IMPROVING THE QUALITY OF THE WRITTEN INFORMATION SENT TO WOMEN ABOUT CERVICAL SCREENING

Evidence-based Criteria for the Content of Letters and Leaflets

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PREFACE

These guidelines are an update of the 1997 NHS Cervical Screening Programme (NHSCSP) Publications No 5 and No 6. They are 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 Cervical Screening Programme and Cancer Research UK. The authors and the NHSCSP would like to give special thanks to all those who generously provided them with unpublished work and grey literature.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.

EXECUTIVE SUMMARY

Review aims

This systematic review was commissioned to update NHSCSP Publications No 5 and No 6, which were published in 1997. It aims to improve the quality of the content of letters and leaflets sent to women at all stages of the cervical screening process. In particular, the review addressed the following questions:

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

The answers to these questions have guided the recommendations for the content of leaflets and letters to be used in the NHS Cervical Screening programme (NHSCSP).

Methods

Data sources

Systematic searches of 12 electronic databases (1996 to July 2004) were conducted. Additional references were located by searching the table of contents of selected journals and the reference sections of relevant papers. Grey literature was identified from Internet resources and contact with subject area specialists. Both published and unpublished studies were included.

Study selection

All studies that evaluated the content of information materials provided to women about cervical screening or that addressed the information needs of women at all stages of the cervical 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 what the test involves') was prepared. Outcomes were drawn from NHSCSP Publication No 6 and new research evidence. 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. This was adapted to suit the review questions and 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 were considered separately for every outcome.

Results

A total of 1063 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, 233 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 79 of the papers. Following data extraction and assessment of methodological quality, a total of 32 papers were included in the systematic review.

Recommendations have been included for letters that relate to the NHSCSP. However, little research literature has been published that specifically addresses questions concerning the content of screening letters and the information needs of women receiving these materials.

Summary recommendation tables plus additional notes have been developed for the invitation, abnormal result, colposcopy and treatment leaflets. There has been limited new research evidence applicable to the invitation leaflet. However, new evidence was considered for a number of outcomes detailed in the other leaflets. The quantitative evidence included in the review received quite low overall evidence ratings. This may generally be explained by the study designs used (ie cross-sectional and descriptive studies), which are rated lower in the GRADE evidence hierarchy as opposed to methodological issues such as selection bias or unreliable outcome assessment.

Key points of the new evidence-based guidance are that:

- simple statements should be used to describe cervical screening test results instead of complicated descriptions
- information about human papillomavirus (HPV) infection should be included when explaining the causes of an abnormal screening result
- further practical details about the colposcopy visit should be presented
- more information about aftercare following colposcopy and/or treatment should be provided
- a number of terms and statements commonly used in screening materials are not well understood by women and should be avoided if possible (eg ‘pre-cancer’, ‘atypical’, ‘certain changes’, ‘cure’, ‘no big deal’ and ‘wart virus’).

Recommendations

The NHSCSP should continue to use the existing letter templates. However, consideration should be given to the signatory, provision of fixed appointments and result availability.

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 NHSCSP should endeavour to produce leaflets that incorporate the concepts presented in the full summary recommendation tables. Examples of items that might be included in each leaflet are given below.

Invitation leaflet

- Nature and purpose of the test.
- Validity of the test (including information on false positive and false negative results).
- Eligible population and screening interval.
- Test procedure.
- Test results (including the meaning of inadequate, normal and abnormal results).
- Causes of an abnormal result.
- Further tests.

The possible reasons for further tests and the likelihood of being asked to return for another test should be given in the invitation leaflet. However, detailed information about colposcopy and subsequent treatment should not be given until later in the screening process. The amount of information provided about further tests and investigations and the effectiveness of treatment and follow up should increase as a woman progresses from the abnormal result stage to colposcopy and treatment.

Abnormal result leaflet

- Meaning and causes of an abnormal result (describe the frequency of follow up).
- Abnormal result outcomes (ie women are unlikely to have cancer).
- Further tests and investigations (explain what colposcopy involves).
- Effectiveness of treatment.
- Importance of attending follow up.
- Sexual advice.

Colposcopy leaflet

- Explanation of why colposcopy is needed.
- Description of the colposcopy visit (include practical information).
- Explanation of the outcomes of colposcopy examination (including the possibility that treatment may be performed at the first visit).
- Effectiveness of treatment.
- Follow up.
- Aftercare (including practical information such as details about bleeding/discharge and sexual advice).

Treatment leaflet

- Explanation of why treatment is needed.
- Description of the treatment visit (including practical information).
- Aftercare (including practical information and sexual advice).
- Explanation of the outcomes and effectiveness of treatment.
- Follow up.

1. INTRODUCTION

1.1 Cervical cancer

Cervical cancer is among the most common female cancers in many countries in the developing world. In the UK, it is ranked eleventh for women. Currently, around 3000 new cases of invasive cervical cancer are diagnosed each year in the UK.[1] Although incidence and mortality have decreased since the late 1980s, the disease still caused 1123 deaths in 2002.[2]

1.2 Screening

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'.[3] The aim of screening is to reduce mortality or morbidity 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 Cervical Screening Programme

Cervical screening is not a test for cancer. It is a method of preventing cancer by detecting and treating early abnormalities that, if left untreated, could lead to cancer in a woman's cervix (the neck of the womb). Until recently, all women between the ages of 20 and 64 in the UK were eligible for a free cervical screening test every three to five years, depending on where they lived. However, following recent evidence, screening will start at age 25 years and will be conducted at different intervals depending on age.[5] From the next scheduled screening appointment, the screening intervals will be three yearly for women aged 25–49 and five yearly for those aged 50–64. Screening is ceased for women aged 65 and over unless they have not been screened since the age of 50 or they have recently received an abnormal result. Women younger than 25 years will no longer be routinely invited for screening.

1.3.1 Screening methods

Until recently, most cervical screening was conducted using the Papanicolaou (Pap) smear test in which a sample of cells is scraped from the cervix at the junction between the endocervix (covered by columnar epithelium) and the ectocervix (covered by squamous epithelium). This area is known as the transformation zone. In this technique, the collected cells are smeared onto a slide, fixed and then sent to the laboratory for examination. A newer method for obtaining a sample, known as liquid based cytology (LBC), has been assessed at three pilot sites across England and is now being introduced. Rather than smearing the sample onto a microscope slide, as happens with the Pap smear, the head of the spatula or brush, where the cells are lodged, is broken off into a small glass vial containing preservative fluid or rinsed directly into the preservative fluid. At the laboratory, the sample is mixed and treated to remove unwanted material, and then a thin layer of the cell suspension is placed on a slide

for inspection. The remaining sample is available for subsequent human papillomavirus (HPV) testing.[6]

1.3.2 Introduction of HPV testing into cervical screening

If HPV testing is adopted for widespread use within the NHSCSP, women taking part in the programme will need to receive appropriate information about all aspects of HPV infection.[7] The sexually transmitted nature of HPV, lack of knowledge about the virus and the health of sexual partners will raise new issues for women whose result is positive at screening.[8–10] The dissemination of thorough, sensitive and factual information will be essential to address the complex issues raised by HPV testing.[7,10–12]

1.3.3 Cervical screening results

In England in 2003/2004, approximately 3.5 million women aged 20–64 years had a cervical screening test.[13] The majority of women that attended a screening appointment during this period received a normal result;[13] these women will be recalled for another routine screening test within three to five years. However, in the same period, 249 000 women aged 20–64 years received an abnormal result, indicating that the laboratory had identified cervical cell changes known as dyskaryosis.[13] Dyskaryosis ranges from borderline through to severe. Depending on the persistence and degree of severity of dyskaryosis, women may be asked to have a repeat screening sample in 6–12 months or they may undergo a further procedure called colposcopy to provide a histological diagnosis of cervical intraepithelial neoplasia (CIN). Not all grades of abnormality are referred for immediate treatment.[6]

Inadequate screening samples are those for which no result can be issued. These include samples containing blood and other matter that make it impossible to see the cells on the slide properly. If this occurs, women are invited back for a second test.[6] Currently, this affects about 9% of women screened.[13] The pilot LBC study showed that the introduction of the new technology resulted in a clear reduction in the reported rate of inadequate screening samples (from 9% to 1–2%).[14] A reduction in the inadequate rate could be of considerable benefit to women in terms of reducing anxiety, uncertainty and the need for repeat screening samples.[14]

1.4 Psychological response to cervical screening

Women are known to experience high levels of anxiety at all stages in the process of detecting and treating cervical abnormalities.[15–19] Other negative emotional reactions include depressed mood, impaired sexual functioning, changes in self-perception (impaired body image, lowered self-esteem), anger, guilt, sadness and embarrassment.[16–18,20] Written information has been used as an intervention to minimise adverse psychological consequences and improve screening uptake.[15,16,18,21–23] Such educational interventions appear to improve knowledge scores,[16,24–26] but the impact on formal measures of anxiety is unclear.[18,24–28] Nevertheless, the provision of good reliable information is highly valued by women.[24,29–31]

1.5 Women's understanding of cervical screening

Screening healthy women for abnormal cervical changes exposes them to fears about cancer and their current health status.[15,16] Women often do not understand the risks and uncertainties and are less aware of the limitations associated with screening than of the benefits.[32] The main causes of anxiety for women have been identified as misconceptions

about the purpose of the test and the health implications if an abnormality is detected, further investigated and possibly treated. 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 an abnormal result.[15]

The ongoing challenge of general screening information is to convey that dyskaryosis and CIN fall between normality and invasive disease and that medical intervention is preventative rather than curative. A woman going through all of the stages of the cervical screening process from initial testing to colposcopy and possible treatment may receive up to 10 letters (including reminders) and at least three leaflets.[33] Researchers looking at the information needs of women in the cervical screening programme have shown that women feel inadequately informed at almost every stage of the screening process.[15] 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 the cervical screening programme requires careful consultation and assessment.

In a study of 42 women attending a pre-colposcopy counselling session, Byrom et al.[34] developed a set of 38 standards to assess current UK colposcopy leaflets. The women were encouraged to discuss their concerns and to ask questions about abnormal screening samples and colposcopy; those questions that were asked by 50% or more of the women were used to devise the criteria. None of the leaflets in use at that time answered all 38 criteria, and few leaflets addressed the majority of the points raised. The NHSCSP leaflet scored the highest, with 82.9% of the criteria being addressed.[34] This study clearly demonstrates that a gap remains between the information needs of women and the available screening materials; hence, it is timely and important to integrate the current research evidence in an updated set of guidelines.

1.6 Written information and informed choice

The *NHS Cancer Plan*[35] 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. A recent White Paper[36] also emphasised the need for more factual health information that is up to date and accurate. An important priority of the NHSCSP is the continual improvement of the quality of written information sent to women about cervical screening at all stages of the screening process.[15] The cervical screening programme is also committed to the provision of clear and balanced information about the benefits and limitations of cervical screening for all women.[6] This updated systematic review of the literature related to cervical screening information presents a set of recommendations that will help to inform the development and revision of materials produced by the cervical screening programme. The recommendations were shaped by the ethical imperative of all screening programmes, ie to do more good than harm.

1.7 Review aims

This systematic review was commissioned to update the 1997 NHSCSP Publications No 5 and No 6, which provide guidance to improve the quality of the content of letters and leaflets sent to women at all stages

of the cervical screening process. In particular, the review addressed the following questions:

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

The answers to these questions have guided the recommendations for the content of leaflets and letters to be used in the NHSCSP.

2. METHODS

2.1 Electronic database search strategy

Systematic searches were conducted of the following electronic databases: MEDLINE, PsychINFO, EMBASE, CINAHL, 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 searches covered the period from 1996 to July 2004.

Appendix 1 shows the search strategy used for the four main electronic databases (MEDLINE, PsychINFO, EMBASE and CINAHL). A combination of text terms and medical subject heading (MeSH) terms was used to maximise the amount of literature retrieved.

2.2 Other search methodologies

The NHSCSP literature database and update publications were searched by one reviewer from 1995, Issue No 1, to 2004, Issue No 19, August (note, however, that Issue No 6, March 1998, was not available for review). The journals included in this resource are listed in Issue 1, September 1995, but no update of this publications list has been produced since (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) administration/economics and evaluation; (3) primary care and smear taking; (4) diagnosis/management and treatment; (5) psychological aspects/acceptability and health education; and (6) general interest.

The tables of contents of selected journals were handsearched from April to December 2004. The relevant journals were: *American Journal of Epidemiology*, *American Journal of Health Promotion*, *American Journal of Public Health*, *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 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* and *Psychology Health and Medicine*.

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 August

2004 (see Appendix 2). Three main categories of sites were searched: (1) cervical screening services; (2) general health sites and cancer agencies; and (3) women's health sites.

An information letter was distributed at the April 2004 International Agency for Research on Cancer Working Group Meeting on Cervical Cancer Prevention, and an email was sent in June 2004 to a group of international cervical screening information experts to solicit any relevant unpublished reports and/or research.

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 cervical screening at all stages of the cervical screening process, including letters, leaflets, booklets and sheets.
- Studies that specifically evaluated the content of any information materials provided to women about cervical 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 cervical screening process.
- Studies that did not (as a primary objective) evaluate the information needs of women at all stages of the cervical screening process but that provided evidence which helped to answer the review aims.

2.4 Exclusion criteria

Studies that looked at:

- cervical screening from a general practice point of view
- laboratory based research
- interventions centred on medical professional education
- non-information based predictors of cervical screening uptake
- risk factors for cervical screening (except smoking and HPV related information needs)
- cervical screening methods/technology
- protocols and technical aspects of treatment for CIN and cervical cancer
- research that was not original (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, older and adolescent women, and individuals from particular cultural or linguistic groups)
- knowledge, attitudes, health beliefs or barriers towards cervical screening without reference to information needs or written information materials.

2.5 Study selection and review process

There were six stages to the study selection and review process. The study selection (stages 1–3) process 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

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 3). The data extraction form was developed using guidelines produced by the NHS Centre for Reviews and Dissemination (CRD)[37] and several other publications.[4,38,39] Any uncertainty was resolved by discussion.

The data extracted included identification of each study's aims, setting, design, sample size and follow up rates along with the study's 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 4, which was adapted from publications produced by the Non-Randomised Studies in Cochrane Reviews Methods Group[40] and the Agency for Healthcare Research and Quality.[41] The quality of each study was then scored using methodology checklists adapted from Scottish Intercollegiate Guidelines Network (SIGN),[42] Critical Appraisal Skills Programme (CASP)[43] and the New Zealand Guidelines Group[44] for quantitative designs (Appendix 5). A single checklist derived from CASP[43] and the UK Government Chief Social Researchers' Office[45] was developed for qualitative studies (Appendix 5). 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 Appendix 6 (quantitative studies) and Appendix 7 (qualitative studies). 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.[46] 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,

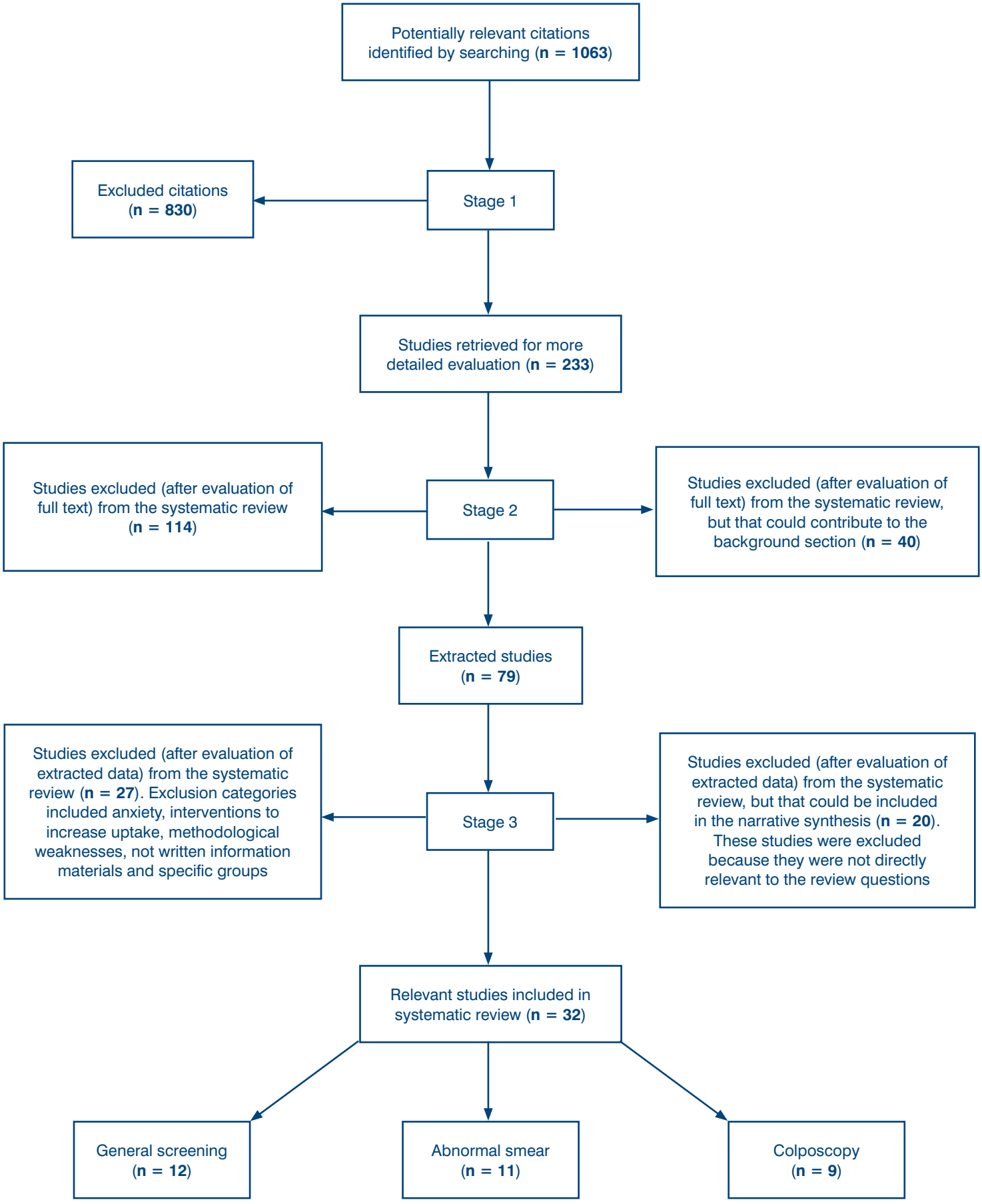

Figure 1 Flow diagram of study selection process.

consistency and directness.[46] One of the main benefits of the GRADE 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 what the test involves') was prepared. Outcomes were drawn from the 1997 NHSCSP report[15] and new research evidence. Quantitative and qualitative studies were considered separately for every outcome.

2.10.1 Quantitative studies

Study design and study quality were determined as 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. The categories were high (randomised controlled 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, whereas 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. 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 Study Methodology Checklist 5 (Appendix 5). 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. Details of this process are given in Appendix 8.

