

**IMPROVING THE QUALITY OF THE WRITTEN
INFORMATION SENT TO WOMEN ABOUT BREAST
SCREENING**

**Evidence-based Criteria for the Content of
Letters and Leaflets**

**Megan Goldsmith
Clare Bankhead
Joan Austoker**

**NHSBSP Publication No 64
August 2007**

Published by:

NHS Cancer Screening Programmes
Fulwood House
Old Fulwood Road
Sheffield
S10 3TH

Tel: 0114 271 1060

Fax: 0114 271 1089

Email: info@cancerscreening.nhs.uk

Web site: www.cancerscreening.nhs.uk

© NHS Cancer Screening Programmes 2007

The contents of this document may be copied for use by staff working in the public sector but may not be copied for any other purpose without prior permission from the NHS Cancer Screening Programmes.

ISBN 978-1-844663-043-1

Further copies of this publication are available from the Department of Health Publications Orderline quoting NHSBSP Publication No 64

Tel: 08701 555 455

Fax: 01623 724 524

Email: doh@prolog.uk.com

Typeset by Prepress Projects Ltd, Perth (www.prepress-projects.co.uk)
Printed by Charlesworth

CONTENTS

	Page No
PREFACE	v
EXECUTIVE SUMMARY	1
Review aims	1
Methods	1
Results	2
Recommendations	3
1. INTRODUCTION	5
1.1 Breast cancer	5
1.2 Screening	5
1.3 NHS Breast Screening Programme	5
1.4 Psychological response to breast screening	6
1.5 Women's understanding of breast screening	7
1.6 Written information and informed choice	7
1.7 How to present risk information	8
1.8 Review aims	8
2. METHODS	10
2.1 Electronic database search strategy	10
2.2 Other search methodologies	10
2.3 Inclusion criteria	11
2.4 Exclusion criteria	11
2.5 Study selection and review process	12
2.6 Stage 1: initial citation assessment	12
2.7 Stage 2: assessment of full study report	12
2.8 Stage 3: data extraction	12
2.9 Stage 4: quality scoring	12
2.10 Stage 5: synthesis and evidence grading	12
2.11 Stage 6: recommendations	15
3. RESULTS	16
3.1 Search results	16
3.2 Report recommendation system	16
3.3 Guide to the review findings	18
3.4 Letters	19
3.5 Invitation leaflet	20

3.6	Recall leaflet	20
4.	DISCUSSION	47
4.1	Invitation leaflet	49
4.2	Recall leaflet	50
	REFERENCES	51
	APPENDIX 1: DCIS INFORMATION	57
	APPENDIX 2: STUDIES AIMED AT IMPROVING MAMMOGRAPHY UPTAKE AND MAINTAINING ADHERENCE	61
	APPENDIX 3: ELECTRONIC DATABASE SEARCH STRATEGIES	65
	APPENDIX 4: LIST OF INTERNET SITES VISITED	73
	APPENDIX 5: STAGE 3 DATA EXTRACTION FORM	75
	APPENDIX 6: STAGE 4 QUALITY SCORING: STUDY DESIGN ALGORITHM	77
	APPENDIX 7: STAGE 4 QUALITY SCORING: STUDY METHODOLOGY CHECKLISTS	79
	APPENDIX 8: STAGE 5 SYNTHESIS AND EVIDENCE GRADING: MATERIALS	85
	APPENDIX 9: DESCRIPTION OF QUANTITATIVE STUDIES	89
	APPENDIX 10: DESCRIPTION OF QUALITATIVE STUDIES	97
	APPENDIX 11: DESCRIPTION OF EXPERT OPINION REPORTS AND CHECKLIST TYPE STUDIES INCLUDED IN THE INVITATION LEAFLET EVIDENCE PROFILES	109

PREFACE

The evidence presented in this report is based on a systematic review undertaken by staff at the Cancer Research UK Primary Care Education Research Group. The project was supported by the NHS Breast Screening Programme and Cancer Research UK. The authors would like to give special thanks to all those who generously provided them with unpublished work and grey literature. Particular thanks are due to our colleagues for their advice and guidance.

Guidelines based on this evidence, including an update of guidelines published in 1998 (*Guidelines on Improving the Quality of the Written Information Sent to Women who are Recalled for Assessment*; NHSBSP Publication No 38), are published as a separate document: *Improving the Quality of the Written Information Sent to Women about Breast Screening: Guidelines on the Content of Letters and Leaflets* (NHSBSP Publication No 65).

EXECUTIVE SUMMARY

Screening has been described as ‘a public health service in which members of a defined population, who do not necessarily perceive they are at risk of, or are already affected by a disease or its complications, are ... offered a test, to identify those individuals who are more likely to be helped than harmed by further tests or treatment to reduce the risk of a disease or its complications’. The aim of screening is to reduce mortality from the disease in question by detecting risk factors, early disease or a preclinical condition before symptoms occur, in order to prevent or reverse the disease process. Screening healthy women for breast cancer exposes them to fears about cancer and their current health status. Women often do not understand the risks and uncertainties associated with breast screening and are less aware of the limitations than the benefits. The 2000 *NHS Cancer Plan* placed increasing importance on attaining informed choice in screening, and the need for more factual and timely health information was highlighted in two recent Department of Health White Papers – *Choosing Health: Making Healthy Choices Easier* (2004) and *Our Health, Our Care, Our Say: A New Direction for Community Services* (2006). An important priority of the NHS Breast Screening Programme (NHSBSP) is the continual improvement of the quality of written information sent to women about breast screening at all stages of the screening process.

Review aims

The aim of this review is to improve the quality of the content of letters and leaflets sent to women at all stages of the breast screening process. Previous evidence-based guidance was published in 1998 for the information materials associated with recall (NHSBSP Publication No 38). However, no screening standards have been produced for the invitation materials. Two main questions were addressed:

- What is the existing research evidence base regarding the content of written information sent to women at all stages of the breast screening process?
- What are the information needs of women at all stages of the breast screening process?

The answers to these questions helped to guide the development of the recommendations for the content of all of the leaflets and letters to be used in the NHSBSP.

Methods

Data sources

Systematic searches of 13 electronic databases (between 1989 and August 2005) were conducted. Additional references were located by searching the table of contents of selected journals, the reference sections of relevant papers and Internet resources. Both published and unpublished studies were included.

Study selection

All studies that evaluated the content of information materials provided to women about breast screening or that addressed the information needs of women at all stages of the breast screening process were assessed for inclusion.

Data extraction

The data extraction form and quality assessment criteria were developed from published resources. Two reviewers independently assessed titles and abstracts of papers as well as full study reports. Data were extracted from relevant studies by one reviewer and checked by a second reviewer. Any uncertainty was resolved by discussion.

Data synthesis

A non-quantitative synthesis was conducted and a tabular evidence profile for each important outcome (eg 'Explain the need for breast compression') was prepared. Outcomes were drawn from research evidence, the 1998 NHSBSP recall information guidelines and expert opinion. The overall quality of evidence for each outcome was then assessed using an approach published by the Grading of Recommendations Assessment, Development and Evaluation (GRADE) working group that was adapted to suit the review questions and modified to include qualitative research evidence. Four key elements were considered in each evidence profile: study design, study quality, consistency and directness. Quantitative and qualitative studies as well as expert opinion were considered separately for every outcome.

Results

A total of 3536 citations were identified as potentially relevant by electronic database searches and other search strategies. After the titles and abstracts of the citations had been independently prescreened by two reviewers, 361 papers remained for possible inclusion. The full report of each of these papers was obtained and scanned for relevance – full data extraction was conducted for 100 of the papers. Following data extraction and assessment of methodological quality, a grand total of 31 papers were included in the systematic review.

Recommendations were included for the breast screening programme letters, although little research literature has been published that specifically addresses questions related to the content of screening letters and the information needs of women receiving these materials.

Summary recommendation tables were developed for the invitation and recall leaflets. The list of outcomes considered for the invitation leaflet was extensive and a number of papers – both quantitative and qualitative as well as expert opinion – were assessed. Research evidence was considered for almost every section of the invitation leaflet; however, there was limited evidence available for a number of the items of information. The quantitative evidence included in the review received quite low overall evidence ratings. This may generally be explained by the study designs used (ie non-comparative descriptive studies), which are rated lower in the GRADE evidence hierarchy as opposed to methodological issues such as selection bias or unreliable outcome assessment. The content of the existing NHSBSP invitation leaflet was included in the summary tables to allow for comparison with current practice.

New research evidence was assessed for a majority of recall leaflet outcomes. Several new items of information were added to the outcomes recommended in the 1998 NHSBSP guidance. A selection of the changes incorporated include:

- mention technical errors
- present information about the future risk of developing breast cancer
- discuss benign conditions that may be seen on mammograms (clearly explain terms such as ‘calcium spots’, ‘calcium deposits’, ‘calcifications’ and ‘cysts’)
- provide information about false positive and false negative results
- indicate that follow up may be necessary.

The diagnosis of ductal carcinoma in situ (DCIS) presents important issues for the breast screening programme. The questions surrounding DCIS are complex – confusion exists regarding disease progression and there is no optimal treatment strategy. Also, a limited amount of research evidence exists regarding women’s information needs about DCIS.

The review process identified some evidence related to interventions designed to improve mammography uptake and maintain adherence. Evidence of improved uptake at invitation was seen with fixed appointments as opposed to open appointments, and there was some evidence of improved uptake when a GP’s signature was included on the screening programme invitation letter. Among screening non-attenders, a GP’s endorsement of screening via letter appeared to be effective and reminders were also found to be useful. The provision of additional educational information did not appear to improve uptake; however, general information may help to maintain mammography adherence. This topic has been covered in detail by a group of systematic reviews, and the search strategy used in this report was not designed specifically to address this issue.

Recommendations

We recommend that the NHSBSP should continue to use the existing letter templates. However, consideration could be given to the content suggested by the European Communication Group and to the evidence provided by the literature addressing interventions designed to improve mammography uptake and maintain adherence.

To help women make suitable decisions about whether or not to attend for screening and to ensure that women receive appropriate information at each step of the screening process, the NHSBSP should endeavour to produce leaflets that incorporate the concepts presented in the full summary recommendation tables. At present, only an invitation leaflet is provided to women taking part in the programme (although further information about breast screening is available on request in the form of a Cancerbackup booklet). A nationally available recall leaflet (including information about DCIS) should be produced and distributed. Examples of items that might be included in the invitation and recall leaflets are given below.

Invitation leaflet

- Screening programme information
- Nature and purpose of the test
- Breast cancer information
- Validity of the test (include information on false positive and false negative results)
- Benefits and risks of mammography
- Eligible population and screening interval
- Test procedure
- Test results (explain the meaning of the results)
- Further tests
- Treatment
- Preventative information

The possible reasons for further tests and treatment should be described in the invitation leaflet. However, detailed information about further investigation and subsequent treatment should not be provided until later in the screening process. The amount of information provided about further tests and investigation, the effectiveness of treatment and follow up should increase as a woman progresses from abnormal result to further assessment and treatment.

Recall leaflet

- Meaning of an abnormal result (provide a clear reason for recall; include information on false positive and false negative results)
- Abnormal result outcomes (ie women are unlikely to have cancer)
- Provide appointment information
- Further tests and investigation (explain what further assessment involves)
- Follow up
- Further information

1. INTRODUCTION

1.1 Breast cancer

One in 10 of all new cancers diagnosed and almost 25% of cancers diagnosed in women worldwide is a female breast cancer.¹ Breast cancer is the most commonly diagnosed cancer in UK women, with over 41 700 new cases in 2002.¹ The disease accounts for 17% of female mortality from cancer in the UK, with almost 13 000 deaths each year.¹ There has been a dramatic reduction in mortality since the late 1980s, when over 15 000 women died each year.²

1.2 Screening

Screening has been described by the National Screening Committee as ‘a public health service in which members of a defined population, who do not necessarily perceive they are at risk of, or are already affected by a disease or its complications, are ... offered a test, to identify those individuals who are more likely to be helped than harmed by further tests or treatment to reduce the risk of a disease or its complications’.³ The aim of screening is to reduce mortality from the disease in question by detecting risk factors, early disease or a preclinical condition before symptoms occur, in order to prevent or reverse the disease process. The value of screening depends on the success of the programme in attracting, identifying and treating those at risk of a particular disease, and the extent to which the associated costs are minimised.⁴

1.3 NHS Breast Screening Programme

Breast screening can detect very early stage breast cancer when the tumour is too small to be felt. Most screen detected breast cancers are early stage, and around 62% of the cancers found at screening are small enough to allow breast conservation surgery.⁵ In April 2001, following an extension of the NHSBSP age range, women aged 65–70 years began to receive routine invitations for breast screening.⁵ The NHSBSP now offers mammography every three years to all UK women aged 50–70 years registered with a general practice. Women over 70 years can request mammography once every three years, but currently they are not routinely invited for screening. The screening process is delivered at 98 breast screening services across the UK at permanent and mobile sites.⁶

1.3.1 Screening methods

The mammogram is a low dose x-ray. Each breast is placed in turn on the x-ray machine and gently but firmly compressed with a clear plate. Until 2004, women were offered two view mammography at their first screen (prevalent screen) and a single oblique view mammogram in subsequent screens (incident screens). At the end of 2003, two view mammography was introduced at every screening visit.⁶ All women are sent written results. For some women, the mammogram is inconclusive and they are invited for further tests at assessment centres run by NHSBSP multidisciplinary teams. Further investigations may include another mammogram, clinical breast examination, ultrasound, core biopsy, fine needle aspiration (cytology) or surgical biopsy.²

1.3.2 *Ductal carcinoma in situ (DCIS)*

Registrations of DCIS have increased markedly since the introduction of breast screening because it is a condition that is usually not palpable and is mostly diagnosed by mammography.^{7,8} A detailed discussion of the DCIS literature falls beyond the remit of this report. However, as DCIS is an important issue for the breast screening programme, further information about this issue is included in Appendix 1.

1.3.3 *Breast screening results*

In 2003/2004, over 1.6 million women in the UK were screened for breast cancer. Of these women, 5.6% (approximately 84 000 women) were referred for further investigations.⁹ After further investigation, a woman may be diagnosed with cancer, a precancerous lesion (eg DCIS) or be given the all clear. The rates of referral for further tests vary dramatically: they are much higher in women who have never been invited for screening before (8.7%) or have never attended for screening (8.8%) than in women who have undergone routine screening (3.8%).⁹ Of the women aged 50–70 years who were referred for further tests, 13 064 (15.5%) were found to have cancer. In other words, women have an approximately 5.6% chance of being recalled and, of those, around one in six have cancer. The remaining five out of six women who are referred are given an ‘all clear’ result.

1.4 **Psychological response to breast screening**

A recent literature review of the psychological impact of breast screening concluded that screening does not appear to create anxiety for the majority of women given an initial clear result after routine screening.¹⁰ However, for women who are recalled for further investigations after a routine mammogram, there are significant short term adverse psychological consequences that may persist in the long term.¹⁰ The intensity of the psychological impact experienced by women was affected by the nature and extent of the further investigations.¹⁰ High levels of anxiety were reported by women who received a clear result after a surgical biopsy and by women who were placed on early recall and asked to come back for further tests after six months or one year.¹⁰ Other negative emotional reactions included depressed mood, worry about breast cancer, intrusive thinking, perception of less healthy breasts and more frequent breast self-examination behaviour.^{10,11} Conflicting evidence was found regarding the effects of the adverse psychological impact of screening on attendance for subsequent screening among women who have previously received a false positive result. In studies in which psychological outcomes were not assessed, lower actual attendance among women who received a false positive result has been observed.¹⁰

Written information has been used as an intervention to minimise adverse psychological consequences and improve screening uptake.^{12–18} Sparse evidence suggests that such educational interventions may improve knowledge scores;^{18,19} however, the impact on formal measures of anxiety is unclear.^{18,19} Nevertheless, the provision of good reliable information is highly valued by women.^{12,20–26}

1.5 Women's understanding of breast screening

Screening healthy women for breast cancer exposes them to fears about cancer and their current health status. Women need to understand the uncertainties associated with the benefits (ie preventing death from breast cancer) and the harms of breast screening.^{27,28} Any harm (physical, emotional, social, financial or psychological) suffered by individual women participating in the NHSBSP may be temporary, lasting around the time of testing and receipt of results, but it may also be permanent. As such, it is important to clarify common misconceptions about screening, including screening tests are for symptomatic individuals, screening reduces the incidence of breast cancer, early detection implies reduced mortality, all breast cancers necessarily progress and early detection is always beneficial.^{27,29} The information that women receive should seek to address potential fears and anxiety in order to reduce any psychological problems associated with the receipt of a suspicious or abnormal result.³⁰ When uncertainty exists, it should be discussed and advice should be explicitly supported by the best available evidence.³¹

The ongoing challenge of general screening information is to convey fuller information about the natural history of breast cancer, the benefits and harms of assessment and diagnostic tests, radiation risks, non-invasive conditions such as DCIS and treatment. A woman going through all stages of the breast screening process from initial testing to further investigations and possible treatment may receive upwards of five letters (including reminders) and at least one leaflet. Researchers looking at the information needs of women in breast screening programmes have shown that women feel inadequately informed at almost every stage of the screening process.^{12,16,23,25,26,32-39} In addition, the information provided by screening programmes about the benefits and disadvantages of breast screening has been accused of being partial and misleading.^{27,28,40-46} In view of the number of women being screened, and the dissatisfaction with screening information, it is clear that the content of written material given to women about breast screening requires careful consultation and assessment.

The breast screening information produced by different countries (including the UK) has been variously assessed by a number of different studies.^{35,46-52} These studies have consistently reported discrepancies between the actual content of the information materials assessed and an ideal content (usually but not always defined by expert consensus). Given that many women taking part in breast screening feel that they require more information and that the available screening materials are falling short of expert expectations, it is timely and important to bring together the current research evidence into a set of guidelines.

1.6 Written information and informed choice

The *NHS Cancer Plan* that was published in September 2000 acknowledged the increasing importance of informed choice in screening by calling for honest, comprehensive and understandable screening materials that inform women of all possible outcomes of participation so that they may make suitable decisions about whether or not to attend.⁵³ The need for more factual health information that is up to date and accurate and the timely provision of appropriate health service materials have been emphasised in two recent White Papers (November 2004 and January 2006).^{54,55}

An important priority of the NHSBSP is the continual improvement of the quality of written information sent to women about breast screening at all stages of the screening process.⁵⁶ The NHSBSP is also committed to the provision of clear and balanced information about the benefits and limitations of breast screening for all women.^{6,57} This systematic review of the literature related to breast screening information presents a set of recommendations that will help to inform the development and revision of materials produced by the NHSBSP. The recommendations were shaped by the ethical imperative of all screening programmes – to do more good than harm.

1.7 How to present risk information

The presentation of risk information is problematic because the interpretation of risk language is not straightforward^{58–63} and consensus is lacking on whether numerical data should be presented and in what form.^{52,59,62} Proponents of the inclusion of quantitative information about risks for disease believe that such information is an important component of informed decision making,^{60,62,64,65} whereas others suggest that the presentation of quantitative expressions may be confusing and meaningless.^{60–62,64} Several strategies for communicating risk information have been proposed,^{60,63,66} but the effectiveness of incorporating such approaches into screening programme materials is unknown. Messages constructed in both numeric and verbal formats may be advantageous because they benefit from the use of ordinary language as well as the precision of numbers.⁶⁴

Although additional research work is required to determine which risk presentation options women prefer and find most useful, a set of key presentation points may be derived from the risk communication literature (Table 1). The key points summarised in Table 1 are largely based on theoretical work. It has been suggested that the risk information provided to women should be simple, balanced and relevant.^{61,67} This is supported by the research described in Appendix 2, in which no evidence of increased mammography uptake among women exposed to interventions incorporating additional educational information was shown.^{68–72} Inadequacies in literacy as well as numeracy must also be taken into account when developing risk information for inclusion in screening materials.^{59,60,64,73}

1.8 Review aims

The aim of this review is to improve the quality of the content of letters and leaflets sent to women at all stages of the breast screening process. Previous evidence-based guidance was published in 1998 for the information materials associated with recall for assessment.³⁰ However, no screening standards have been produced for the invitation materials.

Two main questions were addressed:

- What is the existing research evidence base regarding the content of written information sent to women at all stages of the breast screening process?
- What are the information needs of women at all stages of the breast screening process?

The answers to these questions helped to guide the development of recommendations for the content of all of the leaflets and letters to be used in the NHSBSP.

Table 1 Presenting risk information: key points^{60–63,65,74,75}

Present numerical probabilities as event rates (eg the number out of 100 women)
Use constant denominators rather than constant numerators (eg 4 out of 1000; 15 out of 1000)
Provide a meaningful timeframe over which events occur (10 years, lifetime)
Present event rates with visual aids (such as faces diagrams, bar charts and/or human figure representations)
Analogies may be useful for presenting small risks (eg one person in a concert hall crowd)
Provide the mortality benefit from screening as the probability of death with and without screening
Dual representations should be used (loss and gain, mortality and survival data) to counteract the influence of framing
Absolute risks should be given greater prominence than relative risks
If conditional probabilities are used, the baseline risk of the target condition should be provided
Put disease- or intervention-specific probabilities into context by comparing the risk with other common/uncommon events (eg winning the lottery, road crashes)
Acknowledge uncertainty in estimates by using phrases such as ‘our best guess is ...’, give ranges or provide 95% confidence intervals

2. METHODS

2.1 Electronic database search strategy

Systematic searches of the following electronic databases were conducted: MEDLINE, PsycINFO, EMBASE, CINAHL, Social Science Citation Index, Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials, Cochrane Database of Methodology Reviews, Cochrane Methodology Register, Database of Abstracts of Reviews of Effects (DARE), Health Technology Assessment Database (HTA), NHS Economic Evaluation Database and System for Information on Grey Literature in Europe (SIGLE). The years included in the searches were 1989 to August 2005.

Appendix 3 shows the search strategy used for the four main electronic databases (MEDLINE, PsycINFO, EMBASE, CINAHL). A combination of text terms and MeSH terms was used to maximise the amount of literature retrieved.

2.2 Other search methodologies

The NHS Cancer Screening Programmes Breast Screening Literature Database was searched by one reviewer from Issue No 1 (1989) to Issue No 45 (July 2005); note that Issues No 18 (July 1996) and No 25 (November 1998) were not available for review. The journals included in this resource are listed in Issue No 15 (July 1995), but no update of this publication list has since been published (see www.cancerscreening.nhs.uk for more information). The literature database is produced and updated by The Science Registry Ltd for the NHS Cancer Screening Programmes. Categories searched for this review were: (1) trials, epidemiology and evaluation, (2) management/administration/economic evaluation, (3) psychological aspects/acceptability, (4) health education/breast awareness/breast self-examination and (6) unclassified/general interest.

The table of contents of selected journals from April 2004 to December 2005 were handsearched. The relevant journals were: *American Journal of Epidemiology*, *American Journal of Health Promotion*, *American Journal of Public Health*, *Breast*, *Breast Cancer Research*, *Breast Journal*, *British Journal of General Practice*, *British Medical Journal*, *Canadian Journal of Public Health*, *Cancer Journal*, *European Journal of Gynaecological Oncology*, *European Journal of Public Health*, *Health Education*, *Health Education and Behavior*, *Health Education Research*, *Health Expectations*, *International Journal of Epidemiology*, *International Journal of Gynecology and Obstetrics*, *International Journal of Gynecological Cancer*, *Journal of Cancer Education*, *Journal of Community Health*, *Journal of Epidemiology and Community Health*, *Journal of Medical Screening*, *Journal of Obstetrics and Gynaecology*, *Journal of Public Health Medicine*, *Journal of Women's Health*, *Patient Education and Counseling*, *Preventive Medicine*, *Psychology and Health*, *Psychology Health and Medicine*, and *Psychooncology*.

The reference sections of extracted papers were handsearched by one reviewer for other references relevant to the review question. The reference lists of papers relevant to the background section of the report were also handsearched for pertinent references.

A large number of different Internet sites were visited during September 2005 (Appendix 4). Three main categories of sites were searched: (1) breast screening services, (2) general health sites and cancer agencies and (3) women's health sites.

Retrieved papers were downloaded into Reference Manager. There were no language restrictions, and both published and unpublished studies were included if they met the inclusion criteria.

2.3 Inclusion criteria

2.3.1 Information materials

- Studies that specifically evaluated the content of written information materials provided to women about breast screening at all stages of the breast screening process, including letters, leaflets, booklets and sheets.
- Studies that specifically evaluated the content of any information materials provided to women about breast screening as part of multifaceted patient education programmes or mass media public health interventions.

