, natural history, and resources allocation. The debate also takes place on moral, feminist and political grounds. For example, one critic of screening stated that, *'To be sceptical about screening in this country is to be in favour of sin, against virtue and anti-woman'* (BBC News Online: Health, 2000). The next chapter will include further discussion of these debates and how they affect informed choice.

Screening does not only benefit the individuals who have their disease detected and cured. Many other individuals and organisations benefit and may have a vested interest

[3] These debates focus on the value of breast screening, but there are other debates around cervical screening which are discussed in the next chapter.
[4] The debate centred on whether women in their forties should be screened for breast cancer or not.

in it:[5] clinicians (who base their career on it), politicians (who can win votes from it), radiologists and lab technicians (who are employed by screening programmes), and manufacturers of the tests and equipment (who financially gain from it). Many of the debates surrounding cancer screening (particularly breast cancer screening) are not about the scientific value of screening. Rather, the acrimony in debates reflects the entrance of concerns from political, legal and interests groups (Fletcher, 1997; Lerner, 1998). In addition, Lerner argues that metaphoric language such as 'the war against cancer' has entered scientific debate and, in turn, influenced it. This language, combined with the emotions that screening for cancer (particularly breast cancer) evokes, means that rational analysis of the facts is difficult. However, when 'experts' disagree so vehemently about the effectiveness of an intervention, it may mean that whatever effect may be present is small, and the argument complex (Lerner, 1998).

One particularly difficult issue to resolve in the debates about screening is that (as described in the previous section), it has the capacity to be both beneficial and harmful to individuals. This is a difficult concept to convey to the public. It has been argued that whether the benefits outweigh any harmful consequences is essentially a value judgement, which up until now has been made by *'paternalistic agents of the state'* rather than by those invited for screening (Thornton et al, 2003). By giving people the information on the risks and consequences, they can then make an informed choice or judgement themselves.

1.8 The emergence of informed choice in screening

To maximise cost-effectiveness, the focus of screening programmes has been to have the highest coverage and uptake of the population as possible. Until recently, the benefits of screening for cancer were deemed to be so great that any potential harm or limitations were given little attention (National Screening Committee, 2000). However, even when it is accepted that screening has a net beneficial effect, one of the inherent limitations is that some individuals will be harmed. Moral conflicts, and concerns over patient rights,

[5] This vested interest may well be beneficent and benign. I am not suggesting in any way that those who believe and work in the area of screening are doing it for financial gain. However, careers and reputations linked to screening may influence perceptions of its benefits.

arise where an intervention has the potential to cause both benefit and harm to an individual (Hall, 1992).

In recent years, all areas of healthcare have become increasingly interested in the concept of *informed choice* and the rights of the individual. The doctrines of informed consent and informed choice have ethical, legal and clinical interpretations that will be briefly discussed in this Chapter (and in more detail in Chapter 2). It is important to note from the outset that the expression informed *'choice'* not *'consent'* is principally used in this research, and there are subtle differences between the two terms (see section 2.17). However, the concept of informed choice is largely based on the principles of informed consent. Therefore, any discussions of informed choice draw heavily on the literature and theories of the doctrine of informed consent.

Screening policy makers now consider informed choice alongside more conventional screening parameters such as quality assurance procedures and improvements in survival. For example, in the second report of the National Screening Committee (National Screening Committee, 2000) Henrietta Campbell, the chairperson, writes:

'There is a responsibility to ensure that people who accept an invitation do so on the basis of informed choice, and appreciate that in accepting an invitation or participating in a programme to reduce their risk of a disease there is a risk of an adverse outcome.'

From this message, it is evident that those involved in screening policy have taken responsibility for promoting informed choice. As it may negatively affect cost-effectiveness, reasons why policy makers and screening programmes want to promote it need to be briefly considered.

1.9 Reasons for promoting informed choice: policy makers

Informed choice is likely to increase costs and resource use and may affect uptake. How, or if, it affects other screening outcomes such as uptake is not well understood (Jepson et al, 2001). The *reasons* given by the National Screening Committee for promoting informed choice are to recognise a change in social attitudes, and the acknowledgement of risks and consequences. They see that the *advantage* of increasing informed choice is that it prevents people feeling coerced. It is also seen as having economic advantages in

that an informed choice policy may create opportunities for selective screening based on individual risk profiles (National Screening Committee, 2000). However, even though there is a policy on increasing informed choice, other policies, such as target payments for uptake of cervical screening, may discourage health professionals from promoting it. For example, it has been observed that GPs are rewarded for the number of people they persuade to be screened, not the quality of information they give (Austoker, 1999). Informed choice is a policy that screening programmes are actively pursuing, but may be difficult to implement in practice if other policies hinder implementation. The qualitative study was undertaken when there were still targets for cervical screening. However, since 2004, GP targets for cervical screening have been abolished, and cervical screening is now an additional service which practices are able to opt in, or out of.

1.10 Reasons for promoting informed choice: patient rights

Over the last few decades the public in general, and bio-ethicists in particular, have become concerned about the rights of patients, informed consent and issues of patient control over their healthcare choices (Rogers, 1998). The concept of informed consent has been interpreted clinically, ethically and legally. The primary focus of informed consent is the disclosure of risk (of an intervention or medical procedure). In clinical care, informed consent was developed from an obligation of doctors to disclose information on the risks of procedures and act with beneficence and non-malfeasance.

The conditions required for informed consent are derived from the Declaration of Helsinki (Declaration of Helsinki, 1989). The judicial doctrine of informed consent in healthcare is primarily based on decisions about treatments. As an ethical principle, provision of unbiased information is seen as being the key to respecting patient autonomy and it has been argued that

'Patient autonomy is only protected where there is meaningful choice made by the patient, on the basis of adequate information, about which of the available therapies is acceptable, and as to whether or not to participate in any therapy at all.'(McLeod, 1989;11)

Informed consent is well established in the area of patient choices over treatment options, and participation in clinical trials and medical research. It is argued that to some extent screening policies are also experiments (but at the population level), and should

be governed by the same ethical principles (Skrabanek, 1990). Harm to uninformed individuals caused by screening leads to anger, bitterness and potentially litigation (Raffle, 2001). Informed choice is one way of tackling these issues.

The reasons for promoting informed choice from a patient's (rather than a policy maker's perspective) are to enhance autonomy, and to satisfy ethical and legal requirements. The potential advantages in providing information on the risks and benefits of screening are that it may reduce anxiety through giving people adequate explanations of the purpose of screening, and the meaning of test results (Foxwell and Alder, 1993; Graham et al, 2000; Green et al, 2004b). Conversely, however, such information has the potential to increase anxiety in women, although in one study they reported they wanted the information anyway (Davey et al, 2002). It can also lead to an increased understanding of what screening can offer and what it cannot. Lastly, it may allow individuals to have more control over their healthcare choices, and make their own value judgements about the benefits and harms. However, provision of information will not ensure that people make autonomous choices because other influences, such as coercion and control, may have a bigger impact.

Placing increased emphasis on informed choice may result in shifting the responsibility for screening behaviour away from providers on to individuals. This may have some benefits for the individual (increasing autonomy, satisfaction, and decreasing anxiety). However, it may also have important ramifications (such as the individual being expected to take responsibility for the decision when things go wrong and post-decision regret). Further discussion of this shift of responsibility will be discussed in Chapter 2.

1.11 Summary

This chapter provided an overview of the research including a rational for the methods and methodologies employed, and a brief introduction to some of the issues surrounding informed choice in screening. Screening cannot be viewed purely as a public health policy aimed at disease prevention. It has to be examined in a wider context; historical, political, social, and ideological. These issues will be discussed in more depth in subsequent chapters.

CHAPTER 2. LITERATURE REVIEW

The primary aim of this literature review is to provide a context for the notion of informed choice in cancer screening. A valid measure of informed choice can only be developed if the influences and external pressures on screening choices are understood. It has been argued that

'Not only is the concept of informed consent problematic within its own terms of reference, but ideas of autonomy, freedom and choice belie the extent to which they are both limited and regulated. The dualistic opposition between liberal concepts of freedom and autonomy versus powerful autocratic medical practices fails to recognise that power is not just a phenomenon that is exercised as an external constraint, but that prevailing cultural norms, values and systems of expertise shape the field of choice.' (Corrigan, 2003)

The literature review is divided into six sections. Section 1 considers the historical and political context of screening and choice. Screening is a public health policy; choice is a major value of our age. This section briefly describes some of the historical roots that can provide a useful perspective on the major political and social ideologies that influence them both.

Section 2 describes the literature surrounding the notion of risk. Screening cannot be viewed purely as a neutral strategy to reduce disease; it is embedded within a culture of risk reduction and self-responsibility. The section provides an overview of the discourse surrounding risk and responsibility. Understanding screening policy within this 'culture of risk' can provide insight into factors that may enable or impede informed choice. It will also aid understanding of what information is considered important, and how it is interpreted and used.

The third section focuses on screening and cancer epidemiology. It defines the epidemiological and medical rationale for screening, and some benefits, limitations and consequences of health screening in general. The epidemiology of the three types of cancer (breast, cervical and colorectal) and current screening tests and policies are described. The consequences and limitations of screening of the three cancer sites are highlighted. This section includes the underlying data that are used in provision of screening information.

Section 4 evaluates some of the theories surrounding informed choice. In particular it will look at the theories in relation to autonomy, which is one of the key tenets for informed choice. Some of the tensions between individualism and the 'public good' will also be discussed.

The fifth section discusses the emergence of informed choice in screening, and what is currently known in this area. Major distinctions between informed choice and informed consent will be outlined, as will some of the reasons underpinning the whole rationale for introducing informed choice into a public health policy.

The last section will evaluate some of the theories of risk, risk reduction, health behaviour and decision making, and how applicable they are as theoretical frameworks for the thesis.

SECTION 1. SCREENING AND CHOICE: A HISTORICAL AND POLITICAL PERSPECTIVE

Modern attitudes to health and individual choice can be traced back to the industrial revolution and Victorian times. Before industrialisation, people's outlook on life was defined by religion. Health was seen as *'a gift of God'*; health and suffering were seen as part of the *'eternal cosmos'* (Beck-Gernsheim, 2000). The industrial revolution resulted in millions of people living in over-crowded conditions with contaminated water and disease. The consequence was rampant sickness, and high infant and child mortality and morbidity; life expectancy of the working class averaged 20 years (Porter, 2002). During this period, the prevalence of Adam Smith's 'laissez-faire' economic theory influenced thinking on health; it was seen as the responsibility of the individual rather than the state. Porter describes the thought of that period,

'Government should uphold the law, the individual should be provident, and charity should rectify hardships. Even if the trade you worked was deadly, wasn't that a personal choice, freely taken? When workers fell sick, blame was often laid upon their faulty constitution, regarded or rationalised as the cause of disease.' (Porter, 2002)

There was a commonly held perception that poverty was due to 'idleness and fecklessness'. However, after the introduction of The Poor Law (1834) and following his experiences of workhouses, Chadwick (a prominent campaigner and civil servant) concluded that illness was due to poverty. This converted him to the 'sanitary idea' (the beginnings of preventive medicine).

2.1 The 'old' and the 'new' public health

Since it inception public health has always been subject to political, cultural and economic concerns. Public health has often been described as having two distinct movements; the 'old' public health and the 'new' public health. Initiatives such as the sanitary movement marked the beginning of old public health. The emergence of public health also saw the ideological identification of medicine with the public service and the state. Medical experts were courted by politicians, sat on committees and public enquiries and pronounced on issues such as social health, housing, diet and national welfare (Porter, 1997;635). Doctors saw the benefits that could come from state welfare, and they imperceptibly gained power in the political arena.

In the early 20th century, new notions about health developed and healthcare became integral to the machinery of the industrialised society. It became widely accepted that consumer and capitalist economies required a healthy population; people had to be healthy to succeed in the labour market. In addition, war required able-bodied soldiers and some type of centralised health services (Porter, 1997;632). The concept of 'prevention is better than cure' took hold and investment into screening, health education, and school health began. At this time, responsibility for health was largely taken away from the individual and assigned to the state.

In the mid-20th Century, infectious diseases were largely brought under control and chronic diseases such as cancer assumed prominence. Advances in technological and medical skills meant that screening for diseases such as cervical and breast cancer was possible. The 'new' public health emerged in the 1970's and emphasised 'social' factors such as lifestyle, the importance of the environment and recognition of the multidimensional nature of disease (such as inequalities). It has been argued that the

'new' public health was constructed on the tenets of modernism (Petersen and Lupton, 1996;4). For example, it can be viewed as a progressive activity that draws on expert knowledge, technology, and statistics, in order to improve the health of the population. In addition, public health emphasises rationalism, by focusing on systematic evaluation, costs, and outcomes.

The 'new' public health focused particularly on the health status of populations. The dominant health message from the UK government during the 1970's onwards was about lifestyle, behaviour change and health promotion. In the 1980's a central tension emerged; the relationship between the state and the individual (Petersen and Lupton, 1996;1). Under the Conservative government responsibility for health shifted back towards the individual, who was encouraged to voluntarily co-operate in appropriate health seeking behaviours such as screening programmes (Holland and Stewart, 1990;7). This 'new' public health has been described as,

'The most recent of a series of regimes of power and knowledge that are orientated to the regulation and surveillance of individual bodies and the social body as a whole.' (Petersen and Lupton, 1996;1)

Within the 'new' public health framework, aspects of people's lives are now increasingly subjected to surveillance (e.g. through population screening). Individuals are expected to comply with this scrutiny, and employ a 'duty to be well' attitude (Howson, 1999). The 'new' public health embraces the ideas of health promotion, social marketing, and community participation. Many disciplines are now involved in public health including health economics, health promotion, and epidemiology.

2.2 Epidemiology and its role in screening

Epidemiology provides the foundation for many public health policies including cancer screening. It is a discipline based upon statistical techniques and the calculation of probabilities. As such, it is widely viewed as a rational scientific discipline based on 'hard' facts. Epidemiology and statistical measurement emerged in the late eighteenth and early nineteenth centuries as a means of measuring, classifying and monitoring characteristics of populations. These data were supplemented by technological advances

such as the microscope, which enabled epidemiological exploration of the pathogens of disease and the sources of outbreaks of disease (Petersen and Lupton, 1996;28).

Today, much of epidemiological research is concerned with identifying risk factors, and assessing, reducing or eliminating risk in populations. In epidemiology, risk is generally viewed as a quantifiable entity, a neutral term, and often a dichotomy (e.g. people are classified as high risk or low risk). Systematic collection of population data and the use of statistics have enabled categorisation of people and populations. Much of the rationale for individual screening programmes is based on epidemiological evidence of risk. The reasons for this emphasis on risk and risk reduction are discussed in section 2.

2.3 The rise of individualism and choice

The industrial revolution, as discussed previously, changed values and attitudes towards health. Around the same period, new philosophical and political notions around the individual emerged. One of these was the concept of the 'civil society' where individuals (as opposed to families or other units) pursued private interests and had relationships which were primarily economic (Berki, 1977;177). Ideologies of individual autonomy and freedom and choice also gained prominence during this time. During the late 1970's (when the Conservative government was in office), the economic ideas of Adam Smith again became influential: these included free enterprise, individual choice, competition, and less regulation. People in the 21st century have become consumers who place high value on choice. Thus, market concepts have gained credence in society and more and more types of human activity come to be viewed as a commodity (Thompson, 1995).

Individual responsibility for health is viewed by many as the path to being more autonomous. However, it also attracts blame (Beck-Gernsheim, 2000;124). For example, participation in cancer screening is seen by many to indicate that an individual is taking a responsible and rational approach to their health. Those people who decide not to take part are labelled irresponsible or irrational. One US television commercial stated *'If you are over 35 and haven't had a mammogram you need more than your breasts examined'* (Wright and Mueller, 1995). So on the one hand, responsibility for one's actions and

freedom of choice are seen as part of being autonomous and proclaimed as rights; on the other hand not making the 'right' choice is seen as being morally irresponsible. The notion of risk and an individual's attitude towards their risk of disease (including cancer) plays a role in this debate.

SECTION 2: RISK AND CANCER SCREENING

Much of the rationale for informed choice in cancer screening is centred around giving people information on risk (e.g. risks of developing the disease, risk factors, and risks of the screening tests). Thus, issues, theories, and debates relating to risk are central to this thesis.

The concept of risk is well established in Western culture. One of the features of modern society is the recognition that science and technology, although having the potential to benefit society, can create new parameters of risk and danger (Giddens, 1991;28). Screening and screening technology can benefit the health of populations, but it also creates its own risks and dangers. The National Screening Committee acknowledges this tension between benefit and harm:

'Screening can reduce the risk of developing a condition or its complications but it cannot offer a guarantee of protection. In any screening programme, there is an irreducible minimum of false positive results (wrongly reported as having the condition) and false negative results (wrongly reported as not having the condition).' (National Screening Committee, 2004)

Since the concept of risk is central to cancer screening, the following sections discuss how it emerged as a central tenet of our modern society, and how it may influence health care choices.

Dangers and hazards to humanity have always existed; however the notion of risk is new. In pre-industrialised societies, people faced many dangers and hazards from plagues, earthquakes, famines etc. However, it has been argued that the notion of risk did not exist at this time. People regarded hazards and catastrophes as pre-given; they came from God, or from nature itself (Beck, 1992).

The nature of danger over time has shifted (to some extent) from natural to man made; from 'disease and famine' to 'technological.' Ulrich Beck first used the term 'risk society' in the 1990's. He described a risk society as being linked with the new electronic global economy – a world of technological innovation and scientific development, but where no-one fully understands the possible global risks and dangers

that we face (Beck, 1992). Beck viewed risk as a product of late modernity, whereby human progress and human development have produced more and more hazards which threaten the ecosystem and human health. His statements about risk mainly focus on external hazards and dangers (e.g. pollution and global warming). For Beck, modern society changed fundamentally from a society characterised primarily by social inequalities (e.g. income) to a society where (although such inequalities remain), the chief threats are environmental hazards which cut across traditional inequalities.

Some authors have differentiated between internal and external risk. Judgements about what behaviours are risky and who is at risk from disease have been conceptualised as 'internally imposed risk' (Lupton, 1995;80-1). Lupton argues that it is this which is the mainstay of health promotion activities and which can also apply to screening. Because we have access to statistics and data, we have become preoccupied with understanding what our risks are of potentially life-threatening outcomes. This access to knowledge shapes our beliefs about our individual risk of disease.

2.4 Definitions and meanings of risk

Risk has several definitions and different usage. The Collins English Dictionary defines risk as 'the possibility of incurring a misfortune, loss or a hazard'. Risk is concerned with future happenings as related to present practices (Giddens, 1991;117). The essence of risk therefore is not that an event is happening, but the possibility that it might. Definitions and perceptions of risk have been described as having two 'faces' – those of science and those of everyday life (Bellaby, 2001)). In scientific, medical terms, risk is often expressed as the statistical likelihood that an event may occur (e.g. the lifetime risk of a woman developing breast cancer is 1 in 9). The public, however, view risks differently from clinicians and epidemiologists. Individuals have to apply these population statistics (1 in 9 chance, etc) to themselves; thus the concept becomes subjective (Lupton, 1995;85).

Preoccupation with risk and risk reduction has little to do with the actual prevalence of danger and hazards (Giddens, 1991;115). It has been argued that the public misunderstands the statistical concept of risk. For example, the public tend to exaggerate

the risks when the hazards are great but the probability of it happening is low (e.g. a plane crash). Conversely the public depreciate the risk when the hazard is familiar but the probability may be high (e.g. journeys in cars) (Douglas, 1985;30). Thus the risks which we select as a society as requiring attention, may or may not bear a relationship to the actual magnitude of the danger (Lupton, 1995;80). Mass media have impacted on our selection and perceptions of risk, and emphasise hazards associated with new technologies (Alaszewski and Horlick-Jones, 2003).

It has also been argued that public perceptions of health risk are biased towards optimism. The term 'optimism bias' was used to described the public's belief that they are invulnerable, and consistently consider their own chances of ill health to be below average (Weinstein, 1982). It has been claimed that unrealistic optimism bias may predict behaviour (Weinstein, 1989). Therefore, risk perception may play an important part in how people respond to screening information. Section 2.34 discusses this concept in relation to theories of health behaviour.

Risk has been described as a social construct, political in construction and including moral judgements of blame (Petersen and Lupton, 1996;18). It is commonly accepted that dangers and hazards do exist. However, dangers and hazards are not viewed equally; some are singled out as risks, whilst others are not. It has been maintained that risk has come to replace the notion of sin, as a term which runs across the gamut of social life to moralise and politicise dangers (Douglas, 1992).Douglas also contends that risk has generally been discussed through a 'paradigm of rational choice' and to consider risk assessment independent of culture is useless. Both the cultural setting and personal experiences frame how individuals approach risky situations. Lupton also agrees with this notion of sin by noting,

'When risk is believed to be internally imposed because of lack of will power, moral weakness or laziness on the part of the individual, the symbiotic relationship of sin and the sinned is reversed. Those who are deemed 'at risk' become the sinners, not the sinned against, because of their apparent voluntary courting of risk. They are described as 'risk takers' who insist on ignoring their categorisation into the 'high risk' group. Such people are represented as irrational, self-deluding and irresponsible if they challenge health risk assessment.' (Lupton, 1995;90)

The task of reducing both population and an individual's risk of disease (especially those at high risk) is usually seen as the responsibility of public health and health promotion.

2.5 Risk, public health and health promotion

Our perceptions and attitudes towards risk and risk reduction are central to the 'new' public health (Petersen and Lupton, 1996;18). There is an increasing emphasis on both public health and health promotion bodies to avert risks of disease, particularly in high risk populations. Risk discourse in public health can be separated into two perspectives (Lupton, 1995;77). The first perspective is concerned with external environmental hazards such as pollution and toxic chemicals. The individual has little control over this sort of hazard or risk. The second perspective focuses on risk to health as a result of individual lifestyle choices, and emphasis is thus placed upon self-control. Risk in this sense is internally imposed (as described on page 24). This is where the role of health promotion assumes a prominent role. As Petersen notes,

'The factors of risk the [health promoters] identify are distributed throughout the social body to the extent that (responsible) individuals at every turn face the task of having to monitor, regulate and change (that is refashion) themselves to avoid, modify, control or eliminate behaviours and situations deemed 'risky'.' (Petersen and Lupton, 1996;20)

It has been asserted that public health and health promotion have introduced a new moral meaning around risk (Lupton, 1995;90). Lupton argues that the dominant theme of lifestyle risk discourse in health promotion is that it is the responsibility of individuals to avoid health risks, for the sake of their own health as well as for the greater good of society as a whole. Through the application of epidemiological data, it is now possible to label large groups of people as high risk or low risk. For example, a woman who has multiple sexual partners, smokes and is of low socio-economic status is labelled as high risk of developing cervical cancer. Labelling as high or low risk can produce an expectation of behaviour. For example, by giving an individual the label of high risk, they may have a perception of moral responsibility to reduce that risk.

The discourse of risk may also serve to cast certain individuals and groups as deviant or morally irresponsible if they do not reduce their risk by going for screening. Women who do not go for breast screening have been compared to people who walk into traffic

without looking and are killed (Lerner, 1998;208). In this example, women were seen as culpable if they did not participate in screening, and then went on to develop breast cancer. This argument has been developed by other researchers (e.g. (Pfeffer, 2004b; Vahabi and Gastaldo, 2003)) who assert that there is an assumption that women will be compliant with health experts' recommendations; when that does not occur, women can be labelled as either uninformed or irresponsible. Non-participation is seen as an irrational response to objectively measured risk. One of the basic underlying assumptions of screening for asymptomatic disease is that it is rational and important to have 'knowledge' of the presence of a hidden illness, rather than remaining ignorant. In cancer screening, therefore, it appears that the choice offered is not morally neutral, but may also be embedded within a moral framework of self-responsibility and social obligation (Howson, 1999). This moral aspect has implications for informed choice, in that people may not be able to make the choices they wish through fear of being labelled as irresponsible. It also has implications for the provision of information, which may also not be morally neutral.

2.6 Risk and screening

Screening has been described as 'the institutionalisation of risk' (Thornton et al, 2003). For many people, screening is viewed as a way of eliminating risk and uncertainty. Screening is an area where major technological advances have been made. Industry is aware of the public's interest in risk reduction and screening and therefore creates new technologies to meet that demand. It has been argued that, in the US, preventive services such as screening are marketed to healthy women using a language and a style that mimics that of the women's movement. They emphasise the right of all women to have access to health services and to be actively involved (Lupton, 1995;94). Thus, this is perhaps a cynical marketing device to attract women to services such as mammographic screening. In addition, new screening technology can potentially expose every part of our body to medical scrutiny and make us feel that we are at danger from a range of diseases.

'Simple minded enthusiasm for screening - combined with the industrial opportunity to make fat profits - may mean that soon none of us will be normal. We will be screened not only for cancers of the cervix and breast but also of the prostate, colon, ovary, lung, stomach, and so on. It's always hard to put the case for 'not knowing' but economists - cold hearted beasts that they are- have a wonderful notion of 'rational ignorance'. (Smith, 2003)

The technological revolution in screening may have serious consequences for doctors and patients. For example, expectations of patients are increased and can result in dissatisfaction if the technology does not succeed, especially if the potential limitations have not been disclosed beforehand (McLeod, 1989;4).

2.7 Summary of the literature on risk

From the literature discussed in this section it can be concluded that there is public, professional and commercial preoccupation with risk and risk reduction. Screening is one method of identifying people at risk of particular diseases. However, risk is not a neutral concept, especially when applied to disease status. There is to a greater or lesser extent, a moral imperative in the public health arena for individuals to be responsible for reducing and managing their own risk. Many health professionals and some members of the public may view foregoing screening as being morally irresponsible. Some people and organisations may have a vested interest in perpetuating this moral stance, particularly those involved in developing or running screening programmes. This moral framework has implications for the degree of choice that can be made. The ability for people to make an autonomous choice in cancer screening has to be viewed in the framework of moral responsibility and risk. The possible difficulties in gaining informed choice within such a setting is discussed in later sections of this literature review.

SECTION 3. SCREENING AND CANCER EPIDEMIOLOGY

The aim of this section is to provide a summary of the type of information that is used in informed choice interventions, and in assessing knowledge and understanding in the measure of informed choice. Currently there are two national cancer-screening programmes in Scotland - the Scottish Cervical Cancer Screening Programme, and the Scottish Breast Screening Programme. In addition, a second round of Colorectal Cancer Screening Pilot is underway in England and three regions of Scotland (Grampian, Tayside and Fife).

Screening is the presumptive identification of unrecognised disease by the application of tests, examinations, or other procedures that can be applied rapidly. Screening sorts out apparently well persons, who apparently have a disease, from those who probably do not (Holland and Stewart, 1990). The rationale for screening is that by identifying disease early (in the 'detectable pre-clinical phase') the chance of cure and a reduction in associated mortality is increased (Miller, 1996). Thus one of the main purposes of cancer screening is to reduce mortality in people who develop cancer by detecting it at a stage when treatment is most likely to be effective. However, in some instances, the identification of early disease may just result in a person living with the knowledge that they have the disease for longer, and the prognosis and outcome of the disease may remain unaltered.

Screening can be carried out with the aim of primary prevention (e.g. screening for risk factors such as hypertension), secondary prevention (e.g. early detection of diseases such as cancer) or tertiary prevention (e.g. detection of chronic diseases such as sensorineural deafness to prevent further functional loss). In addition, screening can target different populations; mass screening targets whole populations whilst selective screening is aimed at high risk populations (Holland and Stewart, 1990). Before they are implemented, most mass screening programmes need to meet stringent criteria.

2.8 Criteria for an effective screening programme

The main criteria used to judge the effectiveness of screening are those proposed by Wilson and Jungner in 1968. However, the National Screening Committee has recently adapted these criteria to take into account both the more rigorous standards of evidence required to improve effectiveness and also the greater concern about the adverse effects and consequences of healthcare (Box 1) (National Screening Committee, 1998).

Box 1. Criteria for an effective screening programme

The condition

The condition should be an important health problem.

The epidemiology and natural history of the condition, including development from latent to declared disease, should be adequately understood and there should be a detectable risk factor, disease marker, latent period or early symptomatic stage.

All the cost-effective primary prevention interventions should have been implemented as far as practicable.

The test

There should be a simple, safe, precise and validated screening test.

The distribution of test values in the target population should be known and a suitable cut-off level defined and agreed.

The test should be acceptable to the population.

There should be an agreed policy on the further diagnostic investigation of individuals with a positive test result and on the choices available to those individuals.

The treatment

There should be an effective treatment or intervention for patients identified through early detection, with evidence of early treatment leading to better outcomes than late treatment.

There should be agreed evidence based policies covering which individuals should be offered treatment and the appropriate treatment to be offered.

Clinical management of the condition and patient outcomes should be optimised by all health care providers prior to participation in a screening programme.

The screening programme

There should be evidence from high quality Randomised Controlled Trials that the screening programme is effective in reducing mortality or morbidity.

There should be evidence that the complete screening programme (test, diagnostic procedures, treatment/ intervention) is clinically, socially and ethically acceptable to health professionals and the public.

The benefit from the screening programme should outweigh the physical and psychological harm (caused by the test, diagnostic procedures and treatment).

The opportunity cost of the screening programme (including testing, diagnosis and treatment) should be economically balanced in relation to expenditure on medical care as a whole.

There should be a plan for managing and monitoring the screening programme and an agreed set of quality assurance standards.

Adequate staffing and facilities for testing, diagnosis, treatment and programme management should be available prior to the commencement of the screening programme.

All other options for managing the condition should have been considered (e.g. improving treatment, providing other services).

These criteria were originally developed for population based screening. However there is now a proliferation of individual testing for genetic susceptibility, particularly for cancer. In response to concern that the criteria many no longer be applied in this context, modified Wilson and Jungner criteria have been developed (Goel, 2001; Khoury et al, 2003) which take into account the ethical, legal, psychological and social impact of genetic screening.

Evaluating the effectiveness of screening can be difficult because of inherent biases such as lead-time and length-time bias. Lead-time is the period between early detection of disease and the time of its usual clinical presentation. When evaluating the effectiveness of the early detection and treatment of a condition, the lead-time must be subtracted from the overall survival time of screened patients. Otherwise, early detection only increases the duration of the patients' awareness of their disease without reducing their mortality or morbidity. Length-time bias is where screening detects less aggressive disease with better prognosis.

The use of RCTs in assessing effectiveness can reduce the impact of such biases, and provide information on effective treatments. Researchers and others have struggled to define what the acceptable evidence for screening effectiveness is. However, many people have a false impression of the increases in survival that screening achieves, and do not understand concepts such as lead-time and length-time bias. Some of the criteria require value laden societal judgements (e.g. the test should be acceptable to the population).

2.9 Benefits, limitations, and consequences of screening

By detecting disease before symptoms occur, screening programmes can be an effective method of reducing morbidity and mortality. Screening can also result in less radical treatment for some screen-detected cases, and provide reassurance for those who test negative. Although screening may benefit populations rather than individuals, it is often promoted as being beneficial to everyone who participates, and early detection of disease is nearly always viewed as a beneficial outcome.

As well as the potential benefits of screening, there is a range of limitations, and consequences. In screening for a particular condition, a large number of apparently healthy people are tested in order to identify a small number of people who have pre-clinical disease. In conditions where the incidence is low and the risks from screening high (such as a high number of false positives), a much larger number of people may experience harm from screening than those who experience benefit. In addition, those healthy people who experience harm because of screening are different from those people who experience the benefit. So, it has been argued that harm from screening is inevitable, and the popularity of screening bears little relation to the magnitude of its benefits and risks (Anderson and Nottingham, 1999). The National Screening Committee has recently accepted that although screening has the potential to reduce the risk of developing a condition, it cannot offer a 'guarantee of protection.' Limitations and consequences of screening tests include:

- false positives, which can produce negative consequences such as anxiety, additional risky investigations and unnecessary treatments.
- false negatives, conveying a sense of false reassurance, with the related harm that symptoms may be disregarded and diagnosis delayed.
- equivocal or indeterminate test results.
- screening of inconsequential disease which leads to labelling of people who would have remained asymptomatic until death.
- detection of other conditions such as non-ductal carcinoma in situ (breast screening) and polyps (colorectal screening). These occult diseases with uncertain prognosis then often need treatment.
- longer morbidity for people whose prognosis is unaltered.
- over-diagnosis and over-treatment for questionable abnormalities, or where the natural history of the disease is unclear (e.g. cervical screening).
- social costs - people may be refused life insurance if they are screen positive, and it may have implications for their jobs, and personal circumstances.
- hazards of the screening tests.

There are also psychological and social costs of screening. For example it has been suggested that people who have received a negative result on screening may be more resistant to advice on healthy lifestyles – this attitude has been termed "certificate of health effect" (Stewart-Brown and Farmer, 1997). It can also lead to labelling of individuals and result in increased sickness, absenteeism and adoption of a sick role (Grimes and Schulz, 2002; Haynes et al, 2002). Finally, screening can be expensive to provide, unpleasant and inconvenient.

2.10 Population or selective screening

There is an ongoing discussion on whether to screen the whole of an eligible population, or just those perceived to be at high risk. For example, it has been suggested that there may be advantages to withdrawing low risk women from the cervical screening programme before they reach the recommended age of 64 (Sherlaw-Johnson et al, 1999). For cervical and breast cancer the current policy is to screen all eligible women within a certain age range. However, the National Screening Committee (NSC) has stated that a policy of informed choice would

'Offer opportunities for increasing value for money, for it would allow general policies for whole populations to be tailored to sub-populations or to individuals based upon the profile of risk for that particular sub-group or, if it is possible to calculate, for the particular individual.' (National Screening Committee, 2000)

Thus a policy of informed choice may have wider implications, and may result in selective screening of high risk populations. How these high risk populations will be selected has not been defined by the NSC.

2.11 Wider concerns about screening

Screening is a ubiquitous part of healthcare, yet it does have critics. One of the criticisms of screening is that it focuses on disease rather than health. Some critics contend that the biomedical perspective of early diagnosis is too narrow in its approach. More radically, it has been argued that breast cancer has become a 'growth industry in a capitalist market' (Lerner, 1998). Also, the focus on detection and cure detracts from governmental responsibility for understanding and preventing the primary cause of disease. Other concerns are that screening may create a 'safety-net' philosophy of reliance on health professionals to identify and solve problems, rather than people seeking to improve and maintain health (Holland and Stewart, 1990;7).

Other critics of cancer screening focus on the natural history or nature of the disease. As mentioned previously, the aim of screening is to detect cancers in the 'detectable pre-clinical phase (DPCP).' It is assumed that the earlier in the DPCP the cancer is detected, the greater the chance of cure will be. However, it has been argued that the evidence supporting this assumption for some cancers is weak (Miller, 1996). In cervical

screening, it is not known which abnormal cells will progress to invasive cancer, and which will revert to normal. This can result in over-treatment of abnormal cells.

Finally, some critics argue from a utilitarian aspect: the allocation of limited resources. Wright and Mueller argue that since the benefit achieved is marginal, the risks substantial and the cost enormous, public funding of (breast screening) is not justifiable (Wright and Mueller, 1995). They also assert that public imagination has been captured by mammography and all those involved in screening have a vested interest. It has also been argued that, because the benefit is not great, resources would be best spent on secondary care. For example, one view is that

'..it is galling how the political spin from government agencies suggests that the best way of reducing deaths from breast cancer lies in trawling through the asymptomatic population. We suggest that greater investment in quality of care and research related to treatment could be much more efficient.' (Baum and Tobias, 2000)

From an ethical perspective it has also been argued that the offer of screening (particularly in developing countries) could diminish the overall level of health in a community (if it resulted in fewer resources for other diseases) (Miller, 1996). However, Miller acknowledges that screening can also promote equity, provided it is well organised and efficiently run.

2.12 Summary of issues surrounding screening

Screening is viewed by many as a benign activity aimed at reducing the burden of disease in populations. However, some critics have raised concerns about the focus on disease rather than health; the problems of evaluating effectiveness; and the natural history of the diseases. Others have argued that inappropriate application or interpretation of screening tests can deprive people of their perceived health status, initiate damaging diagnostic testing, and squander health-care resources (Grimes and Schulz, 2002). Screening for cancer is a complex intervention, and it can be difficult to evaluate its effectiveness. Therefore, the provision of accurate, up-to-date unbiased information on topics such as the natural history, risk factors and prognosis is complex and challenging. The following section provides a brief overview of the different cancer screening programmes included in this thesis.

2.13 Breast cancer and breast cancer screening

Breast cancer screening was first introduced in 1988 and is a high profile programme, with wide support from the public. However, it does have its critics. The following section outlines the epidemiology and treatment of disease, evidence of the effectiveness of screening, and some of the current controversies.

Breast cancer epidemiology

Breast cancer is the most common cancer in women and accounts for one in five of all female cancers, and for about one in five of all deaths in women aged 40-50 (McPherson et al, 1994). The incidence is increasing slowly, by about 1-2% a year, particularly among elderly women. Breast cancer tumours are derived from epithelial cells that line the terminal duct lobular unit, and can be either non-invasive or invasive (Sainsbury et al, 2000). The course of breast cancer is unpredictable and the risk of reoccurrence may continue for 20 years or more.

It has been estimated that one in nine women will develop breast cancer at some time in their lives, with the risk increasing with age (ONS, 1999). The incidence of breast cancer in women aged 50-64 (the screening population) is 2 per 1000 per year (Baum and Tobias, 2000). Two breast-ovarian cancer susceptibility genes have recently been identified: BRCA1 and BRCA2 (McPherson et al, 2000).

There are many risk factors for breast cancer including sex (females), increasing age (incidence doubles every 10 years until the menopause), environmental factors, early puberty or later menopause, age at first pregnancy, family history of breast cancer, previous benign breast disease, being exposed to radiation, high intake of saturated fat, oral contraceptive pill or hormone replacement therapy, obesity (for post-menopausal women only) and high alcohol consumption.

Depending on the type and stage of breast cancer, treatment options include surgery, radiotherapy and drug therapy (cytotoxic and endocrine drugs). Advances in treatment have produced significant but modest survival benefits. It has been argued that a better appreciation of factors important in the aetiology of breast cancer would raise the

possibility of disease prevention; one promising avenue for primary prevention is drugs such as tamoxifen (McPherson et al, 2000).

Breast cancer screening

Breast screening as currently practised can reduce mortality but not incidence, and then only in a particular age group (McPherson et al, 2000). The UK breast screening programme (NHSBSP) was established in 1988 and women are currently screened for breast cancer by mammography. The programme was set up following a recommendation from the Forrest Committee, which reported evidence from trials of a significant reduction in breast cancer mortality in women who had been for a mammogram (Forrest, 1986). However, implementation of the programme has been gradual and the 'prevalent' round of screening in England and Wales was not completed until 1995 (Blanks et al, 2000). In Scotland, the first screening centres became operational in 1988 with national coverage being attained in 1991 (ISD, 2002). The Scottish Breast Screening Programme currently invites eligible women aged 50-70 once every three years.

Effectiveness (reduction in mortality and morbidity)

The effectiveness of breast cancer screening in reducing mortality and morbidity is a controversial issue. Supporters and critics have been divided in the way in which evidence is interpreted, and the degree to which results of RCTs should be used in the debate. Meta-analyses of randomised controlled trials have produced varying degrees of effectiveness. Supporters of breast cancer screening reported that it could reduce mortality from the disease in 50-69 year old women by 26% (Kerlikowske et al, 1995). Other analysis of trials in Sweden reported a 21% reduction (Nystrom et al, 2002). In the UK, the effect of breast screening from one study was more conservative – a 6.1% reduction in mortality was directly attributed to screening (Blanks et al, 2000). Sceptics claim that mammography does not save lives and could actually be harmful (Gotzsche and Olsen, 2000; Olsen and Gotzsche, 2001). The authors reported that the two adequately randomised trials found no effect of screening on breast-cancer mortality (pooled relative risk 1·04 (95% CI: 0·84 to 1·27)) or on total mortality (0·99 (95% CI: 0·94 to 1·05)).

Following on from this meta-analysis, an independent panel of US medical experts concluded that there was insufficient evidence to show that mammography prevented deaths from breast cancer (Charatan, 2002). Another group of researchers undertook an observational study, looking at the change in rates of radical surgery and incidence of breast cancer since the introduction of a mammographic screening programme in Italy (Paci et al, 2002). They concluded that the rate of breast conserving surgery had increased since the advent of screening, with a decrease in radical surgery. This study has been criticised as being of poor quality and internally invalid. In particular, it has been argued that mastectomy rates were falling before screening was introduced, and are also falling in countries where there is no organised screening programme (Baum, 2002).

The debates as to the effectiveness of breast cancer screening have not been fully resolved. However, breast screening programmes are major public health initiatives in many countries and continue to be extended. In Scotland, for example, the age range in several regions has recently been extended to 70 years, with an aim to having country wide extension in the near future. Thus, despite the negative conclusions from some meta-analyses, breast cancer screening continues to be viewed as a positive, cost effective and worthwhile public health activity.

Limitations

As with other screening tests, breast screening produces both false positive and false negative results. In the USA, the estimated cumulative risk of a false positive result was 49.1 % (95% CI: 40.3 to 64.1%) after 10 mammograms in women aged 50 to 79 years (Elmore et al, 1998). These false positive results produce adverse effects such as anxiety, complications, and additional expenses. They can result in unnecessary outpatient appointments; referral for assessment by a surgical specialist, and some women will also undergo fine needle biopsy or open biopsy (Marshall and Adab, 2003). Gotzsche et al in their systematic review estimated that screening increased mastectomies by around 20%, mainly because of over diagnosis. Indeed the authors stated that,

'We published the report mainly because we believe it is important for women to know that screening increases their risk of losing a breast.' (Gotzsche, 2002)

As well as breast screening having these limitations, it also has some unintentional consequences.

Consequences

Breast screening may result in the identification of other related diseases and conditions. One consequence of breast cancer screening is the increasing detection of ductal carcinoma in situ (DCIS). The natural history and clinical course of DCIS is not well understood, but most lesions do not progress to invasive cancer. In the USA, DCIS accounted for 14.7% of all newly diagnosed breast cancers in women aged 40-49 in 1993, and perhaps 40% of all mammographically detected breast cancers (Ernster and Barclay, 1997). Research suggests that most women are unaware that screening can detect ductal carcinoma in situ but feel that such information would be relevant (Schwartz et al, 2000). Currently breast screening invitations do not mention that ductal carcinoma in situ accounts for 20% of cancers detected by screening. The consequences of diagnosis of this little understood disease are serious for women and the health service. Women and their doctors have to make difficult decisions and evaluations of risk, which occupies much time in the clinics, and expensive research is required on management of the disease (Thornton et al, 2003).

Debates and historical perspectives on breast cancer screening

The power of mammography has been attributed to the fact that it allowed previously hidden breast cancers to be visualised (Lerner, 1998; 208). There have been heated debates over breast cancer screening since it was first introduced. Most of the debates have focussed on the effectiveness of screening, and whether resources would be better spent elsewhere. However, there have also been debates as to how the screening programmes were set up initially in the UK; if it was a rational process or one that benefited women.

Screening for breast cancer has been largely viewed by lay people, the press, and other organisations as being 'pro-women' and pro women's health. However, it has also been argued that *'women's wants'* are being expressed in both the medical and political arenas by a small number of people who have vested interests, and may not be aware of all the benefits and limitations (Hann, 1995; 4). Hann contends that patriarchal beliefs and

structures embedded within medicine could result in a situation in which policies - which seem to serve the interest of women - in fact do not (pg.135).

One reason for encouraging informed decision making is that it enables a person to make a rational choice. However, Hann debates whether the Forrest Committee (who were set up to evaluate breast screening), used a rational approach when deciding whether breast cancer screening should be introduced. Much of the debate centered on how (and if) screening should be introduced, but not whether it was based on sound scientific evidence. In addition, possible counter-arguments to the desirability of the breast cancer screening were not considered at all (Hann, 1995; 7 & 135). Hann argues that,

'An area which affected only women, the patriarchal thinking in our society declared women unfit to participate in the area of expert discourse.' (pg. 12)

Despite this apparent patriarchal approach to the decision making process, there appeared to be consensus about the desirability of a breast screening programme, and any criticism focused on process, implementation and funding. However, a dissenting minority felt that their arguments were not being listened to (Skrabanek, 1988a), and some of the critics of breast screening were those who were instrumental in setting up or running the breast screening programmes. For example, Maureen Roberts was clinical director of the Edinburgh Breast Screening Project from 1979. Just before her death (of breast cancer) in 1989 she wrote,

'It now seems that the Forrest committee was premature in its recommendations. At the time screening certainly seemed more likely to be of benefit than harm, but I cannot help believing that it was a political decision.' (Roberts, 1989)

The arguments presented in this section indicate that the introduction of breast screening may have been influenced as much by politics as by rational decision making.

Summary

In summary, the evidence of effectiveness for breast cancer screening in reducing mortality is contested and uncertain. In addition, breast screening has some important consequences. These include the potential increased risk of mastectomy, and the identification of other conditions such as DCIS. From a political perspective it has been argued that although breast screening appears to serve the interests of women, actually it

might not. It is beyond the scope of the thesis to discuss in any depth the relative merits of the debates surrounding breast screening. However, the effectiveness and limitations of screening, combined with political interests, have implications for the information given to people in order for them to make an informed choice.

2.14 Cervical cancer and cervical screening

Cervical cancer epidemiology

World wide cervical cancer is the third most common cancer, with at least 400,000 new cases identified throughout the world each year. However, in the UK and developing countries it is less common. In 2002, only 1% of all cancers were due to cervical cancer, compared with 15% due to breast cancer (Cancer Research UK, 2004). More than 90% of cervical cancers develop within a small area of the cervix known as the transformation zone and disease progression from dysplasia to invasive cancer is usually slow, therefore providing the opportunity to detect and treat pre-cancerous disease. The lifetime risk of developing cervical cancer in the UK is around 1 in 100 (Cancer Research UK, 2004).

The primary risk factor for cervical cancer is believed to be human papilloma virus (HPV) infection; more than 90% of squamous cervical cancers contain HPV DNA (Waggoner, 2003). Other known risk factors for cervical cancer include smoking, early onset of sexual activity, the sexual promiscuity of a woman's partner (s), multiple sexual partners and the presence of other sexually transmitted diseases (STDs). In addition, individuals who receive immunosuppressive therapy for organ transplants and those infected with human immunodeficiency virus (HIV) are particularly at risk of developing pre-invasive disease. Primary strategies to prevent the development of cervical carcinoma focus on reducing these known risk factors by encouraging a healthy lifestyle, smoking cessation, and the adoption of 'safe' sexual behaviours aimed at reducing the risk of HPV infection (Shepherd et al, 2002).

Classically presenting symptoms are vaginal discharge and vaginal bleeding, as well as pain or bleeding after sexual intercourse. These symptoms are not specific to cervical

cancer however. Treatment depends on the staging of the cancer using the FIGO staging system (Waggoner, 2003). Most women with early-stage tumours can be cured, although long-term morbidity from treatment is common. Treatment for early stages (stage IA1) includes cone biopsy. Results of randomised clinical trials have shown chemo-radiotherapy should be regarded as the standard of care for women with locally advanced cancers (Waggoner, 2003).

Cervical cancer screening

The main screening test used in cervical screening is the Papanicolau or Pap smear test. The aim of the test is to detect pre-cancerous cell changes in women who otherwise have no symptoms. At this stage, any abnormalities can be easily treated, and treatment is usually very effective. Cervical screening should, therefore, not only reduce mortality from cervical cancer, but also the incidence of invasive cancer. The National Cervical Screening Programme was introduced into the UK in 1988 with the aim of reducing the incidence of invasive cancer. The conventional way of taking a cervical sample is by using a spatula. However, recent guidance from the National Institute for Clinical Excellence (NICE) has recommended of the use of liquid-based cytology (LBC) as the primary means of processing samples in the cervical screening programme in England and Wales (NICE, 2003). The research evidence contained within the guidance found that LBC has better sensitivity (up to 12%) than conventional smears, and lower rates of inadequate samples (1.6% vs. 9.1%). This method is becoming more widespread in Scotland.

Cervical smears are offered to eligible women aged 20-60 at least once every five years. Women aged over 60 can attend on request, and women aged over 60 with a previous abnormal screening history will continue to be invited when appropriate (ISD, 2002). Recent figures for England, where a national screening programme has existed since 1964, showed that 84% of women aged 25 to 64 years had been screened at least once in the previous five years (Dept. of Health 1999). Other cervical cancer screening developments in the UK include piloting a test for the human papilloma virus at three sites in England are being undertaken by the National Screening Committee (NSC) (National Electronic Library Health, 2002).

Effectiveness (reduction in mortality and morbidity)

Unlike other cancer screening programmes, the effectiveness of cervical cancer screening has never been evaluated in RCTs. This is because, in developed countries, screening by Pap smear became widespread during the 1960's and evidence of associated reductions in mortality increased confidence in its effectiveness. In addition to this lack of high quality evidence of effectiveness, it also fails to meet two of the Wilson and Jungner criteria for screening: cervical cancer is relatively uncommon in the UK and its natural course is not well understood (Quinn et al, 1999).

Despite its limitations, it appears that cervical screening is the most likely reason for the decrease in incidence and mortality in women born since the 1930's (Raffle et al, 2003). It has been estimated that cervical screening prevents between 1,100 and 3,900 cases of cervical cancer each year (Sasieni et al, 1996). However a study comparing age specific incidence and mortality, before and after the introduction of the national call and recall system in 1988 in the UK, concluded that falls in mortality in older women were largely unrelated to screening, but without screening there might have been 800 more deaths from cervical cancer in women under 55 in 1997 (Quinn et al, 1999). The conclusion of this report (i.e. that 800 deaths might have been prevented) has been criticised for being based on completely arbitrarily selected data (Vaidya and Baum, 1999). Indeed the authors of the criticisms go on to say that, using the same logic as the original authors, screening may have caused up to 2900 extra deaths in 1997. In summary, where comprehensive screening programmes exist, studies have shown that Pap smear screening can be linked to increasing trends in cervical cancer survival, by identifying precancerous lesions, reducing their incidence and selectively preventing more aggressive cancers (Gatta et al, 1999).

Limitations and consequences

The reliability of the cervical screening using the Pap test is dependent both on the expertise of the health professional taking the smear and the individual examining the smear. A systematic review of the accuracy of conventional and new methods of Papanicolau testing found that in the 12 studies with the least biased estimates,

sensitivity ranged from 30% to 87% and specificity ranged from 86% to 100% (Nanda et al, 2000). The reviewers concluded that,

'The best estimates suggest that it is only moderately accurate and does not achieve concurrently high sensitivity and specificity.'

False negative smear rates vary but even in the best laboratories 5-15% of abnormal smears may be reported as normal (Nottingham, 1998). This lack of test accuracy has implications for women who take part in cervical screening. Individuals may experience such detrimental side effects as anxiety, false alarms, false reassurance, unnecessary biopsies, over-diagnosis, and over-treatment (Austoker, 1999). Particularly important issues for Pap smear screening not only include the rate of false negatives but also the possibility that lower grade cervical abnormalities will never progress to invasive cancer.

One concern about cervical screening is the rate of over-diagnosis, and over-diagnosis bias. For each death prevented many women have to be screened and many are treated who would not have developed a problem (Raffle et al, 2003). In many cases the lower grades of cervical dysplasia will spontaneously regress or never develop into cancer. Women with such grades of dysplasia may suffer adversely through receiving an abnormal smear test result and perhaps undergoing unnecessary treatment. Abnormal results from cervical cancer screening are common, but the actual disease that screening is attempting to prevent is rare. For every 250 000 women screened annually for cervical cancer, 40 or so would die annually amongst this number. However, over 15,000 women will have an abnormal cytological finding but would never have a problem from cervical cancer (Raffle, 1997b).

Debates and perspectives on cervical screening

Debates around cervical screening focus on the lack of high quality evidence of effectiveness, and moral aspects of the disease itself. For example, it is argued that in the case of cervical cancer, some doctors have defined the disease as being the 'women's fault' (i.e. for being promiscuous) (Hann, 1995; 132). In addition, many have ignored the fact that HPV, a major risk factor, is a sexually transmitted disease and therefore men may have some responsibility for the spread of the disease. Indeed it has been asserted

that men are excluded from surveillance of their sexuality, and that the cervical screening discourse exacerbates and reproduces gender inequalities (Bush, 2003).

When cervical screening was widely introduced, some feminists supported it whilst others were more critical. For those in favour, cervical screening[6] was a symbol of the health service recognising the needs of women. Others argued that [cervical] cancer screening programmes treat women as passive patients who are rebuked if they do not go, and criticised if they develop cancer (Robinson, 1985). It has been suggested that if women were to be active rather that passive controllers of their own bodies, they would opt for primary prevention (i.e. use of condoms and becoming celibate) (Robinson, 1985).

Cervical screening is both labour intensive and costly. In the NHS cervical screening programme around 1000 women need to be screened for 35 years to prevent one death. Over 80% of women with high grade cervical intraepithelial neoplasia will not develop invasive cancer, but all need to be treated. For each death prevented, over 150 women have an abnormal result, over 80 are referred for investigation, and over 50 have treatment (Raffle et al, 2003).

Summary

Cervical screening is the most likely explanation for the decreases in incidence and mortality of cervical cancer. However, for each death prevented many women have to be screened and many are treated who would not have developed a problem. It is labour intensive, costly, and has a high false positive rate. Critics argue that women should concentrate on primary prevention.

[6] A similar point of view was expressed for breast screening

2.15 Colorectal cancer and colorectal screening

Colorectal cancer epidemiology

Colorectal cancer, or cancer of the large bowel, mostly occurs in the colon and the rectum. Colorectal cancer is the third most common cancer in the UK (after lung and breast cancer) and is one of the most common causes of morbidity and mortality. Overall, it is equally common in both men and women but in Scotland the incidence of colorectal cancer is higher in men than women among each of the seven deprivation categories (Boyle and Langman, 2002). The lifetime risk of developing a large bowel malignancy is 1:25, and the overall five year survival rate is 40% (Dunlop, 1997). However, survival can be as high as 70% after curative surgery.

Risk factors thought to be associated with colorectal cancer are primarily related to diet (low in fibre and vegetables, and high in red meat and alcohol), sedentary lifestyle, cigarette smoking and genetic predisposition (Midgley and Kerr, 1999). Two genetic conditions have been identified: hereditary non polyposis colorectal cancer (HNPCC) and familial adenomatous polyposis (FAP) (Dunlop, 1997). However, over 75% of all new cases of colorectal cancer are in people with no known predisposing factors for the disease, with the remaining occurring in people who are higher than average risk (Winawer et al, 1997).

Signs and symptoms of colorectal cancer include abdominal pain, change in bowel habits, rectal bleeding, abdominal mass, anaemia and weight loss (Winawer et al, 1997). Diagnosis is often made in the later stages of the disease, when infiltration through the bowel wall has already occurred, and curative treatment is not possible.
Preventive measures include diet and chemoprevention with agents such as non-steroidal anti-inflammatory drugs (Pignone and Levin, 2002). Treatment for colorectal cancer includes surgical resection and palliation, as well as more novel approaches such as immunotherapy and gene therapy (Chung-Faye and Kerr, 2000; Dunlop, 1997). However, despite advances in cancer treatment, the five year survival rate has not significantly altered over the past decade (Chung-Faye and Kerr, 2000).

Colorectal cancer screening

The aim of screening for colorectal cancer is to identify individuals who have colorectal cancer or adenomatous polyps. Screening for colorectal cancer is attractive because early identification can result in better prognosis and more effective treatment (Austoker, 1994). Screening tests for colorectal cancer include faecal occult blood tests (FOBt) such as Haemoccult, which can detect blood from any part of the bowel. Sigmoidoscopy is also used as a screening test, as it is more sensitive for detecting small lesions, and can remove them at the same time as diagnosis. However, it is invasive, more expensive, and there is a risk of bowel perforation.

Ongoing projects of colorectal cancer screening using the FOBt are underway in England (Rugby, Coventry and Warwickshire) and Scotland (Tayside, Fife and Grampian). The pilots began in 2000 and for a two year period, men and women aged between 50 and 69 who were registered with a participating GP in one of the pilot sites were offered a FOBt to screen for bowel cancer (UK Colorectal Cancer Screening Pilot Group, 2004).

Effectiveness (reduction in mortality and morbidity)

A Cochrane review of six colorectal cancer screening RCTs reported that that those allocated to FOBt screening had a reduction in colorectal cancer mortality of 16% (RR 0.84, CI: 0.77 to 0.93) (Towler et al, 2002). When adjusted for screening attendance in the individual studies, the mortality reduction was 23% (RR 0.77, CI: 0.57 to 0.89). Thus, if 10 000 people were offered a biennial FOB test and uptake was two-thirds for at least one test, there would be 8.5 deaths (CI: 3.6 to 13.5) from colorectal cancer prevented over 10 years. A USA guideline on colorectal cancer screening concluded that, among all the screening tests for colorectal cancer, the FOBt was the only one to have strong direct evidence of a reduction in mortality (Winawer et al, 1997).

Consequences and limitations

The main diagnostic test for colorectal cancer is colonoscopy. However, whilst colonoscopies will only detect a few cancers, they will detect a large number of polyps which may need to be removed. This detection can be seen as a benefit of screening (removal of the small number of polyps that may progress to invasive cancer). However it can also be viewed as a negative consequence (regular colonoscopies for people who

have had a benign or inconsequential polyp removed) (Barratt et al, 1999). The Cochrane review concluded that harmful effects of colorectal screening include the physical complications of colonoscopy, disruption to lifestyle and stress and discomfort of testing and investigations (Towler et al, 2002).

Although the FOBt appears to have the strongest evidence of effectiveness (compared with tests such as sigmoidoscopy), it also has limitations. Only a few adenomatous polyps bleed, so the test is mainly aimed at detecting cancer after it develops rather than finding and removing precancerous lesions (Winawer et al, 1997). In addition, cancers bleed intermittently which limits the successfulness of the FOBt. Finally, it is estimated that of every 100 people who have a positive test result, only 2-6 would have cancer, but all 100 would have been exposed to the risks associated with colonoscopy which include perforation and haemorrhage (Winawer et al, 1997). The incidence of perforation has been estimated at 1.96/1000 procedures (Gatto et al, 2003).

Debates and perspectives on colorectal cancer screening

Unlike breast and cervical screening, colorectal cancer screening has attracted little debate and it is beyond the scope of the thesis to evaluate the reasons for this. Screening for colorectal cancer as part of an organised programme is still being evaluated. However, false positive rates are relatively high, and one of the consequences of screening is the detection of polyps, which may be inconsequential.

2.16 Summary of the epidemiology of the cancers, and the individual screening programmes

The previous sections have outlined the different types of cancers and their corresponding screening programmes. What is clear is that each cancer varies in incidence, mortality, natural history and treatment options. In addition, each of the screening programmes has specific target populations and different benefits, limitations and consequences. Some of the screening tests may also have political and moral values ascribed to them (e.g. breast and cervical screening). The information presented in these sections was used in the development of the knowledge questions in the measure of informed choice.

SECTION 4. INFORMED CHOICE AND AUTONOMY

This section outlines the historical development of the concept of informed consent. It focuses in particular on the relationship between informed choice and autonomy. It includes a substantial discussion of both concepts, and shows how the validity of the informed choice process may be affected by the context in which it is applied.

2.17 Informed choice and informed consent

As stated in the introduction to this thesis, informed choice is based on the theories of informed consent. Choice rather than consent is the term often used within the context of screening because people are normally sent a letter of invitation (to participate in health screening), and *choose* whether to do so or not.[7] However, choice is not the same as consent, and it is important to outline the major distinctions between the two concepts.

Both informed choice in cancer screening and informed consent in medical care (and in research) have one overarching principle. Conceptually, both are concerned with promoting patient autonomy by providing information on risks and benefits of an intervention, or treatment. However, informed choices in screening and informed consent (for a treatment or intervention) differ in populations, context and setting.

As mentioned previously, screening is performed on healthy individuals, and contact is made by the health service. Apparently healthy people in the community are invited to choose whether to participate or not. This is different from informed consent, where the individual is actively seeking, or encouraged to have, some form of treatment for a disease or condition.

The setting for screening is often a screening unit, clinic or primary care, or home (for colorectal screening) and there may be little direct contact with a health professional. This is in contrast with informed consent where there is direct contact and discussion with a health professional and it often takes place in secondary care (e.g. consent to undergo an invasive procedure).

[7] It is also the most common term used in the body of literature relating to screening.

Another important distinction between informed choice and informed consent is that consent implies agreement, where as choice does not. Generally, informed consent means that an individual agrees to a procedure but is aware of the risks and benefits. Informed choice, however, implies a stage before a decision has been reached. In cancer screening, no formal agreement with a health professional is made. The individual either participates or does not. Whether these differences in type of individual (patient or healthy individual), setting, or context affect autonomy is not well understood.

Definitions of informed consent

There are several ethical and legal definitions of informed consent. For example, in the bioethical literature, one of the most widely used definitions of informed consent is that the person must:

'Agree to the intervention based on an understanding of the relevant information 2) consent must not be controlled by influences that would engineer the outcome and 3) the consent must involve the intentional giving of permission for an intervention.' (Faden and Beauchamp, 1986; 51)

Within the legal system, a new judicial standard was created in 1972. This followed much controversy over the medical, legal and ethical interpretations of informed consent. It was the reasonable person standard under which:

'The decision about whether a patient should have been informed of a risk is based on whether a reasonable person in that patient's position would want to be informed.' (Mazur, 2003)

Definitions of informed choice

In recent years, there have been several definitions of informed choice and decision making. Informed choice has been defined as:

'One that is informed, consistent with the decision-maker's values and behaviourally implemented.' (O'Connor et al, 1999)

This definition is widely used to develop measures of satisfaction and informed choice (see Chapter 3). An informed decision has been defined as:

'One where a reasoned choice is made by a reasonable individual using relevant information about the advantages and disadvantages of all the possible courses of action, in accord with the individuals beliefs.' (Bekker et al, 1999)

An evidence-based choice has been described as:

'The use of evidence-based information as a way of enhancing people's choices when these people are patients.' (Hope, 1996)

Finally, an autonomous choice has been defined as:

'One which occurs when people act 1) intentionally, 2) with understanding, and 3) without controlling influences that determine their actions.' (Beauchamp and Childress, 1994)

This last definition forms the basis for much of the following discussions because autonomy, as seen from the following sections, is one of the central tenets of informed choice and informed consent.

2.18 A brief history of informed consent in healthcare

In order to understand the contemporary nature of informed choice and how it is implemented and evaluated, it is essential to look at the history of informed choice (Faden and Beauchamp, 1986). It has been argued that medicine has long been committed to ethics and morality when dealing with the patient, although this commitment may be incomplete at times. For example, the historian Pernick amassed evidence about informed consent and concluded that,

'Truth telling and consent seeking have long been part of an indigenous medical tradition, based on medical theories that taught that knowledge and autonomy had demonstrated beneficial effects on most patients' health.' (Pernick in Faden, 1986; 56)

However, a different and competing view proposes that:

'Disclosure in medicine has served the function of getting patients to agree to what physicians wanted them to agree to in the first place.' (Katz in Faden, 1986; 58)

Fadden and Beauchamp largely agree with the latter view, proposing that traditional medical practices of disclosure and information giving were largely based on a 'beneficence model' rather than an 'autonomy model.'

Legal interest in informed consent and the rights of patients has been evolving in the past hundred years. In the early twentieth century, certain principles and agendas regarding the law's concern for the 'bodily integrity of the individual' and 'patient determination' came to the fore (Wear, 1998; 11-12). This concern required patient consent to

treatment, however uninformed. Thus, there was the recognition that patients were autonomous human beings with rights and interest independent of medicine. However, it wasn't until 1957 that the term 'informed consent' was first introduced into the judicial lexicon (Mazur, 2003).There is a judicial standard - the reasonable person standard - which states that

'The decision about whether a person should have been informed of a risk is based on whether a reasonable person in that patient's position would have wanted to be informed.' (Mazur, 2003)

Ethical concerns over informed consent have also been around since the early 20th century. However, it was not until the mid-1950s that an autonomy model rather than a beneficence model governed the justifications for informed consent. The beneficence model depicts the physicians' primary obligation as providing medical benefit. The provision of information in this model serves as a way of maximising a person's benefits from health care rather than enhancing their autonomy (Faden and Beauchamp, 1986; 59). These models embrace different perspectives on responsibilities to patients, and can emerge in conflict. The beneficence (or paternalistic) model of medicine can conflict with respect for individual autonomy in exactly the same way.

The doctrine of informed consent emerged to some extent because of the perception that patients were uninformed, thus powerless in health care (i.e. without autonomy). One way to redress this imbalance of power was to inform them. Alongside the doctrine of informed consent evolved the right to refuse treatment. This right to refuse, combined with the ethos of informed consent, was constructed to enable patients to retain control over their lives and their healthcare (Wear, 1998; 29). Thus there was a shift, from paternalism and beneficence in medicine (however benign), towards a partnership between patient and physician.

Informed consent has been described as, *'a creature of a broad range of social practices and institutions in the twentieth century'* (Faden and Beauchamp, 1986; 55). The informed consent process is depicted as an antidote to counter medical paternalism and as such, a polar position has been established with the empowered, informed, autonomous decision-making patient at one end of the divide and an all-powerful

paternalistic authority at the other (Corrigan, 2003). However, in understanding the relationship between informed consent and a policy such as screening, we need to consider whether screening is essentially paternalistic. If so, this may have implications for the autonomy of the decision making process for invitees. Section 2.21 provides a more detailed discussion of this issue.

2.19 The relationship between informing and being informed

It is clear that informed choice is important for legal and ethical reasons. Clinicians and providers of care have a duty to provide information on benefits, limitations, and consequences of health care decisions. However, what the information should comprise, and how best to inform people (or make them informed), is the subject of a large body of research. It has been recognised that the provision of information is not necessarily sufficient in itself to ensure that people become informed. There is also debate and uncertainty as to what is necessary and what constitutes 'sufficient' information. Later sections will briefly outline the literature on interventions such as decision aids, which are aimed at bridging the gap between information provision and understanding. To aid my own understanding of the relationship between informed and informing, I developed a matrix (see Figure 1).

Figure 1. Difference between informing and being informed

	Complete information available to individual **(informing)**	*Partial information available* **(partially informing)**	*No information available to individual* **(not informing)**
Person reads, listens to or watches information and understands it **(informed)**	Informed (information provision): Yes Informed (understanding and knowledge): Yes	Informed (information provision): Partial Informed (understanding and knowledge): Partial	Informed (information provision): No Informed (understanding and knowledge): No
Person partially reads, listens to or watches information and/or partially understands it **(partially informed)**	Informed (information provision): Yes Informed (understanding and knowledge): Partial	Informed (information provision): Partial Informed (understanding and knowledge): Partial	Informed (information provision): No Informed (understanding and knowledge): No
Person does not read, listen to or watch information and/or does not understand it **(not informed)**	Informed (information provision): Yes Informed (understanding and knowledge): No	Informed (information provision): Partial Informed (understanding and knowledge): No	Informed (information provision): No Informed (understanding and knowledge): No

Since informing (provision of information) is a pre-requisite of being informed (having adequate knowledge and understanding), a person is informed only in the first cell (shaded). I would expect that, currently, the majority of people are given partial information and only partially understand it. It is acknowledged that measuring understanding will not ascertain the source of the information by which the person became informed. For example, the person might already be well informed through magazines or electronic media, and the provision of information from a screening programme may confer little additional benefit.

2.20 Criticisms of informed choice/ consent within screening

It has been argued that the principles of individual consent are not easy to apply to screening. Problems arise because information is often not accessible, it is difficult to weigh probabilistic information, and it is too time consuming (Irwig and Glasziou, 2000a; Irwig and Glasziou, 2000b). Because of these potential obstacles, Irwig

suggested a community informed consent process, in the form of a survey. This would establish the distribution of preferences among fully informed people eligible to be screened. Community consent would occur if most of the target population thinks that the benefits of screening outweigh the harms. In this instance, Irwig proposes that when screening is offered, people should be informed that a representative sample of people like them who have been given detailed information about the screening process thought that the benefits outweighed the disadvantages. Irwig argues that only if the target population is divided about benefits versus harms, is there a need for individualised decisions. If the sample believes that screening is harmful then it should not be offered at all (Irwig and Glasziou, 2000a).

2.21 Concept and theories of autonomy

Provision of unbiased information (particularly risk information) is regarded as being the key to respecting patient autonomy. However, there are different understandings of autonomy, which need to be understood in the context of informed choice. The following section outlines some of the main theories of autonomy; in particular, the predominant theory of autonomy in relation to informed consent and choice within healthcare. This theory will be discussed in detail within the context of measuring and understanding informed choice in cancer screening. Autonomy within shared decision-making and the concept of individual autonomy within public health policies will also be discussed.

Autonomy (in relation to the individual) has been defined as: *liberty to follow one's will, personal freedom* (Oxford English Dictionary Online, 2003). Although the notion of patient autonomy is relatively new, theories of individual autonomy have been around much longer. For example, in 1883 Kant writes,

'What else then can freedom of the will be but autonomy, that is the property of the will to be a law to itself.' (Kant, 1883)

There are three main philosophical perspectives on which our modern understanding of autonomy and freedom are based. These are the concept of freedom as a natural right; personal freedom which is not subject to external control; and rational free will (Rogers, 1998). However, these definitions of individual autonomy are subject to intense debate

(O'Neill, 2003). The predominant theory of autonomy in relation to patient choice and health care is that proposed by Faden and Beauchamp (Faden and Beauchamp, 1986). They distinguished between autonomous actions and autonomous persons. They define a person acting autonomously if the person acts intentionally, with understanding, and without controlling actions. The next sections discuss these three pre-requisites in relation to informed choice in cancer screening.

Autonomy and intentionality

Faden and Beauchamp argue that the person must have the sense that they can make an action happen; actions cannot be accidents, and they cannot happen unintentionally; intentions alone do not qualify as an *intentional action.* In cancer screening, an intentional action would be attending for screening or sending back a completed FOBt.

It is this distinction between an act of intending and an intentional act that may prove problematic in the case of informed choice in cancer screening. Firstly, this thesis is concerned with the choice (i.e. the act of intending) rather than the behaviour (i.e. the action). There may be a gap between intention and behaviour. For example, once the choice to go for cervical screening has been made, an appointment needs to be made and kept. Secondly, individuals get invited for screening (as opposed to intentionally visiting or not visiting a doctor for a health problem). Thus the notion of intentionality may be problematic. Whether intentionality is a pre-requisite for autonomy when the choice has been imposed on a person, has not been evaluated in other studies. I would argue that because of the nature of screening (inviting healthy people to attend for screening); intentionality might not be of primary importance when defining autonomy in this setting.

Autonomy and understanding

It is important to theorise about some of the implications of having understanding as a pre-requisite for autonomous actions (or intentions). Faden and Beauchamp argue an action cannot be autonomous if the person does not have an understanding of the action

they are performing.[8] On the one hand, this argument fits in well with that of informed choice enhancing patient autonomy. However on the other hand, by making understanding a pre-requisite of autonomy, it could actually diminish an individual's ability to be autonomous. For example, a strong a priori belief or experience may over-rule any information needs.

In the context of this thesis, the main issue which needs to be resolved centres on whether a person can perform an autonomous action that is not informed. The argument seems, on the face of it, to challenge the notion of using informed choice to enhance patient autonomy. It is not; it is arguing that understanding should not be a pre-requisite of autonomy in cancer screening. For if autonomy is about freedom, then it can be argued that people should have the right to make decisions, in the way that they want to (with or without understanding). This concept of freedom as a right is apparent in the writings of JS Mill, a British philosopher and economist of the 19th Century.[9] However, he does argue that autonomy requires understanding of the consequences:

'If either a public officer or any one else saw a person attempting to cross a bridge which had been ascertained to be unsafe, and there were no time to warn him of his danger, they might seize him and turn him back, without any real infringement of his liberty; for liberty consists in doing what one desires, and he does not desire to fall into the river.' (Mill, 1869)

Applying this argument in the context of screening, a woman who was invited for a cervical smear, but has been sexually abused in the past may have already decided without any information that she would not go. It could be argued that any information about cervical screening is extraneous to her ability to make an autonomous decision and act autonomously. Conversely, however, it could be argued that it is important for her to have information on the consequences of not going (such as the symptoms of cervical cancer, preventive strategies, and risk factors).

In the qualitative data, the only examples of people not wanting information to make a choice were primarily concerned with the *process* of screening rather than the *principle*

[8] They define this as understanding the nature of the action and the foreseeable consequences and possible actions that might follow as a result of performing or not performing the action.
[9] For example he writes 'Over himself, over his own body and mind, the individual is sovereign'.

of screening. Perhaps this comes back to Mill and his definition *'he does not desire to fall into the river.'* Few of us would desire to develop cancer but, using Mill's example, some people were deterred by the screening process and would not participate. Thus they might not need information, for example, on the risks of screening to make the choice about participation. However, as mentioned previously, they may need information on symptoms and preventive measures.

In the context of cancer screening, although information can enhance patient autonomy, I argue that it does not necessarily mean that it will enable it, nor is it essential to it. Informed consent can protect choices that lack autonomy just as much as it protects choices which are autonomous (O'Neill, 2003). Wear argues that nowhere in the conceptualisation of autonomy is knowledge a condition for freedom (Wear, 1998; 41). In a recent paper on the 'right not to know' in genetic testing, it is contended that:

'Autonomy understood in a wider sense, provides a theoretical basis for the right not to know [one's genetic status].' (Andorno, 2004)

Having understanding (e.g. knowing the risks and limitations of screening) as a pre-requisite for autonomy can be viewed as being paternalistic, and rather than enhance autonomy, may be a form of control. For example, as discussed in the section on risk, people may be seen to be irrational and irresponsible if they do not make the 'right decision' based on the information. In addition, policy makers and health professionals may become the gatekeepers for information provision, deciding what information a person needs to be informed. Section 2.25 discusses the issues of information provision in more depth.

In summary, I would argue that if we are to accept that the provision of information is central to autonomy, then only one piece of information is needed for a person to make an *autonomous* choice in cancer screening (as opposed to an *informed* choice). This is the knowledge that they have a choice (i.e. to take up the offer or decline it). This would seem obvious, but many people today are not presented with the invitation as a choice.[10]

[10] For example, my recent invitation for a smear simply stated, 'It is time for your smear. Please make an appointment to attend.'