2.11 Stage 6: recommendations

The standards for the production of evidence-based guidelines have become increasingly rigorous since the publication of the 1997 NHSCSP report.[15] In the original publication, a recommendation system was adopted that incorporated two distinct levels: definite and suggestive. In the updated guidelines, a separate recommendation system with three levels (screening standard, new definite and suggestive) has been adopted. The three levels are described in more detail in Table 1. The definite and suggestive categories cannot be compared between the two versions of the guidelines because they are based on different criteria.

Table 1 Description of report recommendation system

Recommendation	Recommendation definition
Screening standard (definite recommendations from 1997 report)	Existing definite (D) recommendation set by the NHSCSP in the 1997 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
New definite (D)	New definite (D) recommendation where available quantitative and/or qualitative research evidence was graded as high and/or moderate
Suggestive (S)	Existing suggestive (S) or optional recommendation set by the NHSCSP in the 1997 report for which no new evidence was available for evaluation OR New quantitative and qualitative research evidence was available and graded as low and/or very low New suggestive (S) recommendation where available quantitative and qualitative research evidence was graded as low and/or very low

3. RESULTS

3.1 Search results

A total of 1063 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, 233 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 79 of the papers (7% of all identified citations; 79/1063).

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 total of 32 papers were included in the review (3% of all identified citations; 32/1063), of which 12 addressed general screening issues, 9 were focused on colposcopy and 11 investigated issues related to the receipt of an abnormal result.

The literature was drawn from studies conducted in the UK, Sweden, the USA, Australia, Canada, the Netherlands and Italy. A full description of all the quantitative and qualitative studies included in the systematic review is in Appendices 6 and 7.

3.2 Report recommendation system

Outcomes in the 'main issues' sections of the original report for which no new evidence was obtained during the current review process were designated as 'screening standard' or 'suggestive' depending on the recommendation level set by the 1997 NHSCSP report.[15]

A 'new definite' recommendation was assigned to individual outcomes where a body of quantitative and/or qualitative research evidence was graded as 'high' and/or 'moderate'. A 'suggestive' recommendation was assigned to individual outcomes where a body of quantitative and qualitative research evidence was graded as 'low' and 'very low'. If an outcome was given a 'suggestive' recommendation by the original report and the new research evidence was graded as 'high' and/or 'moderate', the recommendation level in the updated guidelines was changed to 'new definite'.

If an outcome was given as a 'definite' recommendation by the 1997 NHSCSP report[15] and the new research evidence 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 research evidence base in the 1997 NHSCSP report[15] was determined to be weak.

All outcomes included in the 'optional issues' sections of the original report were designated as 'suggestive' and incorporated into the 'main issues' sections of the updated guidelines. If new research evidence relevant to a particular outcome in one of these sections was graded as 'high' and/or 'moderate', the recommendation level in the updated guidelines was changed to 'new definite'. If new research evidence relevant to a particular outcome in one of these sections was graded as 'low' and/or 'very low', the recommendation level remained as 'suggestive'.

3.3 Letters

The existing letters used by the NHSCSP are based on the guidance published in NHSCSP Publications No 5 and No 6 and have been approved by the Advisory Committee on Cervical Screening.[15] Since the publication of the 1997 report, very little research evidence has been produced that specifically addresses questions related to the content of cervical screening programme letters and the information needs of women receiving these materials. However, a body of evidence related to the following outcomes can be considered: GP as the signatory, fixed appointments and availability of results.

3.3.1 Invitation letter

Fixed appointments

One randomised controlled trial,[51] one retrospective case–control study[52] and one qualitative study[69] provided some evidence of support for the use of invitation letters with fixed appointments instead of open invitations. Women felt that they would be more likely to attend for screening if they were sent a fixed appointment.[52,69] Although a fixed appointment may be the most effective strategy for encouraging attendance, it may not be the most cost-effective.[15]

GP as the signatory

Two randomised controlled trials[47,51] and one cross-sectional study[54] were identified by the search. The two trials looked at screening invitations from different sources of authority and were primarily concerned with screening uptake. One trial was conducted in general practice in Australia among 7000 potentially eligible women overdue for screening, and the other involved 8385 eligible women due for screening who were listed on the practice rosters of participating GPs in the city of Turin. Both reported a significant increase in uptake for invitation letters from GPs compared with invitation letters from health clinics[47] and from screening programme coordinators.[51] Similar results were reported for the observational study.

3.3.2 Colposcopy letter

Result availability

Eight studies were identified by the search – three qualitative and five quantitative.[25,26,28,30,31,34,65,66] Women consistently questioned when the examination results would be available. The provision of information about the expected time frame for the receipt of results may help to address anxiety experienced at this stage of the screening process.

3.3.3 Recommendations

We recommend that the screening programme should continue to use the existing letter templates but modifications should be considered according to the research evidence described in this section. Also, care should be taken to ensure that the language used in the letters is consistent with that recommended for the leaflets. Abnormal result letters should include the medical term for the observed condition (eg dyskaryosis or cervical intraepithelial neoplasia), regardless of the signatory. This enables women to seek further information from appropriate sources. 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 ensure that abnormal result letters are not sent so that they arrive at a weekend or on a Friday when many women may have difficulty contacting their care providers.[68]

Table 2 Invitation letter outcome evidence profiles

	Assessment					Summary of findings	
Studies	**Design**	**Quality**	**Consistency across studies**	**Directness**	**Other factors***	**Overall assessment**	**Overall recommendations**
6. Appointment information 6.4 Fixed appointment time							
NHSCSP[15]						No equivalent	Suggestive
Johnston[52]	RCC	+	No important inconsistency	Direct	None	Low	
Segnan[51]	RCT	++		Direct			
Van Til[69]	Qualitative	++	Only one study	Uncertain	None	Low	
14. Signatory 14.1 GP signatory							
NHSCSP[15]						Optional	Suggestive
Bowman[47]	RCT	++	No important inconsistency	Uncertain	None	Very low	
Kant[54]	CSS	+		Direct			
Segnan[51]	RCT	++		Direct			

CSS, cross-sectional study; RCC, retrospective case–control study; RCT, randomised controlled trial.
*Imprecise or sparse data, strong or very strong association, high risk of reporting bias, evidence of a dose–response gradient, effect of plausible residual confounding, close conformity of findings based on direct evidence.

Table 3 Colposcopy letter outcome evidence profiles

	Assessment					Summary of findings	
Studies	**Design**	**Quality**	**Consistency across studies**	**Directness**	**Other factors***	**Overall assessment**	**Overall recom-mendations**
3. Colposcopy visit 3.3 Mention when the results will be available							
NHSCSP[15]						Screening standard	Screening standard
Gath[30]	NCDS	++	No important inconsistency	Direct	None	Very low	
Olamijulo[25]	NCDS	+		Direct			
Bonevski[31]	NCDS	+		Direct			
Tomaino[26]	Quasi-RCT	+		Direct			
Howells[28]	RCT	++		Uncertain			
Kavanagh[65]	Qualitative	++	No important inconsistency	Direct	Close conformity based on direct evidence	High	
Byrom[34]	Qualitative	++		Direct			
Neale[66]	Qualitative	++		Direct			

NCDS, non-comparative descriptive study; Quasi-RCT, quasi-randomised trial; RCT, randomised controlled trial.
*Imprecise or sparse data, strong or very strong association, high risk of reporting bias, evidence of a dose–response gradient, effect of plausible residual confounding, close conformity of findings based on direct evidence.

3.4 Leaflets

3.4.1 Invitation leaflet

There was limited new evidence in the research literature to inform the recommendations set out in Table 4 for the invitation leaflet. Where new research evidence was considered, it was graded as 'low' and/or 'very low' for every outcome examined. For the majority of the outcomes, the recommendations were determined following a review of the references in the original report. In spite of a general lack of research evidence in this section, several important issues were raised in the literature. For example, the term 'precancer' is not well understood and its use should be avoided when describing early cervical cell changes. Also, women's understanding of cervical screening test results has been found to improve when simpler statements are used instead of more complicated descriptions. Women taking part in several studies requested further information about HPV infection, which led to the inclusion of 'Explain the cause(s) of an abnormal screening result' under 'Further tests'. Finally, the term 'cure' should not be used to reassure women who have received an abnormal screening result that the vast majority of conditions found can be treated.

Table 4 Invitation leaflet: summary of recommendations

Main issues	Overall assessment		
Outcomes	**Quantitative studies**	**Qualitative studies**	**Overall recommendations**
1. Nature of the test			
1.1 Explain the preventative nature of the test		Very low	Screening standard*
1.2 Exclude the timescale for cervical cancer to develop			Screening standard
2. Purpose of the test			
2.1 Explain the purpose of the test			Screening standard
2.2 Mention the detection of early cell changes; avoid using the term 'pre-cancer'		Very low	Screening standard*
2.3 Exclude that the purpose of the test is to detect cancer			Screening standard
3. Validity of the test			
3.1 Mention the validity of the test	Very low		Screening standard*
4. Eligible population			
4.1 Mention who the test is for			Screening standard
4.2 Refer to 'all' women			Screening standard
4.3 Mention the age group			Screening standard
4.4 Mention that the test is for women who have ever had sex			Screening standard
4.5 Mention specific issues for older and younger women			Suggestive†
4.6 Mention that the cervical screening test is still applicable for menopausal women			Suggestive†
5. Screening interval			
5.1 Mention the screening interval			Screening standard
5.2 Mention why the specified interval is used		Very low	Screening standard*
6. Test procedure			
6.1 Explain what the test involves	Low	Very low	Screening standard*
6.2 Describe the location of the cervix			Screening standard
6.3 Mention how long the test will take			Screening standard
6.4 Describe how the test will feel			Screening standard
6.5 Explain what the speculum is			Screening standard
6.6 Mention not to make an appointment for during a period			Suggestive†
6.7 Mention to avoid using spermicides before having a screening sample			Suggestive†
6.8 Mention that a full skirt is appropriate to wear			Suggestive†
7. Choice of venue			
7.1 List options in the leaflet or on a separate sheet	Low		Screening standard*
8. Sample taker			
8.1 Mention who takes the sample			Screening standard
8.2 Mention if the woman's GP takes the sample	Low		Screening standard*
8.3 Mention the availability of a female sample taker	Low	Low	Screening standard*

Table 4 Continued

Main issues	Overall assessment		
Outcomes	**Quantitative studies**	**Qualitative studies**	**Overall recommendations**
9. Test results			
9.1 Explain how to obtain the result			Screening standard
9.2 Mention approximate waiting time			Screening standard
9.3 Explain the meaning of inadequate, normal and abnormal results	Very low	Very low	Suggestive
9.4 Mention that the majority of screening samples are normal			Suggestive†
10. Further tests			
10.1 Explain the possible reasons for further tests			Suggestive†
10.2 Mention the likelihood of being asked to return for further tests			Suggestive†
10.3 Explain the cause(s) of an abnormal screening result		Low	Suggestive
10.4 Mention that the vast majority of conditions found can be treated; avoid using the term 'cure'			Suggestive†
10.5 Exclude any information about colposcopy and treatment			Screening standard
11. Preventative information			
11.1 Give preventative information			Suggestive†
11.2 Explain the role of smoking	Low		Suggestive†
11.3 Explain the role of condoms			Suggestive†
12. Further information			
12.1 Explain where the woman can get further information; provide a name/ telephone number and provide names of organisations/books			Screening standard

*Recommendation retained as 'Screening standard' following review of references in the original report.[15]
†'Suggestive' or 'Optional issue' recommendation set by the NHS Cervical Screening Programme in the original report.[15]

Notes to Table 4

Recommendation 2: Purpose of the test

2.2 Mention the detection of early cell changes

- Evidence collected from women who have received an abnormal screening result indicates that the term 'precancer' is not well understood and should be avoided.[29,60,65]

Recommendation 9: Test results

9.3 Explain the meaning of inadequate, normal and abnormal results

- It is important to convey that a normal result means 'low risk rather than no risk' of developing future cervical abnormalities.[48,50]
- Women's understanding of cervical screening test results is improved when simpler statements are used instead of more complicated descriptions.[48,50]

Recommendation 10: Further tests

10.3 Explain the cause(s) of an abnormal screening sample

- Further information about HPV infection was requested by women taking part in several studies.[9,11,61]
- When describing HPV infection, the term 'wart virus' should be avoided.[9]

10.4 Mention that the vast majority of conditions found can be treated

- Evidence collected from women who have received an abnormal screening result indicates that the term 'cure' creates confusion and should be avoided.[63]

Table 5 Invitation leaflet outcome evidence profiles: main issues

	Assessment					Summary of findings	
Studies	**Design**	**Quality**	**Consistency across studies**	**Directness**	**Other factors***	**Overall assessment**	**Overall recommendations**
1. Nature of the test 1.1 Explain the preventative nature of the test							
NHSCSP[15]						Screening standard	Screening standard†
Evans[61]	Qualitative	+	No important inconsistency	Uncertain	None	Very low	
Van Til[69]	Qualitative	++		Uncertain			
2. Purpose of the test 2.2 Mention the detection of early cell changes							
NHSCSP[15]						Screening standard	Screening standard†
Evans[61]	Qualitative	+	Only one study	Uncertain	None	Very low	
3. Validity of the test 3.1 Mention the validity of the test							
NHSCSP[15]						Screening standard	Screening standard†
Michie[50]	Quasi-RCT	+	Only one study	Uncertain	None	Very low	
5. Screening interval 5.2 Mention why the specified interval is used							
NHSCSP[15]						Screening standard	Screening standard†
Evans[61]	Qualitative	+	Only one study	Uncertain	None	Very low	
6. Test procedure 6.1 Explain what the test involves							
NHSCSP[15]						Screening standard	Screening standard†
Johnston[52]	RCC	+	Only one study	Direct	None	Low	
Evans[61]	Qualitative	+	Only one study	Uncertain	None	Very low	
7. Choice of venue 7.1 List options in the leaflet or on a separate sheet							
NHSCSP[15]						Screening standard	Screening standard†
Johnston[52]	RCC	+	Only one study	Direct	None	Low	

Table 5 Continued

	Assessment					Summary of findings	
Studies	**Design**	**Quality**	**Consistency across studies**	**Directness**	**Other factors***	**Overall assessment**	**Overall recommendations**
8. Sample taker							
8.2 Mention if the woman's GP takes the sample							
NHSCSP[15]						Screening standard	Screening standard†
Johnston[52]	RCC	+	Only one study	Direct	None	Low	
8.3 Mention the availability of a female sample taker							
NHSCSP[15]						Screening standard	Screening standard†
Johnston[52]	RCC	+	Only one study	Direct	None	Low	
Van Til[69]	Qualitative	++	Only one study	Uncertain	None	Low	
9. Test results							
9.3 Explain the meaning of inadequate, normal and abnormal results							
NHSCSP[15]						Suggestive	Suggestive
Marteau[48]	Quasi-RCT	+	No important inconsistency	Uncertain	None	Very low	
Michie[50]	Quasi-RCT	+		Uncertain			
Evans[61]	Qualitative	+	No important inconsistency	Uncertain	None	Very low	
Philips[67]	Qualitative	+		Uncertain			
10. Further tests							
10.3 Explain the cause(s) of an abnormal screening result							
NHSCSP[15]						No equivalent	Suggestive
Evans[61]	Qualitative	+	No important inconsistency	Uncertain	None	Low	
McCaffery[9]	Qualitative	++		Direct			
Anhang[11]	Qualitative	++		Uncertain			
11. Preventative information							
11.2 Explain the role of smoking							
NHSCSP[15]						Optional	Suggestive
Marteau[49]	RCT	–	Only one study	Direct	None	Low	

Quasi-RCT, quasi-randomised trial; RCC, retrospective case–control study; RCT, randomised controlled trial.
*Imprecise or sparse data, strong or very strong association, high risk of reporting bias, evidence of a dose–response gradient, effect of plausible residual confounding, close conformity of findings based on direct evidence.
†Recommendation retained as 'Screening standard' following review of references in the original report.[15]

3.4.2 Abnormal result leaflet

The recommendations described in Table 6 represent a synthesis of a number of papers – new evidence was considered for almost every part of the abnormal result leaflet. It is interesting to note that the quantitative research evidence often received a lower grade than the qualitative research evidence. New issues covered in the current report mainly address those terms and statements that should be avoided, such as 'pre-cancer', 'wart virus', 'slight abnormality', 'atypical', 'certain changes', 'cure', 'nothing to worry about' and 'no big deal'.

