NHS Croydon

CERVICAL SCREENING
OPERATIONAL POLICY
May 2010 to April 2013
October 2012 Revision

<table>
<thead>
<tr>
<th>Relevant to:</th>
<th>All staff and contractors involved in the NHS Croydon Cervical Screening Programme</th>
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</thead>
<tbody>
<tr>
<td>Developed and reviewed by:</td>
<td>NHS Croydon District Cervical Screening Committee Commissioning Group Management team November 2012</td>
</tr>
</tbody>
</table>
| Responsible directors:           | Dr Mike Robinson, DPH
                                    | Paula Swann Managing Director                                                   |
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Policy Validity Statement

This policy is due for review in April 2014. After this date the document will become invalid.

It is the responsibility of each policy user to ensure that they are consulting the currently valid version of the documentation.

Version 2 October 2012
Review Date – 30 April 2014 or earlier in response to national policy changes.
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1.0 Introduction

This policy sets out operational standards for the cervical screening services commissioned by NHS Croydon. It is developed by, and reviewed by the NHS Croydon District Cervical Screening Committee. It is applicable to all commissioners and contractors of the NHS Croydon Cervical Screening Committee.

2.0 Background

Cervical screening has taken place in the UK since the 1960s. The NHS Cervical Screening Programme was set up in 1988 when the Department of Health instructed all health authorities to introduce computerised call-recall systems to ensure all women eligible for cervical screening were offered regular tests.

The objective of the NHS Cervical Screening Programme (NHSCSP) is to reduce cervical cancer incidence and mortality rates throughout the UK. In line with national policy, NHS Croydon commissions services to provide cervical screening for the population of Croydon.

The aim of the cervical screening programme is to reduce the incidence of cervical cancer in women through treatment of pre-invasive disease. Pre-invasive disease can be detected by screening. In order to achieve the desired reduction in incidence at least 80% of eligible women need to be regularly screened (women aged 25-49 at 3 yearly intervals and those aged 50 –64 years at 5 yearly intervals). Cervical screening coverage is a performance indicator which PCTs are assessed against by the Quality Care Commission.

Approximately 4 million women per year are invited for a cervical smear test in England. It is estimated that the national programme prevents 4500 deaths per year.

Continued effort is required to maintain and further reduce the incidence of cervical cancer and to improve access and reduce inequalities in service provision. The quality, accessibility and acceptability of services provided are key issues in achieving these objectives.

3.0 Quality

3.1 Quality of Services

Responsibility for the quality of the local programme rests with the Director of Public Health for NHS Croydon. The Director in Public health works collaboratively with the local Hospital Based Programme Co-ordinator for the Acute Trust, PCT commissioners, Primary Care Support Services (call/recall), primary care, community services, and the clinical governance leads. The following standards should be met at all times:

- The information held on the register of eligible women will be up to date and accurate
- High quality of cervical screening sample taking
- All cervical screening should be undertaken through liquid-based cytology
(LBC) technology
- Where indicated patients will be directly referred to colposcopy
- Cervical samples will be tested for HPV in line with policy
- High quality cervical sample screening and reporting will be in place along with appropriate internal and external quality assurance measures within the laboratory and the call/recall centre
- Reporting of cervical screening results should be within national standards.
- Arrangements for referral and treatment are within national standards.
- Appropriate fail-safe mechanisms should be in place
- There will be continued monitoring and evaluation of the programme in the light of national guidance

3.2 Acceptability of Services

The following principles should be followed at all times:

- The service needs to be accessible, effective and equitable.
- The service needs to take into account ethnic, cultural, linguistic considerations and any disability needs.
- There needs to be flexibility about where and when the sample is taken and between the personnel involved.
- A woman has the choice whether to accept this service.

3.3 Quality Assurance Reference Centre (QARC)

The quality of the cervical screening programme is managed by the NHS Cancer Screening Programmes Quality assurance reference centre. The NHSCSP provides a regional system of quality assurance for the programme. Regional coordination has been set up to:

- Set quality assurance standards (see appendices 1 and 2 and www.cancer.screening.nhs.uk).
- Monitor and review performance against these quality assurance standards.
- Identify training needs and advise on how they should be met.
- Identify research needs.
- Advise the programme on professional matters.

4.0 Programme Management

The cervical screening programme is managed at national, regional and local level. Service provision is commissioned by PCTs and performance managed on behalf of the Strategic Health Authority.