Autonomy and freedom from coercion

This third criterion of autonomy (freedom from coercion) suggested by Faden and Beauchamp is perhaps the least difficult to resolve. It fits in well with other constructions of autonomy which relate to freedom of will and lack of coercion. For example, it has been argued that it is freedom from coercion which is the best reason for taking informed consent seriously (O'Neill, 2003). However, the term coercion suggests that some sort of active pressure is put on an individual. But coercion can be more subtle. For example, telling a person that their smear is due, without any further information, could be seen to be a subtle act of coercion. In this instance, a GP may want a person to follow a definite course of action (take up the offer of screening). No option is given to make an alternative. Thus I would argue that, to ensure autonomy, a person needs to know that a choice is available, and that neither choice is regarded as being the 'wrong choice' for that individual. It might be a 'wrong choice' from another person's perspective, but that is a different issue.

Autonomy and informed choice

In the light of the arguments outlined above, it is reasonable to argue that although being informed may increase and enhance autonomy, it does not ensure it, nor is it essential. For example, O'Neill argues that,

'If informed consent is ethically important, this cannot be because it secures some form of individual autonomy.' (O'Neill, 2003)

She reasons that the purpose of informed consent should be to provide reassurance that patients and others are neither deceived nor coerced. Thus it would seem that a definition of autonomy which is based on freedom to choose, rather than being informed may be more appropriate in the case of screening. From this definition, a person, who rejects screening (for whatever reason), can be making an autonomous choice without being informed. As long as a person is making the choice that they want to make, this could be deemed to be acting autonomously. Equally, if a person decides that (s)he wants to be informed but does not want to make the final decision, it could be argued that (s)he is autonomously opting out of the decision making process. For example, there is evidence that some people do not wish to be involved in making decisions about their care (Robinson and Thomson, 2001). A person may want to be informed, but choose to let

someone else make the decision, or they may wish to make the decision with a health professional (shared decision making)

Autonomy and informed shared decision making

Shared decision making occurs in the purest form when both doctor and patient reveal treatment preferences and both agree on the decision to implement (Charles et al, 1999). Informed shared decision making has been described as 'decisions that are shared by doctor and patient and informed by best evidence, not only about risks and benefits but also patient specific characteristics and values' (Towle et al, 1999). In shared decision making, both the health professional and the patient are assumed to have a legitimate investment in the treatment decisions (Elwyn and Charles, 2001). It may be seen as both reducing and increasing patient autonomy. For example, Elwyn and Charles go on to state that,

'If they disagree [about a treatment option], each participant may try to persuade the other of the merits of his or her favoured option.'

However, a person can make an autonomous choice to share the decision with a health professional and this does not mean that the person has not acted autonomously. Thus autonomy can exist within shared decision making, but it may be reduced. It has been argued that people are ill-informed about what is entailed in the process of shared decision making. For people to make an informed decision about the extent to which they participate in shared decision making, they should be given some indication of the likely benefits of doing so (Robinson and Thomson, 2001). There is also evidence that older people are less likely to want to participate in the decision making process (Beisecker, 1988) and this may have implications for informed choice interventions and the measurement of informed choice in cancer screening, in particular the robustness of an instrument in different age groups.

At the present time, screening (with the exception of cervical screening) resides outside the traditional patient- doctor framework. It takes place at the level of organised, centralised screening programmes, with little interaction between screening invitees and health professionals. Therefore, consideration of the implications of shared decision making on patient autonomy are not of great relevance in this context. However, it is

acknowledged that people may wish to be more involved in some decisions about screening than others. Thus it may be important to distinguish between evaluating what information is being given, and evaluating whether or not a person wants to take responsibility for deciding whether to have a treatment or intervention.

Individual autonomy in the public health arena

Currently cancer screening is primarily a public health policy. Within screening, promoting informed choice is viewed as a way of enhancing patient autonomy. The central issue, however, is whether government-sponsored health initiatives are compatible with the concept of respect for individual autonomy. This concept is grounded in the theory of liberalism, and implies that individual rights are paramount (Roberts and Reich, 2002). However, many public health policies, such as screening, are grounded in positions based on outcomes (the theory of utilitarianism). Thus there may be a tension between a paternalistic policy aimed at the benefit of the population, and other policies promoting individual autonomous decision-making.

Public health medicine, with its grounding in utilitarianism, is by nature paternalistic, in that it acts 'for the public good' with little consultation with individuals. It has been contended that public health has expanded its remit to include controlling, or attempting to control, the choices, or even the desires, of human beings. Thus there has been a shift from health protection to health promotion.
It has been argued that,

'In trying to influence the pattern of human choice and motivation, public health practitioners are utilising scientific techniques in order to develop the power to alter people's behaviour. Ethically it is not easy to reconcile this with values such as autonomy, integrity, responsibility, or a respect for justice.'
(English et al, 2002)

The more effective a public health campaign becomes (e.g. by reducing injustice), the greater potential there is for governmental interference with autonomy (Faden, 1987). Faden describes three types of social influence that are of concern in this area: persuasion, psychological manipulation and manipulation of information (see section 2.23 for more discussion of these issues). For Fadden, there is a direct relationship between the justification for a public health campaign and the extent to which it is

morally acceptable for that campaign to violate the principle of respect for autonomy. Therefore, when considering individual autonomy within the context of public health it is necessary to consider how it competes with the desire for public good. It has been argued that:

'By placing too much emphasis on the promotion of individual patient choice especially when such choices are actually made alone, brings with it the danger that we might neglect either the interest of others or the broader public interests.' (Parker, 2001)

How and if these two important concepts (individual autonomy versus desire for public good) - embodied in individual informed choice and outcomes such as uptake - can be compatible is one of the themes that will run through this thesis.

Autonomy, society and culture

The concept of autonomy can be viewed as overly individualistic, ignoring the fact that we are all 'socially embedded' (Parker, 2001). However, Parker argues that whilst individuals may make choices, these are not necessarily selfish. For example, people may participate in screening the hope that, even if it does not necessarily benefit them directly, it might benefit others. One way of doing this is through the use of decision aids, which could encourage people to consider the social as well as the individual consequences of their choices (Entwistle, 2001).

It has also been contended that if informed choice is premised largely on the autonomous individual and his or her rights, with little or no conception of the social aspects, it can become stripped away from its context and reduced to a rational-choice model of action. This has been described as an 'empty ethics model' (Corrigan, 2003). Corrigan also contended that the model was limited because it was premised on a universal standard principle, which not only reduces the significance of other ethical principles but also ignores the cultural context within which the process of consent takes place. For example, cultural differences between and within societies exist that emphasise individual autonomy, and autonomy which is derived from membership of a family, group or community.

Whilst these arguments are persuasive, it is important to consider that screening is an intervention aimed at 'healthy' people who are approached by the screening service to participate in screening. It could be argued that both autonomy and information are particularly important in situations where healthy people could be harmed as a result of participation.

Informed choice approaches to screening are mainly to be found in situations where the consequences of uninformed screening are viewed as unacceptable or have a moral dimension. In antenatal screening, for example, termination of pregnancy is a possible outcome. Thus, a policy of informed choice is seen as central to individual autonomy and to avoiding eugenic practice (Marteau and Kinmonth, 2002). Whether cancer screening invitees need, or will be given, the same amount of autonomy in their decision making compared to antenatal screening is not yet known.

2.22 Summary of the literature on informed choice and autonomy

In this thesis, informed choice and autonomy are being evaluated within the context of a public health policy. From this section, it is clear that being informed does not necessarily mean that the information is used to make a choice, and that the choice is autonomous and free from coercion. The qualitative and quantitative studies both explore the relationships between information, choice, and autonomy in more detail.

The central aim of this thesis is not to measure autonomy per se, but to measure informed choice. As mentioned previously, however, autonomy and freedom from coercion are central tenets of informed choice, and need to be taken into account. What is perhaps most important in evaluating autonomy is whether people have made a choice which is free from coercion, in the knowledge that they have a choice, and with some understanding of the consequences of that choice. Information can enhance autonomy, but is not vital to it.

SECTION 5. INFORMED CHOICE IN CANCER SCREENING

Informed choice emerged as an important feature of health care in the early 1990s. A search of the electronic databases found that the term 'informed choice' was first used in 1991 in the areas of contraceptive use (Dobree, 1991; Rands, 1992) followed by maternity care (Biggins, 1992). In 1994, two articles highlighting the importance of informed choice in antenatal screening were published (Crossley et al, 1994; Summers, 1994). Articles about cancer screening that specifically mentioned the term 'informed choice' were not published until the mid-1990s. However even in 1988 people were arguing for the provision of information on risks and benefits. For example, Skrabanek wrote,

'Screening healthy people without informing them about the magnitude of the inherent risks of screening is unjustifiable.' (Skrabanek, 1988b)

This article was followed shortly after with an article by Dr Roberts (clinical director of the Edinburgh Breast Screening project) who said,

'I hope very much that pressure is not put on women to attend. The decision must be theirs, and a truthful account of the facts must be made available to the public and the individual patient. It will not be what they want to hear.' (Roberts, 1989)

It took several years before the arguments were raised again in the medical literature, and the term 'informed choice' used. In the mid 1990's Angela Raffle, who was director of the cervical screening programme in Bristol, published several articles about the importance of informed choice in cervical screening, and some of the limitations of the cervical screening programme (Raffle, 1997a; Raffle, 1997b; Raffle, 1999; Raffle, 2000; Raffle, 2001; Raffle et al, 2003; Raffle and Morgan, 1998; Raffle et al, 1995). In 1999 Joan Austoker, who was involved in the breast screening programme, wrote about the misconceptions among the public about the purpose of screening and the accuracy of screening tests and the importance of informed choice in cancer screening (Austoker, 1999).

2.23 Provision of information to make an informed choice

Up until recently, provision of information about cancer screening has either been non-existent, or focused on the benefits and/or the process (e.g. having a cervical smear). In effect, the population has largely been treated as passive recipients of screening, rather than active participants who make an informed choice. It has been argued that in order to make an informed decision about whether to participate in screening, an explicit sharing of information about the risks and benefits is required (McCormick, 1996). This is likely to become more evident in the UK with the recent guidance issued by The General Medical Council (General Medical Council., 1999) which states that doctors should give information on the following:

- the purpose of the screening
- the likelihood of positive and negative findings and possibility of false positive/negative results
- the uncertainties and risks attached to the screening process
- any significant medical, social or financial implications of screening for the particular condition or predisposition
- and follow up plans, including the availability of counselling and support services.

These guidelines were developed by a GMC Standards Committee working group. The working group prepared draft guidance which was issued for public consultation. Replies to the consultation were received from Council members, patient groups, medical bodies and other organisations with a particular interest in consent (personal communication, August 2004). In preparing the guidance, the Standards Committee took detailed advice on case law in this area, to establish at least the minimum standards of acceptable practice. However, the aim was to produce ethical rather than legal advice.

There is an assumption that if information on risks and benefits has been given, the person will be informed and be able to carry out their intended choice. However, provision of good reliable information does not ensure that the recipient understands it. In addition, it does not ensure that they have the option of making a choice, or use this information in the decision making process.

Currently, little is known about how information is used in cancer screening and what information people want and need in order to make an informed choice. It has been argued that people do not just want information on risks and benefits to make an

informed decision. They may also want information on how people who have been through a negative experience have coped, what it is like to experience a particular health state, and outcomes that are important to them (e.g. quality of life) (Entwistle and O'Donnell, 2001). People vary in the amount of information they need or want in order to make a decision. This issue is discussed further in Chapters 3 and 5.

2.24 Public understanding of screening

Public understanding of screening is primarily limited to the benefits of screening. In addition, there are misconceptions about the purpose of screening and the accuracy of screening tests. For example, an Australian study found that although 68% of study respondents had heard of screening, only 21% correctly understood that screening was for asymptomatic people (Cockburn et al, 1995). Another study, undertaken in Switzerland, found that most women were either uninformed or overestimated the effectiveness of breast cancer screening (Chamot and Perneger, 2001). These misperceptions may be a result of poor communication of screening information to the public. A review of 58 pamphlets on breast cancer screening (also undertaken in Australia) found that information about the accuracy of screening tests was provided only occasionally (Slaytor and Ward, 1998). The most common piece of information provided in the leaflets was on incidence (as opposed to mortality).

2.25 Providers of information on cancer screening

Provision of information is undertaken largely by charities such as Cancer Backup or by those who provide the service. For example, the UK Breast Screening and Cervical screening programmes now produce leaflets entitled, 'Breast screening: The Facts', and 'Cervical screening; The Facts' (DoH, 2003a; DoH, 2003b). Much of the information contained in these informed choice leaflets are based on the GMC guidelines (see section 2.23) supplemented by focus group work. However, it could be argued that when the information is developed and disseminated by provider of the service, the information given might not be wholly impartial. For example, when talking about these screening leaflets, Julietta Patnick, national co-ordinator for the NHS Screening Programme, wrote

'We are confident breast screening is saving lives, and so we very strongly encourage women to accept their invitation for a mammogram, but in the end it is not our choice, it's up to the individual woman.' (Patnick, 2003)

In this statement, there is still a strong emphasis on the benefits of screening, and information produced by the programmes is likely to reflect this bias. A study evaluating information on screening Websites reported that information material provided by governmental organisations is severely biased in favour of screening and only a few fulfilled accepted standards for informed consent (Jorgensen and Gotzsche, 2004). As mentioned in previous sections, manipulation of data may compromise autonomy and render people ignorant by constraining information relevant to their decision (Faden, 1987). Faden also asserts that information which overwhelms, provokes fear, or presents information in a way to draw predictable conclusions, is also manipulative.

2.26 Informed choice or informed compliance

As mentioned previously, the goal of enhancing choice cannot be to encourage a specific choice to be made (Hope, 1996). Many health education campaigns used information as a way of persuading people to choose certain health behaviours (e.g. stopping smoking). However, there is debate about when persuasion becomes coercion. It has been argued that one central feature of persuasion is that the reasons that make an argument persuasive (e.g. breast screening saves lives) must exist independent of the persuader (Faden, 1987). However, if the persuader manipulates the information (by omission, giving excessive detail or presenting the information to mislead) this may compromise autonomy. Choices are not always presented as equal and morally neutral (see section 2.8). A qualitative study evaluating evidence-based leaflets in primary care reported that choices in many leaflets were deemed to be 'right' and 'wrong' choices, rather than informed choices. The authors concluded that the culture into which leaflets on informed choice were being introduced resulted in *informed compliance* rather than *informed choice* (Stapleton et al, 2002).

It appears that there may be a grey area between promoting informed choice, and persuading someone that it is the best thing for them to do. There is the concern about what exactly are the 'true' facts' about any screening programme, especially in the more

controversial screening programmes such as that for cervical cancer (Raffle, 2001). Even where there is 'truth', the way it is presented may influence decision making.

2.27 Risk communication in cancer screening

Education and communication are seen as logical ways to raise awareness of risk or correct misperceptions. There is now a large body of literature on health risks, and risk-related topics. Approaches to communication of risk are based on the assumption that individuals will rationally review evidence and choose the course of action that will maximise benefit to health. However, rationality is not the only component in decision making; apparently irrational influences and considerations exert strong pressures (Thornton, 2003); the way in which people assess and interpret risk information can be highly contingent on the socio-cultural content (Vahabi and Gastaldo, 2003).

There are two main types of risk information presented to people who go for screening, information about the disease (personalised and general risk information); and information about the risks of taking part in screening. The way that information is presented may be as important as the information itself. The available evidence shows that the way risk information is presented can have significant effects on decisions made (Edwards et al, 2001; Gurm and Litaker, 2000; Lauver and Rubin, 1990; Sarfati et al, 1998).

Information on individual risks (of the disease) and risk reduction can also be presented in two ways. Firstly, the same data on risk reduction can be presented as relative risk or absolute risk. For example, 'colorectal cancer screening reduces deaths by 17%' (relative risk reduction) versus 'colorectal cancer screening reduces lifetime risk from 3.7% to 3.4%' (absolute risk reduction). A telephone survey of Australians reported that respondents were most likely to accept screening when the benefits were presented as relative risks. Conversely, they were most likely to reject screening when benefits were presented as numbers needed to screen to save a life (Sarfati et al, 1998). The authors concluded that,

'Health professionals must choose between framing the benefits in the most positive light, to enhance participation rates, and presenting information in such a way as to reduce framing effects. Clearly there may be a tension between these approaches; the former is arguably manipulation, and the latter may enhance informed choice but may also reduce participation in screening programmes.'

Secondly, data can also be 'framed' positively or negatively. For example, the risk of an individual having a disease can be described as '1 in 9 chance of having it' or an '8 out of 9 chance of not having it.' 'Loss framing' is more effective in influencing screening uptake behaviours than 'gain framing' (odds ratio 1.18 (95% CI: 1.01 to 1.38) (Edwards et al, 2001).

There has also been research into different formats to present information. For example, one study evaluated decision aid formats which illustrate visually the outcomes for 1000 women and 100 women choosing each alternative: breast screening or no breast screening (Marshall and Adab, 2003).[11] Another suggested different ways of presenting the same numerical data (e.g. quantitatively, qualitatively, and/or by "anchoring" to everyday experiences) (Goyder et al, 2000).

Previous sections have outlined how the concept of risk has been constructed and incorporated into the area of health (see section 2.5). It has been argued that communication of risk information needs to take into account the public's knowledge and perceptions of health risk. In addition, doctors need to understand that they may no longer be trusted as a source of information (Alaszewski and Horlick-Jones, 2003). A systematic review of risk communication in screening programmes found that personalised risk communication was associated with increased uptake of screening programmes (Edwards et al, 2003). However, as the authors note, this may not be interpretable as evidence of informed decision making. What is evident from the literature on presentation of risk information is that it has the potential to significantly affect behaviour.

[11] I used the decision aid reported in this paper in my last two breast screening focus groups (see pg 201)

2.28 Tensions between informed choice and high uptake

High rates of uptake need to be attained if screening programmes are to have a significant population impact in reducing mortality and/or morbidity from a disease. Consequently, however, tensions arise between promoting informed choice, where the individual may choose not to undertake screening, and promoting effective public health policies such as screening. Table 1 outlines the advantages and problems of the two different types of information.

At the current time, there is no evidence from RCTs to justify concerns that informed choice will negatively affect uptake rates. The majority of trials of interventions to increase uptake of screening have been primarily promoting uptake not informed choice. However, those trials that have evaluated informed choice interventions have not conclusively shown whether giving information on the risks and benefits affects uptake (Jepson et al, 2001) (see also Chapter 3 Part 2). Whether the provision of information has a differential effect, depending on the disease/condition being screened for, is also not known.

Table 1. The advantages and problems of giving promotional information versus givi full information about harm and benefit[12]	
Information to encourage uptake	Information to explain potential limitations and adverse effects as well as benefits
Advantages	*Advantages*
Achieves maximum participation and therefore maximum capacity to benefit	Fulfils GMC guidance about informed consent
Low cost if simple leaflets and posters used, with minimum staff time needed for detailed explanations	Respects principle of individual autonomy
	Creates better working environment for staff involved in screening if public and professionals understand the training and quality standards, and if limitations are recognised as not the fault of staff
	Achieves better public and professional understanding to enable open debate about existing and future investments in screening
Problems	*Problems*
Ignores principal of autonomy	Risks a reduction in uptake and thus a reduction in capacity to benefit
Risk of harm to individuals if symptoms are disregarded because of lack of public and professional understanding	Likely to increase the staff time needed for explaining limitations as well as benefits
Risks legitimate individual and public anger when implied promises are not met	If full information leads to such low uptake that the service is barely viable, then the cost-effectiveness would be reduced
Creates problems for staff in screening who carry blame for problems that are in fact inherent	
Creates problems for achieving open public debate about existing and future investment in screening because of lack of public understanding	

The central tenet of this debate is that people who would have gone along for screening may be less likely to attend if they are given the 'full facts'. However, the opposite may also be true; those people who would not have gone for screening will decide to go. One explanation for the concern over uptake could be that policy makers are aware that screening is not as effective, nor as safe, as it has been promoted over the last decades. If screening for a particular disease or condition was effective, fulfilled all of the Wilson and Jungner criteria, and the risks and limitations outweighed the benefits, then it could be hypothesised that uptake would be little affected by the provision of information. However, other outcomes of screening such as anxiety and satisfaction may be much improved.

[12] Table reproduced from (Raffle, 2001) with permission of the publishers

There is also a concern that the take up of screening in disadvantaged groups might be jeopardised with a policy of informed choice. If it results in low uptake (due to people making an informed choice *not* to be screened), new ways of organising screening may need to be considered. What is important is how the basis of this principle is going to be implemented, and if it will negatively affect people such as the disadvantaged.

2.29 Definitions of informedness for those who choose not to participate

People may choose at the outset to reject being part of a screening programme (or accept it) because they have a strong prior belief or experience that affects their choice.[13] The information needs (and therefore the definitions of 'being informed') may differ for those who choose not to participate. For example, if a person knows they do not want to participate in screening there may be little additional benefit of being given information on the risks and hazards of a particular screening test. However, there may be benefit in her being informed about the risk factors and symptoms and other consequences of not being screened. Information on the risk factors may enable a person to modify their lifestyles to reduce their individual risk; symptoms may alert them to the presence of disease. What is clear is that people who do not participate in screening should not be labelled as 'uninformed' if they do not know the consequences of a particular screening test.

2.30 Effect of informed choice on other screening outcomes

In a time of limited resources, it is important to consider how respect for autonomy and informed choice compete with other outcomes of screening. For increasing informed choices may result in an increased or decreased use of health services and in some situations maximum health gain will not be reached. In addition, resources spent on promoting informed choice may result in under-funding of other areas in screening.

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[13] For example, they may have a strong belief ('God will protect me') or life experience (sexual abuse) which means that they will not participate in screening under any circumstances.

2.31 Summary of the literature on informed choice and cancer screening

Informed choice in cancer screening is a relatively new concept. Although it is now part of screening policy, there are concerns that increasing informed choice will result in a decrease in uptake. These concerns may affect how policies of informed choice may be implemented. Information provision may be subject to subtle manipulation which may not present choices in an unbiased manner. Understanding of how best to present and discuss risks and benefits of health care in general, and screening in particular, is still limited. However, the way that information on risks is presented can have a major impact on informed choice.

SECTION 6: THEORETICAL FRAMEWORKS FOR THE THESIS

Different theories and models have been applied to try to understand and predict a range of health behaviours. They have also been applied to screening intention and behaviour. These include theories of risk and risk reduction, decision making, and health behaviour. This section discusses their importance in cancer screening, and as a theoretical framework for measuring informed choice.

2.32 Theories of health behaviour

Theories of health behaviour were developed to understand factors that determine health behaviours. The main theories of health behaviour are based on social cognition models. Such models assume that an individual's behaviour is best understood by perceptions of the social environment (Conner and Norman, 2001). There are two distinct types of health behaviour models. Firstly, those that can be seen as continuum accounts of behaviour (the Health Belief Model, and the Theory of Planned Behaviour) and secondly, those that are stages of behaviour (e.g. Transtheoretical Model) (Rutter and Quine, 2002).

Theories of health behaviour have been used as a basis for interventions to increase the uptake of screening and to predict screening behaviour. For example, 38 of the 190 trials included in the systematic review of interventions to increase the uptake of screening used a health theory or model to develop the intervention (Jepson et al, 2000). The most common theory was the Health Belief Model (17/38) followed by the Theory of Reasoned Action (4/38). It is the continuum models that have been used most often in cancer screening and therefore discussion is limited to these models.

Health Belief Model

The Health Belief Model (HBM) was originally developed in the 1950s to identify appropriate targets for health education programmes. Originally, the HBM proposed that an individual's readiness to take action for a specific health behaviour is dependent on: 1) a person's perceived *susceptibility*, and perceived *severity* of illness; 2) expectancy of potential *benefit* in reducing susceptibility weighed against *barriers* (i.e. financial,

physical and psychological); and 3) *cues to action* which can be both internal (perception of body states) and external (interpersonal interaction and/or mass media communication). More recently, self-efficacy (one's confidence in the ability to perform an action successfully) has been incorporated into a revised explanatory model (Rosenstock et al, 1988).

Predictive utility of the Health Belief Model in cancer screening

A considerable number of studies have used the HBM to understand participation in cancer screening. A review assessing the utility of HBM for predicting breast cancer screening analysed 16 studies (Yarbrough and Braden, 2001). The authors found that, at best, the model explained 47% of the variance in screening behaviour when socio-economic status was included. Otherwise predictive power was low, ranging from 15% to 27%. The authors concluded that the HBM does not appear to have the power to consistently predict breast screening behaviour.

There have been several individual studies evaluating the HBM as a predictor of cervical screening uptake (Bish et al, 2000; Gillam, 1991; Murray and McMillan, 1993; Orbell et al, 1996). In one Scottish study, health beliefs, socio-demographic variables and number of sexual partners accounted for 57% of variance in screening uptake (Orbell et al, 1996). In this study, the effects of social class on screening uptake were mediated by perceived susceptibility, perceived aversiveness of the test procedure, and perceived aversiveness of a positive result. Another study used two social cognition models; the Health Belief Model (HBM) and the Theory of Planned Behaviour (TPB). The authors reported that neither model was able to account for a significant proportion of variance in behaviour, but that TPB explained considerably more variance in intentions than the HBM (51% vs. 4% by the HMB) (Bish et al, 2000).

The predictive ability of the HBM in colorectal screening has been less well investigated. A qualitative study investigated decision-making among a group of older adults who declined the offer of flexible sigmoidoscopy screening for bowel cancer. One factor that emerged which was consistent with the HBM was perceived susceptibility to colorectal cancer (McCaffery et al, 2001).

Theory of Reasoned Action and the Theory of Planned Behaviour

The Theory of Reasoned Action (TRA) is based on the assumption that, 'human beings are usually quite rational and make systematic use of the information available to them' (Ajzen and Fishbein, 1980b). The TRA proposes that the main determinant or predictor of behaviour is one's intention to perform (or not perform) a particular behaviour. The theory also attempts to understand the determinants of the behaviour as well as predict it. It proposes that there are two basic determinants of behaviour. Firstly, whether the person has a good or a bad attitude towards performing that behaviour. Secondly, the person's perception of the social pressure towards performing the behaviour (referred to as the subjective norm) (Ajzen, 1988). Thus the Theory of Reasoned Action suggests that the pathway to an individual performing behaviour is as follows: beliefs inform an attitude, which leads to their intent to perform the behaviour and then the behaviour is enacted.

The Theory of Planned Behaviour (TPB) is an extension of the Theory of Reasoned Action and recognises that not all behaviours are under a person's volitional control. Underpinning these two models is the principle of compatibility which asserts that each attitude and behaviour involves four elements which are: action, target, context and time (Ajzen, 1988). For example, a person concerned about their risk of breast cancer would go for screening (action) on her breast (target) at a health centre as part of a national screening programme (context) every 5 years (time). The main difference between the TPB and the HBM is that the HBM attempts to predict the actual probability of behaving in a certain way, whilst the TPB predicts behaviour via behavioural intention (Connor 1994). The Theory of Planned Behaviour was used to develop items on attitudes in a measure of informed choice developed for antenatal screening (Marteau et al, 2001) (see Chapter 3).

Predictive utility of the TPB in cancer screening and informed choice

Screening has not been the behaviour of interest in most studies evaluating the predictive value of this model. However, a recent meta-analysis of 185 independent studies published up to the end of 1997, reported that the TPB accounted for 27% and 39% of the variance in behaviour and intention, respectively (Armitage and Conner, 2001). As

discussed in the previous section, one study found that the TPB explained considerably more variance in intentions than the HBM (Bish et al, 2000).

Limitations of the models in cancer screening

The usefulness of these health behaviour models in predicting screening behaviour is unclear. Overall, it appears that the HBM does not have the power to consistently predict screening behaviour. A number of fundamental difficulties with the HBM have been identified, which could explain the lack of predictive power in cancer screening in particular. One difficulty relates to the conceptualisation of the susceptibility component. Most studies evaluating the model do not ask the participants whether they have ever heard of the threat in question (Weinstein, 1988).

Optimism bias (as mentioned in section 2.6) may also affect the predictive power of the models. Two studies of cancer screening behaviour assessed the extent to which unrealistic optimism occurred in relation to each of the elements of the HBM: severity and curability of cancer and the benefits of, and barriers to, having a screening test. Women had an optimistic bias in relation to breast cancer risk and severity and barriers to having a screening mammogram but not in relation to the benefits of screening. For prostate cancer, there was an optimistic bias for all HBM variables: risk and severity of prostate cancer and barriers to and benefits of screening. It was concluded that unrealistic optimism was evident for all elements of the HBM (Clarke et al, 2000).

The usefulness of TRA/TPB has not been well evaluated in cancer screening. In addition, neither the TRA nor the TPB take into account a person's past behaviour. One of the most consistent predictors of screening behaviour is prior screening behaviour (Jepson et al, 2000). The effect of prior behaviour, like other external variables, is assumed to be mediated via intention (Sutton, 1994). Thus, the models may have limited usefulness in predicting screening behaviour.

2.33 Theories of decision making

Theories of decision making have been used both to understand cancer screening behaviour, and within the area of informed choice. Decision theory is designed to help understand how a decision-maker chooses among a set of alternatives in light of their possible consequences. Decision theory can apply to conditions of *certainty, risk*, or *uncertainty*. Decision under *certainty* means that each alternative leads to a single consequence and a choice among alternatives is equivalent to a choice among consequences. Decision under *risk* means that each choice will have one of several possible consequences and the probability of occurrence for each consequence is known. Decision under *uncertainty* is when the probability of occurrence for each consequence is unknown (Wright, 1984). Theories related to decisions under risk include the (Subjective) Expected Utility Theory, and the Game Theory. Decision making theory can be classified into three categories (Bekker et al, 1999):

Normative decision making theory assumes that people are rational. Such theories are usually based on mathematical and statistical proofs (e.g. Subjective Expected Utility Theory).

Behavioural decision theory describes how people make decisions, and some of the psychological models of health behaviour outlined previously could fit into this category.

Prescriptive theories recognise that people can be poor decision-makers and are concerned with the development of decision aids.

Informed decision making interventions

Two systematic reviews have evaluated the ways that information is used in decision making. A systematic review of informed decision-making interventions suggested that information and education are relatively ineffective ways of facilitating informed decision making, compared with contextual and social influences (Bekker et al, 1999). A systematic review of decision aids concluded that whilst they improve knowledge, reduce decisional conflict, and stimulate more active decision-making they have little effect on satisfaction and a variable effect on decisions (O'Connor et al, 1999). Thus, the most consistent benefit of the decision aids was better knowledge of the options rather that aiding the decision.

2.34 Theories of risk communication

Theories of risk indicate that there are two fundamental ways in which human beings comprehend risk. The analytic system (sometimes called rational) which uses algorithms and normative rules and the experiential system (intuitive and emotional), which is mostly automatic, and not very accessible to conscious awareness (Slovic et al, 2004). Slovic et al argue that advocates of formal risk analysis tend to view affective or emotional responses to risk irrational, but rational decision making cannot be effective unless it is guided by emotion.

Theoretical models for risk communications are derived either from cognitive psychology models, or decision-making theory. Some models such as the Theory of Planned Behaviour and the Health Belief Model seek to provide an understanding of people's perception of risk and how this influences behaviour (Edwards and Bastian, 2001). Both emphasise the perceived value of a presented consequence and are often used as the basis for risk communication interventions. As discussed previously, these models are concerned with predicting changes in a person's behaviour. However, as Edwards argues, they are one step removed from being models by which to understand risk communication (interaction between a professional and a patient). Informed choice is also concerned with how information is effectively communicated to patients, and how it is utilised. Edwards, whilst acknowledging the lack of theoretical models for risk communication, draws attention to pragmatic research on how risk information is communicated. For example how risk information is presented. This research was described in section 2.23.

2.35 Relevance of theories to the thesis

The purpose of developing the measure of informed choice (MICICS) was to evaluate whether people have the information they need to make an informed choice and had the freedom to make the choice. Whilst informed choice may enable more rational decision-making, its primary aim is to enhance patient choice and autonomy (regardless of the rationality of the decision). The HBM in particular has been criticised for its abstract nature and its emphasis on the rationality of patients' behaviour (Gillam, 1991). This criticism could also be applied to the TRA/TPB, and theories of decision making. If the

underlying constructs and purpose of these models is rationality, then they may have limited relevance to constructing a measure of informed choice.

In addition, several of these models assume that people have an understanding of the risks and severity of disease. That is, they pre-suppose an existing knowledge base. The qualitative data (see Chapter 5) revealed that many people did not know what the risks of disease were, or the potential negative consequences of their screening behaviour.

The theories discussed in this section may provide a useful framework for understanding the degree to which people use information in cancer screening. They will be used in the analysis of the qualitative data, and in the development of some of the items in the measure of informed choice. For example, both intention and behaviour were assessed in the measure. However, none of these theories were thought to be adequate to use, on their own, as an underlying theoretical framework for developing the measure of informed choice.

2.36 Summary

This literature review aimed to provide a framework for defining the essential components of informed choice. The rationale for screening is to reduce the risk associated with a disease or condition. Information deemed important to make an informed choice in cancer screening is primarily concerned with risks (e.g. risk relating to the disease, and risk relating to the screening process). Cancer screening programmes differ in the incidence of the disease, as well as the risks and consequences associated with the tests.

It is beyond the scope of this thesis to undertake a comprehensive assessment of the impact of politics, economic concerns, technological advances, and new ideologies on screening. However, from the historical perspective outlined in section 1, several observations can be made. Firstly, public health and choice appear to be linked (at least historically) with economic and political concerns. Secondly, the rise of technology, combined with our increasing preoccupation with risk and risk reduction, influences attitudes towards screening. Finally, responsibility for aspects of health such as

prevention of disease appears to shift between the individual and the state. Currently, in public health policies such as screening, the balance of responsibility appears to lie somewhat uneasily between the two. The introduction of choice (individualism) into a state health initiative could present a conflict between public health interests, and the rights of individuals to refuse health interventions imposed by the state.

Cancer screening is neither morally, socially nor politically neutral; it is rooted within political, economic and ideological frameworks. Disease prevention initiatives such as screening may be embedded in a moral framework that blames individuals who fail to participate. Thus a paradox appears to exist regarding choice within preventive medicine; if you make the 'wrong' choice you are deemed to be irresponsible. Therefore, the whole concept of informed choice may be at variance with public health policies. However, current policy outlines the responsibility of screening programmes to allow individuals to make an informed choice. How this is to be achieved, and indeed whether it is achievable, forms a large part of this thesis.

CHAPTER 3. SYSTEMATIC REVIEWS

The purpose of this chapter was to provide a thorough examination of the empirical literature on informed choice in cancer screening. Three types of literature were thought to be important in the development of the measure of informed choice: studies which measured informed choice and patient preference; qualitative studies which explored meanings of informed choice; and quantitative studies that evaluated informed choice. Part 1 is a systematic review of other measures of informed choice in the healthcare literature.

The second part of this chapter focuses on a systematic review of both the qualitative and quantitative literature. It is part of a larger Cochrane review which I am undertaking with colleagues in France (Broclain et al, 2004). Originally I had only intended to include RCTs. However, The Cochrane Collaboration and other bodies have recently provided compelling reasons for including qualitative research into systematic reviews (Cochrane Qualitative Methods Group, 2004; Thomas et al, 2004). I therefore decided to use a relatively new approach (Thomas et al, 2004) to evaluate both qualitative and RCTs on informed choice in cancer screening. This will be discussed in more detail in part 2.

PART 1. SYSTEMATIC REVIEW OF INFORMED CHOICE MEASURES IN HEALTH CARE

Systematic review methods have been developed primarily to summarise research that investigates the effectiveness of health care interventions. This review applies the concepts of systematic review methods to the area of instrumentation. The methods are based on a systematic review to identify instruments measuring the involvement of patients in shared decision making (Elwyn et al, 2001). Thus, where possible, the inclusion criteria, search strategy and methods are undertaken in a systematic, transparent and repeatable fashion, similar to the systematic review of informed choice interventions undertaken in Part 2.

3.1 Aims and objectives

The main aim was to undertake a systematic review of instruments that focused on measuring the extent to which patients and individuals make an informed choice about healthcare decisions. The main rationale for developing any new instrument is that no other similar measure exists. Therefore a thorough search needed to be undertaken to identify existing instruments. The main objective was to identify whether other instruments in this area were so similar that development of a new instrument was not justified. If no similar instrument existed, I wanted to establish whether related instruments were relevant to a measure of informed choice in cancer screening. If so, whether they could be used in the development of the measure of informed choice

3.2 Criteria for inclusion

I included any study evaluating a measure of informed choice or informed consent within the context of screening or health care. In addition, any measure of informedness (risk and benefits of screening) or autonomy, two of the key domains of informed choice were included. To be included in the review, the scale must also have been validated and used in a least one setting. Scales measuring shared decision-making were excluded as these were considered to be looking at a different type of decision-making. I was interested in how informed choice was measured as opposed to shared decision making. These studies have been evaluated extensively in another systematic review (Elwyn et al, 2001).

3.3 Search Strategy

The search strategy was developed to identify studies that reported the development or use of instruments that aimed to evaluate informed choice. Electronic databases searched were: MEDLINE, BIDS Science Citation Index, EmBase, CancerLit, CINAHL, PsycInfo, and The Cochrane Library (Cochrane Controlled Trials Register, HTA and the National Research Register). As this subject area is not clearly indexed, the strategy was designed to achieve high sensitivity rather than specificity (see Appendix 1 for details of search strategy). The search strategy was devised with the input of an experienced medical librarian. Additional references were located through searching the bibliographies of related papers and contacting specialists in the subject area of the

review. There were no language restrictions, and both published and unpublished studies were included. The search was last updated in October 2004.

3.4 Methods

All abstracts were screened for relevance. Paper copies were obtained of those that appeared to meet the inclusion criteria. Full paper copies were read in detail, and they were included in the review if they measured informed choice, informedness, or autonomy. Descriptive data for each instrument were collected which included: the stated objective, the theoretical or conceptual basis, methods of assessment, reports of instrument development and/or first use, and the apparent scope of its use.

Quality of instruments was determined by assessing the validity and reliability. Methods for both developing and confirming the validity and reliability of health measurement instruments are described in Norman and Streiner (1995), and these were used as the basis for assessing the quality of instruments in this review.

3.5 Results

1941 de-duplicated references were retrieved (original number before de-duplication was 2498). All abstracts were read and full paper copies of those thought to be relevant (or potentially relevant) were obtained (n=27). A broad approach was used - that is; studies were included in this review if it was thought that they would inform the development or validation of the measure of informed choice.

Five scales were identified that met the broad inclusion criteria. Table 2 provides a description of the scales and Table 3 outlines how the scales were developed and their reliability and validity. One scale measured informed choice in antenatal screening (Marteau et al, 2001); one measured decisional conflict (O'Connor, 1995); one measured satisfaction with decision (Holmes-Rovner et al, 1996); one measured knowledge in making decisions about prostate screening (Radosevich et al, 2004); and one measured opinions regarding the pros and cons of mammography screening (Rakowski et al, 1997). Appendix 2 details the items included on each of the scales, and the five scales are described in detail in the following sections.

Table 2. Descriptive data for instruments which contributed to the development of the informed choice measure

Instrument (First author) Country	Conceptual framework/construct Theoretical perspective	Method of assessment	Aspects of decision making considered	Population where used Types of decisions considered
Multi-dimensional measure of informed choice (MMIC) (Marteau 2001) UK	Informed choice Theory of planned behaviour	Twelve item scale (multiple choice items for knowledge, and 7 point Likert scale for attitudes).	Attitudes, knowledge and behaviour, decision choice (using the decisional conflict scale)	Pregnant women Antenatal screening for Down's Syndrome
Decisional Conflict Scale (DCS) (O'Connor 1995) Canada	Decisional conflict Construct of decisional conflict	16-item scale (5 point Likert scale for all items) 1=strongly agree; 5 = strongly disagree. Three subscales: Decision uncertainty Factors contributing to uncertainty Perceived effective decision making	Decision uncertainty, factors contributing to uncertainty, perceived effective decision making	Health science students, respiratory patients; women eligible for breast cancer screening; oncology patients (used in other settings as well) Flu injections; breast cancer screening; palliative chemotherapy
Satisfaction with Decision Scale (SWD) (Holmes-Rovner, 1996) USA	Satisfaction with decisions Built on conceptual model of an effective (informed) decision	Six-item scale (5 point Likert scale for all outcomes)	Satisfaction with decision	All healthcare decisions Postmenopausal HRT; influenza injections
PROCASE Knowledge Index (Radosevich 2004) USA	Informed choice Shared decision making	17 knowledge questions	Knowledge of prostate screening	Male veteran patients age 50 or over Whether to undertake prostate screening or not
Decisional Balance (Rakowski 1997) USA	Decision-making Transtheoretical Model of behaviour change	5 items for pros of mammography screening 9 items for cons of mammography screening	Opinions about screening (decisional balance)	Community living women aged 50-80 Intention to undergo mammography screening

Table 3. The development, validity and reliability testing of instruments that met the inclusion criteria

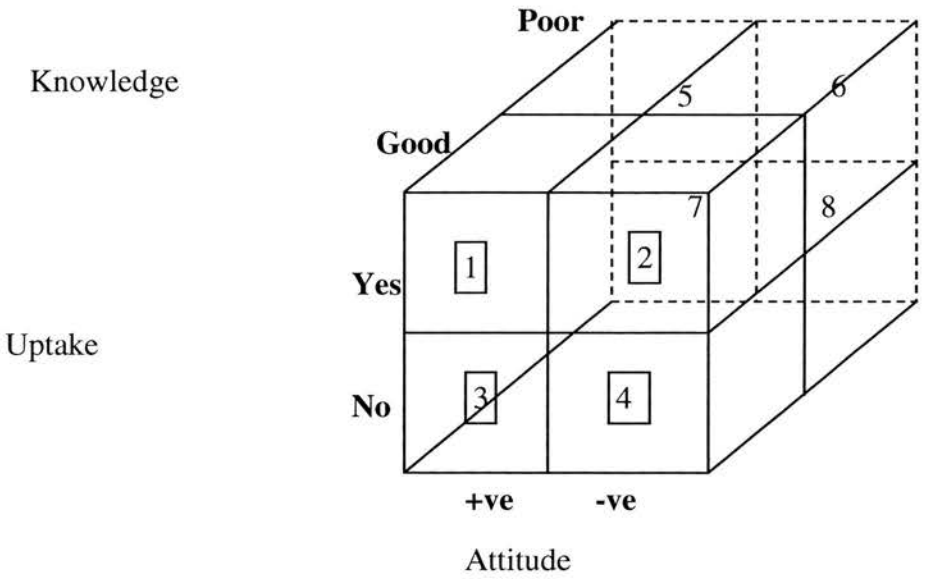
Instrument (First author)	**How was the instrument developed?**	**Reported Validity Assessments**	**Reported Reliability Assessments**
Measure of informed choice (Marteau, 2001)	Knowledge items were based on professional guidelines; attitudes items were operationalised from the Theory of Planned Behaviour. The knowledge items were piloted on pregnant women (number not stated)	Validated on a group of women receiving low risk results following serum screening for Down's syndrome. Component scales of knowledge and attitude were internally consistent (alphas = 0.68 and 0.78 respectively) (Michie et al, 2002)	**In women offered a screening test in pregnancy, the internal reliability (alpha coefficients) of both the knowledge and the attitude scales was 0.82 and 0.83 respectively.**
Decisional Conflict Scale (O'Connor, 1995)	Developed using items derived from the decisional conflict construct: uncertainty, selected factors contributing to uncertainty, and perceptions of effective decision making.	The scale was evaluated with 909 individuals deciding about influenza immunisation. Internal consistency coefficients ranged from 0.78 to 0.92 (O'Connor et al, 1999). Also validated on two groups of oncology patients who had to make decisions about their treatment. Construct validity was partly supported. Criterion validity was substantiated. In evaluating the factorial validity, it was found that the original three-factor model had to be rejected (Koerdoot (2002))	**Immunisation** **A sub sample of respondents was retested two weeks later. The test-retest reliability coefficient was 0.81.** **Breast cancer** **The reliability coefficients of the three subscales were 0.52, 0.80, 0.84, and 0.74, 0.83, 0.83 in the two samples,**
Satisfaction with decision scale (Holmes-Rovner, 1996)	Not clear how the scale was developed, but the scale was piloted on 120 women recruited from faculty and staff	Discriminant validity, tested by performing principal-components analysis of items pooled from the SWD scale and two conceptually related measures, was good. Correlation of the SWD scale with measures of satisfaction with other aspects of the decision-making process showed the SWD scale was correlated most highly (0.64) with "decisional confidence," and least with "desire to participate in health care decisions" and "satisfaction with provider."	**Cronbach's alpha = 0.86**
PROCASE Knowledge Index (Radosevich 2004)	Generated by research team, focus groups, and previous research	Content validity: from focus groups Convergent validity established by calculating Odds Ratios to measure associations between respondents' characteristics and being either a high or a low score. Criterion validity: compared the results of the test with a gold standard	**KR-20 was 0.68**
Decisional Balance (Rakowski 1997)	Unclear, possibly from previous studies (Rakowski et al, 1992). Also selected by NCI Breast Screening Consortium	Construct validity – principal components factor analysis Other aspects of validity not discussed or reported.	**Cronbach's alpha for pros scale = 0.76** **Cronbach's alpha for cons scale = 0.60**

1. Multidimensional Measure of Informed Choice (MMIC) (Marteau 2001)

This was the only measure identified that measured informed choice in health screening. It was based on the following definition of an informed choice: *one that is based on relevant knowledge, consistent with the decision-maker's values and behaviourally implemented.* The measure comprised an eight item scale of knowledge, a four item scale assessing attitudes towards undergoing the screening test and a record of test uptake. In women offered a screening test in pregnancy, the internal reliability of both the knowledge and the attitude scales was acceptable (alpha coefficients 0.82 and 0.83, respectively). Another validation study of the measure administered the scale to 225 pregnant women in two general hospitals in the UK, who were receiving low-risk results following serum screening for Down's syndrome (Michie et al, 2002). The MMIC was administered before testing and the Ottawa Decisional Conflict Scale was administered 6 weeks later. The component scales of the MMIC, knowledge and attitude, were internally consistent (alpha values of 0.68 and 0.78, respectively).

A matrix was devised to classify people (see Figure 2) as either making an informed or uninformed choice. Those people who had good knowledge, and their attitudes were consistent with their behaviour, were classified as *informed* (cells 1 and 4). Otherwise, people were classified as being *partially* uninformed if they had poor knowledge and a choice consistent with their attitudes (cells 5 and 8), or they had good knowledge but had made a choice that was inconsistent with their attitude (cells 2 and 3). People were classified as being *completely* uninformed if they had poor knowledge and a choice inconsistent with their attitudes (cells 6 and 7) (Marteau et al, 2001).

Figure 2. Matrix of informed choice in antenatal screening



I thought that this measure had several limitations. Firstly, the classification of informed choice was not entirely logical - for example a person who had good knowledge but a negative attitude to screening was classified as *partially uninformed* - the same classification given to a person who had poor knowledge and a positive attitude. It is not clear why good knowledge was viewed as being partially uninformed. The inconsistencies between behaviour and attitude may reflect underlying barriers, or perhaps influence from others.

The second limitation relates to the first limitation: although this is a measure of informed choice, it is behaviour (i.e. uptake) that is measured, not choice. Thus, the assumption made is that people's screening behaviour is always consistent with the choice they had made. What this assumption does not take into account is the possibility a person was not able to carry out their choice. For example, a woman may have good knowledge, choose not to be screened (and have a negative attitude towards it or vice versa), but be 'persuaded' at the clinic to take the test. In this example, autonomy of the

individual is compromised. In the MMIC, this woman would be classified as making a partially uninformed choice. One of the central tenets of informed choice as discussed in Chapter 2 is autonomy, yet it is not assessed in this measure.

Thirdly, I do not believe it is valid to classify some one who does not take part as *uninformed* if they do not know the risks of taking part. Making an informed choice not to be screened may require different information from making an informed choice to be screened. For example those choosing not take part might need to know about the consequences of their choice (e.g. in the event of having a child with Down's syndrome, what resources are available). In cancer screening it might be that a person who makes an informed choice not to be screened is one who knows about the risk factors and symptoms of the disease.

Fourthly, the MMIC measures attitudes, but the items appear mainly to concentrate on attitudes towards the screening test, rather than attitudes towards the whole screening process. This process includes the test results, possible follow-up, diagnosis, and treatment. These could be far more important than the test itself, particularly for antenatal screening where one of the consequences could be termination of pregnancy. Thus the attitude items included on this scale were thought to be too specific for use in a scale to measure attitudes towards cancer screening. In addition it does not assess attitudes towards the condition that is been screened for (Down's syndrome). In summary, although the MMIC was useful as a starting point for developing the current measure, it has several limitations, and was not useful as a gold standard by which to assess criterion validity.

2. Decisional Conflict Scale (O'Connor 1995)

The decisional conflict scale (DCS) was designed to elicit: 1) health-care consumers' uncertainty in making a health-related decision; 2) the factors contributing to the uncertainty; and 3) health-care consumers' perceived effective decision making. The definition of decisional conflict used by the authors was, *'a state of uncertainty about the course of action to take.'* The scale was developed using items derived from the decisional conflict construct. These items included decisional uncertainty, selected factors contributing to uncertainty, and perceptions of effective decision making. Three

subscales reflecting these dimensions evolved. The scale was evaluated with 909 individuals deciding about influenza immunisation or breast cancer screening. A sub sample of respondents was retested two weeks later. The test-retest reliability coefficient was 0.81 and internal consistency coefficients ranged from 0.78 to 0.92. The DCS discriminated significantly ($p < 0.0002$) between those who had strong intentions either to accept or to decline invitations to receive influenza vaccine or breast cancer screening and those whose intentions were uncertain. The scale also discriminated significantly ($p < 0.0002$) between those who accepted or rejected immunisation and those who delayed their decisions to be immunised. There was a weak inverse correlation ($r = -0.16$, $p < 0.05$) between the DCS and knowledge test scores. A Dutch version of the scale was further validated amongst two groups of oncology patients (Koedoot et al, 2001). The reliability coefficients of the three subscales were 0.52, 0.80, 0.84, and 0.74, 0.83, 0.83 in the two samples, respectively.

Several of the items on the scale initially appeared to be measuring some of the domain of informed choice. In particular, the subscale of *'factors contributing to uncertainty'* included items on knowing the benefits and limitations of an intervention, and feeling that they had made an informed choice. Therefore the whole of this scale was included in the initial draft of the questionnaire (see Chapter 4). However, after focus group discussions most of the scale was removed, except for the subscale on factors contributing to uncertainty. People found it difficult to answer the questions, and did not consider them relevant to informed choice.

3. Satisfaction with Decision Scale (SWD) (Holmes-Rovner 1996)

This scale was developed from the conceptual model of an effective (informed) decision, i.e. one that is informed, consistent with the decision maker's values and behaviourally implemented. It was designed for situations in which there is a choice to be made based on a critical evaluation of existing medical evidence and on patient values for outcomes. Most of the questions on the scale were framed so that the patient could delegate responsibility for the decision. It was also designed so that situations requiring informed consent and other occasions requiring patient decision making could be evaluated using this scale. It was piloted on 120 female University staff. The SWD scale correlated moderately with the Decisional Conflict Scale (-0.54) which was anticipated, and

positively with the Confidence in Decision Scale (0.64). The authors also examined the relationship between the SWD scale and actual decision making in the context of postmenopausal hormone replacement therapy (HRT) decisions. Although satisfaction with the decision (SWD scale scores) and decision certainty were significantly correlated at 12 months, this correlation was low ($r=0.27$, $p<0.05$).

As can be seen from the focus group data presented in Chapter 5, satisfaction is an important outcome, and a reason for giving people information. Initially it was thought it might be useful to include this measure in the questionnaire. However, the questionnaire was already felt to be very long, and as it was not an essential element, it was not included.

4. PROCASE Knowledge Index (Radosevich et al, 2004)

This was a scale to assess patient knowledge about the risks and benefits of prostate cancer (CaP) screening. The measures included a 10-item knowledge index and four single-item measures, used in previous studies. Validity and reliability of these measures was assessed on a sample of 1152 male veteran patients aged 50 and older. All knowledge index items had acceptable levels of discrimination, difficulty, and reliability.

This scale was published towards the end of my PhD fellowship (in August 2004). This meant that it was not able to be used in the initial development of the questionnaire. However, the domains of knowledge were very similar to those used in the MICICS questionnaire developed in this research. Therefore the analytical framework outlined in this paper was used in the analysis of knowledge questions for the measure of informed choice (MICICS) (see Chapter 4 and Chapter 5).

5. Decisional Balance Instrument (Rakowski et al, 1997)

This measure was based on the Transtheoretical model (TAM) of behaviour change and used to assess decisional balance in mammography screening. Study participants were 8,914 women ages 50-80, recruited from 40 primarily rural communities in the USA. Analysis of variance supported the associations between readiness to obtain screening (i.e., stage of adoption) and opinions about mammography (i.e. decisional balance). This was a large study but the validity of the measure was not well reported. It was not clear how the items were selected, and whether they had content validity. Although I could

have used some of these items in my measure, some were specific to the US context (e.g. one of the items was 'the cost of mammograms would cause you to hesitate to get one'). In addition, I was concerned that value judgements were being made as to what were 'pro and cons.' For example; the statement, 'You are more likely to go for a mammogram if your doctor tells you it is important' was seen as a 'pro'. It could also be viewed as a 'con' (potentially being persuaded and coerced). This measure might be suitable to be used for further validation of my measure, but might not be valid in an UK setting.

3.6 Scales identified but not used

Initially I thought that another scale, the Autonomy Preference Index (Ende et al, 1989), would be relevant. This was an instrument that measured patients' preferences for two identified dimensions of autonomy, their desire to make medical decisions and their desire to be informed. The authors found that patients prefer decisions to be made principally by their physicians, not themselves, although they wanted to be informed. There was no correlation between patients' decision making and information-seeking preferences ($r = 0.09$; $p = 0.15$). After reviewing this paper, I decided that it was not useful for two reasons. Firstly, because there was little theoretical explanation as to why decision making and information acquisition were the two domains of patient's desire for autonomy. Secondly, the questions related primarily to decisions about treatment for a given disease. They had little relevance to decisions undertaken in cancer screening.

Several scales were mainly concerned with satisfaction with decisions or quality of decision making (Decision Making Quality Scale (Hollen, 1994); Decision Regret Scale (Brehaut et al, 2003); Patient satisfaction with mammography (Loeken et al, 1996; Loeken et al, 1997) and the Medical Care Preference Scale Decision Attitude Scale (Sainfort, 2000). Although satisfaction is potentially an important outcome in the provision of information, it was not central to a measure of informed choice. A further scale, measuring women's experiences of the stages of the breast screening process, has recently been published (Brett and Austoker, 2004). However, this was not measuring knowledge or decision making.

3.7 Discussion

One of the purposes of this review was to identify relevant measures and evaluate their relevance and potential uses in the development and validation of the measure being developed for the PhD. Of the five scales that met the inclusion criteria for this review, only one was specifically designed to measure both informedness and choice (MMIC) (Marteau et al, 2001; Michie et al, 2002). However, it was designed for antenatal screening, not cancer screening and had several limitations.

As discussed in the context of the MMIC scale, behaviour may be influenced by external factors and thus may not adequately reflect choice. None of the existing scales of informed choice or decision making attempt to measure the potential gap between behaviour and choice, but appear to make the assumption that the behaviour was always consistent with the intended choice, and that the choice itself was autonomous. For example, the relationship between the SWD scale and actual decision making in the context of postmenopausal hormone replacement therapy (HRT) decisions was examined. The authors reported significant (but low) correlations between SWD scale scores and decision certainty. The behaviour (whether the postmenopausal women took HRT or not) is used as the measurement of actual choice and decision making. The authors do not measure intentions before the behaviour. What we do not know in this example is whether the women intended to take HRT (or not) and were for some reason, not able to carry out their choice. To someone who chose to have screening but was not able to have that choice (perhaps due to illness), questions such as, *' The decision I made was the best decision possible for me personally'*; or *'I am satisfied that my decision was consistent with my personal values'* are irrelevant.

For some health behaviours, this may be a correct assumption and there may be no difference between the choice and the behaviour. However, it is important to make sure that choice is the same as behaviour, if behaviour is used as a proxy for choice.

In cancer screening behaviour, there is likely to be some variance in screening choice and screening behaviour, and this may vary between site of cancer, and populations. The

difference between intention and behaviour was conceptually important for developing this current measure of informed choice in cancer screening.

3.8 Conclusions

Five scales met the inclusion criteria for this review, but only one was specifically designed to measure informed choice (MMIC). However, this scale was for antenatal screening and had a number of limitations. None of the existing scales of informed choice or decision making attempt to measure the gap between behaviour and choice, but appear to make the assumption that the behaviour was consistent with the intended choice, and that the choice itself was autonomous.

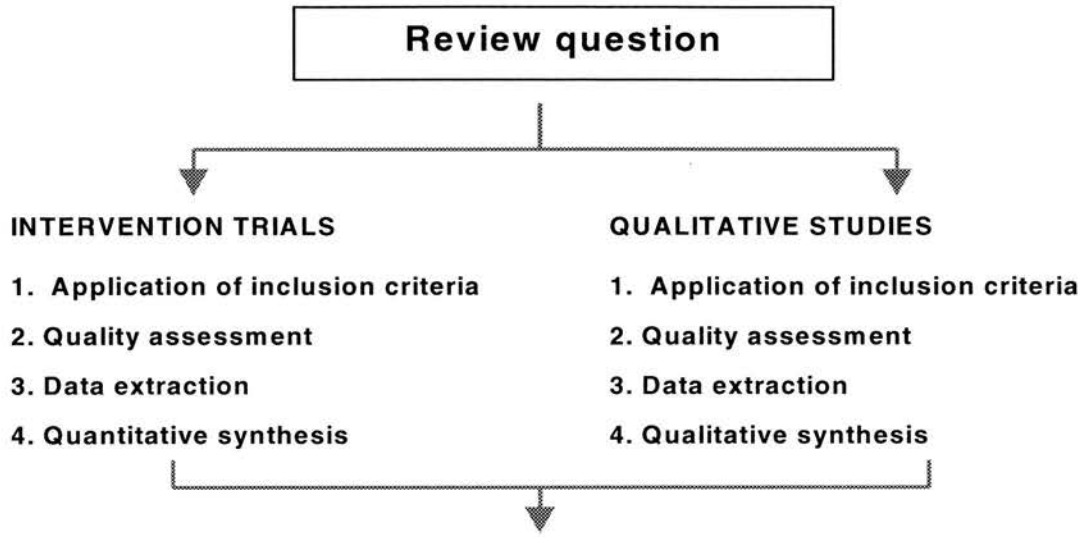
There is currently no other measure of informed choice in cancer screening. This lack of an existing scale provides justification for the development of a new one. Two of the scales were thought to be useful in the development or analysis of the measure of informed choice – the Decisional Conflict Scale, and the PROCASE Knowledge Index.

PART 2. SYSTEMATIC REVIEWS OF INFORMED CHOICE IN CANCER SCREENING

Until recently trials of educational interventions in cancer screening have had the primary purpose of increasing uptake. However in recent years, some educational trials have begun to focus on informed choice (e.g. Flood 1996; Michie 1997; Davison 1999; Schapira 2000; Rimer 2001), and outcomes other than uptake have been included. In 2000, colleagues and I published a systematic review of interventions to increase uptake of screening (Jepson et al, 2000). However, due to the shift in emphasis towards informed choice, this was followed by another systematic review of informed choice interventions in healthcare screening (Jepson 2001). In this review we concluded that changing the format of informed choice interventions in screening did not alter knowledge, satisfaction, or decisions about screening. It was not clear, however, whether they affected uptake. The review was focused on outcomes, not the content of the interventions and their validity.

For the first draft of this chapter (which I undertook in the first year of this study), I updated this published review, but only for interventions relating to cancer screening. Using traditional systematic review methods, I focused on the outcomes of the trials such as uptake, knowledge and informed choice. However, after undertaking the focus group work, and instrument development, it was unclear how such a systematic review fitted within the framework of this thesis. In particular I was interested in definitions of informed choice, and whether there was any concurrence between the trials. After learning about a new approach, which combined the findings of both qualitative and quantitative studies, I decided that this would be a more suitable technique (Thomas et al, 2004). Figure 3 outlines the methods used by Thomas to separately synthesise, and then combine the results, from both qualitative studies and quantitative trials, and it was this approach I used in the review.

Figure 3. Methods for the systematic review



In the review reported in this chapter, I decided not to focus exclusively on evaluating the effectiveness of the informed choice interventions. Instead, the main emphasis of the review was on how researchers define informed choice in the interventions. These data could then be compared to the findings from the qualitative studies on what screening invitees deemed to be important, and to the policy recommendations. This combined synthesis enabled a much broader understanding of how the concept of informed choice is being constructed and evaluated in the research environment. It is also the approach that is used in the Cochrane review which I am undertaking with colleagues from France (Broclain et al, 2004). However, the Cochrane review focuses on all health screening, and will not be completed until December 2005.[14] The review presented here only includes trials of cancer screening. I did not include all areas of health screening primarily because I did not consider that domains of information, and the choices people were asked to make, were necessarily comparable for other types of screening (e.g. antenatal screening, child health screening). Table 4 shows the four reviews I have been involved with and how they relate to each other.

[14] I originally intended that this systematic review would become a Cochrane review with myself as the lead reviewer. However, my topic area had already been registered by Dominique Broclain. It was decided that I would join with Dominique Broclain. As he had registered the review title first, he took the role of lead reviewer.

Table 4. Systematic reviews of information and informed choice in screening

Review	Aim	Types of screening	Study design
Jepson 2000	To evaluate interventions to increase the uptake of screening	All screening	RCTs/CCTs
Jepson 2001	To see how informed choice affects outcomes such as uptake, anxiety and decision making	All screening	RCTs/CCTs
Broclain 2003	To see how informed choice affects outcomes such as uptake, anxiety and decision making	All screening	Quantitative and qualitative
This review	To understand how informed choice has been conceptualised and operationalised within the context of cancer screening	Cancer screening	Quantitative and qualitative

3.9 Aims and objectives

The main aim was to evaluate how informed choice had been conceptualised and operationalised in cancer screening trials. The main objectives were to evaluate:

- what experiences/ideas do screening invitees have about the information they need/want to make an informed choice?
- to what extent do interventions build on these experiences/ ideas?
- how do researchers define informed choice within the context of interventions studies and how do their definitions correspond with recommendations and guidelines from 'experts', and what screening invitees wish to know?
- what do the above suggest for developing effective and appropriate interventions to be tested in the future?

3.10 Criteria for considering trials and studies

Only studies that explicitly stated that the purpose of the research was to increase or understand informed choice or informed decision making (by giving information on the risks and benefits of screening) were included. The Cochrane review has a wider definition of informed choice and will include any trial that evaluates information on benefits and risks. The reason that I focused on those with the explicit purpose of increasing informed choice was because some trials might be evaluating informed choice interventions by chance.[15]

[15] That is some interventions to increase uptake might mention information on risk factors or some limitations of screening. I was more interested in those which were explicit in their purpose to increase informed choice or decision making, as I was interested in how the concept had been operationalised.

3.11 Qualitative review inclusion criteria

The following inclusion criteria for types of studies were adopted:

- Qualitative components built into RCTs of health interventions (qualitative studies embedded in trials)
- Qualitative studies conducted outside of RCTs. To be included, qualitative research must have addressed the objectives of this review by exploring the public's screening decision-making process(es); the determinants of the public's screening choices; or the public's and health professionals' use of interventions
- Other qualitative ways of understanding lay perspectives on information and cancer screening (e.g. DIPEx (DIPEx, 2005))

Participants in the studies were any individual invited to take part in cancer screening, or had taken part in cancer screening.

3.12 Quantitative review inclusion criteria

Randomised controlled trials (RCTs), quasi-RCTs (e.g. using pseudo-randomisation, such as alternation or date of birth), controlled trials (non-randomised cohort with concurrent control) and non-randomised cohorts (with non control) of cancer screening were included. All cancer screening programmes (universal, selective or opportunistic) that aimed to identify early the presence or absence of a specific cancer during the presymptomatic phase or before clinical detection were included.

I included any intervention that aimed to increase informed uptake or informed choice in cancer screening. The definition of 'comprehensive' used in this review is based on ideas and recommendations by experts (Holmes-Rovner 2001; GMC 1998; Barratt 1999). Ideally 'comprehensive' interventions should contain most of the following information:

- facts about the disease
- the purpose of the screening and the screening test
- the known benefits of going through the whole screening process from screening to treatment
- the possibility of false positive/negative results and the likelihood of positive/negative findings
- information about equivocal, abnormal or inconclusive test results;
- acknowledgement of inconsequential disease
- description and rates of side effects of available confirmatory diagnostic tests and available treatments

- any significant medical, social or financial implications of screening for the particular condition or predisposition
- follow up plans, including availability of counselling and support services

I evaluated the following outcomes: uptake of screening; intentions or preferences; informed decision-making/choice; knowledge; autonomy and barriers.

I excluded studies of self-examination procedures, such as breast self-examination and testicular self-examination, based on the premise that the dynamics of self-screening are fundamentally different.

3.13 Search strategy for identification of studies

For the original systematic review, a comprehensive search strategy was developed (Jepson (2000)). This search strategy was updated and revised with the input of an experienced medical librarian. Electronic databases searched were: Medline, BIDS Science Citation Index, EmBase, CancerLit, Cinahl, PsycInfo, and The Cochrane Library (Cochrane Controlled Trials Register, HTA and the National Research Register) (see Appendix 3 for details of search strategy). Additional references were located through searching the bibliographies of related papers and contacting specialists in the subject area of the review. In addition, the DIPEx website was searched (DIPEx, 2005). DIPEx is a charity which has a website that contains interviews with people about their own experiences of serious illness, health problems or health related matters. There were no language restrictions, and both published and unpublished studies were included if they met the inclusion criteria. The date of the most recent search was October 2004.

3.14 Methods of the review

One reviewer (RJ) screened titles and abstracts of all retrieved studies. Paper copies were obtained for any study that appeared to meet the inclusion criteria. For quantitative studies, data on the characteristics of the study were extracted, as well as outcome data. For qualitative studies, data on each of the themes were extracted, as well as information on the participants, aim of the study and methods used. Quality of both the qualitative and quantitative studies was assessed. For quantitative studies, validity checklists in

CRD Report Number 4 (CRD, 2001) were modified and each item was graded as adequate (+), unknown, unclear or partial (+/-), or inadequate (–). The quality criteria were not used to obtain an overall quality score. Instead, the information was compiled into Table 7 and the results reported descriptively in the text. A checklist, modified from two existing quality checklists (CASP, 2002; Malterud, 2001) was also used to assess the qualitative studies in the review (see Appendix 4).

No formal analysis or meta-analysis of the quantitative data was performed, as that was not the primary objective of the review, and there was too much heterogeneity in types of screening, and interventions. However, the effectiveness of the interventions on factors such as uptake, knowledge, and decision making were reported descriptively. Data from the qualitative studies were extracted and thematic analysis performed. Only published data were used. The aim of the qualitative analysis was to determine which items of information were key to those taking part in screening. The results of the qualitative studies were then combined with the results of the quantitative studies.

3.15 Results

The search strategy resulted in a total of 717 references. However, due to the difficulties in defining search terms (see page 106) most were neither about cancer screening, nor about informed choice. All the abstracts were read and full paper copies were obtained if they were thought to be relevant. Of the 717 references, 24 qualitative studies and 27 quantitative trials were read and assessed. Separate analysis was performed, and then the results were combined.

3.16 Qualitative studies

Six qualitative studies broadly met the inclusion criteria (Chan et al, 2003; Chan and Sulmasy, 1998; McFall and Hamm, 2003; Pfeffer, 2004a; Schapira and VanRuiswyk, 2000; Silverman et al, 2001). The DIPEx website also included data about cervical screening information (DIPEx, 2005). Four of the qualitative studies had some focus on information needs in prostate cancer invitees, two focused on breast screening and DIPEx contained information on cervical screening. Reporting (and therefore the estimated quality) of the studies was very variable (see Table 5).Two studies (Chan et al,

2003; Silverman et al, 2001), however, were of relatively high quality (assessed using the checklist described in Appendix 4). These were also the studies which were most relevant to the review. Using the methodological approach of Thomas et al (outlined in Figure 3), I copied the authors' findings verbatim and performed thematic analysis of this textual data (Thomas et al, 2004). Table 6 provides more details of the purpose of the included studies and the main findings.

Table 5. Quality of qualitative studies included in the review

Items on the quality checklist	Chan 1998	Schapira 2000	Chan 2003	McFall 2003	Silverman 2001	Pfeffer 2004	DIPEx 2005
Type of screening	Prostate	Prostate	Prostate	Prostate	Breast	Breast	Cervical
Ethics and consent adequate?	Yes	N/S	Yes	No	No	Yes	Partial
Sample and data collection issues addressed?	Yes	N/S	Yes	Yes	Yes	No	N/a
Data organisation and analysis fully described?	Yes	No	Partial	Yes	Yes	No	Partial
Are strategies used to validate results presented?	No	No	Yes	Yes	Yes	No	Partial
Are the findings relevant to aim of the study?	Yes	Yes	Yes	Yes	Yes	Partial	N/a
Are the findings discussed in relation to original research questions?	Yes	No	Yes	Partial	Yes	No	N/a
Is the presentation of the findings well organised?	Yes	No	Yes	Yes	Yes	No	Yes
Did the researcher explain how the data presented (like quotes) were selected and are they used adequately?	N/a	N/a	No	No	Partial	No	Yes
Are the researcher's motives sufficiently dealt with, and did they critically examine their own potential biases?	Partial	No	Partial	No	Partial	No	N/a
Are questions about internal validity and external validity addressed?	Partial	No	Partial	No	No	No	N/a
Were contradictory or unexpected findings discussed sufficiently?	Yes	No	Partial	No	Yes	No	Yes
Discussion of the evidence both for and against researcher's arguments?	Partial	No	No	Partial	Partial	No	N/a
Are the shortcomings accounted for and discussed?	Yes	No	Partial	Partial	Yes	No	N/a
Is the report easy to understand?	Yes	Yes	Yes	Yes	Yes	No	N/a
Possible to distinguish between the voices of the informants and those of the researcher?	N/a	No	Unclear	No	Yes	No	Yes
Does the researcher highlight contribution to existing knowledge?	Yes	Partial	Yes	Partial	Yes	No	No

Table 6. Details of qualitative studies and main findings in relation to informed choice

	Chan 1998 **USA**	**Chan 2003** **USA**	**McFall 2003** **USA**	**Schapira 2000** **USA**	**Pfeffer 2004** **UK**	**Silverman 2001** **USA**	**DIPEx 2005** **UK**
Screening	Prostate	Prostate	Prostate	Prostate	Breast	Breast	Cervical
Research question	To identify and compare what facts experts and patients thought men should know	To determine how African Americans, Hispanics, and Caucasians want information about screening with PSA	To obtain reactions to numerical information about events and outcomes related to prostate screening	To test the effect of a prostate cancer screening decision-aid	To critically evaluate some information provided to women on breast screening and self-examination	To learn how women view breast cancer, their personal risk of breast cancer, and how screening mammography affects that risk	To interview people about their own experiences of serious illness, health problems or health related matters
Study design	Delphi panel and nominal group techniques	Focus groups	Focus groups	Focus groups	Focus groups	Focus groups	Individual interviews
Participants	Experts and couples with screened and unscreened men	African American, Hispanic, and Caucasian couples	African American, Hispanic, and Caucasian men	Male veterans aged 50-80 years	Women from different ethnic groups	Women of different ages, race and socioeconomic status	Women with different experiences of screening
Main findings relating to information needs	Experts generally overestimated patient knowledge and failed to emphasise some facts that patients find important. In addition to information about the risks and limitations, people also wanted information on what the screening test was for, incidence of prostate cancer and risk factors	There may be differences in definitions of informed consent Differences in type of information wanted by different ethnic groups	No single topic was seen as sufficient for the screening decision. Important information included quality of life issues. Little attention was given to unnecessary treatment and lack of interest in the disadvantages of biopsy	People had awareness of prevalence of prostate screening, but knowledge deficits about risk factors, symptoms, risk and benefits.	No information on what women wanted to make informed choice, but she discusses cultural meanings of words used to describes breast cancer	Women wanted information on the mechanics of (doing) the mammogram, information on what screening was for, and the benefits of mammography. Few women wanted to know more about accuracy.	Talked mainly about the information people received rather than the information that they wanted.

The following sections provide more detail of the findings of the included studies, which I have grouped by type of screening.

Prostate screening

Four out of the six studies evaluated some element of informed choice in prostate screening. The first study undertaken in this area compared what facts experts and patients thought men should know about prostate screening (Chan and Sulmasy, 1998). The authors recruited a Delphi panel of national experts (6 urologists and 6 non-urologists) and also conducted 6 focus groups of couples (48 subjects) with 24 screened and unscreened men from a university hospital. They used couples rather than men because health promotion practices recommended targeting women to reach the men in their lives (Rubenstein, 1994). The couples in the focus groups all watched a video about PSA testing and then were asked what facts they thought men should know.[16] After completing a content analysis of the conversations, the authors found that couples in both screened and unscreened groups consistently mentioned seven categories of facts that men ought to know. These were:

1. False positive prostate-specific antigen (PSA) test or digital rectal examination (DRE) results are possible

2. There are advantages and disadvantages to taking the PSA test (e.g. worrying about what an elevated PSA result means)

3. It is unclear if PSA screening reduces the mortality from prostate cancer

4. What the PSA test is—a blood test

5. Risk factors for getting prostate cancer

6. Incidence and prevalence of prostate cancer

7. False negative PSA results are possible

Areas where both 'experts' and the couples felt that information was important are indicated in italics. The authors commented that the experts generally overestimated patient knowledge and failed to emphasise some facts that patients find important. For example, the experts did not include 'what a PSA test is' among their 10 most important facts to disclose. Therefore, the information men want may differ from the information that experts think is important.

[16] This video is used in 5 of the intervention studies (see next section).

The same researcher conducted another study to evaluate how people from different ethnic groups wanted information presented (Chan et al, 2003). Twenty couples, with men age 50 and older, participated in four focus groups. The researchers found that there were content and graphic design differences in the way ethnic groups wanted information presented about the prostate, prostate cancer, risk, and screening. For example, Caucasians likened the size of the prostate to a walnut; Hispanics, to a small lime. In addition, Hispanics emphasised how advanced prostate cancer can be symptomatic; Caucasians, how early prostate cancer can be asymptomatic. African Americans wanted risk information specific for them and the advantages and disadvantages of a PSA and DRE; Hispanics, did not.

Another study in the US used focus groups to obtain reactions to numerical information about events and outcomes related to prostate cancer screening (prevalence, natural history, accuracy of screening, and treatment outcomes) (McFall and Hamm, 2003). Participants in the focus groups were both men and women, and from different ethnic backgrounds. The main purpose of the research was to design a decision aid. The authors were not interested in finding out what information people wanted, but how they interpreted and used the information given to them. Thus, the researchers already had a predefined concept of informed choice. However, the selection of topics in the focus group discussions (and therefore definitions of informed choice) was guided by the research done by Chan et al (see above).