2.3.2 Information needs

- Studies that specifically evaluated the information needs of women at all stages of the breast screening process.
- Studies that did not (as a primary objective) evaluate the information needs of women at all stages of the breast screening process but that provided evidence which helped to answer the review aims.

2.4 Exclusion criteria

Studies that looked at:

- breast screening from a general practice point of view
- laboratory based research
- interventions centred on medical professional education
- non-information based predictors of breast screening uptake
- studies reporting risk factors for breast cancer without reference to information needs or written information materials
- breast self-examination
- breast implants
- breast screening methods/technology
- protocols and technical aspects of treatment for DCIS and breast cancer
- studies that were not original research (opinion articles)
- interventions to increase screening uptake (except where the content of participant information materials was evaluated and/or included with the study report)
- specific groups (such as individuals with disabilities, lesbians, younger women and individuals from particular cultural or linguistic groups) – see discussion
- studies reporting knowledge, attitudes, health beliefs, anxiety, perceptions or barriers towards breast screening without reference to information needs or written information materials
- tailored information interventions without a non-tailored information comparison group.

- 2.5 Study selection and review process** There were six stages to the study selection and review process. The study selection process (stages 1–3) is described below and shown diagrammatically in Figure 1.
- 2.6 Stage 1: initial citation assessment** Two reviewers independently assessed titles and abstracts of papers. Where there was insufficient information to determine relevance, full copies of articles were obtained. The papers were initially included or excluded; any uncertainty was resolved by discussion.
- 2.7 Stage 2: assessment of full study report** Included studies were independently prescreened for relevance by two reviewers using the full study report. Any uncertainty was resolved by discussion.
- 2.8 Stage 3: data extraction** Data were extracted from relevant studies by one reviewer and checked by a second reviewer. Data from the included studies were extracted using a standard data extraction form (Appendix 5). The data extraction form was developed using guidelines produced by the NHS Centre for Reviews and Dissemination (CRD)⁷⁶ and several other publications.^{4,77,78} Any uncertainty was resolved by discussion.
- Data extracted included identification of the study aims; setting; design; sample size and follow up rates; study methods including comparative groups; outcomes; and results.
- 2.9 Stage 4: quality scoring** The study design was determined for each extracted paper by two reviewers using the study design algorithm described in Appendix 6, which was adapted from publications produced by the Non-Randomised Studies in Cochrane Reviews Methods Group⁷⁹ and the Agency for Healthcare Research and Quality.⁸⁰ The quality of each study was then scored using methodology checklists adapted from SIGN (Scottish Intercollegiate Guidelines Network⁸¹), CASP (Critical Appraisal Skills Programme⁸²) and the New Zealand Guidelines Group⁸³ for quantitative designs (Appendix 7). A single checklist derived from CASP⁸² and the UK Government Chief Social Researcher's Office⁸⁴ was developed for qualitative studies (Appendix 7). Each criterion on an individual methodology checklist was assessed as well covered, adequately addressed, poorly addressed, not reported or not applicable. The methodological quality of each study was then rated as: ++ (all or most of the criteria have been fulfilled), + (some of the criteria have been fulfilled) or – (few or no criteria have been fulfilled). The quality scores assigned to the individual studies are presented in Appendices 9 and 10. Agreement between reviewers was good and improved over time. Any uncertainty was resolved by discussion.
- 2.10 Stage 5: synthesis and evidence grading** Recently, a new system of grading quantitative research evidence was proposed by an international group of experts in the field of systematic reviews. The approach adopted by the GRADE working group involves constructing a tabular evidence profile for each important outcome.⁸⁵ Quantitative studies that address an outcome of interest are listed individually and analysed together in the evidence profile. The overall level of evidence assigned to each main outcome (taking into account all of the studies) is influenced by four key elements: study design, study quality, consistency and directness.^{85,90} One of the main benefits of the GRADE

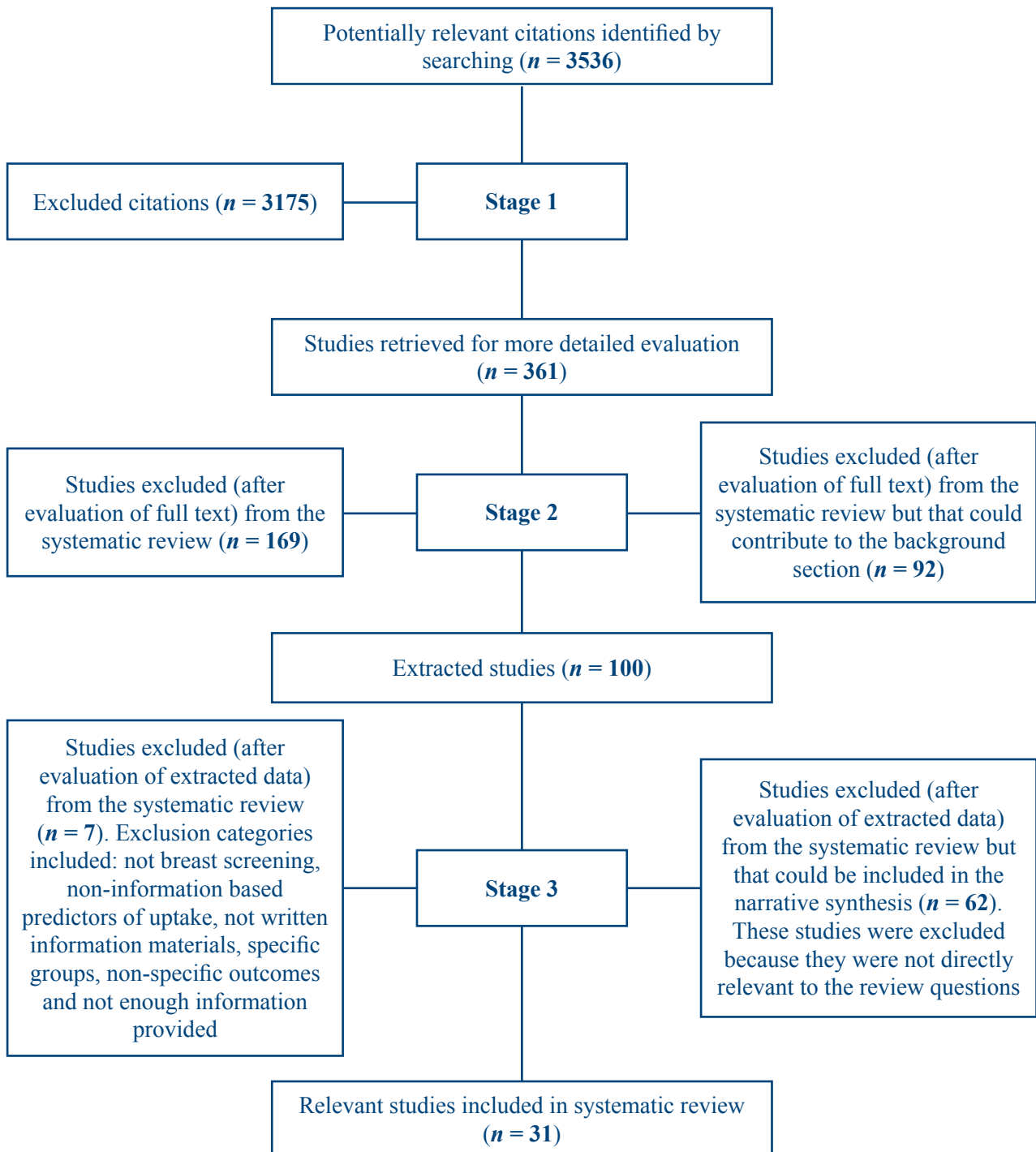


Figure 1 Flow diagram of study selection process.

approach is the ability to increase or decrease the level of evidence assigned to a specific outcome following consideration of factors other than study design alone (see sections 2.10.1 and 2.10.2).

In this review, the GRADE approach was used as a template for a non-quantitative synthesis of all included papers. The system was adapted to suit the review questions (simpler evidence tables were used owing to the types of studies retrieved during the review process) and modified to incorporate qualitative research evidence (Appendix 8). In this way, a tabular evidence profile for each important outcome (eg 'Explain the need for breast compression') was prepared. Outcomes were drawn from research evidence, the 1998 NHSBSP recall information guidelines³⁰ and expert opinion. Quantitative and qualitative studies were considered separately for every outcome.

2.10.1 Quantitative studies

Study design and study quality were described in Stage 4. A group of quantitative studies listed in a particular outcome evidence profile was initially categorised into one of three evidence levels based on study design (Appendix 8). The categories were: high (randomised trials), low (observational studies) or very low (any other evidence). The lowest hierarchical type of evidence (ie study design) of any study in the group provided the basis for the initial evidence level assignment. Subsequently, the level of evidence was modified by one or two levels depending on the corroborative evidence provided by all of the studies in the group. Important inconsistencies in the results between studies in the outcome evidence profile, uncertainty about the directness of the evidence, imprecise or sparse data and/or a high probability of reporting bias could decrease the grade assigned by one or two levels. Strong associations, evidence of a dose-response gradient and/or presence of all plausible residual confounding that would have reduced the effect observed could raise the grade assigned by one or two levels. Consistency refers to the similarity of estimates of effect or observations across studies, while directness refers to the extent to which people, interventions and outcomes are similar to those of interest. All of these additional considerations acted cumulatively on the overall quantitative level of evidence assigned to each outcome (further details of this process are given in Appendix 8).

2.10.2 Qualitative studies

Similarly, a group of qualitative studies listed in a particular outcome evidence profile was initially categorised into one of three evidence levels: high (studies rated as Q++), low (studies rated as Q+) or very low (studies rated as Q-) according to the study quality ratings derived from the Study Methodology Checklist 3 (Appendix 7). The lowest checklist quality score obtained for any study in the group provided the basis for the initial evidence level assignment. Any important inconsistency between studies and/or uncertainty about the directness of the evidence provided by all of the studies related to one particular outcome could decrease the grade assigned by one or two levels. Close conformity of findings based on two or more studies rated as Q++, directly applicable to the target population, could raise the assigned grade by one level. Consistency refers to similarities in developed themes and participant

experiences across studies whereas directness addresses the extent to which people, interventions and outcomes are similar to those of interest. An overall qualitative level of evidence was assigned to each outcome once the cumulative effect of these additional factors had been considered (Appendix 8).

2.11 Stage 6: recommendations

Two separate recommendation systems were developed for the screening materials given out at invitation versus the recall information materials. Different systems were necessary because no evidence-based guidelines currently exist for the NHSBSP invitation materials whereas guidance was published in 1998 on improving the quality of the written information sent to women who are recalled for assessment.³⁰ A recommendation system with four levels (definite, suggestive, expert opinion and current practice) was adopted for the invitation information, and a system with three levels (screening standard, definite and suggestive) was introduced for the recall materials. The two systems are described in more detail in Chapter 3 (see Tables 2 and 3).

2.11.1 Expert opinion

There is a lack of evidence-based guidance in the breast screening literature regarding the essential contents of patient information materials. During the course of the review, we identified a number of expert opinion reports containing various recommendations for the content of breast screening materials as well as studies that used different checklists/questionnaires to evaluate both screening information and women's decision-making about mammography. Often, little information was provided about the development of the checklists used in these studies – there was no indication of why particular items had been included. It was decided that the expert opinion reports and checklist type studies should be included in the review as a separate category of evidence distinct from the other quantitative and qualitative studies. This extra category was necessary to provide a complete picture of the existing evidence. Further details of the above described reports may be found in Appendix 11.^{21,22,47–50,75,87}

3. RESULTS

3.1 Search results

A total of 3536 citations were identified as potentially relevant by electronic database searches and other search strategies. After the titles and abstracts of the citations had been independently prescreened by two reviewers, 361 papers remained for possible inclusion. The full report of each of these papers was obtained and scanned for relevance – full data extraction was conducted for 100 papers (2.8% of all identified citations; 100/3536).

Following data extraction and assessment of methodological quality, two reviewers made a final decision about whether to include or exclude each of the papers. A grand total of 31 papers were included in the review (0.9% of all identified citations; 31/3536). Several papers provided evidence in more than one category, so the total number of studies described as contributing to each category ($n = 35$) is greater than the overall number of papers included in the review. Overall, 14 studies addressed general screening issues, two focused on receipt of results, seven investigated issues related to recall and four addressed DCIS. Eight expert opinion reports and checklist type studies discussed issues relevant to the screening invitation materials.

The literature was drawn from studies conducted in the UK, USA, Australia, New Zealand, Italy, Germany and Sweden.

3.2 Report recommendation system

The report recommendation system used for invitation information is shown in Table 2.

A ‘Definite’ recommendation was assigned to individual outcomes with supporting quantitative and/or qualitative research evidence graded as ‘high’ and/or ‘moderate’.

A ‘Suggestive’ recommendation was assigned to individual outcomes with supporting quantitative and qualitative research evidence graded as ‘low’ and/or ‘very low’.

An ‘Expert opinion’ recommendation was assigned to individual outcomes with supporting quantitative and qualitative research evidence graded as ‘low’ and/or ‘very low’ and expert opinion support.

If no quantitative or qualitative research evidence relevant to a particular outcome was available for assessment but expert opinion supported inclusion, an ‘Expert opinion’ recommendation was assigned.

All outcomes included in the existing NHSBSP invitation leaflet with no research evidence or expert opinion support were designated as ‘Current practice’.

The report recommendation system used for recall information is shown in Table 3.

Key topics from the 1998 NHSBSP report for which no new evidence was obtained during the current review process were designated as ‘Screening standard’.

A ‘Definite’ recommendation was assigned to individual outcomes with supporting quantitative and/or qualitative research evidence graded as ‘high’ and/or ‘moderate’.

A ‘Suggestive’ recommendation was assigned to individual outcomes with supporting quantitative and qualitative research evidence graded as ‘low’ and/or ‘very low’.

If the new research evidence for a key topic set by the 1998 NHSBSP report was graded as ‘low’ and/or ‘very low’, the references from the original report were retrieved and assessed. The recommendation level was downgraded to ‘Suggestive’ only if the evidence base in the 1998 NHSBSP report was determined to be weak.

Table 2 Description of report recommendation system: invitation information

Recommendation	Recommendation definition
Definite (D)	Definite (D) recommendation for which available quantitative and qualitative research evidence was graded as high and/or moderate
Suggestive (S)	Suggestive (S) recommendation for which available quantitative and qualitative research evidence was graded as low and/or very low
Expert opinion (E)	Expert opinion (E) recommendation for which available quantitative and qualitative research evidence was graded as low and/or very low and expert opinion reports supporting inclusion were available OR No quantitative or qualitative research evidence was available but expert opinion reports supporting inclusion were available
Current practice	Current practice recommendation for which an item of information is included in the existing NHSBSP invitation leaflet and no quantitative or qualitative research evidence or expert opinion reports were available

Table 3 Description of report recommendation system: recall information

Recommendation	Recommendation definition
Screening standard (key topics from the 1998 report)	Key topics set by the NHSBSP in the 1998 report for which no new evidence was available for evaluation OR New quantitative and/or qualitative research evidence was available and graded as high and/or moderate
Definite (D)	Definite (D) recommendation for which available quantitative and/or qualitative research evidence was graded as high and/or moderate
Suggestive (S)	Suggestive (S) recommendation for which available quantitative and qualitative research evidence was graded as low and/or very low

3.3 Guide to the review findings

A full description of all of the quantitative and qualitative studies included in the systematic review is located in Appendices 9 and 10.^{11,12,16,21–26,32–40,47–50,58,75,87–93} Evidence related to the NHSBSP letters is discussed at the beginning of the results section. A summary recommendation table and an outcome evidence profile are subsequently presented for the invitation and recall leaflets respectively. Key points from the DCIS literature are highlighted in Appendix 1, and a brief summary of evidence related to interventions designed to improve mammography uptake and maintain adherence is included in Appendix 2.

3.3.1 Letters

Little research evidence has been published regarding screening programme letters. The European Communication Group's recommendations for screening programme invitation letters and other potential modifications are shown in section 3.4 and Table 4.

3.3.2 Invitation leaflet

The recommendations detailed in Table 5 represent a synthesis of a number of papers – both quantitative and qualitative – as well as expert opinion. The list of outcomes considered was extensive and, although research evidence was considered for almost every section of the leaflet, there was limited evidence available for a number of the items of information. Quite a few of the outcomes recommended for inclusion by expert opinion were supported by research evidence graded as 'low' and/or 'very low' if at all. It is also interesting to note that the quantitative studies often received lower evidence grades than the qualitative research. The sections 'Breast cancer information', 'Validity of the test', 'Benefits of mammography', 'Risks of mammography', 'Appointment information', 'Test procedure', 'Test results', 'Further tests' and 'Treatment' contain outcomes with the strongest evidence base. The research evidence is shown in Table 6. A comparison of the content of the existing NHSBSP leaflet is also shown.

3.3.3 Recall leaflet

New research evidence was assessed for a majority of recall leaflet outcomes (Table 7). As before, the qualitative evidence often received a higher grade than the quantitative research. Several new items of information were added to the outcomes recommended in the 1998 NHSBSP report,³⁰ including information about technical errors, future risk of developing breast cancer, benign conditions, false positives and false negatives as well as follow up. Terms related to benign conditions that cause difficulties for women are 'calcium spots', 'calcium deposits', 'calcifications' and 'cysts'. We recommend that a national recall leaflet should be produced for distribution to women who are recalled.

3.3.4 DCIS information

A limited amount of research evidence exists regarding women's information needs about DCIS (Appendix 1). We recommend that a brief paragraph about DCIS should be included in the NHSBSP invitation leaflet and that further in depth DCIS information should be provided at recall.

3.3.5 *Improving mammography uptake and maintaining adherence*

This topic has been covered in detail by a group of systematic reviews.^{13,94,95} A number of studies identified during the course of the review reporting information based interventions aimed at improving mammography uptake and maintaining adherence are briefly summarised in Appendix 2. Evidence of improved uptake at invitation was seen with fixed appointments compared with open appointments, and there was some evidence of improved uptake when a GP's signature was included on the screening programme invitation letter. Among screening non-attenders, a GP's endorsement of screening via a letter appeared to be effective, and reminders were also found to be useful. The provision of additional educational information does not seem to improve uptake, but general information may help to maintain mammography adherence.

3.4 **Letters**

All of the existing invitation and results letters used by the NHSBSP have been approved by the Advisory Committee on Breast Screening, and those sent to women who are recalled for further assessment were developed according to guidance published in NHSBSP Publication No 38.³⁰ Very little research evidence has been produced that specifically addresses questions related to the content of breast screening programme letters and the information needs of women receiving these materials. However, European guidelines have recently been published addressing the content of breast screening invitation materials,⁵² and a single focus group study of women taking part in the NHSBSP has assessed the wording of the results letter.²³

3.4.1 *Invitation letter*

The European Communication Group's recommendations (developed by expert consensus) for the contents of breast screening invitation letters are summarised in Table 4.⁵² The guidance notes suggest that the invitation letter should be written in a simple, clear and readable style and that the topics covered by the letter should be only briefly described because further relevant additional information may be included in an accompanying leaflet. It is also suggested that the letter should refer to the leaflet and that women should be encouraged to read it.⁵²

3.4.2 *Results letter*

In one qualitative research project, 48 women with normal mammogram results who attended the Warwickshire, Solihull and Coventry Breast Screening Service were invited to attend a group discussion. Twenty-seven women screened at various sites attended a series of focus groups. Some women reported being dissatisfied with the wording of the results letter, especially the phrase 'No traces of cancer were found'. The women preferred the phrase 'negative result'.²³

3.4.3 *Recommendations*

We recommend that the screening programme should continue to use the existing letter templates but modifications should be considered according to the above described research work and the evidence presented in Appendix 2. Also, care should be taken to ensure that the language used in the letters is consistent with that recommended for the leaflets. All comments regarding language terms and abbreviations to be avoided or used with caution as detailed in the leaflet section of the guidance should be incorporated into all screening programme materials. Finally, it is important to make certain that result letters are not sent so that they arrive on a weekend or a Friday, when many women may have difficulty contacting their care providers for further information.³⁰

Table 4 European Communication Group guidance on breast screening invitation letter content⁵²

Invitation letter content
Purpose of screening
Who the test is for (target population – age group)
Mention the mammography test and its validity
Screening interval
Indicate whether the test is free or not
The appointment (how to make it, how to change it)
When and how to get the results (mention approximate waiting times)
Mention the possibility of being recalled for further tests
Other logistical information (eg clothing suggestions, deodorants)
Indicate where women can get further information
Data protection/confidentiality

3.5 Invitation leaflet Table 5 shows the summary of recommendations for the invitation leaflet, while Table 6 shows the outcome evidence profiles.

3.6 Recall leaflet Table 7 shows the summary of recommendations for the recall leaflet, while Table 8 gives the outcome evidence profiles.

Table 5 Invitation leaflet: summary of recommendations

Main issues		Overall assessment				Overall recommendations
Outcomes		NHSBSP leaflet	Quantitative studies	Qualitative studies	Expert opinion	
Explain what the leaflet is for						
1. Screening programme information						
1.1	Explain what a screening programme is	Included		Low	Included	Expert opinion
1.2	Mention how women are identified	Included				Current practice
1.3	Mention that the woman should communicate any change of address	Included				Current practice
1.4	Mention data confidentiality			Low	Included	Expert opinion
1.5	Mention quality control/operators' training	Included			Included	Expert opinion
2. Nature and purpose of the test						
2.1	Explain what a mammogram is	Included		Very low	Included	Expert opinion
2.2	Explain the purpose of mammography; early detection of cancer not prevention	Included	Very low	Low	Included	Expert opinion
3. Breast cancer information						
3.1	Provide the incidence of breast cancer			High	Included	Definite
3.2	Give the mortality rates of breast cancer			High	Included	Definite
3.3	State the lifetime risk of developing breast cancer	Included	Very low	High	Included	Definite
3.4	Give the 10 year risk of developing breast cancer		Very low			Suggestive
3.5	Mention the chance of developing breast cancer			High		Definite
3.6	State the lifetime risk of dying from breast cancer				Included	Expert opinion
3.7	Provide the risk of dying from breast cancer				Included	Expert opinion
3.8	Mention survival from breast cancer				Included	Expert opinion
3.9	Describe the natural history of breast cancer			Very low		Suggestive
3.10	Describe breast cancer causes/risk factors			Moderate		Definite
3.11	Mention possible effects of HRT		Very low	Low		Suggestive
3.12	Mention the role of family history in breast cancer		Very low	Moderate		Definite
3.13	Mention possible effects of menopause on mammography			Moderate		Definite
4. Validity of the test						
4.1	Mention test accuracy (mention that some cancers are difficult to see; some cannot be seen; and some may be missed)	Included	Very low	High	Included	Definite
4.2	Give the proportion of breast cancers detected by mammography (sensitivity)				Included	Expert opinion

4.3	Give the proportion of women without cancer who have a normal mammogram (specificity)	Included		Expert opinion
4.4	State the proportion of women with positive mammograms who would have breast cancer (PPV)	Included		Expert opinion
4.5	State the proportion of women with negative mammograms who would not have breast cancer (NPV)	Included		Expert opinion
4.6	Provide information on the number of women needed to screen to avoid death from breast cancer	Included	High	Definite
5. Why have the test				
5.1	State the relative risk reduction mortality	Included		Expert opinion
5.2	Provide the absolute risk reduction mortality	Included		Expert opinion
5.3	Give the risk reduction mortality (not otherwise specified)	Included	Very low	Expert opinion
6. Benefits of mammography				
6.1	Provide mammography benefits	Included	Very low	Definite
6.2	Mention the possibility of less invasive treatment	Included	Very low	Expert opinion
7. Risks of mammography				
7.1	Mention detection of ductal carcinoma in situ (DCIS)	Included	High	Definite
7.2	State the number of women diagnosed with DCIS annually	Included	High	Definite
7.3	Mention the chance of 'pseudodisease' (ie DCIS or inconsequential disease)	Included		Expert opinion
7.4	Mention radiation risks	Included	Low	Expert opinion
7.5	Provide an estimate of radiation risk	Included		Expert opinion
7.6	Mention discomfort/pain (eg how long compression lasts and possibility of persistent pain)	Included	Moderate	Definite
7.7	Explain the need for breast compression	Included	Moderate	Definite
7.8	Mention the possibility of recall	Included	Low	Expert opinion
7.9	Mention possible anxiety due to recall	Included	Moderate	Definite
7.10	Give the proportion of screened women who would be recalled	Included		Expert opinion
7.11	Mention false positive results	Included	Low	Suggestive
7.12	Provide the proportion of women with false positive results	Included		Expert opinion
7.13	Give the screening lifetime risk of false positive results	Included		Expert opinion
7.14	Mention false negative results	Included	Low	Suggestive
7.15	Give the proportion of women with false negative results	Included	Very low	Expert opinion
8. Eligible population				
8.1	Mention who the test is for	Included		Expert opinion
8.2	Explain why asymptomatic women are involved	Included		Expert opinion
8.3	Explain that women are invited on a practice by practice basis	Included	Very low	Current practice

