

## **INTERIM** Good practice guidance for cervical sample takers

A reference guide for primary care and community settings in the NHS Cervical Screening Programme

# INTERIM GOOD PRACTICE GUIDANCE FOR CERVICAL SAMPLE TAKERS

NHSCSP Good Practice Guide No 2 July 2011

#### Editor

#### **Ruth Stubbs**

Quality Assurance Primary Care Co-ordinator, Liverpool Women's NHS Foundation Trust, Crown Street, Liverpool L8 7SSTel (0151) 708 9988, Fax (0151) 702 4028

#### **Editorial Group**

NHS Cancer Screening Programmes National Clinical Primary Care Group Publications Subcommittee

#### Gill Burgess

Cancer Screening Co-ordinator, NHS Croydon

#### **Marilyn Butt**

Clinical Care Training Manager, Bristol and South Gloucestershire Primary Care Trust **Helen Doherty** 

Regional QA Primary Care Nurse lead, Eastern Region Quality Assurance Team

#### Lesley Greenwood

Regional Training Coordinator, Cervical Screening Training, Newcastle Primary Care Trust **Anny Jones** 

Policy and Publications Editor, NHS Cancer Screening

#### **Brenda Sutherland**

Primary Care Training and Development Manager, Leicestershire Country and Rutland Primary Care Trust

#### **Richard Winder**

Deputy Director, NHS Cancer Screening Programmes

#### Published by

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

Tel: 0114 271 1060 Fax: 0114 271 1089

Email: info@cancerscreening.nhs.uk Website: www.cancerscreening.nhs.uk

#### © NHS Cancer Screening Programmes 2011

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

This document is available in PDF format on the NHS Cancer Screening Programmes website.

### **VERSION CONTROL SHEET**

INTERIM Good practice guidance for cervical sample takers		
Version	2 <sup>nd</sup> edition, v1	
Status	Interim: electronic only	
Author/ editor	Ruth Stubbs on behalf of NHS Cancer Screening Programmes National Clinical Primary Care Group Publications Subcommittee	
Responsible Director	Richard Winder	
Approved by	Richard Winder	
Date issued	July 2011	
Last review date		
Next review date	July 2012	
Applies to	All staff in the NHS Cervical Screening Programme	

Version	Description of change	Reason for change	Author/Editor	Date
2 <sup>nd</sup> ed, v1	General update	To reflect changes to the NHSCSP (including HPV triage and test of cure) and the environment in which it operates.	Ruth Stubbs/NHSCSP National Clinical Primary Care Group Publications Subcommittee	July 2011

For details of any changes to this document following its publication in July 2011 please see updates at

https://www.csp.nhs.uk/.

### **CONTENTS**

Acknowledgements	νi
Section one: Introduction  The NHS Cervical Screening Programme Aims of this guidance The impact of cervical screening Cervical cancer: incidence and mortality Risk factors for cervical cancer Coverage of the NHS Cervical Screening Programme Initiatives to improve screening coverage National quality assurance structure of the NHS Cervical Screening Programme Ensuring quality: high quality screening Ensuring quality: QA visits Ensuring quality: what to do if there is a suspected critical incident affecting the NHS Cervical Screening Programme	1 1 1 2 2 3 4 5–6 7 9
Section two: Screening intervals Why women under 25 and women over 65 are not invited for screening Clinical practice guidance for the assessment of young women aged 20-24 with abnormal vaginal bleeding	<b>10</b> 10 11
Women over 65 Cervical screening: call/recall, invitation, results, and non-attenders Good practice for Primary Care Trusts Summary of PCT/screening agency and practice responsibilities for programme management Open Exeter: a handy guide for GP practices Access to Open Exeter Registering with Open Exeter	11 13 14 15–16 17 18
Section three: Human papilloma virus (HPV)  HPV: frequently asked questions  Open Exeter and the HPV vaccination programme  Protocol for HPV triage and management  HPV triage results  HPV triage and test of cure protocol  HPV laboratory terminology and management guidelines	19 19–20 21 22 23 24 25
Section four: Sample taker training Criteria for sample taker mentoring Training supervision The consultation process: the clinical environment Taking a history Taking the sample Some frequently asked questions	26 26 27 28 29 30–31 31
Section five: Laboratory terminology and management guidelines Recall protocol for negative screening Results and management protocol Colposcopy direct referral Summary of standards for colposcopy Guideline for cytological follow up after hysterectomy Failsafe	32 32 33–35 36 37 38 39
Section six: Disabilities and special circumstances Physical and learning disabilities Who to screen in special circumstances	<b>40</b> 40 41
Glossary	42–45
Appendix 1: Local structure of NHS Cervical Screening Programme	46 47

### **ACKNOWLEDGEMENTS**

Illustrations appear by kind permission of

- Hologic, Inc, 35 Crosby Drive, Bedford, MA 01730, USA (page 29)
- Books Beyond Words, Hunter Wing, St George's, University of London, SW17 0RE, from An Easy Guide to Cervical Screening, by NHS Cancer Screening Programmes, England (pages 5, 6, 39).
- LaSCA (NHS), 3 Caxton Road, Fulwood, Preston PR2 9ZZ, from Practice Guide to Open Exeter (page 20).

## SECTION ONE Introduction

#### **The NHS Cervical Screening Programme**

The NHS Cervical Screening Programme (NHSCSP) aims to reduce the number of women who develop invasive cervical cancer and the number of women who die from it. It does this by regularly screening all women at risk so that conditions which might otherwise develop into invasive cancer can be identified and treated. In 2008, over 78% of eligible women in England had attended cervical cancer screening at least once in the previous five years.<sup>1</sup>

More than 100,000 people are involved in the NHSCSP. They include the doctors and nurses who take the samples in GP surgeries and community clinics, the laboratory staff who review them and the people who run the computer systems. These activities are coordinated by the national office of NHS Cancer Screening Programmes through a number of National Quality Assurance Coordination Groups.

#### Aims of this guidance

This is an interim document designed to offer guidance to all cervical sample takers involved in the NHSCSP during the transition to GP commissioning. It aims to

- outline the sample taker's responsibilities in the NHSCSP.
- promote good practice that is consistent with national policy
- outline the training requirements for sample takers in the NHSCSP
- set out the existing roles and responsibilities of GP practices and Primary Care
  Trusts involved in the programme (The role of GP practices under the new NHS
  structure will be reflected in the next revision of this guidance)
- outline the audit and documentation requirements for sample takers in the NHSCSP
- offer clear advice to support consistent delivery of the programme
- advise on some of the issues and frequently asked questions that arise in a consultation.

National Centre for Health Outcomes Development, at <a href="http://www.nchod.nhs.uk/">http://www.nchod.nhs.uk/</a>.

#### The impact of cervical screening

Although cervical screening cannot be 100% effective in detecting cancer, cervical screening programmes have been shown to reduce the incidence of cancer in a population of women. The NHS Cervical Screening Programme was established in 1988; over the next decade the incidence of cervical cancer across England and Wales fell by more than 40 per cent, reflecting screening's impact on a generation of previously unscreened women. Since then cases of cervical cancer have continued to fall, though at a steadier rate. The importance of early detection is underlined in survival rates, with around 68% of cervical cancer patients in England and Wales surviving their disease five years or more after diagnosis.<sup>2</sup>

#### **Cervical cancer: incidence and mortality**

#### Cervical cancer registrations

In 2007 there were 2,276 new registrations of invasive cervical cancer in England.<sup>3</sup>

#### Cancer incidence

Since 1992, there has been an increase in the incidence rates of carcinoma in situ for women aged 30-34 in England and Wales. There has been a similar increase among younger women, but not among those over 34. Incidence rates of invasive cervical cancer, in contrast, have generally shown a downward trend since 1990. The Great Britain agestandardised incidence rate for cervical cancer has decreased by around 44% since 1975, although it presented a slight increase in the 1980s. Cervical cancer incidence and mortality rates have declined substantially in Western countries with screening programmes: in the UK incidence rates rank 141st of the 172 countries worldwide and the mortality rate ranks 148th.<sup>4</sup>

#### Cervical cancer mortality

In 2008, 830 women died from cervical cancer in England and Wales. Mortality rates generally increase with age: in 2008 the highest number of deaths from cervical cancer were recorded in the 80-84 age group. Fewer than 7% per cent of deaths occurred in women under 35.<sup>5</sup>

For the latest combined statistics on cancer incidence, mortality and survival in England, see the <u>Cervical Screening and Cancer e-Atlas</u> (2010).<sup>6</sup>

Cancer Research UK, at http://info.cancerresearchuk.org/cancerstats/

Office of National Statistics, at <a href="http://www.statistics.gov.uk/downloads/theme\_health/2007cancerfirstrelease.xls">http://www.statistics.gov.uk/downloads/theme\_health/2007cancerfirstrelease.xls</a>
 Cancer Research UK, cervical cancer 1975-2006, at <a href="http://info.cancerresearchuk.org/cancerstats/types/cervix/incidence/# world">http://info.cancerresearchuk.org/cancerstats/types/cervix/incidence/# world</a>. For local and national data see also the websites of regional QARCs and Cancer Intelligence Units.

Office of National Statistics, Mortality statistics: deaths registered in 2008, at <a href="http://www.statistics.gov.uk/downloads/theme\_health/DR2008/DR\_08.pdf">http://www.statistics.gov.uk/downloads/theme\_health/DR2008/DR\_08.pdf</a>.

East Midlands Public Health Observatory, <u>Cervical Screening and Cancer e-Atlas</u> (2010) at http://www.empho.org.uk/tcr/cervicalEatlas.aspx.

#### Risk factors for cervical cancer

The exact cause of cervical cancer is not known. However, it is known that

- some types of human papilloma virus, in particular HPV 16 and HPV 18, are found in over 99% of cervical cancers. These are known as 'high risk' types. Other types (eg HPV 6 and HPV 11) cause genital warts. Those which cause genital warts do not place a woman at increased risk of developing cervical cancer. Other types of HPV appear to be harmless
- the majority of sexually active women will come into contact with high risk HPV types at some time in their life. This is true whether they are in heterosexual or same-sex relationships (see pages 18–19). In most women, their body's own immune system will get rid of the infection without them ever knowing it was there. However women persistently infected with high-risk HPV types may develop cervical abnormalities (CIN) which could develop into cervical cancer if left untreated
- women with many sexual partners (or whose partners have had many partners) are more
  at risk of developing cervical cancer, because multiple partners are more likely to expose
  them to HPV. A woman with only one partner could contract HPV if that partner has
  previously been in contact with the virus
- women who are immunosuppressed (for example, those who are taking immunosuppressive drugs after an organ transplant, or women who are HIV positive) may be at increased risk of developing cervical cancer
- women who smoke are about twice as likely to develop cervical cancer as non-smokers.
   This may be because smoking is associated with high risk health behaviours or because it suppresses the immune system allowing the persistence of high risk HPV infection.
   Stopping smoking appears to help clinical abnormalities to return to normal
- using a condom offers only very limited protection from transmission of HPV
- long term use of oral contraceptives increases the risk of developing cervical cancer but the benefits of taking oral contraceptives far outweigh the risks for the majority of women
- women with a late first pregnancy have a lower risk of developing cervical cancer than those with an early pregnancy. The risk rises with the number of pregnancies

Despite these risk factors, cervical screening can prevent around 75% of cancer cases in women who attend regularly.

Screening is one of the most effective defences against cervical cancer.

#### **Coverage of the NHS Cervical Screening Programme**

Coverage refers to the percentage of women eligible for screening who have been adequately tested within the screening interval (3.5 or 5 years, according to age). (It is often confused with 'uptake': the percentage of women invited for screening who are tested within 6 months of receiving their invitation.) The effectiveness of the NHSCSP is judged in part by the percentage of women in the target age group (25 to 64) who have been screened in the last five years. If overall coverage of 80 per cent can be achieved, a reduction in death rates of around 95 per cent may be possible in the long term.

#### Figures for 2008/2009 show that

- for the first time since 2002 the percentage of eligible women aged 25 to 64 who have been screened at least once in the previous 5 years has increased. It is now 78.9% compared with 78.6% in 2008, 81.6% in 2002 and 82.3% in 1999.
- the increase in coverage is more prominent amongst the younger age groups. The proportion of 25 to 49 year olds (screened every 3 to 3.5 years) increased to 72.5% compared with 69.3% last year (a 3.2% increase). Within the older age range (50 to 64 – screened every five years) the proportion of women being screened has fallen slightly to 80.0% compared with 80.3% in 2008
- coverage (25 to 64) was 80% or higher in 67 of the 152 Primary Care Organisations, compared with 63 in the previous year
- but participation in cervical screening varies greatly across the country and is generally lower in the most deprived areas.