The main findings of these focus groups by McFall and Hamm were that the consequences of screening (particularly those that affected the quality of life) were seen as important information. In particular, people wanted information about the problems associated with incontinence and sexual function. Information about treatment options was also seen as being important. However, little attention was paid by the focus group participants to the issue of unnecessary treatment and there was a lack of interest in the disadvantages of the biopsy. The authors attribute this lack of interest to the fact that:

'Participants were more accustomed to worry about the consequences of not getting medical care than about the drawbacks of unnecessary treatment.'

Overall, the authors concluded that no single topic or item of information was seen as sufficient for the screening decision. The balance sheet should cover prevalence and outcomes of screening and treatment.

One RCT of a prostate cancer screening decision-aid (Schapira and VanRuiswyk, 2000)[17] conducted two focus groups with veterans aged 50-80 years. The purpose of the focus groups was to help in the design of the decision aids. The authors found that the men had a general awareness of prevalence of prostate cancer but expressed significant knowledge deficits and misinformation about risk factors, symptoms, screening, treatment options, and prognosis for prostate cancer. They therefore designed the content of the decision aid to reflect the deficits in knowledge most striking in the focus groups. Although the researchers did not ask the men what information they wanted to make an informed choice, this was the only one of the intervention studies which took into account screening invitees' understanding and knowledge of screening when designing the intervention (see section on quantitative studies).

Breast screening

Two studies evaluated information needs in people invited to take part in breast screening (Pfeffer, 2004a; Silverman et al, 2001). The aim of the study by Silverman was to gain an understanding of women's current beliefs about breast cancer and screening. The authors wanted to use the study to guide efforts to promote informed choice by uncovering misunderstandings, conceptual gaps, and areas of concern. Telephone interviews were conducted with 41 women (using quota sampling), of which 80% had been for at least one mammogram. Women were aged 27-84 with a mix of racial groups. An open ended protocol was used to allow women to talk freely before new concepts were introduced. For example, the 1st question was, *'Please tell me everything you know about mammograms'*. Women were asked what information they thought was important for making decisions about mammograms. The most common piece of information wanted was the mechanics of doing the mammogram (over 50%), 20% wanted information on what screening was for, and 20% wanted information on the benefits of mammography. Only 3 women wanted to know more about accuracy.

[17] This RCT is included in the review of interventions to increase informed choice.

The authors comment that 'the concept of informed decision making assumes that the decision maker has assimilated the relevant facts and can therefore make decisions based on preferences'. In deciding about screening, a woman would be considered informed if she understood the potential benefits and harms of screening. According to the researchers, although similar mental models may not lead to similar decision making (i.e. preferences may differ), the more closely the woman's mental model of mammography resembled that of an 'expert', the more informed her decision would be considered to be.

They also commented that women and experts valued the potential harms of screening differently. Although women were aware of the imperfections of mammography (such as false negatives) they seemed to be less concerned about such outcomes. False positives were typically seen as an acceptable consequence of screening, but not as a harm or limitation. In essence, the utility of learning that one did not have cancer outweighed the disutility of the false alarm. The authors concluded that the differences noted between the experts' and women's approaches to informed choice means that we should question the extent to which women can make an informed choice based on current understanding. They also reported that only a single respondent understood that some cancers might be non-progressive, or progress so slowly that they may never affect a woman's health. Some experts worry about over treatment of lesions destined never to progress, where the concept of over-treatment may be totally foreign to women.

Another study evaluated information about breast screening,[18] breast self examination, and breast awareness (Pfeffer, 2004a; Pfeffer, 2004b). The author compared this information with the results of focus groups that included women who spoke little or no English. Although the principal purpose was not to find out what information women wanted to make an informed choice, they raised issues regarding the use of language, especially in relation to non-English speaking languages. Similar to Chan, Pfeffer found that women from different ethnic backgrounds attributed different meanings to words and phrases, especially those describing the symptoms of cancer. The author concluded that, *'The findings exposed inconsistencies, ambiguities, and gaps, which when taken*

[18]The leaflet produced by the NHS Breast Screening Unit called 'Breast screening: the facts'.

together suggest both compliance and non-compliance are being achieved in the absence of informed consent'. However, she provided little empirical evidence from the focus groups to substantiate this viewpoint, and therefore the conclusions should be interpreted with caution.

Cervical screening

No studies were identified which evaluated what information women wanted or need to make an informed choice about participation in cervical screening. The DIPEx website contains a 'module' on cervical screening (DIPEx, 2005). Each of the DIPEx modules is collected and analysed by an experienced and trained researcher and the result published in peer reviewed journals. The 'module' contained a section on information but it largely included a description of what information women received, rather than what information people wanted. There was some description of how the information affected decision making. For example, one young woman explained how she felt less anxious than she might have done about having her first smear test because the nurse had given her a leaflet beforehand and explained to her exactly what the smear test would involve. Some of the younger women were given an explanation of the smear test procedure and the instruments used, but some older women had not had the benefits of the smear test explained to them. One woman explains how she found it helpful to be shown the speculum used during a smear test.

3.17 Themes to emerge from the qualitative data

Using the Thomas methodology, I developed a set of more abstract analytical themes, based on the thematic analysis of all the studies (Thomas et al, 2004). Although there were a limited number of qualitative studies in this area, a number of themes emerged.

-Differences between lay perspectives of information wanted to make an informed choice and that of experts or professionals (2 studies)

-Professionals and experts thought that it was important to give information on risks and harms (2 studies)

-Professionals might assume that people have more knowledge than they have (1 study)

-Lay people want information on the process, the disease and the consequences of doing the test (particularly quality of life issues) (4 studies)

-Lay people may be less concerned about the negative consequences of doing the tests than 'experts' (2 studies)
-There may be cultural differences both in how information is presented and in how informed choice is constructed (2 studies)

3.18 Limitations of this qualitative review

The methods for synthesising data from qualitative reviews is still at a relatively early stage and it has been acknowledged that several issues still need to be dealt with to make the role of qualitative evidence in reviews more systematic (Dixon-Woods and Fitzpatrick, 2001). Firstly, searching for and identifying appropriate qualitative research remains frustrating and difficult. This is partly because indexes and search filters require substantial improvement. Secondly, the problem of how to appraise the quality of qualitative studies has not been resolved. Thirdly there is the problem of how to make qualitative evidence[19] submit to the disciplines of secondary summary and synthesis.

In addition to those limitations acknowledged by Dixon-Woods, I had two further concerns about the review methods. Firstly it was difficult to define the boundaries for inclusion of qualitative research, both for the research design and content. Qualitative studies are undertaken in this area (of cancer screening and information) for a range of purposes. Some may focus on information or choice but others may be centred on barriers, attitudes, and motivators. Although I was as inclusive as possible, and read as many studies as I thought were relevant to the research question, it was difficult to know whether all possible studies which explored information needs were located and included.

Secondly, one of my biggest concerns was the possibility that many studies in this area have not been published. For example, focus groups are routinely used in the development of information leaflets. However, because the purpose of the focus groups is to develop an information leaflet rather than research, the results are not published.

[19] Which may be produced with widely varying theoretical perspectives and diverse analytical approaches.

Thus the studies which are included in this review are unlikely to represent all the views of people about the information they need.

Despite these limitations, the review is useful in that it highlights some of the differences between professionals' definitions of information needed to make an informed choice and those of screening participants. These differences will be explored in the last part of the review when the results of the qualitative studies are compared with the quantitative studies.

3.19 Summary of the qualitative studies

Much has been written on the subject of informed consent in screening, and there are many information leaflets promoting informed choice. However, there is a paucity of published qualitative studies evaluating what information participants in screening want in order to make an informed choice. Not all of the studies included in this review had the primary aim of finding out what information people wanted. Many made prior assumptions about the information needed to make an informed choice, and were more concerned with evaluating how information was used. Only two of the studies set out to find out what information people wanted (Chan and Sulmasy, 1998; Silverman et al, 2001). Both found that people wanted information about the process and the disease itself, and were less interested in the risks and limitations. The authors of these studies also reported that lay perceptions of informed choice might differ from those of the experts. This theme is developed in the section 3.26, when I compare the information contained in the intervention studies with what experts/researcher think is important, and what lay people believe is important.

3.20 Description of intervention studies

Forty-seven full copies were obtained and assessed for relevance. Sixteen trials were included in this review (see Table 7). Most of the included trials evaluated informed choice interventions for prostate cancer screening (ten studies) with the others were concerned with breast (one study), cervical (one study), pancreatic (one study) and colorectal (three studies) screening. The majority of the trials were undertaken in North America (USA or Canada), apart from one for cervical screening (UK), one of prostate

screening (Australia) and one for pancreatic screening (Switzerland). They were all published between 1996 and 2004. Table 7 details some of the study characteristics, including country, study design and outcomes. All studies reported giving information on the risks and benefits of screening, and assessed knowledge in addition to uptake.

3.21 Description of interventions evaluated in the studies

Prostate screening

Ten studies evaluated the effect of information on the decision (or intention) to be screened for prostate cancer. Nine of the studies were undertaken in the US apart from one (Gattellari and Ward, 2003) in Australia. Five of the included studies used the same intervention, which was entitled, *Shared Decision-Making® video, Is a PSA Test Right For You?* (Flood et al, 1996; Frosch et al, 2001; Frosch et al, 2003; Ruthman and Ferrans, 2004; Volk et al, 1999). The video was developed by the Foundation for Informed Medical Decision Making and Health Dialog, and the video covered various topics including information about the prostate, the disease, the tests, and the pros and cons of prostate cancer treatment.

The other five studies used a variety of media. Two studies evaluated written information. One of these (Wilt 2001) compared an "Early Prostate Cancer" pamphlet mailed to patients in the intervention group 1 week before their scheduled clinic appointments (general appointment, not one for screening) with a control group who received usual care. Another study also evaluated written information in the form of a booklet written by the researchers (Gattellari and Ward, 2003). A further study gave the intervention group both oral and written information about the `pros and cons' of prostate screening prior to a periodic health examination (Davidson, 1999). Very little information about the actual intervention was included in the paper describing this study, and no further details could be obtained from the author. Participants were encouraged to discuss this information with their doctor and to participate in making a screening decision to the extent that they were comfortable.

One study evaluated scripted information simulating an informed consent presentation delivered by a research assistant in primary care practices (Wolf et al, 1996). Finally,

one study (Schapira, 2000) gave an intervention group a decision aid, which included quantitative information on the sensitivity and specificity of a combined screening strategy of DRE and PSA, and a description of follow-up tests. The aid included graphical illustrations of the data, and included a statement on the uncertain efficacy of treatment. This intervention was the only one that was developed using focus groups. However, the leaflet was not available for scrutiny.

Breast screening

One US study evaluated informed choice in breast screening (Rimer, 2001). The researchers randomised 2165 women aged 40-50 years to tailored print booklets, tailored telephone counselling plus the booklets, or usual care. The booklets were tailored based on the information the women had provided during the baseline interview. During the tailored telephone counselling, the advisors asked open ended questions about the booklet, and specifically asked if the women had any concerns about the limitations of mammography. However, this study was still concerned with encouraging people to go for screening, rather than offering impartial advice and information. For example, no information was given about ductal carcinoma in situ which is a major issue in breast screening (see Chapter 2).

Cervical screening

One UK study evaluated evidence based information on the benefits and limitations of cervical screening (Adab et al, 2003). It compared the NHS Cervical Screening Programme leaflet with one that the researchers had devised. Although they discuss the guidance from the GMC, they focused on the limitations of the screening test, and did not include information on other areas (e.g. inconsequential disease, financial and social implications).

Colorectal screening

Three US studies evaluated informed choice in colorectal screening (Dolan and Frisina, 2002; Pignone et al, 1999; Wolf and Schorling, 2000). The intervention in one of the studies was a decision aid designed to help patients choose among currently recommended screening programmes (Dolan and Frisina, 2002). The main outcomes were patient decision process and the decision outcome (uptake). Of the three studies, this was the one which contained the most types of information on risks and limitations

of screening. The other two studies measured patient preferences for screening based on the information given to them. One evaluated different ways of presenting information (absolute risk and relative risk) (Wolf and Schorling, 2000). The third study (Pignone et al, 1999) was a three-part educational programme on colon cancer screening. The three segments of the intervention contained descriptive information about colon cancer and screening options (testing procedure information); test performance but with no out-of-pocket costs (test performance information); and hypothetical out-of-pocket costs (cost information). Patient preferences were measured after researchers had described each of these three types of information.

Pancreatic screening

One Swiss study evaluated whether the willingness of the general population to undergo a screening test of questionable effectiveness (pancreatic screening) was influenced by the quality and the extent of the information provided (Gattellari and Ward, 2003). Information was presented in two hypothetical scenarios about implicit and explicit benefits and adverse events of the screening test.

3.22 Methodological quality of the included studies

Overall, the quality of the included studies was good, with most being RCTs including a large number of participants (see Table 7). Twelve of the studies were RCTs, two were controlled trials, one was a non-controlled study, and one was a quasi-RCT allocating people sequentially (Frosch, 2001). This study recruited people to the usual care group differently from the other three intervention groups and this was acknowledged to be a source of bias. Two of the trials (Schapira, 2000; Wilt, 2001) reported the method of randomisation (computer) but none reported whether the allocation was concealed. Blinding of assessors to the intervention was not mentioned in any of the studies. Follow-up and participation rates post randomisation ranged from 50%-100%; none of the studies with losses to follow up or exclusions post randomisation used an intention to intervene approach in the analysis. One study (Frosch, 2001) had refusal rate of over 50% after allocation to intervention groups.

Only three of the studies performed power calculations to derive an adequate sample size (Wilt, 2001, Frosch, 2001; Schapira, 2000). However, most of the studies were relatively large (range 97 to 1287) and should have been able to detect a difference in outcomes.

3.23 Results of included studies

Table 7 provides a summary of the outcomes assessed in this review, and this section describes how the interventions affected these outcomes.

Intentions and uptake of screening

Of the seven studies that measured uptake, three found no difference, three found a decrease in uptake, and one reported an uptake in screening. Ten studies measured intention to have a test. Of these, one reported an increase in interest, six a decrease and three no difference.

The outcomes of uptake and interest differed by type of screening. For colorectal cancer screening, two studies found no difference in intentions between intervention and control groups. The third study found an increase in both intentions and uptake. For cervical screening fewer women in the intervention (79%) than the control group (88%) expressed intention to have cervical screening after reading the information leaflet ($p<0.05$). For breast screening, there were no statistically significant differences in women reporting a mammogram in the last 12 months (interviewed 12 months after the intervention). Uptake was 56% in the usual care group, 52% in the booklet group, and 61% in the booklet and telephone counselling group ($p=0.053$).

For pancreatic screening, interest in having a test was significantly lower in the intervention group. In those studies that measure intentions to have a PSA test (n=6), five reported a significant decrease in interest in testing in the intervention group, and the other reported no difference.

Knowledge

Of the nine studies which assessed knowledge, eight found a significant increase in knowledge in the intervention group compared with the control group, and one found no difference. Five of the interventions which increased knowledge, used the PSA video.

Decision making and decisional conflict

Five studies measured decisional conflict and three found that the intervention decreased the amount of decisional conflict in people deciding whether to be screened or not. The other two reported no difference.

Informed choice

In one study (Schapira, 2000), 77% of the participants at baseline felt that they were sufficiently informed to make a decision about prostate cancer screening. Perceptions of being well informed increased to 93% after the intervention, but with no differences between the intervention and control groups.

Other outcomes

None of the studies evaluated whether the choice was autonomous or whether there were barriers to carrying out the choice.

Table 7. Methodological quality and outcomes of the included studies

	Rimer 2001	Adab 2004	Dolan 2002	Wolf 2000	Pignone 1999	Domenighetti 2000	Davison 1999	Flood* 1996	Frosch* 2001	Frosch* 2003	Gattellari 2003	Ruthman* 2004	Schapira 2000	Volk* 1999	Wilt 2001	Wolf 1996
Country	USA	UK	USA	USA	USA	Switzerland	Canada	USA	USA	USA	Australia	USA	USA	USA	USA	USA
Screening	Breast	Cervical	Colon	Colon	Colon	Pancreatic	Prostate	Prostate	Prostate	Prostate	Prostate	Prostate	Prostate	Prostate	Prostate	Prostate
Sample size	1287	300	97	399	146	1000	100	631	130	226	248	104	257	160	550	254
Design	RCT	RCT	RCT	RCT	cohort	RCT	RCT	CCT	CCT	RCT	RCT	CCT	RCT	RCT	RCT	RCT
Concealment of allocation	Ns	✓	✓	NS	x	x	NS	X	x	✓	✓	x	✓	NS	✓	ns
Power calculations	x	x	NS	✓	x	x	x	X	x	x	x	NS	✓	x	✓	ns
Withdrawal/none completion	132	9	2	NS	x	NS	4	63		26	34	NS	0	0	208	49
Intention to treat	x	x	NS	NS	x	NS	x	X		✓	✓	NS	N/a	N/a	x	x
Outcomes																
Knowledge	↑	N/a	N/a	←→	N/a	N/a	N/a	↑	↑	↑video	↑	↑	↑	↑	↑	N/a
Interest/intent	N/a	↓	N/a	←→	←→	↓	N/a	↓	N/a	↓video	←→	↓	N/a	↓	N/a	↓
Uptake	↑	N/a	←→	N/a	N/a	N/a	←→	↓	↓	N/a	N/a	N/a	←→	N/a	←→	N/a
Decision making/conflict	N/a	N/a	↓	N/a	N/a	N/a	↓	N/a	←→	N/a	↓	←→	N/a	N/a	N/a	N/a

* PSA video NS= not stated; N/A = not applicable (i.e. outcome not measured); ↑ = outcome higher in intervention group; ←→ = no difference; ↓ = outcome lower in intervention group

3.24 Trials excluded from the review

Four trials were initially thought to be relevant but on further scrutiny were excluded from the review (Dolan and Frisina, 2002; Holloway et al, 2003; Myers et al, 1999; Pignone et al, 2000). One study was a cluster RCT of risk communication information undertaken in North Wales (Holloway et al, 2003). The aim of the study was to investigate whether an individualised risk communication package could affect stated preferences for screening interval and actual screening behaviour. The intervention consisted of a brief specific counselling session which comprised risk information of personalised risk scores and population information. The main aim of the study was to enhance informed choice, but the intervention was confined to personalised risk information.

Two other trials were excluded because, although they evaluated the effect of decision-aids, information on risks and benefits of screening were not provided and the main focus was still to increase the uptake of screening (Dolan and Frisina, 2002; Pignone et al, 2000). For example, one trial evaluated a decision aid for FOBt or a flexible sigmoidoscopy or both (Pignone 2000). The aim of both trials was still to increase the uptake of colorectal cancer screening rather than increase informed choice, and therefore the decision people were asked to make was about the choice of screening test, not whether they should undergo screening or not. This raises an interesting issue in that the perception of decision aids is that they provide all of the information so that people can make an informed decision. However, in these two particular trials the basic assumption of the researchers was that screening was beneficial, and the only decision of interest was what type of screening test to undergo. Therefore, although the perception is often otherwise, decision aids are not synonymous with informed choice interventions.

A further trial was excluded because, although information on risks and benefits of prostate cancer screening was provided, the only outcome was uptake (Myers et al, 1999). The objective of the trial was again to increase uptake rather than to assess informed choice; neither knowledge nor informed decision-making was assessed.

3.25 Discussion and summary

All except two of the trials were undertaken in North America, and hence the interventions may lack generalisability due to the difference in the way screening programmes are organised. The majority of the included trials were for prostate cancer screening which is a controversial test that has not been fully evaluated. However, even though it is of unproven effectiveness, the provision of information on risks and benefits did not appear to affect uptake in the higher quality studies (RCTs). There are several possible explanations for this focus on one type of cancer screening. Prostate cancer screening is controversial, as it may not meet all of the Wilson and Jungner criteria. In particular sensitivity and specificity of the test is low, and the effectiveness of treatment is uncertain. Thus, there is an impetus for the limitations and consequences of screening to be explained, as well as the benefits.

The informed choice interventions did appear to increase knowledge of the risks and benefits of screening. However, whether this constitutes informed choice is questionable. For example, it might not be the information that people want in order to be informed, and it may not take into account the gap between intentions and behaviour, or the autonomy of the choice. Also, showing that one group knows more than another is not the same as showing that either of them are adequately informed. Finally, there were methodological issues in all of the studies, and so results should be interpreted with caution.

The majority of the studies measured knowledge. However, another systematic review in the area of newborn screening has commented that knowledge is not the same as understanding (Green et al, 2004a). For example, being able to correctly answer a multiple choice question about risk estimates does not mean that the concept of risk has been understood.

In the only study evaluating informed choice (Schapira, 2000), perceptions of being well informed increased from 77% to 93%, even being given only a pamphlet emphasising the benefits of screening. One explanation for this is that people perceive that they are being given the 'whole truth' when they are presented with a detailed leaflet developed

by experts. It has been argued that people's limited knowledge makes them more vulnerable to options that are strongly supported by the 'expert system' (Vahabi and Gastaldo, 2003).

3.26 Synthesis of both sets of studies

Thomas et al used the results of the qualitative synthesis to combine the findings from the controlled trials and qualitative studies (Thomas et al, 2004). They performed a comparative analysis on the data by devising a matrix that juxtaposed the barriers, facilitators, and implied recommendations from the qualitative studies against the actual interventions that had been implemented and evaluated. I was guided by these methods in the synthesis of the informed choice studies and trials.

Results from the qualitative studies (and the qualitative study in this thesis, see Chapter 5) suggest that professionals and lay people differ in the information they think is needed to make an informed choice. To explore this issue, I evaluated the content of the information in the trials and compared it to what screening invitees might want, what the researchers included, and what the GMC guidelines state should be included. I identified 12 domains of knowledge from the guidelines and the review of the qualitative literature. Table 8 provides details of which of these domains were included in each of the studies and provides details of how the interventions were developed (e.g. based on a theory or developed using focus groups). Some of the studies did not contain enough information for me to make a judgement on the information and I was unable to get further details from the authors.

Most of the studies contained a limited amount of information on the disease, with most giving information on symptoms and risk factors. However, two studies did not contain any information about the disease itself. Although all of the studies were consistent in giving information on benefits of screening, and false positives and negatives, other information was not routinely included. For example, only one of the interventions contained information on follow-up plans. Interventions for prostate cancer were more likely to give information on inconsequential disease and side effects of treatment.

Overall the informed choice interventions were mainly concerned with information on the effectiveness of screening, and also the rate of false positive/false negatives. This is not surprising since the main impetus for promoting informed choice in cancer screening was that screening has limitations as well as risks. Therefore the information deemed important to researchers was information about the risks and consequences of screening. Similar to the findings of this review, a systematic review of psychosocial aspects of genetic screening of pregnant women and newborns (Green et al, 2004a) reported that,

'Professionals have been preoccupied with conveying certain kinds of information (e.g. procedural matters, risk estimates), but have virtually ignored others (e.g. what it is like to bring up a child with the condition in question).'

In addition, although most of the studies in this review explicitly stated that they wanted to give people information on the limitations of screening, this information was limited to the screening test rather than any of the consequences of screening. Screening invitees in both my study and the qualitative studies wanted information on the process of doing the test but this was poorly described in many of the trials.

Although the evidence from the qualitative studies is limited, Column 2 in Table 8 ('Perspective') shows which information people undergoing screening may want, and what the proefessionals recommend should be included. As reported in two of the qualitative studies (and confirmed in the qualitative research in the study, see Chapter 5), professionals and screening invitees differ in the information they think is important to make an informed choice. However, most of the studies satisfied neither patient needs nor professional guidance. It is acknowledged, however, that the GMC guidelines are national, not international guidelines.

As I have previously discussed (see section 2.28), one of the concerns of policy makers is that there is a tension between promoting informed choice and uptake. That is, the more information people receive on the risks and limitations, the less likely they may be to go for screening. Seven of the trials gave reasonable information on the risk and benefits (all for prostate screening). Of these, all reported increases in knowledge, four reported a decrease in interest in screening, and two reported a decrease in uptake. The evidence does suggest that giving people comprehensive information on prostate

screening might decrease both intentions to be screened and actual uptake. However, there is not enough evidence in other types of screening to evaluate whether the effects of increased information are the same.

Table 8. Domains of information included in the interventions

	Perspective	Rimer 2001	Adab 2004	Dolan 2002	Pignone 1999	Wolf 2000	Domenighetti 2000	Davison 1999	PSA Video 1996*	Gattellari 2003	Schapira 2000	Wilt 2001	Wolf 1996	No. studies giving info for each domain
Screening		Breast	Cervical	Colon	Colon	Colon	Pancreatic	Prostate	Prostate	Prostate	Prostate	Prostate	Prostate	
The disease	Professional & Patient	✓	✓	✓	✓	x	✓	x	✓	✓	✓	✓	✓	10/12
Symptoms	Professional	X	x	x	x	x	x	x	✓	✓	✓	x	x	3/12
Risk factors	Patient	✓	x	?	✓	x	x	x	✓	✓	?	✓	✓	6/12
Practicalities	Patient	✓	✓	±	✓	±	±	x	±	±	±	±	±	4/12
Purpose of screening	Professional & Patient	✓	✓	✓	✓	✓	✓	?	✓	✓	✓	x	✓	10/12
Known benefits	Professional & Patient	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	12/12
False +ve/ -ve results	Professional & Patient	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	12/12
Abnormal test results	Professional	X	✓	✓	✓	✓	x	?	x	✓	✓	✓	±	7/12
Inconsequential disease	Professional	X	x	✓	x	x	x	?	✓	✓	?	x	✓	4/12
Side effects of tests and treatments	Professional & Patient	X	x	✓	x	✓	✓	?	✓	✓	?	✓	✓	7/12
Medical, social or financial implications	Professional & Patient	✓	x	x	x	✓	x	?	±	✓	?	✓	✓	5/12
Follow up plans	Professional	X	x	x	x	x	x	?	✓	x	?	x	x	1/12
No. domains covered		7	6	7	7	6	5	2+	9	10	6+	7	8	
Developmental basis for intervention		PAM model	Not stated	Previous decision aid work	Not stated	Not stated	Not stated	Not stated	Not stated	Published research	Focus groups HBM	Patient education specialist	Published research	
Extra information from authors		Yes	No, included in article	Yes	No, included in article	No, included in article	No, included in article	No reply received	Yes	No, leaflet included in article	Yes	No, leaflet included in article	No, leaflet included in article	

*5 trials used same video 'The PSA decision; what you need to know'. Information on video received from Flood; ± = partially

3.27 Summary of the review of qualitative and quantitative studies

This is the first time that these combined methods have been used in the area of informed choice. It offers a useful insight into how informed choice is conceptualised by both lay people and by researchers. The following section outlines the main aims of the review and what was revealed by the synthesis of both qualitative and quantitative studies.

What experiences/ideas do screening invitees have about the information they need/want to make an informed choice?

There has been limited research undertaken in this area. However, several of the qualitative studies reported that people wanted information on the purpose of screening, the mechanics of screening, as well as information on risks and benefits. In addition there may be cultural differences in definitions of informed choice.

To what extent do interventions build on these experiences/ ideas?

Most of the intervention studies focused on giving information on the risks and benefits of the disease. Only one study built on the experiences/ideas of qualitative work (Schapira, 2000).

How do researchers define informed choice within the context of intervention studies and how do their definitions correspond with recommendations and guidelines from policy makers and 'experts', and what screening invitees wish to know?

The majority of the informed choice studies use neither guidelines nor lay perspectives to develop the interventions. Operationalisation of the concept of informed choice was poor, and knowledge was used as a proxy for understanding and making an informed choice. Thus the provision of information was seen as the key to making informed choices. No account of autonomy or barriers was taken into account in these trials.

What do the above suggest for developing effective and appropriate interventions to be tested in the future?

Future interventions need to take into account both the recommendations from 'experts' and the information needs of those invited for screening. Current informed choice interventions are narrowly focused around the risks and benefits of the screening test, but should take into account information about the disease (incidence, symptoms, risk factors) as well as consequences of the screening (quality of life issues, and inconsequential disease). Whilst these interventions might fulfil some of the ethical and policy concerns surrounding informed choice, they may not meet patient needs. In addition, future interventions should assess aspects of choice, such as barriers to participation and influence from others.

CHAPTER 4. METHODS

This chapter outlines the methods for both the qualitative study and the quantitative study. Section 1 describes the methods for the qualitative study, section 2 describes the developing and piloting of the questionnaire and section 3 highlights some of the difficulties and challenges I faced trying to get ethical and institutional approval for both studies.

SECTION 1. QUALITATIVE STUDY

The main purpose of this thesis was to develop a quantitative measure of informed choice. To increase the content validity of the measure, qualitative research methods (focus groups and individual interviews) were considered an integral part of the developmental process. In addition, I was able to gain skills in research methods that were new to me. This chapter outlines the importance of the qualitative approach; the method used, and presents the key findings of the research. I also reflect on the process of sampling, recruiting and conducting the research, and the lessons that I learnt.

Qualitative research is based on the theoretical and methodological principles of interpretative science (Sarantakos, 1993). It has been argued that qualitative research is a prerequisite of good quantitative research, particularly in areas that have been subject to little previous investigation. When researching a new area of health behaviour, the starting point should be understanding how and why people conceptualise issues (Pope and Mays, 1995). Morgan (1977) has described three main ways in which qualitative methods can contribute to the process of developing questionnaires. First, they can ensure that the researcher has a complete picture of all the issues, and all the relevant domains that need to be measured. Second, they can help determine the dimensions that make up each of these domains. This will ensure that the questionnaire has content validity. Content validity is a judgement of whether the instrument includes all the relevant concepts or domains (Streiner and Norman, 1995). Third, qualitative methods can help by providing insights into the wording of questionnaires that effectively convey the researcher's intent to the participants. Several studies have used qualitative data in this way (Arraras et al, 2004; McKinley et al, 1997; Rosen et al, 2004; Travess et al,

2001). Chapter 3 described some of the key qualitative literature in the area of informed choice in cancer screening. The study reported in this thesis added to the existing body of knowledge in this area, and contributed to the development of the measure of informed choice.

4.1 Aims and objectives of the qualitative study

The main aim of the qualitative study was to gain an understanding of what informed choice meant to people invited for cancer screening. The main objectives were:

To identify the key dimensions of informed choice which could be used in the development of questions in the MICICS questionnaire. Qualitative data can contribute to the validity of a questionnaire, particularly content validity.

To elicit what information people undergoing screening feel was important and gain a complete picture of all relevant issues. Without eliciting the views and attitudes of the people who are undergoing screening, it is unlikely that the questionnaire would have face validity. The themes and information gained from the qualitative data informed the development of the scale. For example, what information they would have liked to have, and what information was germane to their choice.

To gain some insight into the dimensions of these issues. For example, to determine the 'threshold' level of detail participants would find useful in their decision-making. It was anticipated that some would abdicate responsibility to their providers, whilst others would make a choice independently.

- To compare the differing types and amount of information that people want for each screening test (breast, cervical and colorectal).
People may evaluate information differently for each type of screening, and also have different information needs.
- To provide insights into the wording of the MICICS questionnaire
Using words or phrases from qualitative data can increase saliency and convey t he researcher's intent effectively to the participants.

Criteria for judging the quality of qualitative research include keeping close to the data, reflexivity, documentation, theoretical sampling and negative case analysis, and transferability (Henwood and Pidgeon, 1992). The qualitative study was designed and carried out, where possible, to meet these criteria.

4.2 Rationale for methods of data collection

This section outlines the rationale for the methods used in the research study. As outlined above, the purpose of the qualitative study was to explore how people made choices about screening, and how they used information to make these choices. The qualitative data were initially intended to be used primarily as a supplementary form of collecting data. That is, a source of preliminary data to inform the development of the MICICS questionnaire. It was originally intended that focus groups would be the only qualitative method employed. They were considered particularly appropriate because informed choice in cancer screening is not a subject that many people have thought much about before. Therefore, the amount and depth of information generated by a focus group was thought to be more satisfactory than a one-to-one interview. However, one of the GP practices participating in selecting cervical screening participants did not feel that this was the appropriate method for their population (which had high levels of unemployment and deprivation). Therefore, individual interviews were conducted in this practice. In addition, a number of other people who were recruited from different sampling methods also preferred to have individual interviews.

4.3 Strengths and weakness of the two methods of qualitative data collection

Both focus groups and individual interviews have advantages and disadvantages as outlined in Table 9.

Table 9. Comparative advantages and disadvantages of focus groups and one-to-one interviews

Focus groups	One-to-one interviews
Advantages	
Can observe interaction on a topic	Greater amount of time for individual to share information
Less control for researcher may allow for better flow of ideas	More control for the interviewer may allow for in-depth insights
Good for topics which have not been thought out in detail	Closer communication between researcher and interviewee
Allows participants to build on ideas of others	Researcher can guide direction of interview
Quick and easy - brings together a number of people for a short amount of time	
Disadvantages	
Greater attention to the role of the moderator - may need to make a choice between controlling or allowing free discussion which may not be directly related to the topic of interest	More difficult to compare experiences across individual interviews
Provide less detail and depth of experience for any individual participant	Interviewee may have little to say on a subject that has not been thought out in detail
Less close communication between interviewer and participants	More time consuming to conduct individual interviews
Group may influence the data that is produced - e.g. tendency towards conformity	

Focus groups explicitly use group interactions as a method of collecting data from several people simultaneously (Kitzinger, 1995). The strength of focus groups as a method of data collection lies in their ability to enable participants to respond and comment on other people's contributions. Ideas and thoughts can then be challenged, extended, developed, undermined or qualified (Willig, 2001). It also enables people to be stimulated by others into different ways of thinking. Thus focus groups are particularly useful when the researcher wants to gain valuable insights into behaviour, attitudes, beliefs and values towards a particular issue. For example, they can be used to elicit cancer patients' information needs and why they may or may not want information (Leydon et al, 2000). In addition, group discussion can enable a researcher to gain evidence about similarities and differences in people's opinions and experiences as opposed to reaching such conclusions from separate post hoc analysis of one-to-one

interviews (Morgan, 1997). However there are disadvantages to focus groups, such as potential over-domination by one member of the group. This may result in themes emerging that reflect one particular voice rather than the group as a whole.

Face to face interviews can enable a greater rapport to develop between the researcher and the interviewee. Because there is nobody else there, the interviewee feels obliged to speak nearly all the time, and thoughts can be developed to a greater extent perhaps than those in the focus groups. In addition, the interviewee may feel more able to speak openly and without sub-consciously filtering their thoughts and ideas to conform to the group norm. In section 4.12 I reflect on the issues I faced as a researcher with no experience in either of these methods, and how the data differed between the two methods.

4.4 The process of selecting and recruiting

The following sections outline the process of selection and recruiting participants for the focus groups and one-to-one interviews. It describes the ethical issues, and some of the difficulties with the project. In the conceptualisation of this research project, the process of selection and recruitment of the research participants was perceived to be relatively unproblematic. However, although we sought advice on recruitment of the sample from the outset of the project, there were many unexpected setbacks (see later sections). The time from when we had the first meetings with the Scottish Screening Programme Director to when the first focus groups were conducted was 20 months. Reasons for the delays and reflections on the process are also discussed in more detail in section 3.

4.5 Selection of participants

Sampling of participants for research differs between qualitative and quantitative research. In quantitative research, researchers are concerned with probability sampling. However, in qualitative research, non-probability sampling methods are primarily employed (Berg, 1989; 30). Types of sampling include convenience, purposive, snowball and quota sampling. Although I employed sampling techniques such as 'snowballing', and recruiting through colleagues, library and cancer charities were also

employed (see later sections) the main method I used was purposive sampling strategy (Silverman, 2000;54). Using this method, selection of participants was structured around key dimensions to reflect the range and diversity present in the target population. The three key dimensions were:

- *The type of screening:* breast, cervical or colorectal
- *The experiences of people who had been invited for screening:* did not attend, false positive, false negative, true positive, true negative. My reason for being particularly interested in views of people with false positive, false negative and true positive results was that they represent the small minority of people who are directly affected by the screening process (either positively or negatively). For the majority of people who have a negative result from screening, the impact of the whole screening process is likely to be small and their information needs (it could be argued) are minimal. In addition, for those people who decide not to be screened, only a small number of them will actually develop any form of cancer; the majority will be unaffected by their choice not to be screened.
- *Sociodemographic factors:* people from different socioeconomic and sociodemographic backgrounds, as well as different age groups, sex (for colorectal cancer) and educational level.

In addition, they needed to have been invited for screening in the last six to 12 months so that they might remember the screening information given.

Between October 2001 and March 2003, there was a series of meetings between the researchers, policy makers, programme directors and GPs to determine the selection criteria and the recruitment process (see Appendix 5 and also section 4.42). Following these meetings, selection criteria were developed to reflect practical and ethical concerns. In particular, the Scottish National Screening Co-ordinator raised issues surrounding the confidential and sensitive nature of information on people with a false negative result. This group was therefore not able to be included in our sample.

Selection criteria: cervical screening

Cervical screening is organised through GP practices and invitations for cervical screening are sent via GP practices. From the discussions with the Programme Director it was agreed that the terms 'false positives', 'true negatives' etc. may not be useful when defining the population, as they are difficult to classify, and may not be appropriate in the time frame (within 6-12 months of being invited for screening). It was decided that women would be selected from the following groups:

- Invited for screening, but did not attend

- Those that were invited but had a negative result
- Abnormal result: high grade (referred directly for colposcopy)
- Abnormal result: low grade (repeated and then referred for colposcopy)
- Abnormal result: low grade (repeated and then deemed to be normal)
- Unsatisfactory result (need to be re-screened)

Selection criteria: breast screening

Breast screening is organised centrally through the Breast Screening Programme and invitations are sent out from the screening units. Screening is organised on a practice by practice basis. Therefore, eligible women from individual GP practices are all sent their invitations from the breast screening unit at the same time. After discussions with project managers and the Programme Director, it was decided that women would be selected from the following groups:

- Invited for screening, but did not attend
- Those who were invited but had a negative result
- Those who were invited and had a positive result and went on to develop cancer ·
- Those who were invited and had a positive result, were brought back for review but did not develop cancer

Selection criteria: colorectal cancer screening

Colorectal cancer screening was, at the time of the study, conducted in limited pilot settings. The service was organised centrally through the Pilot Colorectal Screening Programme and invitations to Scottish invitees are sent out from the Pilot Centre in Dundee. Before I started the PhD fellowship and during the early stages, I was involved in evaluating the workload impact of the pilot on primary care (Jepson et al, 2005a). Similar to breast screening, eligible individuals from individual GP practices are all sent their invitations at the same time. Both men and women were invited to participate. After discussions with the Scottish arm of the UK Pilot it was agreed that it would be possible to identify three different types of potential participants:

- Those who were invited but did not send back a screening kit
- Those who were invited but had a negative result
- Those who were invited and had a positive result and were referred on for further investigations

4.6 Recruitment of participants

Once the selection criteria had been determined, the next step was recruiting potential participants. Recruitment of cervical screening invitees had to take place through primary care. Three GP practices, whose patient population represented a range of sociodemographic characteristics, were contacted and agreed to take part. A search strategy that reflected the inclusion criteria was devised in GPASS[20] to identify eligible women. This strategy was run by each of the participating practices to select 60 women who fulfilled the criteria.

Recruitment was slightly different for breast and colorectal screening invitees. A list of practices which had taken part within the last 6-12 months was identified through the Scottish Breast Screening Programme (SBSP) or the Colorectal Cancer Screening Pilot Unit. From this list, suitable practices were identified (using sociodemographic characteristics as the main variable). Those practices that agreed to participate were sent a list of suitable participants, which was generated by the screening units. From this list, 60 eligible people were selected, based on the selection criteria described previously.

Practice managers sent out letters and information sheets using the practice letterhead (see Appendix 6) for copies of the letters and the information sheet. Letters were signed by a GP within the practices. The potential participants were asked to contact myself if they were interested in taking part by returning a completed consent form. I then contacted them to arrange a suitable date, time, and venue. Originally it was thought that 20 letters would be enough to get a response rate of 6-8 (enough for one focus group). However, after a poor response rate from one practice (for cervical screening), the number invited to participate was increased to 60.

Other methods used to recruit people

Whilst waiting for ethical approval for the study, I undertook a pilot focus group on non-NHS patients eligible for cervical screening (friends and colleagues). Using these participants gave me an opportunity to run my first focus group in a supportive setting. I

[20] The computer software used by GPs to store information on patients

also advertised in two local libraries in an attempt to recruit people and received two responses. At each focus group and individual interview I mentioned to the participants that I was keen to speak to other people (particularly those who had not participated in screening), and asked them if they knew of anyone else who might be interested. I gave them my details to pass onto people, but said it was up to individuals to contact me. From this snowballing technique I interviewed a further three people. Snowballing techniques are argued to be one of the best ways to locate people with certain attributes (Berg, 1989; 31).

As mentioned previously, because of issues surrounding the confidential and sensitive nature of the data, I was not given permission to get access to people who had false negative results. Voluntary organisations were contacted to try to elicit views from such an important group (e.g. Maggie's Centre in Edinburgh, and CancerBACUP and Cancer Care). Although the organisations were extremely helpful, I only received one response (i.e. one interviewee) using this method.

Incentives to increase response rates

Recruitment of both practices and participants to the study proved more difficult than originally expected. Initial letters to both practices and participants resulted in a very low response rate. It was therefore decided that the use of incentives and financial reimbursement was one way of getting both practices and patients to participate.

Reimbursement for practice staff time

After sending out initial letters to GP practices and getting a poor response, I consulted with the Primary Care Research Networks (Lothian and Tayside). We decided that the best approach was to reimburse practices for sending out the letters to the potential participants. We also decided that the co-ordinators of the Networks would send an initial letter, introducing my project to GPs, and clearly stating the amount of money they would be reimbursed. I then sent a follow-on letter, and suggested meeting with them to discuss the project. As a result three out of the four practices we contacted in Tayside agreed to participate for colorectal cancer screening, two out of the four practices we contacted for breast screening and three out of the four we contacted for cervical screening. The offer of reimbursement created *'good will'* and enabled me to

develop good relationships with practice staff. On several occasions I went out to the practice to explain the research.

Use of incentives for patient participation

Originally, participants were only going to be reimbursed for travel expenses. However, to increase the response rate, it was decided to offer a flat rate of £15 to cover travel expenses and inconvenience. Both Tayside and Lothian Research Ethics Committees were contacted to see if this was acceptable practice and both agreed that it was.

During the interviews and focus groups I noted (where possible) people's attitudes and reactions to being given the incentive. In the second focus group (cervical screening out in West Lothian) women talked about what they would do with the money, including buying lipstick and items for their children. These participants were primarily professional women. This contrasted with the third focus group (breast screening in an urban, deprived area) in which two women said that they were going to give the money to their local community, and another asked me to donate it to a cancer charity. These were all women with low paid jobs, retired or unemployed. In other focus groups, some people may have been influenced to attend because of the incentives, but others were clearly surprised when they were given the money, and had forgotten that they would get it. In the individual interviews, motivation for some of the single mothers in particular to attend could have been the incentives. However, such incentives enabled me to access a 'hard to reach' group.

It has been suggested that offering people an incentive might lower the quality of the response as people are motivated by the incentive rather than the topic area (McColl et al, 2001). This motivation might also mean that a different group of people would respond than would have done so without the incentive. I would argue that an incentive is unlikely to deter people who would have volunteered anyway. However, it is perhaps likely to attract people who would not have responded, but whose views I wished to take into account. This might include people from more deprived areas, single parents etc. From a pragmatic point of view, I felt that I had spent 18 months trying to organise focus groups which had resulted in financial and resource costs. If my recruitment was low (as

suggested by the first round of sampling) the whole research project could have been in jeopardy.

Overall, I think that the use of incentives allowed me to interview a much broader range of people than I would have otherwise achieved. Thus, the sample was more representative of the total screening population. Incentives were also used in the validation study - see section 4.31.

4.7 Maintaining confidentiality

Maintaining patient confidentiality was a major principle that I adhered to in the study. In order to achieve this, I adhered to the following protocol. Practice staff contacted the potential participants on my behalf. Only if these people agreed to participate was I made aware of their identity. I carried out all interviewing and analysis. The secretary who carried out the transcribing of tapes was made aware of issues of confidentiality and signed a confidentiality document. Established mechanisms were in place to safeguard all data gathered from the focus groups and individual interviews. During analysis, confidentiality was maintained by the use of a code number on the transcripts and following data collection all relevant information was destroyed. All transcript tapes were stored in locked filing cabinets in university premises. In writing up the results, names and reference to places of work, medical institutions, streets, towns etc were anonymised by the use of pseudonyms. I was the only person who had access to the data once they had been transcribed.

4.8 Ethical Approval

Ethical approval was sought from the Lothian Research Ethics Committee and Tayside Research Ethics Committee. Both these ethics committees granted ethical approval in July 2002. However, I also had to get approval from the Privacy Advisory Committee to have access to Community Health Index (CHI) numbers for breast and cervical screening invitees. This approval was not granted because I had wanted to contact people directly. Following further discussions over patient sampling and recruitment, I sought an amendment from Lothian Research Ethics Committee that was granted in December 2002. Management approval from the Lothian Primary Care Trust and West

Lothian Primary Care Trust (see later sections on the process involved in recruiting for the study) was also granted.

4.9 Running the focus groups

Focus groups were held within several venues: the practice from which participants came, a hotel conference room, or at a room in the University of Edinburgh. Refreshments were provided, and the focus groups lasted between 60 and 90 minutes. The focus groups were all tape-recorded and consent for this was checked before the focus groups began.

At the start of the focus groups, participants were given a summary of the project, the goals of the focus groups and the importance of their ideas and input into the project. They were reminded of the issues of confidentiality outlined in the information sheet (e.g. all identifiers were removed when transcribing, tapes were destroyed). Ground rules for focus groups were outlined. These included respecting other people's views, and giving other people a chance to talk. Participants were then asked to introduce themselves so that their names were recognisable for the person transcribing the tapes. Where possible I had either a co-moderator for the focus groups, or someone to assist me in the technical aspects of running the focus groups (e.g. making sure the microphone was working properly, arranging refreshments and payment of incentives).

After discussion with other researchers, a discussion guide was developed (Appendix 7). People were asked firstly to describe what information they had received in their invitations, and the experiences they had of screening. They were then asked general questions about screening and informed choice. I then showed them some prompt cards with information about screening (such as how common the particular cancer was the risk factors, the reliability and limitations of screening (see Appendix 8)). Before showing these prompts, I asked participants about their current understanding. After showing them the information, I asked them to reflect on the information, in particular if it would affect their decision to be screened, or whether they thought it would affect others, and how useful they thought it was. At the end I asked them three questions: the amount of information they would have liked; if they would have liked to have discussed

their decision with others; and how important the decision (to be screened or not) was. As the focus groups and interviews were semi-structured, when people raised a new issue I attempted to explore it with them in some depth. If I thought it was relevant to my project, I then incorporated it into subsequent interviews and focus groups.

The pilot focus group and revision of questions

The pilot focus group was with a group of ten friends and colleagues. I had a co-moderator and a set of questions. Because the group was relaxed and most of the people knew each other, for the first half of the session my involvement was minimal - people had a lot to say, and the discussion flowed well. What was striking for me was that it became apparent that many of the questions I had prepared were irrelevant, particularly those related to the information they had received. This was because most of the participants had not received any information at all, or did not recall having received any.

The second half of the session developed rather differently from the one which I had planned. I had expected the women to know some facts about cervical cancer and cervical screening. However, although these women were all educated to degree level and had participated in screening for many years they had very little knowledge about cervical screening. They asked me for more information which they used for the basis of their discussions. It was after this focus group that I decided that I needed to use prompts (i.e. information about risks, benefits and limitations of screening).

Inviting people who were familiar to me (and largely each other) for this first pilot focus group was very useful for me in two ways. Firstly, it meant that I was more at my ease than I would have been if I did not know them. Secondly, because they had all met at least one person in the group before, the group dynamics were very good, and members of the group seemed at their ease as well. All the people contributed to discussions, which were very wide ranging, and lively. Humour seemed to be a common element of many of the subsequent focus groups I ran. Many times people were laughing and using humour to describe difficult or embarrassing experiences.

I read through the transcripts of this focus group afterwards, and although I did not do any formal analysis, certain topics arose which I thought would be useful to explore in greater depth in subsequent focus groups and interviews. These included the differences in attitudes towards screening between men and women; the amount of information people wanted; the amount of choice they wanted in the decision making process, and the notion of the 'good patient'.

4.10 One-to-one interviews

Interviews took place in the person's home or in one of the rooms within the University of Edinburgh. Dates and times were arranged that suited the interviewees. I asked the person at the time of arranging the interview whether they agreed to be tape-recorded. One woman did not agree, but was happy for me to take hand-written notes. For security, I always let a member of staff know where I was going and rang them when I had finished the interview.

Before beginning the interview, I discussed issues of confidentiality, and the fact that the interviewees could stop the interview at any time. To put them at their ease, I began with very general questions, before moving onto more sensitive areas. I had a semi-structured interview schedule, but did not stick to it rigidly if they introduced an area that I wanted to explore in more depth.

Many times, one of the reasons that women had agreed to participate was because they had a 'story' to tell. I felt a commitment to listen to them, and take an interest, before moving on to issues that were relevant to the project. I also felt it was very important for building rapport that is essential for in depth exploration. I knew which areas I wished to cover, and at the end of the interview, I checked through the schedule to make sure that I had covered everything.

4.11 Developing themes and incorporating new issues

The keeping of a journal is an important part of building up documentation, stimulating creative thoughts and increasing researcher reflexivity (Henwood and Pidgeon, 1992; Pidgeon and Henwood, 1997). After each focus group or interview, I wrote down my observations of the process in a diary. I reflected on what had been said, and which new issues had emerged. For example, in one focus group people raised issues about perceptions of responsibility and gender differences. I then explored these issues further in subsequent focus groups and interviews. I did not have time between focus groups and interviews to transcribe and code the data, although this would have been preferable. This was because of the short period of time I had to conduct the study. I ran seven focus groups and did 13 interviews in the space of six weeks as I was already behind in my schedule (dues to delays which are outlined in more detail in later sections). I also wanted to get the data collection phase completed before the holiday period when many people might have been away. As I ran more focus groups and interviews, fewer and fewer new themes developed. In the last two focus groups, I felt that most of the common issues had been covered before. However, I was aware that many other groups (such as people with disabilities and those for whom English was not their first language) may have other issues relating to informed choice. However, it was not possible, due to time and financial restraints, to continue data collection with these groups.

4.12 Reflections on running the focus groups and interviews

Overall, I found the interviews and focus groups a very positive experience for me as a researcher. As someone who has been involved primarily in quantitative research, the opportunity to ask people how they felt about issues was invaluable. I also found that many people who took part in the study enjoyed it and found it a positive experience. On several occasions, people actively said at the end of the session how much they had enjoyed it. In particular they appreciated talking about issues that they did not normally get the opportunity to talk about. In all of the focus groups people ended up contributing to the discussions. In several of the groups there was much laughter and animated debate of the topics. People also liked to talk about their own personal experiences, and others commented on how they had appreciated listening to these experiences.

Strengths and weaknesses of the two methods of data collection

Both methods of collecting data had their strengths and weaknesses when exploring the issues. Focus groups often depended on the particular dynamics of the individuals within them. One difficulty was that in some focus groups (particularly for breast cancer screening) the more educated women would dominate the group. It was not generally an issue in the first part of the focus groups when we were talking generally about people's experiences of screening. It was more evident when I was showing information in the second half of the focus groups.

I often ended up trying to draw the quieter, less articulate, women into the discussions. However, on one occasion, I could see that a woman was clearly withdrawing from the conversation even though I was trying to include her. She seemed overwhelmed with the other women who were talking knowledgeably about the issues. Towards the end of the focus group (it was longer than expected) she made her apologies and left. I felt that if I had had an individual interview with her I would have been able to find out more information and others would not have intimidated her.

Another difficulty was that some groups took longer than others to get to the stage where they would discuss issues amongst themselves. In one focus group in particular, part of the session was more question and answers between me and the participants, rather than a discussion amongst the participants. It was difficult to get them talking amongst themselves rather than to me directly. Possible reasons were a lack of ease within the group; I felt they were more comfortable directing the conversation to me rather than within the group. Also, they genuinely wanted to know more about the subject, and in order to move on to open discussions, I felt they needed to have some of their questions answered.

A further problem was that, although the focus groups enabled a range of opinions to be expressed, often they did not allow for depth of issues to be explored, particularly in areas which might have been embarrassing. For example, in one colorectal focus group a woman revealed that she had never been for cervical screening. She said that, *'It's not embarrassment; it's not a reaction to it.'* Later on, she obviously wanted to tell me/the

group why and was starting to say, '*And I'd love to be able to, go for a [cervical] screen but....*' when somebody else interrupted and took the conversation in a different direction. I did not feel that I was able to take the conversation back, although I was interested in why she would not take part. If it had been an individual interview, it would have been easier for her to tell me and to explore the issue in more depth.

As mentioned previously, the main reason for doing individual interviews was that the women were from deprived areas and might not feel comfortable in a focus group setting. They gave me an opportunity to explore in depth some of the issues that were raised. This was often not possible in a focus group when the conversation moved more quickly. However, the individual interviews were more time consuming, and took longer to transcribe and analyse.

The interview as a product of social interaction; my position as researcher

It is inevitable that the interaction between the researcher and the research participant will affect the data that is collected and the way in which it is analysed. For example, the participants may have tried to give me an account of their understanding of screening that they thought I would want to hear. In Chapter 1, I described my personal perspectives on the issues surrounding informed choice in screening. In each of the interviews and focus groups I made it clear that I myself had no strong views about screening, was non-judgemental about their screening choices and was just interested in the types of information they wanted. Normally I told people that I had a background in nursing. The reason I positioned myself as a health professional was to make the participants more comfortable about talking about 'health' issues. However, people might have disclosed other information had I positioned myself as (for example) a social scientist.

To enable people to talk as freely as possible, one of my aims as a researcher was to get people to relax and feel able to talk about issues without feeling judged. This was particularly important when I was interviewing people who had not taken part in screening. I tried to dress appropriately for the interview or focus group. For example, when I knew I was going out to visit a young single mother in a deprived area I wore

casual clothes such as jeans and a t-shirt. Once I had gone into a person's house, I looked around for something which would make a connection between me and the interviewee, establish rapport and put them at their ease. In many cases the area we had in common was a child. With the single parents, I sometimes mentioned that I was a single parent as well, which was received very favourably, and I could see them immediately relax. With older women I talked about pets, or their grandchildren. I found that once I had established rapport, the interviews flowed very well without exception. With the focus groups of older men and women, I dressed more smartly, but still attempted to establish rapport with each participant as they entered the room.

The groups that I found most challenging as a researcher were with the older men in the colorectal focus groups, who were often nervous and clearly not used to such a situation. These groups also differed in the ways I felt I 'performed' as a researcher. However, even though I had some doubts about the success of these focus groups, when I re-contacted some of the men for a second round of focus groups (to pilot the questionnaire), the majority of them agreed to take part. At the end of the second round, one man even asked if there were any more as he had enjoyed them so much.

4.13 Preparing the data for analysis and interpretation

All tapes were transcribed either by me or by a secretary. After a secretary transcribed a tape, I listened to it with the written transcript in front of me. Listening to the tapes personally served two important purposes. First, I could fill in any passages that the secretary could not understand, and make sure that the transcriptions were accurate. Second, listening to the transcripts served to remind me of the humour, interactions and subtle nuances which did not come across when the tapes were transcribed. Once the transcripts had been checked and edited, they were then imported into the NVivo software package (QSR, 2000). NVivo is a computer-assisted qualitative data analysis software package. This programme was used as a tool for the management of the data, helping to facilitate analysis and interpretation.

4.14 Data analysis and interpretation

There are several theories and methods that can be used to drive data collection and analysis in qualitative research. These include interpretative, narrative and performance, discourse, content and grounded theory analysis. Data analysis and interpretation in this study was based to some extent on the principles of grounded theory. Grounded theory was developed by Glaser and Strauss (Glaser and Strauss, 1967). It is concerned with local contextual theory, explorations of meanings in their full complexity, and reflecting participants' construction of the world. The value of grounded theory is that it suggests a set of procedures which can put into practice the requirement to actively engage in close and detailed analysis of the research material (Pidgeon and Henwood, 1997). Although the approach I used in data collection and analysis was based on the some of the principles of grounded theory, it was not based wholly on this theory for two main reasons.

First, grounded theory is designed to facilitate the process of 'discovery or 'theory generation' in qualitative research. In particular, some grounded theorists argue that the research should be undertaken before consulting any literature to ensure that pre-existing constructs do not shape the analysis (Gibbs, 2002), although others reject such a rigid stance and argue that such an inductive approach pays insufficient attention to the role of the researcher (Charmaz, 1995; Henwood and Pidgeon, 1992) The aim of my qualitative study (as discussed in section 4.1) was to develop items for my questionnaire, rather than develop new theory. Therefore, I used a slightly different approach. When I was asking people to define informed consent, the difficulty I found was that people did not have enough information to give a complete answer. Therefore, if I had not had an *a priori* idea as to what constituted informed consent, I would have had very little data from participants with which to work. For example, in the first focus group I hoped to be guided by the participants' understanding of informed choice in cervical screening. However, it became clear early on in the focus group that the participants had no knowledge of either cervical cancer or cervical screening. Thus in order to have a discussion about informed choice in future groups, I had to provide information and prompts based on pre-existing knowledge and literature. This provision of information meant that I was actively constructing the data to some extent and interacting with the

participants (Charmaz, 1995). However, I used this information as 'points of departure' to develop rather than limit my ideas (Charmaz, 1995).

Second, grounded theory emphasises that analysis must take place during data collection. In this study, this was not possible due to delays and time constraints. However, I did try to incorporate new issues as they emerged into subsequent interviews and focus groups. The main way in which I used grounded theory was by following its basic principles and key strategies including:

- Theoretical sampling
- Constant comparative analysis
- Negative case analysis
- Present results using exemplars – quotes that illuminate the theory (Willig, 2001)

4.15 Development of themes

Codes were added to the data using the NVivo software package, version 1.3 (QSR, 2000). The technique I used to analyse and code the data was the constant comparative method. In this method the researcher is

'Urged to be constantly alert to the similarities and differences which exist between instances, cases and concepts, to ensure that the full diversity and complexity of the data is explored' (Pidgeon and Henwood, 1997)

I constructed themes drawing both on theories of informed choice and also inductively from the data. Therefore, the construction of themes was both data-driven and concept-driven. I moved between both of these sources, and many times had to go back to the data and recode. In this way much of the construction of the themes was done using a constant comparative approach. Using such an approach helped to ensure that the text coded in the themes was well grounded in the data. To ensure that the data analysis was rigorous and valid I also took account of the 'negative' cases (Esterberg, 2002; Pidgeon and Henwood, 1997). Negative cases are used to disconfirm hypotheses and theories. Exploring such negative cases is useful to both challenge initial assumptions and categories and modifying and elaborating theory.

To ensure a reflexive process of analysis, I asked other researchers and my supervisors to code pieces of the text for me, and/or we discussed how to code it. Themes were used

not only to categorise passages of text, but as a focus for thinking about the text and interpreting it in its wider context.

Reflexivity

The constructionist view of research acknowledges the way in which both the researcher and the research itself inevitably shapes the object of inquiry (Pidgeon and Henwood, 1997). It has been argued that it is important to be reflexive about how researchers interpret their data, their role in the analytic process and preconceived ideas and assumptions we bring to the analysis (Mauthner and Doucet, 2003; Pidgeon and Henwood, 1997). In coding and analysis of the data I was conscious of the role I had as a researcher (see section 4.12).

SECTION 2. DEVELOPING THE MICICS QUESTIONNAIRE

The main aim of the thesis was to develop the MICICS questionnaire in cancer screening (MICICS) questionnaire. Box 2 outlines the stages of development of the questionnaire. These stages were developed using recommendations by Streiner and Norman (1995). This chapter reports on the development of the scale (Step 3) piloting of the questionnaire (Step 4) and refinement of the scale (Step 5). This chapter will also briefly summarise previous steps (1 and 2) in the development of the questionnaire.

Box 2. Development of the MICICS questionnaire

SCALE DEVELOPMENT	*POPULATION GROUPS AND OTHER SOURCES*	*PURPOSE*
Step 1 Searching the literature		To identify other scales of potential relevance (see Chapter 3.)
Step 2. Development of items	Focus groups GMC guidelines	Generate themes Content validity (see Chapter 5.)
Step 3. Development of scale and pre-pilot	Focus groups GMC guidelines Panel of experts	Generate themes Content validity
Step 4. Piloting of the questionnaire	Screening population	Content validity Endorsement Usefulness of items Item properties
Step 5. Refinement of scale		Final scale development
Step 6. Further validation of scale	Screening population	Construct validity Effects of variables such as age and sex (see Chapter 5)

4.16 Aims and objectives of the MICICS questionnaire

Informed choice in cancer screening is a relatively new concept that has not been evaluated empirically. The main aim of the MICICS questionnaire was to describe informed choice and to measure the degree to which people had made an informed choice when invited for screening. Secondary aims were to explore some of the explanatory variables (e.g. sex, age and social class), and provide a greater understanding of the role of information in the choices that people make. The primary objectives were:

- To develop a valid and reliable measure of informed choice in cancer screening which could differentiate between those people made informed choices and those that didn't
- To explore relationships and associations between different individual or groups of variables (e.g. attitudes and knowledge, age, sex, social class, and type of screening)
- To compare levels of informed choice between different populations (e.g. different types of screening, sex of participants)
-

4.17 Step 1. Literature review and justification for the development of a measure

The rationale behind developing any new measure or scale is that no other similar measure exists. In Chapter 3 a systematic search for empirical evidence of measuring informed choice was undertaken to identify other relevant instruments. Only one other similar measure of informed choice was found (measuring informed choice in antenatal screening (Marteau et al, 2001)). This measure incorporated questions on knowledge, attitudes, and behaviour. However, it did not include questions about influences on choice such as autonomy and barriers. Thus, it was not measuring some of the key domains of informed choice (see Chapter 3 for a fuller discussion of some of the limitations of this measure in this context). In addition, antenatal screening differs from cancer screening with regard to the disease-specific information needed. The lack of an appropriate measure of informed choice in cancer screening justified the development of a new one. The second step in developing the measure was to define the factors that could affect informed choice in cancer screening and the constructs underpinning informed choice.

4.18 Step 2. Defining the underlying constructs of informed choice

Informed choice is not a directly measurable phenomenon such as blood pressure or cholesterol levels. It is made up of constructs that cannot be measured directly. In scale development, such constructs are termed latent variables (DeVellis, 2003). These variables have two chief features. First, they are latent rather than manifest. For example, informed choice is not directly observable. Second, the construct is variable rather than constant. Informed choice may vary with regard to time (e.g. whether measured just before or in between invitations to be screened), type of screening, gender or sociodemographics. It may also vary between individuals, not just between these groups.

Three main sources of data and information were used to generate these potential constructs or latent variables. Firstly, the data from the focus groups (see Chapter 5) were used to develop items for the MICICS questionnaire. In particular, they were used to develop the questions on knowledge and attitudes. This approach has been used in the development of other questionnaires (e.g. McKinley et al, 1997). Secondly, GMC guidelines on informed consent to screening were used (General Medical Council., 1999), as were the leaflets on informed choice in cancer screening (DoH, 2003a; DoH, 2003b) and an article on informed choice in breast screening (Thornton et al, 2003). Thirdly, constructs were developed from the theories of informed choice and autonomy as discussed in previous chapters. Beauchamp defined informed choice as acting intentionally, autonomously and with understanding (Beauchamp and Childress, 1994). All three of these factors were included in the questionnaire. Questions were also based initially on the Theory of Planned Behaviour, the Health Belief Model and the Theory of Reasoned Action (see Chapter 2 for a more detailed discussion of these models and their applicability to cancer screening).

From the latter three sources described above, the following seven key domains were identified and these were published in a recent article (see Appendix 9, (Jepson et al, 2005b)).

1. Degree of 'informedness'
In this context 'informed' is taken to mean the knowledge and understanding a person has rather than the provision of information (i.e. the term informed is used as an adjective rather than a verb. See Chapter 2, section 2.19 for a more detailed discussion).

2. Preferred or intended choice
A person's preferred or intended choice (as opposed to behaviour) should be measured after they have received the invitation (with or without information) and before they participate (or not). See Chapter 2 for more discussion on choice.

3. Barriers towards carrying out the choice.
Barriers may be internally or externally imposed. Internal barriers may include physical or mental health problems and language. External barriers could include availability of the service/intervention and access.

4. Attitudes, values and beliefs
The person's choice should reflect their underlying values and beliefs regarding their choice. These attitudes, values, and beliefs are often measured using theories of health behaviour. However, chapter 2 outlines some of the limitations of these theories. Section 4.21 provides further discussion of the use of the theories of health behaviour in the development of the questionnaire.

5. Degree of preferred involvement
People may wish to be involved in the decision over whether to be screened or not to a greater or lesser degree. Therefore it may be important to evaluate to what extent people wish to be involved (or make a choice) in the decision to be screened.

6. Degree of choice and perceived availability of choice
People may differ in the amount of choice or control they have in the decision to be screened. This domain should measure the degree to which the choice was autonomous and free from coercion. Both the choice to participate and the choice not to participate should be equally available.

7. Behaviour carried out
The behaviour evaluated was whether the individual either attended for screening (whether or not it was performed adequately) or sent back a test kit (whether or not it was adequately completed). Behaviour has been described as comprising four elements: the action, the target at which the action is directed, the context in which it occurs and the time at which it is performed (Ajzen and Fishbein, 1980b). Applying these four elements to screening behaviour, I was interested in screening behaviour undertaken

within National Screening Programmes in the recommended screening intervals. I was not interested in measuring ad hoc screening behaviour which may be very different with regard to attitudes and values.

4.19 Step 3. Development of a psychometric measure

Psychometrics is the term used to describe measurement of psychological phenomena such as informed choice. There are widely accepted procedures for development and assessment of psychometric measures. Development often begins with a large number of items which purport to cover the different facets of the theoretical construct to be measured (in this instance informed choice). Then empirical data are collected from a sample of the population for whom the measure is intended. After appropriate analysis of this data, a subset of the original list of items is then selected and becomes the actual multi-indicator measure (Heath and Martin, 1997). The measure is then formally assessed for reliability and validity. Measuring informed choice is an attempt to objectify a subjective state and as such is likely to have problems in establishing the properties of good reliability and validity. It is necessary to conduct validation studies for each new instrument that is developed.

Psychometric measurement involves the use of tests, measures or scales. Although these terms are often used interchangeably, it is useful to clarify the differences and define explicitly what the measure of informed choice consists of. A *measure* can be broadly defined as an instrument constructed according to psychometric principles, and displaying psychometric properties of reliability and validity. A measure may contain scales, or tests, as well as explanatory variables such as age and sex. In psychometrics, a *scale* is described as a collection of items related to a phenomenon which is combined into a composite score (DeVellis, 2003). Scales consist of effect indicators which are items whose values are caused by an underlying construct. To constitute a scale the items must share a common cause. Scaling involves ordering and comparison of performance without any absolute or mean performance level. A *test* has been described as comparing individual performance on a measuring instrument against standard (mean) performance on the instrument (Loewenthal, 2001) or in comparing sub-populations. In tests, there are usually correct and incorrect answers.

The MICICS questionnaire developed in this study was a questionnaire of tests and scales. The questionnaire also includes explanatory variables such as age and sex. The collection of knowledge items fit into the description of a test. This is because for each of the knowledge questions, there is a correct or incorrect answer (see next section for more details on how the knowledge questions were devised). A test is not appropriate for the measurement of attitudes and beliefs as these are not considered either correct or incorrect. Therefore, attitudes and beliefs related to informed choice were measured using scales and subscales.

Determining whether a scale is measuring what it is supposed to be measuring, requires evidence of validity (Streiner and Norman, 1995). Types of validity used to assess a scale include face validity, content validity, context validity and criterion validity. However, Streiner and Norman (1995; 146) also argue that validation is a process of hypothesis testing, and that rather than being constrained by trying to establish these different types of validity, researchers should only be constrained by devising experiments to test their hypotheses. DeVaus also suggest that it is not the measure that is valid or invalid, but the use to which it is put (DeVaus, 2002). Each of these types of validity and their relevance to the measure of informed choice are considered in the following section.

Content and face validity

Content validity is a judgement of whether the instrument includes all the relevant concepts or domains. Face validity refers to whether the scale looks reasonable and it appears to be measuring the desired constructs (Streiner and Norman, 1995). Both types of validity are subjective assessments based on a review of the measure by experts and members of the target population. Thus empirical methods are not used to determine whether a measure has face and content validity. Section 4.27 outlines how face and content validity were established. In addition, the PROCASE measure of knowledge was published in the last year of this thesis, and the domains of information were almost identical to those that I had defined (see Chapter 3).

Criterion validity

In order to have criterion related validity, a scale should have an empirical association with another scale or 'gold standard' (DeVellis, 2003). However there are two problems with this approach. Firstly it assumes that there is an existing measure, and secondly it assumes that the existing measure is valid (De Vaus, 2002). As discussed previously, informed choice in cancer screening is a new area for measurement and no other scales at the time of devising the scale had been devised. Other scales have measured constructs such as Satisfaction With Decision Making (Holmes-Rovner et al, 1996) and Decisional Conflict Scale (DCS) (O'Connor et al, 1995) and were used in the initial development of the questionnaire However, data from the second round of focus groups found that these many of questions were irrelevant, or not easily understood (see Chapter 4), and were removed from later versions of the questionnaire. A subscale of the DCS scale was kept in – *'factors contributing to uncertainty'*

I am aware of the choice I have to make

I feel know the benefits of (treatment)

I feel I know the risks and side effects of (treatment)

Construct validity

One of the purposes of a scale is to measure an underlying hypothetical construct. Construct validity evaluates a measure by how well the measure conforms with theoretical expectations (De Vaus, 2002). A valid scale will be one which allows us to make accurate inferences about a person. It also allows us to discriminate between different populations (i.e. informed and uninformed). De Vaus (2002) contends that this approach may be reasonable if the theory used is well established, but it is open to two dangers. First it may be difficult to distinguish whether it is the theory or the measure that is invalid; second a test should not be developed to support the theory; if a theory is used to validate the measure, and then the measure is used to test the theory, nothing will have been established. There is no one single study that can establish the validity of a construct, and construct validation is an ongoing process of learning more about the construct, making new predictions and then testing them

(Streiner and Norman, 1995). Section 4.18 describes how the underlying constructs of informed choice were defined in the measure.

4.20 Devising questions on knowledge and understanding

There is a lack of literature evaluating how best to measure a person's knowledge and understanding. Sudman and Bradburn, 1982 devised a checklist of major points (see Box 3) when designing questions about knowledge. These guidelines were followed where possible.

Box 3. Asking questions about knowledge

- Before asking attitude questions about issues or persons, ask knowledge questions to screen out respondents who lack sufficient information
- Consider whether the level of difficulty of the questions is appropriate for the study. For new issues, simple questions may be necessary
- Where possible, reduce the threat of knowledge questions by asking them as opinions or using phrases such as 'do you happen to know'
- When identifying persons or organisations, avoid overestimates of knowledge by asking additional information or including fictitious names
- If 'yes/no' questions are appropriate, ask several to reduce the likelihood of successful guessing
- For knowledge questions requiring numerical answers, use open-ended questions to avoid either giving away the answer or misleading the respondent.
- To increase reliability when obtaining information about a geographical area, use multiple key informants or individual respondents.
- Consider the use of pictures and other non-verbal procedures for determining knowledge
- When attempting to determine level of knowledge, do not use mail or other procedures that allow the respondent to look things up.

Sudman also suggested using a *'Don't know'* category to reduce threat. This category was incorporated into many of the questions in the measure about knowledge. Although one of the purposes of the 'Don't know' option in the measure was to reduce threat, it also served two other purposes. Firstly it enabled exploration of the specific pieces of information that people did not know. This also allowed for comparison across the three cancer screening types. Secondly, it was hoped that it would reduce the amount of guessing.

The domains of information were chosen after analysing the qualitative data (see Chapter 5), and also based on the qualitative data in Chapter 3, part 2. The main aim of these questions was to determine people's understanding of the concepts of screening,

rather than their knowledge of, for example, the probability of adverse events. It has been argued that being able to correctly recite the risk of an adverse event does not mean that the concept of risk has been understood (Green et al, 2004a). The main domains of understanding included in the questionnaire were

- incidence of the disease, risk factors and symptoms
- meaning of various results
- some of the main limitations and consequences
- the possible negative effects of screening and treatment.

Most questions related more to understanding of the concepts of screening, and possible consequences using a true/false format. A few of the questions in these domains directly related to measuring knowledge (e.g. incidence, risk, factors and symptoms).

4.21 Devising questions on attitudes, degree of coercion and decision making

There have been many texts published on definitions and measurement of attitudes (e.g. (Ajzen and Fishbein, 1980a; Ajzen and Fishbein, 1980b; Oppenheim, 1992). An attitude has been described as:

'A state of readiness, a tendency to respond in a certain manner when confronted with certain stimuli.'(Oppenheim, 1992)

Oppenheim describes attitudes as being dormant, and only aroused or expressed when the object of the attitude is perceived. Thus, an attitude about screening would generally only be aroused when people were invited for screening. Oppenheim also expresses the opinion that attitudes are reinforced by beliefs (the cognitive component) and often attract strong feelings which may lead to a behavioural intention (the action tendency component). Attitudes are abstract concepts, though real enough to the person that holds them. Oppenheim states that attitudes differ in content, intensity and endurance. For example, people's attitudes towards screening may change over the course of their life.

Initially, questions on attitudes and behaviour were going to be based on one of the theories of health behaviour, such as the Theory of Planned Behaviour. However, the literature review undertaken in Chapter 2, uncovered weakness in the model in its ability to predict screening behaviour. In addition, this model is based on the assumption that

people have a certain level of knowledge of the disease of interest. For example, the models build on people's perceptions of their susceptibility to the disease, and the perceived severity of illness. Data from the focus groups (see Chapter 5) suggested that many people knew little about the different cancers or screening. In addition, these questions were not well answered or thought to be appropriate in the second round of focus groups (see section 4.28). It was decided that using one of these theories as the main basis for questions on attitudes was not useful. Instead a more inductive approach was used, whereby the information derived from focus groups was used. I felt that by grounding the questions in the data, the questionnaire would be more likely to have content validity.