Table 6 Abnormal result leaflet: summary of recommendations

Main issues	Overall assessment		
Outcomes	**Quantitative studies**	**Qualitative studies**	**Overall recommendations**
1. Meaning of the result			
1.1 Explain the meaning of the result	Very low	High	Screening standard
1.2 Exclude the term 'pre-cancer'	Very low	High	New definite
1.3 Exclude generic non-specific terms, eg 'mild cellular changes' or 'certain changes'		High	New definite
1.4 Exclude statements intended to reassure, eg 'not to worry', 'nothing to worry about' or 'no big deal'	Very low	High	New definite
1.5 Mention the name of the condition		High	Screening standard
1.6 Use the word 'normal' instead of 'negative'	Very low		Screening standard*
1.7 Mention how common it is to have inadequate, normal or abnormal screening results	Very low	High	Screening standard
1.8 Mention if repeat screening is required	Very low	High	Screening standard
1.9 Mention what action is required for abnormal and normal results			Suggestive†
1.10 Mention that repeat screening is necessary to give the cervix a chance to return to normal	Very low	High	Screening standard
1.11 Give reasons for an inadequate screening sample			Suggestive†
1.12 Exclude that further investigation is due to infection/inflammation			Suggestive†
2. Cause(s) of an abnormal screening result			
2.1 Explain the cause(s) of an abnormal screening result	Very low	High	Screening standard
2.2 Exclude the term 'wart virus'		High	New definite
3. Outcome of the abnormality			
3.1 Mention that the woman is unlikely to have cancer	Very low	High	Screening standard
3.2 Mention the likelihood of treatment being effective; avoid using the term 'cure'	Very low		Screening standard*
4. Further investigation			
4.1 Explain the nature of further investigation	Very low	High	Screening standard
4.2 Explain what colposcopy involves			Screening standard
4.3 Describe how colposcopy feels			Screening standard
4.4 Mention that treatment is effective			Screening standard
4.5 Mention that treatment can be carried out as an outpatient procedure			Screening standard
5. Follow up			
5.1 Mention the importance of follow up because of the possibility of progression of the condition	Very low	High	Screening standard

Table 6 Continued

Main issues	Overall assessment		
Outcomes	**Quantitative studies**	**Qualitative studies**	**Overall recommendations**
6. Give sexual advice			
6.1 Mention that treatment should not affect the woman's reproductive or sexual function	Very low	High	Screening standard
6.2 Give advice about sex after receipt of an abnormal screening result			Screening standard
7. Preventative information			
7.1 Give preventative information; explain the roles of condoms, smoking and the importance of regular screening			Suggestive†
8. Further information			
8.1 Explain where the woman can obtain further information; mention the possibility of a GP appointment; provide a telephone number and provide names of organisations/ books			Screening standard

*Recommendation retained as 'Screening standard' following review of references in the original report.[15]
†'Suggestive' or 'Optional issue' recommendation set by the NHS Cervical Screening Programme in the original report.[15]

Notes to Table 6

Recommendation 1: Meaning of the result

1.1 Explain the meaning of the result

- The terms 'abnormal', 'slight abnormality' and 'atypical' should be avoided. If 'borderline' and 'abnormal' are used, these terms require careful explanation.[29,58,60]

Recommendation 2: Cause(s) of an abnormal screening result

2.1 Explain the cause(s) of an abnormal screening result

- Further information about HPV infection was requested by women taking part in several studies.[11,34,55]
- Information was also requested about the impact of smoking on an abnormal screening sample.[34,59]

Recommendation 3: Outcome of the abnormality

3.2 Mention the likelihood of treatment being effective

- Evidence collected from women who have received an abnormal screening result indicates that the term 'cure' creates confusion and should be avoided.[63]

Recommendation 4: Further investigation

4.1 Explain the nature of further investigation

- The technical term punch biopsy and the abbreviation LEEP (loop electrosurgical excision procedure) caused difficulties for women interpreting information about the nature of further investigation.[29]

Recommendation 5: Follow up

5.1 Mention the importance of follow up because of the possibility of the condition progressing

- Women require a clear explanation about what follow up involves and the reasons for attending any future appointments.[29]

Table 7 Abnormal result leaflet outcome evidence profiles: main issues

	Assessment					Summary of findings	
Studies	**Design**	**Quality**	**Consistency across studies**	**Directness**	**Other factors***	**Overall assessment**	**Overall recommendations**
1. Meaning of the result							
1.1 Explain the meaning of the result							
NHSCSP[15]						Screening standard	Screening standard
Lauver[57]	NCTS	+	No important inconsistency	Direct	None	Very low	
Manning[58]	NCDS	+		Uncertain			
Idestrom[56]	NCDS	+		Direct			
Maissi[55]	CSS	++		Direct			
Zapka[60]	NCDS	–		Direct			
Kuehner[29]	Qualitative	++	No important inconsistency	Direct	Close conformity based on direct evidence	High	
Karasz[64]	Qualitative	++		Direct			
Forss[63]	Qualitative	++		Direct			
1.2 Exclude the term ‘precancer’							
NHSCSP[15]						No equivalent	Definite
Zapka[60]	NCDS	–	Only one study	Direct	None	Very low	
Kavanagh[65]	Qualitative	++	No important inconsistency	Direct	Close conformity based on direct evidence	High	
Kuehner[29]	Qualitative	++		Direct			
1.3 Exclude generic non-specific terms, eg ‘mild cellular changes’ or ‘certain changes’							
NHSCSP[15]						No equivalent	Definite
Forss[63]	Qualitative	++	Only one study	Direct	None	High	
1.4 Exclude statements intended to reassure, eg ‘not to worry’, ‘nothing to worry about’ or ‘no big deal’							
NHSCSP[15]						No equivalent	Definite
Zapka[60]	NCDS	–	Only one study	Direct	None	Very low	
Kavanagh[65]	Qualitative	++	No important inconsistency	Direct	Close conformity based on direct evidence	High	
Forss[63]	Qualitative	++		Direct			
1.5 Mention the name of the condition							
NHSCSP[15]						Screening standard	Screening standard
Karasz[64]	Qualitative	++	No important inconsistency	Direct	None	High	
Forss[63]	Qualitative	++		Direct			
1.6 Use the word ‘normal’ instead of ‘negative’							
NHSCSP[15]						Screening standard	Screening standard†
Manning[58]	NCDS	+	Only one study	Uncertain	None	Very low	

Table 7 Continued

	Assessment					Summary of findings	
Studies	**Design**	**Quality**	**Consistency across studies**	**Directness**	**Other factors***	**Overall assessment**	**Overall recommendations**
1.7 Mention how common it is to have inadequate, normal and abnormal screening results							
NHSCSP[15]						Screening standard	Screening standard
Maissi[55]	CSS	++	Only one study	Direct	None	Very low	
Kavanagh[65]	Qualitative	++	Only one study	Direct	None	High	
1.8 Mention if repeat screening is required							
NHSCSP[15]						Screening standard	Screening standard
Zapka[60]	NCDS	–	Only one study	Direct	None	Very low	
Somerset[68]	Qualitative	++	No important inconsistency	Direct	Close conformity based on direct evidence	High	
Karasz[64]	Qualitative	++		Direct			
1.10 Mention that repeat screening is necessary to give the cervix a chance to return to normal							
NHSCSP[15]						Screening standard	Screening standard
Manning[58]	NCDS	+	No important inconsistency	Uncertain	None	Very low	
Zapka[60]	NCDS	–		Direct			
Somerset[68]	Qualitative	++	Only one study	Direct	None	High	
2. Cause(s) of an abnormal screening result							
2.1 Explain the cause(s) of an abnormal screening result							
NHSCSP[15]						Screening standard	Screening standard
Lauver[57]	NCTS	+	No important inconsistency	Direct	None	Very low	
Onyeka[59]	NCDS	+		Direct			
Maissi[55]	CSS	++		Direct			
Kavanagh[65]	Qualitative	++	No important inconsistency	Direct	Close conformity based on direct evidence	High	
Byrom[34]	Qualitative	++		Direct			
Anhang[11]	Qualitative	++		Uncertain			
2.2 Exclude the term ‘wart virus’							
NHSCSP[15]						No equivalent	Definite
Kavanagh[65]	Qualitative	++	No important inconsistency	Direct	None	High	
Anhang[11]	Qualitative	++		Uncertain			
3. Outcome of the abnormality							
3.1 Mention that the woman is unlikely to have cancer							
NHSCSP[15]						Screening standard	Screening standard
Lauver[57]	NCTS	+	No important inconsistency	Direct	None	Very low	
Manning[58]	NCDS	+		Uncertain			
Idestrom[56]	NCDS	+		Direct			
Maissi[55]	CSS	++		Direct			
Kavanagh[65]	Qualitative	++	No important inconsistency	Direct	None	High	
Somerset[68]	Qualitative	++		Direct			

Table 7 Continued

	Assessment					Summary of findings	
Studies	**Design**	**Quality**	**Consistency across studies**	**Directness**	**Other factors***	**Overall assessment**	**Overall recommendations**
3.2 Mention the likelihood of treatment being effective; avoid using the term 'cure'							
NHSCSP[15]						Screening standard	Screening standard†
Gath[30]	NCDS	++	No important inconsistency	Direct	None	Very low	
Lauver[57]	NCTS	+		Direct			
Maissi[55]	CSS	++		Direct			
4. Further investigation							
4.1 Explain the nature of further investigation							
NHSCSP[15]						Screening standard	Screening standard
Lauver[57]	NCTS	+	Only one study	Direct	None	Very low	
Kuehner[29]	Qualitative	++	Only one study	Direct	None	High	
5. Follow up							
5.1 Mention the importance of follow up because of the possibility of the condition progressing							
NHSCSP[15]						Screening standard	Screening standard
Gath[30]	NCDS	++	No important inconsistency	Direct	None	Very low	
Lauver[57]	NCTS	+		Direct			
Zapka[60]	NCDS	–		Direct			
Somerset[68]	Qualitative	++	No important inconsistency	Direct	Close conformity based on direct evidence	High	
Kuehner[29]	Qualitative	++		Direct			
Karasz[64]	Qualitative	++		Direct			
6. Give sexual advice							
6.1 Mention that treatment should not affect the woman's reproductive or sexual function							
NHSCSP[15]						Screening standard	Screening standard
Lauver[57]	NCTS	+	No important inconsistency	Direct	None	Very low	
Idestrom[56]	NCDS	+		Direct			
Kuehner[29]	Qualitative	++	Only one study	Direct	None	High	

CSS, cross-sectional study; NCDS, non-comparative descriptive study; NCTS, non-comparative time series study; Quasi-RCT, quasi-randomised trial; RCC, retrospective case–control study; RCT, randomised controlled trial.
*Imprecise or sparse data, strong or very strong association, high risk of reporting bias, evidence of a dose–response gradient, effect of plausible residual confounding, close conformity of findings based on direct evidence.
†Recommendation retained as 'Screening standard' following review of references in the original report.[15]

3.4.3 Colposcopy leaflet

New research evidence was assessed for the majority of colposcopy leaflet outcomes (see Table 8). As before, the qualitative evidence was frequently graded more highly than the quantitative evidence. Several new sections were added to the original report recommendations, including information about the potential need for sanitary protection immediately after the colposcopy visit and advice for pregnant women. Further aftercare advice relating to bleeding/discharge, driving and the appropriate level of activity after a colposcopy appointment was also included. 'Mention what instruments are used' and 'Mention the possibility of treatment at the first visit' in parts 2 and 3, respectively, were upgraded from a suggestive recommendation in the original report to a new definite recommendation in the current review.

Table 8 Colposcopy leaflet: summary of recommendations

Main issues	Overall assessment		
Outcomes	**Quantitative studies**	**Qualitative studies**	**Overall recommendations**
1. Explain why colposcopy is needed			
1.1 Explain the meaning of an abnormal screening result	Very low	Moderate	Screening standard
1.2 Give a name for the condition on the screening sample (dyskaryosis)			Screening standard
1.3 Mention the possibility of progression of the condition	Very low	High	Screening standard
1.4 Explain the cause(s) of an abnormal screening result	Very low	Moderate	Screening standard
1.5 Mention how common it is to have an abnormal screening result	Very low	High	Screening standard
2. Colposcopy visit			
2.1 Mention that the woman can bring someone along to the clinic	Low	High	Screening standard
2.2 Mention who will be present at the examination	Very low	High	New definite
2.3 Mention how long the examination will take	Very low		Suggestive
2.4 Mention that the woman should bring sanitary protection		High	New definite
2.5 Explain the examination	Very low	Moderate	Screening standard
2.6 Mention what instruments are used, eg colposcope, stirrups, speculum	Very low	High	New definite
2.7 Mention that the colposcope does not go inside			Suggestive†
2.8 Mention the possibility of a biopsy being taken	Very low	High	Screening standard
2.9 Provide advice for pregnant women		Low	Suggestive
2.10 Mention what is felt during the examination	Very low		Suggestive*
2.11 Mention if any pain is felt during the examination	Very low	High	Screening standard
2.12 Mention the possibility of local anaesthetic	Very low	High	New definite
2.13 Mention that the clinic staff are happy to answer questions	Moderate		New definite
2.14 Mention what to wear			Suggestive†
2.15 Give advice about menstruation and appointment date	Low		Suggestive
2.16 Give advice about relaxation (breathing), distraction and/or other coping techniques			Suggestive†
3. Explain the outcome of colposcopy examination			
3.1 Give a name for the diagnosed condition (CIN)	Very low	High	Screening standard
3.2 Mention the possibility of treatment at the first visit	Very low	High	New definite

Table 8 Continued

Main issues	Overall assessment		
Outcomes	**Quantitative studies**	**Qualitative studies**	**Overall recommendations**
3.3 Mention (local) treatment options	Very low	High	Screening standard
3.4 Mention that treatment is effective	Very low	High	Screening standard
3.5 Mention the likelihood of treatment being effective; avoid using the term 'cure'	Very low	Moderate	Screening standard
3.6 Mention that the woman is unlikely to have cancer	Very low	Moderate	Screening standard
3.7 Explain the follow up procedure	Very low	Moderate	Screening standard
4. Aftercare			
4.1 Give practical advice	Very low	High	Screening standard
4.2 Give advice about bleeding/discharge	Very low	High	New definite
4.3 Give advice about driving	Very low	High	New definite
4.4 Give advice about activity level after appointment		High	New definite
4.5 Give advice about sex after colposcopy	Very low	Low	Suggestive*
4.6 Exclude advice to a woman to change her form of contraception		High	New definite
4.7 Mention that examination should not affect future fertility/pregnancy	Very low	Moderate	Screening standard
4.8 Explain if partner should be checked			Suggestive†
4.9 Mention emotional upset	Very low		Suggestive†
5. Further information			
5.1 Explain where the woman can get further information; provide a name/telephone number for the clinic and provide names of organisations/books			Screening standard

*Recommendation changed to 'Suggestive' following review of references in the original report.[15]
†'Optional issue' recommendation set by the NHS Cervical Screening Programme in the original report.[15]

Notes to Table 8

Recommendation 1: Explain why colposcopy is needed

1.1 Explain the meaning of an abnormal screening result
- Women have unanswered questions about their cervix and a diagram may be a useful tool.[34]

1.3 Mention the possibility of progression of the condition
- Further details about follow up and the importance of regular cervical screening tests were requested by women newly referred for colposcopy after receiving an abnormal screening test result.[25]

1.4 Explain the cause(s) of an abnormal screening result
- Most women in several qualitative studies did not understand the specific meanings of terms such as 'wart virus' and 'precancer'; these terms should be avoided.[62,65]
- More information about HPV, including symptoms and treatment, was requested by women taking part in two studies.[62,66]

Recommendation 2: Colposcopy visit

2.2 Mention who will be present at the examination
- Women wanted to know whether their partner could come into the treatment room during the procedure and whether a nurse would be there to support them.[34]

2.5 Explain the examination
- The technical term punch biopsy and the abbreviation LEEP caused difficulties for women interpreting information about the colposcopy examination and treatment in one qualitative study.[29]

2.11 Mention if any pain is felt during the examination

- Women newly referred for colposcopy value the provision of information about pain that may be experienced during the examination, but the details presented should not be too explicit, such as to indicate that the procedure is inherently painful.[25]

Recommendation 3: Explain the outcome of the colposcopy examination

3.2 Mention the possibility of treatment at the first visit

- The women participating in one qualitative study expressed frustrations about not getting definitive treatment while a wait-and-see approach to care was followed.[29]

3.5 Mention the likelihood of treatment being effective

- Evidence collected from women who have received an abnormal screening result indicates that the term 'cure' creates confusion and should be avoided.[63]

3.7 Explain the follow up procedure

- A clear explanation of the number of follow up appointments required and the possibility of recurrence of abnormalities was requested by women in several studies.[29,59,62]

Table 9 Colposcopy leaflet outcome evidence profiles: main issues

	Assessment					Summary of findings	
Studies	**Design**	**Quality**	**Consistency across studies**	**Directness**	**Other factors***	**Overall assessment**	**Overall recommendations**
1. Explain why colposcopy is needed							
1.1 Explain the meaning of an abnormal screening result							
NHSCSP[15]						Screening standard	Screening standard
Gath[30]	NCDS	++	No important inconsistency	Direct	None	Very low	
Olamijulo[25]	NCDS	+		Direct			
Bonevski[31]	NCDS	+		Direct			
Tomaino[26]	Quasi-RCT	+		Direct			
Howells[28]	RCT	++		Uncertain			
Lauver[57]	NCTS	+		Direct			
Zapka[60]	NCDS	–		Direct			
Kavanagh[65]	Qualitative	++	No important inconsistency	Direct	Close conformity based on direct evidence	Moderate	
Fernbach[62]	Qualitative	+		Direct			
Kuehner[29]	Qualitative	++		Direct			
Byrom[34]	Qualitative	++		Direct			
1.3 Mention the possibility of progression of the condition							
NHSCSP[15]						Screening standard	Screening standard
Olamijulo[25]	NCDS	+	No important inconsistency	Direct	None	Very low	
Bonevski[31]	NCDS	+		Direct			
Onyeka[59]	NCDS	+		Direct			
Neale[66]	Qualitative	++	Only one study	Direct	None	High	
1.4 Explain the cause(s) of an abnormal screening result							
NHSCSP[15]						Screening standard	Screening standard
Gath[30]	NCDS	++	No important inconsistency	Direct	None	Very low	
Tomaino[26]	Quasi-RCT	+		Direct			
Kavanagh[65]	Qualitative	++	No important inconsistency	Direct	Close conformity based on direct evidence	Moderate	
Fernbach[62]	Qualitative	+		Direct			
Byrom[34]	Qualitative	++		Direct			
Neale[66]	Qualitative	++		Direct			
1.5 Mention how common it is to have an abnormal screening result							
NHSCSP[15]						Screening standard	Screening standard
Olamijulo[25]	NCDS	+	No important inconsistency	Direct	None	Very low	
Howells[28]	RCT	++		Uncertain			
Byrom[34]	Qualitative	++	Only one study	Direct	None	High	
2. Colposcopy visit							
2.1 Mention that the woman can bring someone along to the clinic							
NHSCSP[15]						Screening standard	Screening standard
Howells[28]	RCT	++	Only one study	Uncertain	None	Low	
Byrom[34]	Qualitative	++	No important inconsistency	Direct	None	High	
Neale[66]	Qualitative	++		Direct			

Table 9 Continued

	Assessment					Summary of findings	
Studies	**Design**	**Quality**	**Consistency across studies**	**Directness**	**Other factors***	**Overall assessment**	**Overall recommendations**
2.2 Mention who will be present at the examination							
NHSCSP[15]						Optional	Definite
Gath[30]	NCDS	++	No important	Direct	None	Very low	
Olamijulo[25]	NCDS	+	inconsistency	Direct			
Tomaino[26]	Quasi-RCT	+		Direct			
Howells[28]	RCT	++		Uncertain			
Byrom[34]	Qualitative	++	No important	Direct	Close	High	
Neale[66]	Qualitative	++	inconsistency	Direct	conformity based on direct evidence		
2.3 Mention how long the examination will take							
NHSCSP[15]						Suggestive	Suggestive
Olamijulo[25]	NCDS	+	No important	Direct	None	Very low	
Tomaino[26]	Quasi-RCT	+	inconsistency	Direct			
Howells[28]	RCT	++		Uncertain			
2.4 Mention that the woman should bring sanitary protection							
NHSCSP[15]						No equivalent	Definite
Byrom[34]	Qualitative	++	Only one study	Direct	None	High	
2.5 Explain the examination							
NHSCSP[15]						Screening standard	Screening standard
Bennetts[53]	CSS	++	No important	Direct	None	Very low	
Gath[30]	NCDS	++	inconsistency	Direct			
Olamijulo[25]	NCDS	+		Direct			
Bonevski[31]	NCDS	+		Direct			
Tomaino[26]	Quasi-RCT	+		Direct			
Howells[28]	RCT	++		Uncertain			
Lauver[57]	NCTS	+		Direct			
Fernbach[62]	Qualitative	+	No important	Direct	Close	Moderate	
Kuehner[29]	Qualitative	++	inconsistency	Direct	conformity based on direct evidence		
Byrom[34]	Qualitative	++		Direct			
2.6 Mention what instruments are used, eg colposcope, stirrups, speculum							
NHSCSP[15]						Suggestive	Definite
Gath[30]	NCDS	++	No important	Direct	None	Very low	
Bonevski[31]	NCDS	+	inconsistency	Direct			
Tomaino[26]	Quasi-RCT	+		Direct			
Howells[28]	RCT	++		Uncertain			
Byrom[34]	Qualitative	++	Only one study	Direct	None	High	