Table 5 continued

Main issues	Overall assessment				Overall recommendations
	NHSBSP leaflet	Quantitative studies	Qualitative studies	Expert opinion	
8.4	Mention the age group (explain that women will be called for the first time between the ages of 50 and 53 years)	Included	Very low	Very low	Suggestive
8.5	Explain why women outside the age group are not invited for screening		Very low	Low	Suggestive
8.6	Provide advice for women under 50 years who want to be screened			Low	Suggestive
8.7	Provide advice for women over 70 years who want to be screened	Included		Low	Suggestive
9. Screening interval					
9.1	Mention the screening interval	Included	Very low	Very low	Expert opinion
9.2	Mention why the specified interval is used			Very low	Suggestive
9.3	Mention increasing incidence with age/risk factor	Included		Very low	Expert opinion
9.4	Mention increasing mortality with age				Expert opinion
10. Appointment information					
10.1	Explain how to change an appointment				Expert opinion
10.2	Explain where to go for the test, eg mobile unit or static screening centre	Included		High	Definite
10.3	Explain how long an appointment lasts	Included			Current practice
10.4	Provide advice about avoiding the use of talcum powder and spray deodorant before mammography	Included		Low	Suggestive
10.5	Mention if there are any documents women should bring			Low	Expert opinion
10.6	Explain that the test is free		Very low	Low	Expert opinion
10.7	Mention that a separate top is appropriate to wear instead of a dress	Included		Low	Suggestive
11. Test procedure					
11.1	Explain how test is performed (handling and positioning of breast)	Included	Very low	Moderate	Definite
11.2	Explain how long the test takes	Included		Moderate	Definite
11.3	Mention if the woman can bring someone to the appointment			High	Definite
11.4	Mention the gender of radiographers and staff	Included		Low	Expert opinion
11.5	Mention that screening staff are happy to answer questions	Included		High	Definite
11.6	Mention that screening staff may ask personal history questions	Included		High	Definite
11.7	Explain who reads the tests				Expert opinion
11.8	Explain double readings				Expert opinion

12. Test results								
12.1	Explain how to obtain the results	Included	Very low	Moderate	Included	Definite		
12.2	Mention approximate waiting time for results	Included	Very low	High	Included	Definite		
12.3	Explain the meaning of the results		Very low	Moderate	Included	Definite		
12.4	Mention benign breast abnormalities			Moderate		Definite		
12.5	Explain residual low risk not no risk of developing cancer		Very low	High	Included	Definite		
12.6	Mention when and how woman will be contacted about next appointment		Low	Low		Suggestive		
13. Further tests								
13.1	Mention further assessment	Included	Very low	Moderate	Included	Definite		
13.2	Describe further assessment		Very low		Included	Expert opinion		
14. Treatment								
14.1	Mention available treatments			Moderate	Included	Definite		
14.2	Describe available treatments				Included	Expert opinion		
14.3	Mention high quality treatment	Included				Current practice		
14.4	Mention the possibility of inclusion in a treatment trial	Included		Moderate		Definite		
14.5	Mention the likelihood of treatment being effective	Included		Very low		Suggestive		
15. Preventative information								
15.1	Mention the possibility of interval cancers	Included				Current practice		
15.2	Include <i>Five Point Breast Awareness Code</i>	Included				Current practice		
15.3	Advise women to see a doctor if breast symptoms/changes occur	Included				Current practice		
16. Further information								
16.1	Explain where the woman can get further information	Included	Very low	Low	Included	Expert opinion		
16.2	Provide a name/telephone number and provide names of organisations/books							
17. Publication information								
17.1	Evidence base for leaflet				Included	Expert opinion		
17.2	Year of publication				Included	Expert opinion		
17.3	Sender/organisation identification				Included	Expert opinion		

HRT, hormone replacement therapy; NPV, negative predictive value; PPV, positive predictive value.

Table 6 Invitation leaflet outcome evidence profiles: main issues

Assessment		Summary of findings					
Studies	Design*	Quality	Consistency across studies	Directness	Other factors†	Overall assessment	Overall recommendations
Explain what the leaflet is for							
NHSBSP leaflet						Not included	Expert opinion
Barratt ⁷⁵	Expert opinion					Included	
1. Screening programme information							
1.1 Explain what a screening programme is							
NHSBSP leaflet						Included	
Giordano ⁴⁸	Expert opinion					Included	Expert opinion
Cameron ⁸⁸	Qualitative	+	Only one study	Direct	None	Low	
1.4 Mention data confidentiality							
NHSBSP leaflet						Not included	
Giordano ⁴⁸	Expert opinion					Included	Expert opinion
Cameron ⁸⁸	Qualitative	+	Only one study	Direct	None	Low	
1.5 Mention quality control/operators' training							
NHSBSP leaflet						Included	
Kurzenhauser ⁴⁹	Expert opinion					Included	Expert opinion
Giordano ⁴⁸	Expert opinion						
2. Nature and purpose of the test							
2.1 Explain what a mammogram is							
NHSBSP leaflet						Included	
Davey ²¹	Expert opinion					Included	Expert opinion
Giordano ⁴⁸	Expert opinion						
Schechter ⁹¹	Qualitative	-	No important inconsistency	Uncertain	None	Very low	
Hamilton ²³	Qualitative	++		Direct			
2.2 Explain the purpose of mammography							
NHSBSP leaflet						Included	
Lawrence ⁸⁷	Expert opinion					Included	
Webster ⁵⁵	NCDS	++	Only one study	Direct	None	Very low	
Schechter ⁹¹	Qualitative	-	No important inconsistency	Uncertain	None	Low	
Roche ⁸⁸	Qualitative	++		Direct			Expert opinion
Cameron ⁸⁸	Qualitative	+		Direct			
Lagerlund ³²	Qualitative	++		Direct			
Silverman ⁹²	Qualitative	++		Uncertain			
Hamilton ²³	Qualitative	++		Direct			
Prinjha ²⁻⁶	Qualitative	++		Direct			

Table 6 continued

Studies	Assessment		Summary of findings				
	Design*	Quality	Consistency across studies	Directness	Other factors†	Overall assessment	Overall recommendations
3.8 Mention survival from breast cancer							
NHSBSP leaflet						Not included	
Slyator ⁵⁰	Expert opinion					Included	Expert opinion
Kurzenhauser ⁴⁹	Expert opinion						
Giordano ⁴⁸	Expert opinion						
3.9 Describe the natural history of breast cancer							
NHSBSP leaflet							
Zapka ⁹³	Qualitative	+	No important inconsistency	Uncertain	None	Very low	Suggestive
Silverman ⁹²	Qualitative	++		Uncertain			
Pfeffer ⁴⁰	Qualitative	++		Uncertain			
3.10 Describe breast cancer causes/risk factors							
NHSBSP leaflet							
Zapka ⁹³	Qualitative	+	No important inconsistency	Uncertain	None	Moderate	
Savage ⁹⁰	Qualitative	++		Uncertain			
Cameron ⁸⁸	Qualitative	+		Direct			Definite
Lagerlund ³²	Qualitative	++		Direct			
Silverman ⁹²	Qualitative	++		Uncertain			
Prinjha ²⁶	Qualitative	++		Direct			
3.11 Mention possible effects of HRT							
NHSBSP leaflet							
Webster ³⁵	NCDS	++	Only one study	Direct	None	Very low	
Cameron ⁸⁸	Qualitative	+	No important inconsistency	Direct	None	Low	Suggestive
Lagerlund ³²	Qualitative	++		Direct			
Silverman ⁹²	Qualitative	++		Uncertain			
Pfeffer ⁴⁰	Qualitative	++		Uncertain			
3.12 Mention the role of family history in breast cancer							
NHSBSP leaflet							
Webster ³⁵	NCDS	++	Only one study	Direct	None	Very low	
Zapka ⁹³	Qualitative	+	No important inconsistency	Uncertain	None	Moderate	Definite
Savage ⁹⁰	Qualitative	++		Uncertain			
Cameron ⁸⁸	Qualitative	+		Direct			
Lagerlund ³²	Qualitative	++		Direct			
Silverman ⁹²	Qualitative	++		Uncertain			
Hamilton ²³	Qualitative	++		Direct			

3.13 Mention possible effects of menopause on mammography

NHSBSP leaflet							Not included
Marshall ²⁴	Qualitative	++	No important inconsistency	Direct	None	Moderate	Definite
Silverman ⁹²	Qualitative	++		Uncertain			
Pfeffer ⁶⁰	Qualitative	++		Uncertain			

4. Validity of the test

4.1 Mention test accuracy

NHSBSP leaflet							Included
Davey ²¹	Expert opinion						Included
Webster ⁵⁵	NCDS	++	Only one study	Direct	None	Very low	Definite
Lagerlund ³²	Qualitative	++	No important inconsistency	Direct	None	High	
Silverman ⁹²	Qualitative	++		Uncertain			
Prinjha ²⁶	Qualitative	++		Direct			

4.2 Give the proportion of breast cancers detected by mammography (sensitivity)

NHSBSP leaflet							Not included
Slaytor ⁵⁰	Expert opinion						Included
Schwartz ²²	Expert opinion						Expert opinion
Kurzenhauser ⁴⁹	Expert opinion						
Giordano ⁴⁸	Expert opinion						

4.3 Give the proportion of women without cancer who have a normal mammogram (specificity)

NHSBSP leaflet							Not included
Slaytor ⁵⁰	Expert opinion						Included
Croft ⁴⁷	Expert opinion						Expert opinion
Kurzenhauser ⁴⁹	Expert opinion						

4.4 State the proportion of women with positive mammograms who would have breast cancer (PPV)

NHSBSP leaflet							Not included
Slaytor ⁵⁰	Expert opinion						Included
Croft ⁴⁷	Expert opinion						Expert opinion
Kurzenhauser ⁴⁹	Expert opinion						
Giordano ⁴⁸	Expert opinion						

4.5 State the proportion of women with negative mammograms who would not have breast cancer (NPV)

NHSBSP leaflet							Not included
Croft ⁴⁷	Expert opinion						Included
Kurzenhauser ⁴⁹	Expert opinion						Expert opinion

Table 6 continued

Studies	Assessment			Summary of findings			
	Design*	Quality	Consistency across studies	Directness	Other factors†	Overall assessment	Overall recommendations
4.6	Provide information on the number of women needed to screen to avoid death from breast cancer						
NHSBSP leaflet						Not included	
Slaytor ⁵⁰	Expert opinion					Included	Definite
Kurzenhauser ⁴⁹	Expert opinion						
Giordano ⁴⁸	Expert opinion						
Lagerlund ³²	Qualitative	++	Only one study	Direct	None	High	
5. Why have the test?							
5.1	State the relative risk reduction mortality						
NHSBSP leaflet						Not included	
Slaytor ⁵⁰	Expert opinion					Included	Expert opinion
Schwartz ²²	Expert opinion						
Kurzenhauser ⁴⁹	Expert opinion						
Giordano ⁴⁸	Expert opinion						
5.2	Provide the absolute risk reduction mortality						
NHSBSP leaflet						Included	
Slaytor ⁵⁰	Expert opinion					Included	Expert opinion
Kurzenhauser ⁴⁹	Expert opinion						
Giordano ⁴⁸	Expert opinion						
5.3	Give the risk reduction mortality (not otherwise specified)						
NHSBSP leaflet						Included	
Davey ²¹	Expert opinion					Included	Expert opinion
Nekhyudov ³³	NCDS	+	Only one study	Direct	None	Very low	

Table 6 continued

Assessment		Summary of findings					
Studies	Design*	Quality	Consistency across studies	Directness	Other factors†	Overall assessment	Overall recommendations
7.4 Mention radiation risks							
NHSBSP leaflet						Included	
Schwartz ²²	Expert opinion					Included	
Kurzenhauser ⁴⁹	Expert opinion						
Giordano ⁴⁸	Expert opinion						
Webster ⁵⁵	NCDS	++	Only one study	Direct	None	Very low	
Schechter ⁹¹	Qualitative	-	No important inconsistency	Uncertain	None	Low	
Zapka ⁹³	Qualitative	+		Uncertain			Expert opinion
Marshall ²⁴	Qualitative	++		Direct			
Savage ⁹⁰	Qualitative	++		Uncertain			
Cameron ⁸⁸	Qualitative	+		Direct			
Lagerlund ³²	Qualitative	++		Direct			
Padgett ³⁷	Qualitative	++		Direct			
Silverman ⁹²	Qualitative	++		Uncertain			
Pfeffer ⁶⁰	Qualitative	++		Uncertain			
7.5 Provide an estimate of radiation risk							
NHSBSP leaflet						Not included	Expert opinion
Giordano ⁴⁸	Expert opinion					Included	
7.6 Mention discomfort/pain							
NHSBSP leaflet						Included	
Kurzenhauser ⁴⁹	Expert opinion					Included	
Davey ²¹	Expert opinion						
Webster ⁵⁵	NCDS	++	No important inconsistency	Direct	None	Very low	
Nekhlyudov ³³	NCDS	+		Direct			
Zapka ⁹³	Qualitative	+	No important inconsistency	Uncertain	None	Moderate	Definite
Marshall ²⁴	Qualitative	++		Direct			
Cameron ⁸⁸	Qualitative	+		Direct			
Lagerlund ³²	Qualitative	++		Direct			
Silverman ⁹²	Qualitative	++		Uncertain			
Hamilton ²³	Qualitative	++		Direct			

7.7 Explain the need for breast compression

NHSBSP leaflet		Included	
Roworth ³⁴	NCDS	++	No important inconsistency
Webster ³⁵	NCDS	++	No important inconsistency
Zapka ⁹³	Qualitative	+	No important inconsistency
Cameron ⁸⁸	Qualitative	+	No important inconsistency
Lagerlund ³²	Qualitative	++	No important inconsistency
Padgett ³⁷	Qualitative	++	No important inconsistency

7.8 Mention the possibility of recall

NHSBSP leaflet		Included	
Ong ³⁰	NHSBSP standard		
Webster ³⁵	NCDS	++	Only one study
Cameron ⁸⁸	Qualitative	+	Only one study

7.9 Mention possible anxiety due to recall

NHSBSP leaflet		Included	
Austoker ¹²	NCDS	++	Only one study
Lagerlund ³²	Qualitative	++	Only one study
Silverman ⁹²	Qualitative	++	Only one study
Hamilton ²³	Qualitative	++	Only one study
Pfeffer ⁴⁰	Qualitative	++	Only one study

7.10 Give the proportion of screened women who would be recalled

NHSBSP leaflet		Included	
Slaytor ⁵⁰	Expert opinion		
Kurzenhauser ⁴⁹	Expert opinion		
Davey ²¹	Expert opinion		
Giordano ⁴⁸	Expert opinion		

7.11 Mention false positive results

NHSBSP leaflet		Included	
Nekhlyudov ³³	NCDS	+	Only one study
Cameron ⁸⁸	Qualitative	+	Only one study
Lagerlund ³²	Qualitative	++	No important inconsistency
Silverman ⁹²	Qualitative	++	No important inconsistency
Pfeffer ⁴⁰	Qualitative	++	No important inconsistency

		Expert opinion	
		None	Very low
		None	Low
		None	Suggestive

Table 6 continued

Assessment		Summary of findings					
Studies	Design*	Quality	Consistency across studies	Directness	Other factors†	Overall assessment	Overall recommendations
7.12 Provide the proportion of women with false positive results							
NHSBSP leaflet						Not included	
Slaytor ⁵⁰	Expert opinion					Included	
Croft ⁴⁷	Expert opinion						Expert opinion
Kurzenhauser ⁴⁹	Expert opinion						
Giordano ⁴⁸	Expert opinion						
Nekhlyudov ³³	NCDS	+	Only one study	Direct	None	Very low	
7.13 Give the screening lifetime risk of false positive results							
NHSBSP leaflet							
Schwartz ²²	Expert opinion					Not included	
Barratt ⁷⁵	Expert opinion					Included	Expert opinion
7.14 Mention false negative results							
NHSBSP leaflet							
Webster ³⁵	NCDS	++	No important inconsistency	Direct	None	Very low	
Nekhlyudov ³³	NCDS	+	No important inconsistency	Direct	None		Suggestive
Cameron ⁸⁸	Qualitative	+	No important inconsistency	Direct	None	Low	
Lagerlund ³²	Qualitative	++		Direct			
Silverman ⁹²	Qualitative	++		Uncertain			
7.15 Give the proportion of women with false negative results							
NHSBSP leaflet							
Croft ⁴⁷	Expert opinion					Not included	
Giordano ⁴⁸	Expert opinion					Included	Expert opinion
Nekhlyudov ³³	NCDS	+	Only one study	Direct	None	Very low	
8. Eligible population							
8.1 Mention who the test is for							
NHSBSP leaflet							
Giordano ⁴⁸	Expert opinion					Included	Expert opinion

8.2 Explain why asymptomatic women are involved						
NHSBSP leaflet						Included
Lawrence ⁸⁷	Expert opinion					Included
Giordano ⁴⁸	Expert opinion					Included
Schechter ⁹¹	Qualitative	-	No important inconsistency	Uncertain	None	Very low
Savage ⁹⁰	Qualitative	++		Uncertain		Expert opinion
Lagerlund ³²	Qualitative	++		Direct		
8.4 Mention the age group						
NHSBSP leaflet						Included
Webster ³⁵	NCDS	++	Only one study	Direct	None	Very low
Schechter ⁹¹	Qualitative	-	No important inconsistency	Uncertain	None	Very low
Cameron ⁸⁸	Qualitative	+		Direct		Suggestive
Hamilton ²³	Qualitative	++		Direct		
8.5 Explain why women outside of the age group are not invited for screening						
NHSBSP leaflet						Not included
Webster ³⁵	NCDS	++	Only one study	Direct	None	Very low
Patnick ⁸⁹	Qualitative	+	No important inconsistency	Direct	None	Low
Cameron ⁸⁸	Qualitative	+		Direct		Suggestive
Hamilton ²³	Qualitative	++		Direct		
Pfeffer ⁴⁰	Qualitative	++		Uncertain		
8.6 Provide advice for women under 50 years						
NHSBSP leaflet						Not included
Cameron ⁸⁸	Qualitative	+	Only one study	Direct	None	Low
						Suggestive
8.7 Provide advice for women over 70 years						
NHSBSP leaflet						Included
Cameron ⁸⁸	Qualitative	+	Only one study	Direct	None	Low
						Suggestive
9. Screening interval						
9.1 Mention the screening interval						Expert opinion
NHSBSP leaflet						Included
Lawrence ⁸⁷	Expert opinion					Included
Kurzenhauser ⁴⁹	Expert opinion					
Giordano ⁴⁸	Expert opinion					Expert opinion
Webster ³⁵	NCDS	++	Only one study	Direct	None	Very low
Schechter ⁹¹	Qualitative	-	No important inconsistency	Uncertain	None	Very low
Zapka ⁹³	Qualitative	+		Uncertain		

Table 6 continued

Assessment		Summary of findings					
Studies	Design*	Quality	Consistency across studies	Directness	Other factors†	Overall assessment	Overall recommendations
9.2 Mention why the specified interval is used							
NHSBSP leaflet							
	Qualitative	–	No important inconsistency	Uncertain	None	Not included	
Schechter ⁹¹	Qualitative	+		Uncertain		Very low	Suggestive
Zapka ⁹³	Qualitative	++		Direct			
Hamilton ²³	Qualitative	++		Uncertain			
Pfeffer ⁴⁰	Qualitative	++					
9.3 Mention increasing incidence with age/risk factor							
NHSBSP leaflet							
	Expert opinion					Included	
Lawrence ⁸⁷	Expert opinion					Included	
Croft ⁴⁷	Expert opinion						
Kurzenhauser ⁴⁹	Expert opinion						
	Qualitative	–	No important inconsistency	Uncertain	None	Very low	Expert opinion
Schechter ⁹¹	Qualitative	+		Uncertain			
Zapka ⁹³	Qualitative	++		Uncertain			
Savage ⁹⁰	Qualitative	++		Uncertain			
Cameron ⁸⁸	Qualitative	+		Direct			
Silverman ⁹²	Qualitative	++		Uncertain			
Pfeffer ⁴⁰	Qualitative	++		Uncertain			
9.4 Mention increasing mortality with age							
NHSBSP leaflet							
	Expert opinion					Not included	Expert opinion
Kurzenhauser ⁴⁹	Expert opinion					Included	
10. Appointment information							
10.1 Explain how to change an appointment							
NHSBSP leaflet							
	Expert opinion					Not included	Expert opinion
Giordano ⁴⁸	Expert opinion					Included	
10.2 Explain where to go for the test							
NHSBSP leaflet							
	Expert opinion					Included	
Davey ²¹	Expert opinion	++	Only one study	Direct	None	High	Definite
Lagerlund ³²	Qualitative						
10.4 Provide advice about avoiding talcum powder and spray deodorant before mammography							
NHSBSP leaflet							
	Qualitative	+	Only one study	Direct	None	Included	Suggestive
Cameron ⁸⁸	Qualitative					Low	

10.5 Mention if there are any documents women should bring						
NHSBSP leaflet						
Giordano ⁴⁸	Expert opinion					Not included
Cameron ⁸⁸	Qualitative	+	Only one study	Direct	None	Included Low
10.6 Explain that the test is free						
NHSBSP leaflet						
Davey ²¹	Expert opinion					Not included
Giordano ⁴⁸	Expert opinion					Included
Nekhlyudov ³³	NCDS	+	Only one study	Direct	None	Very low
Cameron ⁸⁸	Qualitative	+	Only one study	Direct	None	Low
10.7 Mention that a separate top is appropriate to wear instead of a dress						
NHSBSP leaflet						
Cameron ⁸⁸	Qualitative	+	No important inconsistency	Direct	None	Included Low
Hamilton ²³	Qualitative	++		Direct		Suggestive
11. Test procedure						
11.1 Explain how the test is performed (handling and positioning of breast)						
NHSBSP leaflet						
Croft ⁷	Expert opinion					Included
Kurzenhauser ⁴⁹	Expert opinion					Included
Barratt ⁷⁵	Expert opinion					
Davey ²¹	Expert opinion					
Giordano ⁴⁸	Expert opinion					
Roworth ³⁴	NCDS	++	No important inconsistencies	Direct	None	Very low
Webster ³⁵	NCDS	++		Direct		Definite
Zapka ⁹³	Qualitative	+	No important inconsistencies	Uncertain	None	Moderate
Marshall ²⁴	Qualitative	++		Direct		
Lagerlund ³²	Qualitative	++		Direct		
Silverman ⁹²	Qualitative	++		Uncertain		
Hamilton ²³	Qualitative	++		Direct		
11.2 Explain how long the test takes						
NHSBSP leaflet						
Giordano ⁴⁸	Expert opinion					Included
Marshall ²⁴	Qualitative	++	No important inconsistencies	Direct	None	Moderate
Cameron ⁸⁸	Qualitative	+		Direct		Definite
Lagerlund ³²	Qualitative	++		Direct		
Hamilton ²³	Qualitative	++		Direct		

Table 6 continued

Assessment		Summary of findings					
Studies	Design*	Quality	Consistency across studies	Directness	Other factors†	Overall assessment	Overall recommendations
11.3 Mention if the woman can bring someone to the appointment							
NHSBSP leaflet						Not included	Definite
Hamilton ²³	Qualitative	++	Only one study	Direct	None	High	
11.4 Mention the gender of radiographers and staff							
NHSBSP leaflet						Included	Expert opinion
Davey ²¹	Expert opinion					Included	
Marshall ²⁴	Qualitative	++	No important inconsistencies	Direct	None	Low	
Patrick ⁸⁹	Qualitative	+		Direct			
11.5 Mention that screening staff are happy to answer questions							
NHSBSP leaflet						Included	Definite
Lagerlund ³²	Qualitative	++	Only one study	Direct	None	High	
11.6 Mention that screening staff may ask personal history questions							
NHSBSP leaflet						Included	Definite
Hamilton ²³	Qualitative	++	Only one study	Direct	None	High	
11.7 Explain who reads the tests							
NHSBSP leaflet						Not included	Expert opinion
Giordano ⁴⁸	Expert opinion					Included	
11.8 Explain double readings							
NHSBSP leaflet						Not included	Expert opinion
Giordano ⁴⁸	Expert opinion					Included	
12. Test results							
12.1 Explain how to obtain the results							
NHSBSP leaflet						Included	
Giordano ⁴⁸	Expert opinion					Included	
Nekhlyudov ³³	NCDS	+	Only one study	Direct	None	Very low	Definite
Marshall ²⁴	Qualitative	++	No important inconsistencies	Direct	None	Moderate	
Cameron ⁸⁸	Qualitative	+		Direct			
Hamilton ²³	Qualitative	++		Direct			