Where possible, statements on attitudes were developed using actual statements from people taking part in the qualitative studies (for example, 'having a smear is part of being a woman') described in Chapter 5. A much larger group of items was used for the pilot than was expected to contribute to the final questionnaire. Statements were worded to express fairly strong opinions and attitudes (e.g. 'I can't be bothered to do the test'). The reason for strong statements was that mild statements may elicit too much agreement and may not be useful in differentiating between people with strong opinions (DeVellis, 2003). The way questions are worded is crucial in maximising the validity of the questionnaire (Sudman and Bradburn, 1982). The questionnaire was not aimed at increasing uptake, nor was it to promote the benefits of screening. Therefore, particular attention was paid to trying to ensure that an individual's decision (i.e. the person completing the questionnaire) to participate or not was not seen to be a 'good choice' or 'bad choice.' Questions relating to attitudes ranged from positive to negative.

Some questions about attitudes and beliefs were initially included from a pre-existing scale ('Decisional Conflict Scale' (O'Connor, 1995), see Chapter 3, section 1). This scale had four subscales which measured decisional uncertainty, factors contributing to uncertainty, satisfaction with decision, and perceived effective decision making. Some of the questions seemed relevant to the measure, and could have been one way of assessing criterion validity. However, feedback from the second round of focus groups suggested that these questions were difficult to interpret (see page 162).

4.22 Scaling responses

Once the items had been devised it was necessary to choose a method by which responses would be obtained, and define the format of the variables (i.e. interval/ratio, ordinal, nominal or dichotomous). Some of the items relating to knowledge had the option to give simple 'yes/no' answers which produced dichotomous variables. Other knowledge questions were multiple choice or true/false/don't know (nominal variables). Attitudes and beliefs were measured using a Likert five point scale whereby responses were elicited on an 'agree-disagree' continuum. Although these scales produce ordinal variables it has been argued that (if sample sizes are large) they can be treated as interval/ratio variables because of the relatively large number of categories they generate (Bryman, 2001). The questionnaire also had to be acceptable to the target population so the format of the questionnaire was carefully considered to maximise the response rate.

4.23 Designing the questionnaire: layout and format

The format of the questionnaire was designed, where possible, using the results of an HTA report on the design and use of questionnaires (McColl et al, 2001), and a systematic review of interventions to increase response rates (Edwards et al, 2002). However, there were constraining factors, such as resources, which limited the ability to carry out all of the recommendations. As many of the respondents were likely to be older people, I also tried to follow guidelines for font size and colour from the Royal National Institute for the Blind (RNIB, 2004). The font (Arial) and the font size (11) were chosen because they are easy to read by those with a visual impairment. Capitals were used sparingly as they can be difficult to read. White space was used to make it easier for people to complete it. Originally each section was going to be printed in a different colour, but printing would have proved to be too costly. Instead, coloured paper was used. Yellow paper was chosen as it contrasts well with black font

The readability of the questionnaire was assessed using the Flesch-Kincaid Grade Level score which is found in the Word software package. The score rates text on an U.S. grade-school level. For example, a score of 8.0 means that an eighth grader (approximately 14 years old) can understand the document. The Flesch-Kincaid Grade Level score for the questionnaire was 4.6. The language was rated according to the

Flesch Reading Ease score. This score rates text on a 100-point scale; the higher the score, the easier it is to understand the document. The score for the questionnaire was 81.2 out of 100, suggesting that it was easy to read.

The general non-threatening questions about how much information people got were placed at the beginning of the questionnaire. These were followed by the questions on knowledge (people in the pilot found these the most engaging questions, so they were put near the beginning). This set of questions was followed by a set on attitudes. Questions about choice were left until near the end as some people could perceive these to be threatening. Open ended questions were included in several areas to ensure that no topic of importance to patients was excluded. Lastly personal details were asked on occupation and educational status.

4.24 Defining sociodemographic variables

Sociodemographic data were collected on age, sex and postcodes (from screening unit and GP records), occupational and educational level. There were three main reasons for collecting sociodemographic data. Firstly, it enabled internal comparisons to be made between responders and non-responders. Secondly, it allowed analysis to be undertaken to see if any sociodemographic variables were important in informed choice (e.g. age or sex). Thirdly, it enabled some external comparison to be made to see how the sample compared with the population from which it was drawn and also Scotland as a whole.

Social deprivation

Postcode was used as the primary indicator of social deprivation of the participants' geographical area. After discussion with staff in the Data Library it was decided that the best indicator of social deprivation to use in this study was the Scottish Indices of Multiple Deprivation (SIMD) 2003(Social Disadvantage Research Centre, 2003). Postcodes for each person in the study were transformed by a member of staff in the Data Library into both the composite and individual domain scores. The composite SIMD score was used in the analysis. This summary score is the combined sum of the weighted, exponentially transformed domain rank of the domain score. It is an ordinal scale and the bigger the SIMD score, the more deprived the ward. However, because of the exponential distribution, it is not possible to say, for example, that a ward with a

score of 40 is twice as deprived as a ward with a score of 20. However, available data for larger areas (e.g. Lothian or Scotland) was only available as averages (means) (Social Disadvantage Research Centre, 2003).

Occupation

The National Statistics Socio-economic Classification (NS-SEC) is used for all government surveys and official statistics. This was the classification used in this study. The version of the classification, which was used (the analytic version), has eight classes, the first of which can be subdivided (see Box 4). There are three methods of deriving a score: Full, Reduced and Simplified. At the eight-class level the reduced method correctly allocates 98% of cases compared to the full method. The simplified method correctly allocates 83% of cases compared to the full method.

Data from the initial pilot and focus groups discussing the questionnaire suggested that asking for people's occupation was a sensitive area. People did not understand the rationale behind asking these questions. Therefore, rather than a detailed number of questions (as required for the full method), data were only collected on a person's present or previous occupation. This only allowed me to use the simplified method. While this is an obvious limitation of the data (along with the fact that I allowed people to opt out of answering the question), I had to trade off precision with acceptability. Asking one simple question enabled me to get some measure of social class which was acceptable to the population. Asking several questions would have increased the length of the questionnaire, and people may not have answered them. To enable comparisons to be made between the sample, and Census data from the local area and Scotland, social classes 1.1 and 1.2 were collapsed into a single category.

Box 4. Analytic Classes and Operational Categories and of NS-SEC	
Analytic Classes	Operational Categories
1.1	Employers in large organisations
	Higher managerial occupations
1.2	Higher professional occupations
2	Lower professional and higher technical occupations
	Lower managerial occupations
	Higher supervisory occupations
3	Intermediate occupations
4	Employers in small organisations
	Own account workers
5	Lower supervisory occupations
	Lower technical occupations
6	Semi routine occupations
7	Routine occupations
8	Never worked and long term unemployed
*	Full time students
*	Occupations not stated or inadequately described
*	Not classifiable for other reasons

* For complete coverage, categories L15, L16 and L17 are added as 'Not Classified'. The composition of 'Not Classified' will be dependent on the data source. NS-SEC Categories marked with an *, NS-SEC Analytic Class 8 and Not classified do not appear on the derivation tables

Educational level

Education was measured by asking if the respondents had any of the following qualifications. If their particular qualifications were not listed they were asked to tick nearest equivalent.

- No qualifications
- Standard grades / O grades or equivalent
- Highers or equivalent
- Other professional or technical qualification / diploma
- Degree
- If you do not wish to answer this question, please tick here

These categories are directly comparable to those used in the 2001 Census, and thus comparisons were made at both the local level and for Scotland as a whole.

4.25 Efforts to reduce respondent bias

There is a tendency to answer attitude-scale items in a particular way, almost irrespective of content (Oppenheim, 1992). This tendency is sometimes referred to as response set bias or responder bias. There are several types of response set bias. Social desirability bias means that respondents answer in a way that they believe reflects

socially desirable attitudes. Acquiescence bias means that people will generally agree with a statement rather than disagree with it. End-aversion bias refers to the reluctance some people might have to using the extreme categories on the scale (i.e. strongly agree and strongly disagree) (Streiner and Norman, 1995). Thus, if this bias was present, the extremes of a Likert scale would never be used, rendering it a three point scale. To minimise some of these biases, some questions had reverse statements. For example rather than 'I will do the test' we used statements such as 'I can't be bothered to do the test'. Some of the socially undesirable statements were deliberately put at the beginning ('I can't be bothered to go for screening'), rather than starting off with statements that could be perceived to be socially desirable ('I think screening is a good thing'). These questions were placed first because a person who was not in favour of doing the test might be discouraged by positive statements.

4.26 Efforts to increase response rates

One of the main issues when developing and piloting a questionnaire is ensuring a high response rate. Non-response to postal questionnaires reduces the effective sample size and can introduce bias. Several strategies have empirical evidence to suggest they enhance response rates (Edwards et al, 2002). For example, personalised questionnaires and letters increased response rates (OR 1.16; 95% CI: 1.06 to 1.28), as did the use of coloured ink (OR 1.39; 95% CI: 1.16 to 1.67). Questionnaires designed to be of more interest to participants were more likely to be returned (OR 2.44; 1.99 to 3.01), but questionnaires containing questions of a sensitive nature were less likely to be returned (OR 0.92; 0.87 to 0.98). When I sent out the pilot questionnaires I did not know whether the topic would be salient to those receiving it. It was hoped that sending out the questionnaire just after people received their invitation (and in the case of bowel screening, their test kit) would increase saliency. It was not possible to use all the strategies suggested in the Edwards paper due to financial, structural and time constraints. However, attention was given to the design and layout of the questionnaire (see section 4.22) as well as other issues such as including a stamped addressed envelope. The questionnaire had a University logo on it, and the letters came on letter headed paper either from myself, or the invitee's GP.

4.27 Pre-testing of the questionnaire to ensure content and face validity

Once the key factors had been identified and questions developed, the questionnaire was pre-tested using focus groups and experts. The purpose of this pre-testing was to assess face and content validity. Several aspects of content validity were considered. Firstly, was the questionnaire relevant to those people filling in the questionnaire? Secondly, was the questionnaire accurate in respect to the knowledge and terminology used? Thirdly, were the questions worded in such a way that validity was maximised? In this study I assessed content validity first and then face validity.

A second round of focus groups was undertaken in the pre-testing phase. One purpose of these focus groups was an additional check, to make sure that that the items derived from the previous round of focus groups did have content validity. The focus groups were also used to test the readability of the questionnaire, to determine whether questions were understood as intended, to check how people set about answering the questions, and to eliminate items that were felt by the participants to be irrelevant, difficult, or likely to cause offence.

I drew my participants from the same sample that I had used for the initial focus groups (see Chapter 5). However, for this second round of focus groups I was more purposive in my sampling. Where possible I deliberately chose people who came from more deprived areas and had said that they did not have professional occupations. This was because I anticipated that they would have the most trouble in filling in the questionnaire. Although the primary purpose of these focus groups were to assess the readability, acceptability and content validity of the questionnaire, other issues such as the format and length of the questionnaire were also discussed.

Results for second round of focus groups

Six focus groups (two for each of the screening tests) were conducted to ascertain people's responses to the questionnaire. As mentioned previously, all participants were people who had previously been involved in the first round. People were sent the questionnaire in advance and asked to try to fill it in before the focus groups. Due to

time constraints, these focus groups were not fully transcribed, but detailed notes were made of people's responses to the questionnaires.

Overall, people thought that the questionnaire reflected what had been said in the focus groups and their opinions on the knowledge they wanted to make an informed choice and the range of attitudes and beliefs. Several people commented on how they enjoyed filling it in, and had found it easy to do so. With regard to the format, the men in particular thought that it was too long, and would that it would deter some people from completing it. People thought the layout and the font size was acceptable. There is some evidence from RCTs that a response is more likely when short questionnaires are used (OR 1.86; 95% CI: 1.55 to 2.24) (Edwards et al, 2002). However, the definition of a short or long questionnaire in the trials varied. Initially the questionnaire contained 76 questions. Following feedback from the focus groups (and the panel of experts, see next section) the number of questions was reduced to around 50.

People reported most difficulty with the Decisional Conflict Scale (see section 4.21) particularly questions such as, *'It's hard to decide if the benefits are more important to me than the risks, or if the risks are more important than the benefits.'* In the revision of the questionnaire, most of these questions were omitted, although the subscale of questions relating to uncertainty was left in.[21] The scale was developed for a different context (flu vaccinations) and the third question had to be reworded to, 'I feel I know the limitations of screening.'

I had initially included questions about perceived susceptibility and seriousness of the disease (which related to the theories of health behaviour). For example, one statement was 'I think I am at high risk of colorectal cancer' with answers on a Likert scale (from strongly disagree to strongly agree). However, several people commented on the fact that they couldn't answer this question because they did not know what the risks were. This question was re-worded to a multiple choice option (yes, no, I don't know what the risks are).

[21] I'm aware of the choice I have to make; I feel I know the benefits of * screening; I feel I know the risks and side effects of screening

Several people did not like a multiple choice question that asked about the type of job they did, and that of their spouse. This was replaced with a more open ended question about their job. In addition, people were given the option to not answer questions about their personal details. Although it could be argued that these details were crucial, I thought that it would be better to have this option rather than potentially have a large number of missing values. Where possible, pointers were put in so that people could skip questions which were not relevant. The questionnaire was changed and revised to reflect the comments from these focus groups, and then sent to an expert panel for comments (see next section).

Establishing face validity

The next step was to establish whether the questionnaire had face validity. Face validity was achieved by sending the measure to a panel of experts. The panel consisted primarily of two distinct sets of people: those involved in the organisation and/or implementation of screening programmes and those involved in promoting informed choice in cancer screening. The first group – professionals involved in cancer screening - included the programme directors for Breast, Cervical cancer screening in Edinburgh and Colorectal screening in Dundee, and the project managers at the National Services Division. They provided particularly useful input on correct terminology and whether questions on knowledge were factually correct. People who were involved in informed choice in cancer screening were also asked to comment on the questionnaire (e.g. researchers and patient advocates). They helped ensure that I was measuring all the factors acknowledged to be involved in informed choice. I also invited comments from other people working in the area of cervical screening and informed choice. Once I had all their comments, I revised the questionnaire further.

4.28 Step 4. Piloting the MICICS questionnaire

Once the pre-testing phase had been completed, the questionnaire was piloted in the populations invited to be screened for the three types of cancer. The purposes of the pilot were to:

1. Identify which questions were answered appropriately.
2. Estimate likely response rates
3. Identify likely non-response bias
4. Test the survey procedures under 'main survey' conditions

5. Estimate rate and speed of response of the main survey
6. Check timings and establish systems and routines (McColl et al, 2001).

Piloting of the questionnaire took place through the Screening Units and GP practices. As this pilot was primarily to determine the readability and acceptability in the target population, a sample of 50 per screening type was deemed to be an adequate number. Where possible I asked screening and practice staff to select a sample to represent the variation in types of respondents (e.g. age, sex, screening type and screening status). After discussion with the screening units, it was decided that a non-personalised letter from me should go in with the questionnaire for breast and colorectal screening. The use of non- personalised rather than a personalised letter was to increase confidence that researchers did not have access to personal contact information. For the initial pilot it was decided not to send out reminders. As we had to send out the questionnaires through the screening units, we did not want to place an extra burden on them by having to keep track of who had been sent one. For cervical screening, the participating doctor decided that the letter would be best coming from him rather than a non-personalised one from me. For all questionnaires, a reply paid envelope with my name on it was included in the envelope.

It has been suggested that piloting should include some cognitive pre-testing (McColl et al, 2001) to ascertain, for example, what people think when they open the questionnaire. Cognitive testing can indicate how well different aspects of the postal package are working, and whether the covering letter is fulfilling the aims of communicating the project information to the recipient. Whilst this might have increased the response to the questionnaire, it was beyond the time and financial resources of this study to undertake this approach.

4.29 Pilot test results

One hundred and fifty MICICS questionnaires were sent out (50 for breast, cervical and colorectal invitees respectively). Practice and screening staff were asked, where possible, to send out equal numbers of the questionnaires to people who had been invited before (prevalence round) and to those who had not been invited before (incident round). For

colorectal cancer they were also asked to send out to equal numbers of men and women. No further sampling was requested at this stage and there was no data linkage.

Characteristics of respondents

Table 10 details the response rate for each type of screening. Overall, the response rate was 36%, but the response rate varied by screening type. Breast cancer screening had the highest response rate (54%) compared with 30% for colorectal cancer and only 24% for cervical screening. This was a statistically significant difference (p = 0.004). For colorectal screening, 6/15 (40%) were male.

Table 10. Response rate by type of screening

Type of cancer screening	Sent back questionnaire		Total sent
	Yes	No	
Bowel	15 (30%)	35 (70%)	50 (100%)
Cervical	12 (24%)	38 (76%)	50 (100%)
Breast	27 (54%)	23 (46%)	50 (100%)
Total	54	96	150

$\chi^2_2 = 10.98$ *(p=0.004)*

The response rate also varied by screening history. Although the total number of incidence and prevalence invitees in the sample was determined by the screening unit, we relied on self reported data from the respondents to tell us whether or not they had been invited for screening previously. The majority of people who returned the questionnaire (45/54, 83%) said that they had previously been invited. Only 12% of people (9/75) who had never been screened before returned questionnaires (see Table 11). Respondents who had previously been invited were asked if they actually participated. Only two people replied that they had not participated previously (3.7% of the total number of respondents). In addition, only one respondent said that they might not participate in screening.

Table 11. Response rate by screening history (confirmed by screening providers)

History of screening	**Sent back questionnaire**		**Total sent**
	Yes	No	
Incidence (new invitees)	9 (12%)	66 (88%)	75 (100%)
Prevalence (previous invitees)	45 (60%)	30 (40%)	75 (100%)
Total	54	96	150

$\chi^2_1 = 37.50$ (p<0.001)

Respondents were also asked a question about their education level (Table 12). There was no significant difference in response rates between the different levels of education. Six of the respondents (9%) did not answer the question.

Table 12. Highest level of education completed

Educational level	Frequency	Percent
No qualifications	8	15
Standard grades / O grades or equivalent	16	30
Highers or equivalent	4	7
Other professional / technical qualification / diploma	12	22
Degree	8	15
Do not wish to answer the question	6	11
Total	54	100%

Frequency of endorsement

One of the purposes of the pilot was to test for attributes such as endorsement frequency. This is the proportion of people (p) who give each response alternative to an item (Streiner and Norman, 1995), for example, the proportion of people answering 'yes' or 'no' to a question about using information to make their choice. Usually items are eliminated when one alternative has a very high (or low) endorsement rate. Streiner and Norman (1995) assert that if p is over 0.95 most people will be answering the question in the same way and little will be achieved by including the question.

Although some of the general items were assessed for endorsement frequency, it was not deemed appropriate for questions on knowledge. This is because there are certain domains that were thought to be essential components of informed choice. High or low endorsement would simply indicate the domains in which people were well informed or under informed.

As indicated previously, response rate was low, and the respondents may not represent the range of people undergoing screening (e.g. people not taking part in screening were not well represented). Therefore it was not appropriate to undertake any major analysis and delete even general items just because they had high or low endorsement. For example, a question on barriers to screening might have low endorsement in a population that had already participated. Internal consistency of the scale was not assessed due to the bias in the sample. It was decided that this pilot would focus on how

people filled in the questionnaire, the 'problem' questions and give some baseline data on patient characteristics.

Readability and acceptability

Readability of the questionnaire, assessed by missing values and comments on the questionnaires, was very good. People did not have difficulties in filling in the questionnaire, and there were minimal missing values. As indicted in section 4.21, statements on attitudes and beliefs were devised to differentiate between people with strong positive and negative opinions. Most of the attitude questions did have a good distribution across the categories (from strongly agree to strongly disagree) with no clustering between the agree/disagree responses. These results indicate that the items were able to reflect differences in attitudes.

4.30 Step 5. Revision of questions

The MICICS questionnaire went through several revisions after feedback from the focus groups and expert panel, and also following basic analysis of the pilot questionnaire. The final questionnaire was re-circulated to some of the experts, and also to my supervisors. Some items were removed from the final list. These included items which had a high percentage of missing values, or items which were people found unacceptable or ambiguous. For example, even though it was a common expression in the focus groups, several women questioned the statement *'Going for my (smear/mammogram) is part of being a woman.'* This item was removed from the final version of the questionnaire. Other items removed were some of the statements taken from the decisional conflict questionnaire that were not filled in or were adversely commented on.

Overall people found the questions on knowledge acceptable, and filled them in appropriately. Many used the 'Don't know' category rather than missing out the question altogether, or randomly picking an answer. The main question that people did not like was 'What do you think some of the disadvantages of screening might be?' On reflection, the term disadvantage could be viewed as a value judgment. To overcome this, the statements were slightly reworded and asked as true/false questions (e.g. 'Some people might be diagnosed as having cancer when they feel well'). This was not

presented as either a disadvantage or an advantage of screening, but in with a set of other True/False questions. In addition, the number of risk factors detailed was thought to be too long and this was shortened. Most of the more general questions had only minimal or no missing values. However, questions on barriers to screening were not well filled in, and these questions were re-worded.

4.31 Ethical Approval and ethical issues

Separate ethical approval had to be obtained for the two quantitative studies. Although Tayside Research Ethics Committee gave Ethical Approval for both the pilot and the larger study, I had to obtain separate approval for pilot and the larger study from Lothian Research Ethics Committee. The main ethical issue for the larger study was that I wanted data on the postcodes, year of birth and previous screening history (attended, did not attend or new invitee). This was approved by both committees, on the understanding that I had no access to personalised information of participants.

When the questions on knowledge were being designed, I was concerned about asking people questions without providing the answers. I contacted both of the ethics committees and it was agreed that I could ask people to send their names and addresses if respondents wanted an answer sheet and further information. The envelopes were opened by a secretary who then sent out an information sheet so I had no access to the names and addresses.

After the low response rates for the pilot study, I decided to use incentives as the odds of response have been shown to be more than doubled when a monetary incentive was used (OR 2.02; 95% CI: 1.79 to 2.27) (Edwards et al, 2002; McColl et al, 2001). The incentive was to be included in a prize draw for 'Choice' vouchers (4 valued at £25 or 1 valued at £100). Choice vouchers can be exchanged in a range of high street stores, but are not linked to any one retailer. Both screening unit personnel and the Ethics Committees agreed to their use.

It has been suggested that offering incentives (particularly in postal surveys) could lower the quality of the response; people might be less motivated to give thoughtful answers if

their interest in the study was motivated by the incentive (McColl et al, 2001). This could result in respondent bias. Whilst this might be true, there was no way of measuring it. However, as demonstrated in the Chapter 5 missing values were minimal, suggesting that people were taking time to complete it. On the other hand, incentives may also increase response rates and include a wider range of participants.

4.32 Reflections on the pilot study

The response rate for the pilot study was lower than anticipated which limited any formal analysis of the data. Overall, the respondent characteristics indicated that the respondents were primarily people that had been invited and had taken part in screening. Thus it was possible that their views towards screening were more favourable than the total target population. However, the purpose of the pilot was not to ascertain all aspects of the questionnaire's validity, but rather determine its readability, acceptability and highlight redundant or unhelpful items. In this respect the pilot was useful in determining that readability and acceptability were good. It also provided an opportunity to use further strategies for increasing the response rate.

4.33 The main validation study

Once the pilot study had been completed and the questionnaire revised the larger study was undertaken. This used a similar population to the pilot study but the main difference was that reminders were sent, and information on whether people actually participated in screening or not was collected. The purpose of this validation study was to evaluate the reliability and validity of the MICICS questionnaire. See Appendix 10 for the three different questionnaires which were sent out.

Methods and process

Questionnaires were sent out to people for all three types of cancers just after they had been invited to be screened. The timing was so that people could fill in the questionnaires before they had performed the behaviour. The reason for the timing was because it was important to understand what people's attitudes towards, and knowledge of, screening was at the time of making the decision. Collecting data after a behaviour has occurred may alter knowledge and attitudes.

Generating a sample

There is little guidance as to the recommended sample size for a validation study. Some experts recommend a fixed number ranging from 200-300 (Streiner and Norman, 1995). Another approach is to base the calculation around reliability coefficients. However, the pilot study did not give us enough information to calculate these coefficients. Other similar validation studies (Guerriere and Llewellyn-Thomas, 2001; Horne et al, 2001; Koedoot et al, 2001; Loeken et al, 1997; Wills and Holmes-Rovner, 2003) provided no details of sample size calculations and samples ranged from around 90 – 450 people. After discussions with a statistician it was decided to send out 400 questionnaires for each type of cancer screening. Based on the response rates from the pilot study, this would give a final data set of 400 questionnaires which was considered adequate for the analysis.

Process and problems

Details of the way screening programmes are organized, and therefore the way that samples are generated, have been discussed previously. The following sections describe some of the issues I faced with recruiting participants invited for the three types of cancer screening

Colorectal screening

The larger validation study began with people invited for colorectal screening[22]. To maximize the representativeness of the responses, the Colorectal Screening Unit in Dundee was asked to produce a random sample which included men and women, different ages, from different practices. I also asked them to over sample people who had not taken part in screening in the previous round. This was because few of these people had responded in the pilot, thus biasing the responses in favour of people who had taken part. It was anticipated that, by over-sampling, I would increase the number of responses from this group. People who did not participate in colorectal screening have been found to differ from people who do. That is, they are more likely to be younger, male, from more socially deprived areas than participants, have different attitudes towards screening and be more at risk of developing the disease (UK evaluation team, 2004). They are also

[22] I had received ethical approval to do the study in Tayside (i.e. colorectal invitees) before approval was granted from Lothian

less likely to return questionnaires (in the pilot of this questionnaire, less than 10% of responders were non-participants in screening). Because of these differences, it was thought important to over sample them in this study.

Sampling for this study was restricted to certain geographical areas, as the Pilot was only screening three areas of Scotland (Tayside, Fife and Grampian). Originally, I had intended to sample practices from the three geographical areas, and from practices with different levels of deprivation. However, due to time constraints and other difficulties (see later sections), I only had a limited period to send out the questionnaires. Therefore, I was limited to consecutive practices on the Screening Unit's list, which were all located in Montrose, or close by. A random sample was generated within four GP practices. Unfortunately, due to a misunderstanding, the initial sampling of 100 people per practice did not include any people who had not been invited before. As a considerable amount of work had been involved in generating the sample, I asked the Screening Unit to generate an additional sample of 20 people per GP practice who had never been screened before. Thus the final sample number identified was 480. After generating a sample, the Screening Unit allocated each individual in the sample a unique number from 1-480. This was so that I could then number envelopes and questionnaires which would be linked to the unique number. They could link the number to confidential information such as name, address and date of birth. I was given information on sex, postcode, year of birth and screening history.

I sent the Screening Unit numbered, stamped, envelopes which contained the research packs (a non-personalised letter, an information sheet, the questionnaire and a replied paid envelope). The Screening Unit then sent out these questionnaires after people had been sent their invitation to take part in screening.[23] After three weeks, I sent them numbered packs for those who had not replied and they also sent these out. After three months I asked for data on which of the sample had participated on screening (to obtain data on behaviour). This numbering system and process was also used for the breast and cervical screening questionnaires.

[23] The Screening Unit did not want the questionnaire to be sent out at the same time as the invitation as they thought that it was too much information to give to people at one time.

Breast screening

Whilst the colorectal questionnaires were being sent out, I contacted the Scottish Breast Screening Unit in May 2004 to discuss whether this process could be repeated in the Unit, and also the necessary time frames. Although the Director of the Screening was willing to help in the research, she indicated that it would be six months before they would be able to send out the questionnaires. To keep delays to a minimum, I started liaising with the Acting Centre Administrator to determine how best to select the sample. She also allowed me to visit one of the mobile vans to see how mammographies were performed out with the screening centre.

From my meeting with the Administrator, we determined that screening would be taking place in East Lothian from September onwards. The number of practices that I could sample from would be determined by their size and time constraints. As with colorectal screening, practices are screened consecutively. Therefore, if there was a very big practice, screening all the eligible women might take several weeks. The Administrator indicated that there might be some difficulties generating a sample in the same way as the Colorectal Screening Unit had done, due to differences in software, and the way information was stored. However, we kept a dialogue going as how it might best be performed. Unfortunately, the Administrator went off on maternity leave in August before she was able to generate a sample of women, or find out how it could be done. I was then put in touch with her replacement, but she was the PA to the Director, knew very little about the process, and was very busy with her own work. I liaised between her and the computer people, but it became obvious that it was going to be very difficult to get a predetermined sample of women based on age, and screening history. After several phone calls in early September 2004 trying to organise a sample, it became clear that if I wanted to get the questionnaire sent out by the end of September, a sample would have to be generated within the constraints of resources, personnel, and computing capabilities.

The practice being screened at that time was a very large one, and another one would not be screening until late October/early November. After discussing the difficulties with my supervisors it was decided that I would use a single practice, even though there would be

limitations to this sample. Another problem with the sample was that it became a random sample of the practice, rather than a stratified sample. However, a similar sampling strategy was also used for the cervical screening invitees.

Cervical screening

I discussed which samples should be included in the cervical screening group with two cervical screening facilitators from the Scottish Cervical Screening Programme. On my behalf they wrote to four practices (two inner city practices and two more rural) to ask them if they would participate, and three practices agreed. Due to the limitations of the software, I was again unable to predetermine the sample. Instead, each practice sent out the questionnaires at the same time that they sent out their monthly cervical screening invitations. However, each of the samples contained a mix of people who had previously been screened and those who had not.

Limitations of the sampling frame

I had originally planned a sample that would be from different GP practices, with a mix of ages (and sex for colorectal screening), with an over sampling of people who had not participated in screening in the previous round. However, I was only able to employ this sampling frame for colorectal screening. Even then, I wasn't able to choose a mix of GP practices (e.g. by locality, or level of deprivation) as I only had the time to use consecutive practices. For cervical and breast screening, the limitations of the computer software meant that the only sample that could be generated was a random mix of people invited for screening. In addition, I was only able to sample one GP practice for breast screening. The limitations of the sampling frame may have resulted in bias which will be discussed in more detail in the results.

Hawthorne effect or response bias

The Hawthorne effect refers to the effect that being a participant in research has on the participants' responses and behaviour. In this study, people who know that they are answering questions about informed choice may be more likely to read the information leaflets sent to them. Therefore, the questionnaire itself might have acted as an intervention. There is little evidence from which to estimate the likelihood of any 'Hawthorne' effect on patient behaviour in health service settings. However, findings

from a study on colorectal screening showed that people sent a questionnaire were slightly faster to take up screening than those not sent a questionnaire, but no significant difference in absolute service uptake rate at six months was observed (O'Sullivan et al, 2004). Chapter 5 evaluates the effect of response bias.

4.34 Preparing the data for analysis

The following sections outline the methods used in preparing the data for analysis, and undertaking the analysis. These methods were used for all three types of cancer screening.

After the questionnaires had been returned, I entered the data into an Access database. Data were checked for errors in data entry, and then several variables had to be recoded for the analysis. People who had not received the questionnaire (due to not being at the contact address), who were deceased or were not able to fill in the questionnaire were excluded from the analysis. After data entry, the data were checked for errors and it were then exported into SPSS for analysis. Further coding was also done within SPSS.

Assessing data and response set bias

Missing data refers to questions that are left blank by the respondents. There are two problems with missing data – either they can lead to loss of statistical power if the numbers are large, or they can lead to bias if it is non-random (related to either respondent characteristics or respondent bias). There are three ways of dealing with missing data: 1) exclude them from the analysis by deleting cases or variables; 2) substitute with the mean; 3) impute the missing values using more complex methods (SPSS, 1998). Missing value analysis (MVA) was primarily used to determine whether data were missing completely at random (MCAR) or missing at random (MAR). If data are MCAR, then the data are unrelated to any respondent characteristics. If data are MAR, then a response/non response to that item may relate to a respondent characteristic (e.g. age) (SPSS, 1998). Separate variance t-tests were calculated for the items, and tabulated patterns of missing data were examined. No patterns were found, so the EM (Expectation-Maximisation) approach was used to impute missing values for the attitudinal and belief items. This approach is based upon the statistical method of

maximum likelihood, which has been asserted as superior to other approaches such as listwise deletion, pairwise deletion, or mean substitution (SPSS, 2004).
Computations were done within SPSS to check for evidence of response set bias – people who provided the same answers to the set of attitudinal questions measured on a Likert scale. No response set bias was found for any of the three sets of data (cervical, colorectal and breast screening).

4.35 Coding the sociodemographic variables

The main socio-demographic variables were age, sex, educational level, occupation, and postcode (as a proxy for social deprivation). There were three main reasons for collecting sociodemographic data. Firstly, it enabled internal comparisons to be made between responders and non-responders. Secondly, it enabled some external comparison to be made to see how the sample compared, both with the population from which it was drawn, and also Scotland as a whole. Thirdly the variables were used in the modelling to see how they were associated with the key variables.

Social deprivation and occupational level

The composite Scottish Indices of Multiple Deprivation (SIMD) score was used in the analysis (see Chapter 4.). This summary score is the combined sum of the weighted, exponentially transformed domain rank of the domain score (Social Disadvantage Research Centre, 2003). It is an ordinal scale and the bigger the SIMD score, the more deprived the ward. However, because of the exponential distribution, it is not possible to say, for example, that a ward with a score of 40 is twice as deprived as a ward with a score of 20. Available data for larger areas (e.g. Lothian or Scotland) were only available as means (Social Disadvantage Research Centre, 2003). Therefore, to allow comparisons between responders, and higher level areas the mean SIMD score was computed. No composite score for Scotland was available, but the average SIMD score in all the Local Authority Areas (n=32) ranged from 9.07 to 46.88 (mean 21.38).

Occupational level

To enable comparisons to be made on occupational between the sample, and Census data from the local area and Scotland, social classes 1.1 and 1.2 were collapsed into a single

category. The Census data included an 'unclassified' category (approximately 25% of the population) which was equivalent to the missing value/not answered category in the sample data. Data in these unclassified categories were excluded from the analysis.

Educational level

The categories used in the item relating to education level were directly comparable to those used in the 2001 Census, and thus comparisons were able to be made at both the local level and for Scotland as a whole. For modelling of the data, the categories were collapsed into three categories (no qualifications, school qualifications and post-school education). This categorisation was performed because categories 4 (other professional or technical qualification / diploma) and 5 (degree) may not be hierarchical.

4.36 Methods used in the analysis of sociodemographic data

The methods used in the analysis were similar for the three types of data. Table 13 outlines which data were available for the sample, the local area, and Scotland. Data on deprivation were available for all levels (using postcodes and 2001 Census data), but data on occupational and educational level were only available for the responders, and the general population.

Table 13. Sociodemographic data available for analysis

Type of socio demographic data	Total sample/non responders	Responders	Local area	Scotland
Deprivation score*	✓	✓	✓	✓
Age	✓	✓	Not applicable	Not applicable
Sex	✓	✓	✓	✓
Occupational level	x	✓	✓	✓
Educational level	x	✓	✓	✓

*from postcodes

Pearson's Chi-square was calculated for nominal variables (sex, educational level and occupational status), a t-test was calculated for normally distributed continuous variables (age) and a Mann Whitney test was performed for ordinal variables (e.g. social deprivation, educational level) and non-normally distributed variables. All hypothesis testing was two-tailed, and $p<0.05$ was considered significant.

4.37 Assessing non-response bias

The lower the response rate to a questionnaire, the greater the likelihood that those who responded are significantly different from non-responders and so the greater the risk of systematic bias (non-response error) in the results. Such error occurs if those people who do not take part in surveys are different from those who take part. To investigate the differences between responders and non-responders, comparisons were made for several key variables – previous screening history (last round), screening behaviour (current round), sex, age, and social deprivation score. Educational and occupational levels were not compared, as data on these variables were not available for non-responders.

Analysis was performed on the key sociodemographic variables (deprivation scores, educational level, sex[24] and occupational status) to determine how representative the responders were of the general population from which they were drawn, and also the Scottish population.

4.38 Methods used in analysing questionnaire results

The flow of the analysis was structured to reflect the key domains of informed choice outlined in Chapter 3. These were:

1. Degree of 'informedness' (knowledge of screening etc.)
2. Preferred or intended choice
3. Behaviour carried out
4. Barriers towards carrying out the choice.
5. Attitudes, values and beliefs (including degree of preferred involvement, degree of coercion or control, degree of choice and perceived availability of choice)

The following section outlines how the questions in the questionnaire were used in the analysis, using the cervical screening questionnaire as an example (see Appendix 10).

1. Degree of 'informedness' (knowledge)

A total knowledge score was calculated from 10 items contained within 4 questions *(questions 3 – 7)* designed to evaluate a person's knowledge of cancer and cancer screening. These questions included knowledge of the disease, what screening was for,

[24] For colorectal cancer screening only

results of screening tests, limitations, and consequences of screening. As discussed in Chapter 3, lay people and professionals may have different definitions of informed choice and the information required. The results of the qualitative study also found that people wanted information about the disease and results as much as information on the risks and limitations. Deciding which domain of information is most important in the decision to be screened is subjective. Therefore, all of the domains of information were assigned equal weight. Each item was given a score a one point if it was answered correctly. For symptoms and risk factors, a point was given if one or more risk factor was known. Therefore the highest total score for knowledge of cervical cancer and screening was 12 points. The knowledge score was used in the theoretical definition of informed choice, and as a dependent variable in the modelling.

Analysis was also performed on the whole set of items to determine whether they could be used as a valid and reliable scale measuring knowledge and understanding. The analysis was consistent with an approach used in developing a multi-item knowledge index for prostate screening (Radosevich et al, 2004). The approach concentrated on four psychometric dimensions - item difficulty, item discrimination, reliability, and validity.

Item difficulty was defined as the proportion of respondents who answered an item incorrectly, or one minus the proportion of correct responses. In this analysis, 'don't know' responses were treated as an incorrect response. The higher the score, the more difficult an item was to answer. According to Radosevich et al, items of moderate difficulty (approximately 50% correct response) add more to the reliability of an item. Item uncertainty was defined as the proportion of people answering 'don't know' and also the missing values. The greater the item uncertainty, the higher the confusion related to an item. Homogeneity of the items was also assessed. One of the most recognised methods for checking the homogeneity of the items is item-total correlation (Streiner and Norman 1995; 61) which is the correlation of the individual item with the scale total omitting that item. It is generally recommended that it should be greater than 0.5 to be retained in the scale.

Item discrimination was determined using two different approaches. Firstly a corrected item-total correlation was computed whereby each item was correlated with the total

score removing that item. Items with high discrimination (r>0.3) add more to the overall reliability of the test. The second approach was an index of discrimination. This index (D) compared the proportion of correct responses for those items with total scores in the upper 50^{th} versus lower 50^{th} percentiles. D-values greater than 0.4 (40%) are acceptable for discrimination, while those below 0.2 (20%) are inadequate (Radosevich et al, 2004).

2. Preferred or intended choice and 3. behaviour carried out

Intended choice was measured in the questionnaire using a single multiple choice question (question 8). Behaviour (uptake or non-uptake of screening) was determined from screening records. Analyses were performed to evaluate the relationship between intentions measured in the questionnaire and behaviour obtained through the providers of screening.

4. Barriers to the choice

One question asked about barriers to carrying out the choice (question 9). Analysis of barriers to the choice was also performed although this analysis was limited as the data set was very small and only collected for those people not intending to participate in screening.

5. Attitudes and beliefs

A set of items (question 11. all twenty statements) related to attitudes and beliefs about screening, degree of preferred involvement, degree of coercion or control, degree of choice and perceived availability of choice. All questions on opinions and beliefs were measured on a 5 point Likert scale from 'strongly agree' (1) to 'strongly disagree' (5). Where the items were heavily skewed, transformations, such as the natural log, were applied where they were able to reduce the skew, which was only possible for a few variables. If they were still heavily skewed, they were either removed from further analysis, or the original variables were dichotomised. The next section describes in detail how the psychometric properties of the items were established.

4.39 Establishing the psychometric properties of the attitudinal items

In analysing the data from this study, I was interested in identifying the underlying latent variables from the set of manifest items. That is, to reduce the attitude and belief items on the questionnaire (question 11. of the cervical questionnaire, all twenty statements) to a set of variables that specified the domains of informed choice. The aim of the analysis was to produce a simple structure; a pattern of results where each variable loaded highly on one and only one factor. Therefore exploratory factor analysis was the most appropriate method to use. Given the nature of the variables, I chose Principal Axis Factoring (PAF) rather than Maximum Likelihood because PAF has no distribution assumptions.

In factor analysis, the rotation of the variables[25] can be either oblique or orthogonal. Some statisticians argue in favour of oblique rotations rather than orthogonal solutions for these types of variables (Fabrigar et al, 1999). They contend that the dimensions of interest to psychologists are not often dimensions we would expect to be orthogonal. In addition, if the latent variables are correlated, then an oblique rotation will produce a better estimate of the true factors and a better simple structure than will an orthogonal rotation. If the oblique rotation indicates that the factors have close to zero correlations between one another, then the analyst can go ahead and conduct an orthogonal rotation (which should then give approximately the same solution as the oblique rotation). In an oblique rotation, discriminant validity is demonstrated if the correlation between factors is not so excessive (e.g. >0.85) as to lead one to think the two factors are conceptually equal. For the preliminary analysis, an oblique rotation was used.

The set of items was assessed for its factoring adequacy by visually inspecting the correlation matrix, and using the Kaiser-Meyer-Olkin (KMO) and the Bartlett's Test of Sphericity statistics. Measures of Sampling Adequacy (MSA) were inspected in an Anti-Image correlation matrix and any items with a value of <0.5 were excluded.
Once the factors had been defined, reliability analysis was performed and each of the factors was treated as a subscale. For scales which are used as research tools to compare

[25] A technique which makes items load more clearly onto one factor or another

groups, Cronbach's alpha values of 0.7 to 0.8 are regarded as satisfactory (Bland and Altman, 1997). Corrected item-total correlations were also calculated for each item within each scale. It is generally recommended that these correlations should be greater than 0.5 to be retained in the scale (SPSS, 1998; 182).

Creating factor scores

There are two main ways of combining the items from a scale into a single measure of that scale. One way is to use the factor scores that are calculated for each case. These are calculated by multiplying the original values by a set of weighting coefficients. The mean for the scores is 0 with a standard deviation of one. An alternative method is to pick the items with the highest loading and then compute a variable which is the sum or mean of the items. The most robust method is the former (using the factor scores) and this was the method used for this analysis. These factor scores were then used in the modelling of the data.

4.40 Defining and measuring informed choice

Two variables were used to measure the concept of informed choice, and used in the modelling of the data. The first was the participants' subjective/personal definition of informed choice (perceived informedness). Three items in the questionnaire asked about people's perceptions of informed choice. These items were:

- I feel I know the benefits of screening
- I feel I know the limitations of screening
- I feel I have made an informed choice

In the factor analysis (see section 4.39 and results in Chapter 6) these three questions represented a single factor of 'perceived informedness' for colorectal and cervical screening invitees and therefore the factor score was used in the modelling.

For breast screening invitees, the three items did not factor together. In addition for breast screening the item, 'I feel I have made an informed choice' was highly skewed with 90% of people either strongly agreeing (50%) or agreeing (40%) with the item. Transforming the data would not have corrected the distribution. Therefore, the data were dichotomised into strongly agreeing and not strongly agreeing. This dichotomising of the data has some validity, as some researchers have found that these two categories

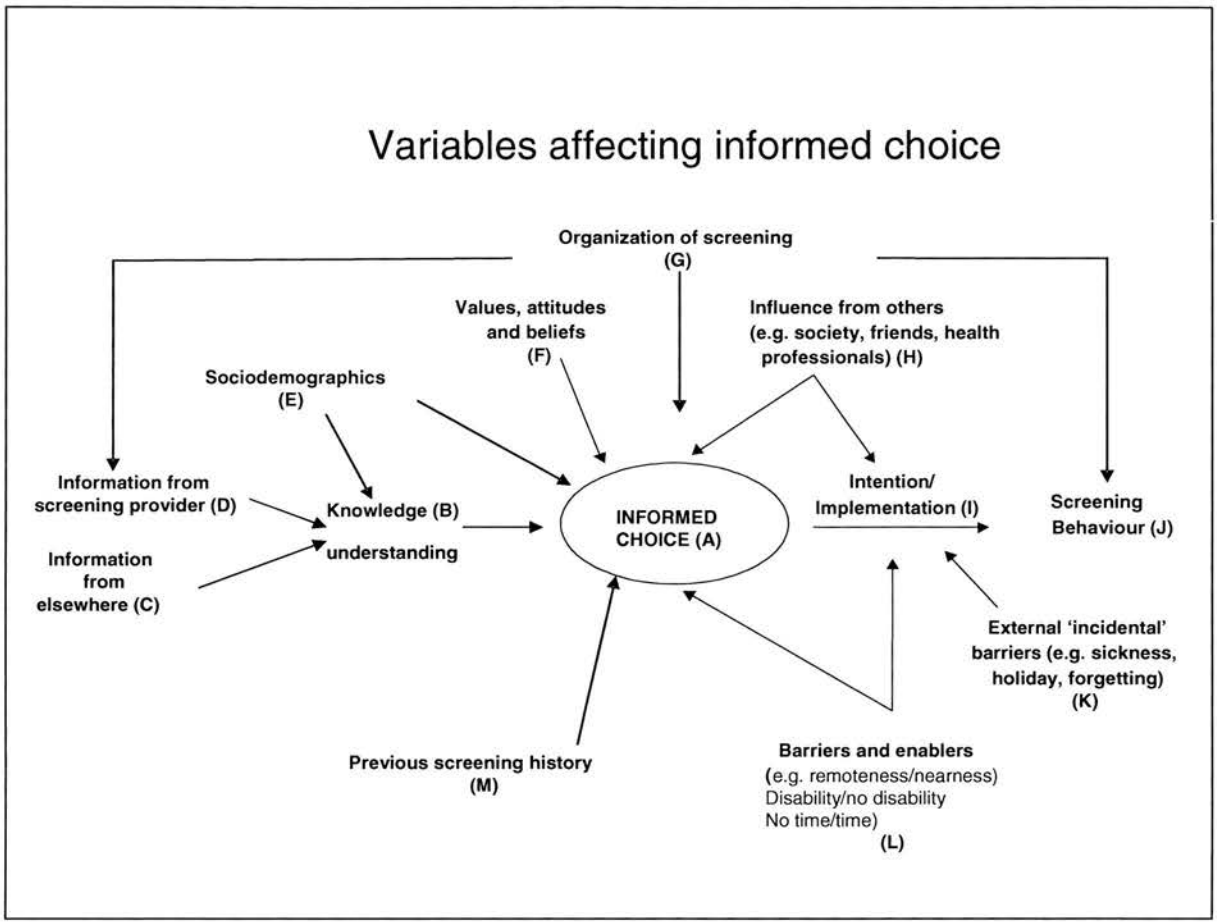
might mean something different (Collins and O'Cathain, 2003; Streiner and Norman, 1995). For example, Collins and O'Cathain found that for some participants, being satisfied with healthcare was described as care being adequate or average; for others it meant that there were aspects of healthcare that could be improved, or that something was missing and that optimal care was not achieved. It has also been used in other studies to overcome problems of highly skewed distributions (Bikker and Thompson, 2005; Jackson et al, 2001).

The second way of defining informed choice was by creating a variable which comprised the key conceptual domains of informed choice. I created this variable by drawing upon the theories of informed choice described in Chapter 2, the findings of the systematic reviews in Chapter 3, the results of the qualitative study described in Chapter 5 and the definition produced by myself and colleagues and used in the Cochrane review (Broclain et al, 2004). We defined informed choice in screening (not just cancer screening) as

'Being aware (from evidence-based, relevant and up-to-date information) of the potential benefits, uncertainties, physical risks, and psychological, moral, social and financial costs associated with the three key steps of any screening process: 1. of the screening test or its alternatives (no screening, primary prevention); 2. of undergoing additional confirmatory diagnostic test(s) when the screening test result is abnormal; 3. of the existing treatment options. In addition, potential participants in screening should have the opportunity to make an autonomous choice over whether to participate or not.'

Figure 4 outlines a proposed model of informed choice which I used in the theoretical definition of informed choice, and in the modelling of the data.

Figure 4. Proposed model of informed choice



For the purpose of this analysis, I defined informed choice as having:

1) knowledge of the disease being screened for (including symptoms and risks factors), the purposes of screening, the meaning of test results and some of the risks and limitations (B)

and

2) a belief that there is a choice to be made (B)

3) no coercion or pressure from others (H)

4) a belief that screening would be beneficial (F)

5) no barriers to prevent them carrying out their intended choice (L)

Variables which might affect or predict informed choice are previous screening history (M); organisation of screening (G); sociodemographics (E); information from the screening provider (D) or elsewhere (C) or external barriers (K). These variables were included where possible in the modelling of the data.

The operationalisation of the definition gave equal weight to both *informedness/knowledge* and *choice*. The variable consisted of two scores – the knowledge score (see section 4.38) and a choice score (see below). The total knowledge scores differed between the three different types of screening, so the scores were standardised. These two scores were multiplied together to give the final variable.

Four items contributed towards the *choice* score. Three of these were attitudinal questions asked on a five point Likert score, and one was the question on barriers. The four items were:

- I think that I would benefit from doing the test (score range 1-5)
- I feel pressure from others to do the test (score range 1-5)
- I feel there is a choice (to do the test or not) (score range 1-5)
- Barriers of access and illness were also included as dummy variables (1 = no barrier, 0=barrier).

The scores from the three access questions (1-5), plus the score for the two barriers (0-2) were added, giving an overall 'choice' score which had a possible range of 3-17. A low score indicated that there was little or no choice, whilst a high score indicated that the person had a high degree of choice.

Standardised scores were calculated for both the knowledge scores and the choice scores to enable comparison between the three types of screening and to ensure that equal weight was given to both scores. The formula used to create standardised scores was: z = (total score for individual – mean score of the total sample)/standard deviation for the total sample

The final composite variable of informed choice was calculated by multiplying the standard scores of knowledge and choice. However, the problem with composite variables is that it can be difficult to interpret the middle scores. Very low scores indicate that a person is neither well informed nor able to make an autonomous choice. A very high score indicates that a person is able to make a knowledgeable, autonomous choice. However, people in the middle may score high on knowledge but low on choice and vice versa. I therefore also collapsed the variable into four categories using quartiles. The lowest quartile included people who had low levels of informedness and choice; the highest quartile included people who had high levels of informedness and choice. The two middle quartiles were a mixture of people who could have high knowledge and low choice or vice versa. This categorisation enabled me to do analyses comparing people in the lowest quartile with those in the highest quartile. I defined the lowest quartile as a 'low choice/low knowledge' and the highest as 'informed choice' (high choice/high knowledge).

4.41 Modelling the data

Modelling was undertaken to understand the predictive nature of variables once other variables had been controlled for. One of the main aims of this analysis was to evaluate the relationship between informedness and choice, and the predictors of informed choice. A secondary aim was to understand which variables predict outcomes such as behaviour, intentions, and high levels of knowledge.

Analyses performed

Regression techniques were used to model the data. For binary outcomes (e.g. screening behaviour), logistic regression rather than discriminant analysis was the preferred analytical technique because it does not rely on strict assumptions of normality, linearity and lack of collinearity of the independent variables. Linear regression was used to model the interval data (e.g. knowledge scores).

In linear regression analysis, independent variables are assumed to be interval or ratio. Several of the sociodemographic items (social deprivation score, educational level and

occupational level, pre-screening history, intentions) were either ordinal or categorical variables. Therefore, these variables were transformed into dummy variables. For ease of interpretation, the high deprivation scores (indicating the most deprived area), the lowest educational level (no education), and lowest occupational classification (level 7) were used as the reference categories.

A theoretical approach was taken when deciding the method and order of entering variables, particularly the sociodemographic variables and previous screening history. Extensive research suggests that such variables have an effect on uptake of screening and knowledge (e.g. (Goel et al, 1996; Jepson et al, 2000; Nijs et al, 2000; Orbell, 1996; Orbell et al, 1996; Sutton et al, 1994; UK evaluation team, 2004). Removing the influence of such variables enables a researcher to focus on the extra explanatory contribution of other variables (e.g. such as knowledge) (de Vaus, 2002). Therefore, for the analyses of predictors of uptake and knowledge, I used hierarchical methods and entered these variables first.

Data assumptions

One of the assumptions of multiple regression is that the predictor (independent) variables are not correlated. Multi-collinearity occurs when one predictor variable is a linear function of the others. The variables were tested for multi-collinearity using the variance-inflator factor (VIF). This tests for the proportion of variance in a variable unaccounted for by other variables. The greater the value of VIF, the more the variance is inflated by its relationship to other variables (SPSS, 1998). Variables with high VIF values (>2) were removed from the analysis.

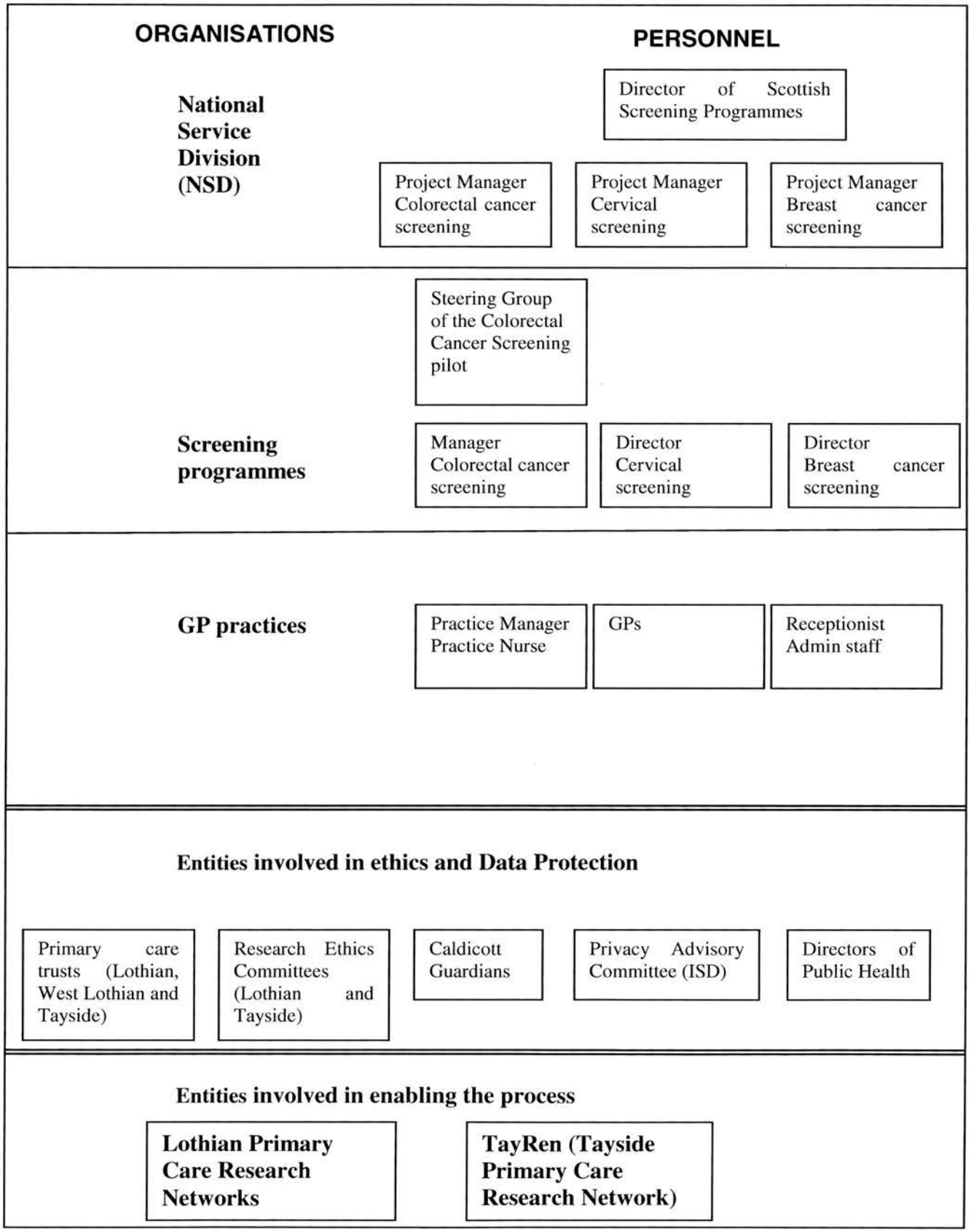
SECTION 3. THE SETTING AND CONTEXT OF BOTH STUDIES

This section outlines the complex setting for both of the studies. It includes a discussion of the different organisations I had to contact and liaise with as well as the problems with obtaining the different samples, and acquiring ethical approval.

The process of gaining permission to obtain a sample of patients for the focus groups proved very difficult. In particular it was difficult to understand how different bodies such as the Ethics Committees, National Services Division (NSD)[26], the Privacy Advisory Committee (PAC), Primary Care Research Networks, the Caldicott Guardians, and the Primary Care Trusts worked together, and which ones I needed to seek approval from first. Figure 5 outlines the organisations, entities, and personnel that we had to liaise with. Multiple ethical applications or approvals were required from the different organisations.

[26] National Services Division (NSD) has responsibility for ensuring the provision of both national screening programmes and specialist services on behalf of NHSScotland.

Figure 5. Organisations, entities and personnel approached in the study



4.42 The process of gaining approval for the qualitative study

The first discussions about selecting and recruiting the samples took place in September 2001 (see Appendix 5). Originally we had envisaged recruiting via GP practices, but the programme manager for the Colorectal Screening pilot said that the Information and Statistics Division (ISD) could provide us with a sample of patients for the focus groups. However, this would mean obtaining approval from the Caldicott Guardians and Directors of Public Health. In January 2002 my supervisor (Professor David Weller) and I met the Director of Scottish Screening Programmes to discuss this issue further and she agreed that we should go through ISD. We had several further meetings to discuss how this would happen and whom we would need to get approval from. Several of these meetings were postponed and rearranged so the delays increased.

The final strategy proposed by the Director of Scottish Screening Programmes (after discussions with the members of the Privacy Advisory Committee) was to generate a list of relevant people from the Scottish Morbidity Records (SMRs). This would include people with false positive, true negative and true positive results as well as those that did not attend. A sample of people with a false negative result could not be obtained due to issues of confidentiality. The data, which would be requested, included an individual's Community Health Index (CHI) number and the name of their GP.

Although the Lothian Research Ethics Committee granted ethical approval for this strategy in July 2002, the Privacy Advisory Committee (ISD)[27] turned down our application for access to medical information in September 2002. In October 2002, David Weller and I met with the chair of the Privacy Advisory Committee (PAC) and the Project Manager, Screening Programmes to discuss why it had been rejected. They had concerns about releasing information such as CHIs to researchers and advised us that the best way forward was to go through the screening programmes. We then had to

[27] The Privacy Advisory Committee (PAC) is an independent body, which provides advice on requests for the release of patient identifiable information by Information Services (ISD). ISD is a division of 'National Services Scotland' (formerly the Common Services Agency) within NHS Scotland and is the principal source for health services information in Scotland.

start again with redefining both our sample and recruitment process and lengthy delays ensued.

Following this meeting, David Weller and I met with two Project Managers at ISD and agreed a new recruitment process. However, for colorectal cancer screening we needed to gain approval of the Steering Group of the Colorectal Cancer Screening pilot project. This was obtained shortly after this meeting. We also met with the Director of the Cervical Programme and the Breast Screening Programme. They also agreed that they could obtain a sample, but that the process of recruitment (i.e. sending out the invitations) would have to be done by GP practices. The next step was to identify suitable GP practices. The organisations that eventually helped me were the Primary Care Research Networks (Lothian and TayRen).

One of the main difficulties I faced with setting up this project was trying to understand the relationships between all the different organisations and ethical and regulatory bodies. We were confused about whom we had to get permission from and at which level (policy, management or practice). Indeed we ended up having to get permission at all three levels and also from the regulatory bodies at each of these levels. For example, we had to get permission of Primary Care Trusts to undertake work at a practice level.

The impact of the Data Protection Act

The Data Protection Act of 1998 imposes a range of new conditions that must be satisfied before medical information may be collected, stored, or disclosed to others (Boyd, 2003). Its impact on medical research is particularly strong. The way that the organisations and regulatory bodies interpreted the Data Protection Act may have had some impact on the delays encountered in this study. My knowledge of the Data Protection Act at the beginning of the study was very limited. For example I did not know that I was unable to have any direct contact with NHS patients. The limitations imposed upon me as a researcher, as a result of the Data Protection Act meant that I needed to gain approval on several organisational levels, and involve general practice staff to a much greater level than originally anticipated. This was very time consuming. Such delays have been also encountered by other researchers (Redsell and Cheater,

2001) who assert that requirements for researchers to use "intermediaries" (to obtain consent from and recruit participants to studies) increases the risk of selection bias, may expose the practitioner to ethical difficulties, and may compromise the external validity of trial results. They also assert that research costs may soar when the Data Protection Act (1998) is fully realised.

Factors which caused delays

Several other factors resulted in unforeseen delays. For example, I had time delays in getting lists and responses from the screening units (breast and colorectal). Initially the breast-screening unit sent out lists of GPs which were for the wrong year (2001 instead of 2002). I then had to wait several weeks before being sent the relevant ones. Once I had identified and got agreement of GPs to participate, I had to wait again before the lists of patients were sent from the screening unit to the GPs. It is understandable as they are busy screening units and my research was not a priority for them. However, it highlighted the different and competing priorities of organisations involved in the delivery of screening, and researchers involved in evaluating or researching screening.

I think that one major setback which I had not anticipated at the start of the project was that I was not able to contact people directly. This meant that all contact and sending out of letters had to be done by a third party. This created both extra work for people who were already overstretched and it also made me feel that I was not fully able to engage in my research. It also made me feel uncomfortable about asking other (very busy) people to do tasks on my behalf. Many of the ideals I had for a 'perfect' sample could not be realised because of practicalities of involving other people with very different priorities. This is not a criticism of the practices and screening programmes who did participate as it was their goodwill which enabled this project to progress.

Factors which helped the process

The factors I think influenced people's participation were the initial letter from the research networks, and the financial reimbursement for both practices and participants (see section 4.24). In addition, the Primary Care Research Network also allowed me to present at one of their meetings. One of the GPs whom we had contacted actually attended the meeting and was very interested in the subject area. She already had the

research on the agenda to discuss at the next practice meeting, and a few days later wrote to say that they would participate.

Following the practices' agreement to participate, I worked hard at establishing a relationship with a named person in the practice (usually the Practice Manager) and liaised with them to make the process as uncomplicated and as easy as possible. In several instances, I went out to the practices to visit.

Overall, the process involved in recruiting for both studies was far more complex and difficult that I had originally anticipated.

4.43 Summary

In this Chapter I have outlined the methods used in the qualitative and quantitative studies, and described the difficulties I encountered in using these methods. Chapter 5 reports on the analysis of the qualitative data, and Chapter 6 describes the analysis of the quantitative data.

CHAPTER 5. QUALITATIVE STUDY RESULTS

Chapter 4 described the methodology for selecting participants and running the focus groups and individual interviews. The following sections outline the main themes that emerged from the data. These themes were then used to develop both the key dimensions and the specific items for the MICICS questionnaire.

5.1 Results

Both men and women were interviewed, as well as those with different experiences of screening (normal, abnormal results and non-participation). People came from a wide range of socio-economic and socio-demographic backgrounds, and were aged between 20 and 65. Appendix 11 provides a brief description of the people who participated in the study.

A total of 180 people were invited through GP practices using a purposive sampling strategy (see Chapter 4). Of those invited 54 people took part [28] and 14 people were recruited from other sources (giving a total of 68 participants). Of these, 18 had been invited for bowel cancer screening, 19 had been invited for breast screening, and 31 had been invited for cervical screening. In the most recent round of screening, 30 had had an abnormal result, 28 had had a normal result, and 10 had not attended.

Nine focus groups and 15 one-to-one interviews were undertaken between June and December 2003. In addition to the focus groups and interviews, those people returning the 'informed choice' questionnaire were asked to comment on various issues (for example, reasons for not taking part in screening). Although these comments do not form a major part of this study, I coded them and analysed them in a similar way to the qualitative study. Where appropriate I have included their comments in the results.

After each quotation, I have included details of the pseudonym of the person, type of screening (e.g. cervical screening), and whether the person took part in a focus group

[28] I received around 66 replies but 12 people could not be interviewed (because of holidays or other commitments) or did not attend the focus groups.

(FG) or individual interview (I). If the comment was from a questionnaire, I have noted this fact in the text and included details of the age and sex of the person.

5.2 Themes identified from the qualitative data

The order of the themes relates to the questions I asked in the interviews or focus groups (Appendix 7) and also the information I presented (Appendix 8). I began with general questions about screening and their experiences of screening, and then asked people what they knew about the disease or screening. I then showed them the prompts, and asked for their thoughts on the information I had presented. Finally, I asked which pieces of information they thought were most important, or might affect their decision to be screened or not. During these conversations I also asked about how they made their choices, how important they were and their attitudes and beliefs about screening. Table 13 shows the main themes that arose from the data.

Table 14. Themes identified in the qualitative data

Theme	Sub-themes
Provision of information about the disease and screening	Information in leaflets and letters
	Information from other sources (e.g. media)
Current understanding and information important for decision making	Symptoms
	Incidence
	Risk factors
	Consequences/ limitations
Role of the information in people's decision making	Use of the information
	Presentation of the information
Choices and informed choice	
Degree of coercion and control	
People participating in screening	Attitudes and beliefs
People not participating in screening	Attitudes and beliefs
	The process
The experience of being screened	
Lifecycle and gender	

5.3 Provision of information about cancer and screening

At the time of undertaking the study, breast and colorectal screening invitees were sent an information leaflet with their invitations. For cervical screening in Lothian[29], GP practices were provided with a set of guidelines, which outline the expected format of the letters. There was also a leaflet, produced by NHS Lothian, which was meant to be included with the screening invitations and was available to all GPs on request. However, it was difficult to assess whether letters from GPs were meeting recommended guidelines and whether women routinely received the leaflets.

Generally, people invited for breast and colorectal screening remembered having received a leaflet and an invitation letter. In contrast, only a minority of women invited for cervical screening reported getting or seeing an information leaflet (these were mainly young women). Most women reported that all they received was a letter telling them that it was time for their smear. As one woman commented,

'I don't remember there being much information in it [the letter] beyond, 'It's time for your, you know, your next smear and please phone us and make an appointment.' But there wasn't any more information in it than that, I don't think.' (Julie, Cervical Screening FG)

Although provision of information was generally poor for cervical screening invitees at the time of their invitation, several women reported that the provision of information was good if they had to attend for further investigations for abnormal smears. Although health professionals did not appear to be primary providers of information on cervical screening, several women thought that they should be.

'Well, you can't assume that people get their information from other sources. I think that the onus is on the GP to give you the information you need.' (Mary, Cervical Screening FG)

Women not only wanted information about cervical cancer and cervical screening, they also saw it largely as the responsibility of the GP (or the provider of the service) to make it available.

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[29] Lothian differs from other Health Boards in Scotland in that it does not operate the call-recall system centrally but instead GPs send out the invitations

Many people (particularly women) talked about finding out information from the media (e.g. television, newspapers, and magazines) rather than from health professionals. For breast screening invitees in particular, information about breast cancer and breast screening was obtained primarily from the media (magazines and television) and friends. Participants in all groups also mentioned soap operas as a way in which issues surrounding cancer were raised, and information was provided.

'I think you will always find that whenever there's an article appears in a magazine or in newspapers or there's been something shown in one of the soaps that highlights it there's always usually a number or some way in which you can find out more information there's usually always someone saying something if you want to know more about this and there's a number.' (Lily, Breast screening FG)

In the colorectal screening groups, several people reported that the media was primarily used for promotional campaigns announcing the existence of the screening programme, rather than giving information on the disease.

'It was advertised on the local news and the national news an' all.' (Jim, Colorectal screening FG)

For colorectal participants the main source of information about the screening process and colorectal cancer was from the information leaflets sent out with their test, or in the notification slips. Most people said they knew little about colorectal cancer before receiving their information to be screened.

Cervical screening invitees were not well informed by the providers of screening and did not report getting information on cervical cancer and screening from the media to the same extent that breast screening invitees did.

5.4 Current understanding and information important for decision making

Symptoms: current understanding and information wanted

One of the limitations of screening is that people who have had a normal result may not visit their doctor if they have symptoms. When women are notified of their result of cervical screening, the slip does mention that women should consult their doctor if they

have symptoms. However, it does not state what the symptoms are. For colorectal and breast cancer screening, symptoms are described in the notification slips.

The majority of women had no knowledge of the symptoms of cervical cancer. This was in contrast to breast cancer screening, when most women were aware of symptoms such as lumps. In addition, several participants in the colorectal cancer focus groups were able to list at least one symptom. However, in all of the focus groups, people identified lack of knowledge of symptoms as an issue. For example, they were concerned that, if they did not know what the symptoms were, they might not know when to consult a doctor.

' .. how do you know that you are not just having breakthrough bleeding or not? Or something like that but if you don't know what the symptoms are how do you know what to look for? How can you raise your suspicions with your doctor if you don't know what you've to be suspicious about?' (Helen, Cervical Screening FG)

This opinion was echoed by another woman, Madge, when she spoke about symptoms for bowel cancer (her husband was diagnosed with bowel cancer through the colorectal screening programme):

'I'm saying my husband had no symptoms but really to be honest I wasn't sure what the symptoms were for it. I mean everybody knows mammograms and smear tests, and things like bowel cancer are not so widely…' (Madge, Colorectal Screening FG)

The large majority of people wanted information on symptoms, and it was not viewed as being controversial. However, one woman called Michelle did have some concerns that it might cause additional anxiety in cervical screening. When asked about the information she said,

'.. my understanding is the sort of symptoms aren't great, they are not specific to cervical cancer and if they are, they are usually at quite a late stage so rather than panicking somebody because they have had bleeding between a period thinking, 'oh my god it must be cervical cancer because they said in that leaflet.' (Michelle, Cervical Screening I)

When asked about the effect of symptom information on screening decisions, no-one thought that this information would affect their decision to be screened, and most said that they would go to the doctor if they had symptoms. The majority wanted this information to be included in information materials. In addition to this information being important to those people who get a normal result, it could be argued that this might be

one of the most important pieces of information for people to know if they decide not to be screened.

Understanding of how common the cancer is: current understanding and information wanted

Knowledge of the incidence of the cancers varied both within and between focus groups. For example, some thought cervical cancer was rare, others thought it was common. One woman put the incidence at 1 in 200, another put it at 1 in 3. A young woman called Kylie questioned why women might think that cervical screening was more common than it was:

'But do you think that is because you do go for, you know you're sent for screening regularly so you think it's more common than it actually is?' (Kylie, Cervical Screening FG)

Proactively inviting people to be screened through screening programmes, combined with media representation of cervical cancers, could contribute to women's overestimation of the incidence and prevalence of the disease. In addition, the high level of abnormal cytology could also result in an overestimation of its incidence. It has been asserted that the lifetime risk of having abnormal cytology detected could be as high as 40% for women born since 1960 (Raffle et al, 2003).

Some women also overestimated the risk of breast cancer, but overall, more women than those in the cervical groups knew how common it was (i.e. a 1 in 9 chance of developing breast cancer over the course of a woman's life). For colorectal cancer, many people were surprised when I said that the lifetime risk was one in 25. However, as for cervical cancer, some thought it would be higher, others lower.

The information I gave people about incidence caused much discussion and conflicting views, particularly about whether it should be included in information materials. These conflicting views seemed to be particularly noticeable when interviewing women about cervical cancer. Some people were worried that telling people it was a relatively uncommon cancer might put people off attending. For example, Hilary thought that the information might put people off:

'I think that's maybe a good thing to point out [risks of disease] but obviously that's going make women think 'well I don't think I really need to get this done.' But then you kind of think 'well that could be a dangerous thing but how could it be if the risks are low'.' (Hilary, Cervical Screening I)

However, a young single mother called Coral who had never gone for screening said she would be more likely to go, because she thought the risks were low. When asked if the information would make her more or less likely to go she replied,

'More, more I suppose aye definitely seeing that it's only 1 out of 4000 women[30].' (Coral, Cervical Screening I)

Thus, it appeared that Coral might go because the risk of disease was low, and she thought that she would be likely to get a normal result. In later sections, I will discuss why people go for screening. It is likely that some go to find out whether they have the cancer or not, whereas others go to get the reassurance of a negative result. If the incidence is low they are more likely to get that reassurance.

Risk factors: current understanding and information wanted

Most people had a limited understanding of the risk factors for the different types of cancer. However, particular risk factors were more widely known than others. Smoking was commonly cited as a risk factor for breast cancer, along with family history. Diet was the most commonly cited risk factor for colorectal cancer. The most commonly cited risk factors for cervical cancer were 'risk taking' behaviours such as the number of sexual partners and smoking. None of the women had heard of Human Papilloma Virus (HPV), even though certain types are now linked to around 95% of cases of cervical cancer.

People generally wanted information on risk factors; it was seen as being of interest and adding to the general context of screening. However, similar to the information on incidence, it was also perceived as being information that might affect people's choices to be screened. The way that it would either encourage or discourage people to participate was widely debated. It was perceived that it could put off both those people at

[30] Probability of a woman under 30 dying from the disease each year.

low risk, and also those people at high risk. This line of reasoning was summed up by Michelle, who said,

'I think it might put, I think the second one [about the risk factors] might put people off, women off, maybe women like me who see themselves as low risk and then the women who might get really frightened and say, 'oh God I smoke and I shag lots' you know and feel like a guilt like, 'I've not been a good girl so I am not going to show myself up.' (Michelle, Cervical Screening I)

In this example, it is interesting to note the use of words and phrases such as 'guilt' and 'not being a good girl.' In Chapter 2 I discussed issues around morality and risk within the health promotion setting (2.8 and 2.9), in particular the notion that those who are 'at risk' become the sinners (Lupton, 1995;90). Michelle reasoned that if a person has been undertaking risk taking behaviours she will feel guilt if she goes for screening and is found to have cervical cancer. This may be an issue particularly for cervical screening, as several of the risk factors relate to sexual behaviour.

In the colorectal screening focus groups, some people also mentioned the effects the risk factor information might have on modifying health-related behaviours. Jenny commented,

'I think diet-wise. For instance people who don't eat a lot of vegetables and that might have thought, 'Well maybe I should start eating more of that and less red meat or whatever'.' (Jenny, Colorectal FG)

Similar to information on symptoms, this information might be particularly useful for those people who do not want to participate in screening, yet wish to prevent getting the disease. Finally, for a few participants the information on risk factors created anxiety. For example, Leone commented,

'See it's quite scary when you say that if you take the pill it increases your chances of developing cervical cancer. And if you smoke and take the pill you double your chances. Again, so that's scary.' (Leone, Cervical Screening FG)

Similar to the information on incidence, this information was perceived to have the potential to both increase anxiety and affect people's screening choices. However, it was seen as important contextual information.