Table 9 Continued

	Assessment					Summary of findings	
Studies	**Design**	**Quality**	**Consistency across studies**	**Directness**	**Other factors***	**Overall assessment**	**Overall recommendations**
2.8 Mention the possibility of a biopsy being taken							
NHSCSP[15]						Screening standard	Screening standard
Olamijulo[25]	NCDS	+	No important	Direct	None	Very low	
Tomaino[26]	Quasi-RCT	+	inconsistency	Direct			
Howells[28]	RCT	++		Uncertain			
Byrom[34]	Qualitative	++	No important	Direct	Close	High	
Neale[66]	Qualitative	++	inconsistency	Direct	conformity based on direct evidence		
2.9 Provide advice for pregnant women							
NHSCSP[15]						No equivalent	Suggestive
Fernbach[62]	Qualitative	+	Only one study	Direct	None	Low	
2.10 Mention what is felt during the examination							
NHSCSP[15]						Screening standard	Suggestive†
Bonevski[31]	NCDS	+	No important	Direct	None	Very low	
Tomaino[26]	Quasi-RCT	+	inconsistency	Direct			
Howells[28]	RCT	++		Uncertain			
2.11 Mention if any pain is felt during the examination							
NHSCSP[15]						Screening standard	Screening standard
Olamijulo[25]	NCDS	+	No important	Direct	None	Very low	
Bonevski[31]	NCDS	+	inconsistency	Direct			
Tomaino[26]	Quasi-RCT	+		Direct			
Howells[28]	RCT	++		Uncertain			
Byrom[34]	Qualitative	++	Only one study	Direct	None	High	
2.12 Mention the possibility of local anaesthetic							
NHSCSP[15]						Optional	Definite
Olamijulo[25]	NCDS	+	No important	Direct	None	Very low	
Howells[28]	RCT	++	inconsistency	Uncertain			
Byrom[34]	Qualitative	++	No important	Direct	Close	High	
Neale[66]	Qualitative	++	inconsistency	Direct	conformity based on direct evidence		
2.13 Mention that the clinic staff are happy to answer questions							
NHSCSP[15]						Optional	Definite
Tomaino[26]	Quasi-RCT	+	Only one study	Direct	None	Moderate	
2.15 Give advice about menstruation and appointment date							
NHSCSP[15]						No equivalent	Suggestive
Olamijulo[25]	NCDS	+	Only one study	Direct	None	Low	

Table 9 Continued

Studies	Assessment					Summary of findings	
	Design	Quality	Consistency across studies	Directness	Other factors*	Overall assessment	Overall recommendations
3. Explain the outcome of colposcopy examination							
3.1 Give a name for the diagnosed condition (CIN)							
NHSCSP[15]						Screening standard	Screening standard
Olamijulo[25]	NCDS	+	Only one study	Direct	None	Very low	
Byrom[34]	Qualitative	++	No important	Direct	Close	High	
Neale[66]	Qualitative	++	inconsistency	Direct	conformity based on direct evidence		
3.2 Mention the possibility of treatment at the first visit							
NHSCSP[15]						Suggestive	Definite
Gath[30]	NCDS	++	No important	Direct	None	Very low	
Olamijulo[25]	NCDS	+	inconsistency	Direct			
Howells[28]	RCT	++		Uncertain			
Kuehner[29]	Qualitative	++	No important	Direct	Close	High	
Byrom[34]	Qualitative	++	inconsistency	Direct	conformity based on direct evidence		
Neale[66]	Qualitative	++		Direct			
3.3 Mention (local) treatment options							
NHSCSP[15]						Screening standard	Screening standard
Olamijulo[25]	NCDS	+	No important	Direct	None	Very low	
Bonevski[31]	NCDS	+	inconsistency	Direct			
Howells[28]	RCT	++		Uncertain			
Kavanagh[65]	Qualitative	++	No important	Direct	Close	High	
Byrom[34]	Qualitative	++	inconsistency	Direct	conformity based on direct evidence		
3.4 Mention that treatment is effective							
NHSCSP[15]						Screening standard	Screening standard
Bennetts[53]	CSS	++	Only one study	Direct	None	Very low	
Byrom[34]	Qualitative	++	Only one study	Direct	None	High	
3.5 Mention the likelihood of treatment being effective; avoid using the term ‘cure’							
NHSCSP[15]						Screening standard	Screening standard
Gath[30]	NCDS	++	No important	Direct	None	Very low	
Bonevski[31]	NCDS	+	inconsistency	Direct			
Kavanagh[65]	Qualitative	++	No important	Direct	Close	Moderate	
Fernbach[62]	Qualitative	+	inconsistency	Direct	conformity based on direct evidence		
Byrom[34]	Qualitative	++		Direct			

Table 9 Continued

	Assessment					Summary of findings	
Studies	**Design**	**Quality**	**Consistency across studies**	**Directness**	**Other factors***	**Overall assessment**	**Overall recommendations**
3.6 Mention that the woman is unlikely to have cancer							
NHSCSP[15]						Screening standard	Screening standard
Bennetts[53]	CSS	++	No important inconsistency	Direct	None	Very low	
Gath[30]	NCDS	++		Direct			
Olamijulo[25]	NCDS	+		Direct			
Bonevski[31]	NCDS	+		Direct			
Tomaino[26]	Quasi-RCT	+		Direct			
Howells[28]	RCT	++		Uncertain			
Lauver[57]	NCTS	+		Direct			
Kavanagh[65]	Qualitative	++	No important inconsistency	Direct	Close conformity based on direct evidence	Moderate	
Fernbach[62]	Qualitative	+		Direct			
Byrom[34]	Qualitative	++		Direct			
3.7 Explain the follow up procedure							
NHSCSP[15]						Screening standard	Screening standard
Gath[30]	NCDS	++	No important inconsistency	Direct	None	Very low	
Olamijulo[25]	NCDS	+		Direct			
Bonevski[31]	NCDS	+		Direct			
Lauver[57]	NCTS	+		Direct			
Onyeka[59]	NCDS	+		Direct			
Fernbach[62]	Qualitative	+	No important inconsistency	Direct	Close conformity based on direct evidence	Moderate	
Kuehner[29]	Qualitative	++		Direct			
Byrom[34]	Qualitative	++		Direct			
Neale[66]	Qualitative	++		Direct			
4. Aftercare							
4.1 Give practical advice							
NHSCSP[15]						Screening standard	Screening standard
Gath[30]	NCDS	++	No important inconsistency	Direct	None	Very low	
Bonevski[31]	NCDS	+		Direct			
Tomaino[26]	Quasi-RCT	+		Direct			
Howells[28]	RCT	++		Uncertain			
Kavanagh[65]	Qualitative	++	No important inconsistency	Direct	Close conformity based on direct evidence	High	
Byrom[34]	Qualitative	++		Direct			
Neale[66]	Qualitative	++		Direct			
4.2 Give advice about bleeding/discharge							
NHSCSP[15]						No equivalent	Definite
Olamijulo[25]	NCDS	+	Only one study	Direct	None	Very low	
Kavanagh[65]	Qualitative	++	No important inconsistency	Direct	Close conformity based on direct evidence	High	
Byrom[34]	Qualitative	++		Direct			

Table 9 Continued

	Assessment					Summary of findings	
Studies	**Design**	**Quality**	**Consistency across studies**	**Directness**	**Other factors***	**Overall assessment**	**Overall recommendations**
4.3 Give advice about driving							
NHSCSP[15]						No equivalent	Definite
Olamijulo[25]	NCDS	+	Only one study	Direct	None	Very low	
Neale[66]	Qualitative	++	Only one study	Direct	None	High	
4.4 Give advice about activity level after appointment							
NHSCSP[15]						No equivalent	Definite
Neale[66]	Qualitative	++	Only one study	Direct	None	High	
4.5 Give advice about sex after colposcopy							
NHSCSP[15]						Screening standard	Suggestive†
Bennetts[53]	CSS	++	No important	Direct	None	Very low	
Howells[28]	RCT	++	inconsistency	Some uncertainty			
Fernbach[62]	Qualitative	+	No important	Direct	None	Low	
Byrom[34]	Qualitative	++	inconsistency	Direct			
4.6 Exclude advice to a woman to change her form of contraception							
NHSCSP[15]						Optional	Definite
Byrom[34]	Qualitative	++	Only one study	Direct	None	High	
4.7 Mention that examination should not affect future fertility/pregnancy							
NHSCSP[15]						Screening standard	Screening standard
Bennetts[53]	CSS	++	No important	Direct	None	Very low	
Gath[30]	NCDS	++	inconsistency	Direct			
Fernbach[62]	Qualitative	+	No important	Direct	Close conformity based on direct evidence	Moderate	
Kuehner[29]	Qualitative	++	inconsistency	Direct			
Byrom[34]	Qualitative	++		Direct			
4.9 Mention emotional upset							
NHSCSP[15]						Optional	Suggestive
Lauver[57]	NCTS	+	Only one study	Direct	None	Very low	

CSS, cross-sectional study; NCDS, non-comparative descriptive study; NCTS, non-comparative time series study; Quasi-RCT, quasi-randomised trial; RCC, retrospective case–control study; RCT, randomised controlled trial.
*Imprecise or sparse data, strong or very strong association, high risk of reporting bias, evidence of a dose–response gradient, effect of plausible residual confounding, close conformity of findings based on direct evidence.
†Recommendation changed to 'Suggestive' following review of references in the original report.[15]

3.4.4 Treatment leaflet

A moderate amount of new evidence was assessed to inform the recommendations set out for the treatment leaflet (see Table 10). It was uncommon for both quantitative and qualitative research evidence to be considered for each outcome. Items of particular interest include the addition of two points to part 2 'Explain the treatment visit', which suggest that women would like further details about who will be present at the treatment appointment and the possibility of receiving anaesthetic during the procedure. As for previous leaflets, technical terms and abbreviations have the potential to cause difficulties for women interpreting information about treatment.

Table 10 Treatment leaflet: summary of recommendations

Main issues	Overall assessment		
Outcomes	**Quantitative Studies**	**Qualitative Studies**	**Overall recommendations**
1. Explain why treatment is needed			
1.1 Explain what the condition is	Very low	High	Screening standard
2. Explain the treatment visit			
2.1 Mention that the woman can bring someone along to the clinic (outpatient)	Very low	High	Screening standard
2.2 Mention who will be present at the treatment appointment		High	New definite
2.3 Explain the procedure	Very low	Moderate	Screening standard
2.4 Mention sensations during the procedure, eg what is felt, seen, smelt and heard			Screening standard
2.5 Mention if any pain is felt during the examination	Very low		Screening standard*
2.6 Mention the possibility of anaesthetic		High	New definite
2.7 Mention how long the procedure will take (outpatient)		High	New definite
2.8 Mention how long hospitalisation will take (inpatient)			Suggestive†
3. Aftercare			
3.1 Give practical advice; mention recovery period, use of sanitary pads/tampons, bleeding/discharge after treatment, possible pain after treatment, use of painkillers and emotional upset	Very low	High	Screening standard
3.2 Give advice about sex after treatment	Very low	Low	Screening standard*
3.3 Mention that treatment should not affect future fertility/pregnancy		High	Screening standard
3.4 Give advice on future contraception			Screening standard
4. Treatment outcome			
4.1 Explain outcome of treatment			Screening standard
4.2 Mention that treatment is effective		High	Screening standard
4.3 Mention the likelihood of treatment being effective; avoid using the term ‘cure’		Moderate	Screening standard
4.4 Mention that the woman is unlikely to have cancer		Moderate	Screening standard
5. Follow up			
5.1 Explain the follow up procedure; mention how many follow up visits are needed and what happens at these follow up visits		Moderate	Screening standard
6. Further information			
6.1 Provide a name/telephone number for the clinic			Screening standard
6.2 Provide names of organisations/books			Screening standard

*Recommendation retained as ‘Screening standard’ following review of the references in the original report.[15]
†‘Suggestive’ recommendation set by the NHS Cervical Screening Programme in the original report.[15]

Notes to Table 10

Recommendation 1: Explain why treatment is needed

1.1 Explain what the condition is

- The term 'CIN' requires careful explanation.[25]

Recommendation 2: Explain the treatment visit

2.3 Explain the procedure

- The technical term 'cold coagulator' and the abbreviation LLETZ (large loop excision of the transformation zone) caused difficulties for women interpreting information about the treatment procedure.[25]

2.5 Mention if any pain is felt during the examination

- Women indicated that the information provided about pain during the treatment procedure should not be too explicit.[25]

Recommendation 3: Aftercare

3.1 Give practical advice

- Few of the women participating in one qualitative study knew how to interpret symptoms after treatment or what to do about any symptoms that developed.[65]

Recommendation 4: Treatment outcome

4.3 Mention the likelihood of treatment being effective

- Evidence collected from women who have received an abnormal screening result indicates that the term 'cure' creates confusion and should be avoided.[63]

Table 11 Treatment leaflet outcome evidence profiles: main issues

	Assessment					Summary of findings	
Studies	**Design**	**Quality**	**Consistency across studies**	**Directness**	**Other factors***	**Overall assessment**	**Overall recommendations**
1. Explain why treatment is needed							
1.1 Explain what the condition is							
NHSCSP[15]						Screening standard	Screening standard
Olamijulo[25]	NCDS	+	No important inconsistency	Direct	None	Very low	
Lauver[57]	NCTS	+		Direct			
Kavanagh[65]	Qualitative	++	No important inconsistency	Direct	Close conformity based on direct evidence	High	
Neale[66]	Qualitative	++		Direct			
2. Explain the treatment visit							
2.1 Mention that the woman can bring someone along to the clinic (outpatient)							
NHSCSP[15]						Screening standard	Screening standard
Olamijulo[25]	NCDS	+	Only one study	Direct	None	Very low	
Byrom[34]	Qualitative	++	Only one study	Direct	None	High	
2.2 Mention who will be present at the treatment appointment							
NHSCSP[15]						No equivalent	Definite
Byrom[34]	Qualitative	++	Only one study	Direct	None	High	
2.3 Explain the procedure							
NHSCSP[15]						Screening standard	Screening standard
Olamijulo[25]	NCDS	+	No important inconsistency	Direct	None	Very low	
Lauver[57]	NCTS	+		Direct			
Fernbach[62]	Qualitative	+	No important inconsistency	Direct	Close conformity based on direct evidence	Moderate	
Kuehner[29]	Qualitative	++		Direct			
Byrom[34]	Qualitative	++		Direct			
2.5 Mention if any pain is felt during the examination							
NHSCSP[15]						Screening standard	Screening standard†
Olamijulo[25]	NCDS	+	Only one study	Direct	None	Very low	
2.6 Mention possibility of anaesthetic							
NHSCSP[15]						No equivalent	Definite
Byrom[34]	Qualitative	++	Only one study	Direct	None	High	
2.7 Mention how long the procedure will take (outpatient)							
NHSCSP[15]						Suggestive	Definite
Byrom[34]	Qualitative	++	Only one study	Direct	None	High	

Table 11 Continued

	Assessment					Summary of findings	
Studies	**Design**	**Quality**	**Consistency across studies**	**Directness**	**Other factors***	**Overall assessment**	**Overall recommendations**
3. Aftercare							
3.1 Give practical advice							
NHSCSP[15]						Screening standard	Screening standard
Olamijulo[25]	NCDS	+	Only one study	Direct	None	Very low	
Kavanagh[65]	Qualitative	++	No important inconsistency	Direct	Close conformity based on direct evidence	High	
Byrom[34]	Qualitative	++		Direct			
3.2 Give advice about sex after treatment							
NHSCSP[15]						Screening standard	Screening standard†
Olamijulo[25]	NCDS	+	Only one study	Direct	None	Very low	
Fernbach[62]	Qualitative	+	No important inconsistency	Direct	None	Low	
Byrom[34]	Qualitative	++		Direct			
3.3 Mention that treatment should not affect future fertility/pregnancy							
NHSCSP[15]						Screening standard	Screening standard
Fernbach[62]	Qualitative	+	No important inconsistency	Direct	Close conformity based on direct evidence	High	
Kuehner[29]	Qualitative	++		Direct			
Byrom[34]	Qualitative	++		Direct			
4. Treatment outcome							
4.2 Mention that treatment is effective							
NHSCSP[15]						Screening standard	Screening standard
Byrom[34]	Qualitative	++	Only one study	Direct	None	High	
4.3 Mention the likelihood of treatment being effective – avoid using the term ‘cure’							
NHSCSP[15]						Screening standard	Screening standard
Kavanagh[65]	Qualitative	++	No important inconsistency	Direct	Close conformity based on direct evidence	Moderate	
Fernbach[62]	Qualitative	+		Direct			
Byrom[34]	Qualitative	++		Direct			
4.4 Mention that the woman is unlikely to have cancer							
NHSCSP[15]						Screening standard	Screening standard
Kavanagh[65]	Qualitative	++	No important inconsistency	Direct	Close conformity based on direct evidence	Moderate	
Fernbach[62]	Qualitative	+		Direct			
Byrom[34]	Qualitative	++		Direct			

Table 11 Continued

	Assessment					Summary of findings	
Studies	**Design**	**Quality**	**Consistency across studies**	**Directness**	**Other factors***	**Overall assessment**	**Overall recommendations**
5. Follow up 5.1 Explain the follow up procedure							
NHSCSP[15]						Screening standard	Screening standard
Fernbach[62]	Qualitative	+	No important inconsistency	Direct	Close conformity based on direct evidence	Moderate	
Kuehner[29]	Qualitative	++		Direct			
Byrom[34]	Qualitative	++		Direct			

NCDS, non-comparative descriptive study; NCTS, non-comparative time series study.
*Imprecise or sparse data, strong or very strong association, high risk of reporting bias, evidence of a 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.[15]

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 cervical 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.[46] 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 cross-sectional and 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 controlled trials in this field may result from ethical concerns.

Studies that looked at the information requirements of specific groups (such as individuals with disabilities, older and adolescent 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 the base on which to build. Studies that described interventions designed to increase screening uptake were not included in 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 cervical screening was excluded from the review process unless women's information needs were discussed or written information materials were described. The graphic 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.

Women attending for routine cervical screening expect to receive confirmation that they are healthy; a cervical screening test may even be viewed as a form of 'insurance policy' against cancer.[29,63,68] Few women actually consider what an abnormal result might mean for them personally until the moment that such a result is received.[29,63] Fear of cancer and worry about death are significant issues for women with abnormal results.[16] Women are also troubled by the lack of a label for their condition. The first abnormal result notification neither indicates that a disease is present nor confirms a state of good health.[63,64] In fact, both remain a possibility. Women poorly understand the inherent ambiguity associated with an abnormal screening result, and this uncertainty is an important source of distress.[63,64] Another aspect of the screening process that

causes confusion is the follow up procedure. Women appreciate that it is important to attend for further tests but become frustrated by the fact that follow up appointments are scheduled for many months ahead instead of immediately.[29,58,60,64,65] Therefore, a clear explanation of the rationale behind a 'wait-and-see' approach would be helpful.