12.2 Mention approximate waiting time for results

NHSBSP leaflet		Included	
Giordano ⁴⁸	Expert opinion		Included
Webster ³⁵	NCDS	++	Very low
Nekhlyudov ³³	NCDS	+	Definite
Marshall ²⁴	Qualitative	++	High
Hamilton ²³	Qualitative	++	High
12.3 Explain the meaning of the results			
NHSBSP leaflet			Not included
Davey ²¹	Expert opinion		Included
Webster ³⁵	NCDS	++	Very low
Silverman ⁹²	Qualitative	++	Moderate
12.4 Mention benign breast abnormalities			
NHSBSP leaflet			Not included
Silverman ⁹²	Qualitative	++	Moderate
12.5 Explain residual low risk not no risk of developing cancer			
NHSBSP leaflet			Not included
Lawrence ⁸⁷	Expert opinion		Included
Webster ³⁵	NCDS	++	Very low
Lagerlund ³²	Qualitative	++	High
12.6 Mention when and how woman will be contacted about next appointment			
NHSBSP leaflet			Not included
Cameron ⁸⁸	Qualitative	+	Low
13. Further tests			
13.1 Mention further assessment			
NHSBSP leaflet			Included
Kurzenhauser ⁴⁹	Expert opinion		Included
Davey ²¹	Expert opinion		
Giordano ⁴⁸	Expert opinion		
Austoker ¹²	NCDS	++	Very low
Webster ³⁵	NCDS	++	Definite
Nekhlyudov ³³	NCDS	+	Definite
Marshall ²⁴	Qualitative	++	Moderate
Silverman ⁹²	Qualitative	++	Moderate
			Suggestive

Table 6 continued

Studies	Assessment			Summary of findings			
	Design*	Quality	Consistency across studies	Directness	Other factors†	Overall assessment	Overall recommendations
13.2 Describe further assessment NHSBSP leaflet						Not included	
Barratt ⁷⁵ Giordano ⁴⁸	Expert opinion Expert opinion					Included	Expert opinion
Nekhlyudov ³³	NCDS	+	Only one study	Direct	None	Very low	
14. Treatment							
14.1 Mention available treatments NHSBSP leaflet						Not included	
Lawrence ⁸⁷ Davey ²¹	Expert opinion Expert opinion					Included	Definite
Marshall ²⁴ Pfeffer ⁴⁰	Qualitative Qualitative	++ ++	No important inconsistencies	Direct Uncertain	None	Moderate	
14.2 Describe available treatments NHSBSP leaflet						Not included	Expert opinion
Barratt ⁷⁵	Expert opinion					Included	
14.4 Mention the possibility of inclusion in a treatment trial NHSBSP leaflet						Included	
Pfeffer ⁴⁰	Qualitative	++	Only one study	Uncertain	None	Moderate	Definite
14.5 Mention the likelihood of treatment being effective NHSBSP leaflet						Included	
Schechter ⁹¹ Savage ⁹⁰ Silverman ⁹²	Qualitative Qualitative Qualitative	- ++ ++	No important inconsistencies	Uncertain Uncertain Uncertain	None	Very low	Suggestive

16. Further information						
16.1	Explain where the woman can get further information					Included
NHSBSP leaflet						
Kurzenhauser ⁴⁹		Expert opinion				Included
Webster ³⁵	NCDS	++	Only one study	Direct	None	Very low
Cameron ⁸⁸	Qualitative	+	No important inconsistencies	Direct	None	Low
Hamilton ²³	Qualitative	++		Direct		
17. Publication information						
17.1	Evidence base for leaflet					Not included
NHSBSP leaflet						
Kurzenhauser ⁴⁹		Expert opinion				Included
Barratt ⁷⁵		Expert opinion				Expert opinion
17.2	Year of publication					Not included
NHSBSP leaflet						
Kurzenhauser ⁴⁹		Expert opinion				Included
17.3	Sender/organisation identification					Expert opinion
NHSBSP leaflet						
Giordano ⁴⁸		Expert opinion				Not included
						Included
						Expert opinion

*NCDS, non-comparative descriptive study.

†Imprecise or sparse data, strong or very strong association, high risk of reporting bias, evidence of dose-response gradient, effect of plausible residual confounding, close conformity of findings based on direct evidence.

HRT, hormone replacement therapy; NPV, negative predictive value; PPV, positive predictive value.

Table 7 Recall leaflet: summary of recommendations

Main issues	Overall assessment				Overall recommendations
	Overall assessment		Overall assessment		
	Quantitative studies	Qualitative studies	Quantitative studies	Qualitative studies	
1. Meaning of the result					
1.1 Give a clear reason for recall; exclude 'for a variety of reasons tests have to be repeated'	Very low	High			Screening standard
1.2 Mention technical errors		High			Definite
1.3 Include 'being recalled is part of routine (or second stage) screening'					Screening standard
1.4 Include 'most women recalled are found to have normal breasts'		Low			Screening standard*
1.5 Include 'a substantial number of women are recalled'		Low			Screening standard
1.6 Provide proportion of screened women who would be recalled		High			Suggestive
1.7 Mention future risk of developing breast cancer – is it higher if you are recalled or found to have a benign condition?					Definite
1.8 List benign conditions that may be seen on mammograms	Very low	Moderate			Definite
Difficult terminology includes 'benign', 'calcium spots', 'calcium deposits', 'calcifications' and 'cysts'					
1.9 Mention false positives		High			Definite
1.10 Mention false negatives		High			Definite
1.11 Avoid saying 'not to worry', 'not to be alarmed'		High			Screening standard
1.12 Avoid saying 'x-rays have been unclear'	Very low	High			Screening standard
1.13 Avoid the words 'something wrong', 'cancer', 'treatment' or 'abnormality'		High			Screening standard
1.14 Avoid using the term 'hospital' use 'centre, unit, clinic'					Screening standard
1.15 Avoid 'nurse counsellor' use 'breast care nurse'					Screening standard
2. Appointment information					
2.1 Explain how to get to the assessment centre	Very low				Screening standard*
2.2 Mention who may accompany the woman to the appointment					Screening standard
2.3 Explain how to change the appointment					Screening standard
2.4 Mention how long the appointment will take		Low			Screening standard*
2.5 Mention who the woman will see at the assessment centre	Very low				Screening standard
2.6 Mention that screening staff are happy to answer questions		Low			Suggestive

3. Test procedure					
3.1 Describe what tests will be carried out					Screening standard
3.2 Do not provide a detailed description of fine needle aspiration, instead indicate that a 'sample will be taken'	Very low	Moderate			Screening standard
3.3 Use the term 'biopsy' with caution		Low			Suggestive
4. Test result					
4.1 Say how and when the results will be available	Very Low	High			Screening standard
5. Follow up					
5.1 Mention that follow up may be necessary	Very Low	High			Definite
6. Further information					
6.1 Explain how to get further information		High			Screening standard
7. Other information					
7.1 Do not send letter to be received on Saturday					Screening standard
7.2 Minimise waiting time for appointment					Screening standard

*Recommendation retained as 'Screening standard' following review of the references in the original report.³⁰

1.11 Avoid saying 'not to worry', 'not to be alarmed'						
NHSBSP						Screening standard
Zapka ³⁸	NCDS	-	Only one study	Direct	None	Very low
Padgett ³⁷	Qualitative	++	Only one study	Direct	None	High
1.12 Avoid saying 'x-rays have been unclear'						
NHSBSP						Screening standard
Ong ³⁶	Qualitative	++	Only one study	Direct	None	High
1.13 Avoid the words 'something wrong', 'cancer', 'treatment', or 'abnormality'						
NHSBSP						Screening standard
Padgett ³⁷	Qualitative	++	Only one study	Direct	None	High
2. Appointment information						
2.1 Explain how to get to the assessment centre						
NHSBSP						Screening standard
Smith ¹⁶	CRCT	-	Only one study	Direct	None	Very low
2.4 Mention how long the appointment will take						
NHSBSP						Screening standard
Smith ¹⁶	CRCT	-	Only one study	Direct	None	Very low
Cameron ⁸⁸	Qualitative	+	Only one study	Direct	None	Low
2.6 Mention that screening staff are happy to answer questions						
NHSBSP						Screening standard
Cameron ⁸⁸	Qualitative	+	No important inconsistency	Direct	None	Low
Padgett ³⁷	Qualitative	++		Direct		Suggestive
3. Test procedure						
3.1 Describe what tests will be carried out						
NHSBSP						Screening standard
Smith ¹⁶	CRCT	-	No important inconsistency	Direct	None	Very low
Zapka ³⁸	NCDS	-		Direct		
Ong ³⁶	Qualitative	++	No important inconsistency	Direct	None	Moderate
Cameron ⁸⁸	Qualitative	+		Direct		
Padgett ³⁷	Qualitative	++		Direct		
3.3 Use the term 'biopsy' with caution						
NHSBSP						Screening standard
Cameron ⁸⁸	Qualitative	+	No important inconsistency	Direct	None	Low
Padgett ³⁷	Qualitative	++		Direct		Suggestive

Table 8 continued

Studies	Assessment			Summary of findings			
	Design*	Quality	Consistency across studies	Directness	Other factors†	Overall assessment	Overall recommendations
4. Test result							
4.1 Say how and when the results will be available							
NHSBSP							
Zapka ³⁸	NCDS	-	Only one study	Direct	None	Very low	Screening standard
Ong ³⁶	Qualitative	++	No important inconsistency	Direct	None	High	
Padgett ³⁷	Qualitative	++		Direct			
5. Follow up							
5.1 Mention that follow up may be necessary							
NHSBSP							
Zapka ³⁸	NCDS	-	Only one study	Direct	None	Very low	Definite
Padgett ³⁷	Qualitative	++	Only one study	Direct	None	High	
6. Further information							
6.1 Explain how to get further information							
NHSBSP							
Ong ³⁶	Qualitative	++	Only one study	Direct	None	High	Screening standard

*CRCT, clustered randomised trial; NCDS, non-comparative descriptive study.

†Imprecise or sparse data, strong or very strong association, high risk of reporting bias, evidence of dose-response gradient, effect of plausible residual confounding, close conformity of findings based on direct evidence.

‡Recommendation retained as 'Screening standard' following review of the references in the original report.³⁰

4. DISCUSSION

These recommendations bring together the research evidence regarding women's information needs and the content of written information materials provided to women about breast screening at all stages of the screening process. A range of research evidence was examined during the course of the review. The main research questions were best answered by both quantitative and qualitative study findings. After assessing various guideline standards, it was decided that the GRADE system offered the most sensible and adaptable method for both types of research.⁸⁵ Integrating quantitative and qualitative research into the same guideline presented a significant methodological challenge and little has been published in the literature that addresses this problem from a practical point of view. The quantitative evidence included in the review received quite low overall evidence ratings. This may generally be explained by the study designs used (ie non-comparative descriptive studies), which are rated lower in the GRADE evidence hierarchy as opposed to methodological issues such as selection bias or unreliable outcome assessment. The lack of randomised trials in this field may result from ethical concerns.

Two separate recommendation systems were developed for the invitation and recall materials respectively. This was necessary as evidence-based guidelines existed for the recall letters and leaflets.³⁰ However, no guidance had previously been published addressing the content of the NHSBSP invitation materials. Also, a number of expert opinion reports were identified in the breast screening literature that set out essential or ideal topics to be covered in written screening invitation information but that gave little indication as to the source of the supporting evidence. It was decided that for the invitation leaflet outcome evidence profiles, the expert reports should be noted in a separate category distinct from the quantitative and qualitative studies. The presentation of both the expert opinion and the available research evidence provides a more complete picture of the existing evidence base. Outcomes assigned a 'Definite' or 'Screening standard' recommendation should be included in the invitation and recall leaflets. Outcomes designated as 'Expert opinion' may be incorporated into the invitation materials – in particular, those already covered in the NHSBSP leaflet. Other 'Expert opinion' items should be treated with caution as there is insufficient evidence in favour of the inclusion of these items to warrant a 'Definite' recommendation. It is clear that further research is required to determine whether a number of the information outcomes considered in this review would be helpful for women making breast screening decisions.

Studies that looked at the information requirements of specific groups (such as individuals with disabilities, younger women and individuals from particular cultural or linguistic backgrounds) were excluded because the mandate of the review was to produce guidelines for the development of English language templates for the general screening population. Information materials for women from different communities should be developed separately for each target group using these recommendations as a base on which to build. Studies that described interventions designed

to increase screening uptake were not included in the main body of the review unless the content of the participant information materials used was evaluated and/or included with the study report. Research that provided evidence of knowledge, attitudes, health beliefs or barriers towards breast screening was excluded from the review process unless women's information needs were discussed or written information materials were described. Studies reporting tailored information interventions without a non-tailored comparison group were excluded from the review because it is not practical for a national screening programme to specifically adapt information materials for each woman screened. The graphical design of the leaflets and letters has not been considered in this report as we expect that the guideline recommendations will be incorporated into current screening programme materials using existing, established designs.

The clear communication of risk information to women participating in the screening programme is a continuing challenge. It has been suggested that such information should be simple, balanced and relevant.^{61,67} A number of studies have indicated that mammography uptake is not improved when additional educational information is provided.^{68–72} None of the grey literature that was obtained during the course of the review provided further evidence to support the inclusion of statistical descriptions. It is proposed that this issue should be explored further in a series of focus groups with women at various stages of the breast screening process.

Many women attending for routine screening expect to receive confirmation that they are healthy – a screening test may even be viewed as a form of 'insurance policy' against cancer.^{92,96,97} Women have been found to consistently overestimate their risks of developing and dying from breast cancer, and consequently the benefits they might expect from mammography.^{21,22,45,92,98–100} The ongoing debate about how to assess the impact of breast screening may enhance rather than clarify public uncertainty.^{21,27,101} Women also poorly understand that cancer is often asymptomatic and that a lack of family history of cancer does not greatly reduce susceptibility.^{23,32,90,91,93} Age is rarely recognised as a risk factor for breast cancer.^{90,91,93} Different groups of women have been caught unawares by the mammography procedure – they have shown surprise and concern about having to lift their breasts onto a machine and having their breasts positioned by screening staff^{23,34} as well as the compression process.^{32,34,88,93} Women with mobility issues may not be aware that they may have difficulty positioning themselves during mammography.²³ Few women actually consider what an abnormal result might mean for them personally until the moment that such a result is received.^{12,37} Fear of cancer and depressed mood are significant issues for women with abnormal results.¹⁰ Distress may be increased when a clear reason for recall is not provided^{36–38} and the meaning of benign conditions is not explained in detail.^{36,38} Women are also concerned about treatment for breast cancer and fearful of mastectomy.⁴⁰ It has been suggested that the literature about breast screening for women is incomplete,^{21,47–50,52} and that the information currently available may not fully address these issues.^{48–50,52}

Consistent terminology should be used in all screening materials, and unnecessary technical terms and abbreviations should be avoided. Statements that intend to reassure, such as ‘not to be alarmed’ or ‘not to worry’, should not be included because they do not match the woman’s perception that ‘something’ has been discovered by the breast screening test.^{30,37,38} General non-specific statements about screening results (‘x-rays are unclear’ or ‘something wrong’) are not helpful and should also be avoided. Terms related to benign conditions and DCIS such as ‘cysts’, ‘calcium spots’ and ‘calcifications’ were problematic for women and should be carefully described.^{36,38,88} When explaining what is felt during the mammogram, some women suggested that the term ‘discomfort’ should be used instead of ‘pain’ because it was less threatening.²⁴

Increasing importance is being placed on attaining informed choice in screening.^{27,43,45,101} As such, it is vital that women understand both what screening aims to do and the limitations of breast screening.

There is a lack of research evidence that specifically addresses questions related to the content of the breast screening letters. We therefore recommend that the screening programme should continue to use the existing letter templates. However, consideration could be given to the points raised in section 3.4 and Appendix 2.

We recommend that the NHSBSP should endeavour to produce leaflets that incorporate the concepts presented in the full summary recommendation tables in a clear and accurate manner so that women can make suitable decisions about whether or not to attend and to ensure that women receive appropriate information at each step of the screening process. At present, only an invitation leaflet is routinely provided to women taking part in the programme (a more detailed Cancerbackup booklet is available only on request).¹⁰² A nationally available recall leaflet (including information about DCIS) should be produced and distributed. Examples of items that might be included in the invitation and recall leaflets are given below.

4.1 Invitation leaflet

- Screening programme information
- Nature and purpose of the test
- Breast cancer information
- Validity of the test (include information on false positive and false negative results)
- Benefits and risks of mammography
- Eligible population and screening interval
- Test procedure
- Test results (explain the meaning of the results)
- Further tests
- Treatment
- Preventative information

The possible reasons for further tests and treatment should be described in the invitation leaflet. However, detailed information about further investigation and subsequent treatment should not be provided until later in the screening process. The amount of information provided about further tests and investigation, the effectiveness of treatment and follow up should increase as a woman progresses from abnormal result to further assessment and treatment.

4.2 Recall leaflet

- Meaning of an abnormal result (provide a clear reason for recall; include information on false positive and false negative results)
- Abnormal result outcomes (ie women are unlikely to have cancer)
- Provide appointment information
- Further tests and investigation (explain what further assessment involves)
- Follow up
- Further information

REFERENCES

1. *CancerStats: Breast Cancer*. London: Cancer Research UK Cancer Information Resource Centre, 2006.
2. Bankhead C, Austoker J. Breast Screening – UK. In: Toms JR, ed. *CancerStats Monograph 2004*. London: Cancer Research UK, 2004: 33–38.
3. UK National Screening Committee [homepage on the Internet]. UKNSC (accessed March 2006). What is Screening? Available from: <http://www.nsc.nhs.uk>
4. Bankhead CR, Brett J, Bukach C, et al. The impact of screening on future health-promoting behaviours and health beliefs: A systematic review. *Health Technology Assessment*, 2003, 7(42): 1–88.
5. *Breast Screening Programme, England: 2004–05*. London: NHS Health and Social Care Information Centre, Community Health Statistics, 2006: Statistical Bulletin 2006/02/HSCIC.
6. NHS Breast Screening Programme [homepage on the Internet]. NHS Cancer Screening Programmes (accessed March 2006). Available from: <http://www.cancerscreening.nhs.uk/breastscreen/index.html>
7. Burstein HJ, Polyak K, Wong JS, et al. Ductal carcinoma in situ of the breast. *New England Journal of Medicine*, 2004, 350(14): 1430–1441.
8. Vainio H, Bianchini F, eds. *Breast Cancer Screening*. Lyon: IARC Press, 2002, Vol. 7.
9. Patnick J, ed. *One Vision: NHS Breast Screening Programme Annual Review 2005*. Sheffield, UK: NHS Cancer Screening Programmes, 2005.
10. Brett J, Bankhead C, Henderson B, et al. The psychological impact of mammographic screening. A systematic review. *Psychooncology* 2005, 14(11): 917–938.
11. Bluman LG, Borstelmann NA, Rimer BK, et al. Knowledge, satisfaction, and perceived cancer risk among women diagnosed with ductal carcinoma in situ. *Journal of Women's Health and Gender Based Medicine*, 2001, 10(6): 589–598.
12. Austoker J, Ong G. Written information needs of women who are recalled for further investigation of breast screening: results of a multicentre study. *Journal of Medical Screening*, 1994, 1(4): 238–244.
13. Jepson R, Clegg A, Forbes C, et al. The determinants of screening uptake and interventions for increasing uptake: a systematic review. *Health Technology Assessment*, 2000, 4(14): 1–133.
14. Lerman C, Ross E, Boyce A, et al. The impact of mailing psychoeducational materials to women with abnormal mammograms. *American Journal of Public Health*, 1992, 82(5): 729–730.
15. Kendall C, Hailey BJ. The relative effectiveness of three reminder letters on making and keeping mammogram appointments. *Journal of Behavioral Medicine*, 1993, 19(1): 29–34.
16. Smith S, Botha JL, Goosey R, et al. Audit of user satisfaction with the Leicestershire Breast Screening Service; women attending for assessment of abnormal mammograms. *Journal of Public Health Medicine*, 1991, 13(3): 166–171.
17. Decker KM, Harrison M. Evaluating information for women referred for breast screening abnormalities. *Journal of Cancer Education*, 2002, 17(1): 28–32.
18. Street RLJ, Van Order A, Bramson R, et al. Preconsultation education promoting breast cancer screening: does the choice of media make a difference? *Journal of Cancer Education*, 1998, 13(3): 152–161.

19. Madden S, Johnston M, Parbhoo S. Evaluation of women's worries and the effects of a preparatory booklet for patients attending a breast clinic. *Breast*, 1994, 3(3): 169–172.
20. Davey HM, Barratt AL, Davey E, et al. Medical tests: women's reported and preferred decision-making roles and preferences for information on benefits, side-effects and false results. *Health Expectations*, 2002, 5(4): 330–340.
21. Davey C, White V, Gattellari M, et al. Reconciling population benefits and women's individual autonomy in mammographic screening: in-depth interviews to explore women's views about 'informed choice'. *Australian and New Zealand Journal of Public Health*, 2005, 29(1): 69–77.
22. Schwartz LM, Woloshin S, Sox HC, et al. US women's attitudes to false positive mammography results and detection of ductal carcinoma in situ: cross sectional survey. *British Medical Journal*, 2000, 320(7250): 1635–1640.
23. Hamilton EL, Wallis MG, Barlow J, et al. Women's views of a breast screening service. *Health Care for Women International*, 2003, 24(1): 40–48.
24. Marshall AA, Smith SW, McKeon JK. Persuading low-income women to engage in mammography screening: source, message, and channel preferences. *Journal of Health Communication*, 1995, 7(4): 283–299.
25. De Morgan S, Redman S, White KJ, et al. 'Well, have I got cancer or haven't I?' The psycho-social issues for women diagnosed with ductal carcinoma in situ. *Health Expectations*, 2002, 5(4): 310–318.
26. Prinjha S, Evans J, McPherson A. Women's information needs about ductal carcinoma in situ before mammographic screening and after diagnosis: a qualitative study. *Journal of Medical Screening*, 2006, 13(3): 110–114.
27. Thornton H, Edwards A, Baum M. Women need better information about routine mammography. *British Medical Journal*, 2003, 327(7406): 101–103.
28. Goyder E, Barratt A, Irwig LM. Telling people about screening programmes and screening test results: how can we do it better? *Journal of Medical Screening*, 2000, 7(3): 123–126.
29. Gigerenzer G. *Reckoning with Risk: Learning to Live with Uncertainty*. London: Penguin Books Ltd, 2002.
30. Ong G, Austoker J, Brouwer A. *Guidelines on Improving the Quality of the Written Information Sent to Women who are Recalled for Assessment*. NHS Breast Screening Programme, 1998 (NHSBSP Publication No 38).
31. Entwistle VA, Sheldon TA, Sowden AJ, et al. Supporting consumer involvement in decision making: what constitutes quality in consumer health information? *International Journal for Quality in Health Care*, 1996, 8(5): 425–437.
32. Lagerlund M, Widmark C, Lambe M, et al. Rationales for attending or not attending mammography screening – a focus group study among women in Sweden. *European Journal for Cancer Prevention*, 2001, 10(5): 429–442.
33. Nekhlyudov L, Li R, Fletcher SW. Information and involvement preferences of women in their 40s before their first screening mammogram. *Archives of Internal Medicine*, 2005, 165(12): 1370–1374.
34. Roworth MA, McIlwaine GM, Wallace AM. Women's views of the Scottish Breast Screening Programme: a national consumer opinion survey. *Public Health*, 1993, 107(3): 185–192.
35. Webster PN. *Information Needs and Informed Choice: Investigating the Information Requirements of Women Who are Invited to Attend Breast Screening to Enable Them to Make an Informed Choice About Participation* [dissertation]. University of Oxford, 2003.