For details see the NHSCSP website and the <u>Cervical Screening and Cancer e-Atlas</u> (2010).<sup>8</sup>





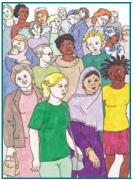


Posters are produced by NHS Cancer Screening Programmes and may be ordered online at <a href="https://www.orderline.dh.gov.uk">www.orderline.dh.gov.uk</a>, or call 0300 123 1002 to set up an account, or call 0300 123 1003 (no account required).

Because it is a snapshot of a changing situation, the coverage figure always relates to a specific date. (See also Glossary.)

East Midlands Public Health Observatory, <u>Cervical Screening and Cancer e-Atlas</u> (2010) at http://www.empho.org.uk/tcr/cervicalEatlas.aspx.

#### Initiatives to improve screening coverage



© Books Beyond Word

All providers and commissioners of NHS healthcare, have a duty to recognise the diversity of their population and the diverse experiences, aspirations and needs of staff and patients.

There are a number of ways to encourage women to attend for regular cervical screening. Listed below are some initiatives that have been shown to have a positive effect on coverage rates

When checking prior notification lists (PNLs) ensure that 'ghost' patients are removed and addresses are correct.

It is recognised that women often give low priority to their own health needs and may need regular encouragement to attend for screening and advice.

Use leaflets, information in appropriate languages and (where appropriate) text reminders. Many women are unclear about aspects of the tests.

Consider whether clinic times are appropriate. Offer regular evening and weekend clinics and take into account community events which may be barriers to attendance.

Provide information on alternative clinics outside the practice where women can have samples taken if more convenient times are available.

NHS CSP information leaflets for cervical screening should be readily available.

Ensure patients know that the sample can be taken by a female doctor or nurse.

Make sure that your service is culturally sensitive and that a female staff member is available and trained to offer information and guidance where language barriers exist.

Ensure that the sample taking environment is suitably equipped and offers complete privacy.

Highlight medical records and insert computer prompts for all women who fail to attend.

For non-attenders, ensure that screening is raised at the next appropriate visit and that the patient is fully informed of the benefits of regular screening.

Reception staff should have access to appropriate update training and information sessions so they are fully informed of any changes to the screening programme.

Reception staff should encourage attendance for screening, if appropriate. Computer prompts may help with this.

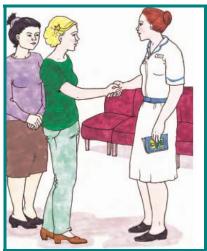
When considering these initiatives, it should be borne in mind that the final decision on whether to participate in screening rests with the individual.

#### **Useful resources**

- Cervical Screening: the Facts. (NHSCSP leaflet available in 19 languages).
- Promoting Informed Choices on Cancer Screening in a Diverse Community. NHS Cancer Screening Programmes, 2009 (NHSCSP Publication No 6)
- Communicating Risk Information about Breast and Cervical Cancer and Cancer Screening to Women from Minority Ethnic and Low Income Groups. NHS Cancer Screening Programmes, 2009 (NHS CSP Publication No 5)
- Equal Access to Cervical Screening for Disabled Women. NHS Cancer Screening Programmes, 2006 (NHS CSP Publication No 2)
- An Easy Guide to Cervical Screening, NHS Cancer Screening Programmes, 2006 (leaflet for women with learning difficulties)
- HPV Triage and Test of Cure: Draft Implementation Guidance. NHS Cancer Screening Programmes, 2011. (NHSCSP Good Practice Guide No 3).
- Cervical Screening in Lesbian and Bisexual Women. NHS Cancer Screening Programmes, 2009, (leaflet)
- Cervical Screening: A Multimedia Educational Programme for Physicians and Patients. NHS Cancer Screening Programmes, 2009 (available in six languages)

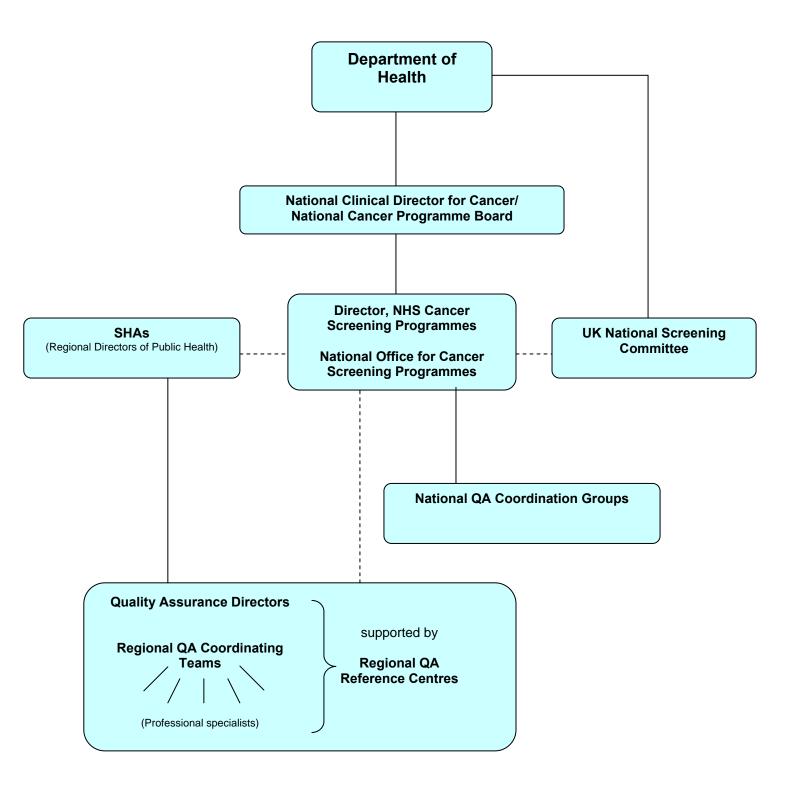
All of these, and details of the full range of NHS CSP publications, information leaflets, CDs and DVDs in up to 20 languages (including British Sign Language), can be accessed by clicking on NHS Cervical Screening Programme Publications.

Leaflets may be ordered online at <a href="https://www.orderline.dh.gov.uk">www.orderline.dh.gov.uk</a>, or call 0300 123 1002 to set up an account, or call 0300 123 1003 (no account required).



© Books Beyond Words

Fig 1: National Quality Assurance structure of NHS Cervical Screening Programme



## **Ensuring quality High quality screening**

The quality of cervical screening in England is assured through a network of regional Quality Assurance Directors (or QADs), and these are responsible to their regions' Directors of Public Health. (See Figure 1.) Each QAD is supported by a regional administrative hub, known as the Quality Assurance Reference Centre. These centres help to ensure that national standards set by the NHS Cervical, Breast and Bowel Screening Programmes are achieved, and support the development of effective, locally-delivered, screening services

Quality Assurance Reference Centres (or QARCs) are the first point of contact for information about cervical screening programmes in their region. Their role is to establish high quality systems for coordinating and monitoring all aspects of screening. To do this they work with the local cervical screening programmes, Primary Care Trusts, laboratories, colposcopy clinics and genitourinary medicine services that participate in the NHS Cervical Screening Programme. They collect and analyse data on the performance of local screening programmes and compare them with national standards. They support local programmes with staff training, guidance on good practice, and quality audits. They implement policy and arrange formal assessment visits to organisations that provide cervical screening. Every Primary Care Trust (PCT) has a nominated person responsible for its cervical screening programme and for implementing national guidelines.

National QA Coordination Groups contribute to the development of policy and guidance across the NHSCSP, advise on standards for staff and technical equipment, and monitor performance. Among the groups supporting their work are the National Colposcopy, Laboratory and Clinical Primary Care QA Groups and the National Cervical Screening User Group.

## **Ensuring quality QA visits**

QA visits are an integral part of ensuring a high quality screening service and represent one element in the continuous process of monitoring and enhancing performance. Their functions include

- assessing a local cervical screening service's compliance with minimum standards and its relationships with other parts of the programme
- identifying and promote good practice
- identifying areas for improvement and make recommendations for achieving it.

Visits normally take place once every three to four years. They are undertaken by a multidisciplinary QA team with the support of the regional Quality Assurance Reference Centre (QARC).

Information about visits, their timing and organisation can be obtained from your QARC. More detailed guidance on the principles and practice of QA visits is set out in *Guidelines for Quality Assurance Visits in the Cervical Screening Programme*. Cancer Screening Programmes, 2008 (NHSCSP Publication No 30), at <a href="http://www.cancerscreening.nhs.uk/cervical/publications/nhscsp30.html">http://www.cancerscreening.nhs.uk/cervical/publications/nhscsp30.html</a>

#### **Ensuring quality**

What to do if there is a suspected critical incident affecting the NHS Cervical Screening Programme

#### Introduction

There have in the past been a number of widely publicised incidents in the Cervical Screening Programme. Many of them involved problems with the reporting of samples by cervical cytology laboratories. Today, however, improvements in the quality assurance of laboratories mean that incidents are more likely to occur in primary care, or between laboratories and PCT call/recall departments.

#### What counts as an incident?

An incident may be defined as: any unintended or unexpected occurrence which could have or did lead to harm to patients, or to staff, or to visitors to the Programme's premises, or that is likely to give rise to public concern or adverse media interest.

#### **Dealing with incidents**

All NHS CSP staff should familiarise themselves with their site's local policies and procedures for managing incidents, suspected incidents and near misses. In particular, you should be aware of the need for prompt and accurate reporting.

The confidentiality of NHS CSP patients and staff must be protected in accordance with policy and legal requirements.

All incidents and suspected incidents should be reported in the first instance to your manager/ supervisor who will then report it to your PCT Clinical Governance team or Clinical Risk lead.

If a more formal investigation is needed the QARC will be notified. This is usually done by your Programme Director/ Programme Manager or by the PCT, and agreed procedures for a prompt and thorough response will be followed.

Serious incidents in the NHS CSP may also involve other agencies within or outside the NHS. Cooperation and collaboration with other agencies is therefore key to understanding what went wrong and learning how the risk of similar incidents occurring in the future can be reduced.

For detailed guidance see *Interim Guidelines for Managing Incidents in the NHS Cervical Screening Programme*, 2<sup>nd</sup> edition. Cancer Screening Programmes, 2010 (NHSCSP Publication No 11), available on the <u>NHSCSP intranet site</u>.

## SECTION TWO Screening intervals

Age group (years)	Frequency of screening	Call and recall
25-49	3 yearly  First invitation issued at 24.5 to ensure screening starts promptly at 25.	The administrative tasks associated with the call and recall of women in the NHSCSP are undertaken by PCTs or their local screening agencies. These tasks include
50-64 65+	Only screen those who have not been screened since age 50 or have had recent abnormal tests. (See box on page 11.)	<ul> <li>ensuring all eligible women aged 25-64 are included in the screening programme</li> <li>inviting all eligible women to attend for screening</li> <li>notifying women of their test result</li> <li>ensuring appropriate follow up and recall</li> </ul>

#### Why women under 25 and women over 65 are not invited for screening

Cervical cancer is very rare in women under 25. Evidence has shown that screening women under the age of 25 may suggest that they have cervical abnormalities when in reality it is simply that the cervix is still developing. This can cause anxiety and prompt unnecessary investigations which may damage the cervix and lead to premature births later in life. Compared with other age groups, moreover, screening women under 25 has little or no effect on the incidence of cervical cancer. Starting screening at age 25 means that lesions which are destined to progress will still be screen-detectable and those that would regress will no longer be a source of anxiety. Younger women will not have to undergo unnecessary investigations and treatments.

Any woman under 25 who is concerned about her risk of developing cervical cancer, or her sexual health generally, should contact her GP or Genitourinary Medicine (GUM) Clinic.

Cervical screening is not a diagnostic tool. Women under 25 years of age who present with symptoms should be referred to a gynaecologist.

In June 2009 the Advisory Committee on Cervical Screening reviewed the policy of starting screening at age 25 and agreed unanimously there should be no change in the current policy.<sup>9</sup>

For details see the Department of Health website [ARCHIVED CONTENT] Screening: Department of Health - Health care; for the Minutes of the Advisory Committee see <a href="http://www.cancerscreening.nhs.uk/cervical/cervical-review-minutes-20090519.pdf">http://www.cancerscreening.nhs.uk/cervical/cervical-review-minutes-20090519.pdf</a>. See also Peter Sasieni, Alejandra Castanon, Jack Cuzick, *The Impact of Cervical Screening on Young Women: a Critical Review of the Literature 2002-2009*, NHS Cancer Screening Programmes, 2010 (NHSCSP)

Publication No 31) at http://www.cancerscreening.nhs.uk/cervical/publications /nhscsp31.html.