The cervical screening programme is an established and accepted component of the healthcare system. However, the public is much less aware of and knowledgeable about HPV. A recent study investigating beliefs about risk factors for cervical cancer in a sample of the British population showed that knowledge of the role of HPV in cervical cancer aetiology was low; therefore, any information provided about the role of sexual transmission may be at odds with current beliefs.[12] If HPV testing is adopted for widespread use within the NHS, thorough information about all aspects of HPV infection will have to be provided in the invitation materials.[7] Because of the large amount of information that must be covered to meet informed choice requirements, a separate leaflet dedicated to HPV education is likely to be required to address the many issues raised by the provision of HPV testing.[7,10,12] In one qualitative study, women struggled to understand how HPV infection could resolve over time without intervention and expressed confusion about how cervical screening test results can be normal if HPV is present.[11] The distinction between low risk and high risk forms of HPV is not well understood, particularly when any explanation is linked with the term 'wart', which for many women carries a significant stigma.[9,11] The sexually transmitted nature of the virus, along with the present lack of knowledge about HPV itself and the sexual health of partners, means that the screening programme will be entering into a new and complex health education domain.[8,9] Further information about the relationship between smoking and the progression of HPV infection to cancerous changes will also be required.[7] Any new information materials will need to be developed with care so that participants do not acquire the wrong impression that the cervix and not the woman is the main focus and concern of the programme.[29,70]

The clear communication of these concepts to women participating in the screening programme is a continuing challenge. A number of studies have indicated that women's understanding is improved when thorough yet simple information materials are provided.[27,48,50,51] The addition of further explanatory sentences or the inclusion of detailed statistics have not yet been shown to improve understanding beyond that achieved with simple statements.[48,50] None of the grey literature that was obtained during the course of the review provided further evidence to support the inclusion of statistical descriptions. We propose to explore this issue further in a series of focus groups with women at various stages of the cervical screening process.

Consistent terminology should be used in all screening materials, and unnecessary technical terms and abbreviations should be avoided. It has been suggested that the use of a light hearted tone is not helpful because it may give the impression that a serious health concern is being trivialised.[61] Similarly, statements that intend to reassure, such as 'it's nothing'

or 'not to worry', should not be included because they do not match the woman's perception that 'something' has been discovered by the cervical screening test.[60,63–65] The term 'cure' should be avoided because it does not help to clarify that dyskaryosis and CIN fall between normality and invasive disease; as a result, women are uncertain of exactly what they can be cured of by treatment.[63]

Increasing importance is being placed on attaining informed choice in screening.[71–74] As such, it is vital that women understand both the aims and the limitations of cervical screening.

Since the publication of the 1997 guidelines,[15] very little research evidence has been produced that specifically addresses questions related to the content of cervical screening letters. We therefore recommend that the screening programme should continue to use the existing letter templates. However, consideration could be given to the signatory, provision of fixed appointments and result availability.

We recommend that the NHS Cervical Screening Programme 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. Examples of items that might be included in each leaflet are given below.

4.1 Invitation leaflet

- Nature and purpose of the test.
- Validity of the test (including information on false positive and false negative results).
- Eligible population and screening interval.
- Test procedure.
- Test results (including the meaning of inadequate, normal and abnormal results).
- Causes of an abnormal result.
- Further tests.

The possible reasons for further tests and the likelihood of being asked to return for another test should be given in the invitation leaflet. However, detailed information about colposcopy and subsequent treatment should not be given until later in the screening process. The amount of information provided about further tests and investigations and the effectiveness of treatment and follow up should increase as a woman progresses from the abnormal result stage to colposcopy and treatment.

4.2 Abnormal result leaflet

- Meaning and causes of an abnormal result (describe the frequency of follow up).
- Abnormal result outcomes (ie women are unlikely to have cancer).
- Further tests and investigations (explain what colposcopy involves).
- Effectiveness of treatment.
- Importance of attending follow up.
- Sexual advice.

4.3 Colposcopy leaflet

- Explanation of why colposcopy is needed.
- Description of the colposcopy visit (include practical information).
- Explanation of the outcomes of colposcopy examination (including the possibility that treatment may be performed at the first visit).
- Effectiveness of treatment.
- Follow up.
- Aftercare (including practical information such as details about bleeding/discharge and sexual advice).

4.4 Treatment leaflet

- Explanation of why treatment is needed.
- Description of the treatment visit (including practical information).
- Aftercare (including practical information and sexual advice).
- Explanation of the outcomes and effectiveness of treatment.
- Follow up.

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APPENDIX 1: ELECTRONIC DATABASE SEARCH STRATEGIES

MEDLINE®: 1996–2004(06)
WebSPIRS SilverPlatter Version 4.30

1. cervical smear test in ti,ab
2. cervi*screen* in ti,ab
3. smear test* in ti,ab
4. cervi* smear* in ti,ab
5. papanicolaou* in ti,ab
6. pap* smear* in ti,ab
7. (pap adj test*) in ti,ab
8. vagi* smear* in ti,ab
9. colposcop* in ti,ab
10. explode 'Vaginal-Smears'/all subheadings in MIME,MJME
11. explode 'Colposcopy-'/all subheadings in MIME,MJME
12. #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11
13. cervi* neoplasm* in ti,ab
14. uter* cervi* cancer in ti,ab
15. cervi* dysplas* in ti,ab
16. cervi* intraepithelial neoplas* in ti,ab
17. cervi* disease* in ti,ab
18. cancer of cervi* in ti,ab
19. cervi* cancer in ti,ab
20. cervi* malignanc* in ti,ab
21. cervi* tumo?r in ti,ab
22. cervi* carcinoma* in ti,ab
23. cervi* adenocarcin* in ti,ab
24. explode 'Cervix-Neoplasms'/without-subheadings ,classification ,diagnosis ,ethnology ,epidemiology ,mortality ,nursing ,prevention-and-control ,psychology in MIME,MJME
25. explode 'Cervical-Intraepithelial-Neoplasia'/without-subheadings ,classification ,diagnosis ,ethnology ,epidemiology ,mortality ,nursing ,prevention-and-control ,psychology in MIME,MJME
26. explode 'Cervix-Diseases'/without-subheadings ,classification ,diagnosis ,ethnology ,epidemiology ,mortality ,nursing ,prevention-and-control ,psychology in MIME,MJME
27. #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21 or #22 or #23 or #24 or #25 or #26
28. #12 or #27
29. explode 'Mass-Screening'/without-subheadings ,economics ,organization-and-administration ,psychology ,trends ,utilization in MIME,MJME
30. #28 and #29
31. #28 or #30
32. (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
33. #32 and #31
34. (consumer* or patient* or client* or recipient* or adult*) in ti,ab
35. (wom?n or female*) in ti,ab
36. (adher* or consent* or choice* or complian* or accept* or right* or anxi* or fear* or understand*) in ti,ab
37. #34 and #36
38. #37 and #35
39. #38 or #32
40. explode 'Patient-Acceptance-of-Health-Care'/without-subheadings ,ethnology ,psychology ,statistics-and-numerical-data ,trends ,utilization in MIME,MJME
41. #40 and #39
42. #41 and #31
43. explode 'Attitude-to-Health'/without-subheadings ,ethnology ,psychology ,statistics-and-numerical-data ,trends ,utilization in MIME,MJME
44. #43 and #39
45. #44 and #31
46. explode 'Health-Behavior'/without-subheadings ,ethnology ,psychology ,statistics-and-numerical-data ,trends ,utilization in MIME,MJME
47. #46 and #39
48. #47 and #31
49. explode 'Health-Knowledge-Attitudes-Practice'/all subheadings in MIME,MJME
50. #49 and #39
51. #50 and #31
52. explode 'Health-Education'/without-subheadings ,methods ,organization-and-administration ,supply-and-distribution ,statistics-and-numerical-data ,trends ,utilization in MIME,MJME

53. #52 and #39
54. #53 and #31
55. #42 or #45 or #48 or #51 or #54
56. explode 'Motivation-'/without-subheadings ,classification ,ethics in MIME,MJME
57. #31 with #56
58. uptake in ti,ab
59. #31 near3 #58
60. information need* in ti,ab
61. #31 and #61
62. attitude* in ti,ab
63. #31 near #62
64. attend* in ti,ab
65. #31 near2 #64
66. cancer information in ti,ab
67. #31 and #66
68. perception* in ti,ab
69. #31 near4 #69
70. understand* in ti,ab
71. #70 near4 #31
72. knowledge in ti,ab
73. #72 near4 #31
74. health belie*
75. #74 and #31
76. #57 or #59 or #61 or #63 or #65 or #67 or #69 or #71 or#73 or #75
77. #33 or #55 or #76

PsycINFO®: 1996–2004(04)
WebSPIRS SilverPlatter Version 4.30

1. cervical smear test in ti,ab
2. cervi* screen* in ti,ab
3. smear test* in ti,ab
4. cervi* smear* in ti,ab
5. papanicolaou* in ti,ab
6. pap* smear* in ti,ab
7. (pap adj test*) in ti,ab
8. vagi* smear* in ti,ab
9. colposcop* in ti,ab
10. explode 'Cervix-' in DE
11. #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10
12. cervi* neoplasm* in ti,ab
13. uter* cervi* cancer in ti,ab
14. cervi* dysplas* in ti,ab
15. cervi* intraepithelial neoplas* in ti,ab
16. cervi* disease* in ti,ab
17. cancer of cervi* in ti,ab
18. cervi* cancer in ti,ab
19. cervi* malignanc* in ti,ab
20. cervi* tumo?r in ti,ab
21. cervi* carcinoma* in ti,ab
22. cervi* adenocarcin* in ti,ab
23. explode 'Neoplasms-' in DE
24. #14 or #15 or #16 or #17 or #18
25. #11 or #24
26. #25 and #23
27. #25 or #26
28. explode 'Health-Screening' in DE
29. #27 and #28
30. #27 or #29
31. (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
32. #31 and #30
33. (uptake or information need* or attitude* or attend* or cancer information or perception* or understand* or knowledge or health belie* or adher* or fear*) in ti,ab
34. #33 and #30
35. explode 'Help-Seeking-Behaviour' in DE
36. #35 and #30
37. explode 'Health-Care-Utilization' in DE
38. #37 and #30
39. explode 'Behaviour-' in DE
40. #39 and #30
41. explode 'Attitudes-' in DE
42. #41 and #30
43. explode 'Health-Knowledge' in DE
44. #43 and #30
45. explode 'Health-Education' in DE
46. #45 and #30
47. explode 'Client-Education' in DE
48. #47 and #30
49. explode 'Health-Promotion' in DE
50. #49 and #30
51. #36 or #38 or #40 or #42 or #44 or #46 or #48 or #50
52. #32 or #34 or #69

EMBASE®: 1996–2004(06)
WebSPIRS SilverPlatter Version 4.30

1. cervical smear test in ti,ab
2. cervi* screen* in ti,ab
3. smear test* in ti,ab
4. cervi* smear* in ti,ab
5. papanicolaou* in ti,ab
6. pap* smear* in ti,ab
7. (pap* adj test*) in ti,ab
8. vagi* smear* in ti,ab
9. colposcop* in ti,ab

10. explode 'Vagina-Smear'/all subheadings in DEM, DER, DRM, DRR
11. explode 'Colposcopy-'/all subheadings in DEM, DER, DRM, DRR
12. #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11
13. cervi* neoplasm* in ti,ab
14. uter* cervi* cancer in ti,ab
15. cervi* dysplas* in ti,ab
16. cervi* intraepithelial neoplas* in ti,ab
17. cervi* disease* in ti,ab
18. cancer of cervi* in ti,ab
19. cervi* cancer in ti,ab
20. cervi* malignanc* in ti,ab
21. cervi* tumo?r in ti,ab
22. cervi* carcinoma* in ti,ab
23. cervi* adenocarcin* in ti,ab
24. explode 'Uterine-Cervix-Disease'/without-subheadings, complication, clinical-trial, diagnosis, disease-management, epidemiology, prevention, side-effect in DEM, DER, DRM, DRR
25. #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21 or #22 or #23 or #24
26. #12 or #25
27. explode 'Mass-Screening'/all subheadings in DEM, DER, DRM, DRR
28. explode 'Screening-test'/all subheadings in DEM, DER, DRM, DRR
29. #27 or #28
30. #26 and #29
31. #26 or #30
32. pamphlet* in ti,ab
33. #32 and #31
34. brochure* in ti,ab
35. #34 and #31
36. leaflet* in ti,ab
37. #36 and #31
38. letter* in ti,ab
39. multiple letter* in ti
40. #38 not #39
41. #40 and #31
42. information leaflet* in ti,ab
43. #42 and #31
44. information disseminat* in ti,ab
45. #44 and #31
46. risk communication in ti,ab
47. #46 and #31
48. written information in ti,ab
49. #48 and #31
50. informed uptake in ti,ab
51. #50 and #31
52. #33 or #35 or #37 or #41 or #43 or #45 or #47 or #51
53. (consumer* or patient* or client* or recipient* or adult*) in ti,ab
54. (wom?n or female*) in ti,ab
55. (adher* or consent* or choice* or complian* or accept* or right* or anxi* or fear* or understand*) in ti,ab
56. #53 and #55
57. #56 and #54
58. (pamphlet* or brochure* or leaflet* or information leaflet* or information disseminat* or risk communication or written information or informed uptake) in ti,ab
59. #57 or #58
60. explode 'attitude'/all subheadings in DEM, DER, DRM, DRR
61. #60 and #59
62. explode 'patient-information'/all subheadings in DEM, DER, DRM, DRR
63. #62 and #59
64. explode 'health-education'/all subheadings in DEM, DER, DRM, DRR
65. #64 and #59
66. explode 'health-behavior'/all subheadings in DEM, DER, DRM, DRR
67. #66 and #59
68. explode 'illness-behavior'/all subheadings in DEM, DER, DRM, DRR
69. #68 and #59
70. #61 or #63 or #65 or #67 or #69
71. #71 and #31
72. uptake in ti,ab
73. #31 near9 #72
74. information need* in ti,ab
75. #31 and #74
76. attitude* in ti,ab
77. #31 near #76
78. attend* in ti,ab
79. #31 near4 #78
80. cancer information in ti,ab
81. #31 and #80
82. perception* in ti,ab
83. #31 near4 #82
84. understand* in ti,ab
85. #84 near4 #31
86. knowledge in ti,ab
87. #86 near8 #31
88. health belie*
89. #88 and #31
90. anxi* in ti,ab
91. #90 near #31

92. #73 or #75 or #77 or #79 or #81 or #83 or #85 or #87 or #89 or #91
93. #52 or #71 or #92

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1. cervical smear test in ti,ab
2. cervi* screen* in ti,ab
3. smear test* in ti,ab
4. cervi* smear* in ti,ab
5. papanicolaou* in ti,ab
6. pap* smear* in ti,ab
7. (pap adj test*) in ti,ab
8. vagi* smear* in ti,ab
9. colposcop* in ti,ab
10. explode 'Cervical-Smears'/all topical subheadings/without-subheadings, in-adolescence, in-adulthood, in-old-age, in-middle-age in DE
11. explode 'Colposcopy-'/all topical subheadings/without-subheadings, in-adolescence, in-adulthood, in-old-age, in-middle-age in DE
12. #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11
13. cervi* neoplasm* in ti,ab
14. uter* cervi* cancer in ti,ab
15. cervi* dysplas* in ti,ab
16. cervi* intraepithelial neoplas* in ti,ab
17. cervi* disease* in ti,ab
18. cancer of cervi* in ti,ab
19. cervi* cancer in ti,ab
20. cervi* malignanc* in ti,ab
21. cervi* tumo?r in ti,ab
22. cervi* carcinoma* in ti,ab
23. cervi* adenocarcin* in ti,ab
24. explode 'Cervix-Neoplasms'/without-subheadings ,classification ,diagnosis, education, ethnology ,epidemiology, familial-and-genetic, mortality, nursing, prevention-and-control ,psychosocial-factors, risk-factors, trends/without-subheadings, in-adolescence, in-adulthood, in-old-age, in-middle-age in DE
25. explode 'Cervical-Intraepithelial-Neoplasia'/without-subheadings ,classification ,diagnosis, education, ethnology ,epidemiology, familial-and-genetic, mortality, nursing, prevention-and-control ,psychosocial-factors, risk-factors, trends/without-subheadings, in-adolescence, in-adulthood, in-old-age, in-middle-age in DE
26. explode 'Cervix-Diseases'/without-subheadings ,classification ,diagnosis, education, ethnology ,epidemiology, familial-and-genetic, mortality, nursing, prevention-and-control ,psychosocial-factors, risk-factors, trends/without-subheadings, in-adolescence, in-adulthood, in-old-age, in-middle-age in DE
27. #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21 or #22 or #23 or #24 or #25 or #26
28. #12 or #27
29. 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
30. #28 and #29
31. #28 or #30
32. (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
33. #32 and #31
34. (consumer* or patient* or client* or recipient* or adult*) in ti,ab
35. (wom?n or female*) in ti,ab
36. (adher* or consent* or choice* or complian* or accept* or right* or anxi* or fear* or understand*) in ti,ab
37. #34 and #36
38. #37 and #35
39. #38 or #32
40. 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
41. #39 and #40
42. explode 'Attitude-to-Health'/without-subheadings ,education ,ethnology ,evaluation ,trends/without-subheadings ,in-adolescence ,in-adulthood ,in-old-age ,in-middle-age in DE
43. #39 and #42
44. explode 'Health-Knowledge'/all topical subheadings/without-subheadings ,in-adolescence ,in-adulthood ,in-old-age ,in-middle-age in DE
45. #39 and #44
46. explode 'Health-Behavior'/without-subheadings ,education ,ethnology ,evaluation ,trends/without-subheadings ,in-adolescence ,in-adulthood ,in-old-age ,in-middle-age in DE
47. #39 and #46
48. #41 or #43 or #45 or #47
49. #48 and #31
50. explode 'Motivation-'/without-subheadings

,classification ,education ,ethnology ,evaluation ,trends ,utilization/without-subheadings ,in-adolescence ,in-adulthood ,in-old-age ,in-middle-age in DE
51. #31 and #60
52. uptake in ti,ab
53. #31 and #62
54. information need* in ti,ab
55. #31 and #64
56. attitude* in ti,ab
57. #31 and #66
58. attend* in ti,ab
59. #31 and #68
60. cancer information in ti,ab
61. #31 and #70
62. perception* in ti,ab
63. #31 and #72
64. understand* in ti,ab
65. #74 near #31
66. knowledge in ti,ab
67. #76 near6 #31
68. health belie*
69. #78 and #31
70. #61 or #63 or #65 or #67 or #69 or #71 or #73 or #75 or #77 or #79
71. #43 or #61 or #82