36. Ong G, Austoker J. Recalling women for further investigation of breast screening: women's experiences at the clinic and afterwards. *Journal of Public Health Medicine*, 1997, 19(1): 29–36.
37. Padgett DK, Yedidia MJ, Kerner J, et al. The emotional consequences of false positive mammography: African-American women's reactions in their own words. *Women and Health*, 2001, 33(3–4): 1–14.
38. Zapka JG, Puleo E, Taplin SH, et al. Processes of care in cervical and breast cancer screening and follow-up: the importance of communication. *Preventive Medicine*, 2004, 39(1): 81–90.
39. Brown M, Koch T, Webb C. Information needs of women with non-invasive breast cancer. *Journal of Clinical Nursing*, 2000, 9(5): 713–722.
40. Pfeffer N. 'If you think you've got a lump, they'll screen you.' Informed consent, health promotion, and breast cancer. *Journal of Medical Ethics*, 2004, 30(2): 227–230.
41. Dixon-Woods M, Baum M, Kurinczuk JJ. Screening for breast cancer with mammography. *Lancet*, 2001, 358(9299): 2166–2167.
42. Raffle AE. Information about screening – is it to achieve high uptake or to ensure informed choice? *Health Expectations*, 2001, 4(2): 92–98.
43. Austoker J. Gaining informed consent for screening. It's difficult – but many misconceptions need to be undone. *British Medical Journal*, 1999, 319(7212): 722–723.
44. Hann A. 'Controversy'. Propaganda versus evidence based health promotion: the case of breast screening. *International Journal of Health Planning and Management*, 1999, 14(4): 329–334.
45. Ward J. Population-based mammographic screening: does 'informed choice' require any less than full disclosure to individuals of benefits, harms, limitations and consequences? *Australian and New Zealand Journal of Public Health*, 1999, 23(3): 301–304.
46. Jorgensen KJ, Gotzsche PC. Content of invitations for publicly funded screening mammography. *British Medical Journal*, 2006, 332(7540): 538–541.
47. Croft E, Barratt A, Butow P. Information about tests for breast cancer: what are we telling people? *Journal of Family Practice*, 2002, 51(10): 858–860.
48. Giordano L, Rowinski M, Gaudenzi G, et al. What information do breast cancer screening programmes provide to Italian women? *European Journal of Public Health*, 2005, 15(1): 66–69.
49. Kurzenhauser S. Welche Informationen vermitteln deutsche Gesundheitsbroschüren über die Screening-Mammographie? [What kind of information do German health information pamphlets provide on mammography screening?]. *Zeitschrift für ärztliche Fortbildung und Qualitätssicherung*, 2003, 97(1): 53–57.
50. Slaytor EK, Ward JE. How risks of breast cancer and benefits of screening are communicated to women: analysis of 58 pamphlets. *British Medical Journal*, 1998, 317(7153): 263–264.
51. Ong G, Austoker J, Brouwer A. Evaluation of the written information sent to women who are called back for further investigation of breast screening in the UK. *Health Education Journal*, 1996, 55(4): 413–429.
52. Giordano L, Webster P, Segnan N, et al. Guidance on breast screening communication. In: Perry N, Broeders M, de Wolf C, et al., eds. *European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis*, 4th edn. Luxembourg: European Communities, 2006: 379–394.
53. Department of Health. *The NHS Cancer Plan: A Plan for Investment, A Plan for Reform*. London: Department of Health, 2000: 1–97.

54. Department of Health. *Choosing Health: Making Healthy Choices Easier*. London: Department of Health, 2004: 1–207.
55. Department of Health. *Our Health, Our Care, Our Say: A New Direction for Community Services*. London: Department of Health, 2006: 1–236.
56. Patnick J, ed. *Informing Choice in Breast Screening: NHS Breast Screening Programme Annual Review 2001*. Sheffield, UK: NHS Cancer Screening Programmes, 2001.
57. Advisory Committee on Breast Cancer Screening. *Screening for Breast Cancer in England: Past and Future*. NHS Cancer Screening Programmes, 2006 (NHSBSP publication No 61).
58. Roche RA, Stovall CE, Suarez L, et al. Language differences in interpretation of breast cancer health messages. *Journal of Cancer Education*, 1998, 13(4): 226–230.
59. Schapira MM, Nattinger AB, McHorney CA. Frequency or probability? A qualitative study of risk communication formats used in health care. *Medical Decision Making*, 2001, 21(6): 459–467.
60. Schwartz LM, Woloshin S, Welch HG. Risk communication in clinical practice: putting cancer in context. *Journal of the National Cancer Institute Monographs*, 1999, 25: 124–133.
61. Edwards A, Elwyn G, Mulley A. Explaining risks: turning numerical data into meaningful pictures. *British Medical Journal*, 2002, 324(7341): 827–830.
62. O'Connor AM, Llewellyn-Thomas H, Stacey D, eds. *International Patient Decision Aid Standards (IPDAS) Collaboration Background Document*. IPDAS, 2005: 1–54.
63. Paling J. Strategies to help patients understand risks. *British Medical Journal*, 2003, 327(7417): 745–748.
64. Schwartz LM, Woloshin S, Black WC, et al. The role of numeracy in understanding the benefit of screening mammography. *Annals of Internal Medicine*, 1997, 127: 966–972.
65. Fischhoff B. Why (cancer) risk communication can be hard. *Journal of the National Cancer Institute Monographs*, 1999, 25: 7–13.
66. Marshall T, Adab P. Informed consent for breast screening: what should we tell women? *Journal of Medical Screening*, 2003, 10(1): 22–26.
67. Edwards A, Unigwe S, Elwyn G, et al. Effects of communicating individual risks in screening programmes: Cochrane systematic review. *British Medical Journal*, 2003, 327(7417): 703–709.
68. Rakowski W, Ehrich B, Goldstein MG, et al. Increasing mammography among women aged 40–74 by use of a stage-matched, tailored intervention. *Preventive Medicine*, 1998, 27(5, part 1): 748–756.
69. Segnan N, Senore C, Giordano L, et al. Promoting participation in a population screening program for breast and cervical cancer: a randomized trial of different invitation strategies. *Tumori*, 1998, 84(3): 348–353.
70. Clark MA, Rakowski W, Ehrich B, et al. The effect of a stage-matched and tailored intervention on repeat mammography. *American Journal of Preventive Medicine*, 2002, 22(1): 1–7.
71. Seow A, Straughan PT, Ng EH, et al. A randomized trial of the use of print material and personal contact to improve mammography uptake among screening non-attenders in Singapore. *Annals of the Academy of Medicine Singapore*, 1998, 27(6): 838–842.
72. Barr JK, Franks AL, Lee NC, et al. A randomized intervention to improve ongoing participation in mammography. *American Journal of Managing Care*, 2001, 7(9): 887–894.

73. Nekhlyudov L, Partridge A. Breast cancer risk communication: challenges and future research directions: workshop report (United States). *Cancer Causes and Control*, 2003, 14(3): 235–239.
74. Gigerenzer G, Edwards A. Simple tools for understanding risks: from innumeracy to insight. *British Medical Journal*, 2003, 327(7417): 741–744.
75. Barratt A, Trevena L, Davey HM, et al. Use of decision aids to support informed choices about screening. *British Medical Journal*, 2004, 329(7464): 507–510.
76. Khan KS, ter Riet G, Glanville J, et al., eds. *Undertaking Systematic Reviews of Research on Effectiveness: CRD's Guidance for those Carrying Out or Commissioning Reviews*, 2nd edn. York: York Publishing Services Ltd, NHS Centre for Reviews and Dissemination, University of York, 2001: No. 4.
77. Guyatt GH, Sackett DL, Cook DJ. Users' guides to the medical literature. II. How to use an article about therapy or prevention. A. Are the results of the study valid? Evidence-Based Medicine Working Group. *Journal of the American Medical Association*, 1993, 270(21): 2598–2601.
78. Oxman AD, Sackett DL, Guyatt GH. Users' guides to the medical literature. I. How to get started. The Evidence-Based Medicine Working Group. *Journal of the American Medical Association*, 1993, 270(17): 2093–2095.
79. The Cochrane Non-Randomised Studies Methods Group [homepage on the Internet]. NRSMSG, 2000 (updated Sep 2001; accessed Mar 2006) *Draft Chapters for the Guidelines on Non-randomised Studies in Cochrane Reviews*. Available from: <http://www.cochrane.dk/nrsmsg/guidelines.htm>
80. West S, King V, Carey TS, et al. *Systems to Rate the Strength of Scientific Evidence*. Rockville, MD: Agency for Healthcare Research and Quality, 2002: No. 47, Publication No. 02-E016.
81. Scottish Intercollegiate Guidelines Network [homepage on the Internet]. Edinburgh: SIGN, 2001–2005 (updated May 2004; accessed Dec 2005) *SIGN 50: A Guideline Developers' Handbook*. Available from: <http://www.sign.ac.uk/guidelines/fulltext/50/index.html>
82. Critical Appraisal Skills Programme (CASP) and Evidence-based Practice [homepage on the Internet]. Oxford: Public Health Resource Unit, Milton Keynes Primary Care NHS Trust, 2005 (updated Dec 2005; accessed Dec 2005) *Critical Appraisal Skills Programme: Making Sense of Evidence – CASP Appraisal Tools*. Available from: http://www.phru.nhs.uk/casp/critical_appraisal_tools.htm
83. Lethaby A, Wells S, Furness S, et al. *Handbook for the Preparation of Explicit Evidence-based Clinical Practice Guidelines*. Farquhar C, ed. Auckland, NZ: New Zealand Guidelines Group, Effective Practice Institute of the University of Auckland, 2001.
84. Spencer L, Ritchie J, Lewis J, et al. *Quality in Qualitative Evaluation: A Framework for Assessing Research Evidence*, 2nd edn. London: Government Chief Social Researcher's Office, 2004.
85. Atkins D, Best D, Briss PA, et al. Grading quality of evidence and strength of recommendations. *British Medical Journal*, 2004, 328(7454): 1490. doi: 10.1136/bmj.328.7454.1490 [published Online First: 19 Jun 2004].
86. Glasziou P. [personal communication]. Jan 2005.
87. Lawrence VA, Streiner D, Hazuda HP, et al. A cross-cultural consumer-based decision aid for screening mammography. *Preventive Medicine*, 2000, 30(3): 200–208.
88. Cameron J. *Evaluation of BreastScreen Aotearoa Print Resources*. New Zealand: Folio Communication Ltd, 2000: 1–69.
89. Patnick J, Austoker J, Wolff T. Revision of 'NHS breast screening: the facts': an evaluation. *Journal of Medical Screening*, 1995, 2(1): 15–17.

90. Savage SA, Clarke VA. Older women's illness representations of cancer: A qualitative study. *Health Education Research*, 1998, 13(4): 529–544.
91. Schechter C, Vanchieri CF, Crofton C. Evaluating women's attitudes and perceptions in developing mammography promotion messages. *Public Health Reports*, 1990, 105(3): 253–257.
92. Silverman E, Woloshin S, Schwartz LM, et al. Women's views on breast cancer risk and screening mammography: a qualitative interview study. *Medical Decision Making*, 2001, 21(3): 231–240.
93. Zapka JG, Berkowitz E. A qualitative study about breast cancer screening in older women: Implications for research. *Journal of Gerontology*, 1992, 47 (Spec No): 93–100.
94. Sin JP, St Leger AS. Interventions to increase breast screening uptake: do they make any difference? *Journal of Medical Screening*, 1999, 6(4): 170–181.
95. Bonfill X, Marzo M, Pladevall M, et al. Strategies for increasing women participation in community breast cancer screening. *Cochrane Database of Systematic Reviews Online Update Software* 2001, 1: CD002943.
96. Goldsmith MR, Bankhead C, Austoker J. *Improving the Quality of the Written Information Sent to Women About Cervical Screening: Evidence-based Criteria for the Content of Letters and Leaflets*. Sheffield, UK: NHS Cervical Screening Programme, Cancer Research UK (NHSCSP Publication No 26).
97. Denberg TD, Wong S, Beattie A. Women's misconceptions about cancer screening: implications for informed decision-making. *Patient Education and Counselling*, 2005, 57(3): 280–285.
98. Domenighetti G, D'Avanzo B, Egger M, et al. Women's perception of the benefits of mammography screening: population-based survey in four countries. *International Journal of Epidemiology*, 2003, 32(5): 816–821.
99. McMenamin M, Barry H, Lennon AM, et al. A survey of breast cancer awareness and knowledge in a Western population: lots of light but little illumination. *European Journal of Cancer*, 2005, 41(3): 393–397.
100. Black WC, Nease RFJ, Tosteson AN. Perceptions of breast cancer risk and screening effectiveness in women younger than 50 years of age. *Journal of the National Cancer Institute*, 1995, 87(10): 720–731.
101. Baines CJ. Are there downsides to mammography screening? *Breast Journal*, 2005, 11 (Suppl 1): S7–S10.
102. Robertshaw K, Coats D. *Understanding Breast Screening* [booklet]. UK: CancerBACUP 2004.

APPENDIX 1: DCIS INFORMATION

Ductal carcinoma in situ (DCIS) is a non-invasive form of breast carcinoma that arises in the ducts of the normal breast.¹ Data suggest that DCIS represents an early stage in the development of breast cancer in which the characteristic molecular changes seen in invasive cancer are present but the full malignant phenotype has not been assumed.² Registrations of DCIS have increased markedly since the introduction of breast screening because it is a condition that is usually not palpable and is mostly diagnosed by mammography.^{1,2} DCIS accounts for approximately 20% of all cancers detected by the NHSBSP in the UK.³ Because the classification of DCIS lesions is continuing to evolve and the invasive potential of each DCIS lesion is uncertain, an optimal disease management strategy has not been determined.^{1,4}

Concern has been voiced that the detection of DCIS results in overdiagnosis of breast cancer, as some of these lesions may never progress or threaten a woman's life.^{5,6} It has been suggested that, when making a decision about breast screening participation, women should be fully aware of both the benefits and the harms of the screening process, including the consequences of being diagnosed with a non-invasive lesion.^{7,8} Also, the uncertainty surrounding the natural history of DCIS and lack of consensus regarding the most appropriate treatment may leave women with complicated treatment choices.^{2,5,7,9,10}

In the face of these uncertainties, the question then becomes, 'What do women need to know about DCIS in order to make an informed decision about breast screening?' Currently, relatively little research evidence is available which directly answers this question. A number of key points related to DCIS information provision are summarised below.

The information topics described above are not exhaustive and further work is required to assess the information needs of women taking part in the breast screening programme about DCIS. These points represent a minimum standard of information that should be available to women during the screening process. A recent study of a small sample of 10 UK women diagnosed with DCIS following screening showed that none of the women had been aware of DCIS before their diagnosis and that most would have liked more information about DCIS when invited for routine screening.⁶ At present, no information about DCIS is included in the screening programme invitation leaflet; however, women may request a copy of Cancer-backup's booklet *Understanding Breast Screening*,¹² which covers some of the points listed above.

We recommend that a brief paragraph about DCIS should be included in the NHSBSP invitation leaflet and that more in depth DCIS information should be provided at recall because DCIS becomes much more of an issue at further investigation than at basic screening. A separate DCIS leaflet may be necessary. The information points described in this section should be updated and expanded as new research evidence becomes available. The Sloane Project – a UK wide prospective audit of screen detected non-invasive and atypical hyperplasias of the breast – is scheduled for completion in 2008 (www.sloaneproject.co.uk/Index.html) and should provide detailed information about DCIS related diagnosis, treatment and clinical outcomes. The issue of the timing of DCIS information provision requires additional investigation.¹⁰

DCIS information: key points

Meaning of the result

Explain the meaning of the result (eg state if cancer present or not)^{5,6}

Mention the name of the condition (ie DCIS)¹¹

Include the number of women diagnosed with DCIS annually⁶

Indicate whether the condition is invasive^{5,6,9}

Natural history

Describe the uncertain natural history and progression of the condition^{5,6,9}

Indicate that DCIS may be asymptomatic^{5,9}

Indicate that a breast lump is not always formed⁹

Describe the different degrees of seriousness^{6,9}

Discuss how long it takes to develop⁶

Indicate whether watchful waiting or lifestyle modifications might be helpful^{6,9}

Risk factors (eg HRT)⁶

Difficult technical terminology includes ‘precancerous’, ‘preinvasive’, ‘non-invasive’, ‘intraductal’, ‘non-progressive cancer’ and ‘carcinoma’^{5,6}

Treatment

Describe treatment options^{6,9,11}

Indicate why mastectomy is used for DCIS⁵

Describe the emerging nature of evidence about effectiveness of various treatment options^{5,6}

Mention the likelihood of treatment being effective^{5,11}

Describe breast reconstruction⁶

Risk information

Future risk of developing breast cancer⁹

Future risk of developing breast cancer in the other breast⁹

Future risk of developing breast cancer if both breasts have been removed⁹

Daughter’s risk of developing DCIS¹¹

Further information

Explain how to get further information

Provide information about support groups⁶

HRT, hormone replacement therapy.

REFERENCES

1. Vainio H, Bianchini F, eds. *Breast Cancer Screening*. Lyon: IARC Press, 2002: Vol. 7.
2. Burstein HJ, Polyak K, Wong JS, et al. Ductal carcinoma in situ of the breast. *New England Journal of Medicine*, 2004, 350(14): 1430–1441.
3. Patnick J, ed. *One Vision: NHS Breast Screening Programme Annual Review 2005*. Sheffield, UK: NHS Cancer Screening Programmes, 2005.
4. The Sloane Project [homepage on the Internet]. West Midlands Cancer Intelligence Unit, Association of Breast Surgery, NHS Breast Screening Programme, Pfizer Pharmaceuticals, 2006 (accessed Mar 2006) *The Sloane Project*. Available from: <http://www.sloaneproject.co.uk/>
5. De Morgan S, Redman S, White KJ, et al. ‘Well, have I got cancer or haven’t I?’ The psycho-social issues for women diagnosed with ductal carcinoma in situ. *Health Expectations*, 2002, 5(4): 310–318.
6. Prinjha S, Evans J, McPherson A. Women’s information needs about ductal carcinoma in situ before mammographic screening and after diagnosis: a qualitative study. *Journal of Medical Screening*, 2006, 13(3): 110–114.
7. Thornton H, Edwards A, Baum M. Women need better information about routine mammography. *British Medical Journal*, 2003, 327(7406): 101–103.

8. Goyder E, Barratt A, Irwig LM. Telling people about screening programmes and screening test results: how can we do it better? *Journal of Medical Screening*, 2000, 7(3): 123–126.
9. Bluman LG, Borstelmann NA, Rimer BK, et al. Knowledge, satisfaction, and perceived cancer risk among women diagnosed with ductal carcinoma in situ. *Journal of Women's Health and Gender Based Medicine*, 2001, 10(6): 589–598.
10. Webster PN. *Information Needs and Informed Choice – Investigating the Information Requirements of Women Who are Invited to Attend Breast Screening to Enable Them to Make an Informed Choice About Participation* [dissertation]. University of Oxford, 2003.
11. Brown M, Koch T, Webb C. Information needs of women with non-invasive breast cancer. *Journal of Clinical Nursing*, 2000, 9(5): 713–722.
12. Robertshaw K, Coats D. *Understanding Breast Screening* [booklet]. UK: CancerBACUP, 2004.

APPENDIX 2: STUDIES AIMED AT IMPROVING MAMMOGRAPHY UPTAKE AND MAINTAINING ADHERENCE

The review search strategy was designed to identify papers that specifically evaluated the contents of written materials (such as letters and leaflets) provided to women about breast screening as well as women's information needs. The search strategy was not designed to retrieve a comprehensive list of studies whose main aim was to improve screening uptake (ie intervention studies where mammography uptake is reported but intervention contents are not assessed). Several detailed systematic reviews have collated and evaluated the research evidence related to this topic.¹⁻³ However, during the course of the review process, a number of papers were identified that reported information based interventions aimed at improving mammography uptake and maintaining adherence. These studies are briefly summarised below (similar results are reported in the other reviews). For the purposes of this section, studies that fell into the following categories were excluded: non-comparative descriptive and cross-sectional studies; studies that recruited participants who were not taking part in an organised screening programme; individually tailored interventions; interventions that included financial incentives; studies with no written information material versus control group comparison; and reports with unclear outcomes.

Research evidence reporting information-based interventions aimed at improving mammography uptake at invitation

Raising mammography awareness prior to invitation

No evidence of increased uptake⁴⁻¹⁹

Additional educational information

No evidence of increased uptake²⁰⁻²²

Fixed versus open appointments

Improved uptake with fixed appointments^{21,23-25}

Signatory on invitation – GP versus screening programme

Some evidence of improved uptake with GP signatory^{21,26,27}

Complex interventions

Single study; unclear which aspects of the interventions were effective²⁴

Research evidence reporting information-based interventions aimed at maintaining mammography adherence

Message framing

No evidence of improved adherence with either positive or negative framing²⁸⁻³⁰

Educational information

Single study; general information may be effective³¹

Research evidence reporting information-based interventions aimed at improving mammography uptake among screening non-attenders

Raising awareness – GP endorsement versus other

Improved uptake with GP endorsement of screening via letter^{32,33}

Additional educational information

No evidence of improved uptake with additional information^{34,35}

Reminders

Improved uptake with reminders^{25,36–38}

Complex interventions

Improved uptake; unclear which aspects of the interventions were effective^{24,39–41}

REFERENCES

1. Sin JP, St Leger AS. Interventions to increase breast screening uptake: do they make any difference? *Journal of Medical Screening*, 1999, 6(4): 170–181.
2. Bonfill X, Marzo M, Pladevall M, et al. Strategies for increasing women participation in community breast cancer screening. *Cochrane Database of Systematic Reviews Online Update Software*, 2001, 1: CD002943.
3. Jepson R, Clegg A, Forbes C, et al. The determinants of screening uptake and interventions for increasing uptake: a systematic review. *Health Technology Assessment*, 2000, 4(14): 1–133.
4. Ornstein SM, Garr DR, Jenkins RG, et al. Computer-generated physician and patient reminders. Tools to improve population adherence to selected preventive services. *Journal of Family Practice*, 1991, 32(1): 82–90.
5. Landis SE, Hulkower SD, Pierson S. Enhancing adherence with mammography through patient letters and physician prompts. A pilot study. *North Carolina Medical Journal*, 1992, 53(11): 575–578.
6. Curry SJ, Taplin SH, Anderman C, et al. A randomized trial of the impact of risk assessment and feedback on participation in mammography screening. *Preventive Medicine*, 1993, 22(3): 350–360.
7. Mayer JA, Clapp EJ, Bartholomew S, et al. Facility-based inreach strategies to promote annual mammograms. *American Journal of Preventive Medicine*, 1994, 10(6): 353–356.
8. Taplin SH, Anderman C, Grothaus L, et al. Using physician correspondence and postcard reminders to promote mammography use. *American Journal of Public Health*, 1994, 4(4): 571–574.
9. Maurer WJ. Breast cancer screening complacency and compliance. *Wisconsin Medical Journal*, 1995, 94(6): 305–306.
10. Mohler PJ. Enhancing compliance with screening mammography recommendations: a clinical trial in a primary care office. *Family Medicine*, 1995, 27(2): 117–121.
11. Burack RC, Gimotty PA, George J, et al. The effect of patient and physician reminders on use of screening mammography in a health maintenance organization. Results of a randomized controlled trial. *Cancer*, 1996, 78(8): 1708–1721.
12. O'Connor AM, Griffiths CJ, Underwood MR, et al. Can postal prompts from general practitioners improve the uptake of breast screening? A randomised controlled trial in one east London general practice. *Journal of Medical Screening*, 1998, 5(1): 49–52.
13. Davis NA, Nash E, Bailey C, et al. Evaluation of three methods for improving mammography rates in a managed care plan. *American Journal of Preventive Medicine*, 1997, 13(4): 298–302.
14. Bodiya A, Vorias D, Dickson HA. Does telephone contact with a physician's office staff improve mammogram screening rates? *Family Medicine*, 1999, 31(5): 324–326.
15. Mayer JA, Lewis EC, Slymen DJ, et al. Patient reminder letters to promote annual mammograms: a randomized controlled trial. *Preventive Medicine*, 2000, 31(4): 315–322.
16. Richards SH, Bankhead C, Peters TJ, et al. Cluster randomised controlled trial comparing the effectiveness and cost-effectiveness of two primary care interventions aimed at improving attendance for breast screening. *Journal of Medical Screening*, 2001, 8(2): 91–98.