## Clinical practice guidance for the assessment of young women aged 20-24 with abnormal vaginal bleeding

Cases of cervical cancer in women younger than 25 years are rare – generally fewer than 50 cases per year. However the Department of Health notes that in a significant number of these cases there is a delay in diagnosis. This is because of delayed examination following self-referral with abnormal vaginal bleeding, which is relatively common in this age group.

It has been estimated that postcoital bleeding is reported by around 1 in 600 women aged 20-24 per year. Intermenstrual bleeding is more common than this and it may be that 0.5-1% of women in this age present with abnormal vaginal bleeding each year. There are around 1.5m women aged 20-24 in England and it could, therefore, be estimated that 7,500 – 15,000 women per year will report abnormal vaginal bleeding. In practice the number could be larger than this.

In its Clinical Practice Guidance for the Assessment of Young Women aged 20-24 with Abnormal Vaginal Bleeding, the Department of Health advises that the cardinal symptom of cervical cancer in this age group is postcoital bleeding, but persistent intermenstrual bleeding (which is more common) also requires attention. The critical intervention in the diagnosis of cervical cancer is an immediate speculum examination to enable a clear view of the cervix. Following a relevant history, it is therefore necessary for women who present with postcoital bleeding or persistent intermenstrual bleeding to be offered a speculum examination either in primary care or at a GUM clinic. This could be performed by a practice nurse experienced in cervical screening.

If the cervix looks abnormal and suspicious, which will be the case in a very small proportion of cases, the correct action is urgent referral to colposcopy. If there is a benign lesion, such as cervical polyp, a routine gynaecological referral will suffice. If the cervix looks normal, the recommended action will be a pregnancy test and testing for cervical infection (eg Chlamydia, N Gonorrhoea, Herpes), which could be performed in general practice, family planning clinics or GUM clinics. Any positive tests for sexually transmitted infections would need to be appropriately treated.

For a summary of this guidance see Figure 2 below. For fuller details see <a href="http://www.dh.gov.uk/prod\_consum\_dh/groups/dh\_digitalassets/@">http://www.dh.gov.uk/prod\_consum\_dh/groups/dh\_digitalassets/@</a> <a href="http://www.dh.gov.uk/prod\_consum\_dh/groups/dh\_digitalassets/@">dh/@en/@ps/documents/digitalasset/dh\_113553.pdf</a>.

#### Women over 65

If the next test due date is over 65 years of age, the woman will be taken out of the call/recall system automatically **unless** she needs ongoing surveillance or follow up in accordance with NHSCSP guidelines. Cytological surveillance is generally required if a woman has had an abnormal result in any of her three most recent tests or is recommended for early repeats owing to a previous abnormality. In sentinel site areas a woman may be ceased from recall after a recent mild or borderline result provided that an HPV test is negative. Women aged 65 and over who have never had a sample taken are entitled to a test.

Fig 2: Investigating abnormal vaginal bleeding in women under 25

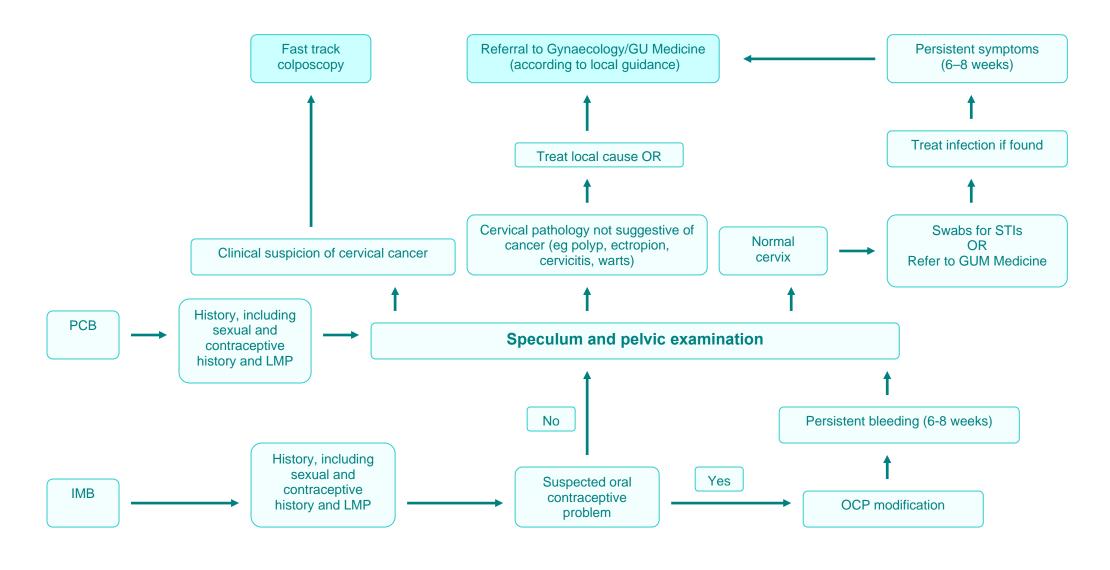
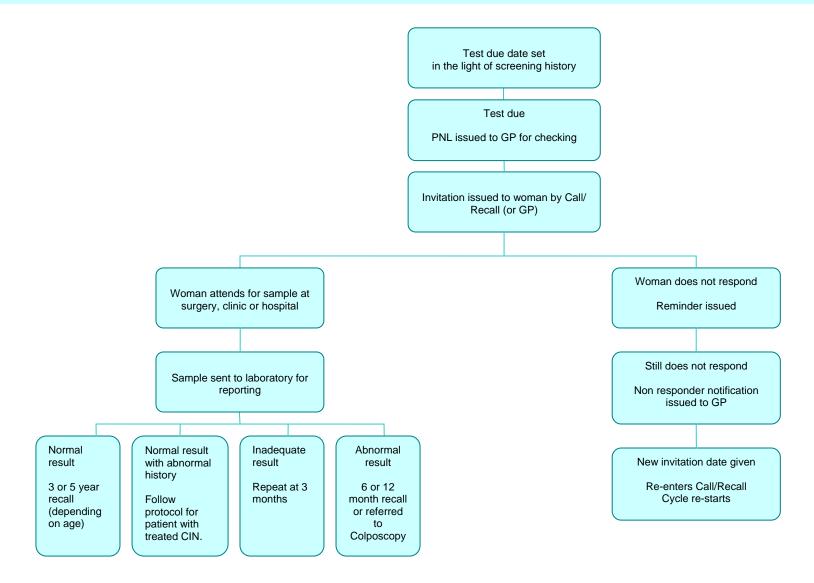


Fig 3: Cervical screening: routine call/ recall, invitation, results, and non-attenders (For HPV triage see Section Three)



#### **Good practice for Primary Care Trusts (PCTs)**

### The PCT commissions the services of the screening agency.

The PCT is responsible for devising relevant local procedures and protocols to support the delivery of the cervical screening programme in accordance with NHS CSP guidance. It must also ensure that these are fully understood by staff delivering the programme.

The first responsibility of screening staff is to ensure that eligible women are included in the screening programme.

- All women aged 25–64 registering with a GP must be invited for screening if their screening record is not up to date.
- Women aged under 25 should be sent their first invitation at 24½ years.
- Women aged over 25 should be sent a letter of routine invitation five to six weeks before the date their test is due, and not later than the test due date.

#### For more information see:

Time Dependent Response to Invitation for Cervical Screening. NHS Cancer Screening Programmes, 2007, (NHSCSP Publication No 29).

Cervical Screening: the Facts. (NHSCSP brochure)

Both are available at

www.cancerscreening.nhs.uk/cervical/.





#### Inviting eligible women

Send the NHSCSP leaflet *Cervical Screening: the Facts* with all invitation and reminder letters. The webpage (<a href="http://www.cancerscreening.nhs.uk/cervical/publications/in-04.html">http://www.cancerscreening.nhs.uk/cervical/publications/in-04.html</a>) gives details of its availability in other languages and formats.

- GP practices may, if they wish, add a limited amount of free text to the standard invitation letters: eg to advise women of the availability of a practice nurse to take tests and of female sample takers and chaperones, or to provide details of clinic times.
- If invitation letters are returned marked 'undelivered', set call/recall system to ensure a new letter is produced on receipt of new address.
- Write to GP practice to notify them of any cases where an invitation for an 'early repeat' test is returned undelivered.

#### Recording and notifying test results

- Return any results that fail system validation checks to the laboratory for clarification.
- Notify the woman's GP if the result letter is returned undelivered.
- Send the result letter to the address given by the woman at the time of her test. If records show she has moved since that date, forward result to new PCT.

#### Ensuring appropriate follow up/recall

- Send non-responder notifications to GP practices for any women who fail to respond to the invitation letter and subsequent reminder.
- Send notification to GP practice for any newly registered women who are on early recall.
- Set the computer system to ensure screening histories for women who move to live in another area are transferred on a daily basis.

For more information see *Cervical Screening System User Reference Manual*, at <a href="http://www.connectingforhealth.nhs.uk/systemsandservices/ssd/downloads/cervical/index.html">http://www.connectingforhealth.nhs.uk/systemsandservices/ssd/downloads/cervical/index.html</a>

## Summary of PCT/screening agency and practice responsibilities for programme management

PCT/ screening agency	PRACTICE
Call and recall	
Ensure all eligible women are included in the Programme.  Check with the GP practice to ensure invitation is appropriate (by sending the prior notification list electronically or in hard copy).  Send letter of withdrawal to women who wish to withdraw from screening and are fully aware of what this involves. PCT will cease, confirm this to women in writing, and copy to GP.	Complete and return Prior Notification Lists (PNL). GP or PN to authorise PNL if a woman is removed from the list for any reason other than moved away  Ask PCT to defer invitation if  woman has been recently tested sample not appropriate at time fully informed woman declines current invitation.  Ask PCT to cease recall owing to age or no cervix.  If a woman advises that she wants no further invitations, ensure she has sufficient accurate information to make an informed choice to withdraw from the Programme and has expressed in writing (to the PCT) her desire to be ceased.
Invitation	
Send the woman an invitation five to six weeks before screening is due.	Flag records for discussion when woman next attends the practice
Send first reminder if the woman fails to respond to the invitation.  PCT may send second reminder if woman	Send second and/or third reminder (depending on local protocol) if woman fails to respond. GP reminders may be written or verbal.
fails to respond to first reminder. (This depends on local protocol; it may be done by GP practice.)	
Send first and then, if necessary, final non-responder notification to the GP practice if no response is received.	
Sample taking	
Commission appropriate cervical screening services.	Ensure that all those invited receive and <i>The Facts</i> leaflet and encourage them to read it.
Keep a register of all sample takers in the PCT.	Agree with the woman how she will be informed of the result (normally letter from PCT).
Monitor the training and development needs of all sample takers in the PCT and provide adequate and appropriate novice and update	Take cervical sample as set out in national guidance (see Section Four of this document, pages 29–30).
training.	Complete request form with accurate name, demographic and clinical details: visualisation of the cervix, sampler used, adequate sampling, previous abnormalities and treatment. (Open Exeter system is able to pre-populate HMR101 forms with name and demographic information.)
	Record sample taker ID on request form.
	Document the consultation (see page 30).
	Verify the sample labelling and request form and send the sample the same day to the laboratory.

## Summary of PCT/screening agency and practice responsibilities for programme management/ continued

PCT	PRACTICE	
Results		
Mail the woman her result letter.  If asked not to do so, follow local protocols.	If referral for colposcopy is recommended ensure that  the woman is informed  appropriate referral arrangements have been made.  If urgent referral is required, the woman should be notified on a personal basis in a manner that is appropriate for her individual circumstances.	
Managing non-attendees/failsafe		
If no response is received, send the first and then, if necessary, the final non-responder notification to the GP practice. (See Figure 2 page 12.)		
	<ul> <li>call/ routine recall – flag record for discussion when the woman next attends practice</li> <li>early repeat sample – flag record and ask the woman to attend practice</li> <li>non-attendance at colposcopy – flag record and ask the woman to attend practice</li> <li>GP practices are responsible for ensuring that colposcopy has</li> </ul>	
	taken place, even if direct referral operating (see page 35)  GP responds to laboratory failsafe enquiry.	

#### Ceasing policy

Only cease women who fulfil the criteria or who have asked the PCT/ screening agency in writing be removed from the screening programme.