APPENDIX 2: LIST OF INTERNET SITES VISITED

Cervical screening services

- UK NHS Cervical Screening Programme: http://www.cancerscreening.nhs.uk/cervical/#whatis
- Cervical Screening Wales: http://www.screeningservices.org/csw/index_eng.html
- Cancer in Scotland: Action for Change, NHS Scotland: http://www.show.scot.nhs.uk/sehd/cancerinscotland/
- Scottish Cervical Screening Programme: http://www.show.scot.nhs.uk/nsd/services/cervical/index.htm
- Irish Cervical Screening Programme: http://www.icsp.ie/home/default.asp
- CDC National Breast and Cervical Cancer Early Detection Programme: http://www.cdc.gov/cancer/nbccedp/
- National Cancer Institute, US National Institutes of Health: http://www.cancer.gov
- Australia National Screening Programme: http://www.health.gov.au/pcd/campaigns/cervical/index.htm
- Australia National Screening Programme: http://www.cervicalscreen.health.gov.au/ncsp/index.html
- PapScreen Victoria: http://www.papscreen.org
- New Zealand National Screening Programme: http://www.healthywomen.org.nz
- Alberta Cervical Cancer Screening Programme: http://www.cancerboard.ab.ca/accsp/index.html
- Ontario Cervical Screening Programme: http://www.cancercare.on.ca/prevention_cervicalScreening.htm

General health sites and cancer agencies

- NHS Health Development Agency: http://www.hda-online.org.uk/
- 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
- Cancerbackup: http://www.cancerbackup.org.uk
- Cancer Research UK: http://www.cancerresearchuk.org/
- CancerWEB: http://cancerweb.ncl.ac.uk/cancerweb.html
- DIPEX.org: http://www.dipex.org/
- Electronic Quality Information for Patients: http://www.equip.nhs.uk
- Marie Stopes International UK: http://www.mariestopes.org.uk/index.shtml
- The British Society for Colposcopy and Cervical Pathology: http://www.bsccp.org.uk/
- American Cancer Society: http://www.cancer.org

- American Society for Colposcopy and Cervical Pathology: http://www.asccp.org
- Alliance for Cervical Cancer Prevention: http://www.alliance-cxca.org/
- Canadian Cancer Society: http://www.cancer.ca
- European Research Organisation on Genital Infection and Neoplasia: http://www.eurogin.com/
- International Agency for Research on Cancer: http://www.iarc.fr
- International Federation of Gynecology and Obstetrics: http://www.figo.org
- International Society of Psychosomatic Obstetrics and Gynaecology: http://www.ispog.org/
- ObGynWorld: http://www.obgynworld.com

Women's health sites

- Women's Cancer Network: http://www.wcn.org/
- Women's Health London: http://www.womenshealthlondon.org.uk
- Canadian Women's Health Network: http://www.cwhn.ca
- 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/Research.htm
- Feminist Women's Health Centre: http://www.fwhc.org/

APPENDIX 3: STAGE 3 DATA EXTRACTION FORM [4, 37–39]

Study quality	Study design

Identification **Date** ☐☐☐

Reviewer			**Study number**/Reference manager no	
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

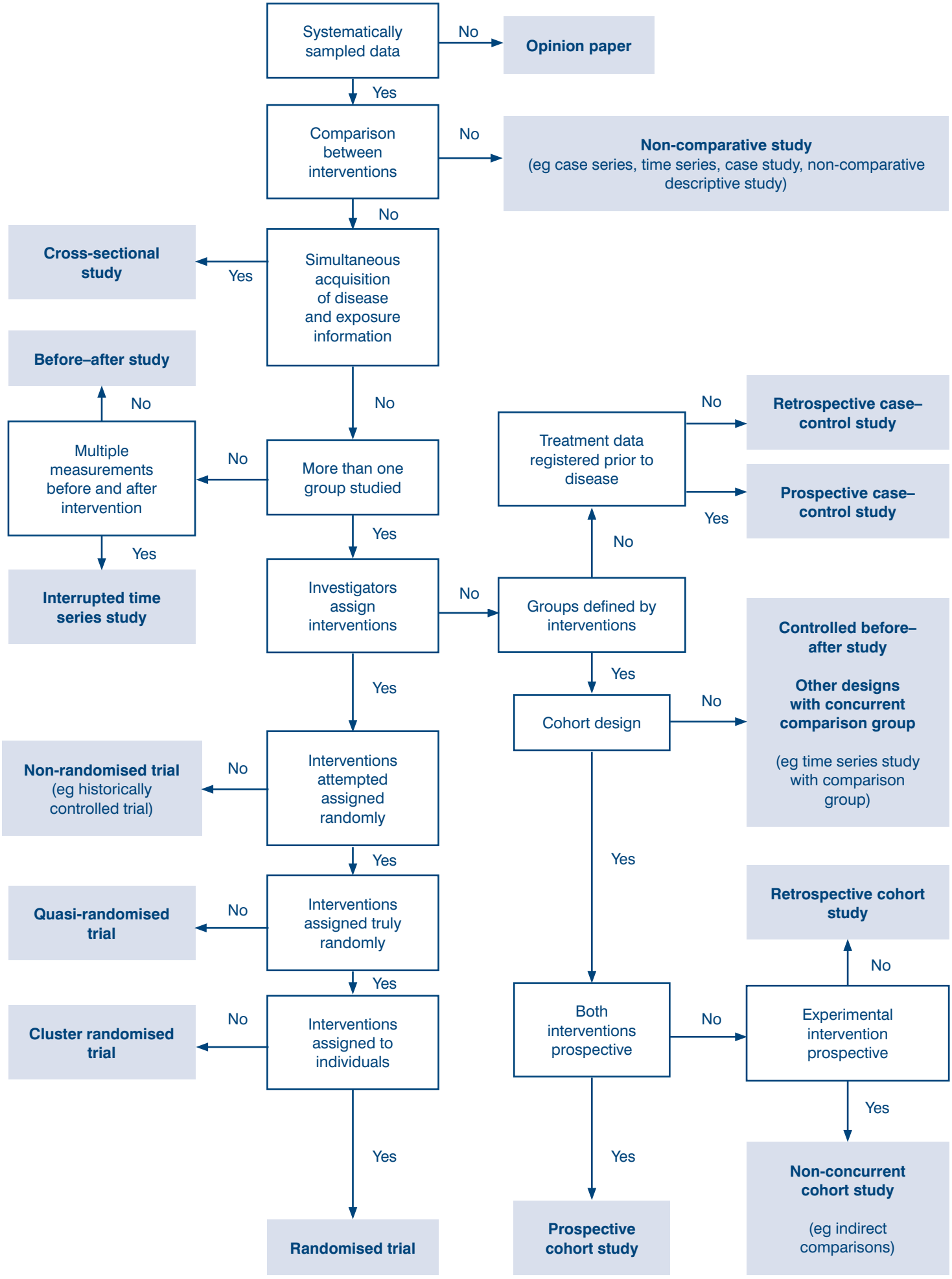
Overall assessment of the study

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 4: STAGE 4 QUALITY SCORING – STUDY DESIGN ALGORITHM[40,41]



APPENDIX 5: STAGE 4 QUALITY SCORING – STUDY METHODOLOGY CHECKLISTS

Study methodology checklist 1: randomised, clustered, quasi-controlled trials and non-randomised trials[42,43]

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 whether 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 who drop out of a study should give concern if that 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 to 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 multisite 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: retrospective case–control study[42,43]

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 cases and controls are taken from comparable populations	Well covered Adequately addressed Poorly addressed	Not reported Not applicable
1.3	The same exclusion criteria are used for both cases and controls	Well covered Adequately addressed Poorly addressed	Not reported Not applicable
1.4	What percentage of each group (cases and controls) participated in the study?	Well covered Adequately addressed Poorly addressed	Not reported Not applicable
1.5	Comparison is made between participants and non-participants to establish their similarities or differences	Well covered Adequately addressed Poorly addressed	Not reported Not applicable
1.6	Cases are clearly defined and differentiated from controls	Well covered Adequately addressed Poorly addressed	Not reported Not applicable
1.7	It is clearly established that controls are non-cases	Well covered Adequately addressed Poorly addressed	Not reported Not applicable
1.8	Measures will have been taken to prevent knowledge of primary exposure influencing case ascertainment	Well covered Adequately addressed Poorly addressed	Not reported Not applicable
1.9	Exposure status is measured in a standard, valid and reliable way	Well covered Adequately addressed Poorly addressed	Not reported Not applicable
1.10	The main potential confounders are identified and taken into account in the design and analysis	Well covered Adequately addressed Poorly addressed	Not reported Not applicable
1.11	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 Study participants may be selected from the target population (all individuals to which the results of the study could be applied), the source population (a defined subset of the target population from which participants are selected) or from a pool of eligible subjects (a clearly defined and counted group selected

from the source population). All cases should be representative of a defined population (geographically and/or temporally).

1.3 All selection and exclusion criteria should be applied equally to cases and controls. Failure to do so may introduce a significant degree of selection bias into the results of the study.

1.4 Differences between the eligible population and the participants are important, as they may influence the validity of the study. A participation rate can be calculated by dividing the number of study participants by the number of eligible subjects. It is more useful if calculated separately for cases and controls. If the participation rate is low, or there is a large difference between the two groups, the study results may well be invalid because of differences between participants and non-participants. In these circumstances, the study should be downgraded or rejected if the differences are very large.

1.5 Even if participation rates are comparable and acceptable, it is still possible that the participants selected to act as cases or controls may differ from other members of the source population in some significant way. A well conducted case–control study will look at samples of the non-participants among the source population to ensure that the participants are a truly representative sample.

1.6 The method of selection of cases is of critical importance to the validity of the study. Investigators have to be certain that cases are truly cases, but must balance this with the need to ensure that the cases admitted into the study are representative of the eligible population. Consider whether there was an established reliable system for selecting all the cases and whether the cases were incident or prevalent.

1.7 Just as it is important to be sure that cases are true cases, it is important to be sure that controls do not have the outcome under investigation. Control subjects should be chosen so that information on exposure status can be obtained or assessed in a similar way to that used for the selection of cases. If different methods of selection are used for cases and controls, the study should be evaluated by someone with a good understanding of the design of case–control studies.

1.8 If there is a possibility that case ascertainment can be influenced by knowledge of exposure status, assessment of any association is likely to be biased. A well conducted study should take this into account in the design of the study.

1.9 The primary outcome measures used should be clearly stated in the study. The study may be rejected if the outcome measures are not stated or if it is clear that the main conclusions are based on secondary outcomes. 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 the exposure was clearly defined and accurately measured, whether subjective or objective measures were used, whether the measurement methods were similar in cases and controls, whether the study incorporated blinding where feasible and whether the temporal relation is correct (did the exposure of interest precede the outcome?).

1.10 Confounding is the distortion of a link between exposure and outcome by another factor that is associated with both exposure and outcome. The report of the study should indicate which potential confounders have been considered, and how they have been assessed or allowed for in the analysis. Judgement should be applied to consider whether all likely confounders have been considered. If the measures used to address confounding are considered inadequate, the study should be downgraded or rejected, depending on how serious the risk of confounding is considered to be.

1.11 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: retrospective cohort and cross-sectional studies[42,44]

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 two groups being studied are selected from source populations that are comparable in all respects other than the factor under investigation	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, in each of the groups being studied	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	The assessment of outcome is made blind to exposure status	Well covered Adequately addressed Poorly addressed	Not reported Not applicable
1.6	Where blinding was not possible, there is some recognition that knowledge of exposure status could have influenced the assessment of outcome	Well covered Adequately addressed Poorly addressed	Not reported Not applicable
1.7	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
1.8	The measure of assessment of exposure is reliable	Well covered Adequately addressed Poorly addressed	Not reported Not applicable
1.9	Could the measurement of exposure status have been influenced by the assessment of outcome? When were the outcomes measured?	Well covered Adequately addressed Poorly addressed	Not reported Not applicable
1.10	The main potential confounders are identified and taken into account in the design and analysis	Well covered Adequately addressed Poorly addressed	Not reported Not applicable
1.11	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 It is important that the two groups selected for comparison are as similar as possible in all characteristics except for their exposure status, or the presence of specific prognostic factors or prognostic markers relevant to the study in question. 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, and should be calculated separately for each branch of the study. A large difference in participation rate between the two arms of the study 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, whether a reliable system has been established for detecting all cases and whether the measurement methods were similar in the different groups.

1.5 If the assessor is blinded to which participants received the exposure, and which did not, the prospects of unbiased results are significantly increased. Studies in which this is carried out should be rated more highly than those where it is not carried out or not carried out adequately.

1.6 Blinding is not possible in many studies. In order to assess the extent of any bias that may be present, it may be helpful to compare process measures used on the participant groups, eg who carried out the observations, the degree of detail and completeness of observations. If these process measures are comparable between the groups, the results may be regarded with more confidence.

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. The study may be rejected if it is clear that the main conclusions are based on secondary outcomes.

1.8 A well conducted study should indicate how the degree of exposure or presence of prognostic factors or markers was assessed. Whatever measures are used must be sufficient to establish clearly that participants have or have not received the exposure under investigation and the extent of such exposure, or that they do or do not possess a particular prognostic marker or factor. Clearly described, reliable measures should increase the confidence in the quality of the study. Consider whether subjective or objective measurements were used and whether all the participants were classified into exposure groups using the same procedure.

1.9 In a cross-sectional study, it is not possible to validly investigate the association between an outcome and an exposure if the outcome of interest can affect the exposure of interest. It is essential to consider whether the exposure was measured before the outcome occurred to check that the investigated association is temporally correct.

1.10 Confounding is the distortion of a link between exposure and outcome by another factor that is associated with both exposure and outcome. The report of the study should indicate which potential confounders have been considered, and how they have been assessed or allowed for in the analysis. Judgement should be applied to consider whether all likely confounders have been considered. If the measures used to address confounding are considered inadequate, the study should be downgraded or rejected, depending on how serious the risk of confounding is considered to be.

1.11 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 4: 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 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 5: qualitative research studies[43,45]

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 etc.)? 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, etc.) 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 6: DESCRIPTION OF QUANTITATIVE STUDIES

Study	Bowman[47]
Study design	Randomised controlled trial
Study quality score	++
Methods	Randomisation – method not stated; eligible women were randomly allocated after stratifying for age and time of last smear (3–5 years ago, more than 5 years ago, never) Concealment of allocation – not applicable Assessor blinding – blind Baseline comparability – no significant differences between study groups for any of the variables examined Follow up – six months Sample size – sample size and power calculations not reported Losses to follow up – 35 women excluded from GP letter group after randomisation; 746/878 women could be contacted at follow up; 659/746 women were included in the final analysis Outcome measure(s) – administrative records; self-report via administered survey % analysed: 72% (659/913)
Population	Country – Australia Setting – general practice Screening status – due Participants – 7000 potentially eligible women in an Australian community were identified by a random household survey (sampling methodology developed by the Australian Bureau of Statistics) Inclusion criteria – age 18–70 years Exclusion criteria – insufficient level of spoken English; infirmity; not at home when contacted; not sexually active; hysterectomy
Interventions	1. GP prompt reminder letter n = 255 (178 analysed) 2. Women's health clinic invitation n = 220 (164 analysed) 3. Pamphlet n = 219 (162 analysed) 4. Control group n = 219 (155 analysed)
Outcomes	Pap smear uptake
Notes	The women were not taking part in an organised screening programme; 10% more women were initially assigned to the general practitioner letter group to accommodate the expected subject loss caused by practitioners who could not be contacted or who were unwilling to take part in the research; comparison of self-reported uptake and administrative records of uptake indicated that women were very accurate in their self-report of screening when it had actually taken place, but inaccurate in almost a quarter of instances when they stated that it had occurred

Study	Howells[28]
Study design	Randomised controlled trial
Study quality score	++
Methods	Randomisation – computer derived random number series Concealment of allocation – well covered Assessor blinding – blind Baseline comparability – no significant differences between study groups for any of the variables examined Follow up – six months Sample size – sample sizes were calculated (100 patients in each arm) to detect with 85% power, at a 1% significance level, a fall of 10 in the Spielberger State Anxiety Inventory Score Losses to follow up – 7/107 women in the intervention group and 3/103 women in the control group defaulted from the clinic and were excluded from the analysis; 33/100 women in the intervention group and 34/100 women in the control group did not attend a follow up appointment Outcome measure – self-report via questionnaire and interview % analysed: 95% (200/210) at the first visit; 63% (133/210) at six month visit
Population	Country – UK Setting – colposcopy clinic at a large district general hospital Screening status – abnormal smear and attending for colposcopy Participants – 210 women diagnosed with moderate dyskaryosis or less, newly referred for colposcopy at a district general hospital clinic Inclusion criteria – cervical cytological abnormality of no greater than moderate dyskaryosis, under 45 years of age Exclusion criteria – previous colposcopy experience, diagnosis of severe dyskaryosis
Interventions	1. Information leaflet sent with the clinic appointment letter n = 107 (100 analysed first visit, 67 analysed second visit) 2. Control group – clinic appointment letter n = 103 (100 analysed first visit, 66 analysed second visit)
Outcomes	Anxiety score difference Psychosexual score difference Information leaflet assessment Conservativeness of treatment approach
Notes	The number of defaulters from the initial visit was not dissimilar from audit figures within the hospital but the default rate was higher than expected on the second visit, which may reflect a reluctance to complete the second questionnaire (interview time > 30 minutes). The number of defaulters was not significantly different between the two study groups. Leaflet text included with the study report The primary outcome for this study was anxiety; as part of the information leaflet assessment, a knowledge outcome was reported only for group 1 with no comparison with the control group – this information represents extrapolated evidence
Study	**Marteau[48] Part I**
Study design	Quasi-randomised trial
Study quality score	+
Methods	Randomisation – sequential (quasi) Concealment of allocation – not reported Assessor blinding – not reported Baseline comparability – no significant difference between study groups in education level Follow up – none Sample size – sample size and power calculations not reported Losses to follow up – refusal rates were not recorded by the agency that conducted the survey but were estimated to be lower than 5% Outcome measure – self-report via questionnaire % analysed: > 95% (305/(305 + less than 5% that refused to take part))

Population	Country – UK Setting – community Screening status – hypothetical Participants – 305 women recruited throughout England by a research agency (Research Initiatives) asked to imagine that they had recently undergone cervical screening and received a normal smear result letter Inclusion criteria – not reported Exclusion criteria – not reported
Interventions	1. Control group – told that smear test result was normal, in line with NHS policy n = 153 (153 analysed) 2. Additional statement explaining that at low risk of having or developing cervical cancer in the next five years n = 152 (152 analysed)
Outcomes	Understanding of a normal smear test result
Notes	Not clear if women were taking part in an organised screening programme. For Part I and Part II combined, 94% (964 women) had undergone a cervical smear test in the past and 21% (220 women) had received an abnormal result; overall, 21% had no formal educational qualifications and 9% were educated to degree level or beyond; this sample was slightly less well educated than the general population of women aged between 20 and 59 years in the UK
Study	**Marteau[48] Part II**
Study design	Quasi-randomised trial
Study quality score	+
Methods	Randomisation – sequential (quasi) Concealment of allocation – not reported Assessor blinding – not reported Baseline comparability – no significant difference between study groups in education level Follow up – none Sample size – sample size and power calculations not reported Losses to follow up – refusal rates were not recorded by the agency that conducted the survey but were estimated to be lower than 5% Outcome measure – self-report via questionnaire % analysed: > 95% (722/(722 + less than 5% that refused to take part))
Population	Country – UK Setting – community Screening status – hypothetical Participants – 722 women recruited throughout England by a research agency (Research Initiatives) asked to imagine that they had recently undergone cervical screening and received a normal smear result letter (including a statement explaining that they were at low risk of having or developing cervical cancer in the next five years) Inclusion criteria – not reported Exclusion criteria – not reported
Interventions	1. Control group – informed that smear test result was normal, in line with NHS policy, and that they were at low risk of having or developing cervical cancer in the next five years n = 188 (188 analysed) 2. Same information as Group 1 and informed that 'the chances of developing cervical cancer are about 1 in 5000 (this means that, on average, out of every 5000 women who have a normal smear test result, one will go on to develop cervical cancer) or, put another way, 4999 of these women will not develop cervical cancer over the next five years' n = 172 (172 analysed) 3. Same information as Group 1 and informed that 'compared with women who have not had a smear test, you are about five times less likely to develop cervical cancer in the next five years' n = 175 (175 analysed) 4. Same information as Groups 1, 2 and 3 n = 187 (187 analysed)
Outcomes	Understanding of a normal smear test result