4.1 National Management

The National Cervical Screening Policy is set by the Department of Health and guided
4.2 Regional Management

The Strategic Health Authorities are responsible for ensuring that population screening is carried out across local communities. In practice these functions are carried out by PCTs which have an overall responsibility for securing provision of the population screening programme and maintaining its effectiveness by monitoring the quality of the service and identifying emerging issues. The Croydon programme structure is outlined in Appendix 3.

Cervical Screening Quality Assurance Reference Centres have been set up to regionally monitor the annual performance of the programme, make recommendations and support the delivery of the service by collecting programme data, providing regional guidance, carrying out multidisciplinary visits and advising on protocols and procedures. The London Quality Assurance Reference Centre (London QARC) monitors the performance for Croydon.

4.3 Local Management

The PCT Director of Public Health maintains the responsibility for commissioning the provision of the cervical screening programme. NHS Croydon has an appointed public health cancer screening lead responsible for maintaining close links with London QARC and for convening the Croydon Cervical Screening Committee, which supports the local delivery of the programme. This group is chaired by a consultant in public health for NHS Croydon. For further details on the Cervical Screening Committee please refer to Appendix 4 for terms of reference, and group membership.

5.0 Service Providers

5.1 Main Providers

The service is provided by:

- Sample takers within the borough of Croydon providing services from the following organisations:
  - Croydon General Practices
  - Croydon GP Led Health Centre (Walk in centre)
  - Community Contraception Clinic

- Call and recall services provided by Primary Care Support Services (PCSS).
- Cytopathology and histopathology services Croydon University Hospital
- Colposcopy services at Croydon University Hospital
6.0 Programme Responsibilities

6.1 Primary Care Trusts (PCTs)

NHS Croydon will:

- Ensure the commissioning of safe, cohesive cervical screening services by working with the Hospital Based Programme Co-ordinator and NHS Trust staff
- Monitor the incidence of registered cervical cancer cases against set targets
- Monitor cases of CIN identified each year with the Consultant Cytopathologist as an indicator of the appropriateness of screening levels
- Monitor quality standards, activity levels and programme costs
- Monitor the effectiveness of the failsafe systems
- Monitor the effectiveness of the call/recall register and programme
- Link the cervical screening programme with other services commissioned by the PCTs
- Present annual reports to the SWL Joint Boards and advise on how best to improve the quality and effectiveness of the programme. Annual reports will also be submitted to the London Quality Assurance Reference Centre
- Monitor uptake and coverage for each programme by practice. Identify local issues relating to uptake/coverage and develop plans to increase coverage year on year
- Develop the primary care function within each programme
- Identify registration issues, including the unregistered population who live in the geographical area for which the PCT is responsible
- Ensure equity of access to local screening programmes, especially amongst socially excluded, ethnic minority and high risk groups
- Identify resources to support the services to comply with national standards and recommendations arising from QA visits

6.2 Hospital Based programme Co-ordinators

The Hospital Based Programme Co-ordinator will:

- Liaise with the departmental leads on a formal basis to co-ordinate and monitor the provision of cytology, histopathology, and colposcopy services and to monitor the effectiveness of hospital fail-safe programmes
- Provide information on a quarterly basis to Trust management and screening commissioners on activity and quality of screening services
- Collate information from all elements of the screening programme and produce an annual report to be signed off by the Trust Chief Executive and forwarded to the PCT screening commissioners for inclusion in the comprehensive reports presented to the PCT boards
- Actively participate in regular audit meetings with clinical leads and management
- Initiate reviews of cases of invasive cervical cancer in line with the requirements of NHSCSP Publication 28 2006
6.3 Primary Care Support Services (PCSS)

Primary Care Support Services (PCSS) are responsible for:

- Inviting eligible women for cervical screening at the appropriate interval in line with National Policy.
- Sending women "Cervical Screening - The Facts" leaflet with every invitation to assist them in making an informed choice about whether to participate in the Programme.
- Processing and recording the screening results.
- Recording results from non NHS providers (private / non UK) and delaying recall accordingly (up to 12 months).
- Postponing or delaying the call/ recall where appropriate (e.g. in pregnancy).
- Informing women in writing of their screening results. Women are sent information leaflets with their results where indicated (e.g. What your abnormal result means and The Colposcopy Examination).
- Notifying GPs if women do not respond to invitations for cervical screening.
- Operating a failsafe system that ensures that women who have not responded to screening invitations are invited for screening again.
- Providing failsafe arrangements for women who are referred to colposcopy.
- Keeping records of women who have signed disclaimers to opt out of the National Programme and ceasing women from the programme for the following three reasons: age, no cervix or the provision of a disclaimer signed by the patient.
- Providing coverage information to QARC (quarterly), the Department of Health (annually) and the screening commissioners (monthly)