17. Simon MS, Gimotty PA, Moncrease A, et al. The effect of patient reminders on the use of screening mammography in an urban health department primary care setting. *Breast Cancer Research and Treatment*, 2001, 65(1): 63–70.
18. Champion V, Maraj M, Hui S, et al. Comparison of tailored interventions to increase mammography screening in nonadherent older women. *Preventive Medicine*, 2003, 36(2): 150–158.
19. Saywell RMJ, Champion VL, Zollinger TW, et al. The cost effectiveness of 5 interventions to increase mammography adherence in a managed care population. *American Journal of Managing Care*, 2003, 9(1): 33–44.
20. Rakowski W, Ehrich B, Goldstein MG, et al. Increasing mammography among women aged 40–74 by use of a stage-matched, tailored intervention. *Preventive Medicine*, 1998, 27(5 part 1): 748–756.
21. Segnan N, Senore C, Giordano L, et al. Promoting participation in a population screening program for breast and cervical cancer: a randomized trial of different invitation strategies. *Tumori*, 1998, 84(3): 348–353.
22. Clark MA, Rakowski W, Ehrich B, et al. The effect of a stage-matched and tailored intervention on repeat mammography. *American Journal of Preventive Medicine*, 2002, 22(1): 1–7.
23. Williams EM, Vessey MP. Randomised trial of two strategies offering women mobile screening for breast cancer. *British Medical Journal*, 1989, 299(6692): 158–159.
24. Irwig L, Turnbull D, McMurchie M. A randomised trial of general practitioner-written invitations to encourage attendance at screening mammography. *Community Health Studies*, 1990, 14(4): 357–364.
25. Hurley SF, Jolley DJ, Livingston PM, et al. Effectiveness, costs, and cost-effectiveness of recruitment strategies for a mammographic screening program to detect breast cancer. *Journal of the National Cancer Institute*, 1992, 84(11): 855–863.
26. Giorgi D, Giordano L, Senore C, et al. General practitioners and mammographic screening uptake: influence of different modalities of general practitioner participation. Working Group. *Tumori*, 2000, 86(2): 124–129.
27. Segura JM, Castells X, Casamitjana M, et al. A randomized controlled trial comparing three invitation strategies in a breast cancer screening program. *Preventive Medicine*, 2001, 33(4): 325–332.
28. Kendall C, Hailey BJ. The relative effectiveness of three reminder letters on making and keeping mammogram appointments. *Behavioral Medicine*, 1993, 19(1): 29–34.
29. Drossaert CH, Boer H, Seydel ER. Health education to improve repeat participation in the Dutch breast cancer screening programme: evaluation of a leaflet tailored to previous participants. *Patient Education and Counselling*, 1996, 28(2): 121–131.
30. Finney LJ, Iannotti RJ. Message framing and mammography screening: a theory-driven intervention. *Behavioral Medicine*, 2002, 28(1): 5–14.
31. Lerman C, Ross E, Boyce A, et al. The impact of mailing psychoeducational materials to women with abnormal mammograms. *American Journal of Public Health*, 1992, 82(5): 729–730.
32. Turner KM, Wilson BJ, Gilbert FJ. Improving breast screening uptake: persuading initial non-attenders to attend. *Journal of Medical Screening*, 1994, 1(3): 199–202.
33. Bankhead C, Richards SH, Peters TJ, et al. Improving attendance for breast screening among recent non-attenders: a randomised controlled trial of two interventions in primary care. *Journal of Medical Screening*, 2001, 8(2): 99–105.
34. Seow A, Straughan PT, Ng EH, et al. A randomized trial of the use of print material and personal contact to improve mammography uptake among screening non-attenders in Singapore. *Annals of the Academy of Medicine Singapore*, 1998, 27(6): 838–842.
35. Barr JK, Franks AL, Lee NC, et al. A randomized intervention to improve ongoing participation in mammography. *American Journal of Managing Care*, 2001, 7(9): 887–894.
36. King ES, Rimer BK, Seay J, et al. Promoting mammography use through progressive interventions: is it effective? *American Journal of Public Health*, 1994, 84(1): 104–106.
37. Majeed A, Given Wilson R, Smith E. Impact of follow up letters on non-attenders for breast screening: a general practice based study. *Journal of Medical Screening*, 1997, 4(1): 19–20.
38. Hayes C, O’Herlihy B, Hynes M, et al. The impact of reminder letters on attendance for breast cancer screening. *Irish Journal of Medical Science*, 1999, 168(1): 29–32.
39. Turnbull D, Irwig L, Adelson P. A randomised trial of invitations to attend for screening mammography. *Australian Journal of Public Health*, 1991, 15(1): 33–36.
40. Stead MJ, Wallis MG, Wheaton ME. Improving uptake in non-attenders of breast screening: selective use of second appointment. *Journal of Medical Screening*, 1998, 5(2): 69–72.
41. Vogt TM, Glass A, Glasgow RE, et al. The safety net: a cost-effective approach to improving breast and cervical cancer screening. *Journal of Women’s Health*, 2003, 12(8): 789–798.

APPENDIX 3: ELECTRONIC DATABASE SEARCH STRATEGIES

MEDLINE ®: 1989–2005(08)

*ERLWebSPIRS*⁵

1. breast in ti,ab
2. mammogram* in ti,ab
3. explode 'Breast-'/without-subheadings, abnormalities, anatomy-and-histology, drug-effects, growth-and-development, injuries, metabolism, physiology, physiopathology, radiography, radiation-effects, radio-nuclide-imaging, secretion, surgery, transplantation, ultrastructure, ultrasonography in MIME,MJME
4. explode 'Mammography-'/all subheadings in MIME,MJME
5. #1 or #2 or #3 or #4
6. breast adj feeding
7. #5 not #6
8. breast-feeding
9. #7 not #8
10. breast-fed
11. #9 not #10
12. breast neoplasm* in ti,ab
13. breast cancer* in ti,ab
14. breast disease* in ti,ab
15. breast malignanc* in ti,ab
16. breast tumo?r* in ti,ab
17. breast carcinom* in ti,ab
18. breast adenocarcin* in ti,ab
19. explode 'Breast-Neoplasms'/without-subheadings, classification, complications, diet-therapy, diagnosis, economics, ethnology, epidemiology, etiology, history, metabolism, mortality, nursing, prevention-and-control, psychology, surgery, therapy in MIME,MJME
20. explode 'Neoplasms-Ductal-Lobular-and Medullary'/all subheadings in MIME,MJME
21. #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20
22. #11 or #21
23. explode 'Mass-Screening'/all subheadings in MIME,MJME
24. #22 and #23
25. #22 or #24
26. (pamphlet* or brochure* or leaflet* or letter* or information leaflet* or information disseminat* or risk communication or written information or informed uptake) in ti,ab
27. #25 and #26
28. (consumer* or patient* or client* or recipient* or adult*) in ti,ab
29. (wom?n or female*) in ti,ab
30. (adher* or consent* or choice* or complian* or accept* or right* or anxi* or fear*) in ti,ab
31. #28 and #30
32. #29 and #31
33. explode 'Patient-Acceptance-of-Health-Care'/without-subheadings ,ethnology ,psychology ,statistics-and-numerical-data ,trends, utilization in MIME,MJME
34. #32 and #33
35. #25 and #34
36. explode 'Attitude-to-Health'/without-subheadings ,ethnology ,psychology ,statistics-and-numerical-data ,trends ,utilization in MIME,MJME
37. #32 and #36
38. #25 and #37

39. explode 'Health-Behavior'/without-subheadings ,ethnology ,psychology ,statistics-and-numerical-data ,trends ,utilization in MIME,MJME
40. #32 and #39
41. #25 and #40
42. explode 'Health-Knowledge-Attitudes-Practice'/all subheadings in MIME,MJME
43. #32 and #42
44. #25 and #46
45. explode 'Health-Education'/without-subheadings ,methods ,organization-and-administration ,supply-and-distribution ,statistics-and-numerical-data ,trends ,utilization in MIME,MJME
46. #32 and #45
47. #25 and #46
48. #35 or #38 or #41 or #44 or #47
49. explode 'Motivation-'/without-subheadings ,classification ,ethics in MIME,MJME
50. #49 with #25
51. information need* in ti,ab
52. #51 and #25
53. attitude* in ti,ab
54. #53 near5 #25
55. attend* in ti,ab
56. #55 near2 #25
57. cancer information in ti,ab
58. #57 and #25
59. perception* in ti,ab
60. #59 near4 #25
61. knowledge in ti, ab
62. #61 near4 #25
63. health belie*
64. #63 and #25
65. #50 or #52 or #54 or #56 or #58 or #60 or #62 or #64
66. #27 or #48 or #65
67. genetic near (test* or assessment or counselling)
68. #66 not #67

PsycINFO ®: 1989–2005(08)

*ERLWebSPIRS*⁵

1. breast in ti,ab
2. mammogra* in ti,ab
3. explode 'Breast-' in MJ,MN
4. explode 'Mammography-' in MJ,MN
5. #1 or #2 or #3 or #4
6. breast adj feeding
7. #5 not #6
8. breast-feeding
9. #7 not #8
10. breast-fed
11. #9 not #10
12. breast neoplasm* in ti,ab
13. breast cancer* in ti,ab
14. breast disease* in ti,ab
15. breast malignanc* in ti,ab

16. breast tumo?r* in ti,ab
17. breast carcinom* in ti,ab
18. breast adenocarcin* in ti,ab
19. explode 'Breast-Neoplasms' in MJ,MN
20. #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19
21. #11 or #20
22. explode 'Health-Screening' in MJ,MN
23. #21 and #22
24. #21 or #23
25. (pamphlet* or brochure* or leaflet* or letter* or information leaflet* or information disseminat* or risk communication or written information or informed uptake) in ti,ab
26. #24 and #25
27. explode 'Health-Care-Utilization' in MJ,MN
28. #24 and #27
29. explode 'Health-Behavior' in MJ,MN
30. #24 and #29
31. explode 'Health-Attitudes' in MJ,MN
32. #24 and #31
33. explode 'Health-Knowledge' in MJ,MN
34. #24 and #33
35. explode 'Health-Education' in MJ,MN
36. #24 and #35
37. explode 'Client-Education' in MJ,MN
38. #24 and #37
39. explode 'Health-Promotion' in MJ,MN
40. #24 and #39
41. #28 or #30 or #32 or #34 or #36 or #38 or #40
42. uptake in ti,ab
43. #24 and #42
44. information need* in ti,ab
45. #24 and #44
46. attitude* in ti,ab
47. #24 near5 #46
48. attend* in ti,ab
49. #48 near4 #24
50. cancer information in ti,ab
51. #24 and #50
52. perception* in ti,ab
53. #52 near5 #24
54. understand* in ti,ab
55. #54 near4 #24
56. knowledge in ti,ab
57. #56 near4 #24
58. health belie* in ti,ab
59. #58 near4 #24
60. fear* in ti,ab
61. #60 near4 #24
62. #43 or #45 or #47 or #49 or #51 or #53 or #55 or #57 or #59 or #61
63. #26 or #41 or #62
64. genetic near (test* or assessment or counseling)
65. #63 not #64
66. breast self-examination

67. #65 not #66

EMBASE®: 1989–2005(07)

*ERLWebSPIRS*⁵

1. breast in ti,ab
2. mammogra* in ti,ab
3. explode 'breast-'/without-subheadings, complication, clinical-trial, diagnosis, epidemiology, etiology, prevention, side-effect in DEM,DER,DRM,DRR
4. explode 'mammography-'/without-subheadings, complication, clinical-trial, diagnosis, epidemiology, etiology, prevention, side-effect in DEM,DER,DRM,DRR
5. #1 or #2 or #3 or #4
6. breast adj feeding
7. #5 not #6
8. breast-feeding
9. #7 not #8
10. breast-fed
11. #9 not #10
12. breast neoplasm* in ti,ab
13. breast cancer* in ti,ab
14. breast disease* in ti,ab
15. breast malignanc* in ti,ab
16. breast tumo?r* in ti,ab
17. breast carcinom* in ti,ab
18. breast adenocarcin* in ti,ab
19. explode 'breast-tumor'/without-subheadings, complication, clinical-trial, diagnosis, disease-management, epidemiology, etiology, prevention, side-effect in DEM, DER, DRM, DRR
20. #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19
21. #11 or #20
22. explode 'Mass-Screening'/all subheadings in DEM, DER, DRM, DRR
23. explode 'Screening-test'/all subheadings in DEM, DER, DRM, DRR
24. #22 or #23
25. #21 and #24
26. #21 or #25
27. uptake in ti,ab
28. #27 near2 #26
29. information need* in ti,ab
30. #26 and #29
31. attitude* in ti,ab
32. #31 near4 #26
33. attend* in ti,ab
34. #33 near2 #26
35. cancer information in ti,ab
36. #26 and #35
37. perception* in ti,ab
38. #37 near3 #26
39. knowledge in ti,ab
40. #39 near2 #26
41. health belie* in ti,ab
42. #26 and #41
43. #28 or #30 or #32 or #34 or #36 or #38 or #40 or #42

44. (pamphlet* or brochure* or leaflet* or information leaflet* or information disseminat* or risk communication or written information or informed uptake) in ti,ab
45. #26 and #44
46. letter* in ti,ab
47. #26 and #46
48. letter in dt
49. #47 not #48
50. #45 or #49
51. (consumer* or patient* or client* or recipient* or adult*) in ti,ab
52. (wom?n or female*) in ti,ab
53. (adher* or consent* or choice* or complian* or accept* or right* or anxi* or fear* or understand*) in ti,ab
54. #51 and #53
55. #52 and #54
56. explode 'attitude'/all subheadings in DEM, DER, DRM, DRR
57. #55 and #56
58. #57 and #26
59. explode 'patient-information'/all subheadings in DEM, DER, DRM, DRR
60. #55 and #59
61. #60 and #26
62. explode 'health-education'/all subheadings in DEM, DER, DRM, DRR
63. #55 and #62
64. #63 and #26
65. explode 'health-behavior'/all subheadings in DEM, DER, DRM, DRR
66. #55 and #65
67. #66 and #26
68. explode 'illness-behavior'/all subheadings in DEM, DER, DRM, DRR
69. #55 and #68
70. #69 and #26
71. #58 or #61 or #64 or #67 or #70
72. #43 or #50 or #71
73. genetic near (test* or assessment or counselling)
74. #72 not #73

CINAHL®: 1989–2005(06)

*ERLWebSPIRS*⁵

1. breast in ti,ab
2. mammogra* in ti,ab
3. explode 'Breast-'/without-subheadings, abnormalities, anatomy-and-histology, drug-effects, injuries, metabolism, physiology, physiopathology, radiography, radiation-effects, ultrasonography/without-subheadings, in-adolescence, in-adulthood, immunology, in-old-age in DE
4. explode 'Mammography-'/without-subheadings, adverse-effects, economics, education, ethical-issues, mortality, nursing, psychosocial-factors, standards, trends, utilization/without-subheadings, in-adolescence, in-adulthood, immunology, in-old-age in DE
5. #1 or #2 or #3 or #4
6. breast adj feeding
7. #5 not #6
8. breast-feeding
9. #7 not #8
10. breast-fed

11. #9 not #10
12. breast neoplasm* in ti,ab
13. breast cancer* in ti,ab
14. breast disease* in ti,ab
15. breast malignanc* in ti,ab
16. breast tumo?r* in ti,ab
17. breast carcinom* in ti,ab
18. breast adenocarcin* in ti,ab
19. explode 'Breast-Neoplasms'/without-subheadings, classification, complications, diet-therapy, diagnosis, economics, education, ethnology, ethical-issues, epidemiology, etiology, history, metabolism, mortality, nursing, prevention-and-control, psychosocial-factors, prognosis, radiography, risk-factors, radiotherapy, symptoms, surgery, trends, therapy, ultrasonography/without-subheadings, in-adolescence, in-adulthood, immunology, in-old-age in DE
20. #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19
21. #11 or #20
22. explode 'Health-Screening'/without-subheadings, administration, economics, education, evaluation, organisations, psychosocial-factors, trends ,utilization/without-subheadings, in-adolescence, in-adulthood, in-old-age, in-middle-age in DE
23. #21 and #22
24. #21 or #23
25. (pamphlet* or brochure* or leaflet* or letter* or information leaflet* or sheet* or information disseminat* or risk communication or written information or informed uptake) in ti,ab
26. #24 and #25
27. (consumer* or patient* or client* or recipient* or adult*) in ti,ab
28. (wom?n or female*) in ti,ab
29. (adher* or consent* or choice* or complian* or accept* or right* or anxi* or fear* or understand*) in ti,ab
30. #27 and #29
31. #28 and #30
32. explode 'Patient-Education'/without-subheadings ,education ,evaluation ,methods ,organizations ,psychosocial-factors ,trends ,utilization/without-subheadings ,in-adolescence ,in-adulthood ,in-old-age ,in-middle-age in DE
33. #31 and #32
34. #24 and #33
35. explode 'Attitude-to-Health'/without-subheadings ,education ,ethnology ,evaluation ,trends/without-subheadings ,in-adolescence ,in-adulthood ,in-old-age ,in-middle-age in DE
36. #31 and #35
37. #24 and #36
38. explode 'Health-Knowledge'/all topical subheadings/without-subheadings ,in-adolescence ,in-adulthood ,in-old-age ,in-middle-age in DE
39. #31 and #38
40. #24 and #39
41. explode 'Health-Behavior'/without-subheadings ,education ,ethnology ,evaluation ,trends/without-subheadings ,in-adolescence ,in-adulthood ,in-old-age ,in-middle-age in DE
42. #31 and #41
43. #24 and #42
44. #34 or #37 or #40 or #43
45. uptake in ti,ab
46. #24 and #45
47. information need* in ti,ab
48. #24 and #47
49. attitude* in ti,ab

50. #24 near5 #49
51. attend* in ti,ab
52. #24 near #51
53. cancer information in ti,ab
54. #24 and #53
55. perception* in ti,ab
56. #24 near5 #55
57. understand* in ti,ab
58. #24 near5 #57
59. knowledge in ti,ab
60. #24 near4 #59
61. health belie* in ti,ab
62. #24 near6 #61
63. #46 or #48 or #50 or #52 or #54 or #56 or #58 or #60 or #62
64. #26 or #44 or #63
65. genetic near (test* or assessment or counselling)
66. #64 not #65

APPENDIX 4: LIST OF INTERNET SITES VISITED

Breast screening programmes

- NHS National Breast Screening Programme: <http://www.cancerscreening.nhs.uk/breastscreen/index.html>
- Cancer in Scotland: Action for Change, NHS Scotland: <http://www.show.scot.nhs.uk/sehd/cancerinscotland/>
- Irish Breast Screening Programme: <http://www.breastcheck.ie/>
- CDC National Breast and Cervical Cancer Early Detection Programme: <http://www.cdc.gov/cancer/nbcedp/>
- BreastScreen Australia: <http://www.breastscreen.info.au/index.htm>
- BreastScreen Victoria: <http://www.breastscreen.org.au/index.htm>
- New Zealand National Screening Programme – BreastScreen Aotearoa: <http://www.healthywomen.org.nz/BSA/DEFAULT.aspx>
- Alberta Screentest program: <http://www.cancerboard.ab.ca/screentest/index.html>
- Manitoba Breast Screening Programme: <http://www.cancercare.mb.ca/MBSP/index.shtml>
- Ontario Breast Screening Programme: http://www.cancercare.on.ca/index_breastScreening.htm
- Screening Mammography Program of BC: <http://www.bccancer.bc.ca/PPI/Screening/Breast/SMPBC+General+Information.htm>

General health sites and cancer agencies

- UK National Institute for Health and Clinical Excellence: <http://www.publichealth.nice.org.uk/page.aspx?o=home>
- NHS Direct: <http://www.nhsdirect.nhs.uk>
- NHS National Electronic Library for Health: <http://www.nelh.nhs.uk>
- UK Department of Health: <http://www.dh.gov.uk/Home/fs/en>
- Electronic Quality Information for Patients: <http://www.equip.nhs.uk/index.html>
- Cancerbackup (formerly CancerBACUP): <http://www.cancerbackup.org.uk/Home>
- Breast Cancer Campaign: <http://www.breastcancercampaign.org/>
- UK Breast Cancer Coalition: <http://www.ukbcc.org.uk>
- Breakthrough Breast Cancer: <http://www.breakthrough.org.uk/>
- Cancer Research UK: <http://www.cancerresearchuk.org/>
- CancerWEB: <http://cancerweb.ncl.ac.uk/cancerweb.html>
- DIPEX.org: <http://www.dipex.org/>
- Europa Donna: http://www.cancerworld.org/cancerworld/home.aspx?id_sito=5&id_stato=1
- Breast International Group: <http://www.breastinternationalgroup.org/>
- European Society of Mastology: <http://www.eusoma.org/Index.aspx>
- World Health Organisation: <http://www.who.int/en/>
- International Agency for Research on Cancer: <http://www.iarc.fr>
- The Susan G. Komen Breast Cancer Foundation: http://www.komen.org/intradoc-cgi/idc.cgi_isapi.dll?IdcService=SS_GET_PAGE&nodeId=298
- National Cancer Institute, US National Institutes of Health: <http://www.cancer.gov>
- American Cancer Society: <http://www.cancer.org/docroot/home/index.asp>
- International Cancer Research Portfolio: <http://www.cancerportfolio.com/index.jsp>
- Canadian Cancer Society: <http://www.cancer.ca>
- Canadian Breast Cancer Research Alliance: <http://www.breast.cancer.ca/Default.asp?language=English>
- National Cancer Institute of Canada: http://www.ncic.cancer.ca/ncic/internet/home/0%2C%2C84658243___langId-en%2C00.html
- Australian National Breast Cancer Centre: <http://www.nbcc.org.au/index.html>

Women's Health Sites

- Women's Cancer Network: <http://www.wcn.org/>
- Canadian Women's Health Network: <http://www.cwhn.ca/indexeng.html>
- National Women's Health Information Centre, US Department of Health and Human Services: <http://www.4woman.gov>
- New Zealand Women's Health Action Trust : <http://www.womens-health.org.nz/>
- Women's Health Australia: <http://www.newcastle.edu.au/centre/wha/>
- Australia Women's Health Network: <http://www.awhn.org.au>

APPENDIX 5: STAGE 3 DATA EXTRACTION FORM^{4,76-78}

Study quality	Study design
---------------	--------------

Date

--	--	--

Identification

Reviewer				Study number/ Reference manager number		
Title						
Author(s)						
Source of information						
Year	Volume	Issue	Page(s)	Country		

General study details

Study aims						
Study setting (primary, secondary, community)						
Primary research	RCT	Non-randomised intervention	Cohort	Case-Control	Cross-sectional	Other (state)
Secondary research	Meta-analysis	Systematic review	Simple overview		Guideline	
Recruitment method						
Description of experimental group (including inclusion/exclusion criteria, participation rate and population characteristics)						
Description of comparison group (including inclusion/exclusion criteria, participation rate and population characteristics)						
Describe basic study method (including randomisation, allocation concealment, case definition and outcome and exposure assessment – objective or subjective)						
Review relevant interventions and/or materials						
Study length			Sample size/power calculations			
Follow up (% participants followed up, drop out information, missing data)						

Results

--

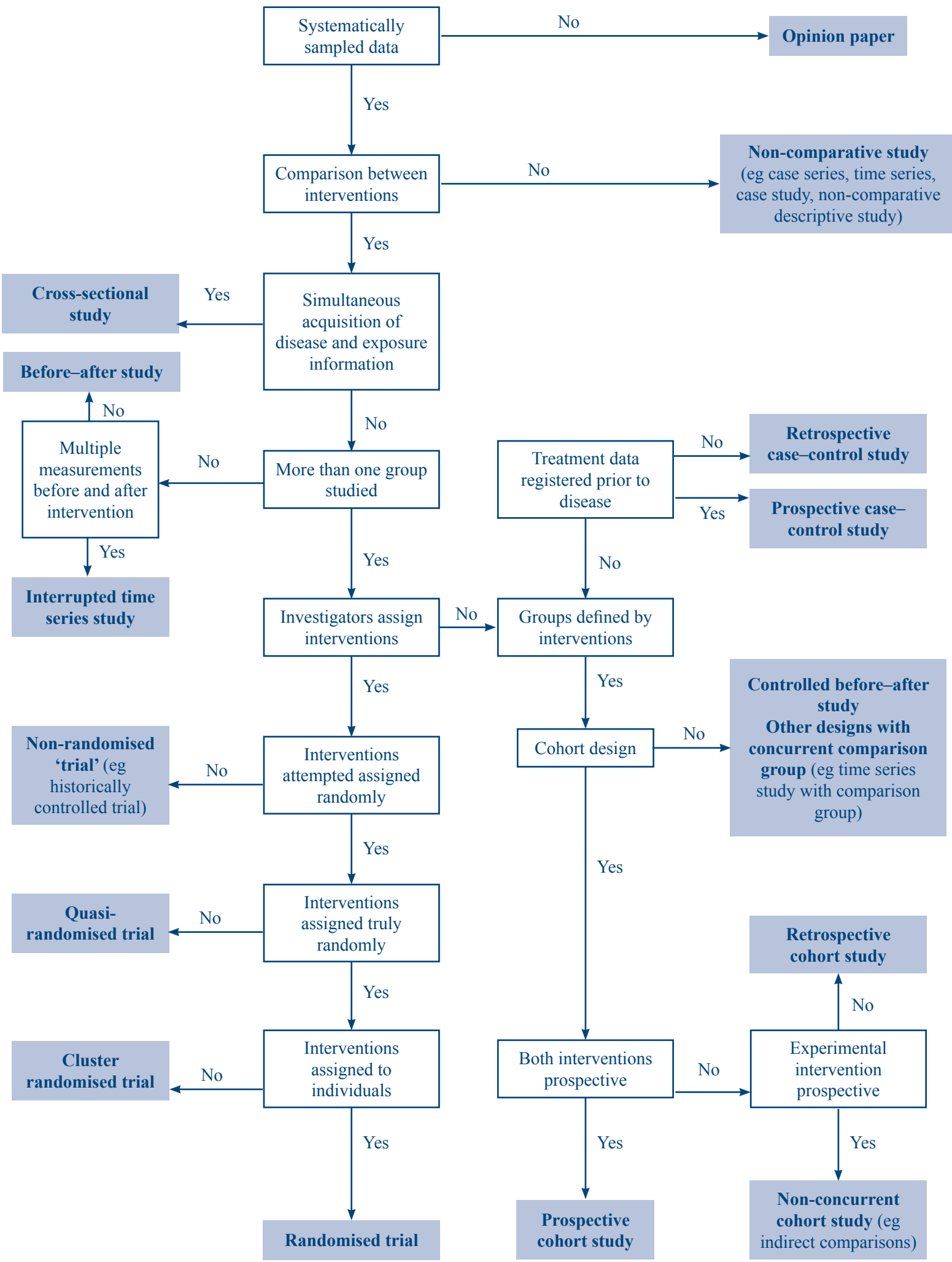
Overall assessment of the study

How well was the study conducted? Code ++, + or – (see methodology tables)
Taking into account clinical and statistical considerations and your evaluation of the methodology used, are you certain that the overall effect is due to the study intervention or the exposure being investigated?
Are the results of this study directly applicable to the participant group targeted by this review?