Notes	Not clear whether women were taking part in an organised screening programme. For Part I and Part II combined, 94% (964 women) had undergone a cervical smear test in the past and 21% (220 women) had received an abnormal result; overall, 21% had no formal educational qualifications and 9% were educated to degree level or beyond; this sample was slightly less well educated than the general population of women aged between 20 and 59 years in the UK
Study	**Marteau[49]**
Study design	Randomised controlled trial
Study quality score	–
Methods	Randomisation – method not stated Concealment of allocation – not reported Assessor blinding – not reported Baseline comparability – not reported Follow up – one week Sample size – sample size and power calculations not reported Losses to follow up – 234/681 women returned a questionnaire Outcome measure – self-report via questionnaire % analysed: 34% (234/681)
Population	Country – UK Setting – general practice Screening status – unclear Participants – 681 women registered with two general practices in the UK Inclusion criteria – smokers Exclusion criteria – not reported
Interventions	1. Extended leaflet (?analysed) 2. Brief leaflet (?analysed) 3. Control group – no leaflet (?analysed)
Outcomes	Perceptions of risk Beliefs about the effectiveness of reducing risk by stopping smoking
Notes	Full report of study not available – information obtained from conference abstract; unclear whether women were taking part in an organised screening programme (selected from the general practice registers without restriction)
Study	**Michie[50]**
Study design	Quasi-randomised trial
Study quality score	+
Methods	Randomisation – sequential (quasi) Concealment of allocation – inadequate Assessor blinding – not blind Baseline comparability – not reported Follow up – none Sample size – sample size and power calculations not reported Losses to follow up – refusal rates were not recorded by the agency that conducted the survey but were estimated to be lower than 5% Outcome measure – self-report via questionnaire % analysed: > 95% (184/(184 + less than 5% that refused to take part))
Population	Country – UK Setting – community Screening status – hypothetical Participants – 184 women recruited opportunistically, 92 outside a shopping centre in London and 92 first-year nursing students outside lectures at a London teaching hospital. The women were told to vividly imagine that they had attended for a cervical smear test three weeks previously and that they had just received a result letter from their GP Inclusion criteria – not reported Exclusion criteria – not reported

Interventions	1. 'Accuracy/risk' group: received a letter emphasising high test accuracy and low residual risk n = 46 (46 analysed) 2. 'Accuracy/not risk' group: received a letter emphasising high test accuracy but not low residual risk n = 46 (46 analysed) 3. 'Risk/not accuracy': received a letter emphasising low residual risk but not high test accuracy n = 46 (46 analysed) 4. Control group, 'Not risk/not accuracy': received a letter not emphasising high test accuracy or low residual risk n = 46 (46 analysed)
Outcomes	Understanding of Pap smear result Desire for screening within six months
Notes	Unclear whether women were taking part in an organised screening programme. More than 97% of the participants had heard of cervical cancer and of cervical screening. A lower proportion of students (39%) had undergone cervical screening than the general public 62% ($\chi^2 = 9.59$, df = 1, P = 0.002). The two samples were analysed as one group because they did not differ on any of the outcome variables
Study	**Segnan[51]**
Study design	Cluster randomised controlled trial
Study quality score	++
Methods	Randomisation – computerised random block design where block = GP Concealment of allocation – well covered Assessor blinding – not applicable Baseline comparability – not reported Follow up – 12 months Sample size – sample size and power calculations not reported Losses to follow up – not reported Outcome measure – administrative records % analysed: 100% (8385/8385)
Population	Country – Italy Setting – general practice Screening status – due Participants – 8385 women listed on the rosters of participating GPs in the city Turin. The women were allocated by GP practice to four different invitation strategies Inclusion criteria – Turin resident, 25–64 years, GP collaborating in city screening programme Exclusion criteria – diagnosis of cervical cancer, terminal illness, severe psychiatric symptoms
Interventions	1. Control group, personal invitation letter (standard text adopted by the city screening programme), signed by GP with a pre-fixed appointment n = 2100 (2100 analysed) 2. Open-ended personal invitation letter, signed by GP prompting women to contact the screening centre within three weeks to make an appointment n = 2093 (2093 analysed) 3. Same letter as Group 1 signed by the city screening programme coordinator n = 2094 (2094 analysed) 4. Personal invitation letter with extended text, signed by the GP with a pre-fixed appointment n = 2098 (2098 analysed)
Outcomes	Pap smear uptake at 12 months
Notes	Out of the 88 GPs contacted during the study period, 43 (48.9%) agreed to collaborate in the programme. The first 35 consecutive GPs immediately available for collaboration were included in the study. Group 1 was considered the control group for all comparisons because it reflected the usual invitation strategy

Study	Tomaino-Brunner[26]
Study design	Quasi-randomised trial
Study quality score	+
Methods	Randomisation – stratified by blocks of women attending in seven day periods to avoid contamination Concealment of allocation – inadequate Assessor blinding – not blind Baseline comparability – no significant differences between study groups for any of the variables examined Follow up – none Sample size – sample sizes were calculated (48 participants in each arm) to detect with 80% power, at a 5% significance level, an effect size of 30% on the knowledge section of the interview Losses to follow up –1/61 women in the intervention group was interviewed but did not complete one of the study instruments Outcome measure – self-report via questionnaire and interview % analysed: 100% (113/113) knowledge; 99% (112/113) anxiety
Population	Country – USA Setting – colposcopy clinic at inner city medical school Screening status – abnormal smear and attending for colposcopy Participants – 113 mainly African American and Hispanic women newly referred for colposcopy during a six month period at an inner city medical school colposcopy clinic Inclusion criteria – able to converse in and read English, received handout in the mail if part of intervention group Exclusion criteria – previous colposcopy experience
Interventions	1. One page colposcopy handout sent to participant by post one week before colposcopy appointment (n = 58) (58 analysed knowledge, 57 analysed anxiety) 2. Control group – no education material sent by post (n = 55) (55 analysed)
Outcomes	Knowledge Anxiety
Notes	3/61 women who had appointments during intervention weeks chose not to participate; 2/57 women who had appointments during non-intervention weeks chose not to participate. A copy of the educational handout was included with the study report
Study	**Johnston[52]**
Study design	Retrospective case–control study
Study quality score	+
Methods	Comparable source populations – adequately addressed Participation rate – 307/660 (46%) non-users and 307/417 (74%) users of the screening service were contacted and interviewed Participant/non-participant comparison – not reported Case definition – well covered Case ascertainment – administrative records Control definition – well covered Exposure measure – self-report via administered questionnaire Confounding – adequately addressed; cases and controls were matched by age and GP Study length – 35 months
Population	Country – UK Setting – general practice Screening status – overdue (cases); women with a recorded test within the previous three years (controls) Participants – 1077 women selected from computerised screening lists of 23 GPs in the Tayside area of Scotland Inclusion criteria – age 20–65 years; listed on screening register of participating GP surgeries Exclusion criteria – not at home when visited

Exposures	1. Overdue (non-users of the screening service) (n = 307) 2. Recorded Pap test within the previous three years (users of the screening service – controls) (n = 307)
Outcomes	Attendance barriers
Notes	A large number of eligible women were not contacted and interviewed – concerned about selection bias; the marital status of users and non-users of the service was significantly different among the three age groups reported ($P < 0.01$) and the social class of users and non-users of the service was significantly different among the three age groups reported ($P < 0.05$)
Study	**Bennetts[53]**
Study design	Cross-sectional study
Study quality score	++
Methods	Comparable source populations – well covered Participation rate – 431/470 (92%) women agreed to participate, of these, 350/431 (81%) completed all of the survey questions; the overall response rate was 350/470 (74%) Participant/non-participant comparison – no details were available on non-participants (aimed to recruit 100 women to the abnormality group and 300 women to the follow up group); the women who did not complete all of the survey questions were older and had completed fewer years of school than the women who answered all of the questions Outcome definition – well covered Outcome assessment – blind Outcome measure – self-report via questionnaire Exposure assessment – well covered Exposure measure – administrative records Confounding – not reported Study length – seven months
Population	Country – Australia Setting – colposcopy clinic at a family planning centre Screening status – women newly referred for colposcopy (abnormality group); women involved in follow up of a cervical abnormality with at least one previous colposcopy (follow up group) Participants – 470 consecutive eligible women newly referred for colposcopy or attending for follow up at a single family planning clinic in Ashfield, Sydney Inclusion criteria – not reported Exclusion criteria – insufficient English literacy skills to understand the questionnaire in its entirety
Exposures	1. Abnormal smear result and newly referred for colposcopy (n = 93) 2. Involved in follow up of cervical abnormality and at least one previous colposcopy (n = 257)
Outcomes	Experience of medical procedures Changes in self-perception Worry about infectivity Effect on sexual relationships
Notes	This cross-sectional study informed the development of a questionnaire (Psychosocial Effects of Abnormal Pap Smears (PEAPS-Q)) to measure the distress experienced by women undergoing follow up investigation after an abnormal Pap smear result and management of cervical abnormalities

Study	Kant[54]
Study design	Cross-sectional study
Study quality score	+
Methods	Comparable source populations – adequately addressed Participation rate – 152/238 (64%) women in the GP group attended for screening and 115/235 (49%) of women in the control group attended for screening Participant/non-participant comparison – not reported; 60 women were excluded from analysis because they were not eligible for screening Outcome definition – well covered Outcome assessment – blind Outcome measure – administrative records Exposure assessment – well covered Exposure measure – administrative records Confounding – poorly addressed; there were differences between the two groups in factors known to be related to attendance for screening Study length – not reported
Population	Country – the Netherlands Setting – general practice Screening status – due Participants – 473 (total) eligible women due for cervical screening registered at two general practices in Nijmegen participating in a GP based call system project and women registered with practices in the Nijmegen area not participating in the GP based intervention project Inclusion criteria – Nijmegen residents, registered with practices in the Nijmegen area Exclusion criteria – cervical smear within the past year, total hysterectomy, receiving follow up care for previous cytological abnormalities
Exposures	1. GP invitation letter (n = 238) 2. Local health authority invitation letter (control) (n = 235)
Outcomes	Pap smear uptake
Notes	

Study	Maissi[55]
Study design	Cross-sectional study
Study quality score	++
Methods	Comparable source populations – adequately addressed Participation rate – 1376/2183 (63%) of invited women took part in the study; rates for each of the four groups not reported Participant/non-participant comparison – not reported Outcome definition – well covered Outcome assessment – blind Outcome measure – self-report via questionnaire Exposure assessment – well covered Exposure measure – administrative records Confounding – well covered Study length – six months and one week
Population	Country – UK Setting – Two centres taking part in the English pilot study of liquid based cytology and HPV testing Screening status – due Participants – 2183 eligible mainly white women that attended for cervical screening at two centres in England Inclusion criteria – routine Pap smear test taken at two of the three centres taking part in the pilot study; Pap smear result indicating borderline or mild dyskaryosis and either an HPV positive or negative result; Pap smear result indicating borderline or mild dyskaryosis not tested for HPV; normal Pap smear result Exclusion criteria – not reported

Exposures	1. Women receiving borderline or mildly dyskaryotic smear test results tested for HPV and found to be HPV positive (n = 563) 2. Women receiving borderline or mildly dyskaryotic smear test results tested for HPV and found to be HPV negative (n = 331) 3. Women not tested for HPV with borderline or mildly dyskaryotic smear results (n = 143) 4. Women receiving normal smear results (n = 366)
Outcomes	State anxiety Distress about the smear result Concern about the smear result Perceived risk of developing cervical cancer Understanding of the smear result
Notes	Written information provided to women with results of smear test included with study report. Outcomes were assessed within four weeks of receipt of results. The formal hypotheses tested were that women with normal results would have anxiety scores significantly lower than all other groups; that women with borderline or mildly dyskaryotic smear test results who were HPV positive would have significantly higher scores than the other three groups; and that women with borderline or mildly dyskaryotic smear test results who were HPV negative would have lower anxiety scores than those who had abnormal smear test results but had not been tested for HPV
Study	**Bonevski[31]**
Study design	Non-comparative descriptive study
Study quality score	+
Methods	Appropriate population – well covered Participation rate – 156/161 (97%) of eligible women approached agreed to be contacted by telephone; 138/161 (86%) women were interviewed (18 participants could not be contacted after three attempts) Outcome definition – well covered Outcome assessment – not blind Outcome measure – self-report via administered telephone survey Exposure assessment – well covered Exposure measure – administrative records Study length – not reported
Population	Country – Australia Setting – seven colposcopy clinics (public hospital (n = 3) and private gynaecology consulting room (n = 4)) Screening status – abnormal smear result and attending for colposcopy (unclear whether newly referred or follow up) Participants – 161 women with abnormal Pap smear results registered with seven colposcopy clinics (public and private) in New South Wales, Australia Inclusion criteria – aged 17 years or over, able to communicate in English, judged by clinicians to be physically and mentally able to participate, registered with one of the seven colposcopy clinics participating in the study Exclusion criteria – not reported
Exposure	Abnormal smear result and attending for colposcopy (n = 138)
Outcomes	Satisfaction with care Information needs before colposcopy Information needs after colposcopy
Notes	One key gynaecologist involved with the study nominated the details of 10 local gynaecologists who provided regular colposcopy services. Colposcopists were contacted using an information letter about the study, an explanatory telephone call and, if necessary, a visit to further discuss the study; 7/10 (70%) practitioners agreed to take part. Consenting participants were telephoned within one week of the clinic visit to complete the computer assisted telephone interview (CATI). The survey took between 10 and 15 minutes to complete

Study	Byrom[34]
Study design	Non-comparative descriptive study
Study quality score	+
Methods	Appropriate population – well covered Participation rate – not reported Outcome definition – well covered Outcome assessment – not blind Outcome measure – self-report via questionnaire Exposure assessment – well covered Exposure measure – administrative records Study length – not reported
Population	Country – UK Setting – colposcopy clinic of a cancer centre Screening status – abnormal smear result and newly referred for colposcopy Participants – 100 consecutive women with abnormal Pap smear results newly referred for colposcopy at a UK cancer centre clinic Inclusion criteria – not reported Exclusion criteria – not reported
Exposure	Abnormal smear result and attending for colposcopy (n = 100)
Outcomes	Timing of information delivery
Notes	This study is one component of a larger investigation evaluating colposcopy information leaflets
Study	**Gath[30]**
Study design	Non-comparative descriptive study
Study quality score	++
Methods	Appropriate population – well covered Participation rate – 102/114 (90%) women were seen at the first assessment, 99/114 (87%) at the second assessment and 96/114 (84%) at the third assessment Outcome definition – well covered Outcome assessment – not blind Outcome measure – self-report via interview and questionnaire Exposure assessment – well covered Exposure measure – administrative records Follow up – eight months Study length – women were approached about participation over a 12 month period
Population	Country – UK Setting – colposcopy clinic of a large teaching hospital Screening status – abnormal smear result and attending for first colposcopy Participants – 114 consecutive eligible women newly referred to the colposcopy clinic at the John Radcliffe Hospital in Oxford Inclusion criteria – abnormal cervical smear either at routine screening or follow up of a previously inconclusive smear; newly referred to colposcopy Exclusion criteria – not reported
Exposure	Abnormal smear result and attending for colposcopy (n = 102, first assessment; n = 99, second assessment; n = 96, third assessment)
Outcomes	Information needs
Notes	The women were interviewed on three occasions. The first interview took place four weeks before each woman's first clinic appointment. The second interview was completed four weeks after the first clinic appointment, and the third 36 weeks after the first clinic appointment. The timing of the third interview was chosen because all patients would be likely to have completed their treatment by then

Study	Idestrom[56]
Study design	Non-comparative descriptive study
Study quality score	+ (downgraded from ++ because of the retrospective nature of question asking – five years previously)
Methods	Appropriate population – well covered Participation rate – addresses were available in the population register for 345/354 (97%) of the sample; 16/345 (4.6%) of questionnaires sent out were returned as unknown address; 242/329 (74%) of women eligible for the study completed the questionnaire Outcome definition – well covered; retrospective by five years, therefore relies on recall Outcome assessment – not blind Outcome measure – self-report via questionnaire Exposure assessment – well covered Exposure measure – administrative records Study length – not reported
Population	Country – Sweden Setting – community screening programme Screening status – repeated mild dysplasia (two consecutive Pap smears) Participants – 329 women with two consecutive Pap smears indicating mild dysplasia during 1993 identified from the records of the Department of Clinical Pathology in Karlstad, Varmland County Inclusion criteria – age 20–62 years, resident in Varmland County, repeated mild dysplasia (two consecutive Pap smears) Exclusion criteria – protected identity, old address listed on the screening programme register
Exposure	Two consecutive Pap smears indicating mild dysplasia (n = 242)
Outcomes	Information needs
Notes	Failure of some respondents to answer particular questions resulted in missing values for certain variables with an average of missing answers of 2.6% (range 0.8–14%). The majority of responders were from rural areas (34% urban) and were well educated compared with the general county level of education. Questionnaire asked about experiences five years previously – potential for recall bias
Study	**Lauver[57]**
Study design	Non-comparative time series
Study quality score	+
Methods	Appropriate population – well covered Participation rate – 75/119 (63%) women completed the initial interview (nine women declined to participate, eight were ineligible and 26 could not be contacted within two weeks of learning their results); 40/75 (53%) women completed questionnaires prior to colposcopy and 35/75 (47%) completed questionnaires after colposcopy Outcome definition – well covered Outcome assessment – not blind Outcome measure – self-report via interview and questionnaire Exposure assessment – well covered Exposure measure – administrative records Study length – 14 months
Population	Country – USA Setting – private and public women's health clinics Screening status – received abnormal Pap test result Participants – 119 mainly white women with abnormal Pap test results who had not previously attended for colposcopy registered at multiple settings similar with regard to offering low cost or subsidised women's health, contraception and sexually transmitted infection services in the Midwestern United States Inclusion criteria – Pap test results revealing significant abnormalities warranting colposcopy evaluation (squamous atypia, dysplasia and HPV with dysplasia); no history of previous colposcopy; able to communicate in English Exclusion criteria – not reported