6.4 The Sample Taker

The sample taker is responsible for providing a safe and sensitive service by:

- The smear taker should hold a recognised training certificate before undertaking smears in Croydon (see Croydon sample takers training policy)
- Undertake regular training and continuing professional development to ensure competence is maintained. The maintenance of knowledge, competence and skills in sample taking is the responsibility of all health care professionals who undertake this procedure and thus access to regular theoretical and clinic update is essential; a minimum of one half day every three years is recommended by the NHSCSP publication No 23 April 2006
- Adhering to local infection control policies
- Ensuring the environment and equipment adhere to national guidelines (e.g. privacy, a range of speculum sizes, adequate light source)
- Advising the woman of the reasons for taking a cervical sample
- Advising the woman of the possible outcomes following screening
- Obtaining informed consent
- Ensuring that the woman’s details are correct on the HMR101 and using pre-printed forms (available on Open Exeter)
- Ensuring that samples are sent to the laboratory within 24 hours of being taken
- Keeping a failsafe log of all samples taken and sent to the laboratory and
cross-referencing them with results received
• Responding to failsafe queries from the laboratory, colposcopy and call/recall
• Informing women whose result indicates invasive cells
• Monitoring the ‘suspend’ and ‘repeat advised’ lists sent by the call/recall centre
• Informing the woman of her test results in accordance with the NHSCSP
   standards. This should be done in writing. This responsibility can be devolved
to the call/recall centre for all negative results
• Ensuring their inadequate sample rate is audited

Valid informed consent must be obtained before the sample is taken. This includes
checking that the woman:

• Is aware of the reasons for performing the screening, its benefits and
  limitations. This includes the reasons for not screening women under 25
• Understands the meaning and likelihood of a negative result. (This may mean
  ensuring information is available in languages other than English)
• Is aware of the processes in place should the results of the cervical sample be
  abnormal. Understands the meaning and likelihood of an abnormal result.
• Is aware that she will be directly referred to CUH should the result warrant
  further investigation
• Is aware that she has a choice of hospital at point of sample taking
• Is aware of the system of HPV triage and test for cure
• Knows that she should receive her result within 14 days
• Understands the importance of reporting any bleeding or discharge to her
  doctor

**The GP retains responsibility for referrals for gynaecological assessment of
women with negative results but who have symptoms requiring investigation.**

It is the GP’s responsibility to ensure that all efforts are made to encourage non
responders to attend.

### 6.5 Laboratory Services

Cytology laboratories are responsible for:

• The transfer of screening results and recommendations for management to
  the call and recall system using standard result and action codes.
• Notifying the sample taker and GP or responsible clinician of screening
  results and recommendations for management.
• Implementing the HPV triage and test for cure process, where results
  indicate
• Referring appropriate women direct to colposcopy where results indicate
• Setting up a failsafe system for women who require further investigation and
  treatment.
• Notifying sample takers of problems with samples received (e.g. quality of
  information on forms)
6.6 Colposcopy Services

Colposcopy clinics are responsible for:

- Participating in the HPV triage and test for cure process
  Sending invitation letters or appointments to women referred for colposcopy following direct referral from the laboratory
- Notifying GPs and responsible clinicians of women who do not respond to invitation letters or appointments.
- Informing women of the results of investigation or treatment and discharging them back to their GP or the responsible clinician.
- Diagnosing and treating precancerous cervical conditions.
- Responding to and acting on failsafe enquiries from laboratories.
- Informing Primary Care Support Services (PCCS) of the outcomes to ensure that the next screening ‘test due’ date is updated.

7.0 The Call and Recall System

Primary Care Support Services (PCSS) is commissioned to provide a call and recall service on behalf of NHS Croydon.

7.1 Call and Recall Processes

The call and recall system was created in 1988. It uses the population database system (NHAIS System) held by PCSS which holds details of all patients registered with an NHS GP in the borough of Croydon.

7.1.1 Eligibility and Routine Screening Interval

The Call/Recall policy in Croydon follows the NHSCSP guidelines:

<table>
<thead>
<tr>
<th>Call</th>
<th>Inviting women for their first cervical screening the month before their 25th birthday. (NB: if women under 25 are already in the call/recall programme they will continue to be recalled as per their last test result).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recall</td>
<td>Routine Recall aged 25-49 every three years. Routine Recall aged 50-64 every five years.</td>
</tr>
</tbody>
</table>

The first screening taken after a woman’s 50th birthday will move them to 5 year recall.