Unless the woman has specifically requested otherwise, the screening office must write to her at her registered address to confirm that recall has ceased and to give instructions on how to rejoin the programme at a future date if this is required

#### For further information see:

Cervical Screening Call and Recall: Guide to Administrative Good Practice. NHS Cervical Screening Programme, 2004 (NHSCSP Publication No. 18)

Withdrawing from the NHS Cervical Screening Programme: interim guidance, NHS CSP October 2009.

Both are available at <a href="https://www.cancerscreening.nhs.uk/cervical/">www.cancerscreening.nhs.uk/cervical/</a>.

Ask PCT to cease recall owing to

- age over 65 (see p11 for details)
- no cervix
- radiotherapy for cervical cancer

If a woman requests no further invitations, ensure that she has sufficient, accurate information to make an informed choice, is capable of making and communicating that choice, and has expressed in writing her desire to be ceased.

#### Open Exeter: a handy guide for GP practices

Open Exeter is a web-enabled viewer developed by NHS Connecting for Health.

It allows PCTs and agencies to share information held on the NHAIS (Exeter) database with other NHS organisations.

It enables GP practices to view information held on the NHAIS system, download it, and submit on-line returns.

All this helps to reduce the amount of paperwork exchanged between the practice and the PCT or agency.

#### Within the cervical screening programme, Open Exeter enables

- **practices** to view a woman's screening records particularly useful when new patients join a practice
- practices to check Cervical Screening Prior Notification lists and submit returns on-line – so the screening agency no longer needs to send weekly listings for practices to complete and return)
- practices to receive non-responder card notifications and submit a response to the screening agency if appropriate
- **laboratories** to give the correct recall advice in the light of the woman's screening history
- **the screening agency** to advise the practice when patients are ceased from recall
- **the screening agency** to notify the practice of any newly registered women who are on 'early follow-up' owing to an abnormal test result
- a sample taker to generate the pre-populated HMR 101 sample request form.

#### **Access to Open Exeter**

#### Access to Open Exeter is very strictly controlled.

Every practice has access **only** to information on its own registered patients. Within each practice, different roles need different information, and the practice grants staff access to each type of information according to individual need.

Each practice must have a named **primary contact**, usually the practice manager or one of the GPs. He or she is responsible for defining who will have access to each area of the system. Access is granted on a strictly 'need to know' basis: it is therefore essential that user ID/passwords are not shared or disclosed within a practice.

For security reasons, **passwords** for new users are set to expire within seven days; it is therefore important to access the system before the seven days elapse. Users are prompted to change their password every 30 days. Registering your smart card with Open Exeter will prevent passwords expiring.

#### **Registering for Open Exeter**

If your practice is already registered to use Open Exeter and wants to add new Open Exeter users, your primary contact will need to approve this. He or she will complete a Data User Certification Form (either on-line or on paper) for each new user and send it to the data controller at the screening agency The form sets out the features of Open Exeter to which the user will have access.

If your practice is *not yet registered* to use Open Exeter, Data User Certification forms must be completed for each user. They can be downloaded from the Open Exeter Information Page via the Links & Downloads section of the Open Exeter web site.

Before registering, your practice needs to designate a member of staff (usually the practice manager) as its **primary contact**. He or she will be responsible for approving all requests within the practice for new users to access the system and will be sent their user names and passwords.

There are two forms to complete for each registering practice, plus a separate Data User Certification form for each individual user. The primary contact will sign off the completed forms and forward them to the data controller at the screening agency.

For more information on Open Exeter and copies of relevant forms see the <u>Connecting for Health</u> website; for guidance on using the system, see the <u>LaSCA Practice Guide to Open Exeter</u>.<sup>10</sup>

These can be found at <a href="http://www.connectingforhealth.nhs.uk/systemsandservices/ssd/">http://www.connectingforhealth.nhs.uk/systemsandservices/ssd/</a> prodserv/vaprodopen exe and <a href="http://www.lasca.nhs.uk/images/contractor\_forms/LaSCA%20open\_%20exeter%20guide.pdf">http://www.lasca.nhs.uk/images/contractor\_forms/LaSCA%20open\_%20exeter%20guide.pdf</a> respectively.

## SECTION THREE Human papilloma virus

The Human Papilloma Virus (HPV) is a very common infection and most women are exposed to it at some time in their life. There are many types of HPV, most of which are harmless and clear up without treatment.

What makes HPV so important for cancer screening, however, is the fact that persistent infection with some 'high risk' types can cause cervical abnormalities and, if left untreated, these may develop into cervical cancer.

With the introduction of HPV triage, the sample of any woman who has a first cervical screening result of borderline changes or mild dyskaryosis is tested for the presence of high risk HPV. This section sets out how these tests are conducted, how their results are reported, and what action is taken in the light of them.

HPV triage will be implemented in all screening centres in the next two years. For an explanation of sample results and their management in the other centres, see below.

#### **HPV:** frequently asked questions

What is human papilloma virus (HPV)? HPV is a virus that comprises over 100 subtypes. Some of these cause non-genital lesions (such as common warts) and some cause genital lesions (including genital warts). Types 6 and 11, which cause genital warts, are not associated with cervical cancer. However around 20 types of HPV (the 'high risk' types) are linked with it. Both high risk and low risk HPV can cause the growth of abnormal cells, but the high risk types — HPV 16 and 18, also 31,33,35,52,56, and, rarely, 39 and 45 — are more likely to integrate into the host genome and be associated with high-grade dysplasia and cancer. HPV 18 may be associated with endocervical abnormalities and the more rapidly aggressive invasive cancers. Almost all women with cervical cancer have at least one of these high risk types of HPV in the cells of their cervix. Of these, types 16 and 18 are associated with around 70% of cancers of the cervix. High risk types of HPV cause growths on the cervix that are usually flat and nearly invisible. The virus replicates within the epithelium or mucosa of the cervix and sheds in exfoliated cells in cytology samples, and it is here that it can be detected.

How is HPV acquired? It is generally accepted that cervical HPV infection is acquired through sexual contact, whether heterosexual or same-sex (see page 28). The epidemiology of cervical cancer has for many years indicated increased risk in women with multiple partners and early onset of sexual activity. This implies that a sexually transmitted agent is involved in the process of cervical carcinogenesis. It is rarely possible to be certain when and how the infection began, especially as the HPV types most often associated with cervical cancer are usually symptomless in both partners. This question needs to be handled with tact, and with a careful explanation of the facts as we understand them.

How long does HPV infection last? HPV infection of the cervix usually occurs earlier in women's sexual lives. We know this because HPV positive rates are around 50% in women around the age of 20. In the majority of cases the infection clears, usually within a year, and protective antibodies may develop to prevent future infection by the same type. This does not always occur, however; nor is it uncommon for women to acquire new HPV infections of a different type. In some cases, probably around 20 to 30%, the infection persists and may do so for years. The longer the infection persists the greater the risk of subsequent abnormality.

How can HPV cause cancer? HPV contains several genes which can disturb the normal mechanisms that control cell division, which then become uncontrolled. It is thought that high risk (HR) HPV alone may not be sufficient to cause cancer and that other factors such as smoking may play a part.

Can HPV infection be treated? There is no currently effective treatment for HPV infection but, as stated, the immune system clears most infections.

What role will HPV vaccines have? The vaccines currently in use in the NHS are reported to be very effective at preventing infection with the two most common virus types that cause cervical cancer. But these types are responsible for only 70–75% of cases. An HPV immunisation programme is in place which will vaccinate girls aged 12 to 13 years. However vaccines are ineffective in women who are already infected, so cervical screening will still be needed in the future.

#### **Based on information from the following sources**

- NHS Cancer Screening Programmes. HPV Sentinel Sites Implementation Project.
   Available at HPV Sentinel Sites Implementation Project
- NHS Cancer Screening Programmes. Factsheet: HPV testing. Information for women.
   Available at <a href="http://www.cancerscreening.nhs.uk/cervical/fact-sheet-hpv-testing-english.pdf">http://www.cancerscreening.nhs.uk/cervical/fact-sheet-hpv-testing-english.pdf</a>.
- North West Cervical Screening Quality Assurance Reference Centre. Frequently Asked Questions: Human Papilloma Virus. Available at http://www.nwcsqarc.org.uk/private/HPV\_FAQ.pdf.

#### See also

- Colposcopy and Programme Management: Guidelines for the NHS Cervical Screening Programme, 2nd ed, NHS Cancer Screening Programmes, 2010 (NHSCSP Publication No 20), section 3.4.
- The Aetiology of Cervical Cancer, NHS Cancer Screening Programmes, 2005 (NHSCSP Publication No 22). Available at NHSCSP No 22: The Aetiology of Cervical Cancer.
- Cervical Screening: A Multimedia Educational Programme for Physicians and Patients. NHS Cancer Screening Programmes, 2009 (This is available in six languages.)
- NHS Cervical Screening Programme. Cervical screening for lesbian and bisexual women. Available at <a href="http://www.cancerscreening.nhs.uk/cervical/publications/lesbian-bisexual-leaflet-sep09.pdf">http://www.cancerscreening.nhs.uk/cervical/publications/lesbian-bisexual-leaflet-sep09.pdf</a>.

## Open Exeter and the Human Papilloma Virus (HPV) vaccination programme

#### **HPV** vaccination

NHS Cancer Screening Programmes require certain details of women's HPV vaccinations to be recorded on their life long cervical screening record via Open Exeter.

Which details are recorded?

- Type of vaccines and dose number. (GSK's Cervarix is approved for NHS use; Sanofi Pasteur MSD's Gardasil may be used privately.)
- Date each dose was administered: three doses of the same vaccines are necessary within a defined timeframe
  - Cervarix: (date 1) first dose; (date 2) + at least 1 month/within 2 months;
     (date 3) + at least 6 months/ within 12 months
  - Gardasil: (date 1) first dose; (date 2) + at least 1 month; (date 3) + at least 3 months/within 12 months
- Refusal code (if applicable)
- Batch number code (optional)
- The date and time the details were entered on the system, along with the user's ID and Open Exeter organisation code.

## For more information on Open Exeter see the Connecting for Health website.<sup>11</sup>

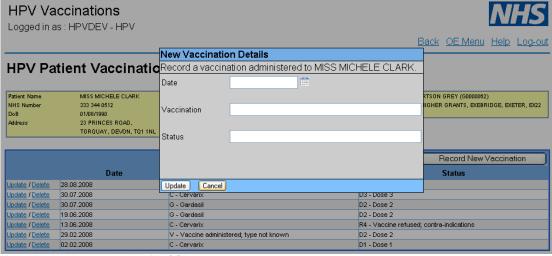


Illustration by kind permission of LaSCA

Available at <a href="http://www.connectingforhealth.nhs.uk/systemsandservices/ssd/prodserv/vaprodopenexe">http://www.connectingforhealth.nhs.uk/systemsandservices/ssd/prodserv/vaprodopenexe</a>.

#### **Protocol for HPV triage and management**

Why test for high risk HPV? It is now very clear that, when low grade abnormalities are found, it is only women with high risk (HR) HPV positive lesions who are at risk of having cervical intraepithelial neoplasia (CIN) which may need treatment. This means that HR-HPV negative women need not be referred to colposcopy, while HR-HPV positive women should be referred without the need for follow up with repeat cytology as this delays the final diagnosis

With HPV triage, women attending for screening whose result shows borderline changes or mild dyskaryosis have a test for HR-HPV performed on their liquid based cytology (LBC) sample. If HR-HPV is found the woman is referred to colposcopy: if it is not, she is returned to routine screening every 3 or 5 years, depending on her age. Women whose cytology results show borderline ?high grade or borderline endocervical cells should be included in the triage protocol.

Women found to have borderline changes or mild dyskaryosis when attending for early repeat screening because of a previous abnormality will not be HPV tested; they will be managed in the usual way.