Reliability and limitations of screening: current understanding and information wanted

The majority of people did not know anything about the inherent limitations of screening. In several focus groups and interviews people said that they had no idea that there were risks associated with screening until I had contacted them with information about the study. For example, Annabel said,

'I mean I never knew there was a down side to going for breast screening. That's come as a surprise to me.' (Annabel, Breast Screening FG)

This comment was in contrast to others who described 'scare' stories in the press, and were aware that there were limitations of screening. However, most people attributed these limitations to individual incidents involving doctors or laboratories, rather than to inherent limitations of the screening programmes.

Many women who had participated in cervical screening had either had an abnormal smear, or knew some one who had had one. However, most did not know how common it was to have an abnormal smear, or what it meant. This lack of information meant that many of the participants had stories about the anxiety and fear they had felt following an abnormal result.

Some people saw it as a personal failing that they did not know or ask about the limitations of screening. Hilary commented,

'I didn't know that [when shown information about screening not identifying 100% of all cancers]. I was so stupid, I thought that if you had cancer it would definitely have picked it up.' (Hilary, Cervical I)

People generally viewed information on reliability and limitations to be very important. Although a few people said it might affect the decision to be screened, the main reason for wanting the information was to reduce the anxiety attached to either waiting for a result, or receiving a result that was either unsatisfactory[31] or abnormal.
Similar to the information on symptoms it was seen as important, but wouldn't affect their decision to be screened.

[31] This study was conducted before liquid-based cytology was used as the primary method of processing samples. The number of unsatisfactory results is reduced using this method.

Participants spent a large amount of time talking about the anxiety and fear they felt about the whole screening process, from receiving the invitation through to receiving the result and any further investigations they received. For example, Anita who had had a traumatic experience because of several unsatisfactory and abnormal smears said,

'I think it would have helped six years ago you know looking at something just like [the slide may have broken] you know just something as simple as that and you think 'well fair enough' that was the first one. Or 'maybe it wasn't done prepared properly' and you think that's the second one but I think if I had something like that I'm not saying I wouldn't have got upset. I probably would have still got upset, but if I had something to read like that it may have helped because I could have probably would have referred to it you know. ..' (Anita, Cervical I)

Again, the reason for wanting this information was not to help Anita make the decision whether to go or not but to reduce anxiety when she got a result which was abnormal.

Other information

Although I asked people what other information they might like, people generally did not have much more they wished to add. However, George said,

'In my case it was simply something that wasn't mentioned in the preliminary information. I've got desperate piles.... so I wrote back to them and said, 'it won't be a lot of use, will it, because they'll get more blood than anything else in samples.' Hospital X were really efficient. They rang back, it must have been the day they got the letter. It doesn't matter, it's degraded blood, go ahead, and they sent me another test which I did. Hospital X were brilliant.' (George, Colorectal FG)

George felt confident enough to ring the screening unit to ask for confirmation. However, there may be other people with similar problems who do not do the tests because of problems such as haemorrhoids. From the comments in the questionnaires, several people said that they did not take part because they had inflammatory bowel disease. The current information leaflets do not give guidance on what to do if a person has other related illnesses such as those mentioned above.

In summary, knowledge of the disease varied between the different types of screening, but few people in any of the groups were aware of many of the risks and consequences of screening.

5.5 Role of the information in people's decision making

A major theme to emerge was the role of information in decision making. For those who thought that screening was a good idea, the majority said that the information given to them would not affect their decision. Equally, those who were put off by the process said that the information would have little impact on their future decisions. Pam, who would not go for breast screening because of the process, likened it to other health behaviours such as smoking:

'.. it wouldnae matter what information. You see it's like smoking. All the information on smoking and I still smoke. Ken, although the big prints on the packet and all that I mean I know a lot of people are giving it up, blah, blah, blah, blah but, I've never wanted to, and you've really got to want to.' (Pam, Cervical I)

However, information did have an effect on some women's decisions. When the single mother Coral who hadn't gone was asked whether the information (on incidence) I had given her would make her more or less likely to go she replied,

'I think that would make me more likely to go. Ken on my luck I would be the one.' (Coral, Cervical Screening I)

As mentioned previously, however, the provision of information was perceived to play an important role in people's experiences of screening, especially in interpretation of results, and the consequences of screening. It was also perceived to be important in decisions about whether to visit the doctor for symptoms. However, not everyone thought that information was necessary to make their choice,

'I don't know that I want to know any of these things. I'm quite happy just to go along and have my smear, but maybe umm ..and not know the risks and the odds or anything like which would just confuse me and there would be more decision making to make in my life and there's plenty of that already. The option is to just go.' (Anna, Cervical Screening FG)

Here Anna reasoned that she was happy to opt out of the decision making and go with what health professionals thought was best for her. This woman was happy to make an uninformed choice, and possibly did not perceive that a choice existed.

Although some people may not read information, many felt it was important to be given it. For example, Sally saw information as being a right,

'I think people have to have information. I think it's their right to have it. It's their responsibility whether they do anything about it but I think if the information is there, for the medical staff to say 'we're not telling you in case it scares you' I think is wrong. I don't think that's appropriate.' (Sally, Cervical Screening FG)

In this quote, Sally separated the responsibilities of health professionals from those of individuals. She felt it was the health professionals' responsibility to provide the information and the individual's responsibility to make the choice.

Ways of presenting information

Some people felt other people's experiences (e.g. family, friends, celebrities and soap opera characters) made the information more salient.

There's a book of many persons, some of whom I didn't even know had had breast cancer and they had written articles about their own individual experience of having the, the cancers. And I think that em, when it's at, you know, in media, general sort of ..... I think that can be more helpful. People can then relate to an individual. (Wendy, Breast screening FG)

Personal stories are thought to help people making decisions to identify what different potential outcomes 'might be like for me.' That is, to take the general information provided by scientific facts and apply it to their own case; to help make the 'imaginative leap' from risk to experience. It has been argued that facts rarely speak for themselves and never in isolation (Gabriel, 2005). Narratives and stories can enable people to make sense of facts, and to identify their significance.

In the course of data collection, an article was published which presented data in two alternative decision aid formats. These alternative formats illustrate visually the outcomes for 100 women choosing each alternative: breast screening or no breast screening (Marshall and Adab, 2003) (see Appendix 12). I decided to use this visual way of presenting information in the last two breast focus groups I ran (in addition to the other information). In the first focus group, people commented on the information used, and the way of presenting it. In the second group, the use of 'smiley' faces was more of an issue. They provoked strong reaction in Wendy, a retired teacher, who asked me if a male had designed the decision aid (I replied affirmatively). She then said,

'Well that's not a surprise.'

I asked her why.

Well it's insulting to women, because it's.... smiley faces is what they use for children and children's words indicate their pain. You know, how many smiley faces or what or you know the grumpy faces. ...It's juvenile. It's very juvenile. What's the implication? You're saying we're so thick that we don't understand words? (Wendy, Breast Screening FG)

However, Annabel disagreed with her and said,

' I quite like the way it is presented cause you can see it at a glance and it doesn't take you too long.... I've got diabetes, and sometimes my head gets.... It's all the information. You know it's sometimes you can't always, take it all in, but when I look at that I can see it more clearer.' (Annabel, Breast Screening FG)

This was a very small sample of women, but even within one or two focus groups it became clear, that presentation of information may be as important as the information itself. It was not the aim of the thesis to look at ways of presenting information, but as discussed in Chapter 2 there is a significant body of work in this area.

5.6 Choices and informed choice

Both before and after giving people information, I asked whether people felt they had made an informed choice to participate in screening or not. The majority of people did not feel that they had. In addition, some people had difficulty in viewing screening or not as a choice. This theme was brought up in the first focus group when Brenda said,

'So it's not really a choice.... it's like, do you want to know or not whether you've got cancer, 'oh well NO please'.' (Brenda, Cervical Screening FG)

This viewpoint was echoed in a colorectal screening group when Neil commented,

'Real informed choice would be if you invited us to choose what sort of test we wanted to go for. You'd have to give us a list of all the possible tests you can go for or any of them. To a certain extent choice is a bit of a con here to a certain extent. You're not being actually given a choice at all. The choice is simply 'do you want to do this or not'.' (Neil, Colorectal FG)

Others in the focus group disagreed with him about this. They felt happy with the idea of seeing participation (or not) in screening as a choice. Later on in the focus group Neil raised another issue about the choice. He said,

'I would say I was not very well informed but it seemed something I was happy to do, but I wouldn't say it was an informed choice. It was a choice that didn't seem to contain much threat or danger or anxiety about it but I wouldn't say I was very informed.' (Neil, Colorectal FG)

Thus Neil differentiated between different types of choices; ones which were potentially dangerous and ones that weren't. He didn't see this choice as being a particularly important choice compared to others faced in daily life. What was evident in several of the interviews and focus groups was that, for many people, screening was not a choice in the same sense as deciding between different treatment options for a specific condition. When asked about other decisions, people often talked about wanting a lot of information. Anita was talking about discussing alternative treatments for back problems and how she wanted a lot of information,

'Yes I mean I ask for information about backs .. I did go and see the doctor about that because I was worried about how I was not so much feeling but how I acted occasionally you know and I did go and speak to him and I said 'I don't want to go on medication' So although I asked the questions I think, this is going to be a contradiction, but I think I know myself what I need to be doing for myself but that contradicts having said, you know you go for your smear and you don't ask a damn question.' (Anita, Cervical Screening I)

Mothers also talked about wanting a lot of information before they took their children for immunisations. Yet none said that they had ever asked for similar amounts of information about cervical smears. For those who participated (particularly in cervical screening) it was viewed to a large extent as normative behaviour which didn't require any information. To some extent this view is reinforced by the letters sent out by GPs. As Leone said,

'You get, I think you just get a standard letter don't you, saying like 'your doctor requires it.' It's not like an invitation; it's more like you're being told really.' (Leone, Cervical Screening FG)

When I asked people about whether it was a big decision to participate or not, people differed in their responses and there was no consistent pattern in breast and colorectal screening. However, many women invited for a cervical smear said that it was not a big decision to go. Many said they never even thought about it,

'I don't [think about it], just every three years it comes round and I go so it's not a thought process.' (Anita, Cervical Screening I)

However, for a few people it was a big decision. For example, Shelly commented,

'Well it was a big decision at the time because I put it off for a while, for a few years and then I took it upon myself so it was a big decision.' (Shelly, Cervical I)

Many people said that it wasn't a big decision whether to go or not, but that once they had made the decision to go they needed to overcome their fear or dislike of the process. When I asked them if they would like to talk the decision over with their doctor or nurse, the majority of people did not want to consult with a health professional about the decision or even get more information from them. They were happy with making the decision themselves. However, several people commented that if they had an abnormal result they would like to discuss this with their doctor.

5.7 Degree of coercion or control

Generally, feeling coerced was not a major issue for people invited for breast and colorectal screening. As people received invitations at home, most saw it as their choice whether they went or not. Even those people who did not participate felt that the choice was respected. When discussing the reaction of her GP to the knowledge that she was not going to have a mammogram, Pam said,

'Oh aye he knew that I didnae go for mammograms, that was why I asked him one time when I was getting my smear, would he examine my breast. No problem.' (Pam, Breast Screening I)

In both these types of screening, the invitation comes from a screening Unit, and the person has little contact with a GP or primary care professional. However, some women invited for cervical screening did feel coerced by their GP, or obliged to behave in a certain way. Several women commented in the questionnaire that they felt pressurised into participating.[32] For some the pressure was viewed as friendly or benign,

'I feel pressure by surgery staff to have one (but in a nice way!).' (Cervical, F28)

whilst another woman felt that the pressure was more coercive,

'I feel well informed but quite pressured to go for a smear although I dread the results afterwards.' (Cervical, F38)

[32] Only women invited for smears commented on feeling pressured. This topic did not arise for breast and colorectal screening

Some women even appeared to feel quite harassed and used the questionnaire as a way of expressing their views to the health professionals,

'Please stop asking me to come in for a smear thanks' (Cervical, F38)

Sarah felt that she had to go for her smear otherwise she would be viewed as a 'bad patient',

'Because it's so routine it's like you're expected just to trundle along and be part of the routine. If you start making a fuss then you'll be the bad one.' (Sarah, Cervical Screening FG)

What was particularly concerning was the view of Michelle who told me about her long-standing mental health problems. She said,

'I was very reluctant to go along and have [a smear] and I felt in the end I'd better because it would affect my relationship with my GP which isn't ... Umm I felt I was under pressure to do it and I felt it was really about them reaching a target rather than actually about my needs and I didn't feel very able to stand up for myself in that situation. Um just because it's very you know, the GP's the gatekeeper and you can't get past them and I've already changed my GP.' (Michelle, Cervical Screening I)

Michelle was one of the most well informed people I interviewed about cervical screening. She knew she was at low risk but felt that she had to have a smear in order to get the care she required for her other health problems. It was her story that made me reflect deeply about the impact of information in a situation where people might feel coerced or under pressure. It was beyond the scope of this study to explore whether certain groups (particularly vulnerable groups such as people with a mental illness, or those with a longstanding illness) are more likely to be coerced. This would be interesting to explore in more detail in another study.

The issue of targets, raised by this woman, was also raised in other cervical focus groups. Several women were aware of the pressure exerted on them and asked me whether GPs had to meet targets.

'Are GP surgeries...do they have to... I don't know how to right word this.. have they to meet a quota, are there government targets where a GP surgery is said we want 80% of women of the age group to respond or something because I felt it was like.... quite... not pressurised.. I don't know the word, but the fact that they kept writing to me saying you

know, 'Come for a smear', it was almost like they had to make a quota or something and I didn't know what pressure they are under?' (Paula Cervical Screening FG)

Other women such as Julie agreed that they had had increasing forceful letters if they did not attend for a smear.

'That would explain why my letter was a bit snippy.' (laughing from others).

They also had alternative explanations for the reason why GPs invited women for screening,

'Are they scared if they don't do somebody's smear and then somebody dies of cancer then they'll get into trouble?' (Sarah, Cervical Screening FG)

Thus, these women reasoned that GPs were pressurised from a higher authority either to meet targets or to avoid the risk of not detecting a cancer. It was, in some ways, a cynical view of health professionals, in that the woman viewed the GPs as acting in their own interests (i.e. meeting targets, taking steps to prevent malpractice claims) rather than in the interests of the women themselves.

In summary, whilst some people invited for breast and colorectal screening felt pressure from friends and families to attend, none felt pressure from health professions. This was in contrast to some women invited for cervical screening who felt undue pressure from health professionals to take part. As discussed in Chapter 2 cervical screening currently takes place within primary care. Organisational differences between screening programmes may affect the autonomy of those invited to participate.

5.8 Reasons why people participate in screening

The reasons people participated in screening centred predominately on their attitudes and beliefs. One common reason for participating, as this woman describes was the view that 'prevention is better than cure.'

'Because I didnnae want to get cancer (laughing). It's because I mean it's prevention is better than cure isn't it? And what's a few minutes inconvenience. It's like the dentist. I go to the dentist every six months regardless or not whether I've got toothache so I feel it's the same sort of scenario.' (Hilary, Cervical Screening I)

Responsibility towards themselves or their children was also cited by some people (mainly women) as a reason for going. For example, when talking about going for cervical screening, Helen said,

'You've only got one life. This isn't a trial run or anything you just get one go, and I think it's your own responsibility to be as faithful to your body as the medical professions going to be.' (Helen, Cervical Screening I)

Unsurprisingly many people went because they wanted to find out whether they had cancer or not. However, there was a presumption among some that they would have a normal result. Ellen, when asked about her reasons for going for breast cancer screening, replied,

'I go to make sure everything is okay. And that's it.' (Ellen, Breast Screening FG)

However in the same focus group Marie said,

'I still go but I wouldnae want to know' [if she had an abnormal result] (Marie, Breast Screening FG)

Thus it was as if some people participated without wanting to think about the consequences of an abnormal result. Many people also talked about the fear surrounding diseases such as cancer. In an individual interview, Pam who didn't go for mammograms reflected on why people did:

'Yes. To take the fear away. And so they are thinking about it all the time, 'Will I get it, will I not get it'. Right I'll go for the mammogram.' And as you say, that's not 100%, really, but they go and it makes them feel better. I think, then it comes back and it's nothing so the next three years they go again and then nothing again, and[they feel] good cos they have done it. Puts their mind at rest.' (Pam, Breast Screening I)

Another common phrase that was used was 'better safe than sorry'

'Yeah just in case, better being safe than sorry, so that's why I decided to go up on Monday.' (Michelle, Cervical I)

Cervical screening in particular was viewed by many as a normative behaviour; common quotes when asked why they went for screening were *'It's part of being a woman'* and *'It's like going to the dentist'*. For example, Anita commented:

'I think it's just because my mum's done it, you know, my friends do it, it's just it's like you're a woman that's what you've to do, you know.' (Anita, Cervical Screening I)

Many women talked about going for a smear either when they first had sexual intercourse, or when they had had children.

Women participating in breast cancer screening in particular said that knowing someone with breast cancer was a primary reason for their participation.

'I've lost a friend to it. A very close friend.' (Jessie, Breast Screening FG)

Influences from others, particularly mothers or friends (for cervical screening) and wives (for colorectal screening) were important factors for some. As Jim put it,

'Well my wife is a nurse as well and she actually forced me into this. She said 'you will do that' and I done it. It wasn't the most pleasant thing I've ever done in my life but I had to do it like. She's a persuasive person.' (Jim, Colorectal Screening FG)

Women such as Jane also reported trying to persuade friends to go along for screening

'I think it's got a lot to do with peer pressure and I know I've sort of hassled friends if they haven't been for smears.' (Jane, Cervical Screening FG)

Many people talked about hating going for screening, and their embarrassment of doing the screening test, but they still participated. Positive attitudes and beliefs about the benefits of screening seemed to override some people's negative experiences. For other people it was persuasion from their GP, friends or family (see also section on coercion pg. 204). However, for some others, the process itself did mean that they would not participate.

Finally, some people (primarily women) also went so that they could not be 'blamed' if they got cancer.

'I go for all of these things, do whatever I should, so that I can't be blamed if something goes wrong for me.' (Jenny, Breast Screening FG)

In Chapter 2 I discussed the issue of blame and how some people may be viewed as culpable if they did not participate in screening, and then went on to develop cancer. As mentioned previously, many people had a strong sense that screening was a good thing to do. Many people thought that screening should be more regular than it was, and some men talked about the value of having a yearly health check, which they described as

'being a sort of MOT.' (Christopher, Colorectal Screening FG). This attitude was also expressed by several men responding to the questionnaires. However, a person's belief that screening is 'a good thing' may be based on information they have received on the benefits of screening.

5.9 Reasons why people do not participate in screening

There were many reasons given for why people did not go, but they were not normally related to having a negative attitude. Although I did not speak to as many people who had not participated as had, I always asked if they knew people who didn't go and the reasons why. What became apparent as I talked to people was that most could not be categorised into 'serial' attendees or non-attendees. Some talked about missing tests for one reason or another, or had attended for one type of screening but not another. Therefore, although I had attempted to get a mix of people who had different screening experiences at their last screen, many had not been consistent in their screening behaviour. This was useful for my study as I had wanted to get views from people who had not attended for screening.

One of the main reasons why people didn't go seemed to relate to how the particular test was carried out. The process was often tied in with personal feelings about having a particular part of their body touched or examined. For example, one woman participated in colorectal but not for cervical screening. When I asked her why she replied,

'You could do any part of my body, could examine any part of my body but not there.' (Madge, Colorectal Screening FG)

Similarly, another woman had been regularly for cervical screening, but would not go for mammogram. She described her reasons for not going,

'No I've never been interested...it's a weird thing.. to me they there to give you a shape [her breasts], but apart fro that I mean, I sortae just ignore them. And I cannae say I even self examined just it ugh, you ken, it just makes me baulky(sick). And if I had a mammogram I would flake oot, I think I'd pass out. Cos I've seen it on telly, ken when you lift your arm, my sisters says it comes down and you're nearly a fried egg sortae thing.' (Pam, Breast Screening I)

Only two men I interviewed had not participated in screening (due to holidays or forgetting about it). However, they did talk about others who had not been. The main reasons that men gave for other men not going for colorectal screening was the process of doing the stool test and feeling 'squeamish'. People also talked about other factors such as holidays. Deidre, who had not sent back the test for colorectal cancer screening (and neither had her sister), gave the following reasons,

'..because my sister is awfy squeamish and she says, when I turned roond she was aboot sick. She was first to get the test and said 'I'm not doing that', she says 'I'll be sick.' Well a few months later I got it a letter like that. I never actually done the faeces test and the second time I got it I was away on holiday so I never actually done the test, but I mean these things dinnae bother me.' (Deidre, Colorectal Screening FG)

A few people talked about fear of consequences as a reason that had put them off, or might put others off. Madge explained how she thought people might be frightened,

'I think a lot of the people are generally frightened to go for anything in case they find something which is to me the wrong choice.. thing to think but it is everybody's choice. I have a friend who is now 71 and she has never had any kind of screening at all because she just doesn't want to go. She just dismisses it. She's had no mammograms, no tests anything.' (Madge, Colorectal Screening FG)

Two young single mothers, Coral and Joan, who had not been for screening cited lack of information as a reason for not going. Coral said,

'I don't know, I suppose it's no because I cannae be bothered and I won't go and do it, it's just like I say it's because I have never really had that much information and why should I go for it really? Or what I am, ken, going to gain out of going for it you know. I mean about cancerous cells in the womb. I dinnae ken what that actually means ken when it says cancer, you know could that mean I had cancer in the womb or I don't really know.' (Coral, Cervical Screening I)

Coral's decision not to go was compounded by receiving a registered letter. When I asked her why this put her off, she replied,

'I don't know because it sounded more serious because it's the first time I've ever had a recorded delivery ken you think, it's obviously something important when you get ken something that you have to sign for maybe no I always think the worse me, I'm pessimistic.' (Coral, Cervical Screening I)

Registered letters are often seen by GP practices as a final resort for getting people to go for screening, or for ensuring that the letter has actually been received. However it

scared Coral, who was a young single mother living in a deprived area, and made her less likely to go.

From the responses in the questionnaires, several other reasons emerged as to why people did not participate in screening. Several people had illnesses such as inflammatory bowel disease that made them not participate: *'I have IBS and worry that the test would only make it worse'* (Colorectal, M50). Other people reported having had a test through private health insurance, or having other problems in their lives that made have a screening test low down on their list of priorities

'My daughter has severe mental health problems and my husband has just had major surgery and has come out of hospital, a cervical smear was not high on my list of things to do.' (Cervical, F 51)

Finally, one person reported not going because she did not want treatment if cancer was found.

In summary, it appears that there are many reasons why people decide not to participate in screening. However, in the people I interviewed, many reasons were related to the process, barriers, or fear of consequences rather than negative attitudes towards screening. In general, even those who did not participate thought that screening was 'a good thing.'

5.10 The experience of being screened

As discussed in the previous section, the process was a major issue that people discussed. However, although many found the process unpleasant, it did not necessarily put them off going. Women in particular talked about how they hated going for their smears. For example, Anita said

'I hate going for my smear but we [she and her friends] never actually raise the conversation to any other level just 'we hate going for it but we go for it'.' (Anita, Cervical Screening I)

The sex of the health professional was also seen as a factor influencing the choice for breast and cervical screening.[33] Again, although it might not prevent them from going, it might put them off if there were other factors present. It was discussed most by women in relation to cervical screening. Many of these women said that they would feel uncomfortable being screened by a male doctor; only a minority of women would have preferred it. This issue was hypothetical for many women, as the majority they had normally had the smear performed by a (female) practice nurse.

Access was another issue that arose in one breast screening focus group. Most of the women there had been along to the mobile van, and some of them had not been for screening when it was only available at the Screening Programme at the other side of town. Ariel said,

'Well I wouldn't have actually went, I haven't got time for one, I know I wouldn't have but it was up at shop X, the van and I had got the letter so I went up there but I don't think I would have really had the time to go but because it was local I went there.' (Ariel, Breast Screening FG)

However, they did feel the service they got at the mobile unit was inferior to that received when they travelled. After talking to breast screening staff, I found out that the staff and the process were exactly the same for both the mobile van and when attending the screening unit. Therefore, it appears that it was more a perception than a reality. Or it could be that because the van was smaller and less private than the screening unit, it made women have a less comfortable experience.

5.11 Lifecycle and gender

Lifecycle was an important theme for several reasons. Firstly, it was perceived by the older participants that younger people had different attitudes which would affect the way in which they used the information given. They also thought that younger people would be less likely to go for screening. When I asked one woman, Abigail why she thought this way she replied,

[33] The sex of the health professional was not relevant in the colorectal discussions as people perform the test themselves.

'Because I think they actually think 'it's nothing it'll not happen to them.' (Abigail, Cervical Screening I)

Another issue relating to the lifecycle was the issue of informed choice. Hilary said,

'Well maybe for like young women you hadn't had a smear test before or have perhaps had one maybe then if they were given this information they would be able to make more of an informed choice than what I could because half of me is thinking 'aye your probably just wasting my time going for one' then the other half of me still thinks ...you still have them, though, because you never know, you know.' (Hilary, Cervical Screening I)

Women also talked a lot about the experiences of childbirth, and how it made them part of the system and less anxious about the process. For example, Helen asked

'Is it maybe because we've had children that we are not maybe just as frightened about the unknown whereas young single girls have not had to, have not had a baby?' (Helen, Cervical Screening I)

Some women talked about gender differences in men and women in relation to screening. The following conversation took place in one of the cervical focus groups (names have been changed to preserve anonymity). Even though all the women had all been educated to degree level, it is a good account of the main topics in this theme.

Brenda: *'I mean testosterone cancer is like equally as relevant.... but you know you don't see men get hauled in every other day to have the test.'*

Paula: *'Yes I know they don't get lots of letters sent (laughing from others), no I agree.'*

Donna: *'It should be..... is that not a real weakness in the medical system should men not be given the opportunity....'*

Mary: *'I think they're trying to encourage men now.'*

Claire: *'And you sort of think, if it was men having to go through that they wouldn't bother (laughing).'*

Brenda: *'Men are only expected to keep an eye on sort of like, you know, down below and be checked you know downstairs... but upstairs too.. now every time I go for a smear it's kind of like, 'Now have you been doing checking your breasts now?' You know, 'Give us a break you know' and I mean I know that's equally as important you know and it should be your responsibility....'*

Sarah: *'They wouldn't.'*

Paula: *'Well they don't and I mean going for like, you know, check ups for testicular cancer and things... that's not nearly as invasive but they wouldn't go and yet there's this expectation that all women will you know....'*

On the one hand women held the view that men should perhaps be offered more screening, yet in many of the focus groups and interviews there was a view amongst women that even if men were offered it they would not take part. However, the men I spoke to, who were generally keen to take part, did not substantiate this view. The third view expressed in this conversation was that it was unfair that women were subject to medical scrutiny in a way that men were not. In addition, there was an expectation that women would comply. In Chapter 2 I raised the issue that women are subject to scrutiny of their sexuality in a way in which men are not, even though HPV, one of the main risk factors for cervical screening, is a sexually transmitted disease.

5.12 Summary

In summary, there were both similarities and differences between the different types of screening, which are summed up in Table 15.

Table 15. Differences and similarities in themes between the three types of screening

Theme	Cervical	Breast	Colorectal
Provision of information	Little received from health provider or media	Letter and leaflet. Media	Letter and leaflet. Little from media
Knowledge of symptoms	Poor	Good	Fair
Knowledge of incidence	Poor	Good	Poor
Knowledge of risk factors	Poor	Fair	Fair
Knowledge of consequences/ limitations	Poor	Poor	Poor
Role of the information in people's decision making	Not really used Risk factors and incidence viewed as controversial information	Used by some	Used by some Risk factor information viewed as a way of modifying lifestyles
Choices and informed choice	Hard to see it as a choice Did not feel they had made an informed choice	Saw it as a choice Did not feel they had made an informed choice	Mixed Did not feel they had made an informed choice
Big decision	No	Mixed	Mixed
Degree of coercion and control	Pressure to attend from health professionals, and friends	Not much pressure	Pressure to attend from family and friends
Reasons people participated in screening	Normative behaviour	Self-responsibility	Self- responsibility
Reasons people do not participate in screening	Fear, not liking the test Possible effect of gender of health professional	Fear, not liking the test	Fear, not liking the test
Anxiety	Much anxiety over test and results	Less anxiety	Little anxiety
The experience of being screened	Unpleasant	Unpleasant	Did not like doing it
Lifestyle and sex	Age might affect	Not clear	Men saw it as being like an 'MOT'

5.13 Discussion

The focus groups and comments from the questionnaires raised several important themes. People were generally not knowledgeable about either the disease being screened for or the limitations of screening. This lack of knowledge was particularly apparent in women participating in cervical screening. When people were asked about what information they would like (to make an informed choice), many wanted information on the disease itself in addition to information on risks and limitations. This information was seen as providing a context for screening, but to some might have also informed their decision. Many said that the information would not affect their decision, but that it would make them less anxious if they got an abnormal result.

When asked about reasons for going for screening, the most common reasons given for cervical screening was that it was a normative behaviour ('like going to the dentist', 'part of being a woman'), a preventive behaviour, or for reassurance. Going for screening was generally viewed as being a 'good thing to do'. When asked about not going for screening, people generally were deterred by the process, external reasons such as holidays, or issues relating to the privacy of their bodies.

Provision of information and information needs

As discussed in previous chapters, the provision of relevant balanced information to people invited to screening is one of the pre-requisites of informed choice. However, it was evident from the focus groups that many people, particularly those invited for cervical screening were not receiving this information. In many instances, women only received a letter telling that it was time for their smear with no additional information.

A recent review of cervical screening in Lothian found that there was insufficient evidence to determine whether GPs were meeting the recommended guidelines surrounding the giving of information (NHS Quality Improvement Scotland, 2003a). Most other NHS Boards in Scotland, however, did conform to this criterion (NHS Quality Improvement Scotland, 2003b). The review of cervical screening stated that because information leaflets are overseen by NSD,

'Women across Scotland are therefore likely to receive uniform information, which contains all the core elements as identified by SCSP[34] to enable informed choice.' (NHS Quality Improvement Scotland, 2003b)

However, in the women I interviewed, this statement was not valid, primarily because the cervical screening programme in Lothian has not yet been centralised. Even though leaflets are available, some GPs still do not appear to be following the guidelines. Therefore, women are unlikely to be able to make choices based on an understanding of the risk and benefits, or even an understanding of what screening is for. Lothian is expected to centralise its cervical screening programme in 2006 which may mean that women will get better information.

An important finding of this research was that the information people wanted in order to be informed differed to some extent from the professionals' view. For example, people did not always view the risks of screening (e.g. false positives) as a negative aspect of screening. This attitude was also found in a study of women's attitudes to and knowledge of both false positive mammography results and the detection of ductal carcinoma in situ after screening mammography (Schwartz et al, 2000). The author reported that women were aware of false positives but viewed them as an acceptable consequence of mammography.

A further difference was that, although information on risk and befits of screening was thought to be important, people also wanted information on the symptoms of the disease, risk factors and incidence. This finding is consistent with the other qualitative research described in Chapter 3. With regard to decision making, this information enables people to assess their own personal risk of getting the disease (or the benefit to them as an individual) and make a judgement of whether the risks involved in screening outweigh the benefits. Chapter 2 discusses risk communication in more detail.

Attitudes towards information disclosure

Although information on the disease was considered important by participants, there was some debate as to whether it should be included in information leaflets. Similar debates take place in the professional arena (Braun and Gavey, 1999). Braun identified two

[34] Scottish Cervical Screening Programme

competing discourses which inform positions on whether or not women should be provided with information regarding sexual risk factors for cervical cancer: 'protectionism' and the 'right to know'. The protectionism discourse highlights the efficacy of screening and maintains that women's best interests are served by maximising the number of women screened. The 'right to know' discourse maintains that people have an absolute right to information that may affect them or their choices. These two discourses are very similar to the one outlined in Chapter 2 (individual autonomy versus public good).

What is interesting is why these debates only affect some pieces of information (incidence and risk factors) and not others (symptoms). Even within the risk factors, giving information on family history was not as contentious as information on sexual partners or smoking. I discussed in Chapter 2 how morality is closely associated with risk taking behaviours. Family history is not something that an individual has any control over, or can be 'blamed' for. However, the number of sexual partners, or smoking, are considered to be risk taking behaviours which can attract blame. If a person is told that they are high or low risk it can produce an expectation that they have a moral responsibility to reduce that risk (by going for screening).

There was another area of cancer screening where the issue of blame arose. This was in relation to the notion of 'getting the blame' if they did not participate and then went on to develop cancer. Two other qualitative studies also found that people worried about being blamed if they made the 'wrong' decision (Charles et al, 1998; Silverman et al, 2001). In screening, the 'wrong' decision is generally perceived as not going for screening. It is unlikely that a person will attract blame if they carry out a behaviour according to the expectations of the health professionals. This raises the issue of the true nature of the choice in screening. When people are faced with the choice to participate or not in screening, the choices are not presented as equal but rather as 'good' or 'bad' choices, 'rational' or 'irrational'. The choice made in the context of screening may differ from choices in other areas of healthcare (e.g. surgery or medication for a health condition) in respect to moral values of responsibility and rationality ascribed to them.

Choice, informed choice and autonomy

The moral inequality in the choices may explain to some extent why the notion of choice in cancer screening was not recognised by all of the participants. It could be postulated that they did not feel it was proper choice because there appeared to be only one way to behave. Whatever the reason, for many people this was not a choice in the same sense as deciding between two different treatment options for a specific condition. Other research also found that in many women who were presented with a choice to undergo some form of adjuvant treatment versus no treatment felt that `doing nothing was no choice' (Charles et al, 1998).

As discussed in Chapter 2, as well as balanced information, autonomy is viewed as being central to the concept of informed choice. In the context of a public health initiative such as screening, there may be an uneasy tension between individual autonomy and collective gain. However, the people I interviewed in my study appeared to be acting largely autonomously when making the decision to be screened or not. This was especially true for colorectal cancer where the people perform the test in their home, and made their decision largely on their own. For breast screening, women also felt autonomous, and those that did participate did not feel coerced into doing so. However, from interviews and focus groups with many women invited for cervical screening, it was this group who seemed to be most coerced and felt under most pressure to attend. Letters from GPs were more coercive than those from the screening units, and many women also felt pressured when they went into see their GPs for another reason. What was particularly worrying was the woman with mental health problems who was low risk and well informed, but felt that she had to have a smear in order to maintain her relationship with her GP. It has also been asserted that within cervical screening, power is sometimes authoritarian and conspiratorial, and there seems to be no choice involved, especially if screening is offered opportunistically (Bush, 2003). It has been argued that if an influential agent (e.g. GP) creates, or in some way has control over, the events that the agent offers as 'reasons' then the influence is either manipulative or coercive (Faden, 1987). Thus both autonomy and therefore informed choice (however informed the person) are compromised.

Screening behaviour (participation or non-participation)

Data from the focus groups suggested that the reasons people do not participate in screening generally relate to either fear of what it might find out, or dislike of the process. No-one in my study had negative attitudes towards screening. Several other qualitative studies have been undertaken to explore the beliefs and attitudes of people who do not take part in screening (Neilson and Jones, 1998; Nielsen et al, 2004; Pfeffer, 2004b). A Dutch study evaluating why people refused health screening found, as in my study, that some had not participated because they did not want possible risk factors to be revealed, or their feeling of good health to be disturbed. However, in contrast to my study, non-participants did not go because they were busy, felt healthy or had recently been examined. Some also emphasised the limitations of health screening and stressed the individual's own responsibility for maintaining good health and believed that a positive attitude promoted health. (Nielsen et al, 2004). The authors concluded that non-participants had rational views both regarding screening and on their own responsibility for maintaining health. Non-attendance was due to a conscious choice which included consulting their GP for symptoms. Whilst non-participants in my study also had rational views, many did not know the symptoms of the cancer they were being screened for which would make consulting their doctor difficult. The people I spoke to also made a conscious choice not to participate, but in contrast to the Dutch study it was primarily because of the process, rather than the limitations of health screening. The findings from my study are similar to another qualitative study of non-participation in cervical screening where the main reasons cited for non-participation were fear and dislike of the test itself (Neilson and Jones, 1998).

Attitudes and beliefs

In this study, attitudes towards screening were generally positive. People's participation in cancer screening centred on views such as 'prevention being better than cure'; wanting to find out if they had cancer, and presuming they would get a normal result. Others studies have also evaluated attitudes towards screening, For example, one study used telephone interviews to understand how women view breast cancer, their personal risk of breast cancer, and how screening mammography affects that risk (Silverman et al, 2001). Similar to the result in my study, they reported that when asked how

mammography worked, almost all repeated the message that *"early detection saves lives."* The authors also found that the belief in the benefit of early detection was so strong that some women advocated scaring other women into getting mammograms because it is *"better to be safe than sorry"*. This was a similar finding to my study in which people actively talked about withholding information on risk (of either the disease or screening consequences) so that other women would go.

What was striking about women who were invited for cervical screening was their view that it was 'part of being a woman' and 'just like going to the dentist.' This view was not held in the other type of cancer, but another study reported that cervical screening was viewed as "just part of being a woman" (Bush, 2003). She also reported that there was a sense of obligation to attend, and a sense that it was the correct behaviour to do. In her study, non-attendance was associated with deviance.

How this research relates to theories of behaviour and choice

Theories of choice and behaviour (see Chapter 2) often focus on people using information to make rational choice about risk. However, others have argued that rationality is not the only component in decision making and apparently 'irrational' influences and considerations exert strong pressures (Thornton, 2003). Key ideas that appeared to shape participation included the fear of breast cancer, trust in technology, and taking responsibility for health (Willis and Baxter, 2003). The results of the study reported here suggest that people may not be making rational choices with regard to the information available to them but they are making rational choices when taking into account other influences.

Although other researchers used some of the domains of the Health Belief Model (e.g. perceived susceptibility, perceived seriousness of the disease) to classified attitudes towards cancer screening (O'Sullivan and Orbell, 2004), I found this approach problematic in my study. As discussed in Chapter 4 (section on results for second round of focus groups), when I asked about their perceived susceptibility (or if they thought they were at high risk), several commented that they did not know what the risks were. In my focus groups, few people had much knowledge about the disease that they were

being screened for. Therefore, many people did not have the basic information to make judgements about perceived susceptibility or severity, which are key domains of the Health Belief Model.

5.14 Strengths and limitations of the qualitative study

There are a number of strengths of this qualitative study. It is one of the few studies that has actually asked cancer screening invitees themselves what information they want to make an informed choice. It used a robust sampling methodology, and a large number of people were interviewed with a variety of different experiences of screening. However, several limitations of the study have to be acknowledged. Firstly, the sampling of the invitees was restricted to those living in Lothian or Tayside. Barriers to screening, or attitudes and beliefs of people living in other parts of Scotland, particular the rural areas might have been different. As mentioned previously, cervical screening in Lothian is organised differently from other parts of Scotland, and people may have more information given to them elsewhere.

Secondly, although I attempted to talk to people who had not participated in screening, they were still underrepresented in my sample. People who do not undergo screening may have different information needs to those who do, and this issue might need to be explored in further studies.

Thirdly, I did not interview many people from different ethnic backgrounds. However, because screening is population based, it was beyond the scope of the study to interview and represent the views of all groups. I concentrated on ascertaining the information needs of people with different experiences of screening, rather than the information needs of different groups (such as ethnic minority groups, people with learning difficulties, or people with mental health problems). Other qualitative studies would probably be valuable in these areas, although the NHS Screening programmes have produced information leaflets in different languages and for women with learning disabilities. In addition a recent study explored issues of candidacy[35] and compliance in

[35] In this article the author describes candidacy as 'the personal characteristics that make some people more or less likely to succumb to a disease'.

minority ethnic women invited for breast screening. The author concluded that candidacy and ethnicity emerge as similar constructs, manipulated by women to make claims about their risk of breast cancer (Pfeffer, 2004b). A systematic review of breast health information needs of women from minority ethnic groups concluded that there was a dearth of research highlighting breast health and breast cancer screening information needs of women from minority ethnic groups (Watts et al, 2004).

A final limitation of the qualitative study was the use of prompts. The prompts were based on two main sources of information: the GMC guidelines, and the informed choice leaflets developed by the screening units. The reasons I used these sources were twofold. Firstly, I was undertaking the study with the co-operation of the screening units. To ensure their continuing involvement (without which I would not be able to do the study), I felt obliged to use their information leaflets and follow the guidelines. I was wary of using any new information that had not been endorsed by them. I was aware of some of the consequences of screening which were not included in the leaflets (e.g. the incidence of cancer), and I supplemented the information with data from CancerBACUP. However, I was aware for example, that there was anecdotal evidence that women who had abnormal smears might not be able to get certain types of insurance but because I was not able to find any reliable evidence on this, I did not want to include it in my prompts. This caused difficulties for me, as I was unable to give information on some of the negative consequences of screening. Therefore, although I found that the people in my study wanted different pieces of information from those seen as important by professionals, I accept that I was not giving them either wholly unbiased or complete information. If I was undertaking the research without the involvement of screening units and programmes, I might have felt more able to include more information.

5.15 Conclusions

The role and importance of information in making choices about cancer screening is not clear. It may be that it has little effect on the choice, but may have a greater effect on other outcomes such as anxiety and satisfaction.

One of the pre-requisites for knowledge and understanding is the provision of balanced information. At the present time this information is not being routinely given to all people invited for screening. Informed choice is not just about knowledge and information giving. It is also about freedom to choose, minimal barriers, and lack of coercion. In cervical screening some women felt pressurised and even coerced by their GPs into taking part. Whether informed, autonomous choices are less likely to be made in people invited for cervical screening rather than breast or colorectal are explored in the quantitative data.

CHAPTER 6. QUANTITATIVE ANALYSIS OF MICICS QUESTIONNAIRE DATA

This chapter reports on the analysis of the MICICS questionnaire data. Several analyses were undertaken. The first analysis describes the sociodemographic features of the sample and the respondents. The aim of this analysis was twofold – firstly, to determine how representative the sample was of the population from which it was drawn (both the local level and for Scotland); and secondly, to test for any effect of non-response bias.

The aim of the second analysis, based on Item Response Theory, was to assess which knowledge items were more difficult than others, and assess the reliability and validity of the items.

The third analysis used factor analysis to explore the underlying attitudes and beliefs, and reduce the number of variables. The factors which were identified were used in modelling the data.

Finally, modelling was used to explore the key predictors of informed choice, using both the participants' personal/subjective definitions of informed choice (perceived informedness) and a theoretical definition. This definition is explained in detail in section 4.40. Briefly, it is a composite score comprising of a knowledge score and items relating to pressure, choice and barriers. This chapter also explored some of the predictors of other key variables such as knowledge, choice, intentions and screening behaviour.

The results are presented separately for each type of screening (colorectal, breast and cervical) prior to a discussion of the similarities and differences in the results (section 6.10).

RESULTS FROM COLORECTAL SCREENING DATA

6.1 Sociodemographic and other characteristics of the sample

The sample comprised men and women aged 50-69 years who had been invited for colorectal screening. A total of 480 questionnaires were sent out to screening invitees from four different GP practices (120 from each practice) located within Montrose and Brechin, which are small East Coast Scottish towns.

Testing for non-response bias

One hundred and ninety one questionnaires (40%) were returned completed.[36] The relatively low response rate could introduce non-response error. Table 16 presents details of the sample population, and the characteristics of those who responded to the questionnaire and those who did not.

Table 16. Colorectal screening: characteristics of the sample

Characteristic	Total sample (n=476)	Respondents (n=191)	Non respondents (n=285)	Statistical testing#
Age in years (median, range)	60 (50-70)	59 (50-70)	60 (50-70)	T-test = 0.73
Social deprivation score‡ (median, range)	16 (10-29)	16 (11-29)	16 (9-29)	$\chi^2_1 = 0.29$
Sex				
Female	241 (51%)	102 (53%)	139 (49%)	
Male	235 (49%)	89 (47%)	146 (51%)	$\chi^2_1 = 0.80$
Previous screening				
Participated	200 (42%)	125 (65%)	75 (26%)	
Did not participate	196 (41%)	36 (19%)	160 (56%)	
Not invited (new invitees)	80 (17%)	30 (16%)	50 (18%)	$\chi^2_2 = 84^{**}$
Current screening				
Participated	231 (49%)	160 (84%)	71 (25%)	
Did not participate	245 (52%)	31 (16%)	214 (75%)	$\chi^2_1 = 72^{**}$
Practice				
Practice 1	120 (25%)	50 (26%)	70 (25%)	
Practice 2	120 (25%)	45 (24%)	75 (26%)	
Practice 3	118 (25%)	42 (22%)	76 (27%)	
Practice 4	118 (25%)	54 (28%)	64 (22%)	$\chi^2_3 = 3.0$

#for differences between responders and non-responders
‡18 postcodes were not able to be computed into deprivation scores
** $p<0.001$

[36] Four were returned uncompleted because either the invitee was deceased or in hospital. These were subsequently excluded from further analysis.

Age and Sex

In the total sample the average age was 60, with almost equal numbers of men and women (49% and 51% respectively). There were no significant differences in age or sex between the responders and non-responders.

Screening behaviour

As shown in Table 16 the response rate was significantly different depending on previous screening history ($p<0.001$). People who had participated in screening previously were more likely to respond to the questionnaire; the responders comprised three times as many people who had previously participated in screening as had not (125 vs. 36; 65% and 19% respectively). There was a low response from new invitees; only 37% (30/80) sent back a completed questionnaire. It is not clear why the response rate in this group was low. One possible explanation is that, because it was a new test for them, they may not have decided on their attitudes and beliefs about it.

Overall, 49% of the total sample (responders and non-responders) participated in the current round of screening. As with previous screening participation, those who participated in the current round were also more likely to respond to the questionnaire than those who did not. The respondents were 5 times as likely (84%) to have participated in screening as not (16%). Later sections compare this level of participation with national levels.

Deprivation scores

The median deprivation score for the total sample was 16 (range 11-29). There were no significant differences in deprivation scores between those who returned the questionnaire and those who did not.

Practices

There were no significant differences in response rates between the four different practices. However, practices did differ by social deprivation levels (Kruskal-Wallis test, $\chi^2_3 = 74.8$, $p<0.001$) (see Table 17). In particular, invitees in practice 2 were from significantly more deprived areas than the other three practices. Furthermore, in this practice, people who responded to the questionnaire were from less deprived areas than

those who did not respond ($p<0.05$). In the other practices, there were no significant differences in deprivation scores between responders and non-responders.

Table 17. Colorectal screening: response by practice and deprivation score

Practice	Total sample		Non-responders		Responders		Significance‡
	N	Median	N	Median	N	Median	
1	114	16	66	16	48	16	Z=-1
2	117	11	73	16	44	11	Z=-2.7*
3	114	19	73	19	56	19	Z=-.65
4	113	19	61	19	52	19	Z=-.31
Total	458†	χ^2_3 74.8**	273		185		

†18 missing values; ‡Mann-Whitney test *p<0.05; **p<0.001

Representativeness of the colorectal screening sample and responders

Analysis was performed on the key sociodemographic variables to determine how representative the responders were of the general population.

Deprivation scores

For the whole sample, and also the responders, the mean score was 16.2 (SD 4.2). In the Local Authority Area of Angus (the geographical area from which the sample was derived), the average SIMD[37] was 15.8, and the average for 4 wards in Montrose and Brechin was 17.2 (Social Disadvantage Research Centre, 2003). Therefore, both the sample, and those who responded, were representative of the local community with respect to deprivation scores. The average SIMD score in all the Local Authority Areas (n=32) in Scotland ranged from 9.07 to 46.88 (mean 21.38). This suggested that areas in which the sample in this study lived were slightly less disadvantaged than Scotland as a whole.

Sex of responders

Slightly more females than males (53% vs. 47%) responded to the questionnaire. However, there were no statistically significant differences between the percentage of males and female responders, and the corresponding percentages in the Montrose/Brechin or Scottish population.

[37] Population weighted average of the combined scores for the wards in a district or Local Authority area

Occupational level of respondents

Census data on occupational level were only available for the age category 55-64. Therefore, comparisons were made for both the total number of respondents and those aged 55-64 (see Table 18). Twenty seven people in the total sample and 12 people in the sample aged 55-64 did not provide data on their occupation and were excluded from the analysis. The respondents were significantly different from both the local population and the Scottish population ($p<0.05$). In responders there was a higher percentage of people in the higher occupational levels and a lower percentage in the lower occupational levels.

Table 18. Colorectal screening: occupational classification for colorectal respondents, Montrose and Scotland[38]

Occupational level	All Respondents	Respondents aged 55-64	Local area aged 55-64	Scotland aged 55-64
	%	%	%*	%**
1. Higher managerial and professional occupations	10	10	5	8
2. Lower managerial and professional occupations	22	20	19	21
3. Intermediate occupations	18	21	9	11
4. Small employers and own account workers	5	5	10	11
5. Lower supervisory and technical operations	7	5	12	10
6. Semi-routine occupations	23	28	19	18
7. Routine occupations	13	12	20	17
8. Never worked or long term unemployed	2	1	4	5
Total	100% (164)	100% (83)	99% (1961)	101% (549732)

Percentages rounded off to nearest integer

* $\chi^2_7 = 36.9$ ($p<0.001$) for all respondents; $\chi^2_7 = 28.4.6$ ($p<0.001$) for respondents aged 55-64

** $\chi^2_7 = 20.7$ ($p<0.05$) for all respondents $\chi^2_7 = 20.4$ ($p<0.05$) for respondents aged 55-64

Highest level of education of respondents

Comparisons were also made between responders and other areas (Montrose and Scotland) for highest level of education (see Table 19). People who did not wish to answer, and missing values were excluded (26 people and 5 respectively) from the comparison analysis. The only published Census data available for other areas was for people in the age range 60-64. Therefore comparisons were made for all responders, and respondents aged 60-64 (n=34).

[38] Census table CAS042 NS-SeC by age (http://www.scrol.gov.uk/scrol/common/home.jsp)

Table 19. Colorectal screening: highest educational level for colorectal respondents, Montrose and Scotland[39]

Educational level	Respondents		Local area	Scotland
	All %	Age 60-64 %	Age 60-64 %*	Age 60-64 %**
No qualification	30	29	64	60
O'levels	18	18	14	15
Highers	8	15	6	7
Diploma	29	15	2	3
Degree	15	23	13	16
Total	100% (160)	100% (34)	100% (923)	100% (261733)

* $\chi^2_4 = 627$ ($p<0.001$) for all respondents; $\chi^2_8 = 664$ ($p<0.001$) for respondents aged 60-64
** $\chi^2_4 = 417$ ($p<0.001$) for all respondents $\chi^2_8 = 385$ ($p<0.001$) for respondents aged 60-64

There were significant differences in educational level between responders and the general population. In particular only 29-30% of respondents had no qualifications compared with 60% of the Scottish population of the same age. However, the classification might be slightly different. The Census data for this group is *'No qualifications or qualifications out with these [4 educational] groups.'* No details were provided as to how missing values were coded. In this study, many of the people chose not to answer the question, and there were also some missing values (31 people in total). If these people were included in the first category, then the percentage would rise to 50%.

The other category where there was a significant difference was for the number of people with a diploma, with 20% of respondents having a diploma compared with less than 3% of the Scottish or Montrose population. In order to try to understand this difference, I examined the characteristics of responders who had diplomas. Almost one third (13/45) of these people were either in the teaching or nursing professions. In addition, amongst the responders, approximately 8% (who gave details of their occupation) worked in education and 10% worked in healthcare. Data from the Census shows that in Scotland the respective percentages are 4% and 2.7%.[40] Therefore, one explanation for the large number of people with diplomas is that the people who responded were more likely to be employed in education or healthcare. This is a

[39] Census Table CAS204 Age by highest level of qualification (http://www.scrol.gov.uk/scrol/common/home.jsp)
[40] Census table CAS036 Sex and industry by age (http://www.scrol.gov.uk/scrol/common/home.jsp)

reasonable explanation, given that the questionnaire was concerned with information and health. However, it does not explain all of the differences in the high level of people with diplomas, as only 2% of people in the local area aged 60-64 have diplomas.

Previous and current participation in screening

As mentioned previously, three different groups of people were invited by the Screening Unit to participate in screening. These included new invitees, previous participants, and previous non-participants. Overall, 49% of the total sample (responders and non-responders) participated in the current round of screening. This compares with an overall uptake of approximately 52% in Scotland (personal communication from the Pilot Screening Unit). In the last round of screening, 45% of Scottish invitees did not participate (UK evaluation team, 2004). For this study, the sample of previous invitees was chosen to comprise 50% of participants and 50% of non-participants (200 in each group). Thus non-participants would be slightly over-representative in the total number sent the questionnaire. The sample also included new invitees. At the time of calculating the numbers for the study, there were no data available on the number of new invitees compared with previous invitees. This information was only available at the end of 2004 (from the Pilot Screening Unit). Therefore, 200 previous participants, 200 non participants, and 80 new invitees were sent questionnaires (42%, 41% and 17% of the total sample respectively).

In the current round of screening, the total number of people invited for screening in Tayside to date was 130 100. Of these, 16 569 were new invitees (13%), and 113 531 were previous invitees (87%). The Screening Unit was unable to provide information on previous screening participation. However, if the previous estimates of 55% being participants are used then the current pilot screening population comprised 48% previous participants, 39% previous non-participants, and 13% new invitees.

Table 20 provides more details of the composition of the sample. There were significant differences between the composition of the sample, and the composition of the screening population with respect to previous history.

Table 20. Colorectal screening: composition of sample and screening population by screening history

Composition of sample			Total sample composition %	Screening population composition at 12/2004 %
Previously invited	Participants	200[II]	42%	48%
	Non participants	196[II]*	41%	39%
New invitees		80	17%	13%
			100% (480)	100% (411 343)

[II]This number is 50% participants and 50% non-participants in previous screening
$\chi^2_2 = 10.2$, $p<0.05$
*This number was originally 200, but 4 were excluded as they had either died or were otherwise unable to participate

Summary of evidence of non response bias, and representativeness of the sample

In summary, there appeared to be no evidence of non-response bias with respect to the variables of age and sex. With regard to deprivation scores, it did appear that there was a non-response bias in one of the practices, but not the other three. There was a significant non-response bias in relation to previous screening history; those who participated previously were more likely to send the questionnaire back. The under-representation of people who did not participate in the current round of screening will have implications for the analysis and interpretation of the results. For example, it may affect the precision of estimates of how the instrument discriminates between those who participate and those who don't.

The responders differed from the general Scottish population (aged 50-65) with respect to deprivation scores (but did not differ from people in the local area in this respect). This meant that they came from less deprived areas than Scotland as a whole. Responders also had higher occupational and educational levels than the population from which they were sampled (and Scotland as a whole) which could also suggest a response bias.[41] This finding is consistent with other research which has found that people who respond to questionnaires tend to be better educated and have a higher socio-economic

[41] I was not able to formally test for evidence of response bias with respect to these variable as data were not available for the total sample

status (McColl et al, 2001). This bias towards more educated respondents, combined with the low response rate may limit any generalisability of the results to the general screening population for colorectal cancer (men and women aged 50-64 years).

6.2 Analysis of colorectal screening data

The following section is an analysis of data primarily taken from the MICICS questionnaire.[42] It includes an analysis of the bivariate relationships between intentions and behaviour, the reliability of knowledge items, and factor analysis of the attitude items. Then modelling is performed to identify the predictors of key variables.

Degree of informedness

Section 4.39 outlined the algorithm used in calculating knowledge scores and how item uncertainty and difficulty were assessed. Thirteen questions assessed knowledge and understanding. The mean score was 7.5 (out of a possible 13) with a standard deviation (SD) of 2.1 and a range of 1 to 12. The mode and the median were both 8.

Item difficulty in the knowledge questions ranged from 0.05 to 0.96 (see Table 21). Several questions appeared to be relatively 'easy' for respondents to answer – these included a question about whether screening was for people with symptoms of disease, and 'some people may be treated when they feel well.' The questions that people had most difficulty with were those relating to the consequences and limitations of screening. Radosevich eliminated those items that were too easy or too difficult, as 'they provided little information regarding patient knowledge.' However, I did not think this was appropriate for this scale. If difficult items were dropped, then the scale would not include items about the limitations and consequences of the test. As I have discussed in previous chapters, there is a consensus amongst policy makers and researchers that such items are important in any definition of informedness (and informed choice) in cancer screening. Deleting such items, a measure may have increased reliability, but it would lack content validity.

[42] Data about past screening history were obtained from the screening unit

Item uncertainty was defined as the proportion of people answering 'don't know' and the missing values. The greater the item uncertainty, the higher the confusion related to an item. The scores for item uncertainty ranged from 0.06 to 0.46. Items with most uncertainty included the two multiple choice questions, which required knowledge of the incidence and the number of false negatives. These items may have to be re-worded if the questionnaire is further developed.

Cronbach's alpha for the scale was 0.63. The corrected inter-item correlation coefficients, given in Table 21, were low, with none achieving the 0.5 cut-off point. As a rule, those items that do not meet this cut-off point should be excluded from the scale. However, removing these items would have affected the validity of the scale. Several of the items had good discrimination, but as can be seen in Table 21 the items with low discrimination were primarily those that related to the limitations and consequences of screening.

Items of information included in the screening leaflet are highlighted in bold in Table 21.Several of the items which had a high item difficulty and item uncertainty score (e.g. number of cancers missed; having a colonoscopy might harm some people; some people might have insurance or job problems if their cancer is found early) were not pieces on information included in the information leaflet. However, they were relevant to the concept of informed choice.

Table 21. Colorectal screening: content domains and knowledge items

Domain	Item	Item difficulty	Item uncertainty	Corrected Item – total correlation	Index of discrimination (D) (%)	Cronbach's coefficient alpha (item deleted)
Natural history	Incidence of bowel cancer	.70	.36	.12	21.5	.64
	Knew any symptoms	.19	.19	.36	44.9	.59
	Knew any risk factors	.41	.41	.44	64.5	.57
Understanding of screening	**Screening is not for people who have symptoms**	.05	.03	.20	26.2	.62
	Screening will not prevent people getting cancer	.13	.06	.24	34.6	.61
Understanding of screening results	**What a negative result means**	.37	.19	.44	58.9	.57
	What a positive result means	.25	.22	.45	57.0	.57
Limitations of the test	**Some cancers will not be picked up by the test**	.30	.24	.27	50.5	.61
	Number of cancers missed	.94	.31	-.02	4.7	.64
	Having a colonoscopy might harm some people	.96	.26	.10	4.7	.63
Consequences of screening/ treatment effectiveness	Some people might have insurance or job problems if their cancer is found early	.84	.43	.07	12.2	.64
	Some people may be diagnosed with cancer when they feel well	.08	.06	.28	37.8	.59
	A cancer might be found that cannot be treated	.29	.23	.39	52.3	.61

Items in bold are those for which information was included in the screening leaflet

Intentions and behaviour

Three variables were collected which related to screening behaviour: past screening behaviour; intentions and current screening behaviour. As shown in Table 16, participation in the current round of screening (uptake) for the total sample was 49%, but 84% for those who returned the questionnaire. Analysis was performed to determine the relationship between previous screening behaviour, current intentions and current screening behaviour (see Table 22). For previous invitees, current participation was significantly associated with previous participation (Wilcoxon Signed Ranks Test $p< 0.001$). For all responders, current participation was also significantly correlated with intentions (Pearson's correlation -0.68, $p< 0.001$). Excluding people who were unsure (n=7), and those who said they had already sent the test back (n=118), 42/54 (78%) of people behaved in a way that was consistent with their intentions.

Table 22. Colorectal screening: current screening behaviour by previous screening and intentions

	Took part in current round of screening		
Previous screening history	Yes	No	Total
Previously taken part	117 (94%)	8 (6%)	125 (100%)
Previously not taken part	17 (47%)	19 (50%)	36 (100%)*
New invitee	26 (87%)	4 (13%)	30 (100%)
Intentions			
Definitely not/probably not	5 (22%)	18 (78%)	23 (100%)
Unsure	3 (43%)	4 (57%)	7 (100%)
Definitely/probably	36 (84%)	7 (16%)	43 (100%)
Already sent it back	116 (98%)	2 (2%)	118 (100%)
Total	160 (84%)	31 (16%)	191
			χ^2_3 p<0.001

All percentages rounded to nearest integer; *Z = -5.1, p<0.001

Reasons why people did not want to do the test (barriers)

People who indicated that they might not participate in screening were asked to give a reason why. Of the 23 people who said that they would not send back a test, 5 said they would not do it because of fear of what it might find out, 7 because of dislike of doing the test, one because of an existing illness, and three because of doing the test before.[43] Other reasons people gave were, 'I would not want any cancer treatment', worries because they had inflammatory bowel disease (e.g. *'I have IBS and worry that the test would only make it worse'*) and having had the test done elsewhere (e.g. through private health insurance).

Attitudes and beliefs

Seventeen items on attitudes and beliefs were included in the questionnaire (see Appendix 10). All the items were rated on a 5 point Likert scale. The only item which was not included in initial exploration of the factors was *'I am satisfied with my decision'* as this was considered to be an outcome of informed choice rather than a key domain.

[43] People could tick more than one box, or choose to write a comment instead

Exploratory factor analysis

The coefficient for the KMO was 0.751, and for Bartlett's Test of Sphericity was 754 (df 66, p<0.001). All of the items had a MSA of >0.5 apart from one item - *'I don't need information from anywhere to make my decision.'* This item was removed from the analysis. After exploring the data using an oblique rotation, including and excluding different items, 13 items with reasonable communalities (>0.3) were included in the factor analysis. In the final model, three factors explained 61% of the variance before rotation and 48% of the variance after rotation, and had eigenvalues greater than one. These factors were defined as motivations (24% of variance), influence from others (18% of variance) and perceived informedness (6% of variance).

The rotated pattern matrix (Table 23) shows which of the items (indicated in bold) loaded most closely with each factor. Three items loaded onto factor 1 (motivations), six onto factor 2 (influences from others), and three onto factor 3 (perceived informedness).

Table 23. Colorectal screening: rotated pattern matrix for the attitudinal variables

	Factor		
	Motivations	Influence from others	Perceived informedness
I think that I would benefit from doing the test	**.841**	.087	-.006
I think screening for bowel cancer is a good thing	**.752**	-.015	.016
I want to know if I have bowel cancer	**.744**	-.085	.042
I would like to discuss my decision with my doctor or nurse	.078	**.696**	-.124
I feel pressure from others to do the test	-.077	**.647**	.012
Deciding whether to do it or not was a big decision for me	-.089	**.595**	.008
I want my doctor or nurse to decide if I do the test or not	-.158	**.585**	-.064
I am anxious about what might happen if I do the test	.098	**.562**	-.020
I would do the test if my friends/family thought I should	.148	**.523**	.240
I feel I know the limitations of bowel cancer screening	-.135	.033	**.724**
I feel I know the benefits of bowel cancer screening	.187	-.107	**.647**
I feel I have made an informed choice	.210	-.035	**.581**

Extraction Method: Principal Axis Factoring. Rotation Method: Oblimin with Kaiser Normalization.

Reliability of the factors

Once the factors had been defined, reliability analysis was performed (Table 24) and each of the three factors was treated as a subscale. Cronbach's Alpha for each of the factors were all greater than 0.70. All the items had a corrected item-total correlation of 0.4 or greater within their individual subscales. The item with the lowest item-total correlation was 'I would do the test if my friends and family thought I should'

(corrected-item-total correlation = 0.4). However as this was felt to be an important item in relation to autonomy and influence from others, the item was left in.

Table 24. Colorectal screening: reliability of the three scales

Item	Corrected Item – total correlation	Cronbach's coefficient alpha (item deleted)
Attitudes and motivation	**Alpha for factor =.81**	
I think that I would benefit from doing the test	.68	.75
I want to know if I have bowel cancer	.73	.67
I think screening for bowel cancer is a good thing	.65	.79
Influence and decision making	**Alpha for factor =.75**	
Deciding whether to do it or not was a big decision for me	.52	.71
I feel pressure from others to do the test	.59	.69
I would do the test if my friends/family thought I should	.40	.75
I would like to discuss my decision with my doctor or nurse	.57	.70
I want my doctor or nurse to decide if I do the test or not	.47	.71
I am anxious about what the test might find out	.49	.72
Perceived informedness	**Alpha for factor =.72**	
I feel I know the benefits of bowel cancer screening	.59	.59
I feel I have made an informed choice	.55	.63
I feel I know the limitations of bowel cancer screening	.50	.69

Numbers in bold indicate the standardised Cronbach's alpha for each scale

Validity of the scale

As mentioned in Chapter 4 (section on results for second round of focus groups) I included a subscale of the Decisional Conflict Scale (O'Connor, 1995):

I'm aware of the choice I have to make
I feel I know the benefits of * screening
I feel I know the risks and side effects of * screening

The first item did not factor in my analysis at all and was removed. However it was used in modelling the data. The second two items contributed to factor 3 (perceived informedness) along with the item 'I feel I have made an informed choice.'

6.3 Modelling the colorectal screening data

As described previously, the sample was not representative of the population from which it was drawn in respect to the key characteristics of screening behaviour and social class. Therefore, the purpose of the modelling was to explain the relationships between key variables in this sample, rather than to draw inferences to the general screening population. The following section describes the modelling of some of the key variables.

Due to the large number of variables, only those with significant results are reported in the tables.

1. Variables predicting perceived informed choice

In this analysis, the factor of perceived informedness was the dependent variable. Sociodemographic variables were entered first using the stepwise method, then the other factors, previous screening history and domains of knowledge were added in. As neither educational nor occupational level were significant in the initial modelling, they were left out, to allow more cases to be included. The rationale for the ordering is described in Chapter 4 (section 4.41).

A total of 191 cases were included. Using the stepwise method within each level of inclusion a significant model emerged ($F_{2, 182}$=53.1, p<0.0001). The adjusted R square was 0.36. The significant variables are shown in Table 25. The factor of attitudes and motivations was the most significant predictor, and knowledge of the disease was the only domain of knowledge which was significant.

Table 25. Colorectal screening: significant predictors of perceived informedness (1)

	Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
	B	Std. Error	Beta			Lower Bound	Upper Bound
Attitudes and motivations	.551	.058	.561	9.477	.000	.436	.665
Knowledge of disease	.170	.055	.182	3.076	.002	.280	.061

This model was re-run with the standardised knowledge variable[44] entered instead of domains of knowledge. The significant predictors were knowledge, attitudes and motivations, and non-participation in the previous round of screening. Attitudes and motivations accounted for most of the variation (see Table 26). The adjusted R square for the model was 0.398. Although this is a slightly higher R square than using the domains of disease, it was more useful to know what specific items of information were explaining the dependent variable rather than the composite score. For example, the domain of knowing about the disease was a significant predictor, suggesting that certain

[44] This variable was created using the formula (total knowledge score for individual – mean knowledge score of the sample)/standard deviation for the total sample

items of knowledge make people feel more informed than others. Therefore the previous model was more informative.

Table 26.Colorectal screening: significant predictors of perceived informedness (2)

	Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
	B	Std. Error	Beta			Lower Bound	Upper Bound
Attitudes and motivations	.458	.068	.479	6.756	.000	.324	.591
Total score for knowledge items	.068	.028	.165	2.462	.015	.123	.013
Previous non participant	.344	.170	.144	2.021	.045	.008	.679

2. Variables predicting informed choice (theoretical definition)

In this analysis the composite variable for informed choice was the dependent variable. Although this was a continuous variable with a normal distribution, it was felt that it was inappropriate to run a linear regression for the reasons outlined in previous sections. Briefly, although the low and high scores for this variable would indicate either low choice/low knowledge or high choice/high knowledge, the other scores could be hard to interpret. Therefore the scores were grouped into four categories, based on quartiles. Two analyses were performed. In the first, multinomial logistic regression of all four categories was undertaken. In the second analysis, just the dichotomy of low knowledge / low choice and informed choice (high choice, high knowledge) were compared using binary logistic regression. The first analysis was poor at predicting membership of the two middle categories, and is not reported here.

Ninety eight cases were included in the analysis using just the two categories of low choice/low knowledge and high choice/high knowledge. The final model included only one significant variable (educational level). The Hosmer and Lemeshow test was not significant indicating that it was a good fit (see Table 27). However, at best it could explain 12-16% of the variance. Overall the model could correctly predict 66% of cases (62% of people who had low choice/low knowledge, and 70% of people who made informed choices).

Table 27. Colorectal screening: significant predictors of informed choice

	B	S.E.	Wald	Sig.	Exp(B)	95.0% C.I. for EXP(B)	
						Lower	Upper
School education	1.781	.888	4.022	.045	.168	.030	.960
Post school education	2.750	1.372	4.015	.045	.064	.004	.942

3. Variables predicting screening behaviour

Although the purpose of this study was to evaluate informed choice, policy makers are interested in which variables affect uptake. The aim of this analysis was to evaluate the effect of sociodemographic variables, the latent factors (identified in the factor analysis), domains of information, and other relevant factors on screening behaviour.

Screening behaviour (screened or not screened) was entered as the dependent variable. Variables were entered in the multiple regression in blocks using a stepwise method. The decision about the best model and the most discriminating variables was based on several considerations. Firstly was the extent to which it could correctly predict the percentage of people identified as participating in screening or not; in particular, the percentage of non-participants correctly identified. Secondly was the significance of the Wald coefficient ($p<0.05$), and thirdly was the significance of the 2 log-likelihood, goodness of fit, and Hosmer-Lemeshow goodness-of-fit statistic. If the p value is less than 0.05 then the model does not adequately fit the data.

Initially, the logistic regression was performed with screening behaviour as the dependent variable, and sociodemographic variables (educational level, occupational level, deprivation scores, age and gender), domains of knowledge, barriers and factor (motivations, influence from others, and perceived informedness) as predictor variables, entered in hierarchical order. However, as neither of these latter variables were significant predictors of screening uptake, the model was rerun excluding these variables, which allowed all 191 cases to be included. The two models were very similar, with the same predictor variables. The model with all 191 cases is reported here. The full model was significantly reliable (Hosmer and Lemeshow Test $\chi^2_8 = 10.65$, $p>0.5$). This model accounted for between 17% and 28% of the variance in step 1, 23% and 38% of the variance in step 2, and 25% to 43% of the variance in step 3. Table 28 gives the

coefficients including the Wald statistic and associated degrees of freedom, and the probability values for each of the predictor variables.

Although step 3 accounted for the greatest variance, it could only classify 43% of non-participants. The best model for predicting behaviour was the first model, with previous participation as the only predictor variable. In this model, although only 84% of predictions were correct (versus 88% in step 3), it was better at predicting non-participants (60% versus 43% in step 3). Adding motivations and attitudes into the model increased the amount of variance explained, but reduced the percentage of non-participants correctly predicted. This reduction may be explained by the findings from the focus groups which suggested that many non-participants still have a positive attitude towards screening. The relatively small number of non-participants (n=30) might reduce the predictive ability of the model.

Table 28.Colorectal screening: significant predictors of screening behaviour

		B	S.E.	Wald	df	Sig.	Exp (B)	95.0% C.I. for EXP(B)	
								Lower	Upper
Step 1(a)	Screening history			30.693	2	.000			
	New invitee	-1.849	.637	8.419	1	.004	.157	.045	.549
Step 2(b)	Motivations and attitudes	.970	.276	12.327	1	.000	.379	.221	.651
	Screening history			17.254	2	.000			
Step 3(c)	Knowing what screening means	1.324	.513	6.654	1	.010	3.760	1.375	10.28
	Motivations and attitudes	1.050	.290	13.088	1	.000	.350	.198	.618
	Screening history			15.366	2	.000			

a Variable(s) entered on step 1: Screening history
b Variable(s) entered on step 2: Motivations.
c Variable(s) entered on step 3: Knowing what screening means.

4. Variables predicting screening intention

Intention was dichotomised into definitely not/probably not (0) and definitely/probably (1) and entered as the dependent variable. People who were unsure were excluded from this analysis due to the small numbers (n=7).

As for the previous analyses, sociodemographic variables were entered first, and then the 5 further independent factors, including domains of knowledge and previous screening history were entered. A total of 126 cases were analysed and the full model was significantly reliable (Hosmer and Lemeshow chi-square = 2.9, df = 8, p>0.5). This

model accounted for between 40%[45] and 73%[46] of the variance in intentions, with 77% of people not intending to participate, and 98% of people intending to participate correctly predicted. Table 29 gives the predictor coefficients, the Wald statistic and the probability factors for each of the predictor variables. This shows that significant positive predictors of screening intention were perceived informedness, attitudes and motivations, and knowledge of the consequences. Non participation in screening, and belonging to occupational level 5 (lower supervisory or technical occupations) also were negative predictors (i.e. they predicted a person's intention not to participate).

Table 29. Colorectal screening: significant predictors of intentions

	B	S.E.	Wald	Sig.	Exp(B)	95.0% C.I. for EXP(B)	
						Lower	Upper
Occupational level 5	-6.153	2.847	4.670	.031	.002	.000	.564
Motivations and attitudes	2.612	.857	9.290	.002	.073	.014	.394
Perceived informedness	3.251	1.094	8.836	.003	25.825	3.027	220.344
Non-participation	-5.178	1.860	7.747	.005	.006	.000	.216
Knowledge of consequences	8.801	3.833	5.272	.022	6640.7	3.626	12163663

Previous sections reported on the bivariate relationship between intentions and behaviour. A variable was created where by 1 = behaviour consistent with choice and 0 = behaviour inconsistent with choice. However only 14 people had a behaviour which was inconsistent with their choice, which meant that there is little reliable information that can be gained through analysis.

5. Variables predicting knowledge

Linear regression was used to test for predictors of knowledge using the standardised knowledge score. Socio-demographic variables (educational level, occupational level, sex, age) were entered first, then previous screening history and the two attitudinal factors. Using the stepwise method, a significant model emerged ($F_{1,157}$=8.88, p<0.0001, adjusted R square = 0.13). Having a higher educational level was associated with higher knowledge levels, and previous non-participation was a predictor of lower knowledge scores (see Table 30). However, the model at best could only predict 13% of the variance in knowledge scores.

[45] Cox & Snell R Square
[46] Nagelkerke R Square

Table 30. Colorectal screening: significant predictors of knowledge

	Unstandardized Coefficients		Standardized Coefficients	T	Sig.	95% CI for B	
	B	Std. Error	Beta			Lower Bound	Upper Bound
Post-school education	1.652	.372	.386	4.437	.000	.917	2.387
School education	1.055	.424	.216	2.486	.014	.217	1.893
Previous non-participation	-1.019	.428	-.176	-2.381	.018	-1.864	-.174

6. Variables predicting choice

The standardised choice score was used as the dependent variable for this analysis. The variable was not normally distributed, so it was dichotomised into high choice and low choice, using 0 (mean) as the cut off. Sociodemographic variables were entered first, followed by knowledge items and pre-screening history. The final logistic regression model accounted for between 24% and 32% of the variance. The model correctly predicted 71% of cases (66% in the low choice and 76% in the high choice). Table 31 shows the significant predictor variables. Knowledge of results was a predictor of high choice, whereas age, non-participation in screening, and new invitees were negative predictors (i.e. predicted lower levels of choice).