7.1.2 Cervical Screening Test for Younger Women

It is a national recommendation and local policy that women under 25 are not routinely invited for cervical screening.

7.2 Prior Notification Lists

Prior Notification Lists (PNLs) are produced weekly and sent to General Practitioners at least six weeks prior to the next test due date containing details of women who are due for cervical screening. The details should be checked against the patients’
records to confirm that the invitation is appropriate. The PNLs should only be returned if there are any amendments to the details on the list of women who are to be invited. For women who should be postponed, this information is recorded on the PNL and returned to Primary Care Support Services.

There is a requirement to record a reason, when delaying a woman from the call/recall system e.g. pregnancy, recent test, under treatment relevant to screening. PNLs should be returned by the date specified. Failure to return the Action Sheets or PNLs by the due date will result in some women being invited to attend for cervical screening inappropriately.

All amendments to PNLs must be authorised by a GP. The task can be delegated within the practice, but the ultimate responsibility for these amendments is retained by the GP.

7.2.1 Electronic PNL

Prior notification lists can be accessed via the Exeter System.

7.3 Processes for Updating and Maintaining the Call/recall System

7.3.1 No Trace Cervical Sample Reports

When Primary Care Support Services have received a screening report and the patient's details cannot be traced on the computer database, the details are checked with the laboratory and if necessary the NHS Spine Portal system. If Primary Care Support Services traces the patient the result is entered onto the Exeter system and a result letter is issued. If there is no trace of the patient, the details and result are entered on the system under a “dummy” GP code (e.g. Dr Cytology) and a result letter is produced and posted to the patient.

7.3.2 Removal and New Patients

Croydon Primary Care Support Services use the Exeter database to transfer cervical cytology data between PCT registers. When a woman registers with a GP Practice in Croydon an application is made, via the network, for her screening record. This ensures that cervical cytology history is updated. This process operates in reverse for women leaving Croydon and registering with a GP practice outside the area.

For women changing their GP practice within Croydon, the screening information remains on the recall system.

7.3.3 Private and Foreign Cervical Screening Tests

National guidance states that when a woman has a cervical screening test carried out by a private provider, the screening should not be considered as part of the call/recall programme. The result from the private provider is recorded on the call/recall system and the recall for the patient is delayed by up to 12 months. (For example if a woman in her thirties has an NHS screen carried out in July 2005 and a private screening done in July 2008, she should be invited for an NHS screening in July 2009).

As many providers do not have the same quality standards in pathology laboratories, the quality of cytology reporting cannot be guaranteed.
If a woman indicates she has had a screening either overseas or privately, an NHS screening may still be offered. If she does not wish to attend for this, on her written instructions, her recall date can be postponed.

7.4 Invitations

- National policy stipulates that all eligible women should receive a written invitation to attend for screening and subsequently should receive their screening results in writing.
- The invitation should reflect that women should have the right to choose where the sample is taken. They also have the right to opt for a female sample taker.
- Information leaflet “Cervical Screening. The Facts” should be sent with every invitation.

Invitations are produced weekly (in line with national policy) as women become due for their cervical screening. These are in the form of a personalised invitation letter, which Primary Care Support Services sends on behalf of the GP. When a woman attends for screening, two patient identifiers should be used. These can be her name, date of birth, NHS number and/or clinic number.

7.5 Reminders

PCSS send a reminder letter to non-attendees 12 weeks after the first invitation.

7.6 Final Non-Responders

20 weeks after the reminder letter (35 weeks following the original invitation) a non-responder letter is sent to the woman’s GP. Negative non-responders are brought back into the recall system after their recommended screening interval.

7.7 Ceasing of Call/Recall

Women who have reached the age of 65 and who have never had a screening test will usually not have responded to several invitations. It is recommended that they may therefore be ceased when they reach the age of 65. This may also apply to women who did not respond to their last invitation. However, these women may be screened opportunistically if appropriate or if they later request a test.

Women who have had an abnormal result in the past should be retained in the programme until any necessary treatment and/or surveillance has been concluded. They can be returned to routine recall following the guidelines in the NHSCSP Publication 20 ‘Colposcopy and Programme Management.’ 2010.

Women should remain in the programme beyond their 65th birthday if their screening histories indicate further recall is necessary.