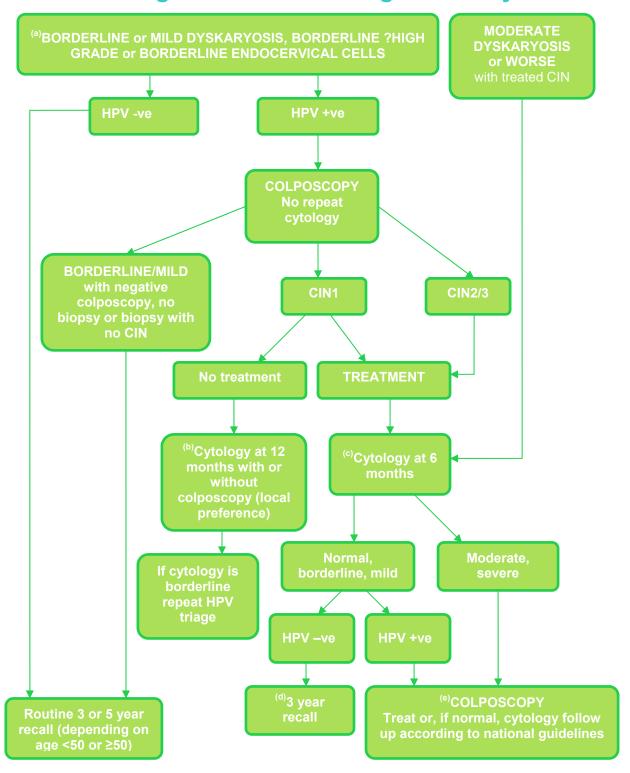
How do we test for HR-HPV? The cervical sample that is used for cytology is also used to detect HR-HPV. This means that when borderline or mild dyskaryosis is reported, the cellular material remaining after the cytology slide has been prepared is used to test for viral DNA.

HPV as a test of cure Women in annual follow up after treatment for CIN are eligible for an HPV test at their next screening to check that no abnormal cells remain present. For more on this 'test of cure' see the HPV Triage and Test of Cure Protocol on page 23.

Cytology result	Management		
(1 <sup>st</sup> occurrence)	Non HPV triage sites	HPV triage sites	
		HR-HPV negative	HR-HPV positive
Borderline	Repeat in 6 months	Routine recall	Colposcopy referral
Mild dyskaryosis	Colposcopy referral	Routine recall	Colposcopy referral

HPV triage results		
Primary screening Result	Recall Interval	
Negative	Routine recall	
Borderline: no HR-HPV detected	Routine recall	
Mild dyskaryosis: no HR-HPV detected	Routine recall	
Borderline: HPV test inadequate or unreliable	Repeat cytology test in 6 months	
Mild dyskaryosis: HPV test inadequate or unreliable	Refer to colposcopy	
Borderline: HR-HPV detected	Refer to colposcopy	
Mild dyskaryosis: HR-HPV detected	Refer to colposcopy	
Moderate dyskaryosis	(No HPV test required) Refer to colposcopy	
Severe dyskaryosis	(No HPV test required.) Refer to colposcopy	
Test of cure protocol following colposcopy		
All women remain at risk after treatment for CIN and should be followed up as shown below		
Cytology negative and HR-HPV negative	Recall in three years regardless of age	
Cytology abnormal	Remain under care of colposcopist, in line with current guidelines	
Cytology negative and HR-HPV detected	Referred back to colposcopy	

Fig 4: HPV triage and test of cure protocol for the management of women aged 25–64 years



#### **NOTES**

(a) If sample is unreliable/inadequate for the HPV test, refer mild and recall borderline for 6 month repeat cytology. At repeat cytology HPV test if negative/borderline/mild. If HPV negative return to routine recall: if HPV positive, refer. Refer moderate or worse cytology. (b) Follow up of 12 month cytology only should follow normal NHSCSP protocols. (c) Women in annual follow up after treatment for CIN are eligible for the HPV test of cure at their next screening test. (d) Women ≥ 50 who have normal cytology at 3 years will then return to 5 yearly routine recall. Women who reach 65 must still complete the protocol and otherwise comply with national guidance. (e) Women referred owing to borderline or mild or normal cytology who are HR-HPV positive and who then have a satisfactory and negative colposcopy can be recalled in 3 years.

## **HPV laboratory terminology and management guidelines**

#### RESULT — HPV TRIAGE BORDERLINE ABNORMALITY HR-HPV detected

#### **Explanation**

Reflex HPV testing showing HR-HPV present in sample.

Borderline nuclear change is often reported in the presence of HPV changes.

#### Action

#### Refer to colposcopy

## RESULT — HPV TRIAGE MILD DYSKARYOSIS HR-HPV detected

#### **Explanation**

Reflex HPV testing showing HR-HPV present in sample.

These are nuclear abnormalities reflecting probable CIN 1 (low grade CIN). Mild dyskaryosis is often associated with HPV.

#### **Action**

#### Refer to colposcopy

## RESULT — HPV TEST OF CURE ABNORMAL CYTOLOGY following treatment for CIN HR-HPV detected

#### **Explanation**

Result of cytology abnormal. No HPV testing required.

#### Action

Patient remains under the care of the colposcopist.

## RESULT — HPV TEST OF CURE NORMAL CYTOLOGY following treatment for CIN HR-HPV detected

#### **Explanation**

Result of cytology normal. However, reflex HPV testing showed HR-HPV present in sample.

#### **Action**

Patient referred back to colpsocopy

## **SECTION FOUR Sample taker training**

The resource pack for trainers of sample takers represents best practice and is available at <a href="https://www.cancerscreening.nhs.uk">www.cancerscreening.nhs.uk</a>. A competency framework has been developed by Skills for Heath relating to Cervical Cytology Sampling CH37 and can be found at <a href="https://www.skillsforhealth.org.uk">www.skillsforhealth.org.uk</a>

#### Organisation of training

Training for sample takers should be in two parts; a theoretical course followed by a period of practical training. Practical training should take place in the practice or clinic where the trainee is based. It should be supervised by the mentor (see Criteria for Sample Taker Mentoring below). Trainees should keep a record of their training.

#### **Theoretical course**

A theoretical training course should cover the following

- the NHSCSP, its background and context
- equality of access to cervical screening
- understanding test results
- · anatomy and physiology of the pelvic organs
- practical aspects of taking cervical samples.

#### **Update training**

Sample takers should undertake a minimum of one half day's update training every three years. E-learning update modules may be used if they fulfil both the national and local requirements. Whatever form it takes, update training **must** cover **all** of the following areas

- current developments in the NHSCSP, nationally and locally
- recent literature relevant to sample taking, sampling devices and women's needs
- changes to local screening policies and procedures
- personal learning needs
- qualitative assessment of 20 recent consecutive samples produced by the sample taker.

#### Criteria for sample taker mentoring

#### **Trainers**

Trainers should have good teaching and communication skills, and ideally hold a relevant teaching qualification. They should undertake regular update training and maintain awareness of developments in the NHSCSP. They must be practising sample takers who are able to demonstrate continuing competence in taking samples for cervical screening with particular reference to

- · transformation zone sampling
- sampling technique
- equipment and sample preparation
- audit of results, including adequacy rates
- effective communication awareness of developments in the NHSCSP.

#### **Training supervision**

#### **Practical training**

For the first practical session/s the trainee should be accompanied by the training mentor and should

- identify training needs in discussion with the mentor
- observe at least two samples being taken
- take a minimum of five samples under supervision.

The mentor and trainee should then decide whether the student may proceed without further direct supervision. Once this is confirmed, the trainee should arrange to take and document a minimum of 20 unsupervised samples. Easy access to a trained colleague is essential throughout this period. The trainee should visit both the cytology laboratory and the colposcopy clinic, documenting the visits in the training record book.

#### **Final assessment**

Both mentor and trainee are expected to maintain regular contact and to discuss progress towards meeting identified training needs and any problems. They should meet for a final evaluation session, which should include a final clinical assessment. The trainee must have completed a minimum of 20 cytologically adequate samples before the final evaluation session. All training should be completed within a nine month period.

#### **Maintaining competence**

To help to ensure continued competence in accordance with their professional codes of conduct, sample takers should conduct continuous self evaluation. They should audit and reflect on their individual rates of inadequate tests and abnormal test results compared with the rates reported by the local laboratory.

### The consultation process

#### The clinical environment

Women may be anxious when attending for cervical screening, so it is important that every effort is made to create a welcoming and reassuring environment. It should be private, with a screened area for changing and the examination, and it should be warm and well lit.

#### **Equipment**

- an examination couch
- a good light source
- · specula of different sizes, reusable or once only use
- disposable gloves
- a supply of test request forms and a black ball point pen
- information leaflets for women
- a supply of Cervex Brooms®
- a supply of Endocervex Brushes®
- a supply of fixative vials: ThinPrep® or SurePath™
- packaging for transporting LBC samples.

#### **Explaining the process**

Explain the purpose of cervical screening to the woman and what will happen at each step of the procedure. Every woman should know

- the purpose of cervical screening and its limitations
- the likelihood of a normal test result (about 92% of adequate tests)
- the meaning of a normal test result (low risk, not no risk).
- the likelihood of an inadequate test (national average of 2.8%)
- the meaning of being recalled following an abnormal test result
- when and how test results will be made available
- the importance of her reporting any abnormal bleeding or discharge to her doctor.

Explain clearly to the woman what you are going to do during the procedure and what she can expect. Women having a test for the first time may need a more detailed explanation, including an explanation of the speculum and the sampling device. They need to know that they will have to remove their underwear and that the speculum will be inserted into their vagina. Some women may wish to have a chaperone irrespective of the sex of the sample taker.

For further guidance see NHSCSP's <u>Liquid Based Cytology LBC</u> <u>Implementation Guidance</u> at http://www.cancerscreening.nhs.uk/cervical/lbc-imp.html.

Figures cited in this paragraph are from the Information Centre's report Cervical Screening Programme England, 2009-2010, at <a href="http://www.ic.nhs.uk/webfiles/publications/008\_Screening/cervscreen0910/Final\_Report\_v2\_20">http://www.ic.nhs.uk/webfiles/publications/008\_Screening/cervscreen0910/Final\_Report\_v2\_20</a> Oct2010.pdf.

### Taking a history

#### Verify the woman's details

- sample history: when and where any abnormal samples taken, result, treatment, follow up
- contraceptive methods used, if any
- whether any abnormal bleeding experienced
- post coital bleeding
- inter menstrual bleeding
- · post menopausal bleeding
- if YES to any of above consider referral to gynaecologist
- consider whether taking a sample is still appropriate.

# The following factors do not *in* themselves justify additional screening outside of normal call/recall

- use of oral contraceptive
- use of intrauterine contraceptive device (IUCD)
- use of hormone replacement therapy
- the woman is pregnant, is about to or has just given birth, or has just had a termination
- presence of genital warts
- presence of vaginal discharge
- presence of pelvic infection
- multiple sexual partners
- heavy cigarette smoking.

# Cervical screening test is not appropriate in the following circumstances unless you think the woman will not re-attend

- during menstruation
- if the woman is pregnant (defer the test unless the woman has previously failed to respond to screening invitations and has gone more than three years without cervical screening)
- less than 12 weeks post-natal
- if there is a discharge or infection present; treat the infection and take sample two weeks later.

Women with symptoms or abnormal bleeding should be investigated further. A screening test is inappropriate in such cases.

### Preparation of the sample request Form (HMR 101)

The HMR101 form, with the woman's demographic and GP details, can be downloaded from the NHAIS open Exeter system https://nww.openexeter.nhs.uk

- full name, address and postcode
- NHS number (if available)
- any previous name
- name and address of GP/code of GP practice
- name/address of sample taker if not GP
- · date of last menstrual period
- date of last cervical sample
- hormones /IUCD
- any relevant history

### Cervical screening of lesbian and bisexual women

Lesbian and bisexual women should be advised that

- All women aged 25-64 who have a cervix are eligible for cervical screening
- Nearly all cases of cervical cancer are associated with the HPV virus, which is a sexually transmitted infection
- HPV can be passed on during sex between women, although the risk of infection through heterosexual intercourse is thought to be higher
- Even if a woman has never had sex with a man, a partner (or a partner's partner) may have, so that woman could still have been exposed to the HPV virus
- Regular cervical screening prevents around 75% of cervical cancers developing.

Screening centres should encourage attendance by lesbian and bisexual women. Sample takers should avoid assuming that all women attending are heterosexual (eg when asking about contraception).

See Fish, J. Cervical screening in lesbian and bisexual women: a review of the worldwide literature using systematic methods. June 2009.

NHSCSP leaflet *Cervical screening for lesbian and bisexual women.* Both at <a href="http://www.cancerscreening.nhs.uk/cervical/publications/publication-topics.html">http://www.cancerscreening.nhs.uk/cervical/publications/publication-topics.html</a>.

### Taking the sample

Using the Cervex Broom®, insert the central bristles of the broom into the endocervical canal so that the shorter, outer bristles splay out over the ectocervix.

Applying pencil pressure, rotate the broom through **FIVE** complete 360° rotations.

In order to ensure good contact with the ectocervix, the plastic fronds of the Cervex Broom® are bevelled for **CLOCKWISE** rotation only.

A high cellular yield will only be achieved with correct use of the Cervex Broom®.

#### Immediately fix the sample

#### For SurePath™

Simply remove the head of the brush from the stem and place into the vial of fixative.