Table 31. Colorectal screening: significant predictors of choice

	B	S.E.	Wald	Sig.	Exp(B)
Age	-.142	.046	9.734	.002	.868
Knowledge of results	.635	.296	4.600	.032	1.887
Not participated previously	-2.486	.662	14.128	.000	.083
New invitee	-1.777	.696	6.511	.011	.169

6.4 Sociodemographic and other characteristics of the sample

The sample comprised women aged 50-71 years who had been invited for breast screening. The sampling frame used was the screening list generated by the South East Scotland Breast Screening Unit. Four hundred and eighty questionnaires were sent out to screening invitees from one GP practice located within West Lothian. Two hundred and sixty three questionnaires (55%) were returned completed, and two were returned uncompleted because the invitees were in hospital. These were subsequently excluded from further analysis.

Testing for non-response bias

Table 32 presents details of the sample population, and the characteristics of those who responded to the questionnaire and those that did not. The mean age was 59 years in both responders and non-responders. Data on current screening uptake were not available for 8 participants.

Table 32. Breast screening: characteristics of the sample

Characteristic	Total sample	Respondents	Non respondents	Statistical testing[#]
Age (mean, s.d)	59 (5.7)	59 (5.7)	59 (5.2)	t = 0.18 (n.s.)
Social deprivation score[‡] (median, range)	23 (5.7-46.2)	23 (5.71-46.2)	23 (5.7-40)	$\chi^2_1 = 3.7$ (n.s.)
Previous screening				
Participated	273 (58%)	181 (70%)	92 (44%)	
Did not participate	116 (25%)	33 (13%)	83 (39%)	
Not invited (new invitees)	83 (18%)	47 (18%	36 (17%)	$\chi^2_2 = 50.1^{**}$
Current screening				
Participated	346 (73%)	226 (87%)	120 (57%)	
Did not participate	126 (27%)	35 (13%)	91 (43%)	$\chi^2_1 = 57.5^{**}$

[#]for differences between responders and non-responders
[‡]474 postcodes could be converted into deprivation scores, of which 214 were non-responders and 259 were responders
[**]p<0.001

Overall, 73% of the total sample (i.e. both responders and non-responders) participated in the current round of screening. However, as for colorectal screening, previous and

current participants in screening were more likely to return the questionnaires than those who had not participated in screening. The median deprivation score for the total sample was 23 (range 5.7-46.2) and there were no significant differences in deprivation scores between those who sent back the questionnaire and those who did not.

Representativeness of the sample

Analysis was performed on the key sociodemographic variables to determine how representative the responders were of the general population. The purpose of this analysis was to determine whether the results could be generalised to the wider Scottish population.

Deprivation scores

For the whole sample, and responders the mean score was 16.2 (SD 4.2). In the Local Authority Area of West Lothian (the geographical area from which the sample was derived), the mean SIMD[47] was 19.76 (Social Disadvantage Research Centre, 2003). The mean SIMD score in all the Local Authority Areas (n=32) in Scotland ranged from 9.07 to 46.88 (overall mean 21.38). Therefore, the sample was from an area with lower levels of deprivation than the local area and Scotland as a whole.

Occupation level of respondents

A total of 262 responders provided details of their occupation (80%) and were included in the analysis. Census data on occupational level were only available for the age category 50-69 (see Table 33). The respondents were not significantly different from women in the local population but were significantly different from the Scottish population ($p<0.001$). There were a higher percentage of respondents in occupational levels 3, 6 and 7 compared with census data from the local area and Scotland. Both respondents and the local population differed from the Scottish population in that there were less people employed in the higher occupational levels and more in the lower occupational levels.

[47] Population weighted average of the combined scores for the wards in a district or Local Authority area

Table 33. Breast screening: occupational classification for respondents, and women in West Lothian and Scotland[48]

Occupational level	All Respondents	Local area aged 50-69	Scotland aged 50-69
	%	%*	%**
1. Higher managerial and professional occupations	3	3	3
2. Lower managerial and professional occupations	15	22	24
3. Intermediate occupations	22	20	17
4. Small employers and own account workers	4	5	7
5. Lower supervisory and technical operations	4	6	5
6. Semi-routine occupations	26	25	23
7. Routine occupations	21	15	14
8. Never worked or long term unemployed	6	4	7
Total	100% (262)	100% (10942)	100% (351598)

* local area compared with respondents $\chi^2_7 = 14$ ($p>0.5$)
**Scotland compared with respondents $\chi^2_7 = 20$ ($p<0.05$)

Highest level of education

Comparisons were also made between responders and women in Scotland and local areas with respect to highest level of education. Women who did not wish to answer, and women who did not answer the question (43 women and 7 women respectively) were excluded from the comparison analysis. The results indicate that fewer responders had no qualifications, and more had a diploma than the general population (see Table 34).

Table 34. Breast screening: educational level for respondents, West Lothian and Scotland[49]

Educational level	Responders	West Lothian aged 50-69	Scotland aged 50-69
	%	%	%
No qualification	38	58	56
O'levels	21	20	17
Highers	6	7	7
Diploma	31	2	3
Degree	4	13	17
Total	100% (212)	100% (17322)	100% (590342)

$\chi^2_4 = 756$ ($p<0.001$) for West Lothian compared to responders
$\chi^2_4 = 729$ ($p<0.001$) for Scotland compared to responders

[48] Census table CAS042 NS-SeC by age (http://www.scrol.gov.uk/scrol/common/home.jsp)
[49] Census table CAS204 Age by highest level of qualification (http://www.scrol.gov.uk/scrol/common/home.jsp)

Previous and current participation in screening

There were significant differences between the composition of the sample, and the composition of the screening population with respect to previous history such that the total sample in this study comprised a higher percentage of non-responders (25% vs. 13%). Table 35 provides more details of the composition of the sample compared to the Scottish breast screening population.

Table 35. Breast screening: composition of sample and screening population

Composition of sample	Total sample composition %	Composition of Scottish breast screening population in 2003 %
Previous participants	57%	66%
Non participants	25%	13%
New invitees	18%	22%
	100% (478)	100% (146555)

χ^2_2=92, p<0.001

Summary of evidence of non response bias, and representativeness of the sample

In summary, the responders differed from non responders in terms of screening history, but not in terms of age or deprivation scores. Responders differed from the women in the general Scottish population in respect of deprivation scores and occupational level (but did not differ from women in the local area in this respect). However, responders were also more educated than both the population from which they were sampled and Scotland.

6.5 Analysis of breast screening MICICS questionnaire data

Degree of informedness

Fourteen questions assessed knowledge and understanding (see Appendix 10). Total scores for the knowledge items ranged from 4-12 (out of a possible score of 14). The mean score was 8.61 (SD 1.6) and the mode was 9. Similar to results for colorectal screening, some questions were difficult for women whilst others were not (see Table 36). In particular, women seemed to have a good understanding of what screening was for, knowing at least one symptom and knowing that a woman could get cancer even if she felt well. Questions that women found difficult included the number of false

negatives, knowing that a mammogram might harm some people, and that some cancers might progress so slowly that they don't need treatment. Women also had less difficulty answering the question about an abnormal result than a normal result. The degree of item uncertainty was related to the questions which people had most difficulty with.

The index of discrimination was calculated by comparing the percentage of correct responses in women with score above 9 with those below. Few items discriminated well between those who scored high on knowledge and those who scored low. Items that did were incidence of the disease, knowledge of a normal result, and knowing that some cancers will not be picked up by the test.

The overall alpha was 0.47 which is not high and suggests that the items together do not comprise a reliable test for knowledge of breast cancer screening. Some of the corrected item-total correlation coefficients were very low, which is similar to the colorectal results. Only two of the items included in the questionnaire were included in the screening booklet[50] and are highlighted in bold in Table 36.

[50] The leaflet 'Breast screening explained', produced by NHS Health Scotland, 2003

Table 36. Breast screening: content domains and knowledge items

Domain	Item	Item difficulty	Item uncertainty	Corrected item – total correlation	Index of discrimination (D) (%)	Cronbach's coefficient alpha (item deleted)
Natural history	**Incidence of breast cancer**	.51	.18	.12	40	.46
	Knew any symptoms	.05	.05	.10	10	.46
	Knew any risk factors	.11	.11	.24	25	.43
Understanding of screening	Screening not just for people with symptoms	.01	.01	.11	4	.47
	Screening will not prevent a person getting cancer	.07	.03	.17	12	.45
Understanding of screening results	What a positive result meant	.43	.13	.32	55	.39
	What a negative result meant	.02	.02	.19	6	.45
Limitations of the test	**Some cancers will not be picked up by the mammogram**	.31	.22	.38	58	.37
	Number of cancers missed	.92	.33	.06	8	.47
Consequences / treatment effectiveness	Insurance or job problems if their cancer is found early	.84	.46	.03	11	.49
	Women may be diagnosed when they feel well	.06	.04	.17	11	.45
	Some cancers progress slowly (DCIS)	.89	.30	.12	15	.46
	A cancer might be found that cannot be treated	.18	.14	.20	26	.44

Items in bold were information contained in the screening information leaflet

Knowledge of symptoms and risk factors

Knowledge of the symptoms of breast cancer was very good with less than 10% not knowing any and nearly 40% knowing all seven. The symptoms which were known by most women were swelling or lump in the armpit, and lump in the breast or thickening in the breast. The symptoms least well known were dimpling of the skin and pain in one breast that is different from normal (see Table 37).

Table 37. Symptoms of breast cancer and number (%) of respondents identifying them

Symptoms	Number correct (%)
Lump in the breast or thickening of the breast	240 (92%)
Swelling, or lump in the armpit	238 (91%)
Discharge from the nipple	209 (80%)
Change in shape or size of breast	192 (73%)
Change in nipple position	172 (66%)
Dimpling of the skin around the breast	167 (64%)
Pain in one breast which is different from normal	166 (63%)

Women were less likely to know risk factors than symptoms. The number of women knowing no risk factors was 10%, with 10% knowing all the risk factors. The risk factor most commonly known was having a family history of breast cancer and the risk factors least commonly know were age and diet (see Table 38).

Table 38. Breast screening: risk factors for breast cancer and number (%) of respondents identifying them

Risk factor	Number (%)
Family history of breast cancer	225 (86%)
Previous history of breast cancer	206 (79%)
Using hormone replacement therapy (HRT) for more than ten years	174 (66%)
The older you are	95 (36%)
Eating a diet high in saturated fat	61 (23%)

Intentions and behaviour

Data from 259 cases were analysed (3 had missing values for behaviour in terms of attending for screening or not). In 2002/2003, uptake of breast screening in Scotland was 74.9%.[51] As shown in Table 32, uptake for the total sample was 73% but it was 87% for those who returned the questionnaire. Analysis was performed to determine the relationship between previous screening behaviour, current intentions and current screening behaviour in responders (Table 39). Previous participation in screening was compared with current participation (excluding new invitees) using a paired Wilcoxon Signed Ranks Test. Previous participation in screening was significantly associated with current participation in screening ($p<0.001$). A Mann Whitney test could not be performed on intentions defined in table 2 because of the empty cells. However, when categories of 'definitely not/probably not' were collapsed and 'definitely/probably' were collapsed, there was no significant difference between intentions and behaviour ($Z=-1.13$, $p>0.05$). Excluding people who were unsure, and those who said that they had already had the test, over 90% (142/157) behaved in a way which was consistent with their intentions.

Table 39. Breast screening: current screening behaviour by previous screening and intentions in responders

	Took part in current round of screening		
Previous screening history	Yes	No	Total
Previously taken part	166 (93%)	13 (7%)	179 (100%)
Previously not taken part	20 (61%)	13 (39%)	33 (100%)
			(Z = -6.2)**
New invitee	40 (85%)	7 (15%)	47 (100%)
Total	226	33	259
Intentions			
Definitely not	3 (60%)	2 (40%)	5 (100%)
Probably not	0 (0%)	4 (100%)	4 (100%)
Unsure	3 (60%)	2 (40%)	5 (100%)
Probably	7 (87%)	1 (12%)	11 (100%)
Definitely	129 (92%)	11 (8%)	141 (100%)
Already been for it	84 (86%)	12 (14%)	98 (100%)
Total	226	32	258*

All percentages rounded to nearest integer; * 1 missing value for intentions;
** $p<0.001$

[51] Source: http://www.isdscotland.org/isd/files/cancer_brstscreen_attendscot_a.xls. Last accessed 01/05

Reasons why women did not want to have a mammogram (barriers)

Fourteen women said that they were definitcly not, unsure, or probably not going to go for a mammogram. Of these, three cited fear of what the test might find out as a reason, seven cited dislike of the test, three indicated that it was because they had done the test previously, and one did not know what a mammogram was.

Attitudes and beliefs

Twenty questions on attitudes and beliefs about breast screening were asked. Exploratory factor analysis was performed on these items. The KMO coefficient was 0.794, and Bartlett's Test of Sphericity was 833 (df 36, $p<0.001$) indicating that the data were appropriate for factor analysis. After exploring the data using an oblique rotation, including and excluding different items, 9 items with reasonable communalities (>0.3) were included in the factor analysis. In the final model, two factors explained 58% of the initial variance and 47% of the variance after rotation, and had eigenvalues greater than one. These factors were defined as motivations and attitudes (37% of variance) and decision-making (10% of variance). The rotated pattern matrix (Table 40) shows which of the items (indicated in bold) loaded most closely with each factor. Seven items loaded onto factor 1 (attitudes and motivations), and two loaded onto factor 2 (decision-making).

Table 40. Breast screening: rotated pattern matrix

	Factor	
	Attitudes and motivations	Decision making
I want to know if I have cancer	**-.538**	-.049
I think that I would benefit from screening	**-.774**	.188
I think screening for cancer is a good thing	**-.775**	.162
I think screening for cancer is a waste of money	**.611**	.102
I think screening is a waste of time	**.619**	.215
I can't be bothered to have a screen	**.622**	.093
I am not a believer in screening for cancer	**.656**	.080
I would like to discuss my decision with my doctor or nurse	-.013	**.701**
I want my doctor/ nurse to decide if I am screened or not	.077	**.677**

Extraction Method: Principal Axis Factoring. Rotation Method: Oblimin with Kaiser Normalization.

Reliability of the factors

Once the factors had been defined, reliability analysis was performed (Table 41). Cronbach's alpha for the motivation factor was 0.84, and for the shared decision making it was 0.69. Corrected item-total correlations were all greater than 0.5.

Table 41. Breast screening: reliability of the two factors

Item	Corrected Item – total correlation	Cronbach's coefficient alpha (item deleted)
Attitudes and motivation	**Alpha for factor =.84**	
I want to know if I have cancer	.51	.83
I think that I would benefit from screening	.60	.82
I think screening for cancer is a good thing	.62	.82
I think screening for cancer is a waste of money	.60	.82
I think screening is a waste of time	.62	.82
I am not a believer in screening for cancer	.64	.81
I can't be bothered to have a screen	.59	.82
Decision making	**Alpha for factor =.69**	
I would like to discuss my decision with my doctor or nurse	.53	n/a
I want my doctor/ nurse to decide if I am screened or not	.53	n/a

Numbers in bold indicate the standardised Cronbach's alpha for the scale

6.6 Modelling of the breast screening data

1. Variables predicting perceived informed choice

As discussed in Chapter 4 (section 4.38), informed choice did not factor as a latent variable. In addition the item, 'I feel I have made an informed choice' was highly skewed towards agree and strongly agree. This variable was dichotomised into strongly agree (1) and not strongly agree (0). Sociodemographic variables were entered first using the stepwise method, then the other factors, previous screening history and domains of knowledge were added using a stepwise model. A total of 262 cases were included. The final model shown in Table 42 included three variables (attitudes and motivations, knowledge of the consequences of screening and not participating previously) which could explain 24%-32% of the variance. Overall the model could correctly predict 73% of cases (66% of people who did not strongly agree with the statement 'I feel I have made an informed choice' and 79% of people who did agree).

Table 42. Breast screening: significant predictors of perceived informedness

	B	S.E.	Wald*	Sig.	Exp(B)	95.0% C.I. for EXP(B)	
						Lower	Upper
Attitudes and motivations	1.321	.260	25.725	.000	3.745	2.248	6.239
Knowledge of consequences	.685	.253	7.312	.007	1.984	1.207	3.260
Not participating previously	1.271	.568	5.011	.025	3.378	1.171	10.846

*df =1

This model was re-run with the standardised knowledge variable entered instead of domains of knowledge. The two significant predictors were knowledge, and attitudes and motivations. Attitudes and motivations accounted for most of the variation. The R square for the model was between .228 and .303.

2. Variables predicting informed choice (theoretical definition)

The analysis was run using all of the four categories of informed choice. However, overall the model could correctly only predict 39% of cases and therefore is not reported here. The analysis was re-run using just the two categories of uninformed choice and informed choice. 104 cases were included in the analysis. The Hosmer and Lemeshow test was not significant indicating that it was a good fit. However, at best it could explain 12-18% of the variance. Overall the model could correctly predict 65% of cases (68% of people who had uninformed behaviours, and 62% of people who made informed choices). The significant variable was using the information to make their choice (see Table 43).

Table 43. Breast screening: significant predictors of informed choice

	B	S.E.	Wald	Sig.	Exp(B)	95.0% C.I. for EXP(B)	
						Lower	Upper
Used the information	.992	.496	4.004	.049	2.696	.990	6.649

3. Variables predicting screening behaviour

Screening behaviour (screened or not screened) was entered as the dependent variable. Variables were entered in blocks using a stepwise (LR) method. As for colorectal screening, the best model was the one which could correctly predict membership of people not taking part in screening. The final model accounted for between 17 and 31% of the variance with the Hosmer and Lemeshow Test showing that it was a good model.

It correctly identified 35% of non-participants and 100% of participants (overall percentage 92%). The significant predictors were previous screening history (previous non-participants and new invitees were less likely to participate than previous participants) and having higher knowledge of the consequences was also a predictor of non-attendance.

Table 44. Breast screening: variables predicting screening behaviour

	B	S.E.	Wald	Sig.	Exp(B)	95.0% C.I. for EXP(B)	
						Lower	Upper
Previous non-participant	-2.304	.639	12.981	.000	.100	.029	.350
New invitee	-1.265	.598	4.471	.034	.282	.087	.912
Knowledge of consequences	-1.294	.475	7.411	.006	.274	.108	.696

4. Variables predicting screening intention and factors predicting differences between intentions and behaviour

An analysis was not run because only 7 people said that they definitely/probably would not be screened.

5. Variables predicting knowledge

Linear regression was performed using the standardised knowledge score as the dependent variable. However, the best model, which had post-school education as a significant predictor only gave an adjusted R square of 0.040, which is too low to be meaningful.

6. Variables predicting choice

The choice variable was far from normally distributed, so was dichotomised into high choice and low choice, using 0 (mean) as the cut off. Sociodemographic variables were entered first, followed by knowledge items and pre-screening history. However, at best the model could only predict 4% of the variance and none of the variables was significant.

6.7 Sociodemographic and other characteristics of the sample

The sample comprised women aged 20-61 years who had been invited for cervical screening. Women from three general practices located within either Edinburgh or West Lothian were sent a questionnaire just after being invited for screening.[52] The practices were chosen to represent a diversity of locations (e.g. Edinburgh and two more rural areas of West Lothian). A total of 352 questionnaires were sent out. Of these, 20 were returned as the person had left the address, and were excluded from any further analysis. Of the 332 that were included, 100 were returned completed (30%).

Testing for non-response bias

Table 37 presents details of the sample population, and the characteristics of those who responded to the questionnaire and those who did not.

Table 45. Cervical screening: characteristics of sample

Characteristic	Total sample (n=332)	Respondents (n=100)	Non respondents (n=230)	Statistical testing[#]
Age Median (IQ range)	35 (19) range: 20-62	38 (21) range: 20-62	34 (18) range:20-59	Z =-3.1*
Social deprivation score[‡] Median (IQ range)	31 (15) range: 0.65-85	31 (12) range: 0.65-85	31 (19) range: 1.1-85	Z=-1.2
Previous screening				
Participated	246 (74%)	79 (79%)	166 (72%)	
Did not participate	35 (11%)	11 (11%)	23 (10%)	
Not invited (new invitees)	51 (15%)	10 (10%)	41 (18%)	$\chi^2_2 = 3.5$
Current screening[$]				
Participated	127 (39%)	57 (59%)	70 (31%)	
Did not participate	196 (61%)	40 (41%)	156 (69%)	$\chi^2_1 = 18.3$**
Practice				
Practice 5	87 (26%)	31 (31%)	55 (24%)	
Practice 6	118 (35%)	36(36%)	81 (35%)	
Practice 7	127 (38%)	33 (33%)	94 (41%)	$\chi^2_1 = 2.8$

[‡]308 postcodes could be converted into deprivation scores

*p<0.01; ** p<0.001

[#] for differences between responders and non-responders; [$]3 in the responders and 12 in non-responders were not eligible (primarily due to pregnancy) or not able to be classified

The age variable amongst the sample was positively skewed with a higher percentage of the sample being younger (median 35 years). Therefore, the median and IQ range are

[52] A single month's screening list was used in each practice to make the process as simple as possible for General Practice staff involved.

reported, a Mann-Whitney test used to test for significant differences between responders and non-responders. As can be seen from Table 45, responders were significantly older than non-responders (38 vs. 34 years, $p<0.01$).

Previous and current participation in screening

The sample comprised 74%, 11%, and 15% of previous attendees, non-attendees and new invitees respectively. There was no difference in previous screening history between responders and non-responders. Of those who had previously been invited for screening (i.e. excluding the new invitees), 87.5% had previously participated in screening. The uptake of cervical screening in Scotland in 2004 was 80.6%[53], and in Lothian it was 88.3%.[54] Therefore the rate of previous participation in the sample was higher than national levels, but similar to local levels.

Current uptake of screening in the sample was 39%, which was much lower than expected. However the women invited for screening were a mixture of people at different stages in the call-recall process. Although the outcome of uptake was measured 3-4 months after the questionnaires had been sent out, that might not be a true reflection of uptake and it might be higher if measured at a later point in time. However, this seemed to offer sufficient time to see most of the effect and avoid delaying the study.

Deprivation scores and practices

The median deprivation score for the total sample was 31 (range 0.64-85.15). There were no significant differences in deprivation scores between those who sent back the questionnaire and those who did not. There were no significant differences in response rates between the three different practices (Table 45). However, the practices had been selected to sample people from a range of areas and therefore practices did differ by social deprivation score (see Table 46). In particular, practice 6 included people from significantly more deprived areas than the other two. However, the large range suggests that the sample included people from both very deprived and very affluent areas. This was in contrast to practice 7, where the participants were almost entirely from wards with a SIMD score of 29.

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[53] Excludes Lothian NHS Board (data unavailable/calculated on a different basis).

[54] Figures are derived from GP self-reporting claim forms submitted to Primary Care Finance in support of claims for target payments (source http://www.isdscotland.org/isd/files/Uptake_rates_by_NHS_board.xls).

Table 46. Cervical screening: practice and deprivation score

Practice	Total sample	
	N	Median (range)
5	86	12 (1-33)
6	103	85 (5-85)
7	119	29 (16-31)
Total	308†	

†24 post codes could not be computed into scores

Representativeness of the sample

Deprivation scores

For the whole sample and responders the mean scores were 31 (SD 25) and 31 (SD 27) respectively. In the Local Authority Area of West Lothian and Edinburgh City (the geographical areas from which the sample was derived), the average SIMD[55] were 19.76 and 16.26 respectively (Social Disadvantage Research Centre, 2003). The average SIMD scores in all the Scottish Local Authority Areas (n=32) range from 9.07 to 46.88 (mean 21.38). Therefore, both the sample and those who responded were from areas which had higher deprivation scores than both West Lothian and Edinburgh, and Scotland as a whole.

Occupation level of respondents

Census data was obtained for women aged 20-59 in West Lothian and Edinburgh combined, and for all Scottish women in that age group. For both groups, the respondents were significantly different from both the local population and the Scottish population ($p<0.001$). In particular women in the sample were more likely to be employed in routine occupations compared with either the local area or Scotland in general (29% vs. 9% and 11% respectively), and less in the managerial and professional jobs See Table 47).

[55] Population weighted average of the combined scores for the wards in a district or Local Authority Area

Table 47. Cervical screening: occupational classification for respondents, women in Edinburgh and West Lothian and Scotland[56]

Occupational level	All Respondents %	Local area aged 20-60 %*	Scotland aged 20-60 %**
Higher managerial and professional occupations	4	10	6
Lower managerial and professional occupations	8	30	27
Intermediate occupations	25	21	19
Small employers and own account workers	1	4	4
Lower supervisory and technical operations	6	4	5
Semi-routine occupations	20	17	21
Routine occupations	29	9	11
Never worked or long term unemployed	8	4	5
	99% (100)	99% (163285)	100% (1196364)

All percentages rounded to nearest integer; *χ^2_7 =53.89 (p<0.001); ** χ^2_7 =36.27 (p<0.001)

Highest level of education

People who did not wish to answer and missing values (14 people and 1 person respectively) were excluded from the comparison analysis. Comparisons were made with women aged 20-59 in West Lothian and Edinburgh combined, and the whole of Scotland (see Table 48).

Table 48. Cervical screening: educational level for respondents, women in Edinburgh and West Lothian and Scotland[57]

Educational level	Respondents %	Local area* Aged 20-59	Scotland** Aged 20-59
No qualification	20	20	30
O'levels	20	24	25
Highers	14	17	15
Diploma	29	7	7
Degree	16	32	22
Total	100% (85)	100% (180695)	100% (1551731)

* χ^2_4 = 67 (p<0.001); ** χ^2_4 = 64 (p<0.001)

There was a statistically significant difference in education level between responders and both the local population and the Scottish population. The main difference between responders and the local area was the higher number of people with diplomas, and relatively low number of degrees. The local area probably had a higher percentage of

[56] Census table S42 Sex and NS-SeC by age (http://www.scrol.gov.uk/scrol/common/home.jsp)
[57] Census table CAS204 Age by highest level of qualification (http://www.scrol.gov.uk/scrol/common/home.jsp)

people with degrees than the general population because Edinburgh is both a University City and the capital of Scotland.

Summary of evidence of non response bias, and representativeness of the sample

Women who responded were more likely to have participated in screening (both currently and previously) than those that did not respond, and also tended to be slightly older (38 vs. 34 years) than non-responders. Although both the sample and those who responded were from areas with higher deprivation (i.e. more deprived) scores than the Scottish average, they were also more educated. Therefore, there was evidence of non-response bias, and the responders were not representative of the Scottish cervical screening population.

6.8 Analysis of cervical screening questionnaire data

The following section is an analysis of data primarily taken from the questionnaire.[58] Firstly the bivariate relationship between intentions and behaviour are examined, then reliability of knowledge items and factor analysis of the attitude items.

Degree of informedness

Twelve items assessed knowledge and understanding of cervical cancer and cervical screening. The mean score was 6.0 (SD 1.9), with the median being 6. Scores range from 0 to 11. Unlike breast and colorectal screening invitees, it is not routine in all General Practices to send invitees an information leaflet. Twenty four percent of women indicated that they had not been given any information, but their knowledge scores were not significantly different (mean 5.92, SD 1.9). Those items of information which are covered in the screening leaflet[59] are highlighted in bold in Table 49.

[58] Data for past screening history was obtained from the screening unit
[59] 'The Cervical Smear Test', produced by Lothian Health

Item difficulty and uncertainty

Item difficulty in the knowledge questions ranged from 0.06 to 0.94 (Table 49). The scores for item uncertainty ranged from 0.04 to 0.59. In particular, women seemed to have a good understanding of what screening was for, and knowing that a woman could get cancer even if she felt well. Questions that women found difficult included the number of false negatives, and knowing that some people might have job or insurance difficulties. Women also had less difficulty answering the question about an abnormal result than a normal result. The degree of item uncertainty was related to the questions which people had most difficult with, which included questions about symptoms and risk factors.

Few items discriminated well between those who score high on knowledge and those who scored low. Those who did were 'knowing at least one symptom', and 'knowing that some cancers will not be picked up by the test'. The overall alpha was 0.63. The corrected inter-item correlations were low, with only one item achieving the 0.5 cut-off point.

Table 49. Cervical screening: content domains and knowledge items

Domain	Item	Item difficulty	Item uncertainty	Corrected Item – total correlation	Index of discrimination (D) (%)	Cronbach's coefficient α (item deleted)
Natural history	Incidence of cervical cancer	.76	.40	.13	24	.63
	Knew any symptoms	.59	.59	.30	50	.60
	Knew any risk factors	.63	.63	.28	26	.61
Understanding of screening	Screening is not only for people who have symptoms	.06	.04	.46	7	.59
	Screening will not prevent people getting cancer	.20	.06	.28	19	.60
Understanding of screening results	**Knowledge of a negative (normal) result**	.69	.18	.14	33	.63
	Knowledge of a positive (abnormal result)	.13	.09	.04	21	.57
Limitations of the test	**Some cancers will not be picked up by the test**	.47	.37	.35	49	.59
	How many do you think will be missed?	.94	.28	.53	2	.64
Consequences of screening/ treatment effectiveness	Some people might have insurance/job problems if their cancer is found early	.91	.38	.07	-1	.64
	Some people may be diagnosed with cancer when they feel well	.17	.10	.41	20	.58
	A cancer might be found that cannot be treated	.42	.27	.38	39	.58

Knowledge of individual risk factors and symptoms of screening

Nearly 60% of women did not know any of the symptoms of cervical screening and less than 10% knew all the symptoms. The symptom most well known was abnormal bleeding, and the symptom least well known was vaginal discharge (Table 50).

Table 50. Symptoms of cervical cancer and number (%) of respondents identifying them

Symptoms	Number (%)
Abnormal bleeding between periods or after sex	37 (36%)
New bleeding after the menopause	25 (25%)
Pain or discomfort during sex	26 (26%)
Vaginal discharge	23 (23%)

Knowledge of cervical risk factors was also poor, with over 60% of women not knowing any of the risk factors.The risk factor most well known was smoking, and the one least well known was being poor. Only 11% of women correct identified Human Papilloma Virus despite the fact that it is the primary risk factor.

Table 51. Risk factors for cervical cancer and number (%) of respondents identifying them

Risk factor	**Number (%)**
Being a smoker	27 (26%)
Having had many sexual partners	20 (20%)
Long term use of the pill	18 (18%)
Having sex at an early age or an early first pregnancy	17 (17%)
Having the Human Papilloma Virus	11 (11%)
Having a partner who has had many sexual partners	10 (10%)
Being poor	3 (3%)

Screening behaviour and intentions

Three variables related to screening behaviour: past screening behaviour; intentions and current screening behaviour. As shown in Table 45, participation in the current round of screening (uptake) for the total sample was 39%, but 59% for those who returned the questionnaire. Analysis was performed to determine the relationship between previous screening behaviour, current intentions and current screening behaviour. Previous participation in screening was significantly associated with current participation ($Z=-5.5$, $p<0.001$) and also whether they intended to go for a smear test (Pearson's correlation 0.504, $p< 0.01$).

Although 62 people said they were probably/definitely going to have a smear test, only 57 had done so three months after receiving their invitation.

Table 52. Cervical screening: current screening behaviour by previous screening and intentions in responders

	Took part in current round of screening		
Previous screening history	Yes	No	Total
Previously taken part	51 (67%)	25 (33%)	76 (100%)
Previously not taken part	1 (9%)	10 (91%)	11 (100%)
			(Z=-5.5)**
New invitee	5(50%)	5 (50%)	10(100%)
Total	57	40	97*
Intentions			
Definitely not/probably not	0 (0%)	4 (100%)	4 (100%)
Unsure	0 (0%)	6 (100%)	6 (100%)
Probably/definitely	34 (55%)	28 (45%)	62 (100%)
Already been for it	23 (92%)	2 (8%)	25 (100%)
Total	57	40	97

All percentages rounded to nearest integer; *3 became pregnant or were otherwise ineligible
** p<0.001

Reasons why women did not want to have a smear test (barriers)

Eleven women said that they were uncertain or definite that they would not send back the test. Of these, six indicated it was because of fear of what it would find out, five said that it was because of doing the test previously and one also said it was for cultural reasons.

Attitudes and beliefs

Similar to breast screening invitees, twenty items on attitudes and beliefs were asked (see section on breast screening). After exploring the data using an oblique rotation, including and excluding different items, seven items with reasonable communalities (>0.3) were included in the factor analysis. In the final model, two factors explained 63% of the initial variance and 50% of the variance after rotation, and had eigenvalues greater than one. These factors were defined as motivations (34% of variance) and perceived informedness (16% of variance). The pattern matrix (Table 53) shows which of the items (indicated in bold) loaded most closely with each factor. Four items loaded onto factor 1 (attitudes and motivations), and three onto factor 2 (perceived informedness).

Table 53. Cervical screening: pattern matrix

	Factor	
	Attitudes and motivations	Perceived informedness
I want to know if I have cervical cancer	**.810**	-.219
I think that I would benefit from having a cervical smear	**.559**	.216
I think screening for cervical cancer is a good thing	**.557**	.199
I feel pressure from others to have a cervical smear	**-.637**	.006
I feel I know the benefits of cervical screening	.003	**.795**
I feel I know the limitations of cervical screening	-.102	**.819**
I feel I have made an informed choice	.220	**.524**

Extraction Method: Principal Axis Factoring. Rotation Method: Oblimin with Kaiser Normalization.
a Rotation converged in 8 iterations.

Reliability of the factors

Once the factors had been defined, reliability analysis was performed. The overall Cronbach's alpha for the eight items was 0.75. Corrected item-total correlations were also calculated for each item and all were 0.4 or greater (Table 54).

Table 54. Cervical screening: reliability of the two factors

Item	Corrected Item – total correlation	Cronbach's coefficient alpha (item deleted)
Attitudes and motivation	**Alpha for factor =.73**	
I think that I would benefit from having a cervical smear	.51	.68
I think screening for cervical cancer is a good thing	.50	.68
I want to know if I have cervical cancer	.60	.63
I feel pressure from others to have a test	.51	.69
Perceived informedness	**Alpha for factor =0.79**	
I feel I know the benefits of cervical screening	.71	.61
I feel I know the limitations of cervical screening	.67	.66
I feel I have made an informed choice	.51	.82

Numbers in bold indicate the standardised Cronbach's alpha for the sub-scale

6.9 Modelling of the cervical screening data

1. Variables predicting perceived informed choice

In this analysis, the factor of perceived informedness was the dependent variable. Sociodemographic variables were entered first using the stepwise method, then the other factors, previous screening history and domains of knowledge were added. As neither educational nor occupational levels were significant in the initial modelling, they were left out, to allow more cases to be included. Age was the only significant sociodemographic predictor of perceived informedness.

All 100 cases were included. Using the stepwise method within each level of inclusion a significant model emerged ($F_{(1,95)}$=4.1, p<0.05). The adjusted R square was 0.26. The factor of attitudes and motivations was the most significant predictor, and knowledge of the disease and knowledge of consequences were the two domains of knowledge which were significant (see Table 55).

Table 55. Cervical screening: significant predictors of perceived informedness

	Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
	B	Std. Error	Beta			Lower Bound	Upper Bound
Age	.014	.006	.185	2.092	.039	.026	.001
Attitudes and motivations	.334	.089	.328	3.758	.000	.158	.510
Knowledge of consequences	.276	.107	.228	2.589	.011	.488	.064
Knowledge of disease	.177	.081	.197	2.193	.031	.337	.017

2) Variables predicting informed choice (theoretical definition)

Forty nine cases were included in the logistic regression modelling analysis (see Table 56). The Hosmer and Lemeshow test was not significant indicating that it was a good fit, and it could explain 25-33% of the variance. Overall the model could correctly predict 70% of cases (53% of people who had uninformed behaviours, and 87% of people who made informed choices). After adjusting for sociodemographic variables, the only significant predictor was previous non-participation.

Table 56. Cervical screening: significant predictors of informed choice

	B	S.E.	Wald	Sig.	Exp (B)	95.0% C.I.for EXP(B)	
						Lower	Upper
Previous non-participant	-2.303	1.156	3.967	.046	.100	.010	.964

3. Variables predicting screening behaviour

The final model which was the best fit for predicting screening behaviour in cervical participants had an R square of between .22 and .30. The full model was significantly reliable (Hosmer and Lemeshow Test $\chi^2_8 = 10.7$, $p>0.5$). Overall it correctly predicted 75% of behaviour (50% of those that did not take part and 90.2% of those that did). The significant variables were previous non-participation, knowing about the results and attitudes towards cervical screening (Table 57).

Table 57. Cervical screening: significant predictors of screening behaviour

	B	S.E.	Wald	Sig.	Exp (B)	95.0% C.I. for EXP(B)	
						Lower	Upper
Non participation	-2.741	1.221	5.043	.025	.064	.006	.706
Knowledge of results	1.444	.556	6.744	.009	4.237	1.425	12.600
Attitudes and motivations	.874	.388	5.082	.024	.417	.195	.892

4. Variables predicting screening intention

This analysis was not performed due to the small numbers of people saying that they would not take part (n=4).

5. Variables predicting knowledge

Socio-demographic variables (educational level, occupational level, sex, age) were entered first, then previous screening history and the factors of attitudes and influence from others. Using the stepwise method, a significant model emerged ($F_{3,81}$ =7.4, p<0.001, adjusted R square = 0.19). Significant predictor variables were a higher educational level and increasing age (Table 58). However, the model at best could only predict 19% of the variance in knowledge scores.

Table 58. Cervical screening: significant predictors of knowledge

	Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
	B	Std. Error	Beta			Lower Bound	Upper Bound
Age	.060	.016	.388	3.810	.000	.029	.091
Post school education	1.661	.507	.437	3.273	.002	.651	2.671
School education	1.112	.544	.278	2.043	.044	.029	2.194

6. Variables predicting choice

The standardised choice score was used as the dependent variable for this analysis. The variable was not normally distributed, so was dichotomised into high choice and low choice, using 0 (mean) as the cut off. Sociodemographic variables were entered first, followed by knowledge items, pre-screening history and the variable of decision-making. The final model accounted for between 20% and 33% of the variance. The model correctly predicted 66% of cases (81% in the low choice and 46% in the high choice) and the significant predictor variable was knowledge of the disease (Table 59).

Table 59. Cervical screening: significant predictors of choice

	B	S.E.	Wald	Sig.	Exp (B)	95.0% C.I. for EXP(B)	
						Lower	Upper
Knowledge of disease	.477	.242	3.889	.049	1.612	1.003	2.589

6.10 Summary and discussion of the results from the survey

The following section summarises the main results from the data analysis, and compares and contrast the findings from the different types of cancer screening.

Response bias and generalisability

Analysis of the sociodemographic and screening data indicated that responders differed from non-responders for all three types of cancer screening. In particular, they had a higher level of education than non responders, were more likely to have previously participated in the previous round, and also more likely to have taken part in the current round. The non-representativeness of the responders raises important issues about the validity and the generalisability of the measures. For example, those people returning the questionnaire may have a more positive attitude to screening, they may also be more informed than non-responders, and also more able to make choices free from coercion or external pressure.

The response rate differed by screening type, with those invited to breast screening being more likely to respond than those invited for colorectal or cervical screening (55% vs. 40% and 31% respectively). These response rates were almost identical to those found in the pilot. It is beyond the scope of this study to assess why women invited for breast screening were more likely to send back a questionnaire. However, age and gender were not able to explain the differences; participants in both the colorectal and the breast cancer groups were of the same age, and the response rate in women in the colorectal group was low. In addition, there was no difference between men and women responding in the colorectal group, so gender does not explain the difference either. The most likely explanation is salience of the topic. Breast cancer is the most widely publicised cancer of the three cancers, especially in women's magazines and other types of mass media.

Knowledge or informedness

People invited to the three types of cancer screening differed in the amount and type of information they knew. Table 60. shows the percentage of people getting the items correct for each type of screening. With regard to the natural history of the disease, those

invited for breast screening were more likely to know the incidence of the disease than colorectal or cervical invitees. In fact, women invited for breast screening were twice as likely to know at least one symptom or risk factor as those invited for cervical screening. This finding is consistent with the findings from the focus groups (see Chapter 5, part 1).

Knowledge about the purpose of screening was high (80%) for all three types of invitees with little difference between the three groups, although cervical screening invitees were less likely to know that screening would not prevent a person getting cancer ($p<0.05$).

Knowledge about the meaning of test results differed between the items; people were more likely to know what a positive result meant than a negative result. There were also variations between the screening invitees; only 32% of women invited for cervical screening knew that a negative normal result did not mean they had cancer compared with 57% and 63% in the breast and colorectal invitees respectively ($p<0.001$). Again these findings are consistent with the finding from the focus groups, whereby people generally thought that a negative result meant that they definitely did not have cancer.

Although over 50% of people knew that some cancers would not be picked up by the test, less than 10% of people knew about other limitations of screening. These were the items of knowledge that people invited for all three types of screening found most difficult.

People knew about some of the consequences of screening, but not others. For example, over 80% of responders knew that some people may be diagnosed with cancer when they feel well, but less than 20% of responders knew that some people might have insurance or job problems if their cancer is found early.

Table 60. Percentage getting knowledge items correct for each of the three types of screening

Domain	Item	Colorectal %	Breast %	Cervical %	Sig*
Natural history	Incidence of cancer	31	49	26	p<0.001
	Knew any symptoms	81	95	42	p<0.001
	Knew any risk factors	59	89	38	p<0.001
Understanding of screening	Screening is not only for people who have symptoms	95	99	96	p=n.s
	Screening will not prevent people getting cancer	87	93	82	p<0.05
Understanding of screening results	What a negative result means	63	57	32	p<0.001
	What a positive result means	75	98	89	p<0.001
Limitations of the test	Some cancers will not be picked up by the test	70	69	54	p<0.05
	Number of cancers missed	6	8	6	p=n.s
	Having further tests might harm some people	4	2	N/a	p=n.s
Consequences of screening/ treatment effectiveness	Some people might have insurance or job problems if their cancer is found early	16	16	9	p<0.05
	Some people may be diagnosed with cancer when they feel well	92	94	85	p<0.05
	Some cancers progress so slowly that they do not need treatment (DCIS)	N/a	11	N/a	N/a
	A cancer might be found that cannot be treated	71	82	59	p<0.05

Percentages rounded to nearest integer; * Kruskal-Wallis Test was used to test for differences between the types of cancer screening

Intentions and behaviour

Intention to take part in screening was associated with final screening behaviour for all three types of screening. However, people were more likely to behave in a way which was consistent with their intentions in the breast screening group (90%) compared with the colorectal (78%) and cervical (57%) screening. In addition, for all three types of screening, previous behaviour was significantly associated with current behaviour.

Reasons why people did not go

Across the three types of screening, the most common reasons people cited for not taking part in screening were fear of what the test might find out and dislike of doing the test. Consistent with the finding from the focus groups, the barriers to participating in

screening were generally about the process, or fear of finding out that they had cancer, rather than having a negative attitude towards the concept of screening.

Attitudes and beliefs

Factor analysis identified different latent variables for the three types of screening, although the factor of attitudes and motivations was common to all three. For colorectal screening three variables were identified - perceived informedness (knowledge of benefits and limitations, and feeling they had made an informed choice), attitudes and motivations and influence from others. For breast screening two variables were identified – attitudes and motivations and decision making. For cervical screening, two variables were also identified - perceived informedness and attitudes and motivations. These two variables of attitudes and informedness were highly correlated with each other in both the cervical and colorectal data, and this relationship was confirmed in the modelling of the data.

6.11 Modelling of the data

The modelling of the data evaluated the predictors of several of the variables of interest, and those included in the model of informed choice (see Figure 4).

Variables predicting perceived informed choice

The factor of perceived informedness was used in this analysis for colorectal and cervical screening; for breast screening it was the variable: 'I feel I have made an informed choice.' However, this variable was highly skewed with most people either agreeing or strongly agreeing with the statement. For cervical and breast cancer, this was the factor of 'perceived informed choice' which represented three or more items This item was converted to a dichotomous variable, 'Strongly agree' vs 'Not strongly agree.' The analysis was undertaken using both the total knowledge score and also the individual domains of knowledge. For all the types of screening, the main predictors of the perceived informedness were knowledge scores and particularly, whether they had a positive attitude towards screening.

However, although a high total knowledge score was a significant predictor of perceived informedness, not all the individual domains of information were significant (see Table

61). For colorectal screening and cervical screening the common significant domain of information was knowledge of the disease. This finding is consistent with the findings from the qualitative study where information about the disease was viewed as being one of the most important pieces of information. This domain of information was not significant for breast screening. However, women in the breast screening sample were more informed than the colorectal and cervical screening invitees about the incidence of the disease, the risk factors and the symptoms. Therefore it is possible that because this information (on breast cancer) is well known, it is not viewed by women as being part of being informed.

Knowing about the consequences of screening was also a significant predictor of perceived informed choice for cervical screening and breast screening, but the direction of the effect was different – for breast screening it was *not* knowing the consequences, whereas for cervical screening it was knowing the consequences. Other significant predictors were age (being older) for cervical screening and not having participated in screening previously (for breast screening).

Breast screening responders did appear to perceive informed choice differently from colorectal and cervical screening responders. These differences are reflected both in the variables, and in the predictors. However, across the three groups, knowing the risks of screening was not a predictor of whether they thought they had made an informed choice.

Table 61 Comparison between the three types of cancer screening for modelling of variable '*perceived* informed choice'

	Linear regression Standardized Coefficients (Beta)		Logistic regression Estimated log odds Exp(B)
	COLORECTAL	**CERVICAL**	**BREAST**
Age	-.043	.185*	n/a
Sex	.051	n/a	n/a
Attitudes and motivations	.561**	.328**	3.745**
Pressure from others[#]	-.044	n/a	n/a
Previous non participant	-.110	-.053	3.378*
New invitee	.044	.011	.092
Knowledge of disease	.182**	.197*	1.314
Knowledge of purpose	.015	.156	1.053
Knowledge of results	.028	.102	1.095
Knowledge of limitations	.021	.159	1.124
Knowledge of consequences	.054	.228*	-1.984*
Adjusted R square	*0.36*	*0.26*	n/a
Nagelkerke R Square	n/a	n/a	*0.32*

* p<0.05; ** p<0.001;
[#] Only colorectal screening had a factor for 'pressure from others'

Variables predicting informed choice (theoretical definition)

Table 62. shows a summary for the three types of cancer. In the binary logistic regression of the extreme quartiles, the only significant predictor of whether a person invited for colorectal screening was uninformed with little choice (compared to informed with a high degree of choice) was educational level. Non-participation was the only significant predictor for cervical screening invitees. For breast screening, the significant predictor was using the information (in the breast screening leaflets) to make their choice.

Table 62. Comparison between the three types of cancer screening for modelling of theoretical variable of informed choice'

	Logistic regression Estimated log odds Exp(B)		
	COLORECTAL	CERVICAL	BREAST
Age	n/a	1.017	.939
School education	.168*	.758	.402
Post school education	.064*	1.849	1.164
Previous non-participant	1.135	.100*	1.293
New invitee	1.622	.000	.409
Used information	.681	n/a	2.696*
Knew as much as they wanted to know	.867	n/a	1.181
Nagelkerke R Square	*0.16*	*0.18*	*0.33*

*p<0.05

The model was run for the whole sample, using screening type as an independent variable. However, after adjusting for educational level and previous screening history, there were no significant predictors of informed choice.

Intentions and behaviour

In this study, previous screening history was a major predictor of behaviour across the three groups. This finding is consistent with other research that has found previous screening history to be a major determinant of screening behaviour in empirical studies (Jepson et al, 2000). Although the factor of attitudes and motivations could predict whether a person participated in screening, it was less useful at predicting people who did not go (especially for colorectal screening).

Knowledge/informedness

The significant predictor of high knowledge for all three types of screening was higher educational level, and for colorectal and cervical, it was having previously participated in screening. Higher educational level has been found to be associated with knowledge in several other studies (e.g. Goel et al, 1996; Hennell et al, 2004; O'Dell et al, 1999). However, educational level was poor at predicting high levels of knowledge in the breast screening participants. This may be because the topic has great salience for all women, and the information is available from a variety of different sources, for example women's magazines and the media. Having the information available in a variety of

different formats and sources may affect understanding and knowledge. A model was run for the whole sample, with standardised knowledge score as the dependent variable and educational level (step 1), and screening type (step 2) as the independent variables. Educational level and type of screening were significant predictors of knowledge (with breast screening being the most significant predictor).

Choice

Whilst educational level was a predictor of knowledge, it was not a predictor of the degree of choice that a person perceived they had had in any of the three types of screening. However, there is no obvious theoretical reason why it might be more associated with some of the items in the choice construct, such as pressure from others, and knowing there is a choice to be made. The main predictors of choice in colorectal screening were age, knowledge of results, and previous screening history. For cervical screening the significant predictor was knowledge of disease, while for breast screening no significant predictors or a good model could be found. These results again suggest that there are differences between the three types of screening. When the model was re-run including the entire sample, with type of screening as a predictor variable, breast screening was a significant predictor of high choice. Previous participation was also associated with high choice.

6.12 Limitations of the survey and analysis

This study has two main limitations. Firstly there was evidence of a response bias for the three types of screening, which meant that modelling of the data on intentions and behaviour was limited, and the results are not easily generalisable. For example, it is not known if the sample is representative of the general population with respect to variables such as knowledge, attitudes and choice. Those people who responded may have higher levels of all three of these variables than non-responders.

Secondly, the analysis of knowledge and understanding was based on the assumption that ticking an item correctly was associated with correct knowledge. However, I acknowledge that such measurement will always be an approximation of the true extent to which people are knowledgeable about screening. Two possible sources of error or bias in the measurement of knowledge need to be acknowledged. Firstly, the higher

knowledge scores might be a reflection of whether a person read the leaflet or not rather than their actual knowledge. People had the information leaflet sent to them a number of days previously and might have found out the answers to the questions from the leaflet (although not all the information was in the leaflet). Secondly, those that did not tick any, or ticked the 'don't know' box might have done so because they were not interested in answering the questions.

6.13 Summary of the analyses

Despite the limitations of the sample and the data, the findings from the analyses of the questionnaire data add to the body of knowledge on informed choice in several ways. The analysis of the knowledge data suggests that all types (breast, colorectal and cervical) of screening invitees lack knowledge of consequences and limitations of the disease. This lack of knowledge occurs even when the invitees are given this information by screening programmes. There are significant variations in knowledge between the three types of screening invitees, with cervical screening invitees having less knowledge about the symptoms and risk factors of the disease, and what a normal result means.

Factor analysis also found differences and similarities between the three types of screening. Whilst perceived informedness was linked with knowledge of the benefits and limitations in colorectal and cervical screening, they were not linked with breast screening. This finding suggest that women going for breast screening may perceive themselves to be informed even when they only know the benefits of screening, rather than the limitations and consequences.

The modelling of the data suggested that perceived informedness was linked with knowledge of the disease for colorectal and cervical screening invitees, which is similar to the results of the qualitative study. When comparing the three types of screening, breast screening invitees were more knowledgeable and had more choice that the other two types of screening.

The aim of this study was to develop a valid and reliable measure of informed choice. It has been argued that validation is a process of hypothesis testing and that, rather than being constrained by trying to establish different types of validity (i.e. construct, content and criterion); researchers should only be constrained by devising experiments to test their hypotheses (Streiner and Norman, 1995; 146). However, whether the MICICS questionnaire has established construct, content and criterion needs to be discussed. The lengthy and rigorous process of developing the measure (i.e. use of qualitative data, expert opinion and theory to develop the items, and the piloting of the questionnaire) has ensured that MICICS has content validity. In addition, the similarities in domains of knowledge between the MICICS measure and the PROCASE measure (Radosevich et al, 2004), confirmed the content validity of the knowledge items.

As outlined in Chapter 4, for criterion validity to be established there needs to be a gold standard. However, one of the purposes of developing this measure of informed choice was that no other measure existed. Therefore, it is not possible to establish criterion validity within this study. This will need to be established in other studies.

Construct validity is the extent to which a construct conforms to theoretical expectations. As mention in Chapter 4, section 4.19) construct validity is an ongoing process, and can not be established in a single study. The underlying assumption of theories of informed choice is that choice would be higher among those people who had more knowledge, but this assumption was not reproduced in the data. However, data from the focus groups suggested that people's choices are not necessarily influenced by their levels of knowledge. There are two possible explanations for this finding. One is that the measure does not have construct validity; the other is that the underlying theory is not valid. Findings from both the qualitative and quantitative work suggest that the relationship between information and autonomy/choice is less clear than previously assumed. Therefore more empirical work needs to be undertaken in this area to determine the validity of the underlying theory.

Reliability is a necessary but insufficient pre-requisite for a valid measure (Bate son, 1984). The alpha coefficients for knowledge items indicated that not all were reliable. However, they were measuring the key domains of informed choice, and thus had validity. The alpha coefficients for the factor analyses for all types of screening indicated that the factors had good internal reliability, but their reliability in different populations (e.g. people who do not participate in screening) has not yet been established. The implications of the findings and further development of the MICICS are discussed further in Chapter 7.

CHAPTER 7. DISCUSSION, CONCLUSIONS AND RECOMMENDATIONS

This Chapter provides an overview of the main findings from the three research components in this thesis; the systematic reviews, the qualitative study, and the quantitative study. It also discusses its strengths and limitations, and how it contributes to the body of knowledge in this area. It also discusses implications for further research, policy and practice.

Summary of findings of the systematic reviews

The systematic review of instruments identified 5 measures of informed choice, knowledge, or decision making. However, no measure of informed choice in cancer screening was found. Most of the instruments identified were not used in the development of the MICICS questionnaire, although one subscale was used in the measurement of attitudes (Decisional Conflict Scale). In addition, one measure of knowledge (PROCASE) was used as a framework for the analysis of knowledge items in Chapter 5.

The qualitative review identified 5 relevant studies and a module of the DIPEx database (in cervical screening). Although all of the included studies included some discussion or analysis of what information people wanted about cancer screening, none of the studies had the specific objective of evaluating how people defined informed choice. The review found that there were several common themes in the studies. Of particular relevance was that participants' perceived definitions of informed choice differed from experts' definitions.

The quantitative review identified 16 intervention studies. The majority of the trials concerned prostate cancer screening. The informed choice interventions did appear to increase knowledge of the risks and benefits of screening. However, whether knowledge constitutes informed choice is debatable.

The synthesis of the qualitative and quantitative studies found that the definitions of informed choice in the studies might fail to adequately take into account the patient perspective. Nor did the interventions take into account the choices that people were able

to make, and how information contributed to these choices. Therefore, the extent to which these studies are measuring informed choice rather than just 'informedness' or knowledge is questionable. In addition, none of the interventions studied included all the domains of information recommended in the GMC guidelines.[60]

Summary of findings of the qualitative study

The qualitative study was initially undertaken to determine the keys areas of knowledge to be used in defining the items in the questionnaire. However, it also provided a rich source of data on how people defined choice, the information they wanted, and how they used it in their screening decisions. The qualitative study identified the following themes:

- People were generally not knowledgeable about either the disease being screened for or the limitations of screening. This lack of knowledge was particularly apparent in women invited for cervical screening.
- When people were asked about what information they would like to make an informed choice, many wanted information on the disease itself in addition to information on risks and limitations.
- Many people wanted the information, but said that it would not alter their decision to be screened. However, for some (particularly women invited for cervical screening) it was seen as a way of reducing anxiety over waiting for a test result, or knowing what unsatisfactory or abnormal results meant.
- Information may not have a large effect on choices people make, but may have an effect on other outcomes such as anxiety and satisfaction.

Summary of findings of the quantitative study

The MICICS questionnaire was developed using the findings of the focus groups and interviews, and the theories described in Chapter 2. It was piloted by sending it to a group of 150 people (50 for each type of cancer screening). It was then validated by sending it out to over 1200 people, just after they had received their invitation to be screened. The sample included people who had previously been invited as well as new invitees. The response rate differed between the three types of screening; 31% in cervical screening; 40% in colorectal screening and 55% in breast screening. This response rate could limit the generalisability of the results, particularly in the cervical screening (see section 7.2).

[60] Most of the studies were undertaken in the US, which may have different guidelines.

Analysis of the knowledge items found that, across the three types of screening, people were more informed about the symptoms than the risk factors. People were also well informed about the reasons for undergoing screening, but less informed about the negative consequences. People invited for screening lacked knowledge on some of the key domains of information, particularly the risks of screening, and some of the consequences. Some of these domains were covered by the information leaflets, whilst others were not.

Modelling of the data found that, although the total knowledge score was a significant predictor of perceived informedness, it was specific domains of knowledge that seemed to be important. In particular, knowledge of the disease was an important predictor of informed choice for colorectal and cervical screening invitees, which is consistent with the findings of the focus groups.

The variable of attitudes and motivations was the strongest predictor of whether people perceived they were making an informed choice. People who had a positive attitude towards screening were more likely to think themselves informed. However, this perceived informedness did not relate to knowledge of consequences. Therefore, perceived informedness appeared to relate more to feeling positive about the test rather than actually being knowledgeable about the risks and limitations. It has been argued that self-assessment (of informedness) may not be useful since a person may be satisfied with very little information, or they may think they understand something fully when they have incomplete or incorrect understanding (Green et al, 2004a).

In the theoretical definition of informed choice, modelling of the data found that there were different predictors of informed choice (high choice/high knowledge) between the three types of screening invitees. High education level was the only significant predictor of informed choice in colorectal screening invitees, while for cervical screening invitees it was previous participation in screening. For breast screening invitees, the significant predictor was using the information (in the breast screening leaflets) to make their choice.

7.1 Strengths of the research

The main aim of the research presented in this thesis was to develop a measure of informed choice in cancer screening. The use of mixed methods was a strength of the study, as were the use of different perspectives, and the inclusion of different types of cancer screening invitees. These strengths are summarised in this section.

In defining the research questions, and interpreting the findings from the empirical work undertaken in this thesis, I drew on a wide range of perspectives and paradigms. These perspectives enabled me to gain a greater understanding of the context, the application, and the interpretation of informed choice. If a strictly positivist and reductionist approach had been taken, then I would have focussed on measuring knowledge, and the behaviour that was undertaken. However I took a broader approach and focused on a number of different domains, which I argued in previous chapters to be important to informed choice. This led to the development of a more complex instrument, but one that had good validity.

The study incorporated three types of research, which meant that the central research question was assessed from different perspectives. In addition, the results from each type of research were used to assess the validity of the others. Synthesising both qualitative and quantitative studies in the systematic reviews was a particularly useful part of the literature review as it enabled me to get a greater understanding of informed choice, and provided me with insights that I would not have had if I had only included quantitative studies.

In a similar way, the qualitative study of informed choice in cancer screening enabled me to conceptualise informed choice in a more meaningful way than if I had been guided only by theoretical definitions (outlined in Chapter 2) or the GMC guidelines. Following the analysis of the qualitative data, I developed items for the MICICS questionnaire which were grounded in the patient perspective, as well as theory and guidelines. Using this combination of approaches meant I was confident that the questionnaire I developed had content validity.

When analysing the data from the questionnaire, I used the qualitative findings to confirm and explain some of the results. For example, one of the findings of the qualitative research was that people wanted information about the disease in order to feel informed, and this finding was confirmed in the analysis of the quantitative data. In addition, the qualitative data suggested that women invited for cervical screening were less knowledgeable than those invited for breast and colorectal, and this was also confirmed in the quantitative data.

Although the response rate was not high, and there was evidence of some response bias (see next section), the respondents came from areas with a range of levels of deprivation. Therefore, although the sample was not representative of the general population in all respects, it did include people from different backgrounds, with different educational levels. In particular, many of the women invited for cervical screening I interviewed in the qualitative research were from economically deprived areas, as well as those who responded to the questionnaire. Having these people included in the sample enable me to gain an insight into their views that is not always obtained in social research.

Finally, it is the first time that data on informed choice in cancer screening have been collected to allow for comparisons across different types of cancer screening. These comparisons in both the qualitative and quantitative data revealed subtle differences between the screening invitees in the way that information is used and choices are made.

7.2 Limitations of the research

Previous data chapters have summarised the limitations of the individual pieces of research. However, some limitations which were common to both the qualitative and quantitative studies need highlighting. Firstly, both the studies were undertaken within a limited geographical area, which may limit the generalisability of results. Secondly, both studies had some degree of response bias, which also limits generalisability to the wider population.

Finally, it is possible that the both the qualitative study and the questionnaire acted as interventions. As discussed in Chapter 4 (section 4.33) there is a possibility of a

Hawthorne effect. I was unable to assess this in the research, but it needs to be acknowledged as a further source of bias. If it did act as an intervention by encouraging people to find out more about screening, then people in the general population may have lower levels of knowledge and understanding.

The factor analysis may have been limited because of the small sample size, particularly for cervical screening (n=100). It has been recommended that factor analysis is not performed on a sample of fewer than 50 observations and preferably the sample should be greater than 100 (Hair and Anderson, 2003). Hair and Anderson (2003) suggest that the most acceptable size is to have a 10-to-one ratio of observations to variables. I had 13 variables which suggest that my sample size should have been at least 130 for each type of screening. However, as described in Chapter 4. (section 4.39), the set of items was assessed for its factoring adequacy by visually inspecting the correlation matrix, and using the Kaiser-Meyer-Olkin (KMO) and the Bartlett's Test of Sphericity statistics. In addition, measures of Sampling Adequacy (MSA) were inspected in an Anti-Image correlation matrix and any items with a value of <0.5 were excluded. Adhering to these set of procedures ensured that it was a robust factor analysis.

7.3 The contribution of this study to knowledge in this field

This research identifies the complexity of the relationship between information and choice. It contributes to the body of knowledge in this area in several ways. Specifically it examines the concept of informed choice from a number of different perspectives, including historical and ethical, patient and professional. These perspectives made me question the whole concept of 'informed choice' in the context of screening. I now believe that the complex relationships between information, knowledge and choice mean that the phrase 'informed choice' is not always either useful or informative. From the exploration of the notions of autonomy and informed choice in Chapter 2 it became clear that whilst knowledge and information can enhance choice and autonomy, there are many other factors which may be important. From the systematic literature reviews, and the primary research I undertook, I concluded that the definitions of informed choice (see Chapter 2) did not adequately reflect, nor take into account, some of the issues in

cancer screening - in particular the issue of individual choice in the context of a public health initiative.

All the research presented here supports the idea that informed choice can be viewed from different perspectives. For the modelling of the data from the questionnaire, I therefore defined informed choice in two different ways. Firstly, from the participants' perspective (perceived informedness) and then from a theoretical perspective. The participants' perspective was using items on informedness in the questionnaire. The theoretical definition was derived from definitions in the literature (see Chapter 2), the definition colleagues and I used in the Cochrane review (Broclain et al, 2004), and the finding from the systematic reviews and qualitative data. I defined a person making an informed choice as having:

1. *Information (or knowledge):* understanding of the disease being screened for (including symptoms and risks factors), the purposes of screening, the meaning of test results and some of the risks, limitations and consequences.
2. *Choice*: knowledge that there is a choice to be made; no coercion or pressure from others; a belief that screening would be beneficial as an individual; no known barriers to prevent their intended choice being implemented.

This definition is similar in many ways to those previously described in the literature, but it does have some important differences. Firstly, the type of information I defined as necessary to be 'informed'. I used the findings from focus groups as well as the GMC guidelines to construct the domains of information. This may be an incomplete list as the number of qualitative studies was small, and my qualitative study may have lacked generalisability. However, the domains are also very similar to those used in the development and validation of measures assessing patient knowledge about the risks and benefits of prostate cancer (CaP) screening (Radosevich et al, 2004). I had already completed my study before this study was published and therefore the similarity of the domains substantiates their validity.

When defining the types of information to be included in these domains, I was interested to know whether people had an understanding of risk, limitations and consequences of screening, rather than having specific knowledge of the magnitude of these risks. The

reason I focused on understanding of concepts rather than knowledge of more complex issues (such as relative and absolute risks) was that it is a new area of knowledge for many people. I think that people need to be aware of the concepts first, before specific items such as relative risks can have salience. This approach does have the potential to conflict with the body of literature on risk communication (discussed in Chapter 2). However, once people know that there are risks, consequences and limitations of screening, then they may be better able to understand the magnitude of these risks and consequences.

My definition of choice included four items. The first one was 'knowing that there is a choice to be made.' I included this item because the literature Chapter 2 suggests that in order for people to make intentional choices, they need to know that there is a choice. Several other definitions of informed choice and decision making include items on attitudes, particularly having an attitude consistent with the action (see section 2.17). I was cautious about including items on attitudes because data from the focus group suggested that many people who do not go for screening still have a positive attitude towards it. In addition, a person may hold conflicting but rational attitudes towards screening (e.g. *I think screening is a good idea, but I don't think it will benefit me*). After much consideration, I decided that the attitude item that was most relevant to informed choice was whether people felt they would benefit from going or not. The main reason I included this variable was that if people went but did not feel they would benefit it might indicate some underlying coercion or pressure. However, I acknowledge that some people may go for screening, not because it benefits them, but because it may benefit others.

In the measure of informed choice in antenatal screening, the authors argued that the attitude of relevance is not the attitude towards the test *per se*, but rather the attitude towards undergoing the test. Thus, an individual may have a negative attitude towards a test (believing it to be painful or embarrassing) but a positive attitude towards undergoing it (e.g. fearing the consequences of not having the test)[61] (Marteau et al,

[61] This is the example provided by Marteau. However, I would not necessarily agree that this is a positive attitude. Positive attitudes from the qualitative study included thinking that screening was a beneficial activity.

2001). Marteau focuses on attitudes towards a specific part of the screening programme (the test) rather than the whole screening programme, which I think is a limitation. As I discussed in Chapter 2, cancer screening comprises a whole programme, from the invitation to be screened through to follow-up diagnostic tests and subsequent treatment for those people who have a positive test result. Attitudes towards different stages or components of the screening programme might be different and their role in decision making may vary. Future definitions of informed choice in cancer screening might incorporate attitudes, but it may also be that attitudes are not an essential element of informed choice.

The last two items related to external influences on choice – pressure from others and barriers to carrying out their choice. I did not include behaviour, as the behaviour (i.e. uptake) contributes little to our understanding of how the choice was made. The measure of informed choice in antenatal screening (Marteau et al, 2001) used behaviour as a proxy for choice. However, I have argued that, when measuring informed choice or informed decision making, it should not be assumed that behaviour reflects the initial choice (Jepson et al, 2005b).

7.4 My changing definitions and understanding of informed choice

When I first began this thesis, my understanding of informed choice was limited to existing definitions and measures (e.g. Bekker et al, 1999; Marteau et al, 2001) which focussed on three components; knowledge, attitudes and behaviour. At the end of my first year I first began to question some of these existing definitions, primarily because they all focussed on behaviour (e.g. uptake) rather than choice. I thought that insufficient emphasis was put on the potential gap between choice and behaviour, and that any definition and operationalisation of informed choice must measure choice rather than behaviour.

In the second year of my thesis, I carried out the qualitative study and also read more widely about the theoretical basis for informed choice (described in detail in Chapter 2).

It became evident to me that whilst most theories of informed choice and consent were built on the concept of autonomy, this was not always reflected in definitions. However, the qualitative study made me realise that whilst information had the potential to enhance autonomy, it could not protect against choices which were made under coercion, or without an understanding of the choice that was to be made.

A greater understanding of these theoretical underpinnings, combined my analysis of the data from the qualitative study, made me believe that any definition of informed choice should take into account that it was a choice made free from coercion, and that there could be a difference between choice and behaviour. I became more persuaded and convinced by the definition of informed consent proposed by Beauchamp and Childress (1994) (see Chapter 2). My ideas surrounding informed choice and how it could be operationalised were beginning to crystallise at this time and these ideas were published in a paper (Jepson et al, 2005) (see Appendix 9).

In the second year I also began writing a Cochrane protocol with two other reviewers. Based on the ideas outlined above, and the ideas of the reviewers, we devised a new definition of informed choice, which took into account autonomy and choice (see Chapter 4, section 4.40). In the third year of my thesis, whilst analysing my results, it became clear that there was more than one perspective of informed choice, and that researchers, policy makes and those participating in screening may have different viewpoints. Therefore, my systematic review concentrated on evaluated definitions of informed choice from different perspectives, in particular, the differences and similarities in the information that different stakeholders felt important to make an informed choice.

In summary, over the course of the thesis my understanding of informed choice changed in several ways: firstly, in the types of information that people might want in order to be informed; secondly, autonomy and choice would be incorporated into any definition; and thirdly, an informed choice may differ according to the different perspectives (policy maker or lay person). In addition, it also became clear that the term informed choice is

not always informative, as the relationship between information and choice is not well understood

7.5 Further research

Following on from the research presented in this thesis, the following areas for further research were identified. The qualitative study raised issues about how lay people conceptualised informed choice, and the information that is important to them. This study was undertaken in a limited geographical area, and the main purpose was to inform the questionnaire rather than develop new theory. Therefore, further qualitative research in different groups of people may be valuable. In particular, it would be useful to understand issues surrounding informed choice in people from different minority ethnic backgrounds, and with chronic illnesses (including some chronic mental health problems). Any further qualitative work should also focus on people's attitudes towards different aspects of screening (e.g. the test, and possible diagnostic tests and treatment), their screening choices, and the information they need or want to make their choices. It would also be valuable to determine the contribution of attitudes to people's perception of informed choice, and which attitudes appear to be most important (if any). Research on the relationship between information and choice or autonomy in the cancer screening context would also be useful.

More needs to be known about the reliability and validity of MICICS. It needs to be further refined and its validity and reliability assessed in other settings and with other groups of people (particularly those people who do not participate in screening). The response rate in the quantitative study was not high, and there was some evidence of non-response bias. Therefore how informed choice is defined in people who did not respond to the questionnaires is not known. These people may be (or feel) less autonomous, or have different attitudes from those people who do respond. Due to the low response rate to the postal questionnaire, other ways of communicating with non-responders may also need to be considered (e.g. telephone surveys).

Further development of the measure

When a scale is measuring a hypothetical construct (such as informed choice) the task is on-going; new hypotheses derived from the constructs require new studies (Streiner and

Norman, 1995; 157). The analysis found that a small number of the items did not substantially contribute to the measurement of informed choice. Therefore, refinement of the questionnaire would include the removal of these items, and the development of new items. Appendix 10 gives details of the items included in the three questionnaires.

The specific items to be re-worded or given further consideration include a multiple choice question on incidence of the cancer [How many people do you think will develop cancer x over the course of their life?]. In retrospect, it could be argued that the information people should know is the incidence for the screening age group, rather than over the course of their life.

The knowledge item which people found difficult to answer and did not discriminate well was regarding the magnitude of false negatives ['If 100 people with cancer x had test x, how many of these 100 cancers do you think would be missed?']. Although it may be important for people to know the amount of false negatives, at this time it may be more important that people understand that a screening test will not detect all cancers. This concept is covered in two other items ['Some cancers will not be picked up by the test x,' and 'A letter which says (normal result) means that a person definitely does not have x cancer']. Additional qualitative work may produce new items of knowledge to include.

Several of the general attitudinal items did not discriminate well (e.g. I think screening for cancer x is a good thing), and may need further refinement. In addition, the factor analysis determined the attitudinal items that represented an underlying construct, and the extent of their communality, for each type of screening. As the underlying constructs and common items differed between the three types of screening, the questionnaire will need to be modified accordingly (i.e. different attitude questions asked for each type of screening). With regard to the attitude items included in the questionnaire, further questions may need to be developed to more accurately measure coercion and external pressure.

7.6 Positioning the current study

This study was conducted within two National (Scottish) Screening Programmes (breast and cervical) and one pilot Screening Programme (colorectal). Study participants were people from the local regions of Tayside (colorectal screening) and Lothian (breast and cervical). As discussed in Chapter 5, the organisation of screening differs between the three types of screening programmes. For cervical screening, it also differs between Health Boards. In addition, it is not known whether people in Scotland have different attitudes and barriers to screening than people in other parts of the UK.

Since my study was initiated, there has been a change in policy in cervical screening. At the time of conducting my study, GPs were paid incentives to meet government targets for cervical screening. However, with the introduction of the new GP contract in April 2004, cervical screening is now an additional service which practices are able to opt in, or out of (http://www.dhsspsni.gov.uk/hss/gp_contracts/contract.asp.). There is also more emphasis on informed choice rather than uptake. For example, the contract states that one of the services is

'The provision of any necessary information and advice to assist women identified by the PCT as recommended nationally for a cervical screening test in making an informed decision as to participation in the NHS Cervical Screening Programme'

This change may have implications for women going for screening, and may make it easier for them to make choices without feeling pressurised. Therefore, the concerns about autonomy and coercion raised in this thesis may no longer be relevant. However, it might be harder to change the prevailing attitudes of GPs towards the test.

One of the pre-requisites for knowledge and understanding is the provision of balanced information. However, there was variation between screening programmes with regard to the information they provided, and none of them addressed all the domains of information included in this measure. Nor did they give all of the pieces of information recommended by the GMC guidelines.

7.7 Policy and practice

As outlined in Chapter 1, this research was undertaken within the context of current UK policy and guidelines on informed choice. Advisory groups such as the National Screening Committee believe that the advantage of increasing informed choice is that it prevents people feeling coerced. However, one of the issues discussed in this PhD is whether informed choice can operate within a structure where both information and choice are, to some extent, regulated by the need to benefit populations rather than individuals. In addition, how is the validity of the informed choice process affected by the competing demands of other screening outcomes (e.g. cost effectiveness and uptake)? Although this thesis is not directly about resolving whether achieving high levels of informed choice in cancer screening is achievable, appropriate or workable, I will comment on this in the context of the findings of the research.

The qualitative study indicated that people still lack knowledge in certain areas, despite information given to them by the screening programmes. Thus screening programmes cannot assume that the provision of information necessarily results in an informed (i.e. knowledgeable) population. However, they still have a responsibility to provide such information, and ensure that it is the information that screening invitees want.

The effect that information and knowledge has on enhancing choice in cancer screening remains unclear. However, findings from the qualitative study indicated that it may not affect people's choice, but may affect other outcomes such as satisfaction. The quantitative analysis indicated that knowledge was not a significant predictor of high or low choice.