Primary Care Support Services can accept the following reasons to cease a woman from recall:

- No cervix
- Patient withdrawn their consent (upon signature of disclaimer by patient).
For further details on ceasing call/recall please refer to “Ceasing women from the NHS Cervical Screening Programme: NHS Good Practice Guide No. 1” in Appendix 6 and Croydon ceasing policy document

7.8 Postponement of Call/recall

Women with a temporary reason not be called or recalled should not be ceased from the recall but postponed. The practice should give a date on which recall should resume, which should not normally be more than 12 months from postponement. Valid reasons for postponement are:

- Pregnancy.
- A woman wishes to defer (the practice should retain relevant documentation).
- A patient is undergoing treatment relevant to screening.
- A recent private cervical screening test.

7.9 Disclaimers

Wherever possible, patients should remain on the Call/Recall system as ‘Non Responders’. A woman should only sign a disclaimer form if she is certain that she does not wish to attend for cervical screening at any time. All women should be offered the opportunity to discuss this with a clinician. There is a standard form issued by PCSS, to be used for disclaimer purposes. The original should be retained in the medical record, a copy sent into the screening section at Primary Care Support Services. Women should be encouraged to read the national cervical screening leaflet “Cervical Screening - The Facts” and should be counselled as part of their decision making process.

The wording of the disclaimer form should be in line with the published guidance ‘Consent to cervical screening’. The wording has been approved and considered appropriate by the legal advisors to the NHS screening programme.

Women who sign a disclaimer will not be contacted by the NHS screening programme and information on disclaimers may not be passed on to a 3rd party as this contravenes the data protection act.

Practices should keep a computerised list of women who have signed disclaimers. General Practitioners are required to offer these women the opportunity to re-consider their decision once every five years and to record the outcome.

NB: When a woman is withdrawn from Call/Recall, she remains part of the eligible population.

8.0 Results letters and notifications

8.1 Reporting of Results

The laboratories commissioned by NHS Croydon report cervical screening results in line with National Policy using the publication ‘Achievable Standards, Benchmarks for reporting and, Criteria for evaluating cervical cytopathology’. This publication is commonly referred to as the ABC guidelines (2nd edition).
Electronic copies of results are sent to the GP (in agreement with the laboratory), the cervical sample taker (if different) and to colposcopy. Where it is not possible to send an electronic copy of the result a hard copy is sent. An electronic copy is sent to PCSS.

Out of area results in hard copy from other laboratories are entered on the recall system manually.

A flow chart of the results process is included in Appendix 7.

8.2 Results Codes

Results are entered using the following result codes:

<table>
<thead>
<tr>
<th>Standard action codes for cervical screening (England and Wales)</th>
</tr>
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<tbody>
<tr>
<td>Code</td>
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<td>------</td>
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</tbody>
</table>
| A    | Routine recall | Set woman’s recall type to ROUTINE  
|      |              | Set woman’s next test due date to 3/5 years from  
|      |              | date of previous test in accordance with local policy  
|      |              | Send notifications unless laboratory to send by local agreement |
| R(m) | Early recall (in ‘m’ months) | Set woman’s recall type to REPEAT ADVISED*  
|      |              | Set woman’s next test due date to ‘m’ months from  
|      |              | date of previous test Send notifications unless  
|      |              | laboratory to send by local agreement |

*If an action code of R accompanies a result code of 1 (inadequate), recall type will be set to INADEQUATE

| S    | Suspend from recall  
|      | Set woman’s recall type to SUSPENDED**  
|      | i) due to referral for further investigation Set woman’s next test due date to maximum of 12 months from date S  
|      | ii) for samples taken during investigation code applied (period dependent upon local policy)  
|      | iii) for samples taken during follow-up Send notifications unless laboratory to send by local agreement  
|      | Place woman on suspend lists  
|      | a) after test entered  
|      | b) after locally defined period  

**If an action code of S accompanies a result code of 1 (inadequate), recall type will be set to INADEQUATE which affects letter text and target payments.

| H    | No action  
|      | Set woman’s recall type to ROUTINE  
|      | Do not change recall date  
|      | Send notifications unless laboratory to send by local agreement |