Exposure	Abnormal Pap test result (squamous atypia, dysplasia and HPV with dysplasia) (n = 75)
Outcomes	Information needs
Notes	Low questionnaire completion response rate; not clear whether the 35 women that completed the questionnaire after colposcopy were the same women as the 40 that completed the questionnaire prior to colposcopy
Study	**Manning[58]**
Study design	Non-comparative descriptive study
Study quality score	+
Methods	Appropriate population – well covered Participation rate – not applicable Outcome definition – well covered Outcome assessment – not blind Outcome measure – self-report via inquiry record forms Exposure assessment – adequately addressed Exposure measure – self-report via inquiry record forms Study length – 18 months
Population	Country – UK Setting – cancer information service in Belfast, Northern Ireland Screening status – not reported Participants – 1241 callers to a cancer information service (Action Cancer) based in Belfast, Northern Ireland; users of the service could be categorised into three groups: (1) relatives or friends seeking information on behalf of a cancer patient (46%), (2) individuals who had recently discovered a worrying and potentially cancer related symptom (33%) and (3) cancer patients (21%) Inclusion criteria – not reported Exclusion criteria – not reported
Exposure	Concerns related to 26 different cancer sites
Outcomes	Information requested about cancer-related symptoms
Notes	Of the 33% of women calling about their own symptoms, cervical cancer worries accounted for 13% of calls (eg about 4% of calls overall) It is unclear whether the callers in this study (or the patients on whose behalf they were calling) were actually taking part in an organised screening programme – the information provided represents extrapolated evidence
Study	**Olamijulo[25]**
Study design	Non-comparative descriptive study
Study quality score	+
Methods	Appropriate population – well covered Participation rate – 123/137 (90%) women completed and returned the study questionnaire Outcome definition – adequately addressed Outcome assessment – not blind Outcome measure – self-report questionnaire Exposure assessment – well covered Exposure measure – administrative records Study length – not reported
Population	Country – UK Setting – colposcopy clinic of a hospital in Dundee, UK Screening status – received abnormal Pap test result and newly referred for colposcopy Participants – 137 women with abnormal Pap smear results newly referred for colposcopy at the Ninewells Hospital in Dundee, UK Inclusion criteria – abnormal Pap smear result; newly referred for colposcopy Exclusion criteria – not reported
Exposure	Abnormal Pap test result and attending for colposcopy (n = 123)
Outcomes	Satisfaction with information leaflet Terms and language used in information leaflet
Notes	Text of the information leaflet provided to study participants included with the study report

Study	Onyeka[59]
Study design	Non-comparative descriptive study
Study quality score	+
Methods	Appropriate population – well covered Participation rate – 82/100 (82%) women completed and returned the study questionnaire (18 questionnaires were excluded because of incomplete or inappropriate completion) Outcome definition – poorly addressed; few details provided Outcome assessment – not blind Outcome measure – self-report via questionnaire Exposure assessment – well covered Exposure measure – administrative records Study length – five months
Population	Country – UK Setting – colposcopy clinic of a hospital in Preston, UK Screening status – mild or severe dyskaryosis and newly referred for colposcopy Participants – 100 consecutive women with mild or severe dyskaryosis newly referred for colposcopy at the Sharoe Green Hospital in Preston Inclusion criteria – diagnosis of mild to severe dyskaryosis; newly referred for colposcopy Exclusion criteria – not reported
Exposure	Mild to severe dyskaryosis and attending for colposcopy (n = 82)
Outcomes	Knowledge
Notes	

Study	Zapka[60]
Study design	Non-comparative descriptive study
Study quality score	–
Methods	Appropriate population – adequately addressed Participation rate – 1087/1561 (69.7%) women completed the telephone survey (80 women could not be contacted, 388 women refused to participate, six 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 smear result Participants – 1561 mainly white non-Hispanic women with abnormal smear results enrolled in one of four care plans across the USA Inclusion criteria – abnormal index Pap test, no Pap tests during the prior 300 days, aged 18 years and over Exclusion criteria – enrolled for fewer than 210 of the 270 preceding days; history of cervical cancer or hysterectomy before the index test
Exposure	Abnormal Pap test result (ASCUS: atypical squamous cells of undetermined significance; AGUS: atypical glandular cells of undetermined significance; LGIL: low grade squamous intraepithelial lesion and HGIL: high-grade squamous intraepithelial lesion) (n = 1087)
Outcomes	Process of care – receipt of confusing or conflicting information
Notes	

APPENDIX 7: DESCRIPTION OF QUALITATIVE STUDIES

Study	**Anhang[11]**
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 – well covered Data analysis – well covered Finding credibility – well covered Study length – August to September 2002
Population	Country – USA Setting – community Screening status – not reported Participants – 48 mainly Hispanic and white women with a high school education or less purposively sampled from a Massachusetts community Inclusion criteria – not reported Exclusion criteria – not reported
Themes	Overestimation of cancer risk Uncertainty Information needs
Notes	Participants were not taking part in an organised screening programme. A purposive sampling method was used to recruit low income and minority women. Eight focus groups, each composed of 3–12 women, were convened. The focus groups were stratified by age range (18–29, 30–54 and ≥ 55 years) when possible
Study	**Byrom[34]**
Study design	Qualitative
Study quality score	++
Methods	Research design – well covered Recruitment – well covered; no recruitment details reported Data collection – observation of a pre-colposcopy counselling session; questions asked and concerns raised were documented Participant/researcher relationship – not applicable Ethics – not reported Data analysis – adequately addressed Finding credibility – well covered Study length – not reported
Population	Country – UK Setting – cancer centre colposcopy clinic Screening status – abnormal smear result and attending for colposcopy Participants – 42 women with abnormal Pap smear results attending a pre-colposcopy counselling session run by two trained specialist colposcopy cancer centre nurses Inclusion criteria – not reported Exclusion criteria – not reported
Themes	A list of questions asked by 50% or more of the women was used to devise a questionnaire
Notes	The mean age in years 34.5 (range 20–58 years) and other demographic characteristics as well as presenting smear abnormalities of the participating women were representative of all women colposcopy attendees

Study	Evans[61]
Study design	Qualitative
Study quality score	+
Methods	Research design – well covered Recruitment – adequately addressed; no recruitment details reported Data collection – individual interviews and focus groups; tape recorded and transcribed Participant/researcher relationship – not reported Ethics – well covered Data analysis – not reported Finding credibility – well covered Study length – not reported
Population	Country – USA Setting – community Screening status – various Participants – 32 women aged 18–56 years with experiences ranging from never having had a Pap smear to having had a hysterectomy because of cervical cancer were identified though a snowball sampling method and interviewed Inclusion criteria – not reported Exclusion criteria – not reported
Themes	Information needs Intervention content Videotaped testimonials Prior knowledge level Order in which information is presented Style
Notes	Participants were not taking part in an organised screening programme. The individual interviews and focus groups were part of a programme of research that aimed to contribute to the development and formative evaluation of an interactive, theory driven CD-ROM intervention. Four focus groups were held (two with women 18–24 years and two with older women)
Study	**Fernbach[62]**
Study design	Qualitative
Study quality score	+
Methods	Research design – not reported Recruitment – adequately addressed; no recruitment details reported Data collection – semi-structured individual interviews (interview schedule) Participant/researcher relationship – not reported Ethics – not reported Data analysis – adequately addressed Finding credibility – adequately addressed Study length – not reported
Population	Country – Australia Setting – hospital dysplasia clinic Screening status – abnormal smear result and attending for colposcopy; some women had been treated for abnormality Participants – 60 women aged 19–56 years diagnosed with CIN1 attending the Royal Women's Hospital dysplasia clinic in Victoria Inclusion criteria – diagnosed with CIN1 Exclusion criteria – not reported
Themes	Information needs Understanding of abnormality Worry Fear Anxiety
Notes	

Study	Forss[63]
Study design	Qualitative
Study quality score	++
Methods	Research design – adequately addressed Recruitment – 11/17 (65%) women contacted from the antenatal health clinic group agreed to take part (six women declined); 19/26 (73%) women contacted from the gynaecological outpatient clinic group agreed to take part (three women did not reply/could not be located and four women declined) Data collection – individual interviews (topic guide); tape recorded and transcribed Participant/researcher relationship – not reported Ethics – not reported Data analysis – adequately addressed Finding credibility – adequately addressed Study length – 1997–1998
Population	Country – Sweden Setting – four antenatal health clinics and two gynaecological outpatient clinics in Stockholm Screening status – abnormal smear result Participants – 30 consecutive women who received information about an abnormal test result attending four antenatal health clinics and two gynaecological outpatient clinics in the same catchment area in Stockholm Inclusion criteria – age 23–60 years, Stockholm region resident, participating in the Stockholm population based cervical screening programme Exclusion criteria – not reported
Themes	Pap smear as routine confirmation of health Ambiguity of abnormal smear result Out of the ordinary contact Unclear/confusing communication Unhelpful statistics Issue of nothing vs something
Notes	One woman contacted from the gynaecological outpatient clinic group declined to participate further after the first interview; each woman was interviewed between one and six times – 30 women/84 interviews were included in an initial assessment, but only 21 women/55 interviews were included in the second, more formal, analytical reading of interviews and 8 women/17 interviews were selected for the final stage of analysis
Study	**Karasz[64]**
Study design	Qualitative
Study quality score	++
Methods	Research design – adequately addressed Recruitment – 53/61 (87%) of eligible women were available to be contacted (eight women refused); a series of names was randomly selected from the remaining list and 24 women were contacted successfully by telephone (two women declined); 17 interviews were completed in total Data collection – semi-structured telephone interviews; verbatim notes taken and transcribed Participant/researcher relationship – well covered Ethics –well covered Data analysis – well covered Finding credibility – well covered Study length – March to July 2001

Population	Country – USA Setting – general practice Screening status – abnormal smear result Participants – 17 women with low grade Pap smear abnormalities recruited from two urban family practice clinics serving ethnically diverse, low income patients in the Bronx, New York City Inclusion criteria – recently notified of a Pap smear classified as atypical, atypical squamous cells of uncertain significance (ASCUS) or low grade squamous intraepithelial lesion (LGSIL) Exclusion criteria – not reported
Themes	Distress Uncertainty Dissatisfaction
Notes	Not clear whether women were participating in an organised screening programme. Mean age was 34 years (range 19–56); ethnic origin Latina (59%) and African American (23%); interview languages English (76%) and Spanish (24%)
Study	**Kavanagh[65]**
Study design	Qualitative
Study quality score	++
Methods	Research design – well covered Recruitment – adequate; no recruitment details reported Data collection – semi-structured individual interviews (theme list); tape recorded and transcribed Participant/researcher relationship – not reported Ethics – not reported Data analysis – well covered Finding credibility – adequately addressed Study length – not reported
Population	Country – Australia Setting – three private outpatient gynaecology services and one women's health service in Canberra Screening status – abnormal smear result and treatment for abnormality Participants – 29 women with abnormal smear test results between late 1990 and mid-1992 registered with three private outpatient gynaecology services and one women's health service in Canberra Inclusion criteria – abnormal smear test result between late 1990 and mid-1992; gynaecological assessment and treatment for abnormality; registered with participating centres Exclusion criteria – invasive disease
Themes	Information needs Being told 'not to worry' Information gate keeping Out of the ordinary contact Diagram/video of cervix and colposcopy
Notes	Not clear whether women were participating in an organised screening programme

Study	Kuehner[29]
Study design	Qualitative
Study quality score	++
Methods	Research design – well covered Recruitment – well covered; 30 women were sent invitation letters and a general handout was available in the gynaecology clinic waiting room; not clear how many women in total were approached Data collection – in-depth structured individual interviews; tape recorded and transcribed Participant/researcher relationship – well covered Ethics – well covered Data analysis – adequately addressed Finding credibility – well covered Study length – not reported
Population	Country – USA Setting – military health care service Screening status – abnormal smear result and treatment for abnormality Participants – six women with abnormal smear results who either sought follow up care or not in a military health care setting Inclusion criteria – history of an abnormal Pap smear with instructions to receive follow up care; willingness to discuss the experience of receiving an abnormal Pap smear result Exclusion criteria – less than 18 years of age
Themes	Pap smear as routine confirmation of health Perceived threat to fertility Information needs Being 'more than a cervix' Follow up requirements Uncertainty
Notes	Not clear whether women were taking part in an organised screening programme. The women ranged in age from 32 to 64 years; three were career active duty military and the other three were military family members
Study	**McCaffery[9]**
Study design	Qualitative
Study quality score	++
Methods	Research design – well covered Recruitment – well covered; no recruitment details reported Data collection – focus groups (topic guide); tape recorded and transcribed Participant/researcher relationship – not reported Ethics – well covered Data analysis – well covered Finding credibility – well covered Study length – July to September 2000
Population	Country – UK Setting – community Screening status – eligible Participants – 71 women aged 20–59 years from four ethnic groups (self-identified as white British, African Caribbean, Indian and Pakistani) eligible for cervical screening within the Greater Manchester area recruited from social and community groups by purposive sampling Inclusion criteria – not reported Exclusion criteria –any history of cervical intraepithelial neoplasia; previous total hysterectomy

Themes	Confusion between high risk HPV types Stigma related to 'warts' Information needs
Notes	Ethnically matched community researchers recruited the participants who were specifically chosen to vary in age, marital/partner status, and socioeconomic position (measured via education) to provide a range of demographic backgrounds and experiences of interest to the research work. Eight focus groups were conducted in English, Gujarati or Urdu, as appropriate, and translated into English where necessary. To ensure that all participants had the same baseline knowledge, basic information about cervical cancer and screening and detailed information about HPV testing was provided at the beginning of the discussion session
Study	**Neale[66]**
Study design	Qualitative
Study quality score	++
Methods	Research design – well covered Recruitment – well covered; no recruitment details reported Data collection – observation of group counselling educational sessions; participants' questions and comments were recorded verbatim as well as any non-verbal communication such as laughter or anxiety Participant/researcher relationship – not applicable Ethics – not reported Data analysis – well covered Finding credibility – well covered Study length – not reported
Population	Country – UK Setting – hospital colposcopy clinic Screening status – abnormal smear result and attending for colposcopy Participants – 47 women with abnormal Pap smear results attending one of five pre-colposcopy group counselling educational sessions run by two specialist hospital colposcopy clinic nurses Inclusion criteria – no previous colposcopy; aged 20–60 years; not pregnant; diagnosed with mild to moderate dyskaryosis Exclusion criteria – not reported
Themes	Information needs
Notes	The women were taking part in a larger randomised controlled study to see whether the pre-colposcopy counselling sessions could reduce anxiety and other psychological distress associated with the procedure. Up to 20 women requiring colposcopy were invited to all of five sessions that lasted for approximately 1.5 hours each
Study	**Philips[67]**
Study design	Qualitative
Study quality score	+
Methods	Research design – well covered Recruitment – adequately addressed; 355 analysable responses were obtained from those asked to interpret the normal smear result and 1002 from those explaining an abnormal smear result; an overall response rate of 27.8% for the larger GP sample and 26.0% for the screening service distribution were achieved Data collection – open ended questionnaire responses Participant/researcher relationship – not applicable Ethics – well covered Data analysis – well covered Finding credibility – adequately addressed Study length – not reported

Population	Country – UK Setting – general practice and community screening programme Screening status – eligible Participants – 1357 women eligible for screening registered with 20 GP practices in the East Midlands and registered with the Nottingham screening service completed questionnaires related to their understanding of the meaning of a normal cervical smear result or an abnormal smear result Inclusion criteria – resident in the catchment area of participating GP practices; recalled for screening by the Nottingham screening service Exclusion criteria – not reported
Themes	Association of normal or abnormal results with technical inadequacy
Notes	Most of the data were obtained from questionnaires offered to women eligible for screening, during routine (non-screening) consultations, by GPs drawn from 20 practices in the East Midlands. Data were also obtained from a random selection of women being recalled for screening by the Nottingham screening service. Two variants of the questionnaire were randomly distributed on a 1:3 ratio for normal:abnormal questionnaires. Investigation of the source of responses from the GP sample indicated that five practices achieved response rates in excess of 50%, whereas a further five practices achieved response rates of < 15%. Response rates for general practice may have been influenced by a particular GP's enthusiasm in questionnaire distribution. There was no evidence of a disproportionate response by questionnaire type ($\chi^2 = 2.0$, $P > 0.10$)
Study	**Somerset[68]**
Study design	Qualitative
Study quality score	++
Methods	Research design – well covered Recruitment – well covered; no recruitment details reported Data collection – semi-structured individual interviews; tape recorded and transcribed Participant/researcher relationship – not reported Ethics – not reported Data analysis – well covered Finding credibility – well covered Study length – original trial six months in 1994; interviews were conducted between 4 and 20 days following the intervention
Population	Country – UK Setting – general practice Screening status – abnormal smear result Participants – 10 nurses and 10 participants taking part in the educational intervention arm of a trial investigating the effect of education on psychological stress in women placed under surveillance instead of immediate colposcopy Inclusion criteria – recruitment continued and interviews were conducted until data saturation had been reached Exclusion criteria – not reported
Themes	Pap smear as routine confirmation of health Fears Timing of information delivery Uncertainty
Notes	In 1994, a primary care based pragmatic randomised controlled trial was set up to examine the impact of providing women with mildly abnormal smear results who were placed under surveillance instead of immediate colposcopy with a structured educational intervention that aimed to reduce psychological distress. A total of 240 consecutive consenting women took part in the trial. General practices were allocated to either the control or the intervention group (in addition to standard care, there was an opportunity to visit the practice nurse and receive the educational package). Nurses were individually trained to use the educational package as part of a consultation with a woman recently in receipt of a mildly dyskaryotic smear result

Study	Van Til[69]
Study design	Qualitative
Study quality score	++
Methods	Research design – well covered Recruitment – well covered; 113/253 (53%) of women contacted agreed to participate (most common reasons given for refusal to participate were lack of interest or a seasonal work schedule); 60/81(74%) of women invited actually attended a focus group Data collection – focus groups (topic guide) and field notes; tape recorded and transcribed Participant/researcher relationship – not reported Ethics – well covered Data analysis – well covered Finding credibility – well covered Study length – May 2000
Population	Country – Canada Setting – community Screening status – due Participants – 60 women aged 45–70 years with no recorded Pap smear in the past five years recruited from across the province of Prince Edward Island Inclusion criteria – aged 45–70 years; no Pap test in the previous five years; intact cervix Exclusion criteria – not reported
Themes	GP preference Prearranged appointments Information needs
Notes	Participants were not taking part in an organised screening programme. Participant eligibility was determined by the PEI Department of Health Epidemiology Unit (laboratory cytology database linked to population registry)

APPENDIX 8: STAGE 5 SYNTHESIS AND EVIDENCE GRADING – MATERIALS

Adapted with permission from *Grading Quality of Evidence and Strength of Recommendations*.[46]

Combining the four elements: quantitative studies

Initial level of evidence

Randomised trial = high
Observational study = low**
Any other evidence = very low

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

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 relationship (+1)
- all plausible confounders would have reduced the effect (+1).

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 5: 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 5: 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 quantitative (Glasziou P, personal communication, 19 January 2005) 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 relationship	Evidence of dose–response relationship	No information	
Plausible confounders	No plausible confounders (or all would have increased effect)		
Close conformity	Two or more studies rated Q++		