It can be argued that the primary prerequisite for autonomous actions is choice. Only once choice is available can information enhance the choice. Therefore, policy makers in cancer screening may need to decide if they really want to increase and promote informed choice, or whether they want to increase informed participation. The main policy reason for promoting informed choice is to enhance autonomy and to prevent people being deceived or coerced. However, this research indicates that the provision of evidence-based information alone does not necessarily mean that an informed choice is

made. People may not read, want, or understand the information, and, additionally, people may not be able to carry out their intended choice. For example, people may feel that they do not have the choice to refuse screening, even though they might wish to do so. Moreover there may be personal barriers, such as physical or mental health problems and language, or organisational barriers, such as the availability of the service and access. If information is given in the absence of choice, then the person cannot make an informed choice.

I made the distinction in Chapter 2 between informing and being informed. As has been shown in this research, information in the leaflets is not always being translated into understanding. If this finding is true for the general population, then the question of relevance is,

'Do we design services to ensure that everyone is given the same information, or do we design a service to ensure that everyone reaches an agreed level of understanding?' (Green et al, 2004a)

Although there are guidelines about what constitutes an informed choice, there is little evidence to indicate what aspects of information within the domains should be assessed to illustrate sufficient understanding so that an informed choice can be made (Green et al, 2004a).

The results of the both the qualitative and quantitative studies show that people want information about the disease in order to feel informed. One reason for this may be that people view screening as one option (out of several) of managing their risk of getting a particular cancer. They may also wish to prevent cancer by reducing their risk, or knowing when to go to the doctors with symptoms. Screening personnel are largely focused on giving information on the technical aspects of screening and some of the consequences. However, if cancer screening is viewed within the context of people's lives, and also in the wider context of cancer policy, screening creates an opportunity for health professionals to directly contact people with information about the cancer (as well as cancer screening). It may have little impact on screening targets, and it may not be seen as the responsibility of screening personnel to give information which could be defined as health promotion (and therefore the remit of other agencies). However, the

findings of the qualitative research indicated that for some people, screening might be the only time that they get targeted information about the cancer. This was particularly evident in the colorectal focus groups, where the information that people knew about risk factors and symptoms of cancer came almost exclusively from the screening leaflets.

Although leaflets can be a valuable source of information, the question of who constructs the information and how it is presented needs to be considered by policy makers. Information about cancer screening needs to be evidence based, balanced, and take into account the information important to those being screened, and the choices that are available. In this thesis I have argued that those involved in either health promotion or screening may not be the most appropriate people to construct the relevant domains of information (see sections 2.25 and 2.5) and that the way that information is presented may be as important as the information itself (section 2.27). The most appropriate information providers are those who can take into account different perspectives (e.g. lay and professional) and present information in an unbiased and neutral fashion.

Although there are cogent arguments from several perspectives that informed choice is important, people should not be judged negatively if they decide they do not wish to be informed. As previously discussed in both the literature review and the qualitative studies, some people may feel that they do not need nor want information. Making knowledge a pre-requisite for autonomy, choice or 'good' decision making could result in a paternalistic approach to information giving and measurement of informed choice.

Informed choice is a complex concept and generally considered to be a desirable feature of screening programmes. However, a great deal of care is needed by policy makers and providers of the service to ensure that informed choice is promoted in a way that can accommodate the wide range of views, perceptions and attitudes of invitees to cancer screening.

7.8 Major conclusions of the thesis

In summary, the major conclusions from this thesis are as follows:

- Information on the disease was as important to people as information on the risks and limitations of screening. However, information may have little part to play in the choices people make. It may have more impact on outcomes such as satisfaction and anxiety.
- People have limited knowledge of the risks and consequences of screening. In addition, perceived informedness was strongly predicted by attitudes rather than the knowledge of the risk and benefits, and high levels of knowledge were not a predictor of the level of choice.
- Lay people define and conceptualise informed choice differently from researchers and policy makers.
- The provision of evidence-based information alone does not necessarily mean that an informed choice is made. The relationship between information and choice is complex, and the term 'informed choice' is not always useful
- The relationship between information and choice is complex, and there are a number of reasons why the concept of 'informed choice' requires more subtle understanding in the context of cancer screening.

This thesis contributes to research in the following ways:

- It is the first time that people invited for screening have been asked what information they want in order to make an informed choice, and how they view informed choice.
- It provides a different definition of informed choice which takes account of the underlying theory
- It provides a set of constructs of informed choice which can be further refined in future research.
- It is the first time that informed choice has been conceptualised and operationalised from both the patient perspective and a theoretical perspective, and the similarities and differences between them explored. It also highlights the similarities and differences between the professional perspectives on informed choice and the patient perspective
- It provides a measure of informed choice which can be further developed and refined in the area of cancer screening

References

Adab, P., Marshall, T., Rouse, A. et al. (2003). Randomised controlled trial of the effect of evidence based information on women's willingness to participate in cervical cancer screening. *Journal of Epidemiology & Community Health.*57:589-593.

Ajzen, I. (1988). *Attitudes, personality, and behavior.* Homewood, IL: Dorsey Press.

Ajzen, I. and Fishbein, M. (1980a). *Attitudes and behavior.* Englewood Cliffs N.J.: Prentice-Hall Inc.

Ajzen, I. and Fishbein, M. (1980b). *Understanding attitudes and predicting social behaviour.* Englewood Cliffs N.J.: Prentice-Hall Inc.

Alaszewski, A. and Horlick-Jones, T. (2003). How can doctors communicate information about risk more effectively? *BMJ.*327:728-731.

Alderson, P. and Goodey, C. (1998). Theories of consent. *BMJ.*317:1313-1315.

Anderson, C. M. and Nottingham, J. (1999). Bridging the knowledge gap and communicating uncertainties for informed consent in cervical cytology screening; we need unbiased information and a culture change. *Cytopathology.*10:221-8.

Andorno, R. (2004). The right not to know: an autonomy based approach. *Journal of Medical Ethics.*30:435-439.

Armitage, C. J. and Conner, M. (2001). Efficacy of the Theory of Planned Behaviour: a meta-analytic review. *British Journal of Social Psychology.*40:471-499.

Arraras, J. I., Wright, S., Greimel, E. et al. (2004). Development of a questionnaire to evaluate the information needs of cancer patients: the EORTC questionnaire. *Patient Education & Counseling.*54:235-41.

Austoker, J. (1994). Screening for colorectal cancer. *BMJ.*309:382-386.

Austoker, J. (1999). Gaining informed consent for screening. Is difficult--but many misconceptions need to be undone. *BMJ.*319:722-3.

Barr, L. (2003). Breast screening: the enthusiast's view. *Pulse.*45-48.

Barratt, A., Irwig, L, Glasziou , P et al. (1999). Users' guides to the medical literature XVII. How to use guidelines and recommendations about screening. *JAMA.*281:2029-2034.

Bateson N (1984). *Data Construction in Social Surveys*, London: George Allen and Unwin.

Baum, M. Are breast screening programmes increasing rates of mastectomy? http://bmj.com/cgi/eletters/325/7361/418 (Last accessed 2004)

Baum, M. (2003). Mammographic screening: the case for informed choice. *Pulse.*42-45.

Baum, M. and Tobias, J. S. (2000). Effect of screening programme on mortality from breast cancer. Investment in treatment would be more cost effective. *BMJ.*321:1528.

BBC News Online: Health Cancer screening: Worth the money? http://news.bbc.co.uk/1/low/health/594751.stm (Last accessed 9/2003)

Beauchamp, T. L. and Childress, J. F. (1994). *Principles of biomedical ethics.* New York ; Oxford: Oxford University Press.

Beck, U. (1992). *Risk Society; towards a new modernity.* London: Sage.

Beck-Gernsheim, E. (2000). Health and responsibility: from social change to technical change and visa-versa. In Adam,B., Beck, U., and Van Loon, J., Eds. *The risk society and beyond. Critical issues for social theory* pp. 122-135. London: Sage.

Beisecker, A. E. (1988). Aging and the desire for information and input in medical decisions: patient consumerism in medical encounters. *Gerontologist.*28:330-335.

Bekker, H., Thornton, J. G., Airey, C. M. et al. (1999). Informed decision-making: an annotated bibliography and systematic review. *Health Technology Assessment.*3:156.

Bellaby, P. (2001). Evidence and risk: the sociology of health care grappling with knowledge and uncertainty. In Edwards, A. and Elwyn, G., Eds. *Evidence-based patient choice - inevitable or impossible* pp. 79-93. Oxford: Oxford University Press.

Berg, B. L. (1989). *Qualitative research methods for the social sciences.* Boston: Allyn and Bacon.

Berki, R. (1977). *The History of Political Thought: A Short Introduction.* London: Dent.

Biggins, A. (1992). The role of the midwife and consumer groups as advocates for the rights of the consumer. *Midwifery.*8:64-68.

Bikker, A. and Thompson, A. (2005). Explaining patient satisfaction in four different modes of health care across a nation (unpublished work).

Bish, A., Sutton, S., and Golombok, S. (2000). Predicting uptake of a routine cervical smear test: A comparison of the Health Belief Model and the Theory of Planned Behaviour. *Psychology & Health.*15:35-50.

Bland, J. M. and Altman, D. G. (1997). Statistics notes: Cronbach's alpha. *BMJ.*314:572.

Blanks, R. G., Moss, S. M., McGahan, C. E. et al. (2000). Effect of NHS breast screening programme on mortality from breast cancer in England and Wales, 1990-8: comparison of observed with predicted mortality. *BMJ.*321:665-669.

Boyd, P. (2003). The requirements of the Data Protection Act 1998 for the processing of medical data. *Journal of Medical Ethics.*29:34-35.

Boyle, P. and Langman, JS. (2002). ABC of colorectal cancer: Epidemiology. *BMJ.*321:805-808.

Braun, V. and Gavey, N. (1999). 'With the best of reasons': cervical cancer prevention policy and the suppression of sexual risk factor information. *Social Science & Medicine.*48:1463-1474.

Brehaut, J. C., O'Connor, A. M., Wood, T. J. et al. (2003). Validation of a decision regret scale. *Medical Decision Making.*23:281-292.

Brett, J. and Austoker, J. (2004). Development and validation of the EBS: a measure to assess women's experience at all stages of the breast screening process. *Journal of Public Health.*26:79-83.

Broclain, D., Jepson, R., and Ferdjaoui, N. (2004). Influence of comprehensive versus partial information on consumers' screening choices (Protocol for a Cochrane Review). In *The Cochrane Library, Issue 1, 2004* Chichester, UK: John Wiley & Sons, Ltd.

Bryman, A. (2001). *Social research methods.* Oxford: Oxford University Press.

Bush, J. (2003). "It's just part of being a woman": cervical screening, the body and femininity. *Social Science & Medicine.*50:429-444.

Cancer Research UK Cervical cancer http://www.cancerresearchuk.org/aboutcancer/specificcancers/cervicalcancer?version=1 (Last accessed 6/2005)

CASP Critical Appraisal Skills Programme, Milton Keynes Primary Care Trust. 10 questions to help you make sense of qualitative research. http://www.phru.org.uk/~casp/qualitative.pdf (Last accessed 6/2005)

Chamberlain, J. (1995). *Evaluation of Cancer Screening.* UK: Springer-Verlag.

Chamot, E. and Perneger, T. V. (2001). Misconceptions about efficacy of mammography screening: a public health dilemma. *Journal of Epidemiology & Community Health.*55:799-803.

Chan, E. C., Haynes, M. C., O'Donnell, F. T. et al. (2003). Cultural sensitivity and informed decision making about prostate cancer screening. *Journal of Community Health.*28:393-405.

Chan, E. C. Y. and Sulmasy, D. P. (1998). What should men know about prostate-specific antigen screening before giving informed consent? *American Journal of Medicine.*105:9.

Charatan, F. (2002). US panel finds insufficient evidence to support mammography. *BMJ.*324.

Charles, C., Gafni, A, and Whelan, T. (1999). Decision-making in the physician-patient encounter: revisiting the shared treatment decision-making model. *Social Science & Medicine.*49:651-661.

Charles, C., Redko, C, Whelan, T et al. (1998). Doing nothing is no choice: lay constructions of treatment decision-making among women with early-stage breast cancer. *Sociology of Health and Illness.*20:71-95.

Charmaz, K. (1995). Grounded theory. In Smith, J.A., Harre, R., and Van Langahove, L., Eds. *Rethinking Methods in Psychology* pp. 27-49. London: Sage Publications Ltd.

Chung-Faye, G. A. and Kerr, D. J. (2000). ABC of colorectal cancer: Innovative treatment for colon cancer. *BMJ.*321:1397-1399.

Clarke, V. A., Lovegrove, H., Williams, A. et al. (2000). Unrealistic optimism and the Health Belief Model. *Journal of Behavioral Medicine.*23:367-376.

Cochrane Qualitative Methods Group Cochrane Qualitative Methods Group & Campbell Process Implementation Methods Group. Proposal to establish a Cochrane Qualitative Methods Group - July 4th 2002. http://mysite.freeserve.com/Cochrane_Qual_Method/index.htm. (Last accessed 12/2004)

Cockburn, J., Redman, S., Mill, D. et al. (1995). Public understanding of medical screening. *Journal of Medical Screening.*2:224-7.

Collins, K. and O'Cathain, A. (2003). The continuum of patient satisfaction - from satisfied to very satisfied. *Social Science & Medicine.*57:2465-2470.

Connor, M. and Norman, P. (1994). Comparing the Health Belief Model and the Theory of Planned Behaviour in health screening. In Rutter, D.R ; Quine, L. *Social Psychology and Health: European Perspectives.* Aldershot: Avebury

Conner, M. and Norman, P. (2001). *Predicting Health Behaviour.* Buckingham: Open University Press.

Corrigan, O. (2003). Empty ethics: the problem with informed consent. *Sociology of Health and Illness.*25:768-792.

CRD. (2001). Undertaking systematic reviews of research on effectiveness: CRD guidelines for those carrying out or commissioning reviews. 4 (2nd edition)York, CRD.

Crossley, J. A., Aitken, D. A., Berry, E. et al. (1994). Impact of a regional screening programme using maternal serum alpha fetoprotein (AFP) and human chorionic

gonadotrophin (hCG) on the birth incidence of Down's syndrome in the west of Scotland. *Journal of Medical Screening.*1:180-183.

Davey, H. M., Barratt, A. L., Davey, E. et al. (2002). Medical tests: women's reported and preferred decision-making roles and preferences for information on benefits, side-effects and false results. *Health Expectations.*5:330-340.

de Vaus, D. (2002). *Analysing social science data.* London: Sage.

Declaration of Helsinki (1989). Declaration of Helsinki. In Ferney Voltaire, Ed. *World Medical Association handbook of declarations* World Medical Association.

DeVellis, R. F. (2003). *Scale development: theory and applications.* London: Sage.

DIPEx Database of Patient Experiences http://www.dipex.org/ (Last accessed 1/2005)

Dixon-Woods, M. and Fitzpatrick, R. (2001). Qualitative research in systematic reviews. *BMJ.*323:765-766.

Dobree, L. (1991). An informed choice ensures peace of mind. Contraceptive counselling in the community. *Professional Nurse.*6:616-618.

DoH. (2003a). Breast screening: The Facts. London, Department of Health Publications.

DoH. (2003b). Cervical screening; The Facts. London, Department of Health Publications.

Dolan, J. G. and Frisina, S. (2002). Randomized controlled trial of a patient decision aid for colorectal cancer screening. *Medical Decision Making.*22:125-139.

Douglas, M. (1992). *Risk and blame: essays in cultural theory.* London: Routledge.

Douglas, M. (1985). *Risk acceptability according to the social sciences.* London: Routledge.

Dunlop, M. G. (1997). Science, medicine and the future: colorectal cancer. *BMJ.*314:1882-1885.

Edwards, A. and Bastian, H. (2001). Risk communication - making evidence part of choices. In Edwards, A. and Elwyn, G., Eds. *Evidence-based patient choice - inevitable or impossible* pp. 144-160. Oxford: Oxford University Press.

Edwards, A., Elwyn, G., Covey, J. et al. (2001). Presenting risk information--a review of the effects of "framing" and other manipulations on patient outcomes. *Journal of Health Communication.*6:61-82.

Edwards, A., Hood, K, and Elwyn, G. (2003). Personalised risk communication for informed decision making about entering screening programs. *In: The Cochrane Library, Issue 1, 2003.Oxford: Update Software.*

Edwards, P., Roberts, I., Clarke, M. et al. (2002). Increasing response rates to postal questionnaires: systematic review. *BMJ.*324:1183.

Elmore, JG., Barton, M. B., Moceri, VM. et al. (1998). Ten-year risk of false positive screening mammograms and clinical breast examinations. *The New England Journal of Medicine.*338:1089-1096.

Elwyn, G. and Charles, C. (2001). Shared decision making: the principals and the competences. In Edwards, A. and Elwyn, G., Eds. *Evidence based patient choice: inevitable or impossible?* pp. 119-143. Oxford: Oxford University Press.

Elwyn, G., Edwards, A., Mowle, S. et al. (2001). Measuring the involvement of patients in shared decision making: a systematic review of instruments. *Patient Education and Counseling.*43:5-22.

Ende, J., Kazis, L., Ash, A. et al. (1989). Measuring patients' desire for autonomy: decision making and information-seeking preferences among medical patients. *Journal of General Internal Medicine.*4:23-30.

English, V., Romano-Critchley, G, Sheather, J et al. (2002). Ethics briefings. *Journal of Medical Ethics.*28:127-128.

Entwistle, V. and O'Donnell, M. (2001). Evidence-based healthcare: what roles for patients? In Edwards, A. and Elwyn, G., Eds. *Evidence based patient choice: inevitable or impossible?* pp. 34-49. Oxford: Oxford University Press.

Entwistle, V. (2001). The potential contribution of decision aids to screening programmes. *Health Expectations.*4:109-15.

Ernster, V. L. and Barclay, J. (1997). Increases in ductal carcinoma in situ (DCIS) of the breast in relation to mammography: a dilemma. *Journal of the National Cancer Institute.Monographs.*22:151-156.

Esterberg, K. G. (2002). *Qualitative research methods in social research.* Boston: McGraw Hill.

Fabrigar, L. R., Wegener, D. T., MacCallum, R. C et al. (1999). Evaluating the use of exploratory factor analysis in psychological research. *Psychological methods.*3:272-299.

Faden, R. R. and Beauchamp, T. L. (1986). *A history and theory of informed consent.* New York:

Faden, R. R. (1987). Ethical issues in government sponsored public health campaigns. *Health Education Quarterly.*14:27-37.

Fletcher, SW. (1997). Whither scientific deliberation in health policy recommendations? -- Alice in the Wonderland of breast-cancer screening. *New England Journal of Medicine.*336:1180-1183.

Flood, A. B., Wennberg, J. E., Nease, R. F. et al. (1996). The importance of patient preference in the decision to screen for prostate cancer. Prostate Patient Outcomes Research Team. *Journal of General Internal Medicine.*11:342-349.

Forrest, A. P. (1986). Breast cancer screening: report to the Health Ministers of England, Wales, Scotland and Northern Ireland. London: HMSO.

Foxwell, M. and Alder, E. (1993). More information equates with less anxiety. Reducing anxiety in cervical screening. *Professional Nurse.*9:32-36.

Frosch, D. L., Kaplan, R. M., and Felitti, V. (2001). The evaluation of two methods to facilitate shared decision making for men considering the prostate-specific antigen test. *Journal of General Internal Medicine.*16:391-398.

Frosch, D. L., Kaplan, R. M., and Felitti, V. J. (2003). A randomized controlled trial comparing internet and video to facilitate patient education for men considering the prostate specific antigen test.[see comment]. *Journal of General Internal Medicine.18(10):781-7.*

Gabriel, Y. (2005). The voice of experience and the voice of the expert - can they speak to each other? In *Narrative Based Medicine* Oxford: BMJ Books.

Gatta, G., Capocaccia, R., Hakulinen, T. et al. (1999). Variations in survival for invasive cervical cancer among European women, 1978-89. EUROCARE Working Group. *Cancer Causes & Control.*10:575-581.

Gattellari, M. and Ward, J. E. (2003). Does evidence-based information about screening for prostate cancer enhance consumer decision-making? A randomised controlled trial. *Journal of Medical Screening.*10:27-39.

Gatto, N. M., Frucht, H., Sundararajan, V. et al. (2003). Risk of perforation after colonoscopy and sigmoidoscopy: a population-based study. *Journal of the National Cancer Institute.*95:230-236.

General Medical Council. (1999). Seeking Patients Consent: the Ethical Considerations. London, General Medical Council.

Gibbs, G. R. (2002). *Qualitative data analysis. Explorations with NVivo.* Buckingham: Open University Press.

Giddens, A. (1991). *Modernity and self-identity : self and society in the late modern age.* Cambridge: Polity Press in association with Blackwell.

Gillam, S. J. (1991). Understanding the uptake of cervical cancer screening: the contribution of the health belief model. *British Journal of General Practice.*41:510-513.

Glaser, B. and Strauss, A. (1967). *The discovery of grounded theory. Strategies for qualitative research.* New York: Aldine.

Goel, V. (2001). Appraising organised screening programmes for testing for genetic susceptibility to cancer. *BMJ.*322:1174-1178.

Goel, V., Glazier, R., Holzapfel, S. et al. (1996). Evaluating patient's knowledge of maternal serum screening. *Prenatal Diagnosis.*16:425-430.

Gotzsche, PC. and Olsen, O. (2000). Is screening for breast cancer with mammography justifiable? *Lancet.*355:129-134.

Gotzsche, P. C. (2002). Screening mammography: setting the record straight. *Lancet.*359:440-441.

Goyder, E., Barratt, A., and Irwig, L. M. (2000). Telling people about screening programmes and screening test results: how can we do it better? *Journal of Medical Screening.*7:123-126.

Graham, W., Smith, P., Kamal, A. et al. (2000). Randomised controlled trial comparing effectiveness of touch screen system with leaflet for providing women with information on prenatal tests. *BMJ.*320:155-160.

Green, J. M., Hewison, J, Bekker, H. L. et al. (2004a). Psychosocial aspects of genetic screening of pregnant women and newborns: a systematic review. *Health Technology Assessment.*8:1-138.

Green, M. J., Peterson, S. K., Baker, M. W. et al. (2004b). Effect of a computer-based decision aid on knowledge, perceptions, and intentions about genetic testing for breast cancer susceptibility: a randomized controlled trial. *JAMA.*292:442-452.

Grimes, D. A. and Schulz, K. F. (2002). Uses and abuses of screening tests. *Lancet.*359:881-884.

Guerriere, D. and Llewellyn-Thomas, H. (2001). Substitute decision-making: measuring individually mediated sources of uncertainty. *Patient Education and Counseling.*42:133-143.

Gurm, H. S. and Litaker, D. G. (2000). Framing procedural risks to patients: is 99% safe the same as a risk of 1 in 100? *Academic Medicine.*75:840-842.

Hall, S. A. (1992). Should public health respect autonomy? *Journal of Medical Ethics.*18:197-201.

Hann, A. (1995). Cancer screening: a feminist issue? Contemporary Political Studies Annual Conference. 1995.

Hann, A. (1996). *The Politics of Breast Cancer Screening.* London: Avebury.

Hair J.F.; Anderson R.E.; Tatham R.L.;Black W.C (2003). Factor Analysis. In *Multivariate data analysis. London: Prentice-Hall*

Haynes, R. B., Devereaux, P. J., and Guyatt, G. H. (2002). Physicians' and patients' choices in evidence based practice. *BMJ.*324:1350.

Heath, A. and Martin, J. (1997). Why are there so few formal measuring instruments in social and political research? 58 CREST. Working Papers Series.

Hennell, S. L., Brownsell, C., and Dawson, J. K. (2004). Development, validation and use of a patient knowledge questionnaire (PKQ) for patients with early rheumatoid arthritis. *Rheumatology.*43:467-471.

Henwood, K. L. and Pidgeon, N. F. (1992). Qualitative research and psychological theorizing. *British Journal of Psychology.*83:97-111.

Holland, W. and Stewart, S. (1990). *Screening in health care. Benefit or bane?* London: Nuffield Provincial Hospitals Trust.

Holloway, R. M., Wilkinson, C., Peters, T. J. et al. (2003). Cluster-randomised trial of risk communication to enhance informed uptake of cervical screening. *British Journal of General Practice.*53:620-625.

Holmes-Rovner, M., Kroll, J., Schmitt, N. et al. (1996). Patient satisfaction with health care decisions: the satisfaction with decision scale. *Medical Decision Making.*16:58-64.

Hope, T. (1996). *Evidence-based patient choice.* London: King's Fund.

Horne, R., Hankins, M., and Jenkins, R. (2001). The Satisfaction with Information about Medicines Scale (SIMS): a new measurement tool for audit and research. *Quality in Health Care.*10:135-140.

Howson, A. (1999). Cervical screening, compliance and moral obligation. *Sociology of Health and Illness.*21:401-425.

Irwig, L. and Glasziou, P. (2000a). Implementing honesty about screening using community informed consent. *BMJ.*321:450-451.

Irwig, L. and Glasziou, P. (2000b). Informed consent for screening by community sampling. *Effective Clinical Practice.*3:47-50.

ISD Key health topics\cancer\screening http://www.show.scot.nhs.uk/isd/cancer/screening/scsp.htm (Last accessed 11/2003)

Jackson, J. L., Chamberlin, J., and Kroenke, K. (2001). Predictors of patient satisfaction. *Social Science & Medicine.*52:609-620.

Jepson, R., Clegg, A., Forbes, C. et al. (2000). The determinants of screening uptake and interventions for increasing uptake: a systematic review. *Health Technology Assessment (Winchester, England).*4.

Jepson, R., Weller, D., Alexander, F. et al. (2005a). Impact of UK colorectal cancer screening pilot on primary care.[erratum appears in Br J Gen Pract. 2005 Mar;55(512):234]. *British Journal of General Practice.*55:20-25.

Jepson, R. G., Forbes, C. A., Sowden, A. J. et al. (2001). Increasing informed uptake and non-uptake of screening: evidence from a systematic review. *Health Expectations.*4:116-126.

Jepson, R. G., Hewison, J, Thompson, A et al. (2005b). How should we measure informed choice? The case of cancer screening. *Journal of Medical Ethics.*55:20-25.

Jorgensen, K. J. and Gotzsche, P. C. (2004). Presentation on websites of possible benefits and harms from screening for breast cancer: cross sectional study. *BMJ.*328:148.

Kant, I. (1883). *Kant's critique of practical reason and other works on the theory of ethics.* London: Longmans, Green & Co.

Kerlikowske, K., Grady, D., Rubin, S. M. et al. (1995). Efficacy of screening mammography. A meta-analysis. *JAMA.*273:149-154.

Khoury, M. J., McCabe, L. L., and McCabe, E R. (2003). Population Screening in the Age of Genomic Medicine. *The New England Journal of Medicine.*348:50-58.

Kitzinger, J. (1995). Qualitative research: Introducing focus groups. *BMJ.*311:299-302.

Koedoot, N., Molenar, S, Oosterveld, P et al. (2001). The decisional conflict scale: Further validation in two samples of Dutch oncology patients. *Patient Education & Counseling.*45:187-19.

Lauver, D. and Rubin, M. (1990). Message framing, dispositional optimism, and follow-up for abnormal Papanicolaou tests. *Research in Nursing & Health.*13:199-207.

Lerner, B. H. (1998). Fighting the war on breast cancer: debates over early detection, 1945 to the present. *Annals of Internal Medicine.*129:74-78.

Leydon, G. M., Boulton, M., Moynihan, C. et al. (2000). Cancer patients' information needs and information seeking behaviour: in depth interview study. *BMJ.*320:909-913.

Loeken, K., Steine, S., Sandvik, L. et al. (1997). A new instrument to measure patient satisfaction with mammography. Validity, reliability, and discriminatory power. *Medical Care.*35:731-741.

Loeken, K., Steine, S., Sandvik, L. et al. (1996). A new measure of patient satisfaction with mammography. Validation by factor analytic technique. *Family Practice.*13:67-74.

Loewenthal, K. M. (2001). *An introduction to psychological tests and scales.* Hove: Psychology Press.

Lupton, D. (1995). *The imperative of health. Public health and the regulated body.* London: Sage.

Malterud, K. (2001). Qualitative research: standards, challenges, and guidelines. *Lancet.*358:483-488.

Marshall, T. and Adab, P. (2003). Informed consent for breast screening: what should we tell women? *Journal of Medical Screening.*10:22-26.

Marteau, T. M., Dormandy, E., and Michie, S. (2001). A measure of informed choice. *Health Expectations.*4:99-108.

Marteau, T. M. and Kinmonth, A. L. (2002). Screening for cardiovascular risk: public health imperative or matter for individual informed choice? *BMJ.*325:78-80.

Mauthner, N. and Doucet, A. (2003). Reflexive accounts and accounts of reflexivity in qualitative data analysis. *Sociology.*37:413-431.

Mazur, D. J. (2003). Influence of the law on risk and informed consent. *BMJ.*327:731-734.

McCaffery, K., Borril, J., Williamson, S. et al. (2001). Declining the offer of flexible sigmoidoscopy screening for bowel cancer: A qualitative investigation of the decision-making process. *Social Science & Medicine.*53:679-691.

McColl, E., Jacoby, A., Thomas, L et al. (2001). Design and use of questionnaires: a review of best practice applicable to surveys of health service staff and patients. *Health Technology Assessment.*5:1-256.

McCormick, J. (1996). Medical hubris and the public health: the ethical dimension. *Journal of Clinical Epidemiology.*49:621.

McFall, S. L. and Hamm, R. M. (2003). Interpretation of prostate cancer screening events and outcomes: a focus group study. *Patient Education & Counseling.*49:207-218.

McKinley, R. K., Manku-Scott, T, Hastings, A. M. et al. (1997). Reliability and validity of a new measure of patient satisfaction with out of hours primary medical care in the united kingdom: development of a patient questionnaire. *BMJ.*314:193.

McLeod, S. (1989). *A patient's right to know. Information disclosure, the doctor and the law.* Aldershot: Dartmouth Publishing Company.

McPherson, K., Steel, CM, and Dixon, JM. (1994). Breast cancer—epidemiology, risk factors and genetics. *BMJ.*309:1006.

McPherson, K., Steel, C. M., and Dixon, J. M. (2000). ABC of breast diseases: Breast cancer---epidemiology, risk factors, and genetics. *BMJ.*321:624-628.

Michie, S., Dormandy, E., and Marteau, T. M. (2002). The multi-dimensional measure of informed choice: a validation study. *Patient Education & Counseling.*48:87-91.

Midgley, R. and Kerr, D. (1999). Colorectal cancer. *Lancet.*353:391-399.

Mill, J. (1869). *On liberty.* London: Longman, Roberts & Green.

Miller, A. B. (1996). *Advances in cancer screening.* London: Kluwer Academic Publishers.

Morgan, D. W. (1997). *Focus groups as qualitative research.* London: Sage.

Murray, M. and McMillan, C. (1993). Health beliefs, locus of control, emotional control and women's cancer screening behaviour. *British Journal of Clinical Psychology.*32:87-100.

Myers, R. E., Chodak, G. W., Wolf, T. A. et al. (1999). Adherence by African American men to prostate cancer education and early detection. *Cancer.*86:88-104.

Nanda, K., McCrory, D. C., Myers, E. R. et al. (2000). Accuracy of the Papanicolaou test in screening for and follow-up of cervical cytologic abnormalities: a systematic review. *Annals of Internal Medicine.*132:810-819.

National Electronic Library Health Screening: Cervical cancer http://www.nelh.nhs.uk/screening/adult_pps/cervical_cancer.html (Last accessed 12/2002)

National Screening Committee First report of the National Screening Committee http://www.nsc.nhs.uk/library/lib_ind.htm (Last accessed 1/2005)

National Screening Committee. (2000). Second report of the National Screening Committee. *http://www.nsc.nhs.uk/library/lib_ind.htm.*

National Screening Committee What is screening? http://www.nsc.nhs.uk/whatscreening/whatscreen_ind.htm (Last accessed 12/2004)

Neilson, A. and Jones, R. K. (1998). Women's lay knowledge of cervical cancer/cervical screening: accounting for non-attendance at cervical screening clinics. *Journal of Advanced Nursing.*28:571-575.

NHS Quality Improvement Scotland Local report- November 2003. Cervical screening http://www.nhshealthquality.org/nhsqis/files/CS%20Lothian.pdf (Last accessed 4/2005)

NHS Quality Improvement Scotland National Overview - November 2003. Cervical screening http://www.nhshealthquality.org/nhsqis/files/cervical_overview.pdf (Last accessed 4/2005)

NICE Guidance on the use of liquid-based cytology for cervical screening http://www.nice.org.uk/pdf/TA69_LBC_review_FullGuidance.pdf (Last accessed 6/2005)

Nielsen, K., Dyhr, L, Lauritzen, T et al. (2004). "You can't prevent everything anyway": A qualitative study of beliefs and attitudes about refusing health screening in general practice. *Family Practice.*21:28-32.

Nijs, H. G., Essink-Bot, M. L., DeKoning, H. J. et al. (2000). Why do men refuse or attend population-based screening for prostate cancer? *Journal of Public Health Medicine.*22:312-316.

Nottingham, J. (1998). Informed consent. Screening programmes need consent forms. *BMJ.*317:948-949.

Nystrom, L., Andersson, I., Bjurstam, N et al. (2002). Long-term effects of mammography screening: updated overview of the Swedish randomised trials. *Lancet.*359:909-919.

O'Connor, A. M. (1995). Validation of a decisional conflict scale. *Medical Decision Making.*15:25-30.

O'Connor, A. M., Rostom, A., Fiset, V. et al. (1999). Decision aids for patients facing health treatment or screening decisions: Systematic review. *BMJ.*731-734.

O'Dell, K. J., Volk, R. J., Cass, A. R. et al. (1999). Screening for prostate cancer with the prostate-specific antigen test: are patients making informed decisions? *Journal of Family Practice.*48:682-688.

O'Neill, O. (2003). Some limits of informed consent. *Journal of Medical Ethics.*29:4-7.

O'Sullivan, I. and Orbell, S. (2004). Self-sampling in screening to reduce mortality from colorectal cancer: a qualitative exploration of the decision to complete a faecal occult blood test (FOBT). *Journal of Medical Screening.*11:16-22.

O'Sullivan, I., Orbell, S., Rakow, T. et al. (2004). Prospective research in health service settings: health psychology, science and the 'Hawthorne' effect. *Journal of Health Psychology.*9:355-359.

Olsen, O. and Gotzsche, P. (2001). Cochrane review on screening for breast cancer with mammography. *Lancet.*358:1340-1342.

ONS. (1999). Cancer trends in England and Wales 1950 - 1999. Office for National Statistics.

Oppenheim, A. M. (1992). *Questionnaire design, interviewing and attitude measurement.* New York: Pinter Publishers.

Orbell, S. (1996). Cognition and affect after cervical screening: The role of previous test outcome and personal obligation in future uptake expectations. *Social Science and Medicine.* Vol 43(8):1237-1244.

Orbell, S., Crombie, I, and Johnston, G. (1996). Social cognition and social structure in the prediction of cervical screening uptake. *British Journal of Health Psychology.*1 (part 1):35-50.

Oxford English Dictionary Online http://dictionary.oed.com (Last accessed 6/2003)

Paci, E., Duffy, SW, Giorgi, D et al. (2002). Are breast cancer screening programmes increasing rates of mastectomy? Observational study. *BMJ.*325:418.

Parker, M. (2001). The ethics of evidence-based patient choice. *Health Expectations.*4:87-91.

Patnick, J. (2003). Women need better information on routine mammography: Women's needs inform contents of screening literature. *BMJ.*327:868-869.

Patton, M. Q. (2000). *Qualitative evaluation and research methods.* London: Sage.

Petersen, A. and Lupton, D. (1996). *The new public health. Health and self in the age of risk.* London: Sage.

Pfeffer, N. (2004a). If you think you've got a lump, they'll screen you. Informed consent, health promotion, and breast cancer. *Journal of Medical Ethics.*30:227-230.

Pfeffer, N. (2004b). Screening for breast cancer: candidacy and compliance. *Social Science & Medicine.*58:151-160.

Pidgeon, N.F. and Henwood, K. (1997). Using grounded theory in psychological research. In Hayes, N., Ed. *Doing qualitative analysis in psychology* pp. 245-273. Hove: Psychology Press.

Pignone, M., Bucholtz, D., and Harris, R. (1999). Patient preferences for colon cancer screening. *Journal of General Internal Medicine.*14:432-437.

Pignone, M., Harris, R., and Kinsinger, L. (2000). Videotape-based decision aid for colon cancer screening. A randomized, controlled trial. *Annals of Internal Medicine.*133:761-769.

Pignone, M. and Levin, B. (2002). Recent developments in colorectal cancer screening and prevention. *Am.*66:297-302.

Pope, C. and Mays, N. (1995). Qualitative research: Reaching the parts other methods cannot reach: an introduction to qualitative methods in health and health services research. *BMJ.*311:42-45.

Porter, R. (1997). *The greatest benefit to mankind. A medical history of humanity from antiquity to present.* London: HarperCollins.

Porter, R. (2002). A history of public health. King's Fund Lecture. London, King's Fund.

QSR. (2000). NVivo qualitative data analysis program (1.3). Melbourne, Australia, QSR International Pty Ltd.

Quinn, M., Babb, P. J., Jones, J et al. (1999). Effect of screening on incidence of and mortality from cancer of cervix in England: evaluation based on routinely collected statistics. *BMJ.*318:908.

Radosevich, D. M., Partin, M. R., Nugent, S. et al. (2004). Measuring patient knowledge of the risks and benefits of prostate cancer screening. *Patient Education and Counseling.*54:143-152.

Raffle, A. E. (1997a). Deaths from cervical cancer began falling before screening programmes were established. *BMJ.*315:1625.

Raffle, A. E. (1997b). Informed participation in screening is essential. *BMJ.*314:1762-1763.

Raffle, A. E. (1999). How long will screening myths survive? *Lancet.*354:431.

Raffle, A. E. (2000). Honesty about new screening programmes is best policy. *BMJ.*320:872.

Raffle, A. E. (2001). Information about screening -is it to achieve high uptake or to ensure informed choice? *Health Expectations.*4:92-98.

Raffle, A. E., Alden, B., Quinn, M. et al. (2003). Outcomes of screening to prevent cancer: analysis of cumulative incidence of cervical abnormality and modelling of cases and deaths prevented. *BMJ.*326:901.

Raffle, A. E. and Morgan, K. (1998). Enhancing patients' compliance Financial inducements are equivalent to coercion. *BMJ.*316:394.

Raffle, A., Mackenzie EFD, and Alden, B. (1995). Detection rates for abnormal cervical smears: what are we screening for? *Lancet.*345:1469-1473.

Rakowski, W., Andersen, M. R., Stoddard, A. M. et al. (1997). Confirmatory analysis of opinions regarding the pros and cons of mammography. *Health Psychology.*16:433-441.

Rakowski, W., Dube, C. E., Marcus, B. H. et al. (1992). Assessing elements of women's decisions about mammography. *Health Psychology.*11:111-118.

Rands, G. (1992). Family planning and the Pill. Informed choice. *Nursing Standard.*6:suppl.

Redsell, S. A. and Cheater, F. M. (2001). The Data Protection Act (1998): implications for health researchers. *Journal of Advanced Nursing.*35:508-13.

RNIB RNIB See it Right pack http://www.rnib.org.uk/xpedio/groups/public/documents/PublicWebsite/public_seeitright.hcsp (Last accessed 6/2004)

Roberts, M. J. and Reich, M. R. (2002). Ethical analysis in public health. *Lancet.*359:1055-1059.

Roberts, M. (1989). Breast screening: time for a rethink? *BMJ.*299:1153-1155.

Robinson, A. and Thomson, R. (2001). Variability in patient preferences for participating in medical decision making: implication for the use of decision support tools. *Quality in Health Care.*10:I34-I38.

Robinson, J. (1985). *Women's health: A Spare Rib reader.*

Rogers, WA. (1998). The moral landscape of general practice. PhD Thesis. University of Flinders.

Rosen, R. C., Catania, J., Pollack, L. et al. (2004). Male Sexual Health Questionnaire (MSHQ): Scale development and psychometric validation. *Urology.*64:777-82.

Rosenstock, I. M., Strecher, V. J., and Becker, M. H. (1988). Social learning theory and the Health Belief Model. *Health Education Quarterly.*15:175-183.

Rubenstein, L. (1994). Strategies to overcome barriers to early detection of cancer among older adults. *Cancer.*74:2190-2193.

Ruthman, J. L. and Ferrans, C. E. (2004). Efficacy of a video for teaching patients about prostate cancer screening and treatment. *American Journal of Health Promotion.*18:292-295.

Rutter, D. and Quine, L. (2002). Social cognition models and changing health behaviours. In Rutter, D.E. and Quine, L.E., Eds. *Changing health behaviour: Intervention and research with social cognition models.* pp. 1-27. England: Open University Press.: Buckingham.

Sainsbury, J., Anderson, T. J., and Morgan, DAL. (2000). ABC of breast diseases: Breast cancer. *BMJ.*321:745-750.

Sarantakos, S. (1993). *Social Research.* Australia: MacMillan Education Australia.

Sarfati, D., Howden-Chapman, P., Woodward, A. et al. (1998). Does the frame affect the picture? A study into how attitudes to screening for cancer are affected by the way benefits are expressed. *Journal of Medical Screening.*5:137-140.

Sasieni, P. D., Cuzick, J., and Lynch-Farmery, E. (1996). Estimating the efficacy of screening by auditing smear histories of women with and without cervical cancer. The

National Co-ordinating Network for Cervical Screening Working Group. *British Journal of Cancer.*73:1001-1005.

Schapira, M. M. and VanRuiswyk, J. (2000). The effect of an illustrated pamphlet decision-aid on the use of prostate cancer screening tests. *Journal of Family Practice.*49:418-24.

Schwartz, LM., Woloshin, S, Sox, HC. et al. (2000). US women's attitudes to false positive mammography results and detection of ductal carcinoma in situ: cross sectional survey. *BMJ.*320:1635-1640.

Seale, C. (1999). *The quality of qualitative research.* London: Sage.

Shepherd, R., Weston, J., Peersman, G. et al. (2002). Interventions for encouraging sexual lifestyles and behaviours intended to prevent cervical cancer. *In: Cochrane Library, Issue 3, 2000.Oxford: Update Software.*

Sherlaw-Johnson, C., Gallivan, S., Jenkins, D. et al. (1999). Withdrawing low risk women from cervical screening programmes: mathematical modelling study. *BMJ.*318:356-361.

Silverman, D. (2000). *Doing qualitative research. A practical handbook.* London: Sage.

Silverman, E., Woloshin, S., Schwartz, L. M. et al. (2001). Women's views on breast cancer risk and screening mammography: a qualitative interview study. *Medical Decision Making.*21:231-240.

Skrabanek, P. (1988a). The debate over mass mammography in Britain. The case against. *BMJ.*297:971-972.

Skrabanek, P. (1988b). The physician's responsibility to the patient. *Lancet.*1:1155-1157.

Skrabanek, P. (1990). Why is preventive medicine exempted from ethical constraints? *Journal of Medical Ethics.*16:187-190.

Slaytor, E. K. and Ward, J. E. (1998). How risks of breast cancer and benefits of screening are communicated to women: analysis of 58 pamphlets. *BMJ.*317:263-264.

Slovic, P., Finucane, M. L., Peters, E. et al. (2004). Risk as analysis and risk as feelings: some thoughts about affect, reason, risk, and rationality. *Risk Analysis.*24:311-322.

Smith, R. (2003). The screening industry. *BMJ.*326 (7395):0

Social Disadvantage Research Centre Scottish Indices of Deprivation 2003 http://www.scotland.gov.uk/library5/social/siod-02.asp (Last accessed 1/2005)

SPSS Survey research using SPSS http://www.spss.com (Last accessed 1/2005)

SPSS. (2004). Missing data: the hidden problem. *SPSS white paper.*

Stapleton, H., Kirkham, M., and Thomas, G. (2002). Qualitative study of evidence based leaflets in maternity care. *BMJ.*324:639-+.

Stewart-Brown, S. and Farmer, A. (1997). Screening could seriously damage your health. *BMJ.*314:533.

Streiner, N. and Norman, GR. (1995). *Health Measurement Scales: A practical guide to their development and use.* Oxford: Oxford University Press.

Sudman, S. and Bradburn, N. (1982). *Asking questions. A practical guide to questionnaire design.* San Francisco: Jossey-Bass Inc.

Summers, A. M. (1994). Informed choice in prenatal screening. *Canadian Family Physician.*40:1688-1691.

Sutton, S. (1994). The past predicts the future: interpreting behaviour-behaviour relationships in social psychological models of health behaviour. In Rutter, D.R. and Quine, L., Eds. *Social Psychology and Health: European perspectives* pp. 71-88. Ashgate: Ashgate Publishing Limited.

Sutton, S., Bickler, G., Sancho-Aldridge, J. et al. (1994). Prospective study of predictors of attendance for breast screening in inner London. *Journal of Epidemiology & Community Health.*48:65-73.

Taubes, G. (1997). Medicine: The breast-screening brawl. *Science.*275:1056-1059.

Thomas, J., Harden, A., Oakley A. et al. (2004). Integrating qualitative research with trials in systematic reviews. *BMJ.*328:1010-1012.

Thompson, A. (1995). Customizing the public for health care. What's in a label? In Kirkpatrick, I. and Lucio, M., Eds. *The politics of quality in the public sector.* pp. 65-83. London: Routledge.

Thornton, H. (2003). Patients' understanding of risk. *BMJ.*327:693-694.

Thornton, H., Edwards, A., and Baum, M. (2003). Women need better information about routine mammography. *BMJ.*327:101.

Towle, A., Godolphin, W, Greenhalgh, T et al. (1999). Framework for teaching and learning informed shared decision making. *BMJ.*319:766-771.

Towler, B. P., Irwig, L., Glasziou , P., Weller, D., and Kewenter, J. Screening for colorectal cancer using the faecal occult blood test, Hemoccult

Travess, H. C., Newton, J. T., Sandy, J. R. et al. (2001). The development of a patient-centered measure of the process and outcome of combined orthodontic and orthognathic treatment. *Journal of Orthodontics.*31:220-234.

UK Colorectal Cancer Screening Pilot Group. (2004). Results of the first round of a demonstration pilot of screening for colorectal cancer in the United Kingdom. *BMJ.*329:133.

UK evaluation team Evaluation of the UK screening pilot http://www.cancerscreening.nhs.uk/colorectal/finalreport.pdf (Last accessed 1/2005)

Vahabi, M. and Gastaldo, D. (2003). Rational choice(s)? Rethinking decision-making on breast cancer risk and screening mammography. *Nursing Inquiry.*10:245-256.

Vaidya, J. and Baum, M. (1999). Screening and mortality from cervical cancer (letter). *BMJ.*319.

Volk, R. J., Cass, A. R., and Spann, S. J. (1999). A randomized controlled trial of shared decision making for prostate cancer screening. *Archives of Family Medicine.*8:333-340.

Waggoner, S. E. (2003). Cervical cancer. *Lancet.*361:2217-2225.

Warren, R. (1988). The debate over mass mammography in Britain. The case for. *BMJ.*297:969-970.

Watts, T., Merrell, J., Murphy, F. et al. (2004). Breast health information needs of women from minority ethnic groups. *Journal of Advanced Nursing.47(5):526-35.*

Wear, S. (1998). *Informed consent. Patient autonomy and clinician beneficence within health care.* Washington DC: Georgetown University Press.

Weinstein, N. D. (1982). Unrealistic optimism about susceptibility to health problems. *Journal of Behavioral Medicine.*5:441-460.

Weinstein, N. D. (1988). The precaution adoption process. *Health Psychology.*7:355-386.

Weinstein, N. D. (1989). Optimistic biases about personal risks. *Science.*246:1232-1233.

Willig, C. (2001). *Introducing qualitative research in psychology. Adventures in theory and method.* Maidenhead: Open University Press.

Willis, K. and Baxter, J. (2003). Trusting technology: women aged 40-49 years participating in screening for breast cancer--an exploratory study. *Australian & New Zealand Journal of Public Health.*27:282-286.

Wills, C. E. and Holmes-Rovner, M. (2003). Preliminary validation of the Satisfaction With Decision scale with depressed primary care patients. *Health Expectations.*6:149-159.

Wilson, J and Jungner, G. (1968). Principles and practice of screening for diseases. Geneva, World Health Organization. Public Health paper no. 24.

Winawer, S. J., Fletcher, R. H., Miller, L. et al. (1997). Colorectal cancer screening: clinical guidelines and rationale. *Gastroenterology.*112:594-642.

Wolf, A. M., Nasser, J. F., Wolf, A. M. et al. (1996). The impact of informed consent on patient interest in prostate-specific antigen screening. *Archives of Internal Medicine.*156:1333-6.

Wolf, A. M. and Schorling, J. B. (2000). Does informed consent alter elderly patients' preferences for colorectal cancer screening? Results of a randomized trial. *J Gen Intern Med.*15:24-30.

Wright, C. J. and Mueller, C. B. (1995). Screening mammography and public health policy: the need for perspective. *Lancet.*346:29-32.

Wright, G. (1984). *Behavioural decision theory. An introduction.* Middlesex: Penguin.

Yarbrough, S. S. and Braden, C. J. (2001). Utility of health belief model as a guide for explaining or predicting breast cancer screening behaviours. *Journal of Advanced Nursing.*33:677-688.

Appendix 1. Search for measures of informed choice or informed decision making

Medline (1966 to Oct 2004) was searched using the terms outlined below. Nine hundred and twenty-two references were retrieved from Medline and imported directly into Reference Manager 10. Of these 76 were duplicates (within Medline) leaving 846 references

CancerLit (1982 to Feb 2002) was searched using the same strategy which retrieved 262 references. Of these 229 were duplicates references to those within Medline, leaving 33 potentially relevant references

EmBase (1980 to Oct 2004) was searched using the same strategy which retrieved 967 of which 197 were duplicates leaving 770 potentially relevant references

CINAHL (1982 to Oct 2004) was searched using all of the above search terms apart from 'Mass screening' (not a MeSH in CINAHL) which retrieved 157 references, of which 46 were duplicates, leaving 111 potentially relevant references.

*PsycInfo (*1966- Oct 2004) was searched using a restricted search. 90 references were imported, after being de-duplicated against the other databases

All abstracts were scanned for relevance. If the reference was thought to either definitely or possible be relevant to the topic then the full copy was ordered.

Web Of Science was searched though Reference Manager using the search terms 'informed choice and 'informed consent' and screening.

Database	Number retrieved	Number duplicates	Total originals
Medline	922	76	846
CancerLit	262	229	33
EmBase	967	197	770
CINAHL	157	46	111
PsycInfo	99	90	90
Web of Science	91	0	91
	2498	638	1941

Search terms used to identify measures of informed choice/consent (MEDLINE)

1 exp Decision Making/ or decision making.mp. (60142)
2 (decision$ adj5 mak$).mp. [mp=title, abstract, registry number word, mesh subject heading] (23204)
3 (inform$ adj5 decision$).mp. [mp=title, abstract, registry number word, mesh subject heading] (8799)
4 (share$ adj5 decision$).mp. [mp=title, abstract, registry number word, mesh subject heading] (468)
5 Informed Consent/ (21479)
6 (inform$ adj choice$).mp. [mp=title, abstract, registry number word, mesh subject heading] (687)
7 (inform$ adj5 uptake).mp. [mp=title, abstract, registry number word, mesh subject heading] (271)
8 (know$ and choice$).mp. [mp=title, abstract, registry number word, mesh subject heading] (6905)
9 exp Mass Screening/ (53682)
10 (Pap$ adj (smear$ or test$)).mp. [mp=title, abstract, registry number word, mesh subject heading] (4293)
11 (cervical adj (smear$ or test$)).mp. [mp=title, abstract, registry number word, mesh subject heading] (1630)
12 (colorectal adj (screen$ or test$)).mp. [mp=title, abstract, registry number word, mesh subject heading] (62)
13 Sigmoidoscopy/ (2895)
14 FOBT.mp. or Occult Blood/ (2425)
15 Psa.mp. or Prostate-Specific Antigen/ (8699)
16 (genetic adj (screen$ or test$)).mp. [mp=title, abstract, registry number word, mesh subject heading] (3897)
17 (cancer adj screen$).mp. [mp=title, abstract, registry number word, mesh subject heading] (4826)
18 screen$.mp. [mp=title, abstract, registry number word, mesh subject heading] (155897)
19 Vaginal Smears/ or vaginal smears.mp. (12078)
20 Mammography/ (12740)
21 mammogra$.mp. [mp=title, abstract, registry number word, mesh subject heading] (15137)
22 FOB$.mp. [mp=title, abstract, registry number word, mesh subject heading] (411)
23 Risk Assessment/ or risk assessment.mp. (19671)
24 Risk Assessment/ or risk assessment.mp. (19671)
25 (risk adj5 assess$).mp. [mp=title, abstract, registry number word, mesh subject heading] (20048)
26 (amniocentesis or down's or prenatal).mp. [mp=title, abstract, registry number word, mesh subject heading] (42794)
27 health surveys/ or health care surveys/ or interviews/ or questionnaires/ (109812)
28 (scale$ or instrument$).mp. [mp=title, abstract, registry number word, mesh subject heading] (166591)
29 measure$.mp. [mp=title, abstract, registry number word, mesh subject heading] (888620)
30 "Outcome Assessment (Health Care)"/ or outcome evaluation.mp. or "Outcome and Process Assessment (Health Care)"/ or Evaluation Studies/ (141331)
31 or/1-8 (92070)
32 or/9-25 (239578)
33 32 not 26 (234785)
34 or/27-30 (1201330)
35 31 and 33 and 34 (922)

Appendix 2. Details of the measures included in the systematic review

1. Multi-dimensional measure of informed choice (Marteau 2001)

A. Knowledge

1. Which of these conditions do you think that the test screens for? (you may tick more than one box for this question)
Spina bifida
Anaemia
Down's syndrome
Most abnormalities
None of these
Don't know

2. If 100 women decided to have the screening test, about how many do you think would have a low-risk result?
100
None
50
95
5
Not sure

3. What do you think a low-risk result means?
The baby definitely does not have Down's syndrome
It is highly unlikely that the baby has Down's syndrome
The baby might have Down's syndrome
It is highly likely that the baby has Down's syndrome
The baby definitely does have Down's syndrome
None of these
Don't know

4. Again, imagine that 100 women undergo the test. About how many do you think would have a high-risk result?
100
None
50
95
5
Not sure

5. What do you think a high-risk result means?
The baby definitely does not have Down's syndrome
It is highly unlikely that the baby has Down's syndrome
The baby might have Down's syndrome
It is highly likely that the baby has Down's syndrome
The baby definitely does have Down's syndrome
None of these
Don't know

6. Imagine 100 women with a high-risk result. About how many do you think will be found to have a baby with Down's syndrome?
100
50
25
2
Not sure

7. Some women are offered further tests (amniocentesis or CVS., which involve inserting a fine needle into the womb). What are the possible consequences of this test?

8. If the further tests show that the baby definitely does have Down's syndrome, what would a woman be offered:
Immediate treatment for the baby
Another type of test
A termination of pregnancy
Extra vitamins
None of these
Not sure

B. Attitudes

For me, having the screening test for Down's syndrome when I am15 weeks pregnant will be:
(a) Beneficial 1 2 3 4 5 6 7 Harmful
(b) Important 1 2 3 4 5 6 7 Unimportant
(c) Bad thing 1 2 3 4 5 6 7 Good thing
(d) Pleasant 1 2 3 4 5 6 7 Unpleasant

2. Decisional Conflict Scale (O'Connor 1995)
Thinking about the choice you (are about to make/just made), please look at the following comment some people make when deciding about (treatment, screening etc.). Please show how strongly you agree or disagree with these comments by CIRCLING THE NUMBER from 1 (strongly agree) to 5 (strongly disagree) that best shows how you feel about the decision you (are about to make/just made).

Decision uncertainty
This decision is hard for me to make
I'm unsure what to do in this decision
It's clear what choice is best for me

Factors contributing to uncertainty
I'm aware of the choice I have to (specify purpose - to protect myself from flu)
I feel I know the benefits of (the 'flu shots)
I feel I know the risks and side effects of (the 'flu shots)
*I need more advice and information about the choices
*I know how important the benefits (of the 'flu shot) are to me in this decision

I* know how important the risks and side effects (of the 'flu shot) are to me in this decision
*It's hard to decide if the benefits are more important to me than the risks, or if the risk are more important than the benefits.
*I feel pressure from others in making this decision
*I have the right amount of support from others in making this choice

Perceived effective decision making
I feel I have made an informed choice
My decision shows what is most important for me
I expect to stick with my decision
*I am satisfied with my decision

*Items are new and are currently being evaluated.

3. Satisfaction with Decision Scale (Holmes-Rovner 1996)
You have been considering whether to consult you health care provider about hormone replacement therapy. Answer the following questions about your decision. Please indicate to what extent each statement is true for you AT THIS TIME.

Use the following scale to answer the questions.
1 = strongly disagree
2 = disagree
3 = neither agree nor disagree
4 = agree
5 = strongly agree

I am satisfied that I am adequately informed about the issues important to my decision.
The decision I made was the best decision possible for me personally.
I am satisfied that my decision was consistent with my personal values.
I expect to successfully carry out (or continue to carry out) the decision I made.
I am satisfied that this was my decision to make.
I am satisfied with my decision.

4. Measuring patient knowledge of prostate cancer (Radosevich et al, 2004)
Natural history of prostate cancer and prostate cancer risk factors
1 Based on what you have heard or read, about how many men diagnosed as having prostate cancer will actually die because of prostate cancer? [Would you say most die because of prostate cancer, about half die because of prostate cancer, or most die because of something else?]
2 The chance of getting prostate cancer increases with age
3 Most men diagnosed as having prostate cancer die of something else
4 Men are more likely to die because of prostate cancer than because of heart disease
5 Prostate cancer is the *most common* cause of problems with urination
6 Prostate cancer is a potentially serious disease that can cause death
7 Prostate cancer *never* causes problems with urination
8 Prostate cancer is one of the *least* common cancers among men

PSA test accuracy and diagnostic tests
9 Based on what you have heard or read, how many men with *abnormal* prostate specific antigen (PSA) test results have prostate cancer? [Would you say most don't have prostate cancer, about *half* have prostate cancer, or most *do* have prostate cancer?]
10 If you have an *abnormal* prostate specific antigen (PSA) test result, your doctor may recommend that you have a prostate biopsy
11 The prostate specific antigen (PSA) test will pick up *all* prostate cancers
12 A prostate biopsy can tell you with more certainty whether you have prostate cancer than a prostate specific antigen (PSA) test can

Treatment efficacy and complications
13 Persistent headaches are a common side effect of prostate cancer treatments
14 Loss of sexual function is a common side effect of prostate cancer treatments
15 Problems with urination are common side effects of prostate cancer treatments
16 Prostate cancer treatments have been shown to extend the life of a man with prostate cancer

Expert agreement
17 All experts agree that men should get annual PSA tests

5. Items for Decisional Balance (Rakowski et al, 1997)
(Agree, Undecided, Disagree)
Pros
Your family will benefit if you have a mammogram
You are more likely to go for mammograms if your doctor tells you it is important for you.
Having mammograms every year or two gives you a feeling of control over your health.
Having mammograms every year or two gives you peace of mind about your health.
Women need mammograms even when they have no family history of breast cancer.

Cons
If you have breast exams from a doctor or nurse, you don't need mammograms
Mammograms often lead to unnecessary surgery.
Having mammograms causes a lot of worry or anxiety about breast cancer.
Once you have a couple of mammograms that are normal, you don't need any more for a few years.
You do not have a mammogram unless you have some breast problem or pain.
The cost of mammograms would cause you to hesitate about getting one.
There is so much different information about how often women should have mammograms you are confused.
You are less likely than most other women your age to get breast cancer.
The pain caused by having a mammogram is bad enough to make you put off getting one.

Appendix 3. Search for qualitative and quantitative studies

Databases searched

The following databases were searched in Oct 2004 - some of the databases are only updated 6 monthly or yearly, which accounts for the discrepancy between the dates (e.g. Medline was last updated in Oct 2004). The table shows how many duplicates were identified

Medline (1980 to Oct 2004) was searched using the terms outlined below. 493 references were retrieved from Medline and imported directly into Reference Manager 10.

CancerLit (1980 to Oct 2004) was searched using the same strategy, which retrieved 262 references. Of these 229 were duplicates references to those within Medline, leavingg 33 potentially relevant references

EmBase (1980 to Oct 2004) was searched using the same strategy which retrieved 167 potentially relevant references

CINAHL (1980 to Oct 2004) was searched using all of the above search terms apart from 'Mass screening' (not a MeSH in CINAHL) which retrieved 66 references.

*PscInfo (*1980 to Oct 2004) was searched using a restricted search. 81 references were imported, after being de-duplicated against the other databases

Web Of Science was searched via Reference Manager using the search terms 'Informed choice and 'informed consent' and screening.

Cochrane Library (Cochrane Database of Systematic Reviews, NHS CRD DARE, CENTRAL, Health Technology Assessment Database), Issue 3 2004 was searched using all of the search terms apart from those for randomised controlled trials (only RCTs/CCTs appear on the Cochrane Library)

All abstracts were scanned for relevance. If the reference was thought to either definitely or possible be relevant to the topic then the full copy was ordered.

Database	Number retrieved	De-duplicated against informed choice measures and within the database	Total number of originals
Medline	493	117	376
CancerLit	141	39	102
EmBase	167	52	115
CINAHL	66	26	40
PsycInfo	81	0	81
Web of Science	0	0	0
NHS CRD DARE	145	0	145
CENTRAL	477		413
Health Technology Assessment Database	34	0	32
Total	1604	201	1304

Search strategy for retrieving trials of informed choice interventions in cancer screening

PART 1. INTERVENTION TERMS

(quantity adj2 information).ti,ab.
(generic adj2 information).ti,ab.
(information$ adj2 intervention).ti,ab.
(disclos$ adj2 information).ti,ab.
(amount$ adj2 information$).ti,ab.
(comprehensive or limited or partial or full or detailed or complete or persuasive) adj2 (inform$ or disclos$)
(risk$ or harm$ or limitation$) adj2 disclosure).ti,ab.
exp Truth disclosure/ or exp Advertising/ or exp Persuasive communication/ or exp Propaganda/ or exp Verbal behavior/ or Language/
Patient education/
(information$ adj5 (leaflet$1 or pamphlet$1 or script$3 or booklet$1 or sheet$1 or brochure$1 or Internet or video)).mp.
(decision$ adj5 aid$).mp.

PART 2. SCREENING TERMS

exp Mass Screening/
exp Population Surveillance
exp *diagnostic tests, routine/
exp Genetic Screening/
exp *colorectal neoplasms/pc
exp *mammography/
exp *cervix neoplasms/pc
exp *prostatic diseases/pc
exp *breast neoplasms/pc
(genetic adj (screen$ or test$)).mp.
(cancer adj screen$).mp.
screen$.mp.
Vaginal Smears/ or vaginal smears.mp.
(Pap$ adj (smear$ or test$)).mp.
(cervical adj (smear$ or test$)).mp.
Sigmoidoscopy/
FOBT.mp. or Occult Blood/
FOB$.mp.
mammogra$.mp.
(psa or Prostate-Specific Antigen).mp.
amniocentesis/ or amniocentesis.mp.
bone density or osteoporosis
chest x-ray or tuberculin patch test

PART 3. OUTCOME TERMS

exp Decision Making/ or decision making.mp.
(inform$ adj5 decision$).mp.
(share$ adj5 decision$).mp.
Informed Consent/
(inform$ adj choice$).mp.
(inform$ adj5 uptake).mp.
(know$ and choice$).mp.
(presumed adj5 consent).mp
screen$ adj5 uptake.mp
Cognition/ or understanding.mp.
exp Knowledge, Attitudes, Practice/ or knowledge.mp.
Patient acceptance of health care.mp
Patient participation/ or patient participation.mp.
Patient compliance/ or patient compliance.mp.
(patient$ or consumer$ or client$) adj5 (participat$ or comply or complian$ or decide$ or decision$ or choice$ or consent$)

Appendix 4. Checklist for qualitative studies

1. Aim:
Is the research question a relevant issue?
Is the aim sufficiently focused, and stated clearly?

2. Method and design:
Are qualitative research methods suitable for exploration of the research question?
Has an appropriate qualitative design been chosen with respect to the research question?
Was the way research was presented to the participants ethical and adequate?
Were ethical issues involved in the study? If so, were issues of informed consent and confidentiality discussed by researcher?

3. Data collection and sampling:
Was the sample recruitment design appropriate to the aims of the research?
Is the strategy for participant recruitment clearly stated (usually purposive or theoretical, usually not random or representative)?
Are the reasons for this choice stated?
Are the consequences of the chosen strategy discussed?
Were procedures of data collection made explicit and discussed?
Was saturation of qualitative findings, where this issue is relevant, considered and achieved?

4. Analysis:
Are the principles and procedures for data organisation and analysis fully described, allowing the reader to understand what happened to the raw material to arrive at the results?
Were concepts used in the study developed from its data?
Are strategies used to validate results presented, such as double or multiple independent coding, cross-checks for rivaling explanations, member checks, respondent validation, or use of several methods of data collection in the same study (triangulation)?

5. Findings:
Are the findings relevant with respect to the aim of the study?
Are the findings discussed in relation to the original research questions?
Is the presentation of the findings well organised and best suited to ensure that findings are drawn from systematic analysis of material, rather than from preconceptions or partial use of data?
Did the researcher explain how the data presented (like quotes) were selected from the original sample?
Are quotes used adequately to support and enrich the researcher's synopsis of the patterns identified by systematic analysis?

6. Discussion:
Are the researcher's motives, background, perspectives, and preliminary hypotheses presented, and is the effect of these issues sufficiently dealt with?
Did the researcher critically examine their own potential biases or influence on sample recruitment, choice of locations, data recording method and data collection (researcher not blinded to some key subgroup characteristics)
Are questions about internal validity (coherence between the study's objectives, design and analytical methods) and external validity (to what other populations or settings the findings can be applied) addressed?
Were contradictory or unexpected findings discussed sufficiently?
Was there adequate discussion of the evidence both for and against the researcher's arguments?
Are the shortcomings accounted for and discussed?

7. Presentation:
Is the report easy to understand?
Is it possible to distinguish between the voices of the informants and those of the researcher(s)?

8. Value of research:
Does the researcher highlight contribution to existing knowledge?

Appendix 5. Diary of events leading to recruitment of sample for the study

Date	Event
Sept 18th 2001	Spoke to programme co-ordinator at ISD who said that they could provide us with a sample of patients for the focus groups etc. However, it has to go through the Caldicott Guardians and Directors of Public Health. She said that we have to write a letter to Director of Scottish Screening Programmes and she should be able to let us know if it is possible and the associated costs.
Sept 19th 2001	Met with Lucy McCloughan of Lothian Primary Care Research Network to discuss issues of support costs and how to organise the project
Sept 20th 2001	Letter sent to Director of Scottish Screening Programmes
Oct 2001	No reply from Director of Scottish Screening Programmes Re-contacted, but no reply. Away on leave
Dec 17th 2001	Meeting arranged with Carol Colquhoun for January 16th 2002
Jan 16th 2002	Meeting cancelled. Rearranged for 27th January
27th Jan 2002	Met with Carol - discussed various options. Carol agreed to talk to relevant people and report back. Meeting scheduled for Wednesday 3rd April 2002. Ruth and David to seek consent from CRC Steering Group
Feb 2002	Agreement by CRC Steering Group in principle to project was given. It is now only necessary to negotiate within Scotland.
3rd April 2002	Met with Director of Scottish Screening Programmes and agreed that 1) We need to get LREC approval for Lothian and Tayside (for colorectal cancer) - 2) It is not going to be possible to get people with a false negative result. It may be possible to recruit them through self-help groups - ISDl suggested Cancer Backup (http://www.cancerbacup.org.uk). 3) The new version of GPASS is not very useful as the call/recall system did not work, so we can't really use this as a source
10th April 2002	Carol Colquhoun spoke to Dr Rod Muir and wrote, *'I think that the appropriate paperwork for Ruth to complete would be an application to the privacy Advisory Committee of the CSA for approval of release of the named breast and colorectal screening data you require.'*
Note	I decided to go ahead and get ethical approval first before applying to the PAC
2nd May 2002	Wrote to Mike Winter (Caldicott Guardian) - no reply received
23rd May 2002	Lothian Research Ethics Committee application submitted
4th June 2002	Wrote to GP practices in Lothian - two replied saying that they would take part
5th June 2002	Tayside Research Ethics Committee application submitted
20th June	Wrote to GP practices in Tayside – no replies received
24th July 2002	Lothian Research Ethics Committee Approval granted
29th July 2002	Tayside Research Ethics Committee Approval granted
2nd July 2002	Reminder letters to Tayside practices
6th August	Submission of application to PAC to use individual records for medical research
20th August	Wrote to CancerBackup and Maggie's centre for focus group participants
19th Sept 2002	PAC met. Email from Rod Muir saying that issues about the use of CHI in study had been raised – CHI is involved as it is basically used as the sampling frame for breast and colorectal screening. Application rejected
17th October 2002	Meeting with Rod Muir, David Steel and later Carole Morton. Discussed options and decided it was best to go through screening programmes. Further meetings to be arranged to discuss this option. David W suggested contacting our practice to discuss holding focus groups here

Date	Event
10th October 2002	Wrote to Breast Cancer Care asking them to advertise the project
18th October 2002	Contacted McKenzie Medical practice - arranged meeting for 6th Nov
6th Nov 2002	Met with Robbie to discuss focus groups – he agreed to send out letters on our behalf
11th Nov 2002	Met with David Weller and Margaret Douglas (Director Cervical Screening). Suggested 2 options. Via GPs or the laboratory APEX system. Project would need to be registered with the trust R&D office and agreed by Caldicott guardian but these could be arranged.
20th Nov 2002	Letters sent out to 21 people in McKenzie Medical Practice – no replies received
22nd Nov 2002	Met with DW, David Steel and Elaine Anderson Breast Screening Unit
25th Nov 2002	Sent amended ethics form to LREC with new sampling procedures
27 Nov 2002	Met with Colette Fulton of LPCRN. LPCRN will send out letters to practices on our behalf and also arrange for CSO funding
04 Dec 2002	Wrote to Dr Duvall with details of project. He might be able to recruit through cervical laboratory (see 11th Nov) – had some correspondence but never eventuated. Went through GP practices instead.
13th Dec 2002	Met with Practice manager to discuss time spent on process of recruitment
December 2002	Amended Ethics Approval received
Jan 16th 2003	First interview with a woman with false negative (recruited through Breast Cancer Care)
Feb 2002	Sent amended ethics form to Tayside Research Ethics Committee with new sampling procedures
Feb 11th 2003	David wrote to Colorectal Managers and Directors about the study asking ' *Ruth needs to assemble some small focus groups to talk about the experiences of people who've participated in the Scottish pilot*
February 2003	PCRN sent out letters to potential GPs – delay due to waiting for approval for CSO funding to reimburse practices
February 2003	Colorectal unit sent list of GP practices. Letters sent out from TayRen and myself
30th Feb 2003	Breast unit sent list of GP practices
6th March	Letters sent out to breast GPs by LPCRN and myself
12th March 2003	Tayside Research Ethics Committee asked for further clarification of project and nomination of local contact person
12th March 2003	Presented project at LPCRN – one potential GP there who then agreed to take part in the study.
17th March 2003	Colorectal Pilot Unit raised concerns about the project. In particular it was stated that the screening unit did not have any formal involvement in the actual project. Project staff were busy and there was confusion as who would send out the letters
28th March 2003	Attended a meeting of Tayside Local Group meeting for the colorectal pilot to discuss my project. Managers agreed to take part after discussions. Need to apply to Director of Public health for permission.
March 2003	Practice in West Lothian agreed to take part but need to apply for additional approval from West Lothian Primary Care Trust.
March to April	Meetings with practice staff who had agree to take part, liaising between screening staff who were producing the lists and practice staff who were receiving the lists.

Date	Event
May to July 2003	Most of the focus groups and interviews undertaken!
December 2003	Some breast screening focus groups undertaken (delays due to practice staff illness)

Appendix 6. Sample letter to GPs inviting them to take part in the study, and patient information sheet

Dear Dr

'Developing a measure of informed choice in cancer screening'

Researchers in the Department of General Practice have been funded by the Chief Scientist's Office to undertake the above research project. The aim of the study is to explore the amount and type of information that people want to be able to make an informed choice over whether to take part in cancer screening. It also aims to identify factors affecting the choice to be screened and what information is particularly important in this decision-making process.

Part of the study involves conducting focus groups with people with the following experiences of screening: false positives, true positives, true negatives and those who have been invited to screening but have declined. All participants will have been invited for breast or cervical cancer screening within the last six months. The focus groups will take place at the Department of General Practice, University of Edinburgh or at another convenient location. Participation is entirely voluntary and confidentiality is assured under the terms of the Data Protection Act. Ethical approval for this research is currently being sought from the Lothian Research Ethics Committee.

We would like to invite some patients (less than 10) from your practice to take part in our study. If you are willing for them to participate then we would be very grateful if you could contact potential participants on our behalf to maintain their anonymity. We would send you the CHI numbers of potential participants (which we will obtain from ISD Scotland), and letters, information sheets and consent forms to send out to them. We are able to pay you for the time taken to complete this exercise and any additional costs incurred.

We would be grateful if you could let us know if you are willing to help us in this research project at your earliest convenience.

Yours sincerely,

Professor David Weller — Ruth Jepson

Head of Department — Research Fellow

Research Information Sheet for Participants

Research title

Sharing information with people about the risks and benefits of cancer screening: how does this affect their choice to be screened?

Introduction

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what will be involved. Please take the time to read the following information carefully and discuss it with others if you wish. Please contact the researcher (details at the end of this sheet) if anything is not clear, or if you would like further information. Thank you for taking the time to read this.

What is the purpose of the study?

It has been recognised recently that it is important to give people information about the risks and benefits of screening. Using this information, people can then make an individual choice over whether to be screened or not. The aim of the study is to explore what sort of information people want in order to make an informed choice over whether to take part in cancer screening. It also aims to identify whether they use this information when making a choice about whether to be screened or not and what other factors affect the choice to be screened.

Why have I been chosen to take part?

You have received an invitation to be screened within the last 6 months and the investigators are interested in people's different experience of this process, both the test itself and what happened afterwards. They are also interested in people who have been offered the test but decided that they did not want to be screened. This general practice has agreed that you can be approached and asked to help with this study.

Do I have to take part?

It is up to you to decide whether or not to take part. If you decide to take part you will first need to read and sign the attached consent form and return it in the prepaid envelope to the principal researcher. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

What do I have to do if I decide to take part?