Screw the lid on and label the vial.

#### For ThinPrep®

Rinse the brush into the fixative vial using a vigorous swirling motion.

Push the brush into the bottom of the vial at least 10 times, forcing the bristles apart. *Firm pressure is necessary or the cells will cling to the brush.* 

Inspect the brush for any residual material and remove any remaining by passing the brush over the edge of the fixative vial.

Ensure that the material reaches the liquid or it will not be preserved.

Tighten the cap so that the torque line passes the torque line on the vial.

If you have placed any material on the edge of the vial, give it a shake.

Label the vial securely as unlabelled vials cannot be processed and will be rejected by the laboratory.

For both methods, it is essential that the sample is placed in the vial at once in order to achieve immediate fixation. Do this before you remove the speculum.

### Using an EndoCervex Brush® as well as a Cervex Broom

On rare occasions the laboratory may advise the use of an endocervical brush such as the EndoCervex Brush® to sample the endocervical canal.

The EndoCervex Brush® should never be used alone but always in combination with a Cervex Broom.

#### It should be used only if

- there is difficulty in inserting the Cervex Broom into the os (eg if the os is narrow or stenosed)
- the woman is being followed up for a previously treated endocervical glandular abnormality.

You should take the EndoCervex Brush® sample **after** the Cervex Broom sample.

Insert the brush gently into the os with the lower bristles remaining visible and rotate slowly between half and a whole turn.

Both samples should be placed in the same vial. Details of use of an additional sampler must be recorded on request form.

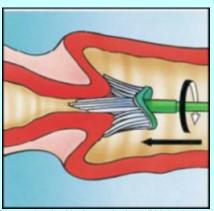


Illustration by kind permission of Hologic, Inc

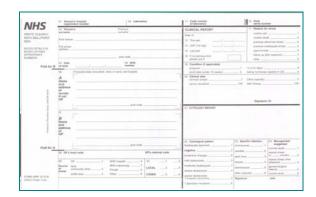
#### **Ending the consultation**

Complete the form with any further clinical details.

Ensure that the woman understands how and when she will receive her result.

Discuss possible results and follow up processes, if appropriate.

Ensure that the woman understands that if she has any abnormal bleeding or discharge in the future she must see her GP



#### **Documentation**

The consultation should be formally documented in the patient's records. The following points should be recorded

- consent was formally obtained
- cervix was fully visualised
- TZ was sampled
- details of additional sampler, if used
- date sample taken and by whom, clinical details (eg unusual appearances)
- previous abnormal results, when/where sample was taken, treatment (if any)
- sample should be dispatched the same day to ensure the women receives her results within two weeks.

#### Some frequently asked questions

**Is it possible to take a cervical sample when the woman is menstruating?** This is not the best time to take a cervical sample as the cells may be obscured by blood, but if this is the only chance to take a sample then do it anyway. Ideally peri-menstrual cervical tests should be avoided. In most situations, the woman should be asked to return when not menstruating.

Should the woman refrain from sexual intercourse prior to her cervical test? The general advice is to refrain from sexual intercourse for 24 hrs before the test, as spermicides, barrier methods of contraception and lubricants contain chemicals that may affect the screening test.

What can you do if passing the speculum on a menopausal or post menopausal woman is too uncomfortable? The main reasons for discomfort are vaginal atrophic changes that lead to vaginal dryness. In these situations, an appropriately sized and well lubricated speculum should be used. Avoid applying lubrication to the tip of the speculum.

If the vagina is atrophic and lubrication is not adequate for insertion of the speculum or visualisation of the cervix, then a short course of intravaginal oestrogen may be prescribed if not contraindicated. This helps to restore the vaginal epithelium so that a speculum may be passed and an adequate sample taken.

### **SECTION FIVE**

# Laboratory terminology and management guidelines

This section offers an explanation of each sample result, the proportion it represented of total results in 2009-2010, and guidance on its management. (See also Section Three for HPV triage.)

Dyskaryosis is the technical term used to describe cellular abnormalities identified cytologically. The corresponding term for histological abnormalities is **CIN** (Cervical Intraepithelial Neoplasia). Typically the cytological and histological terms correlate as follows (although women may have a greater or lesser degree of CIN on biopsy than initially suggested by cytology):

Mild Dyskaryosis = CIN1

Moderate Dyskaryosis = CIN2

Severe Dyskaryosis = CIN3

Recall protocol for negative screening results		
Result category	Recall / referral protocol	
First sample	Routine recall	
Previous screening results negative	Routine recall	
Previously treated for CIN	Follow up of protocol for patient treated for CIN (refer to pages 33-34 and 36)	
Previous Mild or Borderline results (not treated)	At least three negative tests, each 6- 12 months apart, then routine recall	

The statistics shown under 'Explanation' are derived from the Information Centre's report *Cervical Screening Programme England*, 2009-2010, at <a href="http://www.ic.nhs.uk/webfiles/publications/008">http://www.ic.nhs.uk/webfiles/publications/008</a> Screening/cervscreen0910/Final Report v2 20Oct2010.pdf.

32

#### **Results and management protocol**

#### RESULT — NEGATIVE (result code: 2)

#### **Explanation**

In 2009-2010, 92.8% of all samples from women screened showed no nuclear abnormalities

#### **Action**

Ensure the patient is informed of the result; the term 'normal' should be used to inform the woman of her screening result

Recall if/when appropriate

#### **RESULT — INADEQUATE (result code: 1)**

#### **Explanation**

In 2009-2010, 2.8% of samples were reported as inadequate<sup>14</sup>

- sample consisting largely of blood, neutrophils or polymorphs with few squamous cells
- sample showing marked cytolysis where few intact squamous cells remain
- samples lacking endocervical cells in follow up of treated endocervical dyskaryosis or lacking transformation zone material in follow up of treated squamous dyskaryosis
- Box 20 (cervix fully visualised) not ticked

#### **Action**

Refer to Taking the sample (pages 29-30)

The inadequate rates for cervical samples should be audited on a regular basis. This audit should include

- total of samples taken by practice and by individual sample takers
- overall inadequate rate for practice (number and percentage)
- inadequate rate for individual sample taker (number of cases and percentage)
- breakdown of reasons for sample inadequacy.

A breakdown of this information will normally be provided by your local laboratory

Women should be referred for colposcopy after three consecutive inadequate samples. At least 90% of women should be seen in a colposcopy clinic within eight weeks of referral. Cytology should not be repeated at an interval of less than three months. A shorter interval does not allow time for the cervical epithelium to heal, or for small dysplastic lesions to recur between tests, and this decreases the sensitivity of screening. <sup>15</sup>

This is a national average; there may be significant local variation. See *Cervical Screening Programme England, 2009-2010*, pages 27 and 32, at <a href="http://www.ic.nhs.uk/webfiles/publications/008">http://www.ic.nhs.uk/webfiles/publications/008</a> Screening/cervscreen0910/
<a href="mailto:Final\_Report\_v2\_200ct2010.pdf">Final\_Report\_v2\_200ct2010.pdf</a>.

<sup>&</sup>lt;sup>15</sup> Colposcopy and Programme Management, 3rd edition, NHS Cancer Screening Programmes, 2010, (NHS CSP Publication No 20), sections 4.2 and 6.2, at NHSCSP No 20: Colposcopy and Programme Management:
Guidelines for the NHS Cervical Screening Programme.

#### **RESULT — BORDERLINE ABNORMALITY (result code: 8)**

#### **Explanation**

In 2009-2010, 3.7% of all samples showed borderline nuclear changes

These are nuclear changes that cannot be described as normal, but in which there is doubt as to whether or not the nuclear changes reflect true dyskaryosis

Borderline nuclear change is often reported in the presence of HPV changes

#### Action

Repeat sample within six months. The majority of samples will revert to normal by this stage

If there is an associated treatable condition, treat and repeat, screen at no more than six months

If changes persist (three borderline results) refer to colposcopy

Three consecutive negative results, each at least six months apart, are required before returning to routine recall

**Refer immediately to colposcopy** if borderline nuclear changes are present in endocervical cells or if report of borderline ?high grade cannot be excluded

If in a 10 year period there are three non consecutive abnormal results (usually a combination of borderline or mild dyskaryosis), **refer to colposcopy** 

#### **RESULT — MILD DYSKARYOSIS (result code: 3)**

#### **Explanation**

In 2009-2010, 2.1% of all samples showed mild dyskaryosis

These are nuclear abnormalities reflecting probable CIN1 (ie low grade CIN). Mild dyskaryosis is often associated with HPV

In the majority of women changes relating to mild dyskaryosis will regress spontaneously

#### **Action**

**Refer to colposcopy** or repeat sample in 6 months, depending on local service protocol. Many will have returned to normal by this stage

Three consecutive negative results, each at least six months apart, are required before returning to routine recall

If a single mild dyskaryosis result is obtained after treatment for CIN 2 or worse, refer to colposcopy

Women treated for CIN 1 can be returned to routine recall after 2 years (follow-up cytology at six, 12 and 24 months) of negative post biopsy cytology

If in a 10 year period, there are three borderline or mildly dyskaryotic results, refer to colposcopy

#### **RESULT — MODERATE DYSKARYOSIS (result code: 7)**

#### **Explanation**

In 2009-2010, 0.6% of all samples showed moderate dyskaryosis

Nuclear abnormalities reflecting probable CIN 2

#### **Action**

#### Refer to colposcopy

Women should have annual follow up for at least 10 years (cytology at six and 12 months and then annually for nine years) after treatment for CIN 2 or worse, before returning to routine recall

#### RESULT — SEVERE DYSKARYOSIS (result code: 4)

#### **Explanation**

In 2009-2010, 0.7% of all samples showed severe dyskaryosis

Nuclear abnormalities reflecting probable CIN 3

#### **Action**

#### Refer to colposcopy

Women should have annual follow up for at least 10 years (cytology at six and 12 months and then annually for nine years) after treatment for CIN 2 or worse, before returning to routine recall

## RESULT — SEVERE DYSKARYOSIS/?INVASIVE CARCINOMA (result code: 5)

#### **Explanation**

In 2009-2010, less than 0.1% of samples suggested invasive carcinoma.

Cellular abnormalities indicating at least CIN 3, with additional features suggesting possibility of invasive cancer

#### Action

Urgent 2 week referral to colposcopy

## RESULT — GLANDULAR NEOPLASIA/?GLANDULAR NEOPLASIA (result code: 6)

#### **Explanation**

In 2009-2010, dyskaryotic glandular cells were identified in 0.1% of samples. Cells of this type may represent

cervical glandular intraepithelial neoplasia (cGIN), **or** adenocarcinoma of the cervix, **or** adenocarcinoma of the endometrium, **or** extra-uterine adenocarcinomas

#### Action

Urgent 2 week referral to gynaecological oncologist/ colposcopy

## Colposcopy

As set out in the GMS contract,
GPs who provide cervical screening services
are responsible for ensuring that
the test result for each woman
is followed up appropriately,
and that referral for
colposcopy is undertaken
when indicated.

### **Colposcopy direct referral**

The NHSCSP strongly recommends direct referral to colposcopy. This is defined as referral directly from the pathology laboratory to colposcopy. This process has a number of advantages: it speeds up the patient journey, enables better management of clinics and so reduces waiting lists.

Arrangements for direct referral vary and sample takers should familiarise themselves with local protocols and procedures. GPs should be notified when an appointment has been made. If they are not, sample takers are responsible for checking that referral has taken place.

The patient must be given clear advice on how to change the appointment to a more convenient time if desired, or to a different screening colposcopy provider. Practices should ask their PCTs about direct referral schemes in their areas.

## **Summary of Standards for Colposcopy**

Taken from *Colposcopy and Programme Management*, 2nd ed, at <a href="http://www.cancerscreening.nhs.uk/cervical/publications/nhscsp20.pdf">http://www.cancerscreening.nhs.uk/cervical/publications/nhscsp20.pdf</a>

#### Women with symptoms

Women presenting with symptoms of cervical cancer – eg postcoital bleeding, particularly in women over **40** years, intermenstrual bleeding, persistent vaginal discharge – should be referred for gynaecological examination and onward referral for colposcopy if cancer is suspected.

The Advisory Committee on Cervical Screening has developed guidance on the management of young women with gynaecological symptoms such as persistent bleeding on intercourse or between periods. This involves primary care, GUM, gynaecology and cervical screening experts. (See pages 10–11.)

#### **Inadequate samples**

Women should be referred for colposcopy after three consecutive (clinically) inadequate samples. They should be seen within eight weeks of referral.