Notes

Does this study help to answer the key questions?

APPENDIX 6: STAGE 4 QUALITY SCORING: STUDY DESIGN ALGORITHM^{79,80}



APPENDIX 7: STAGE 4 QUALITY SCORING: STUDY METHODOLOGY CHECKLISTS

Study methodology checklist 1:^{81,82} randomised, clustered, quasi-controlled trials and non-randomised trials

Issues to consider in a well conducted trial		In this study this criterion is	
1.1	The study addresses an appropriate and clearly focused question	Well covered Adequately addressed Poorly addressed	Not reported Not applicable
1.2	The assignment of subjects to treatment groups is randomised	Well covered Adequately addressed Poorly addressed	Not reported Not applicable
1.3	An adequate concealment method is used	Well covered Adequately addressed Poorly addressed	Not reported Not applicable
1.4	Subjects and investigators are kept 'blind' about treatment allocation	Well covered Adequately addressed Poorly addressed	Not reported Not applicable
1.5	The treatment and control groups are similar at the start of the trial	Well covered Adequately addressed Poorly addressed	Not reported Not applicable
1.6	The only difference between groups is the intervention under investigation	Well covered Adequately addressed Poorly addressed	Not reported Not applicable
1.7	All relevant outcomes are measured in a standard, valid and reliable way	Well covered Adequately addressed Poorly addressed	Not reported Not applicable
1.8	What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?		
1.9	All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)	Well covered Adequately addressed Poorly addressed	Not reported Not applicable
1.10	Where the study is carried out at more than one site, results are comparable for all sites	Well covered Adequately addressed Poorly addressed	Not reported Not applicable
1.11	An appropriate analysis was used for cluster randomised controlled trials	Well covered Adequately addressed Poorly addressed	Not reported Not applicable

The methodological quality of the study is rated based on your responses to the appropriate methodology checklist using the following coding system:

- ++ *All or most* of the criteria have been fulfilled. Where they have not been fulfilled, the conclusions of the study are thought *very unlikely* to alter
- + *Some* of the criteria have been fulfilled. Those criteria that have not been fulfilled or not adequately described are thought *unlikely* to alter the conclusions
- *Few or no* criteria fulfilled. The conclusions of the study are thought *likely or very likely* to alter

Notes

- 1.1 Unless a clear and well defined question is specified, it will be difficult to assess how well the study has met its objectives or how relevant it is to the question you are trying to answer on the basis of its conclusions. Consider whether the question is ‘focused’ in terms of the population studied, the intervention given and the outcomes chosen.
- 1.2 Random allocation of patients to receive one or other of the treatments under investigation, or to receive either treatment or placebo, is fundamental to this type of study. If the description of randomisation is poor, the study should be given a lower quality rating. Consider the following points: whether the randomisation process was truly random, whether the method of allocation was described (stratification used to balance randomisation?), how the randomisation schedule was generated, how a participant was allocated to a study group and if there were any differences reported that might have explained any outcome(s) (confounding).
- 1.3 Allocation concealment refers to the process used to ensure that researchers are unaware which group patients are being allocated to at the time they enter the study. If the method of concealment used is regarded as poor, or relatively easy to subvert, the study should be given a lower quality rating.
- 1.4 Blinding refers to the process whereby people are kept unaware of which treatment an individual patient has been receiving when they are assessing the outcome for that patient. The higher the level of blinding, the lower the risk of bias in the study. Consider the following points: the fact that blinding is not always possible, whether every effort was made to achieve blinding and ‘observer bias’.
- 1.5 Participants selected for inclusion in a trial must be as similar as possible. The study should report any significant differences in the composition of the study groups in relation to gender mix, age, stage of disease (if appropriate), social background, ethnic origin or comorbid conditions. These factors may be covered by inclusion or exclusion criteria, rather than being reported directly. Failure to address this question, or the use of inappropriate groups, should lead to the study being downgraded.
- 1.6 If some patients received additional intervention, even if of a minor nature or consisting of advice and counselling rather than a physical intervention, this treatment is a potential confounding factor that may invalidate the results. If groups were not treated equally, the study should be rejected unless no other evidence is available (if used as evidence it should be treated with caution).
- 1.7 The primary outcome measures used should be clearly stated in the study. Where outcome measures require any degree of subjectivity, some evidence should be provided that the measures used are reliable and have been validated prior to their use in the study. Consider whether participant outcomes were reviewed at the same time intervals and whether they received the same amount of attention from researchers and health workers (any differences may introduce performance bias).
- 1.8 The number of participants that drop out of a study should give concern if the number is very high. Conventionally, a 20% drop out rate is regarded as acceptable, but this may vary. Some regard should be paid to why participants dropped out, as well as how many. It should be noted that the drop out rate might be expected to be higher in studies conducted over a long period of time. A higher drop out rate will normally lead to downgrading, rather than rejection of a study.
- 1.9 It is rarely the case that all participants allocated to the intervention group receive the intervention throughout the trial, or that all those in the comparison group do not. However, participant outcomes must be analysed according to the group to which they were originally allocated irrespective of the intervention that they actually received (intention-to-treat analysis). The study may be rejected if it is clear that an intention-to-treat analysis was not used.
- 1.10 In multi-site studies, confidence in the results should be increased if it can be shown that similar results were obtained at the different participating centres.
- 1.11 The analysis chosen for cluster randomised controlled trials should be consistent with the design – it should take clustering into account. Valid approaches include: analysing clustered outcome data (unit of analysis is the same as that of randomisation) and individual level analysis accounting for clustering such as random effects regression, generalised estimating equations or robust standard errors.

Study methodology checklist 2: non-comparative descriptive and non-comparative time series studies

Issues to consider in a well conducted study		In this study this criterion is	
1.1	The study addresses an appropriate and clearly focused question	Well covered Adequately addressed Poorly addressed	Not reported Not applicable
1.2	The group being studied is an appropriate and representative sample of the selected source population	Well covered Adequately addressed Poorly addressed	Not reported Not applicable
1.3	The study indicates how many of the people asked to take part did so	Well covered Adequately addressed Poorly addressed	Not reported Not applicable
1.4	The outcomes are clearly defined	Well covered Adequately addressed Poorly addressed	Not reported Not applicable
1.5	Evidence from other sources is used to demonstrate that the method of outcome assessment is valid and reliable	Well covered Adequately addressed Poorly addressed	Not reported Not applicable
1.6	Have confidence intervals been provided?		

The methodological quality of the study is rated based on your responses to the appropriate methodology checklist using the following coding system:

- ++ *All or most* of the criteria have been fulfilled. Where they have not been fulfilled, the conclusions of the study are thought *very unlikely* to alter
- + *Some* of the criteria have been fulfilled. Those criteria that have not been fulfilled or not adequately described are thought *unlikely* to alter the conclusions
- *Few or no* criteria fulfilled. The conclusions of the study are thought *likely or very likely* to alter

Notes

- 1.1 Unless a clear and well defined question is specified, it will be difficult to assess how well the study has met its objectives or how relevant it is to the question you are trying to answer on the basis of its conclusions. Consider whether the question is 'focused' in terms of the population studied, the risk factors studied and the outcomes considered.
- 1.2 Consider whether the sample was representative of a defined population, whether there was something special about the sample and whether everyone was included who should have been included.
- 1.3 The participation rate is defined as the number of study participants divided by the number of eligible subjects. A low participation rate indicates that a significant degree of selection bias may be present, and the study results should be treated with considerable caution.
- 1.4 Outcomes and the criteria used for measuring them should be clearly defined. Consider whether subjective or objective measurements were used, whether the measures used have been validated and whether the measurement methods were similar for all participants.
- 1.5 The primary outcome measures used should be clearly stated in the study. Where outcome measures require any degree of subjectivity, some evidence should be provided that the measures used are reliable and have been validated prior to their use in the study. The study may be rejected if it is clear that the main conclusions are based on secondary outcomes.
- 1.6 Confidence limits are the preferred method for indicating the precision of statistical results, and can be used to differentiate between an inconclusive study and a study that shows no effect. Studies that report a single value with no assessment of precision should be treated with extreme caution.

Study methodology checklist 3:^{82,84} qualitative research studies

Issues to consider in a well conducted study		In this study this criterion is	
1.1	The study addresses an appropriate and clearly focused question	Well covered Adequately addressed Poorly addressed	Not reported Not applicable
1.2	The qualitative methodology used was appropriate	Well covered Adequately addressed Poorly addressed	Not reported Not applicable
1.3	The research design was appropriate to address the aims of the research	Well covered Adequately addressed Poorly addressed	Not reported Not applicable
1.4	The recruitment strategy was appropriate to the aims of the research	Well covered Adequately addressed Poorly addressed	Not reported Not applicable
1.5	The data were collected in a way that addressed the research issue	Well covered Adequately addressed Poorly addressed	Not reported Not applicable
1.6	The relationship between the researcher and the participants was adequately considered	Well covered Adequately addressed Poorly addressed	Not reported Not applicable
1.7	Ethical issues were taken into consideration	Well covered Adequately addressed Poorly addressed	Not reported Not applicable
1.8	The data analysis was sufficiently rigorous	Well covered Adequately addressed Poorly addressed	Not reported Not applicable
1.9	There was a clear statement of findings	Well covered Adequately addressed Poorly addressed	Not reported Not applicable
1.10	The research was valuable	Well covered Adequately addressed Poorly addressed	Not reported Not applicable

The methodological quality of the study is rated based on your responses to the appropriate methodology checklist using the following coding system:

- Q++ *All or most* of the criteria have been fulfilled. Where they have not been fulfilled, the conclusions of the study are thought *very unlikely* to alter
- Q+ *Some* of the criteria have been fulfilled. Those criteria that have not been fulfilled or not adequately described are thought *unlikely* to alter the conclusions
- Q- *Few or no* criteria fulfilled. The conclusions of the study are thought *likely or very likely* to alter

Notes

- 1.1 Unless a clear and well defined question is specified, it will be difficult to assess how well the study has met its objectives or how relevant it is to the question you are trying to answer on the basis of its conclusions. Consider the goal of the research, why it is important and its relevance.

- 1.2 If the research seeks to interpret or illuminate the actions and/or subjective experiences of research participants then qualitative methods are appropriate for the research aims. A fit between the purpose of the study and the style of investigation should be demonstrated.
- 1.3 Has the chosen research design been justified? Consider whether a convincing argument for different features of research design has been presented and whether the researchers have discussed how they decided which methods to use. The limitations of the research design and their implications for the study evidence may also be covered.
- 1.4 Study participants may be selected from a variety of populations. Consider whether the researchers have explained how the participants were selected, why the participants selected were the most appropriate to provide access to the type of knowledge sought by the study and whether there were any discussions around recruitment (eg why some people chose not to take part).
- 1.5 The setting for data collection and the methods chosen should be justified. Is it clear how data were collected (eg focus group, semi-structured interview)? Have the researchers made the methods explicit (eg for interview method, is there an indication of how the interviews were conducted and did they use a topic guide)? If any methods were modified during the study, the researchers must explain how and why. The form of the data should be clear (eg tape recordings, video material, notes) and saturation of the data should be discussed.
- 1.6 It is important that researchers critically examine their own role, potential bias and influence during the formulation of research questions and during data collection, including sample recruitment and choice of location. Consider how the researchers responded to events during the study and whether they considered the implications of any changes in the research design.
- 1.7 Evidence of consideration of ethical issues – sufficient details of how the research was explained to participants should be presented for the reader to assess whether ethical standards were maintained. Consider whether the researchers have discussed issues raised by the study (eg issues around informed consent or confidentiality or how they have handled the effects of the study on the participants during and after the study).
- 1.8 An in depth and clear description of the analysis process should be provided. Consider evidence of how descriptive analytic categories, classes, labels etc have been generated and used and discussion of how any constructed analytic concepts/typologies etc have been devised and applied. If thematic analysis is used, is it clear how the categories/themes were derived from the data? Have the researchers explained how the data presented were selected from the original sample to demonstrate the analysis process? Are sufficient data presented to support the findings and to what extent have contradictory data been taken into account? Have the researchers critically examined their own role, potential bias and influence during analysis and selection of data for presentation?
- 1.9 The research findings should be explicit and credible. The findings/conclusions must be supported by data/study evidence and have a coherent logic. Is there an adequate discussion of the evidence both for and against the researcher's arguments? Have the researchers discussed the credibility of their findings (eg triangulation, respondent validation, more than one analyst)? Are the findings discussed in relation to the original research questions?
- 1.10 A clear discussion of the study's contribution to existing knowledge or understanding should be presented (eg are the findings considered in relation to current practice or policy or relevant research based literature?). Have new areas where research is necessary been identified? Have the researchers discussed whether or how the findings can be transferred to other populations or considered other ways the research may be used?

APPENDIX 8: STAGE 5 SYNTHESIS AND EVIDENCE GRADING: MATERIALS

Combining the four elements: quantitative studies

Adapted with permission from *Grading Quality of Evidence and Strength of Recommendations*.⁸⁵

Initial level of evidence

Randomised trial = high

Observational study = low*

Any other evidence = very low

Decrease grade if

- Serious (–1) or very serious (–2) limitation to study quality
- Important inconsistency (–1)
- Some (–1) or major (–2) uncertainty about directness
- Imprecise or sparse data (–1)
- High probability of reporting bias (–1)

Increase grade if

- Strong evidence of association – significant relative risk of > 2 (< 0.5) based on consistent evidence from two or more observational studies, with no plausible confounders (+1)
- Very strong evidence of association – significant relative risk of > 5 (< 0.2) based on direct evidence with no major threats to validity (+2)
- Evidence of a dose–response gradient (+1)
- All plausible confounders would have reduced the effect (+1)

* Observational studies include: cohort studies, case–control studies, interrupted time series analyses and controlled before–after studies.

The following definitions should be used to assess the quality of evidence described in an outcome evidence profile.

Overall level of evidence

High	Further research is very unlikely to change our confidence in the estimate of effect
Moderate	Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate
Low	Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate
Very low	Any estimate of effect is very uncertain

Notes

This approach initially categorises a group of quantitative studies listed in a particular outcome evidence profile into one of three levels (high, low and very low) based on study design. The lowest hierarchical type of evidence (ie study design) of any study in the group provides the basis for the initial evidence level assignment. There are actually four overall levels of evidence – high, moderate, low and very low. Subsequently, the grade of evidence initially assigned to an outcome may be altered if the studies have serious limitations, if there are important inconsistencies in the results or if uncertainty about the directness of the evidence is warranted. Consistency refers to the similarity of estimates of effect or observations across studies. Directness refers to the extent to which people, interventions and outcomes are similar to those of interest. Imprecise or sparse data and/or high risk of reporting bias can also lower the grade of evidence. Very strong or strong associations,

evidence of a dose–response gradient and/or presence of all plausible residual confounding that would have reduced the observed effect may raise the evidence grade. All of these considerations act cumulatively on the overall quantitative level of evidence assigned to each outcome.

Combining the four elements: qualitative studies

Initial level of evidence*

Checklist quality score Q++ = high
 Checklist quality score Q+ = low
 Checklist quality score Q– = very low

Decrease grade if

- Important inconsistency (–1)
- Some (–1) or major (–2) uncertainty about directness

Increase grade if

- Close conformity of findings based on two or more studies rated as Q++, directly applicable to the target population and with no major threats to validity (+1)

*The study quality ratings Q++, Q+ and Q– were determined for each study on the basis of Study methodology checklist 3: qualitative research studies

The following definitions should be used to assess the quality of evidence described in an outcome evidence profile.

Overall level of evidence

High	Further research is very unlikely to change our confidence in the findings
Moderate	Further research is likely to have an important impact on our confidence in the findings and may change the reported results
Low	Further research is very likely to have an important impact on our confidence in the findings and is likely to change the reported results
Very low	Any of the findings are very uncertain

Notes

This approach initially categorises a group of qualitative studies listed in a particular outcome evidence profile into one of three levels (high, low and very low) based on study quality (as assessed by the Study methodology checklist 3: qualitative research studies). The lowest checklist quality score obtained for any study in the group provides the basis for the initial evidence level assignment. There are actually four overall levels of evidence – high, moderate, low and very low. Subsequently, the grade of evidence initially assigned to an outcome may be altered if there are any important inconsistencies between studies and/or if uncertainty about the directness of the evidence is warranted. Consistency refers to similarities in developed themes and participant experiences across studies. Directness refers to the extent to which people, interventions and outcomes are similar to those of interest. Close conformity of findings based on two or more studies rated as Q++, directly applicable to the target population, may raise the evidence grade. All of these considerations act cumulatively on the overall qualitative level of evidence assigned to each outcome.

Combining the four elements: outcome evidence profile grading key for both quantitative⁸⁶ and qualitative studies

	Increase	Default	Decrease
Limitations		Acceptable	Serious limitations
Precision		Good precision	Imprecise or sparse data
Directness		Direct	Some uncertainty
Full reporting		Good reporting	High probability of reporting bias
Consistency across studies		No important inconsistency	Important inconsistency
Strong association	Strong (odds ratio or relative risk > 2) Very strong (odds ratio or relative risk > 5)		
Dose–response	Evidence of dose–response gradient	No information	
Plausible confounders	No plausible confounders (or all would have increased effect)		
Close conformity	Two or more studies rated Q++		

APPENDIX 9: DESCRIPTION OF QUANTITATIVE STUDIES

Study

Smith¹⁶

Study design	Cluster randomised controlled trial
Study quality score	–
Methods	<p>Randomisation – method not stated; 11 successive assessment clinics were randomly assigned to three letter groups</p> <p>Concealment of allocation – not reported</p> <p>Assessor blinding – not reported</p> <p>Baseline comparability – not reported</p> <p>Follow up – three months</p> <p>Sample size – sample size and power calculations not reported</p> <p>Losses to follow up – overall 12/91 (13%) women did not return the second questionnaire</p> <p>Outcome measure(s) – self-report via questionnaire</p> <p>Percentage analysed – 64% (66/103) first questionnaire</p>
Population	<p>Country – UK</p> <p>Setting – breast screening clinic</p> <p>Screening status – recalled for further assessment</p> <p>Participants – 103 women recalled for further assessment at 11 clinics held at a main hospital site by the Leicestershire Breast Screening Service (LBSS)</p> <p>Inclusion criteria – recalled for further assessment</p> <p>Exclusion criteria –second questionnaire non-response</p> <ol style="list-style-type: none">1. Short recall letter $n = ?$ (15–17 analysed)2. Short recall letter with contact details of breast care sister $n = ?$ (24–25 analysed)3. Expanded recall letter $n = ?$ (26–27 analysed)
Interventions	Satisfaction with information in the letters
Outcomes	Information needs
Notes	This is a report of an audit conducted at the LBSS Assessment Clinic. The audit provided the opportunity to test three versions of the second invitation letter. The first part of the questionnaire was filled in while the women were waiting to be seen in the clinic area and addressed issues surrounding the letter and information about the clinic. The second part was sent, with their results, to those women in whom the possibility of malignancy had been ruled out. Copies of the text of the three letters are included with the report

Study

Austoker¹²

Study design	Non-comparative descriptive study
Study quality score	++
Methods	<p>Appropriate population – well covered</p> <p>Participation rate – 461/484 (95%) women completed the interviewer-led questionnaire while waiting for assessment at recall clinic; 1493/2132 (70%) women completed the postal questionnaire sent two weeks after assessment</p> <p>Outcome definition – adequately addressed</p> <p>Outcome assessment – unclear</p> <p>Outcome measure – self-report via two types of questionnaire</p> <p>Exposure assessment – well covered</p> <p>Exposure measure – administrative records</p> <p>Study length – five months</p>
Population	<p>Country – UK</p> <p>Setting – national screening programme breast screening centres</p> <p>Screening status – recalled for further assessment</p> <p>Participants – 2132 consecutive women 50–64 years attending eight breast screening centres (four from England, three from Scotland, and one from Wales) for further assessment during April to August 1991</p> <p>Inclusion criteria – received a recall letter; appointment at a participating centre</p> <p>Exclusion criteria – recalled due to technically inadequate mammogram</p> <p>Recall for further assessment ($n = 1493$)</p>
Exposure	Information needs (including nine key topics that warranted further information provision)
Outcomes	Use of leaflets
Notes	Extent of information provided
	The results were predominantly based on the postal questionnaire, which authors state may underestimate some of the information needs as the proportions with unmet needs on postal questionnaire were significantly lower than that obtained at the recall clinic (reason for recall, process of assessment, part of the information was worrying)

Study **Bluman**¹¹

Study design Non-comparative descriptive study

Study quality score +

Methods Appropriate population – adequately addressed
 Participation rate – 76/122 (62%) women contacted about the study returned a completed questionnaire (26 eligible women returned decline cards)
 Outcome definition – adequately addressed
 Outcome assessment – unclear
 Outcome measure – self-report via questionnaire
 Exposure assessment – well covered
 Exposure measure – administrative records
 Study length – four weeks

Population Country – USA
 Setting – tumour registry
 Screening status – diagnosed with DCIS
 Participants – 127 women 33–82 years (mean age 56 years) diagnosed with DCIS between 1 January 1993 and 31 December 1996 listed in the Duke University Tumor Registry
 Inclusion criteria – completed questionnaire
 Exclusion criteria – cognitive impairment; serious comorbidity

Exposure DCIS diagnosis (*n* = 122)

Outcomes Knowledge about DCIS/breast cancer
 Information needs (10 statements provided about DCIS/breast cancer with percentage answering correctly)

Notes Not clear whether DCIS was diagnosed as part of an organised screening programme

Study **Nekhlyudov**³³

Study design Non-comparative descriptive study

Study quality score +

Methods Appropriate population – adequately addressed
 Participation rate – approximately 96/203 (47%) women returned a completed survey
 Outcome definition – adequately addressed
 Outcome assessment – not blind
 Outcome measure – self-report via questionnaire
 Exposure assessment – poorly addressed – record data were not up to date
 Exposure measure – administrative records
 Study length – 16 months