If you decide to take part and have returned the consent form, you will be invited to attend a focus group. These focus groups will be consist of about 6-8 people, from either Lothian or Tayside regions, and you will be asked to talk about your experiences and knowledge of screening. Each focus group will last 1-2 hours and

will take place in the Department of General Practice at the University of Edinburgh at a convenient time. Unless you have any objections, these focus groups will be tape recorded

Confidentiality

All information which is collected about you during the course of the research will be kept strictly confidential under the terms and conditions of the Data Protection Act. Any information about you which leaves the surgery will have your name and address removed so that you cannot be recognised from it. Unless you have any objections, the focus groups will be tape recorded for reasons related to accuracy. Before taking part your permission will be sought to be tape recorded. If you do not wish to be tape recorded, hand written notes will be taken. In both cases, information about yourself will be made anonymous as will anything else which might identify you, such as references to GPs, clinics and places.

What are the possible disadvantages and risks of taking part?

There is a slight possibility that you may feel anxious or depressed after talking about your experiences of screening.

What are the possible benefits of taking part?

There are no direct benefits to you as a participant.

What will happen to the results of the research study?

The results of the research study will be written up as reports for the Chief Scientist Office and published in peer reviewed journals.

Who is organising and funding the research?

The research is funded by the Chief Scientist Office and is organised through the Department of General Practice, University of Edinburgh. If you decide to take part you will be reimbursed for travel expenses.

Who has reviewed the study?

The Lothian Research Ethics Committee has reviewed the study.

Contact for further information

Ruth Jepson, Dept General Practice
University of Edinburgh
20 West Richmond Street, Edinburgh
EH8 9DX Tel: 0131 650 9462; Fax: 0131 650 2681;Email: ruth.jepson@ed.ac.uk

08 Jul. 02, Version 2

Centre Number: :

Study Number:

Patient Identification Number for this trial:

CONSENT FORM

Title of Project: Sharing information with people about the risks and benefits of cancer screening: how does this affect their choice to be screened?

Name of Researcher: Ruth Jepson

Please initial box

1. I confirm that I have read and understand the information sheet dated .... version .....) for the above study and have had the opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐

3. I agree to take part in the above study. ☐

4. I understand that my participation in this study will be anonymous and will be treated in the strictest confidence ☐

_____ _____ _____

Name of Participant Date Signature

_____ _____ _____

Name of Person taking consent Date Signature

(if different from researcher)

_____ _____ _____

Researcher Date Signature

Appendix 7. Interview schedule

Research title: Sharing information with people about the risks and benefits of cancer screening: how does this affect their choice to be screened?

Sociodemographics

Asked about personal details such as age, marital status, job etc.

The screening experience and information

I wonder if you can remember back to that last screen that you had and tell me a bit about it, and what happened afterwards

Can you remember what information you received when you were invited to be screened?

Did this information affect your decision to be screened do you think?

Was there any particular piece of information that you were given, or knew about that influenced your decision?

Did your experience of the screening process make sense based on the information you were given?

Did you feel that you were given enough information or were there questions you had which were still unanswered?

What additional information (if any) would you have like to have had before making going along for screening?

Were there any other factors that influenced your decision to be screened?

Prompts were usually introduced at this point

Screening choice

Can you remember feeling that you had a choice over whether to be screened? For example, did you feel that you had the opportunity to refuse screening?

Given your recollection of the information and the choices you were faced with, do you feel that you made an informed choice over whether to be screened or not?

Screening in general

How do you view screening in general?

Have you taken part in any other forms of screening (cervical, antenatal)? What were those experiences like compared to your experience of breast cancer screening?

Did you talk to other people about your decision to be screened?

Is there anything else you would like to tell me about?

Appendix 8. Prompts to women taking part in breast cancer focus groups or interviews.

What is the risk of developing breast cancer?

- The great majority of breast cancers occur in women, less than 1 in 100 occur in men.
- In the UK there over 30,000 new cases of breast cancer in women diagnosed every year.
- Overall about 1 in 12 women will develop a breast cancer at some time during their life.

http://www.cancerbacup.org.uk/questions/specific/womens/breast/common.htm

What are the risk factors for breast cancer?

- In most cases, the cause of breast cancer is unknown. However, the following risk factors have been identified:
- Family history. If you have a sister, mother or daughter with breast cancer your risk of developing it is also increased.
- A personal history of breast cancer carries a risk of the disease recurring.
- Early start of menstrual cycle.
- Late menopause.
- First pregnancy after the age of 30.
- Never having had a child.
- Genetic tendency. A small percentage of breast cancers (5 percent) develop due to genetic tendency
- Ongoing studies are looking at the effect of a diet low in fat, high in fruit and vegetable intake on reducing the risk of developing breast cancer.

How reliable is breast screening?

- Mammography is the most reliable way of detecting breast cancer early but, like other screening tests, it is not perfect.
- For example:
- some cancers are very difficult to see on the x-ray;
- some cancers, even though they are there, cannot be seen on the x-ray at all; and
- the person reading the x-ray may miss the cancer (this will happen occasionally, no matter how experienced the reader is).

- Less than 10% of women screened for the first time and less than seven per cent of those screened for a second or subsequent time should be recalled.

What are the limitations of breast screening?

- Some women are called back for more investigations if the screeners are not sure about their mammogram. After more tests, they will find that many of these women will not have cancer. If you are called back it can cause worry.
- Screening may miss some breast cancers.
- Not all breast cancers that are found at screening can be cured.
- Many women find mammography uncomfortable or painful, but normally just for a brief period of time.

source: www.cancerscreening.nhs.uk/breast

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HOW SHOULD WE MEASURE INFORMED CHOICE? THE CASE OF CANCER SCREENING

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ABSTRACT

Informed choice is increasingly recognised as important in supporting patient autonomy and ensuring that people are neither deceived nor coerced. In cancer screening the emphasis in has shifted away from just promoting the benefits of screening to providing comprehensive information to enable people to make an informed choice. Cancer screening programmes in the UK now have policies in place which state that it is their responsibility to ensure that individuals are making an individual informed choice. There is a need to evaluate whether such policies mean that those people invited for screening are making informed choices, and how comprehensive information affects other variables such as uptake, cost-effectiveness and satisfaction. At the present time, there is no validated measure of informed choice in cancer screening. Such a measure could be used to evaluate the effectiveness of interventions to increase informed choice and levels of informed choice in a population invited for screening. It could encourage health professionals to be accountable. Factors important when measuring informed choice in cancer screening include an individual's understanding of the limitations of screening, the ability to make an autonomous choice, and the difference between choice and behaviour.

Keywords: informed choice, cancer screening

INTRODUCTION

Theories of postmodernism suggest that people have increasingly taken on the role of individualised consumers who place high value on choice and particularly the concept of informed choice. Healthcare professionals are among the leading sources of choices from the cradle to the grave.[1] In recent years, informed choice has found support in many areas of healthcare including cancer screening.[2,3]

Cancer screening for many years has been viewed as a public health policy aimed at disease prevention. In the UK, for example, once a woman reaches 50 years of age she is automatically invited to be screened for breast cancer (providing there are no contraindications). Until recently screening has been promoted as a beneficial, preventative activity that all eligible people should participate in. The benefits of screening for cancer were deemed to be so great that harms and limitations were overlooked.[4] However, informed choice has now been accepted by screening policy makers and is now being considered alongside more conventional screening parameters, such as quality assurance procedures and improvements in survival. For example, the second report of the National Screening Committee (NSC) states: "There is a responsibility to ensure that people who accept an invitation do so on the basis of informed choice, and appreciate that in accepting an invitation or participating in a programme to reduce their risk of a disease there is a risk of an adverse outcome."[4] In addition, recent guidance from the General Medical Council (GMC) states that doctors must ensure that anyone considering whether to consent to screening can make a properly informed decision.[5]

Individual choice within cancer screening programmes

In order to maximise effectiveness, the main focus of screening programmes is to have the highest coverage and uptake of the population as possible. As such, many policies in place in the UK encourage health professionals to increase uptake rather than informed choice. For cervical screening, general practitioners get paid an incentive if they achieve high levels of uptake in their practice. It has been argued that target payments work against the spirit of enabling individuals to make an informed choice about whether they want to be screened.[6] However, there is concern that increasing informed choice may reduce uptake, resulting in programmes no longer being cost effective.

Even when it is accepted that screening has a net beneficial effect, one of its inherent limitations is that some individuals will be harmed and others will benefit. Moral conflicts and concerns over patient rights arise where an intervention has the potential to cause both benefit and harm to an individual.[7] In recent years all areas of health care have become increasingly interested in the concept of informed choice and the rights of the individual. The focus of informed choice is on disclosure of risk information to promote individual autonomy. The concept is grounded in liberal philosophy, which implies that individual rights are paramount.[8] However, public health policies such as screening are grounded in the philosophy of utilitarianism and based on population outcomes such as reduction in the burden of disease.

The purpose of this paper is not to try and place a value on the relative importance of these two theories. Neither is it attempting to evaluate whether they can be compatible. The main aim of this paper is to propose the main elements that are

important to consider in the measurement of informed choice within existing cancer screening programmes.

The concept of informed choice was originally developed within the context of decisions about treatments. It is now seen as being important within public health programmes and is positioned among other outcomes such as uptake and reduction of the burden of disease, all of which have resource implications. There are finite resources in any health programme; thus all of the important aspects within that programme—quality control, high uptake, good educational materials, staff development programmes, and promoting informed choice—must ultimately compete with one another. In addition, the provision of information may also affect other outcomes both positively (for example, a decrease in anxiety) and negatively (a decrease in uptake). There is concern that there will be tension between promoting informed choice and promoting uptake.[9] This concern has not, as yet, been borne out by any empirical evidence. In one systematic review of informed choice interventions in screening, it was concluded that promoting informed choice did not appear to have any impact on uptake,[10] whereas another showed that the disclosure of information on individual risk increased screening uptake.[11] However, as the authors note, this should not be interpreted as making an informed choice.

WHAT IS MEANT BY INFORMED CHOICE?

The concept of informed choice is based on the doctrine of informed consent. The expression "informed choice" not "informed consent" is principally used within health screening because people are normally invited to participate, and they choose (to a greater or lesser extent) whether to do so or not. They may never have any contact with a health professional if they decide not to participate. We would argue that consent implies more active decision making following some contact and discussion with a health professional.

Reasons for encouraging informed choice include supporting patient autonomy and providing reassurance that patients are neither deceived nor coerced.[12] However, what is not known is the extent to which the provision of unbiased, comprehensive screening information increases informed choice. The fundamental goal in enhancing patient choice is to enable patients to come to an autonomous decision which reflects their personal preferences. The goal of enhancing choice cannot, therefore, be to encourage a specific choice to be made.[13] Several recent definitions related to informed choice are given in table 1

Table 1. DEFINITIONS OF CHOICE AND INFORMED CHOICE

Terms	Definition
Informed choice	One that is informed, consistent with the decision-maker's values and behaviourally implemented [14]
Informed decision	One where a reasoned choice is made by a reasonable individual using relevant information about the advantages and disadvantages of all the possible courses of action, in accord with the individuals beliefs [15]
Autonomous choice	One which occurs when people act 1) intentionally, 2) with understanding, and 3) without controlling influences that determine their actions [16]
Evidence based patient choice	The use of evidence-based information as a way of enhancing people's choices when these people are patients [13]

As can been seen from table 1✦, definitions vary both in terminology and in content. The terms "choice" and "decision" are both used in the literature to denote essentially the same underlying concept. In addition, behavioural implementation of the choice is a required criteria in one definition[14] but not in others. Definition of what it means to make an informed choice is difficult; perhaps no definition can fully explain the concept. The purpose of this paper is to understand the factors that affect both "informedness" and choice.

To enable a person to make an informed choice, he or she needs to be provided with adequate, high quality, relevant, unbiased information of all the consequences of making her/his choice. For example, the GMC proposes that people need the following information in order to make such an informed decision (or choice) in screening:

- the purpose of the screening;
- the likelihood of positive/negative findings and possibility of false positive/negative results;
- the uncertainties and risks attached to the screening process;
- any significant medical, social, or financial implications of screening for the particular condition or predisposition;
- follow up plans, including availability of counselling and support services.[5]

Definitions of what comprise an informed choice, however, might differ according to a person's perspective. For the health professional, an informed choice may be a rational one, where the individual chooses the option with the best clinical outcomes. For the individual person, an informed choice may be one where they feel more satisfied and less anxious about their decision. To feel informed, individuals may want information on how people who have been through a negative experience have coped and what it is like to experience a particular health state.[17]

Choice and information

The provision of relevant, high quality information is assumed by some to be sufficient to enable people to make an informed choice. However, for a person to make an informed choice much more is needed than the provision of information. The information needs to have been read and understood. In addition, a person must be able to choose freely between different options and to carry out their intended choice.

The relation between the way information is presented and the choices people make also needs to be considered. Provision of information may not be value free and may be used to direct choice. For example, the way that "logically equivalent" information is presented (framed) has the potential to manipulate consumer decisions.[18] Additionally, a qualitative study reported that choices in many evidence based maternity leaflets were interpreted by patients as indicting "right" and "wrong" choices. The authors concluded that the normative culture in which leaflets on informed choice were being introduced resulted in informed *compliance* rather than informed *choice*.[19] Thus people may be informed but not feel free to make a choice that is not consistent with normative beliefs.

Choice and autonomy

The provision of information may enable a person to become informed, but it may play little part in enabling an autonomous choice to be made. Although comprehensive information is a prerequisite for informed choice, a person can be informed without having (or indeed wanting) a choice. Equally, a person may want to make an autonomous choice without the use of information.

It can be argued that there are three main aspects of choice in the context of healthcare in general and screening in particular. Firstly, there should be options available to choose from and people should know that they have a choice. Secondly, the person should be able to carry out their preferred choice. There may be barriers (for example, disability, language, poor health, access), which mean that, even though a choice is available in principle, it cannot be carried out in practice. Thirdly, the choice should be autonomous. The predominant theory of autonomy in relation to patient choice and healthcare is proposed by Fadden and Beauchamp.[16] They define an autonomous action as one which is performed intentionally, with understanding, and without controlling actions. However, this definition was largely for people making decisions about different treatment options. Whether such notions of autonomy can exist within public health policies is perhaps open to debate.

Informed choice and shared decision making

Informed shared decision making has been described as "decisions that are shared by doctor and patient and informed by best evidence, not only about risks and benefits but also patient specific characteristics and values".[20] In shared decision making, both the health professional and the patient are assumed to have a legitimate investment in the treatment decisions.[21] At the present time most of the decisions regarding cancer screening in the UK are made outwith the patient-doctor consultation. Therefore, consideration of the implications of shared decision making on patient autonomy are not of great relevance. Cancer screening (with the exception of cervical screening) takes place at the level of organised, centralised screening programmes, with modest interaction between screening invitees and health professionals.

THE RELATIONSHIP BETWEEN CHOICE AND BEHAVIOUR

When measuring informed choice or informed decision making, it should not be assumed that behaviour reflects the initial choice. For example, even though a person chooses to participate in screening, participation may not eventuate. The difference between screening behaviour and screening choice may be due to predictable factors (for example, choices available and barriers to participation) and unpredictable factors (for example, acute illness, forgetfulness, competing priorities, and holidays). The disparity between choice and behaviour may also have a temporal element to it; the shorter the timespan between making the choice and carrying out the behaviour, the smaller the impact of unpredictable factors. A person who is invited to be screened opportunistically during a GP visit is unlikely to have their choice affected by unpredictable factors. However, even when there is only a small time lapse between choice and behaviour, using behaviour as a proxy for choice might still not be appropriate. For example, the person who makes a choice at the same time as being offered the test may feel more coerced and have less autonomy.

The relation between choice and behaviour may also partly be dependent on the organisation of screening programmes. In the UK, for example, women are invited via their GP for cervical screening. For breast screening, women are invited via the Breast Screening Programme. To undergo either of these screening tests, most people would have to travel, which introduces external factors such as access, missing the bus, and so on. For colorectal cancer screening, however, people are sent the test and it is self administered. Thus concerns relating to access are less likely to affect those invited to participate in colorectal cancer screening. These issues also relate to the provider of screening services; for example, cervical screening is organised through GPs, whereas colorectal and breast screening are organised centrally.

When defining and measuring choice, therefore, distinctions need to be made between the choice and the final behaviour. People may be well informed but still not be able to carry out their preferred choice. Even if they can carry out their choice, and intend to do so, external factors may prevent them from doing so. Examples are given below of possible scenarios, which illustrate the difference between intention and behaviour. By measuring intention before the behaviour we can see whether the initial intention to be screened was informed.

SOME POSSIBLE SCENARIOS RELATED TO SCREENING ILLUSTRATING THE DIFFERENCE BETWEEN INTENTION AND BEHAVIOUR

Scenario 1.

A woman living in rural Scotland is invited to attend for mammography screening at one of the screening vans. She gets information on the risks and benefits, wishes to go, but on the day of the screening is sick. She had made an informed choice to attend, but was not able to carry out that choice. The next time she receives her invitation she is on holiday, and does not have a car to be able to travel to another site. She decides not to go, even though her preferred choice is to attend.

Scenario 2.

A male amputee is sent screening tests for colorectal cancer screening. He wishes to take part but does not feel able to complete the tests, and is embarrassed to ask anyone else. He had made an informed choice to take part but is unable to do so.

Scenario 3.

A young female is invited for cervical screening, reads all the information, but is agoraphobic. She feels informed, wishes to attend but is not able to do so.

Scenario 4.

A middle aged woman is invited for cervical screening. She has read all the information, and has decided that she does not want to be screened. She gets flu and goes to see her GP whom she respects. He is very pro-screening and notices that she has not been screened. He tells her she should be screened, he can do it there and then, and she feels unable to refuse.

Scenario 5.

A middle aged woman decides not to go for screening for breast cancer. Her friends are horrified and persuade her to go along with them. She was informed, had made a choice not to go, but the influence of family and friends made her go.

MEASURING INFORMED CHOICE

In attempting to measure and understand informed choice in cancer screening three assumptions are made. The first assumption is that informed choice is an important aspect of a screening programme. We accept that there is a potential inconsistency in promoting informed choice within a public health policy; personal autonomy is competing with the greatest benefit for the greatest number. However, policy makers and screening programme organisers in the UK have already decided that promoting informed choice in cancer screening is important. Therefore, this paper aims to explain how such a policy should be evaluated and measured.

The second assumption is that informed choice should be measured, rather than just accepted that it is a good thing. Measuring informed choice may set too high standards which are unachievable in practice. However, it does have important benefits: it encourages health professionals to be accountable, and it defends people from unwanted interventions and from deception and coercion.[1]

The third assumption is that informed choice can be measured in a meaningful way. This assumption is open to debate; concepts such as consent and choice are understood in contradictory ways when people rely on different theoretical models. For example, positivism defines informed choice through dichotomies: informed/uninformed, choice/no choice.[1] It is accepted that no measure of informed choice will be perfect, but this paper is the first stage in attempting to operationalise the concept.

Uses of a measure of informed choice

There are several ways a measure of informed choice in cancer screening could be used. Firstly, it could be used as an outcome measure in trials. Recently trials evaluating the effectiveness of informed choice interventions for cancer screening have been undertaken.[22–25] However, many of these trials only measure knowledge and uptake, and not informed choice. A measure of informed choice in antenatal screening has already been developed, but this is not appropriate to use in cancer screening.[26]

Secondly, if the aim of organisations such as the NSC is to promote informed choice in populations eligible to be screened, then it is important to measure the extent to which the aim has been achieved. Informed choice, even though it might be a very important outcome to be measured in preventative care, is much more difficult to measure than coverage or uptake.[27] Thirdly, as mentioned previously, it can also ensure accountability of screening programmes and act as an aid to ensuring that people are neither deceived nor coerced.

This paper describes some of the important aspects to be considered when measuring informed choice in cancer screening. These aspects of informed choice may be important in other areas of healthcare. It is likely that a wide range of strategies would need to be considered in operationalising any measurement of informed choice (questionnaires, interviews, and so on), which would need to work within system constraints at different levels—that is, constraints on the screening programme, primary care, and the health service. Items for the questionnaire should be derived from focus group discussions, individual interviews, expert opinion, and guidelines (for example, the GMC guidelines[2]) When measuring informed choice using such a questionnaire, the following factors need to be considered:

1.How informed the person is when making their choice

As discussed previously, if the objective of any intervention or health policy is to increase informed choice, then it can be argued that there are at least two prerequisites: (1) the provision of unbiased, up to date, relevant information on the consequences of the choice(s) and (2) the ability of the person to make an autonomous choice between more than one option. When assessing how well informed a person is, two issues need to be taken into consideration. Firstly, the different perspectives of what is deemed to be well informed, and secondly the context of the decision. For example, in countries where healthcare is not free, people might wish to have information on possible costs of treatments before considering themselves well informed.

It is not expected that, to be considered informed, people will be required to recall detailed amounts of information and figures about a screening test. As previous

research has suggested, about 50% of people cannot recall significant information provided to them in relation to a consent given just a short time before.[28] However, it is reasonable to expect that people have an understanding about issues such as the disease being screened for, the screening test, and the consequences of participation or non-participation. At the present time, many people have only a basic understanding of what screening is about and have little or no understanding of limitations, risks, and consequences.

2. Preferred and/ or intended choice

A person's preferred and/or intended choice should ideally be measured after they have received their invitation to be screened but before they carry out the behaviour.

3. Barriers towards carrying out the choice

These may be personal or organisational barriers. Personal barriers may include physical or mental health problems and language. Organisational barriers could include availability of the service/intervention, and access.

4. Values and beliefs

A person's underlying values and beliefs regarding the choices may be important.[26] Theories of health behaviour such as the Theory of Planned Behaviour and the Health Belief Model may be useful in developing questions. The relation between knowledge, understanding, and a person's beliefs can then be explored. For example, a person's belief that screening is "a good thing" may be based on information they have received on the benefits of screening.

5. Degree of preferred involvement

There is evidence that some people do not wish to be involved in making decisions about their care.[29,30] Therefore it may be important to evaluate to what extent people wish to make a choice about screening. For example, they may wish to be informed, but have the choice made by someone else, or they might decide to have little involvement in screening at all and throw away the invitation.

6. Degree of coercion or control

The measure should ideally include the degree to which the choice was perceived to be subject to control or coercion, although this may be difficult to tease out in practice. Understanding the process by which people arrive at this point may give insights into this issue.

7. Perceived availability of choice

The measure should also attempt to measure the degree to which different options were available, as perceived by the recipient. For example, people may feel that they do not have the choice to refuse screening, even though they might wish to. This is important to measure in order to distinguish between informed compliance and informed choice (as discussed previously).

8. Behaviour carried out

Whether screening was undertaken or not is important to measure in order to ascertain if there is a difference between the original choice and the final behaviour. The screening behaviour should be ascertained from screening records, rather than by self report.

CONCLUSIONS

Informed choice is not just about the provision of relevant up-to-date information, it is also about making sure that the appropriate choices are available to people, and that

the choice is autonomous and free from coercion. It should also be recognised that, even with the best of intentions, there are extraneous, unpredictable factors which will prevent people from performing a behaviour which is in keeping with their preferred choice. Thus there may be differences between the intended choice and the final behaviour. This difference needs to be taken into account when designing a measure of informed choice, before we can be sure of the impact of informed choice on uptake or other desired endpoints.

Reference List

1. Alderson P,.Goodey C. Theories of consent. *BMJ* 1998;**317**:1313-5.
2. Austoker J. Gaining informed consent for screening. Is difficult--but many misconceptions need to be undone. *BMJ* 1999;**319**:722-3.
3. Raffle AE. Informed participation in screening is essential. *British Medical Journal* 1997;**314**:1762-3.
4. National Screening Committee. Second report of the National Screening Committee. *http://www.nsc.nhs.uk/library/lib_ind.htm* 2000.
5. General Medical Council. Seeking Patients Consent: the Ethical Considerations. 1999. London, General Medical Council.
6. Anderson CM,.Nottingham J. Bridging the knowledge gap and communicating uncertainties for informed consent in cervical cytology screening; we need unbiased information and a culture change. *Cytopathology* 1999;**10**:221-8.
7. Hall SA. Should public health respect autonomy? *Journal of Medical Ethics.* 1992;**18**:197-201.
8. Roberts MJ,.Reich MR. Ethical analysis in public health. *Lancet.* 2002;**359**:1055-9.
9. Raffle AE. Information about screening -is it to achieve high uptake or to ensure informed choice? *Health Expectations* 2001;**4**:92-8.
10. Jepson RG, Forbes CA, Sowden AJ, Lewis RA. Increasing informed uptake and non-uptake of screening: evidence from a systematic review. *Health Expectations* 2001;**4**:116-26.
11. Edwards A, Unigwe S, Elwyn G, Hood K. Effects of communicating individual risks in screening programmes: Cochrane systematic review. *BMJ* 2003;**327**:703-9.
12. O'Neill O. Some limits of informed consent. *Journal of Medical Ethics* 2003;**29**:4-7.
13. Hope T. Evidence-based patient choice. London: King's Fund, 1996.
14. O'Connor AM, Rostom A, Fiset V, Tetroe J, Entwistle V, Llewellyn-Thomas H *et al.* Decision aids for patients facing health treatment or screening decisions: Systematic review. *BMJ* 1999;731-4.
15. Bekker H, Thornton JG, Airey CM, Connelly JB. Informed decision-making: an annotated bibliography and systematic review. *Health Technology Assessment* 1999;**3**:156.
16. Faden R, Beauchamp T. A History and Theory of Informed Consent. New York: 1986.
17. Entwistle V, O'Donnell M. Evidence-based healthcare: what roles for patients? In Edwards A, Elwyn G, eds. *Evidence based patient choice: inevitable or impossible?*, pp 34-49. Oxford: Oxford University Press, 2001.
18. Edwards A,.Elwyn G. Understanding risk and lessons for clinical risk communication about treatment preferences. *Quality in Health Care* 2001;**10**:I9-I13.

19. Stapleton H, Kirkham M, Thomas G. Qualitative study of evidence based leaflets in maternity care. *British Medical Journal* 2002;**324**:639-+.
20. Towle A, Godolphin W, Greenhalgh T, Gambrill J. Framework for teaching and learning informed shared decision making. *BMJ* 1999;**319**:766-71.
21. Elwyn G, Charles C. Shared decision making: the principals and the competences. In Edwards A, Elwyn G, eds. *Evidence based patient choice: inevitable or impossible?*, pp 119-43. Oxford: Oxford University Press, 2001.
22. Davison BJ, Kirk P, Degner LF, Hassard TH. Information and patient participation in screening for prostate cancer. *Patient Education & Counseling* 1999;**37**:255-63.
23. Flood AB, Wennberg JE, Nease RF, Fowler FJ, Ding J, Hynes LM. The importance of patient preference in the decision to screen for prostate cancer. Prostate Patient Outcomes Research Team. *Journal of General Internal Medicine* 1996;**11**:342-9.
24. Frosch DL, Kaplan RM, Felitti V. The evaluation of two methods to facilitate shared decision making for men considering the prostate-specific antigen test. *Journal of General Internal Medicine* 2001;**16**:391-8.
25. Rimer BK, Halabi S, Sugg SC, Kaplan EB, Crawford Y, Samsa GP *et al.* The short-term impact of tailored mammography decision-making interventions. *Patient Education & Counseling* 2001;**43**:269-85.
26. Marteau TM, Dormandy E, Michie S. A measure of informed choice. *Health Expectations* 2001;**4**:99-108.
27. Schofield T. Evidence-based patient choice in primary health care. In Edwards A, Elwyn G, eds. *Evidence based patient choice: inevitable or impossible?*, pp 181-90. Oxford: Oxford University Press, 2001.
28. Robinson A,.Thomson R. Variability in patient preferences for participating in medical decision making: implication for the use of decision support tools. *Quality in Health Care* 2001;**10**:I34-I38.

Appendix 10. Measure of informed choice (cervical, breast, and colorectal)

INFORMED CHOICE AND CERVICAL SCREENING

Your understanding of cervical cancer and screening

The aim of these questions is to find out how much information women in general know about cervical cancer and cervical screening. We are not testing you personally on what you do or don't know.

1. You may have received information about cervical screening when you got your invitation to go for a smear test. Did you use the information to decide whether or not to go?

No ☐

Yes ☐

I did not receive any information ☐

2. Do you feel you know as much as you want to at the moment about cervical cancer and cervical screening?

No, I want to know more ☐

Yes, I know enough ☐

Not sure ☐

3. How many women do you think will develop cervical cancer over the course of their life?

Please tick one box only

About 1 in 2 women ☐

About 1 in 12 women ☐

About 1 in 120 women ☐

About 1 in 1200 women ☐

I don't know ☐

4. Do you know what any of the symptoms of cervical cancer are?

No, I don't know ☐ ⇨ *Please go to question 5*

Yes ☐

*If **Yes,** please tick all of the following that you think could be symptoms of cervical cancer*

Abnormal bleeding between periods or after sex ☐

New bleeding after the menopause ☐

Pain or discomfort during sex ☐

Vaginal discharge ☐

Other (please describe)..... ☐

Ref: ☐

5. Do you know any reason(s) why some women might be at more risk of developing cervical cancer than others?

No, I don't know ☐ ⇨ *Please go to question 6*

Yes ☐

If ***Yes,*** *please tick all that you think might make women more likely to develop the disease*

- Being a smoker ☐
- Being poor ☐
- Long term use of the pill ☐
- Having had many sexual partners ☐
- Having a partner who has had many sexual partners ☐
- Having sex at an early age or an early first pregnancy ☐
- Having the Human Papilloma Virus ☐
- Other (please describe)..... ☐

6. The following is a list of statements about cervical smears and cervical screening
For each statement, please tick true, false, or don't know

	True	False	Don't know
Cervical smears are only for women who have symptoms of cervical cancer	☐	☐	☐
A cervical smear will prevent (stop) a woman getting cervical cancer	☐	☐	☐
Some cancers will not be picked up by the cervical smear test	☐	☐	☐
Some women might have insurance or job problems if their cancer is found early	☐	☐	☐
A cancer might be found that cannot be successfully treated	☐	☐	☐
Women may be diagnosed with cancer when they feel well	☐	☐	☐
If a woman is told that her cervical smear is normal it means that she definitely does not have cervical cancer	☐	☐	☐
If a woman is invited back for another smear or further tests it means she definitely has cervical cancer	☐	☐	☐

7. If 100 women with cervical cancer took this test, how many of these 100 cervical cancers do you think would be missed?

Please tick one box only

- None ☐
- Less than 10 ☐
- About 10 ☐
- More than 10 ☐
- I don't know ☐

Your choice

8. Do you think you will go for a cervical smear? *Please tick one box only*

Definitely not ☐ Probably ☐ Definitely ☐

Probably not ☐ I have already been for it ☐

Unsure ☐

9. If you think you WON'T go for a cervical smear which of the following, if any, made you reach this decision? *Please tick all that apply*

A. Fear of what it might find out ☐ **E.** Having a smear before ☐

B. Dislike of having a smear ☐ **F.** Finding the time to go/getting there ☐

C. Cultural or religious beliefs ☐ **G.** Other (please specify)..... ☐

D. A disability or illness ☐

Your opinions on screening and the decision you make

10. Do you think you are at high risk of developing cervical cancer?
Please tick one box only

No ☐

Yes ☐

Not sure, I don't know what the risks are ☐

11. Please show how strongly you agree or disagree with these comments by ticking one of the boxes for each statement. **These are your personal opinions and there are no right or wrong answers.**

	strongly agree	agree	neither agree nor disagree	disagree	strongly disagree
I want to know if I have cervical cancer	☐	☐	☐	☐	☐
I think screening is a waste of time.....	☐	☐	☐	☐	☐
I can't be bothered to have a cervical smear.....	☐	☐	☐	☐	☐
I think that I would benefit from having a cervical smear	☐	☐	☐	☐	☐
I think screening for cervical cancer is a good thing.....	☐	☐	☐	☐	☐

	strongly agree	agree	neither agree nor disagree	disagree	strongly disagree
I am not a believer in screening for cervical cancer.....	☐	☐	☐	☐	☐
I think screening for cervical cancer is a waste of money	☐	☐	☐	☐	☐
I am anxious about what might happen if I have a cervical smear	☐	☐	☐	☐	☐

	strongly agree	agree	neither agree nor disagree	disagree	strongly disagree
I would have a cervical smear if my friends/family thought I should	☐	☐	☐	☐	☐
I feel that I have to go for a cervical smear.....	☐	☐	☐	☐	☐
I feel pressure from others to have a cervical smear.....	☐	☐	☐	☐	☐
I am satisfied with my decision.....	☐	☐	☐	☐	☐
I feel there is a choice (to have a cervical smear or not)	☐	☐	☐	☐	☐
I feel I know the benefits of cervical screening	☐	☐	☐	☐	☐
I feel I know the limitations of cervical screening	☐	☐	☐	☐	☐

	strongly agree	agree	neither agree nor disagree	disagree	strongly disagree
I feel I have made an informed choice	☐	☐	☐	☐	☐
Deciding whether to have one or not was a big decision for me	☐	☐	☐	☐	☐
I don't need to be provided with information to make my choice	☐	☐	☐	☐	☐
I would like to discuss my decision with my doctor or nurse.....	☐	☐	☐	☐	☐
I want my doctor/ nurse to decide if I have a cervical smear or not	☐	☐	☐	☐	☐

Details about you

Do you have any of the qualifications listed below?
If your particular qualifications are not listed please tick nearest equivalent.

No qualifications ☐
Standard grades / O grades or equivalent ☐
Highers or equivalent ☐
Other professional or technical qualification / diploma ☐
Degree ☐
If you do not wish to answer this question, please tick here ☐

12. What is (or was) the full title of your main job? .....

If you do not wish to answer this question, please tick here ☐

THANK YOU FOR FILLING IN THE QUESTIONNAIRE

INFORMED CHOICE AND BREAST CANCER SCREENING

Your understanding of breast cancer and screening

The aim of these questions is to find out how much information women in general know about breast cancer and breast cancer screening. They are not to test you personally on what you do or don't know.

1. You may have received information about breast cancer screening when you got your invitation to go for a mammogram. Did you use the information to decide whether or not to go?

No ☐

Yes ☐

I did not receive any information ☐

2. Do you feel you know as much as you want to at the moment about breast cancer and breast cancer screening?

No, I want to know more ☐

Yes, I know enough ☐

Not sure ☐

3. How many women do you think will develop breast cancer over the course of their life?
Please tick <u>one</u> box only

About 1 in 2 women ☐

About 1 in 9 women ☐

About 1 in 200 women ☐

About 1 in 900 women ☐

I don't know ☐

4. Do you know what any of the symptoms of breast cancer are?

No, I don't know ☐ ⇨ *Please go to question 5*

Yes ☐

*If **Yes,** please tick <u>all</u> of the following that you think could be symptoms of breast cancer*

Change in shape or size of breast	☐	Lump in the breast or thickening of the breast	☐
Change in nipple position	☐	Dimpling of the skin around the breast	☐
Discharge from the nipple	☐	Pain in one breast which is different from normal	☐
Swelling or lump in the armpit	☐	Other (please describe).....	☐

Ref: ☐

5. Do you know any reason(s) why some women might be at more risk of developing breast cancer than others?

No, I don't know ☐ ⇨ *Please go to the question*

Yes ☐

*If **Yes,** please tick <u>all</u> that you think might make women more likely to develop the disease*

The older you are ☐

Previous history of breast cancer ☐

Family history of breast cancer ☐

Using hormone replacement therapy (HRT) for more than ten years ☐

Eating a diet high in saturated fat ☐

Other (please describe)..... ☐

6. The following is a list of statements about mammograms and breast cancer screening
For each statement, please tick true, false, or don't know

	True	False	Don't know
Mammograms are only for women who have symptoms of breast cancer	☐	☐	☐
A mammogram will prevent (stop) a person getting breast cancer	☐	☐	☐
Some cancers will not be picked up by the mammogram	☐	☐	☐
Some cancers picked up by the mammogram grow so slowly that even without treatment they would not affect a woman's health	☐	☐	☐
Having a breast biopsy (a further test for breast cancer) might harm some women	☐	☐	☐

	True	False	Don't know
Some women might have insurance or job problems if their cancer is found early	☐	☐	☐
A cancer might be found that cannot be successfully treated	☐	☐	☐
Women may be diagnosed with cancer when they feel well	☐	☐	☐
A letter which says 'examination was satisfactory and showed no evidence of cancer' means that a woman <u>definitely does not</u> have breast cancer	☐	☐	☐
If a woman is invited back for another mammogram, or further tests, it means she <u>definitely has</u> breast cancer	☐	☐	☐

7. If 100 women with breast cancer had a mammogram, how many of these 100 breast cancers do you think would be missed?

None ☐ I don't know ☐

Less than 10 ☐

About 10 ☐ More than 10 ☐

Your choice

8. Do you think you will go for a mammogram?
Please tick one box only

Definitely not	☐	Unsure	☐	Definitely	☐
Probably not	☐	Probably	☐	I have already been for it	☐

9. If you think you WON'T go for a mammogram which of the following, if any, made you reach this decision?

Please tick all that apply

A. Fear of what it might find out ☐

B. Dislike of having a mammogram ☐

C. Cultural or religious beliefs ☐

D. A disability or illness ☐

E. Having a mammogram before ☐

F. Other ☐ (please specify) .....

Your opinions on screening and the decision you make

10. Do you think you are at high risk of developing breast cancer?
Please tick one box only

No ☐

Yes ☐

Not sure, I don't know what the risks are ☐

11. Please show how strongly you agree or disagree with these comments by ticking one of the boxes for each statement. **These are your personal opinions and there are no right or wrong answers.**

	strongly agree	agree	neither agree nor disagree	disagree	strongly disagree
I want to know if I have breast cancer	☐	☐	☐	☐	☐
I think screening is a waste of time.....	☐	☐	☐	☐	☐
I can't be bothered to have a mammogram.....	☐	☐	☐	☐	☐
I think that I would benefit from having a mammogram.....	☐	☐	☐	☐	☐
I think screening for breast cancer is a good thing.....	☐	☐	☐	☐	☐

	strongly	agree	neither	disagree	strongly

	agree		agree nor disagree		disagree
I am not a believer in screening for breast cancer.....	☐	☐	☐	☐	☐
I think screening for breast cancer is a waste of money.....	☐	☐	☐	☐	☐
I am anxious about what might happen if I have a mammogram	☐	☐	☐	☐	☐

	strongly agree	agree	neither agree nor disagree	disagree	strongly disagree
I would have a mammogram if my friends/family thought I should	☐	☐	☐	☐	☐
I feel that I have to go for a mammogram.....	☐	☐	☐	☐	☐
I feel pressure from others to have a mammogram.....	☐	☐	☐	☐	☐
I am satisfied with my decision.....	☐	☐	☐	☐	☐
I feel there is a choice (to have a mammogram or not)	☐	☐	☐	☐	☐
I feel I know the benefits of breast cancer screening	☐	☐	☐	☐	☐
I feel I know the limitations of breast cancer screening	☐	☐	☐	☐	☐

	strongly agree	agree	neither agree nor disagree	disagree	strongly disagree
I feel I have made an informed choice	☐	☐	☐	☐	☐
Deciding whether to do it or not was a big decision for me.....	☐	☐	☐	☐	☐
I don't need to be provided with information to make my choice	☐	☐	☐	☐	☐
I would like to discuss my decision with my doctor or nurse.....	☐	☐	☐	☐	☐
I want my doctor/nurse to decide if I have a mammogram or not..	☐	☐	☐	☐	☐

Details about you

12. Do you have any of the qualifications listed below?
If your particular qualifications are not listed please tick nearest equivalent.

No qualifications ☐

Standard grades / O grades or equivalent ☐

Highers or equivalent ☐

Other professional or technical qualification / diploma ☐

Degree ☐

If you do not wish to answer this question, please tick here ☐

13. What is (or was) the full title of your main job? .....

INFORMED CHOICE AND BOWEL CANCER SCREENING

Your understanding of bowel cancer and screening

The aim of these questions is to find out how much information people in general know about bowel cancer and bowel cancer screening, not to test you personally on what you do or don't know.

1. You will have received information about bowel cancer screening when you got your test kit. Did you use the information to decide whether or not to do the stool test?

No ☐

Yes ☐

2. Do you feel you know as much as you want to at the moment about bowel cancer and bowel cancer screening?

No, I want to know more ☐

Yes, I know enough ☐

Not sure ☐

3. How many people do you think will develop bowel cancer over the course of their life?

Please tick <u>one</u> box only

About 1 in 2 people ☐

About 1 in 25 people ☐

About 1 in 250 people ☐

I don't know ☐

4. Do you know what any of the symptoms of bowel cancer are?

No, I don't know ☐ ⇨ *Please go to question 5*

Yes ☐

*If **Yes,** please tick <u>all</u> of the following that you think could be symptoms of bowel cancer*

Repeated bleeding from the back passage or blood in bowel motions ☐

Change in bowel habit (e.g. diarrhoea or constipation for 6 weeks) ☐

Unexplained tiredness or weight loss ☐

Severe colicky abdominal pain ☐

Other (please describe) ..... ☐

Your understanding of bowel cancer and screening

5. Do you know any reason(s) why some people might be at more risk of developing bowel cancer than others?

No, I don't know ☐ ⇨ *Please go to the question 6*

Yes ☐

*If **Yes,** please tick all that you think might make people more likely to develop the disease*

Having had polyps (growths in the bowel) ☐

Being over the age of 50 ☐

A personal history of bowel inflammation ☐

A family history of bowel cancer ☐

A diet that's high in red meat and fat and low in vegetables ☐

Other (please describe)..... ☐

6. The following is a list of statements about the test and bowel cancer screening
For each statement, please tick true, false, or don't know

	True	False	Don't know
The test is only for people who have symptoms of bowel cancer	☐	☐	☐
The test will prevent (stop) a person getting bowel cancer	☐	☐	☐
Some cancers will not be picked up by the test	☐	☐	☐
Having a colonoscopy (a test for bowel cancer) might harm some people	☐	☐	☐

	True	False	Don't know
Some people might have insurance or job problems if their cancer is found early	☐	☐	☐
A cancer might be found that cannot be successfully treated	☐	☐	☐
People may be diagnosed with cancer when they feel well	☐	☐	☐
A 'negative' result means that a person definitely does not have bowel cancer	☐	☐	☐
A result which 'tested positive for blood' means a person definitely has bowel cancer	☐	☐	☐

7. If 100 people with bowel cancer took this test, how many of these 100 bowel cancers do you think would be missed?

Please tick one box only

None ☐

Less than 10 ☐

More than 10 ☐

I don't know ☐

Your choice

8. Do you think you will send back the completed test kit?

Please tick one box only

Definitely not/probably not ☐

Unsure ☐

Probably/definitely ☐

I have sent it back ☐

9. If you think you WON'T send back the test which of the following, if any, made you reach this decision?

Please tick all that apply

A. Fear of what it might find out ☐

B. Dislike of doing the test ☐

C. Cultural or religious beliefs ☐

D. A disability or illness ☐

E. Doing the test before ☐

F. Other ☐ (please specify) .....

Your opinions on screening and the decision you make

10. Do you think you are at high risk of developing bowel cancer?

Yes ☐

No ☐

Not sure, I don't know what the risks are ☐

11. Please show how strongly you agree or disagree with these comments by ticking one of the boxes for each statement. **These are your personal opinions and there are no right or wrong answers.**

	strongly agree	agree	neither agree nor disagree	disagree	strongly disagree
I want to know if I have bowel cancer	☐	☐	☐	☐	☐
I can't be bothered to do the test.....	☐	☐	☐	☐	☐
I think that I would benefit from doing the test.....	☐	☐	☐	☐	☐
I think screening for bowel cancer is a good thing.....	☐	☐	☐	☐	☐

	strongly agree	agree	neither agree nor disagree	disagree	strongly disagree
I am anxious about what might happen if I do the test.....	☐	☐	☐	☐	☐
I would do the test if my friends/family thought I should.....	☐	☐	☐	☐	☐
I feel that I have to do the test.....	☐	☐	☐	☐	☐

	strongly agree	agree	neither agree nor disagree	disagree	strongly disagree
I feel pressure from others to do the test.....	☐	☐	☐	☐	☐
I am satisfied with my decision.....	☐	☐	☐	☐	☐
I feel there is a choice (to do the test or not)	☐	☐	☐	☐	☐
I feel I know the benefits of bowel cancer screening	☐	☐	☐	☐	☐
I feel I know the limitations of bowel cancer screening	☐	☐	☐	☐	☐

	strongly agree	agree	neither agree nor disagree	disagree	strongly disagree
I feel I have made an informed choice	☐	☐	☐	☐	☐
Deciding whether to do it or not was a big decision for me.....	☐	☐	☐	☐	☐
I don't need to be provided with information to make my choice	☐	☐	☐	☐	☐
I would like to discuss my decision with my doctor or nurse.....	☐	☐	☐	☐	☐
I want my doctor or nurse to decide if I do the test or not.....	☐	☐	☐	☐	☐

Details about you

12. Do you have any of the qualifications listed below?
If your particular qualifications are not listed please tick nearest equivalent.

No qualifications ☐

Standard grades / O grades or equivalent ☐

Highers or equivalent ☐

Other professional or technical qualification / diploma ☐

Degree ☐

If you do not wish to answer this question, please tick here ☐

13. What is (or was) the full title of your main job? .....

If you do not wish to answer this question, please tick here ☐

THANK YOU FOR FILLING IN THE QUESTIONNAIRE

Appendix 11. Description of participants in focus groups and interviews

Focus Group & participants*	Age	Job	Marital status	screening status**	Sex	Other descriptors
Cervical Screening FG (cervical pilot)						
Brenda	Mid 30's	Researcher	Married	Normal	Female	
Sarah	Early 40's	Secretary	Married	Normal	Female	
Donna	Early 40's	Administrator	Married	Abnormal	Female	
Julie	Mid 30's	Librarian	Married	Normal	Female	Has inflammatory breast cancer
Mary	Late 40's	Community worker	Separated	Normal	Female	
Anna	Late 40's	Researcher	Married	Normal	Female	
Paula	Early 40's	Administrator	Married	Abnormal	Female	
Jane	Mid 20's	Researcher	Single	Normal	Female	
Claire	Early 30's	Statistician	Married	Normal	Female	
Focus group 2 (cervical)						
Leone	30's	Fitness instructor	Single	Abnormal	Female	
Elaine	30's	OT	Married	Normal	Female	
Sally	30's	Manager	Married	Normal	Female	
Daisy	40's	Nurse	Married	Normal	Female	
Focus Group 3 (breast cancer)						
Maria	60's	Retired	Married	Normal	Female	Health problems
Marie	60's	Retired	Married	Normal	Female	Smoker
Ariel	50's	Home Help	Married	Did not participate	Female	
Ellen	60's	Child minder	Married	Abnormal	Female	Fostered children. Multiple health problems.
Anna	60's	Retired	Married	Normal	Female	
Focus group 4 (bowel cancer)						
George	Early 40's	House husband	Married	Normal	Male	
Roy	60's	Sick leave	Married	Normal	Male	
Chris	60's	Retired	?	Abnormal	Male	
Jack	60's	Postman	?	Did not participate	Male	
Neil	50's	University worker	?	Abnormal	Male	
Jim	50's	Lorry driver	Married	Normal	Male	
Focus group 5 (bowel cancer)						
Jennie	50's	Yes	married	Abnormal	Female	
Susan	51	Not working	Single	Normal	Female	Long term mental health problems.
Belinda	60's	Retired	Married	Abnormal	Female	
Madge	60's	Not stated	Married	Normal	Female	
Joy	50's	Not stated	Married	Normal	Female	
Deidre	66	Retired	Married	Did not participate	Female	
Focus group 6 (bowel cancer)						
Christopher	Late 50's	Businessman	Married	Normal	Male	
John	60's	Ex-welder	Married	Abnormal	Male	
Jon	60	Ex-scaffolder	Single	Normal	Male	
Denzil	50's	Hairdresser	Divorced	Abnormal	Male	

Focus Group & participants*	Age	Job	Marital status	screening status**	Sex	Other descriptors
Dewar	50's	Social worker	Yes	Abnormal	Male	
Focus group 7 (cervical)						
Kylie	Mid 20's	Administrator	Single	Normal	Female	
May	Late 40's	Administrator	Married	Normal	Female	Mother of Kylie
Rose	50	Drug packager	Married	Abnormal	Female	
Helen	35	Not working	Married	Abnormal	Female	Had a false negative
Heather	56	administrator	Married	Normal	Female	
Focus Group 8 (breast)						
Joyce	58	Researcher	Divorced	Abnormal	Female	
Alison	56	Nurse	Married	Normal	Female	
Margaret	59	Retired	Married	Normal	Female	
Dorothy	Late 60's	Retired	Married	Normal	Female	
Jenny	Late 50's	?	Married	Normal	Female	
Focus Group 9 (breast)						
Jessie	53	2 part time jobs	Married	Did not attend	Female	
Fiona	54	?	Married	Abnormal	Female	
Annabel	60s	Council worker	Married	Normal	Female	
May	53	?	Married	Normal	Female	
Wendy	60's	Retired	Married	Abnormal	Female	
Lily	53	Nurse	Single	Abnormal	Female	
Jill	60s	Retired	Yes	Normal	Female	
Janice	60's	Shift worker	Married	Normal	Female	
Interviews						
Vera (breast)	64	Ex-Occupational Health Nurse	Married	Abnormal	Female	Recruited from Cancer Care
Clara (cervical)	mid 40's	Not working	Married	Normal	Female	
Hilary (cervical)	Late 30's	Bank Clerk	Married	Normal	Female	
Shelly (cervical)	54	Not working	Widowed	Abnormal	Female	Heavy smoker
Emma (cervical)	mid-40's	Not working	Married	Abnormal	Female	Very anxious, did not wish to be tape recorded.
Betty (cervical)	30's	Student	Widowed	Abnormal	Female	From Zimbabwe.
Coral (cervical)	Early 20's	Not working	Single	Did not participate	Female	Single mother
Joan (cervical)	Early 20's	Not working	Single	Did not participate	Female	Single mother
Abigail (cervical)	43	Not working	Divorced	Normal	Female	Had ' cervical cancer' in the past.
Deena (cervical)	Mid 30's	Student	Single	Normal	Female	Venezuelan. Recruited through library.
Michelle (cervical)	Mid-30's	Not working	Single	Did not participate	Female	Long term mental health problems. Recruited through library.
Jo (cervical)	21	Shift worker in factory	Single	Abnormal	Female	
Tania (cervical)	52	Not working	Divorced	Did not participate	Female	Recruited through snowballing. Multiple health problems,

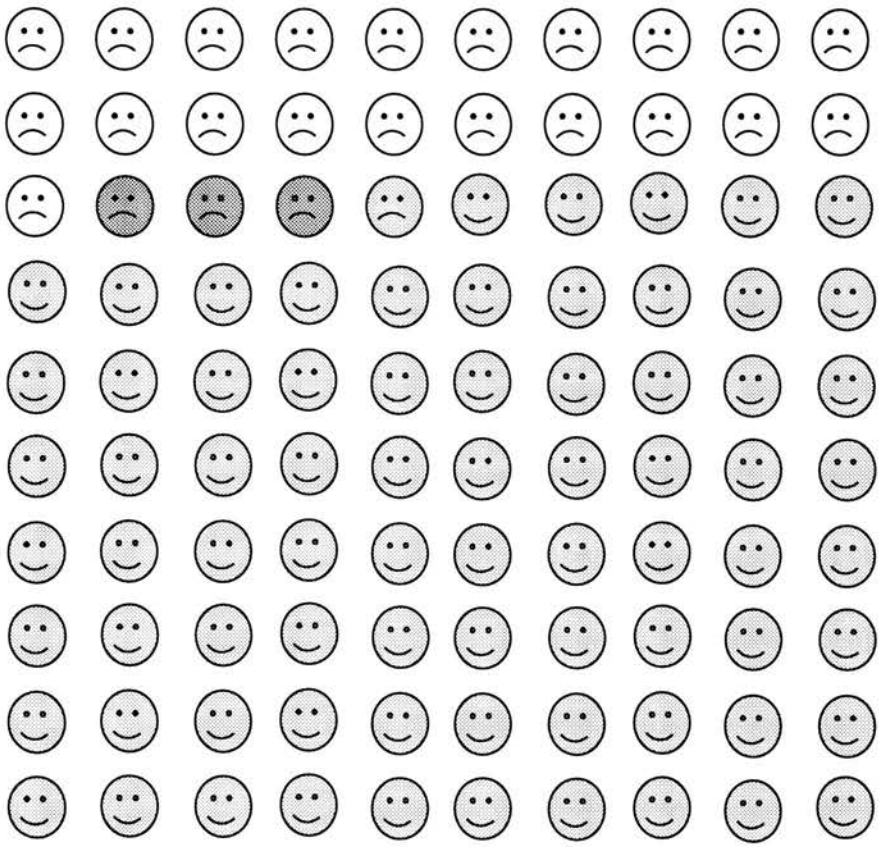
Focus Group & participants*	Age	Job	Marital status	screening status**	Sex	Other descriptors
						agoraphobic.
Anita (cervical)	40	Administrator	Single	Abnormal	Female	Recruited through snowballing.
Pam (breast)	60's	Retired	Divorced	Did not participate	Female	Recruited through snowballing. Mother of Anita. Multiple health problems, heavy smoker.

* all names have been changed; **most recent test result

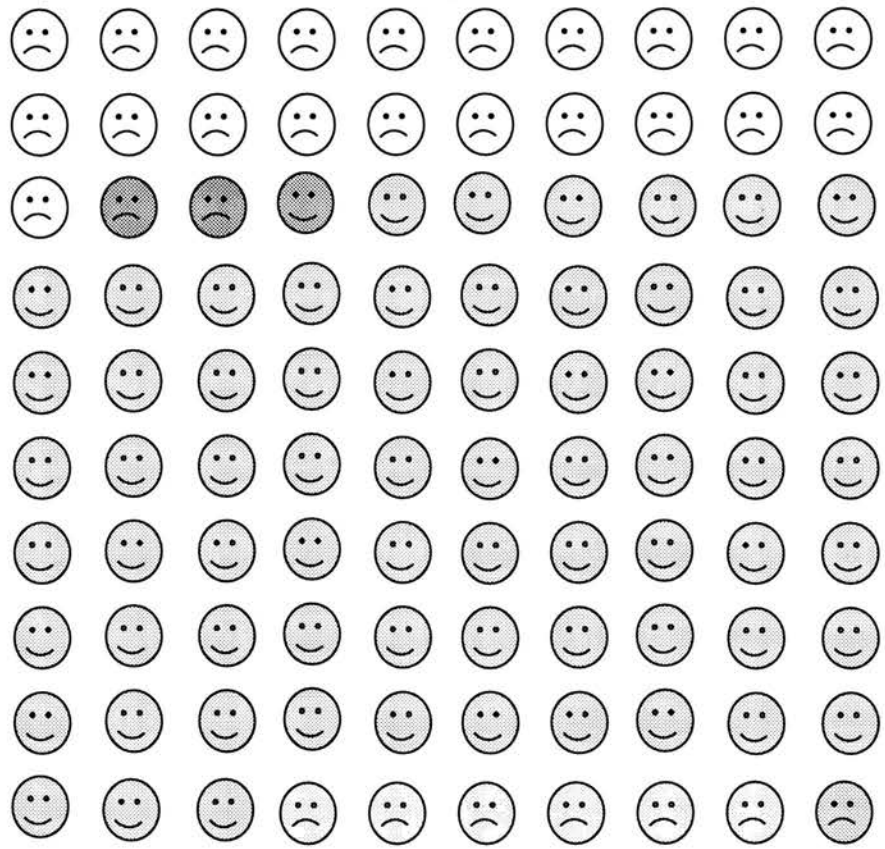
Appendix 12. Decision aid for women invited for breast screening

What happens to 100 women from age 50-75....

If you DO NOT attend breast screening



If you DO attend breast screening



Will die of breast cancer before the age of 75

Will not die before age 75 whether or not you attend breast screening

Breast screening prevents you from dying from breast cancer

Will die before the age of 75

Will have an open biopsy of the breast

Will have a needle biopsy of the breast

Appendix 13 Full tables and correlation matrices for informed choice modelling

Colorectal screening: correlation matrix for predictors of *perceived* informed choice

		Previous non participant	Previous invitee	Attitudes and motivations	Influence from others	Perceived informedness	Knowledge of disease	Knowledge of what screening is	Knowledge of test results	Knowledge of limitations	Knowledge of consequences
Previous non participant	Pearson Correlation	1	.208(**)	.403(**)	-.227(**)	.330(**)	-.150(*)	-.121	-.136	-.016	-.102
	Sig. (2-tailed)	.	.004	.000	.002	.000	.038	.095	.060	.824	.160
Previous invitee	Pearson Correlation	.208(**)	1	.147(*)	.004	.105	.003	-.041	-.142(*)	.023	.017
	Sig. (2-tailed)	.004	.	.043	.960	.148	.965	.575	.050	.748	.816
Attitudes and motivations	Pearson Correlation	.403(**)	.147(*)	1	-.087	.562(**)	-.107	-.030	-.208(**)	-.004	-.154(*)
	Sig. (2-tailed)	.000	.043	.	.231	.000	.142	.679	.004	.961	.033
Influence from others	Pearson Correlation	-.227(**)	.004	-.087	1	-.048	.133	.180(*)	.116	-.094	.070
	Sig. (2-tailed)	.002	.960	.231	.	.507	.067	.013	.111	.198	.334
Perceived informedness	Pearson Correlation	.330(**)	.105	.562(**)	-.048	1	-.239(**)	-.055	-.161(*)	-.018	-.168(*)
	Sig. (2-tailed)	.000	.148	.000	.507	.	.001	.449	.026	.807	.020
Knowledge of disease	Pearson Correlation	-.150(*)	.003	-.107	.133	-.239(**)	1	.153(*)	.342(**)	.142(*)	.239(**)
	Sig. (2-tailed)	.038	.965	.142	.067	.001	.	.035	.000	.050	.001
Knowledge of what screening is	Pearson Correlation	-.121	-.041	-.030	.180(*)	-.055	.153(*)	1	.339(**)	.146(*)	.106
	Sig. (2-tailed)	.095	.575	.679	.013	.449	.035	.	.000	.043	.145
Knowledge of test results	Pearson Correlation	-.136	-.142(*)	-.208(**)	.116	-.161(*)	.342(**)	.339(**)	1	.280(**)	.258(**)
	Sig. (2-tailed)	.060	.050	.004	.111	.026	.000	.000	.	.000	.000
Knowledge of limitations	Pearson Correlation	-.016	.023	-.004	-.094	-.018	.142(*)	.146(*)	.280(**)	1	.158(*)
	Sig. (2-tailed)	.824	.748	.961	.198	.807	.050	.043	.000	.	.029
Knowledge of consequences	Pearson Correlation	-.102	.017	-.154(*)	.070	-.168(*)	.239(**)	.106	.258(**)	.158(*)	1
	Sig. (2-tailed)	.160	.816	.033	.334	.020	.001	.145	.000	.029	.

** Correlation is significant at the 0.01 level (2-tailed).
* Correlation is significant at the 0.05 level (2-tailed).

Table 25. Colorectal screening: predictors of *perceived* informed choice

	Unstandardized Coefficients		Standardized Coefficients	T	Sig.	95% Confidence Interval for B	
	B	Std. Error	Beta			Lower Bound	Upper Bound
Age	.006	.012	.043	.520	.604	.029	.017
Gender	.089	.109	.051	.813	.417	.304	.126
Attitudes and motivations	.551	.058	.561	9.477	.000	.436	.665
Influence from others: colorectal	-.043	-.062	-.044	-.695	.488	-.079	.165
Previous non participant	.242	.156	.110	1.555	.122	-.065	.549
New invitee	-.106	.196	-.044	-.539	.591	-.492	.281
Knowledge of disease	.170	.055	.182	3.076	0.002	.280	.061
Knowledge of what screening is for	.032	.134	.015	-.238	.812	-.296	.232
Knowledge of test results	.031	.081	.028	.388	.698	-.128	.191
Knowledge of limitations	.033	.102	.021	.324	.746	-.169	.235
Knowledge of consequences	.063	.074	.054	.847	.398	.208	.083

Colorectal screening: correlations for variables predicting *theoretical* definition of informed choice (n=191)

		Age	Previous non participant	New invitee	Knowledge of consequences	Informed choice categories	Used the information	Know as much information as I want	School education	Post school education
Age	Pearson Correlation	1	.054	-.656(**)	-.057	-.071	.075	.102	.014	-.180(*)
	Sig. (2-tailed)	.	.457	.000	.430	.495	.305	.162	.865	.022
Previous non participant	Pearson Correlation	.054	1	-.208(**)	-.102	.056	.148(*)	.014	.015	-.055
	Sig. (2-tailed)	.457	.	.004	.160	.592	.042	.849	.853	.486
New invitee	Pearson Correlation	-.656(**)	-.208(**)	1	-.017	.033	-.119	-.090	-.051	.196(*)
	Sig. (2-tailed)	.000	.004	.	.816	.748	.104	.218	.517	.013
Knowledge of consequences	Pearson Correlation	-.057	-.102	-.017	1	-.078	-.047	.132	-.045	.174(*)
	Sig. (2-tailed)	.430	.160	.816	.	.451	.520	.070	.567	.028
Informed choice categories	Pearson Correlation	-.071	.056	.033	-.078	1	.097	-.077	-.038	-.144
	Sig. (2-tailed)	.495	.592	.748	.451	.	.356	.465	.734	.193
Used the information	Pearson Correlation	.075	.148(*)	-.119	-.047	.097	1	-.194(**)	.113	-.107
	Sig. (2-tailed)	.305	.042	.104	.520	.356	.	.008	.157	.179
Know as much information as I want	Pearson Correlation	.102	.014	-.090	.132	-.077	-.194(**)	1	.088	.063
	Sig. (2-tailed)	.162	.849	.218	.070	.465	.008	.	.270	.427
School education	Pearson Correlation	.014	.015	-.051	-.045	-.038	.113	.088	1	-.526(**)
	Sig. (2-tailed)	.865	.853	.517	.567	.734	.157	.270	.	.000
Post school education	Pearson Correlation	-.180(*)	-.055	.196(*)	.174(*)	-.144	-.107	.063	-.526(**)	1
	Sig. (2-tailed)	.022	.486	.013	.028	.193	.179	.427	.000	.

** Correlation is significant at the 0.01 level (2-tailed).
* Correlation is significant at the 0.05 level (2-tailed).

Table 27. Colorectal screening: variables entered for *theoretical* definition of informed choice

	B	S.E.	Wald	Sig.	Exp(B)	95.0% C.I. for EXP(B)	
						Lower	Upper
School education	1.781	.888	4.022	.045	.168	.030	.960
Post school education	2.750	1.372	4.015	.045	.064	.004	.942
Previous non-participant	-.127	.632	.040	.841	1.135	.329	3.918
New invitee	-.484	.673	.516	.473	1.622	.433	6.070
Used information	.384	.520	.545	.460	.681	.246	1.887
Knew as much as they wanted	.142	.513	.077	.782	.867	.317	2.372
Constant	.932	.634	2.160	.142	2.540		

Breast screening 42: correlation matrix variable predicting *perceived* informed choice (n=262)

		Previous non participant	Previous invitee	Knowledge of disease	Knowledge of what screening is for	Knowledge of test results	Knowledge of limitations	Knowledge of consequences	Attitudes and motivations breast
Previous non participant	Pearson Correlation	1	.177(**)	-.128(*)	-.084	-.068	-.031	.012	-.285(**)
	Sig. (2-tailed)	.	.004	.038	.173	.276	.616	.849	.000
Previous invitee	Pearson Correlation	.177(**)	1	.075	-.097	.034	.007	.083	.013
	Sig. (2-tailed)	.004	.	.224	.119	.583	.904	.181	.839
Knowledge of disease	Pearson Correlation	-.128(*)	.075	1	.148(*)	.199(**)	.170(**)	.007	.191(**)
	Sig. (2-tailed)	.038	.224	.	.017	.001	.006	.908	.002
Knowledge of what screening is for	Pearson Correlation	-.084	-.097	.148(*)	1	.190(**)	.053	.005	.079
	Sig. (2-tailed)	.173	.119	.017	.	.002	.390	.939	.202
Knowledge of test results	Pearson Correlation	-.068	.034	.199(**)	.190(**)	1	.237(**)	.165(**)	.162(**)
	Sig. (2-tailed)	.276	.583	.001	.002	.	.000	.007	.009
Knowledge of limitations	Pearson Correlation	-.031	.007	.170(**)	.053	.237(**)	1	.187(**)	-.054
	Sig. (2-tailed)	.616	.904	.006	.390	.000	.	.002	.380
Knowledge of consequences	Pearson Correlation	.012	.083	.007	.005	.165(**)	.187(**)	1	-.071
	Sig. (2-tailed)	.849	.181	.908	.939	.007	.002	.	.255
Attitudes and motivations breast	Pearson Correlation	-.285(**)	.013	.191(**)	.079	.162(**)	-.054	-.071	1
	Sig. (2-tailed)	.000	.839	.002	.202	.009	.380	.255	.
	Sig. (2-tailed)	.000	.803	.000	.000	.013	.719	.964	.000

** Correlation is significant at the 0.01 level (2-tailed).
* Correlation is significant at the 0.05 level (2-tailed).

Table. Breast screening: variables entered into model for perceived informedness

	B	S.E.	Wald	Sig.	Exp(B)	95.0% C.I.for EXP(B)	
						Lower	Upper
Knowledge of disease	.273	.216	1.599	.206	1.314	.861	2.006
Knowledge of screening	-.052	.488	.011	.916	1.053	.405	2.740
Knowledge of results	-.090	.286	.100	.751	1.095	.625	1.916
Knowledge of limitations	-.117	.216	.291	.589	1.124	.736	1.717
Knowledge of consequences	-.685	.253	7.312	.007	1.984	1.207	3.260
New invitee	.092	.283	.101	.761	1.098	.621	1.936
Non-participant	1.217	.564	4.655	.031	3.378	1.118	10.206
Attitudes and beliefs	1.321	.260	25.725	.000	3.745	2.248	6.239
Constant	-2.883	1.188	5.890	.015	.056		

Breast screening: correlation matrix for variables predicting *theoretical model of* informed choice (n=262)

		Age	Previous non participant	New invitee	Informed choice categories	Used the information	Know as much information as I want	School education	Post school education
Age	Pearson Correlation	1	.152(*)	-.535(**)	.024	.091	.124(*)	-.099	.016
	Sig. (2-tailed)	.	.014	.000	.792	.143	.044	.151	.819
Previous non participant	Pearson correlation	.152(*)	1	-.177(**)	.030	.001	.053	-.130	.088
	Sig. (2-tailed)	.014	.	.004	.737	.983	.392	.059	.200
New invitee	Pearson correlation	-.535(**)	-.177(**)	1	-.073	.051	.111	-.006	.096
	Sig. (2-tailed)	.000	.004	.	.416	.413	.073	.931	.162
Informed choice categories	Pearson Correlation	.024	.030	-.073	1	.101	.021	.146	-.240(*)
	Sig. (2-tailed)	.792	.737	.416	.	.262	.817	.138	.014
Used the information	Pearson Correlation	.091	.001	.051	.101	1	.126(*)	.008	.054
	Sig. (2-tailed)	.143	.983	.413	.262	.	.044	.910	.435
Know as much information as I want	Pearson Correlation	.124(*)	.053	.111	.021	.126(*)	1	-.097	.170(*)
	Sig. (2-tailed)	.044	.392	.073	.817	.044	.	.159	.014
School education	Pearson Correlation	-.099	-.130	-.006	.146	.008	-.097	1	-.444(**)
	Sig. (2-tailed)	.151	.059	.931	.138	.910	.159	.	.000
Post school education	Pearson Correlation	.016	.088	.096	-.240(*)	.054	.170(*)	-.444(**)	1
	Sig. (2-tailed)	.819	.200	.162	.014	.435	.014	.000	.

* Correlation is significant at the 0.05 level (2-tailed).
** Correlation is significant at the 0.01 level (2-tailed).

Table 43. Breast screening: variables entered for *theoretical* definition of informed choice

	B	S.E.	Wald	Sig.	Exp(B)
School education	.152	.595	.065	.799	1.164
Post school education	-.912	.479	3.619	.057	.402
Age	-.063	.055	1.328	.249	.939
Did not previously participate	.257	.848	.092	.762	1.293
New invitee	-.894	.703	1.616	.204	.409
Used the information	.992	.496	4.004	.049	2.696
Knew as much as they wanted	.167	.404	.170	.680	1.181
Constant	3.482	3.356	1.077	.299	32.534

Cervical screening: correlation matrix variable predicting *perceived* informed choice (n=100)

		Age	Previous non participant	New invitee	Knowledge of disease	Knowledge of what screening is for	Knowledge of test results	Knowledge of limitations	Knowledge of consequences	Attitudes and motivations	Perceived informedness
Age	Pearson Correlation	1	-.093	-.206(*)	.190	.094	.061	.271(**)	.098	-.028	-.254(*)
	Sig. (2-tailed)	.	.357	.040	.058	.353	.546	.006	.332	.785	.011
Previous non participant	Pearson Correlation	-.093	1	-.117	-.085	-.039	.151	-.147	.094	.270(**)	.111
	Sig. (2-tailed)	.357	.	.246	.400	.704	.135	.145	.354	.007	.272
New invitee	Pearson Correlation	-.206(*)	-.117	1	-.020	-.055	.111	.000	.031	.108	.122
	Sig. (2-tailed)	.040	.246	.	.843	.584	.272	1.000	.756	.284	.225
Knowledge of disease	Pearson Correlation	.190	-.085	-.020	1	.069	.136	.025	.160	-.100	-.301(**)
	Sig. (2-tailed)	.058	.400	.843	.	.494	.178	.807	.112	.322	.002
Knowledge of what screening is for	Pearson Correlation	.094	-.039	-.055	.069	1	.277(**)	.191	.187	-.157	-.271(**)
	Sig. (2-tailed)	.353	.704	.584	.494	.	.005	.057	.063	.119	.006
Knowledge of test results	Pearson Correlation	.061	.151	.111	.136	.277(**)	1	.229(*)	.281(**)	.173	-.135
	Sig. (2-tailed)	.546	.135	.272	.178	.005	.	.022	.005	.085	.181
Knowledge of limitations	Pearson Correlation	.271(**)	-.147	.000	.025	.191	.229(*)	1	.363(**)	.172	-.205(*)
	Sig. (2-tailed)	.006	.145	1.000	.807	.057	.022	.	.000	.087	.041
Knowledge of consequences	Pearson Correlation	.098	.094	.031	.160	.187	.281(**)	.363(**)	1	.006	-.276(**)
	Sig. (2-tailed)	.332	.354	.756	.112	.063	.005	.000	.	.955	.005
Attitudes and motivations	Pearson Correlation	-.028	.270(**)	.108	-.100	-.157	.173	.172	.006	1	.351(**)
	Sig. (2-tailed)	.785	.007	.284	.322	.119	.085	.087	.955	.	.000
Perceived informedness	Pearson Correlation	-.254(*)	.111	.122	-.301(**)	-.271(**)	-.135	-.205(*)	-.276(**)	.351(**)	1
	Sig. (2-tailed)	.011	.272	.225	.002	.006	.181	.041	.005	.000	.

* Correlation is significant at the 0.05 level (2-tailed).
** Correlation is significant at the 0.01 level (2-tailed).

Table 55. Cervical screening: variables entered for *perceived* definition of informed choice

	Unstandardized Coefficients		Standardized Coefficients	T	Sig.	Correlations		
	B	Std. Error	Beta			Zero-order	Partial	Part
(Constant)	1.153	.299		3.851	.000			
Age	.014	.006	.185	2.092	.039	.254	.210	.182
Attitudes and motivations	.334	.089	.328	3.758	.000	.351	.360	.326
Knowledge of consequences	.276	.107	.228	2.589	.011	.276	.257	.225
Knowledge of disease	.177	.081	.197	2.193	.031	.301	.220	.190

A Dependent Variable: Perceived informedness: cervical

B Selecting only cases for which Type of screening = Cervical

Excluded Variables(e)

	Beta In	T	Sig.	Partial Correlation	Collinearity Statistics
					Tolerance
Previous participant	-.053	-.568	.572	-.058	.857
Previous non participant	.011	.117	.907	.012	.906
Knowledge of what screening is for	.156	1.759	.082	.179	.935
Knowledge of test results	.102	1.100	.274	.113	.879
Knowledge of limitations	.159	1.633	.106	.166	.778

Cervical screening: correlation matrix variable predicting *theoretical* definition of informed choice (n=49)

		Informed choice categories	Age	previous non participant	new invitee	Wanted information	Know as much information as I want	School education	Post school education
Informed choice categories	Pearson Correlation	1	.189	-.213	-.196	-.143	-.077	-.201	.208
	Sig. (2-tailed)	.	.180	.129	.164	.312	.588	.196	.180
Age	Pearson Correlation	.189	1	-.093	-.206(*)	-.120	.125	-.198	.002
	Sig. (2-tailed)	.180	.	.357	.040	.236	.215	.070	.985
previous non participant	Pearson Correlation	-.213	-.093	1	-.117	.190	-.068	.023	.027
	Sig. (2-tailed)	.129	.357	.	.246	.058	.502	.835	.809
new invitee	Pearson Correlation	-.196	-.206(*)	-.117	1	-.076	-.107	.156	-.087
	Sig. (2-tailed)	.164	.040	.246	.	.450	.289	.155	.430
Wanted information	Pearson Correlation	-.143	-.120	.190	-.076	1	-.183	.006	-.040
	Sig. (2-tailed)	.312	.236	.058	.450	.	.068	.958	.719
Know as much information as I want	Pearson Correlation	-.077	.125	-.068	-.107	-.183	1	-.065	.005
	Sig. (2-tailed)	.588	.215	.502	.289	.068	.	.554	.964
School education	Pearson Correlation	-.201	-.198	.023	.156	.006	-.065	1	-.663(**)
	Sig. (2-tailed)	.196	.070	.835	.155	.958	.554	.	.000
Post school education	Pearson Correlation	.208	.002	.027	-.087	-.040	.005	-.663(**)	1
	Sig. (2-tailed)	.180	.985	.809	.430	.719	.964	.000	.
	N	43	85	85	85	85	85	85	85

* Correlation is significant at the 0.05 level (2-tailed).
** Correlation is significant at the 0.01 level (2-tailed).

Table 56. Cervical screening: variables entered for *theoretical* definition of informed choice

	B	S.E.	Wald	df	Sig.	Exp(B)
Age	.017	.033	.265	1	.606	1.017
School education	-.277	1.012	.075	1	.784	.758
Further education	.615	.867	.503	1	.478	1.849
Non-participant	-2.303	1.156	3.967	1	.046	.100
New invitee	-21.506	19729.124	.000	1	.999	.000
Constant	-.266	1.539	.030	1	.863	.766