#### Abnormal results of any grade

Women should be referred for colposcopy if they have had three tests reported as abnormal at any grade in a 10 year period, even if returned to routine recall on one or more occasions in that period. They should be seen within eight weeks of referral.

## Borderline nuclear change

#### Squamous

Women should be referred for colposcopy after three tests reported as borderline nuclear change in squamous cells in a series, without the woman being returned to routine recall. They should be seen within eight weeks of referral.

#### Endocervical

Women should be referred for colposcopy after one test reported as borderline nuclear change in endocervical cells.

#### Mild dyskaryosis

Women should be referred for colposcopy after one test reported as mild dyskaryosis, but it remains acceptable to recommend a repeat test. Women must be referred after two tests reported as mild dyskaryosis without a return to routine recall. They should be seen within eight weeks of referral.

#### **Moderate dyskaryosis**

Women must be referred for colposcopy after one test reported as moderate dyskaryosis. They should be seen within four weeks of referral.

#### Severe dyskaryosis

Women must be referred for colposcopy after one test reported as severe dyskaryosis. They should be seen within four weeks of referral.

#### Possible invasion

Women must be referred for colposcopy after one test reported as possible invasion. They should be seen urgently within two weeks of referral.

#### Possible glandular neoplasia

Women must be referred for colposcopy after one test reported as glandular neoplasia. They should be seen urgently within two weeks of referral.

#### **Abnormal cervix**

Women with an abnormal cervix should be referred for gynaecological examination and onward referral for colposcopy if cancer is suspected. They should be seen urgently, within two weeks of referral.

Vaginal vault cytology is not undertaken within the NHS Cervical Screening Programme

#### Guidelines for cytological follow up after hysterectomy

Women who have had a hysterectomy with CIN present are potentially at risk of developing vaginal intraepithelial neoplasia (VaIN) and invasive vaginal disease. There is no clear evidence that colposcopy increases the detection of disease on follow up. As stated in *Colposcopy Programme and Management* (NHSCSP Publication No 20, 2<sup>nd</sup> ed), expert consensus opinion recommends that

- for women on routine recall and with no CIN in their hysterectomy specimen, no further vaginal vault cytology is required
- women **not on routine recall**, and with **no CIN** in their hysterectomy specimen, should have vaginal vault cytology at six months following their hysterectomy
- women who undergo hysterectomy and have completely excised CIN should have vaginal vault cytology at six and 18 months following their hysterectomy
- for women who undergo hysterectomy and have incompletely excised CIN (or uncertain excision), follow up should be as if their cervix remained in situ
  - o CIN 1: vault cytology at six, 12 and 24 months
  - CIN 2/3: vault cytology at six and 12 months, followed by nine annual vault cytology samples
  - Follow up for incompletely excised CIN continues to 65 years or until 10 years after surgery (whichever is later)

As women who have undergone hysterectomy have no cervix, and so are no longer eligible for recall within the NHSCSP, their vault cytology following treatment of CIN must be managed outside the Programme.

- Responsibility for implementing these follow up policies will rest with the gynaecologist and will be informed by the local lead colposcopist
- Any gynaecologist discharging a patient who requires further vault cytology should ensure that the GP receives specific written guidance for follow up
- The clinician in charge (gynaecologist or GP) will be responsible for failsafe mechanisms for this small group of women
- Follow up after discharge will be dealt with by the general practitioner. This excludes cases of incomplete excision, a high risk group that will be dealt with by the colposcopy clinic
- Follow up arrangements for women who need vault cytology after hysterectomy will be agreed locally, along with any failsafe arrangements. There is no national guidance on how this should be achieved. It will be based on consultation with the local screening service, local screening leads, the lead colposcopist and local GPs
- Women who undergo subtotal hysterectomy will still have their cervix in situ, and so must remain within the NHS Cancer Screening Programme
- Women who have radical trachelectomy, as part of conservative management of cervical cancer, should remain under the care and guidance of their treating gynaecologist or gynaecological oncologist. Follow up is recommended with colposcopy and cytology; owing to the limited information on outcome, however, all cases should be subject to local audit. As these women have cancer they are under the individual care of a gynaecologist and are no longer within the NHSCSP
- There is no clear evidence that colposcopy increases detection of disease on follow up.

### **Failsafe**

All GPs (or other clinicians responsible for requesting tests) are responsible for the following failsafe procedures, which aim to ensure that a positive result is followed up appropriately

- maintaining a register of tests taken
- checking that a test result has been received from the laboratory for every sample taken
- ensuring that there is a system for notifying women of their test results in writing (This may be through the routine call and recall system administered by the screening office or primary care organisation)
- ensuring that arrangements are made for women who fall outside the call and recall system to be given their test results in writing (eg temporary residents, women not registered with a GP, or women requesting 'no correspondence')
- acting on non-responder notifications for women who have not responded to an invitation for a routine test
- acting on non-responder notifications for women who have not responded to invitations for an early repeat test
- giving a woman her test result in person when urgent referral is required
- ensuring referral to colposcopy takes place, if required
- acting on the non-responder notification from the colposcopy clinic for women who have not attended for colposcopy
- responding to failsafe enquiries by laboratories and reporting any critical incidents to PCT clinical governance team.

See Guidelines on Failsafe Actions for the Follow-Up of Cervical Cytology Reports, NHS Cancer Screening Programmes, 2004 (NHS CSP Publication No. 21), at <a href="http://www.cancerscreening.nhs.uk/cervical/publications/nhscsp2">http://www.cancerscreening.nhs.uk/cervical/publications/nhscsp2</a> 1.html.







# **SECTION SIX Disabilities and special circumstances**

## Physical and learning disabilities

It should **not** be assumed that disabled women are sexually inactive and therefore do not require screening. Women should not be automatically excluded from the screening programme on the grounds of any physical or learning disability.

Disabled women have the same rights of access as all other women to the NHS Cervical Screening Programme. Wherever possible women with a disability should

- have access to information to enable them to make their own decisions about whether or not to accept an invitation to attend for cervical screening
- know what to expect when they attend for screening so that it is a positive experience
- understand the possible consequences of screening and of not having screening and the need to be aware of changes in their own bodies.

For learning disabled women, as with other women, the issue of valid consent is crucial. The Mental Capacity Act 2005 (www.dca.gov.uk/ menincap/legis.htm) states that people must be assumed to have capacity to make their own decisions unless proved otherwise. Individuals must be given all practicable help to make their own decisions before it is assumed that they cannot do so



© Books Beyond Words

The following points should be considered when assessing a woman's capacity to consent to cervical screening

- does the woman have a basic understanding of what cervical screening is, its purpose, and why she has been invited?
- does she understand that the test does not always find that something is wrong?
- does she understand that an abnormal test result will mean having more tests?
- is she able to retain the information for long enough to make an effective decision?
- is she able to make a free choice (that is, with no pressure from supporters or health professionals)?
- does she have a decision-maker to help her to reach a decision about screening?

An independent mental capacity advocate (IMCA) is someone appointed to support a person who lacks mental capacity but has no one to speak for them. The IMCA makes representations about the person's wishes, feelings, beliefs and values at the same time as bringing to the attention of the decision-maker all factors that are relevant to the decision. The IMCA can challenge the decision-maker on behalf of the person lacking capacity if necessary.

For details see <a href="http://www.patient.co.uk/doctor/Mental-Capacity-Act.htm">http://www.patient.co.uk/doctor/Mental-Capacity-Act.htm</a>.

Learning disabilities alone are not a reason for not taking a cervical sample. NHS CSP materials are available to assist women with learning disabilities to make an informed choice about whether or not to participate in the Programme. See *An Easy Guide to Cervical Screening* at <a href="http://www.cancer-screening.nhs.uk/cervical/publications/easy-guide-cervical-screening.pdf">http://www.cancer-screening.nhs.uk/cervical/publications/easy-guide-cervical-screening.pdf</a> and *Consent To Cancer Screening*, 2<sup>nd</sup> ed, NHS Cancer Screening Programmes, 2009 (Cancer Screening Series No 4) at <a href="http://www.cancerscreening.nhs.uk/publications/cs4.html">http://www.cancerscreening.nhs.uk/publications/cs4.html</a>

## Who to screen in special circumstances

#### Women with a terminal illness

For as long as possible, these women should continue to be treated in the same way as those who do not have a terminal illness. This includes being invited for cervical screening: it is then the woman's decision whether or not to attend. Women's treatment should reflect their individual situation.

#### Radiotherapy

Women undergoing (or who have undergone) radiotherapy treatment for cervical cancer should remain under the care of the gynaecological oncologist. Cervical cytology is inappropriate, as radiotherapy may produce changes which mimic dyskaryosis.

#### **Circumcised women**

Women who have been circumcised remain at risk from cervical cancer and so should remain within the screening programme. Taking a cervical sample in such cases should be handled sensitively and may not always be possible. Every woman should be considered individually.

#### Pregnant or post natal women

Avoid screening during pregnancy. It is not advisable to sample the cervix until 12 weeks post natal. (See section 10.1 of Colposcopy and Programme Management: Guidelines for the NHS Cervical Screening Programme at <a href="http://www.cancerscreening.nhs.uk/cervical/publications/nhscsp20.pdf">http://www.cancerscreening.nhs.uk/cervical/publications/nhscsp20.pdf</a> and Pregnancy and abnormal cervical cells (Cancer Research UK/Cancer Help) at <a href="http://www.cancerhelp.org.uk/type/cervicalcancer/smears/pregnancy-and-abnormal-cervical-cells">http://www.cancerhelp.org.uk/type/cervicalcancer/smears/pregnancy-and-abnormal-cervical-cells</a>



#### Hysterectomy (See page 37)

Women who have undergone total hysterectomy no longer need cervical screening. Women with a subtotal hysterectomy still have a cervix, and should therefore remain in the NHSCSP as they continue to be at risk.

#### Male to female sex change

A person who has undergone a male to female sex change will not have a cervix, so is not at risk and is ineligible for cervical screening.

#### Female to male sex change

Women **in the process** of gender reassignment fall outside normal call and recall arrangements if they appear on the call/recall system as male. They may self refer at routine intervals, however, if they retain their cervix. Because they fall outside the call/recall system, sample takers are responsible for ensuring that written results are posted or handed to these women and that arrangements are in place for making referrals if needed.

#### Women who are immunosuppressed

Depending on the causes of the immunosuppression, women who are immunosuppressed may be at increased risk of developing cervical cancer. More frequent screening and/ or earlier referral for colposcopy is needed in the following cases

- women about to undergo renal transplantation should have had cervical screening within the previous year. If no history of CIN is present, screening should follow the national guidelines for nonimmunosuppressed
- women newly diagnosed with HIV should have cervical cytology performed by, or in conjunction with, the medical team managing the HIV infection. Annual cytology should be performed.

Specialist clinicians should make arrangements with their local laboratory for more frequent screening of these women. (See section 11 of <u>Colposcopy and Programme Management: Guidelines for the NHS Cervical Screening Programme</u>).

## The following do NOT need more frequent screening

- women taking or starting an oral contraceptive, having an IUCD inserted, or receiving long term cytotoxic drugs for rheumatological disorders
- those receiving cytotoxic chemotherapy for non-genital cancers
- women receiving long term steroids
- pregnant women, either antenatally nor postnatally, or after termination
- women with genital warts, vaginal discharge, pelvic infection
- women who have had multiple sexual partners
- women who are heavy cigarette smokers.