Population	<p>Country – USA</p> <p>Setting – health maintenance organisation</p> <p>Screening status – due for first mammogram</p> <p>Participants – 291 women aged 40–44 years due for a first ever scheduled mammography appointment at one of 14 Harvard Vanguard Medical Associates (HVMA) sites in the greater Boston area run by Harvard Pilgrim Health Care (a large health maintenance organisation)</p> <p>Inclusion criteria – 40–44 years; due for first ever mammogram</p> <p>Exclusion criteria – previous mammogram; breast cancer; breast surgery in the prior five years; no primary care visit within one year of the mammogram appointment</p>
Exposure	Due for first ever mammogram appointment ($n = 291$)
Outcomes	Women’s information needs about screening (list of 10 items of information and percentage that agreed was important)
Notes	<p>The study sample was identified using an automated radiology appointment system at HVMA; 144 out of 291 potentially eligible women initially replied – 41 of these women declared that they were not eligible for participation because they had had prior mammograms (that were not captured by the automated radiology record data). A manual search was performed of the records of a random 30% sample ($n = 44$) of the 147 non-respondents and it was found that 11 (25%) were also ineligible because of prior mammograms, mostly done at outside facilities. On the basis of a 25–30% non-eligibility rate, it was estimated that 40 of the 147 non-respondents were ineligible</p>

Study **Roworth**^{3,4}

Study design	Non-comparative descriptive study
Study quality score	++
Methods	<p>Appropriate population – well covered</p> <p>Participation rate – 2586/3000 (86.2%) women returned a questionnaire</p> <p>Outcome definition – adequately addressed</p> <p>Outcome assessment – not blind</p> <p>Outcome measure – self-report via questionnaire</p> <p>Exposure assessment – well covered</p> <p>Exposure measure – administrative records</p> <p>Study length – one week</p>
Population	<p>Country – UK</p> <p>Setting – community screening programme</p> <p>Screening status – due for mammogram</p> <p>Participants – 3000 women 50–64 years who were consecutive first-time attenders at 15 breast screening clinics in Scotland during one week in November 2001</p> <p>Inclusion criteria – 50–64 years; first screening appointment</p> <p>Exclusion criteria – not reported</p> <p>First-time attender for breast screening ($n = 2586$)</p> <p>Information needs</p> <p>The data in this study are derived from a national consumer opinion survey of the Scottish Breast Screening Programme conducted in 1991; 1200 women attended static units and 1800 women attended mobile units. Static units were based in Aberdeen, Dundee, Edinburgh, Glasgow, Inverness and Irvine. The study size was estimated on the basis of an expected 67% overall response rate, and a required maximum standard error of 5% for each screening unit</p>
Exposure	
Outcomes	
Notes	

Study

Webster³⁵

Study design	Non-comparative descriptive study
Study quality score	++
Methods	Appropriate population – well covered Participation rate – 640/948 (67.5%) women completed and returned the study questionnaire Outcome definition – adequately addressed Outcome assessment – unclear Outcome measure – self-report via questionnaire Exposure assessment – not reported Exposure measure – self-report via questionnaire Study length – one month
Population	Country – UK Setting – population Screening status – unclear Participants – 948 women 49–64 years registered with a GP in Oxfordshire as detailed in a database held by the Thames Valley Primary Care Agency (TVPCA) Inclusion criteria – listed in the TVPCA database Exclusion criteria – incorrect address; change of residence; death
Exposure	Aged 49–64 years
Outcomes	Understanding of screening Screening experience Expectation of information needs
Notes	The survey was conducted as part of a DPhil project. A sample size of 1000 (8.3%) out of a possible 12 000 women was taken, allowing a precision level of 4% with a response rate of between 50% and 70%; 72% of the respondents had been invited for breast screening

Study

Zapka³⁸

Study design	Non-comparative descriptive study
Study quality score	–
Methods	Appropriate population – adequately addressed Participation rate – 1134/1433 (79%) women completed the telephone survey (39 could not be contacted, 253 refused to participate, seven women provided only partial information) Outcome definition – poorly addressed; few details provided Outcome assessment – not blind Outcome measure – self-report via administered telephone survey Exposure assessment – well covered Exposure measure – administrative records Study length – 15 months
Population	Country – USA Setting – four health maintenance organisations (HMOs): Group Health Cooperative; Henry Ford Health System/Henry Ford Medical Group; Kaiser Permanente Colorado; and Kaiser Permanente Northern California Screening status – received abnormal mammogram result Participants – 1433 mainly white non-Hispanic women 50 to over 75 years with abnormal mammography results enrolled in one of four care plans across the USA Inclusion criteria – abnormal bilateral screening mammogram; no mammogram or ultrasound during the preceding 270 days Exclusion criteria – enrolled for fewer than 210 of 270 preceding days; age less than 50 at the time of index mammogram; history of invasive or in situ breast cancer; active refusal; no contact
Exposure	Abnormal mammogram results: (1) asked to return for additional views (mammography or ultrasound); (2) immediate clinical evaluation, biopsy or surgery; and (3) repeat imaging (mammography or ultrasound) in 4–6 months (<i>n</i> = 1134)
Outcomes	Receipt of conflicting or confusing information
Notes	A sample of women was identified in each of 15 successive months (8/2000–10/2001). Three categories of abnormal mammogram were defined and, each month during recruitment, a random sample of 11 women was drawn from each of the three test result categories for each site. To minimise the likelihood of selecting women into the sample returning for re-examination of previous abnormal tests it was decided that an interval of 270 days would be sufficient. Approximate interview time was 20 minutes with duration largely dependent on the extent of follow up

APPENDIX 10: DESCRIPTION OF QUALITATIVE STUDIES

Study	Brown³⁹
Study design	Qualitative
Study quality score	++
Methods	<p>Research design – well covered</p> <p>Recruitment – adequately addressed; a convenience sample of women who had undergone surgery for DCIS between 6 and 24 months previously was recruited from one consultant breast surgeon at a South Australian teaching hospital</p> <p>Data collection – open-ended individual interviews; tape recorded and transcribed</p> <p>Participant/researcher relationship – not reported</p> <p>Ethics – well covered</p> <p>Data analysis – well covered</p> <p>Finding credibility – well covered</p> <p>Study length – not reported</p>
Population	<p>Country – Australia</p> <p>Setting – secondary care</p> <p>Screening status – treated for DCIS</p> <p>Participants – six women who had undergone surgery for a non-invasive breast cancer (DCIS) in the care of one consultant breast surgeon</p> <p>Inclusion criteria – treated for DCIS with surgery</p> <p>Exclusion criteria – not reported</p>
Themes	<p>Information needs</p> <p>Information sources</p> <p>Meaning of diagnosis for daughters</p> <p>Timing of information delivery</p>
Notes	One woman was inadvertently included who had undergone surgery four years previously and the increased time span since surgery influenced her ability to recall information

Study	Cameron⁸⁸
Study design	Qualitative
Study quality score	+
Methods	<p>Research design – well covered</p> <p>Recruitment – adequately addressed; convenience samples of women for focus groups in the screening eligible age range were organised through community or recreation centre programmes run for the over fifties, a Mature Employment Centre, a Business and Professional Women's group and community health workers; each of BreastScreen Aotearoa's six lead providers was asked to identify three women who had been recalled for further tests who would be willing to read a leaflet and answer the relevant questionnaire</p> <p>Data collection – focus groups (topic guide); open-ended questionnaire responses</p> <p>Participant/researcher relationship – not reported</p> <p>Ethics – not reported</p> <p>Data analysis – not reported</p> <p>Finding credibility – adequately addressed</p> <p>Study length – not reported</p>

Population	Country – New Zealand Setting – community screening programme Screening status – unclear Participants – 58 women aged 50–64 years eligible to join BreastScreen Aotearoa recruited from the general New Zealand population and 17 women aged 50–64 years recalled for assessment following a mammogram from six lead screening programme provider regions Inclusion criteria – not reported Exclusion criteria – not reported Comments on contents of screening information materials Information needs
Themes	
Notes	This report presents the findings of a review and evaluation of 14 BreastScreen Aotearoa health education print materials. The purpose was to determine whether the resources were effective in providing health education information that is accessible, easily understood and adequate for priority audiences. Four leaflets were of particular interest: (1) 10102 general screening leaflet, (2) 10117 leaflet given out after mammography, (3) 10147 leaflet of frequently asked questions and (4) 10118 leaflet given to women recalled for assessment. The first three leaflets were assessed by 58 women in a series of eight focus groups around New Zealand and the last leaflet was assessed by 17 women asked to return for further investigation during their recall appointment (open-ended questionnaire answers)

Study **De Morgan**²⁵

Study design	Qualitative
Study quality score	++
Methods	Research design – adequately addressed Recruitment – 26/35 (74%) women consented to participate (convenience sample) Data collection – focus groups (topic guide); tape recorded and transcribed Participant/researcher relationship – not reported Ethics – not reported Data analysis – well covered Finding credibility – well covered Study length – July 1998 Country – Australia Setting – secondary care Screening status – diagnosed with DCIS Participants – 26 women aged 40–70+ years from different socioeconomic regions in Sydney and Orange (a rural town in New South Wales) diagnosed with DCIS and recruited consecutively by their clinicians Inclusion criteria – diagnosed with DCIS; clinician with an interest in breast cancer Exclusion criteria – diagnosed less than six months prior to the study, poor spoken English; considered by clinician to be too ill to participate Response to the diagnosis Information needs Difficulty in decision making about treatment Lack of appropriate support services
Population	
Themes	
Notes	It is not clear whether all of the women were diagnosed as part of an organised screening programme. Fifteen clinicians known to the National Breast Cancer Centre with an interest in breast cancer were invited to participate in the study; seven clinicians, including both surgeons and radiation oncologists, agreed to be involved in the study. Five focus groups were conducted (five or six women attended each focus group). Four were conducted in Sydney and one was conducted in a rural town in New South Wales. This group of women may have had greater access to information and support than is general among women diagnosed with DCIS.

Study Hamilton²³

Study design	Qualitative
Study quality score	++
Methods	Research design – well covered Recruitment – women attending a breast screening service were invited to contact the research team through contact information on posters and leaflets placed at each of the screening venues; 27/48 (56%) women who subsequently received a normal result were sent a postal invitation Data collection – focus groups (topic guide); tape recorded and transcribed Participant/researcher relationship – not reported Ethics – not reported Data analysis – well covered Finding credibility – well covered Study length – not reported
Population	Country – UK Setting – breast screening service Screening status – due Participants – 48 women who attended the Warwickshire, Solihull and Coventry Breast Screening Service and who received a normal result Inclusion criteria – 50–64 years; women over 64 years if self-referred Exclusion criteria – not reported Experience of breast screening Information needs Suggestions for improving the results and recall letters
Themes	Four focus groups were conducted in locations that spanned the catchment area of the breast screening service. An average of seven women attended each discussion
Notes	

Study Lagerlund³²

Study design	Qualitative
Study quality score	++
Methods	Research design – well covered Recruitment – eligible women were sent invitation letters and a recruitment assistant attempted to contact all potential participants by telephone; 56/321 (17%) women agreed to take part and were sent a reminder letter Data collection – focus groups (topic guide); tape recorded and transcribed Participant/researcher relationship – not reported Ethics – not reported Data analysis – well covered Finding credibility – well covered Study length – eight months

Population	Country – Sweden Setting – community screening programme Screening status – recently screened women as well as non-attenders Participants – 321 women 44–74 years listed on the Uppsala County regional mammography programme register who recently attended for screening or who had not attended following at least two invitations Inclusion criteria – listed on the screening programme register; an identified telephone number; non-foreign name Exclusion criteria – not reported
Themes	Information needs Tailoring of information to avoid fear Avoidance of detailed information Inclusion of facts about breast cancer
Notes	Computer lists of randomised samples for the focus groups were generated from the mammography register in Uppsala County. A total of 31 women ultimately participated in eight focus groups that ranged in size from two to five women

Study **Marshall**²⁴

Study design	Qualitative
Study quality score	++
Methods	Research design – well covered Recruitment – adequately addressed; no recruitment details reported Data collection – focus groups (topic guide); tape recorded and transcribed Participant/researcher relationship – not reported Ethics – not reported Data analysis – adequately addressed Finding credibility – adequately addressed Study length – not reported
Population	Country – USA Setting – community screening programme Screening status – recent screening attenders and women due for screening Participants – 56 women aged 40 years and over who had attended for screening and 29 women who had not enrolled in the Breast and Cervical Cancer Control Programme Inclusion criteria – 40 years and over; a household income below 250% of the poverty level Exclusion criteria – not reported
Themes	Information needs Use of statistics Use of personal stories and testimonials Preference for positive emotional as opposed to fear appeals Difficult terminology

Notes

Study	Ong³⁶
Study design	Qualitative
Study quality score	++
Methods	<p>Research design – adequately addressed</p> <p>Recruitment – well covered; 1493/2132 (70%) women completed the postal questionnaire; response by study area ranged from 66% to 78%; 95% of women returned the questionnaire within three weeks</p> <p>Data collection – open-ended questionnaire responses</p> <p>Participant/researcher relationship – not applicable</p> <p>Ethics – well covered</p> <p>Data analysis – adequately addressed</p> <p>Finding credibility – well covered</p> <p>Study length – five months</p>
Population	<p>Country – UK</p> <p>Setting – eight breast screening centres</p> <p>Screening status – recalled for assessment</p> <p>Participants – 2132 consecutive women 50–64 years recalled for further investigation at eight breast screening centres throughout the UK</p> <p>Inclusion criteria – 50–64 years</p> <p>Exclusion criteria – recalled for technical reasons</p>
Themes	Information needs
Notes	Confusing terminology

Study	Padgett³⁷
Study design	Qualitative
Study quality score	++
Methods	<p>Research design – well covered</p> <p>Recruitment – adequately addressed; women were contacted by letter and telephone 6–8 months after their index abnormal mammogram; a structured interview survey protocol was administered to respondents ($n = 184$); a one-third subsample of women were invited to participate in a qualitative interview – 57/57 (100%) agreed to participate</p> <p>Data collection – in depth, face to face individual interviews (interview schedule)</p> <p>Participant/researcher relationship – not reported</p> <p>Ethics – adequately addressed</p> <p>Data analysis – well covered</p> <p>Finding credibility – well covered</p> <p>Study length – four years</p>

Population Country – USA
 Setting – two mammography screening sites
 Screening status – abnormal mammography results
 Participants – 57 English-speaking black non-Hispanic women with an average age of 52 years who had abnormal mammography findings from two screening sites in Harlem and Queens, New York
 Inclusion criteria – English speaking; black
 Exclusion criteria – not reported
 Themes Information needs
 Information provision
 Difficult terminology

Notes

Study Patnick⁸⁹

Study design Qualitative
 Study quality score +
 Methods Research design – well covered
 Recruitment – adequately addressed; no recruitment details reported
 Data collection – focus groups
 Participant/researcher relationship – not reported
 Ethics – not reported
 Data analysis – not reported
 Finding credibility – well covered
 Study length – not reported

Population

Country – UK
 Setting – three different screening unit locations
 Screening status – various
 Participants – women aged 35–64 years in two socioeconomic bands in three different locations (north, midlands and south)
 Inclusion criteria – non-attenders for screening were specifically included in the study
 Exclusion criteria – not reported

Themes

Information needs

Comments on leaflet design

The leaflet text is included with the article

Notes

Study**Pfeffer⁴⁰**

Study design

Qualitative

Study quality score

++

Methods

Research design – well covered

Recruitment – well covered; no specific details reported; however, the researchers failed to recruit women born in West Africa, who represent just under 7% of women living in Hackney (1991 census)

Data collection – focus groups (topic guide); tape recorded and transcribed

Participant/researcher relationship – well covered

Ethics – well covered

Data analysis – adequately addressed

Finding credibility – well covered

Study length – two years

Country – UK

Setting – community

Screening status – unclear

Participants – 146 women aged 35–64 years resident in Hackney (an ethnically diverse inner city borough in north east London) recruited from the community by health advocates and professional recruiters

Inclusion criteria – not reported

Exclusion criteria – health care workers; women who had received treatment for, or currently had, breast cancer

Information needs

Themes

The research explored women's perceptions of breast cancer and three approaches to encouraging early presentation (breast self-examination, breast awareness and the NHSBSP). It was carried out in Hackney, which has the lowest uptake of the NHSBSP in the country. The population is economically deprived and socially diverse. Twenty focus groups were held between 1996 and 1998. Sampling sought to capture the diversity of Hackney women and the groups were organised around a mixture of language, faith, skin colour and social status. Respondents were divided into two age groups: women ineligible for the NHSBSP (35–49 years) and women eligible for the NHSBSP (50–64 years). It is not clear whether the women were taking part in the breast screening programme

Study**Prinjha²⁶**

Study design

Qualitative

Study quality score

++

Methods

Research design – well covered

Recruitment – adequately addressed; no recruitment details reported

Data collection – face to face interviews (women were asked to talk uninterrupted about their mammography experience; supplementary questions were asked about specific issues); tape recorded

Participant/researcher relationship – not reported

Ethics – adequately addressed

Data analysis – adequately addressed

Finding credibility – well covered

Study length – 18 months

Population	<p>Country – UK</p> <p>Setting – community</p> <p>Screening status – DCIS diagnosis</p> <p>Participants – 10 women aged 52–69 years diagnosed with DCIS through screening mammography recruited throughout the UK by GPs, support groups, charities and screening centres</p> <p>Inclusion criteria – 50 years and older</p> <p>Exclusion criteria – not reported</p> <p>Knowledge of mammography screening and DCIS before diagnosis</p> <p>Information needs</p> <p>Difficult terminology</p>
Notes	<p>This group of women was part of a larger group of women (40) recruited to discuss their experiences of screening mammography for the DIPEX website. A maximum variation sample was chosen to include younger and older women from various social backgrounds</p>
Study Roche⁵⁸	
Study design	Qualitative
Study quality score	++
Methods	<p>Research design – well covered</p> <p>Recruitment – well covered; no recruitment details reported</p> <p>Data collection – standardised face to face interviews with open-ended questions (interview schedule); tape recorded</p> <p>Participant/researcher relationship – not reported</p> <p>Ethics – not reported</p> <p>Data analysis – adequately addressed</p> <p>Finding credibility – well covered</p> <p>Study length – not reported</p>
Population	<p>Country – USA</p> <p>Setting – breast screening clinics</p> <p>Screening status – unclear</p> <p>Participants – 232 low income women 50 years and older who visited one of six Centers for Disease Control and Prevention funded Breast and Cervical Cancer Control Program clinics in Houston, Texas</p> <p>Inclusion criteria – 50 years and older</p> <p>Exclusion criteria – not reported</p>
Themes	<p>Most commonly understood terms and phrases used in breast cancer education messages</p> <p>Least understood terms and phrases used in breast cancer education messages</p> <p>Information needs</p>
Notes	<p>The sample consisted of roughly equal proportions of white, African American and Hispanic women. Not clear whether the women were participating in an organised screening programme – 70% of women reported having a screening mammogram in the past two years</p>

Study	Savage⁹⁰
Study design	Qualitative
Study quality score	++
Methods	<p>Research design – well covered</p> <p>Recruitment – adequately addressed; participants were recruited by word of mouth using purposive sampling; no woman spoken to by the researcher refused to be involved, although several women spoken to by other women declined to take part</p> <p>Data collection – face to face interviews with open-ended questions (interview schedule but relatively unstructured); tape recorded and transcribed</p> <p>Participant/researcher relationship – not reported</p> <p>Ethics – not reported</p> <p>Data analysis – well covered</p> <p>Finding credibility – well covered</p> <p>Study length – not reported</p> <p>Country – Australia</p> <p>Setting – community</p> <p>Screening status – unclear; women were classified as having previously obtained a screening mammogram or not</p> <p>Participants – 20 women aged 46–69 years from a broad cross-section of the community known to the interviewer or recruited via purposive sampling</p> <p>Inclusion criteria – not reported</p> <p>Exclusion criteria – not reported</p> <p>Information needs</p> <p>Not clear whether the women were participating in an organised screening programme</p>
Themes	
Notes	

Study	Schechter⁹¹
Study design	Qualitative
Study quality score	–
Methods	<p>Research design – adequately addressed</p> <p>Recruitment – adequately addressed; no recruitment details reported</p> <p>Data collection – focus groups</p> <p>Participant/researcher relationship – not reported</p> <p>Ethics – not reported</p> <p>Data analysis – not reported</p> <p>Finding credibility – adequately addressed</p> <p>Study length – one month</p>

Population	Country – USA Setting – community Screening status – most of the participants had at least one mammogram Participants – 83 women aged 40–75 years drawn from two communities – Philadelphia and Kansas City Inclusion criteria – 40–75 years; white or black Exclusion criteria – personal or family history of cancer; ever been told that they might have breast cancer; participated in a focus group in the past 12 months; employed in health, marketing or advertising
Themes	Information needs
Notes	The National Cancer Institute conducted a focus group study whose purpose was to provide research evidence to help design an awareness campaign to increase mammography use. Eight focus groups were held with either 10 or 11 participants in June 1989. The number and composition of the groups were set so that inferences could be drawn about differences in response due to age, race and mammography history, with at least two groups established to reflect each of the variables. The locations were selected to represent urban and suburban settings. Five groups were held in Philadelphia and three groups were held in Kansas City. It is not clear whether women attended for mammography as part of an organised screening programme

Study Silverman⁹²

Study design	Qualitative
Study quality score	++
Methods	Research design – well covered Recruitment – well covered; women were randomly selected from a commercially maintained sample frame (National Decision Systems, Atlanta, Georgia); 191 women randomly selected within strata defined by census tract income and age were approached; 41/191 (21.5%) women agreed to take part, 52 refused, 98 women were disqualified Data collection – in depth face to face interviews (interview checklist); tape recorded and transcribed Participant/researcher relationship – not reported Ethics – not reported Data analysis – well covered Finding credibility – well covered Study length – not reported
Population	Country – USA Setting – community Screening status – unclear Participants – 191 sociodemographically diverse women aged 27–84 years without a history of breast cancer listed on a commercially maintained sample frame Inclusion criteria – meet racial, age or socioeconomic criteria Exclusion criteria – history of breast cancer
Themes	Information needs
Notes	80% of participants had had at least one mammogram. It is not clear whether women attended for mammography as part of an organised screening programme

Study

Zapka⁹³

Study design

Qualitative

Study quality score

+

Methods

Research design – well covered

Recruitment – poorly addressed; few details provided

Data collection – focus groups; transcribed

Participant/researcher relationship – not reported

Ethics – not reported

Data analysis – adequately addressed

Finding credibility – adequately addressed

Study length – one month

Country – USA

Population

Setting – community

Screening status – unclear

Participants – 19 women aged 65–75 years and older with no personal breast cancer history recruited from a Western Massachusetts community by a professional research firm

Inclusion criteria – age 65–75 years and older

Exclusion criteria – personal history of breast cancer

Information needs

Themes

Notes

This study was undertaken to address an objective of the Forum on Breast Cancer Screening in Elderly Women: to develop a research agenda for unanswered questions. In April 1990, three focus groups were conducted in Western Massachusetts (one group with women aged 65–75 years; a second group with women aged 75 years and older; a third group with primary care physicians). It is not clear whether the women ever participated in an organised screening programme

APPENDIX 11: DESCRIPTION OF EXPERT OPINION REPORTS AND CHECKLIST TYPE STUDIES INCLUDED IN THE INVITATION LEAFLET EVIDENCE PROFILES

Study	Details
Slaytor ⁵⁰	Australia 10-item score sheet used to evaluate 58 breast screening leaflets. No information provided on development of items
Lawrence ⁸⁷	USA List of qualitative responses to standardised probes asked during validity testing of a mammography decision aid
Schwartz ²²	USA 13-page questionnaire developed as part of a larger project on women's decision making about mammography
Croft ⁴⁷	Australia 16-item rating form used to assess 54 publications about breast tests. Rating form developed using a consumer oriented book about making health decisions and the General Medical Council guidelines for providing information about screening tests
Kurzenhauser ⁴⁹	Germany 31-item checklist used to assess 27 mammographic screening leaflets. The checklist was adapted from Slaytor ⁵⁰
Barratt ⁷⁵	Australia List of considerations and suggestions for developers of decision aids for screening interventions
Davey ²¹	Australia 15 statements about breast screening were posed to women in order to assess the importance of specific information to mammography decision making. No information provided on the development of items
Giordano ⁴⁸	Italy 36-item score sheet used to assess invitation letters and information leaflets provided by 47 Italian breast cancer screening programmes. Score sheet developed with the consensus of national communication experts