All should have cervical screening in accordance with section 2.4 of <u>Colposcopy and Programme Management: Guidelines for the NHS Cervical Screening Programme.</u>

## **GLOSSARY**

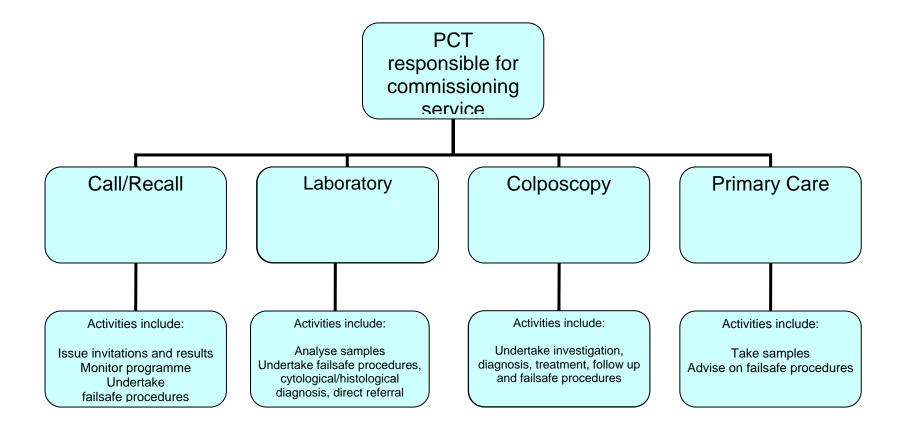
Term	Explanation
	(Terms in bold type have their own Glossary entry)
Adenocarcinoma of the endometrium	Cancer originating in the <b>epithelium</b> that lines the endometrium and forms the endometrial glands.
Biopsy	Removal of a sample of cervical tissue from the layer beneath the surface to assist in the diagnosis of disease
	Punch biopsy: removal of a very small sample of tissue taken to diagnose abnormal cells in the cervix. Usually 'colposcopically-directed': ie the colposcope defines abnormal areas, punch biopsies are then taken from these areas and sent to the Pathology laboratory
	Cone biopsy: removal of a larger, cone-shaped, piece of tissue approximately the size of a thimble from the cervix. The procedure removes abnormal cells; it is diagnostic but may also be a form of treatment. Used with cytology to confirm diagnosis of cervical glandular intraepithelial neoplasia (as colposcopy cannot reliably detect it)
Call and Recall	System designed to ensure that the maximum number of eligible women receive cervical screening by inviting them for a test on a regular three-or five-yearly basis. A woman with a normal result will be recalled in three/ five years: if her result is positive, doubtful or inadequate she will be placed on recall and invited for a further test. A normal result will return her to routine screening; a second abnormal test will result in her suspension from screening while treatment takes place
Carcinoma	A cancer (malignant, uncontrolled overgrowth of abnormal cells) that destroys the surrounding tissue, starting in the lining of body organs such as the cervix
Cervex® broom	A <b>cytology</b> brush used to collect the cervical sample and transfer it to a vial of preservative solution for analysis in the Pathology laboratory. (See also <b>EndoCervex-Brush</b> ®)
?Cervical Glandular Intraepithelial Neoplasia (cGIN)	Suspected abnormal changes occurring in the glandular <b>epithelium</b> of the cervix. (Presumed to be the pre-invasive stage of <b>adenocarcinoma</b> )
Cervical Intraepithelial Neoplasia (CIN)	Abnormal growth of cells in the <b>epithelium</b> of the cervix that are not cancerous but may lead to cancer. A histological term; its cytological equivalent is 'dyskaryosis'
	CIN 1 One third of the thickness of the epithelium is affected. Cytological equivalent is mild dysplasia
	CIN 2 Two thirds of the thickness of the epithelium are affected. Cytological equivalent is moderate dysplasia
	CIN 3 The full thickness of the epithelium is affected. Also known as severe dysplasia or carcinoma in situ
Colposcopy	Cervical screening can detect whether there are abnormal cells present

	on the surface of the ectocervix. Colposcopy is a diagnostic examination of the cervix using a specialised optical instrument (colposcope) that enables a more detailed analysis of these surface abnormalities. By examining an illuminated, magnified view of the cervix and the tissues of the vagina and vulva it is able to detect premalignant lesions and malignant lesions.
Columnar epithelial cells	Epithelial tissue lining the <b>endocervical canal</b> . Cells are columnar, usually at least four times the height of their width. (Compare with <b>squamous epithelial cells</b> )
Coverage	The percentage of women eligible for screening who have been adequately tested within the screening interval (3.5 years for women aged 25-49; 5 years for women aged 50-64).
Cytology	The study of individual cells, their size, structure and abnormalities, in order to make a diagnosis and guide treatment
Cytolysis	Death of a cell following the breakdown of its outer membrane, which causes its contents to spill out
Dyskaryosis	Term used in the screening report to designate abnormal changes to the squamous cells of the cervix
Ectocervix	The part of the cervix that projects into the vagina
Eligible women	Women who are entitled to cervical screening if they meet specific criteria (eg age, presence of cervix)
EndoCervex-Brush®	A <b>cytology</b> brush for collecting cervical samples. Must be used <i>only</i> in combination with the <b>Cervex® broom</b> and, even then, only in exceptional circumstances. (For details see Section Four.)
Endocervical adenocarcinoma of the cervix	Cancer developing from the glandular cells that line the endocervical canal. Because it starts in the <b>endocervical canal</b> it can be more difficult to detect with cervical screening tests
Endocervical canal	The passageway between the external <b>os</b> and the uterine cavity. Also known as the endocervix and the cervical canal.
Endocervical cells	Cells lining the endocervical canal
'Ghost' patients	Patients who have moved away, died etc but whose names have not yet been removed from the GPs' register
Epithelium	Tissue that covers all internal and external surfaces of the body
Extra-uterine adenocarcinomas	<b>Adenocarcinomas</b> occurring outside the uterus (eg in the ovaries, the Fallopian tube)
Failsafe	(a) Action taken by the clinically responsible doctor and Programme office to ensure a positive result is appropriately followed-up
	(b) Screening batch specially created to invite women who may have been missed during routine screening
False negative result	Term used when a woman's initial screening result is recorded as normal but she is later found to have an abnormality
False positive result	When a woman's initial screening result is recorded as abnormal but she is later found <i>not</i> to have an abnormality

Histology	A branch of biology in which the structure and composition of tissue are examined in detail under the microscope
HPV (Human Papilloma Virus)	An extremely common virus with over 100 identified strains. The world's most widespread sexually transmitted infection, though it clears spontaneously in the majority of cases. The principal cause of cervical cancers (For details see Section Three)
Immunosuppressed	Used to describe individuals whose immune responses are inadequate as a result of disease (eg HIV/AIDS) or of active medical intervention (eg drugs used with organ transplant patients to prevent a reaction to other treatment)
In situ	Used to describe a cancer in its very early stages, before it has had time to spread to surrounding tissue. 'In situ' is a Latin term meaning 'in the original place'. (Compare <b>Invasive</b> .)
Incidence	Frequency with which a disease appears in a particular population or area; the number of newly diagnosed cases during a specific time period.
	(Compare 'prevalence', which refers to the number of cases alive on a certain date)
Intermenstrual bleeding	Bleeding between menstrual periods
Invasive	A term used to describe cells that are malignant (ie cancerous), proliferating and spreading from their original site. (Compare <b>In situ</b> )
?Invasive Carcinoma	Suspected <b>invasive</b> malignant tumour (ie cancer) consisting of abnormal epithelial cells
LBC	LBC (liquid based cytology) is used to prepare cervical samples for examination in the laboratory. The sample is collected using a special device which brushes cells from the neck of the womb. Rather than smearing the sample onto a microscope slide as happens with the conventional smear, the head of the brush (where the cells are lodged) is broken off into a small glass vial containing preservative fluid, or rinsed directly into the preservative fluid. The sample is sent to the Pathology laboratory where it is spun and treated to remove obscuring material (for example mucus or pus) and a random sample of the remaining cells is taken. A thin layer of the cells is deposited onto a slide. The slide is examined in the usual way under a microscope by a cytologist
Lesion	A broad term meaning wound, sore, tumour or any other damaged tissue
Mentor	Literally, a wise and faithful adviser or teacher. Often used to describe someone who facilitates an individual's personal and professional growth by sharing knowledge, experience and insights
Morbidity	The number of cases of a specific disease during a defined period of time in a given population
Mortality	Death rate, usually expressed as the number of people in a defined population who die within a defined period. Mortality (like incidence) rates are usually presented per 100,000 people
Neutrophils	Cells of the immune system providing primary defence against bacterial infection. The most common type of <b>phagocyte</b> . They are produced in the bone marrow and circulate in the bloodstream
Os	External os: the external opening of the cervix into the vagina

	Internal os: the narrow opening of the uterine cavity
Phagocytes	White blood cells that protect the body by devouring (or 'phagocytosing') harmful foreign particles, bacteria and dead or dying cells
Polymorphs	Polymorphs (or polymorphonuclear leukocytes) are <b>phagocytes</b> (white blood cells), part of the immune system that defends the body against infectious disease and foreign materials. There are three types of polymorphs: one of them is the <b>neutrophil</b> , and the term polymorph is sometimes used in place of neutrophil
Post menopausal bleeding	Vaginal bleeding occurring after twelve months without a menstrual period in a woman of the age when menopause might be expected
Postcoital bleeding Prevalence	Vaginal bleeding after sexual intercourse  The total number of women who have a cervical pre-cancerous <b>lesion</b> or cancer at a particular time (or during a particular period of time) divided by the population at risk of having a cervical pre-cancerous lesion or cancer in the same time period
Prior notification lists (PNLs)	Lists produced by the Open Exeter system and sent to GPs notifying them that their patients are about to be screened. GPs are invited to check lists and, if necessary, update them before returning them
Screen detectable	Abnormalities that can be detected by cervical screening.
Squamous epithelial cells	Cells resembling fish scales that form the normal covering layer of the skin, (ecto)cervix and vagina
Symptomatic	Showing symptoms.
Transformation Zone (TZ) sampling	The transformation zone (TZ) is the part of the surface of the cervix which was originally columnar epithelium but has been transformed into squamous epithelium. The process of changing is called metaplasia. Metaplasia makes the TZ the area most at risk of abnormal change, and of cervical cancer, which is why it is routinely sampled.  In most women the TZ lies on the cervix but in some it extends on to the
	vagina.
Uptake	The percentage of women invited for screening who are tested within six months of receiving their invitation.

# **APPENDIX 1:** Local structure of NHS Cervical Screening Programme



## **APPENDIX 2: Cytology read codes**

#### Hysterectomy and equivalent codes

For the purposes of nGMS if patients have one of these codes on their record at any time they do not need a smear code.

685H No smear - benign hysterectomy685I No smear- amputation of cervix685K No smear - no cervix

908Y No cervical smear – no uterus

**7E05%** Vaginal excision of uterus

**7E040** Abdominal hysterocolpectomy and excision of periuterine tissue

**7E042** Abdominal hysterocolpectomy NEC **7E043** Total abdominal hysterectomy NEC

7E046 Radical hysterectomy

**7E049** TAH and BSO

7E04B Laparoscopic TAH and BSO

7L0A% Clearance of pelvis

#### Sample taken

HPV test declined

HPV test-neg

Liquid based cytology
Chaperone present
Chaperone refused

Read Code **685R**Read Code **9NP1**Read Code **9NP2** 

·	
RESULT	READ CODE
TRANSFORMATION ZONE MARKERS	
Endocervical and / or metaplastic cells present (non QOF code)	4K2A
No endocx/metaplastic cells seen (non QOF code)	4K2B
CYTOLOGY RESULT	
Inadequate (any reason) Negative Borderline changes Mild dyskaryosis Moderate dyskaryosis Severe dyskaryosis with features of invasion Glandular lesion Vaginal vault smear Vaginal vault smear – negative Vaginal vault smear – atrophic Vaginal vault smear – abnormal	4K21 4K22 4K29 4K23 4K28 4K24 4K25 4K26 7E2A3 4KA1 4KA3
Ca cervix screen – up to date Ca cervix screen done	6856 6859
Screening for malignant neoplasm cx	ZV762
MANAGEMENT SUGGESTED	
Normal recall No action/code Repeat in 3 months Repeat in 6 months Repeat in 12 months Repeat at 36 months Repeat at 60 months Refer Cease recall	4K43 4K45 4K47 4K4B 4K4C 4K48 6855
LIDV DE AD CODES	
HPV READ CODES HPV-pos HPV test consent HPV test-pos HPV-neg	4K3D 685N 685P 4K3E

685O

685Q

Prior notification list (PNL) informs GP practice via Call/Recall (4 weeks before 1<sup>st</sup> invitation letter)

Letter 1: first invitation

(sent by Call/Recall)

No response

Letter 2: reminder letter

(sent by Call/Recall unless a formal arrangement is in place for this to be done by Primary Care)

No response

FIRST non-responder notification sent to GP practice from Call/Recall

Letter 3: GP practice to write to patient

Record Read Code 9083 and Free Text from Practice

Additionally, if patient has been invited verbally and/or by telephone, the following codes may be used

Verbal invite 9023 (+ free text cervical sample)
Telephone invite 9022 (+ free text cervical sample)

No cervical sample taken

FINAL non-responder notification sent to practice

No response to all prompts patient can be **EXCEPTION** reported for 5 years (not the same as permanent ceasing – see below)

6853 Cervical screen not wanted

685L Patient refuses cytology

908S Cervical screen defaulter

**8I6K** Cervical screen not indicated (eg patient terminally ill)

Call/Recall cycle continues

Eligible women can only be CEASED if they have signed a withdrawal form from the PCT **908Q Cervical screening disclaimer received**