Result and Action Code Combinations

<table>
<thead>
<tr>
<th>Result codes Action codes and Infection codes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Inadequate A Routine recall</td>
</tr>
<tr>
<td>Result code</td>
</tr>
<tr>
<td>-------------</td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td>2</td>
</tr>
<tr>
<td>3</td>
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<tr>
<td>4</td>
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<td>7</td>
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<tr>
<td>8</td>
</tr>
<tr>
<td>B</td>
</tr>
<tr>
<td>M</td>
</tr>
<tr>
<td>N</td>
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<table>
<thead>
<tr>
<th>Code combinations accepted by the PCSS computer system</th>
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</thead>
<tbody>
<tr>
<td>2 Negative</td>
</tr>
<tr>
<td>3 Mild dyskaryosis</td>
</tr>
<tr>
<td>4 Severe dyskaryosis</td>
</tr>
<tr>
<td>5 Severe dyskaryosis ? invasive</td>
</tr>
<tr>
<td>6 ?glandular neoplasia</td>
</tr>
<tr>
<td>7 Moderate dyskaryosis</td>
</tr>
<tr>
<td>8 Borderline</td>
</tr>
<tr>
<td>B Borderline HPV tested</td>
</tr>
<tr>
<td>M Mild dyskaryosis HPV tested</td>
</tr>
<tr>
<td>N test of cure HPV tested</td>
</tr>
</tbody>
</table>

| R Repeat at interval specified by laboratory           |
| S Suspend due to referral                             |
| H No action                                           |
| 0 HPV negative                                        |
| 9 HPV positive                                        |
| U unavailable                                         |
8.3 Results Letter / Notification to Patients

All results produced by the NHAIS system and sent out by PCSS follow a standardised letter format generated when a result and action code is entered onto the Exeter system.

All women must receive their written results within 14 days of their test date.

Sample takers are responsible for the clinical management of women with abnormal test results and for offering appropriate counselling following an abnormal or inadequate test.

If a patient has attended for a screening at a clinic and has expressed that she does not wish her result to be sent to her home address, the result is sent to the sample taker who has responsibility for follow up.

9.0 Management of Test Results: HPV Triage and Management

HPV Triage and Management

![HPV Triage and Management Diagram]
NOTES
(a) If a 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.
10.0 Follow up of Patients After Treatment

All women remain at risk following treatment and must be followed up.

10.1 Following an abnormal test result

- Patients treated for all grades of CIN require follow-up cytology 6 months from the date of the original treatment. If they are smear negative/borderline/mild and HPV-HR negative, women are no longer followed up and can return to the programme. If they are HPV-HR negative, they remain under the care of the colposcopy team and are reviewed on a 6 monthly/annual basis. High grade smear results remain under colposcopy.

Follow up on cases of endocervical dyskaryosis/CGIN require samples every 6 months for 5 years then annual samples for a further 5 years. Endocervical cells must be present.

10.2 Following total hysterectomy (Vault cytology samples)

- Recall and follow up of women for vault cytology following CGIN, CIN or cancer is no longer a part of the recall programme

- The responsibility for undertaking and/or managing the follow up care now resides with the gynaecologist.

10.3 Sub-total Hysterectomy

Women undergoing a sub-total hysterectomy still have a cervix and therefore should continue to be part of the call/recall programme. If there is any uncertainty about whether the hysterectomy was total or subtotal it is a clinician’s responsibility to examine the woman to assess whether she has a cervix or not.

11.0 Inappropriate cervical cytology test

The cervical screening test is not a diagnostic test. It is specifically designed to detect pre-cancerous conditions that do not produce symptoms. The “Guidance for Clinical Practice and Programme Management” (second edition NHSCSP 1997) advises that providing a woman is in the eligible screening age group and has had a screen within the previous three to five years, additional cervical screening tests are not justified unless she is due for early recall.

Women with symptoms or signs suggesting cancer should be referred for an urgent gynaecological opinion whatever the result of a screen and without waiting for the result.
12.0 Failsafe Procedures

Failsafe is a backup system which attempts to ensure that women who are temporarily suspended and those with abnormal cytology results are not lost to follow-up. This policy outlines the responsibilities within the services involved in cervical screening.

Call/Recall – PCSS - Exeter system

- To send PNLs to GPs at least 6 weeks before the next test due date for women who have been advised they need a sample repeated earlier than usual
- To send lists of suspended women to GPs at least once a quarter
- To confirm the numbers of results received electronically from the laboratory
- To record the results and recall dates of all test results received
- To issue invitation, reminder and results letters to women according to national guidelines
- Ensure that GPs are made aware of all women registered with them who have a non-negative result
- To send a copy of the AJ–CP list of all results entered on to the system from that file to the laboratory
- To cross-check 10% of hard copy results from each file transferred from the laboratory to the Exeter database
- Operating a failsafe system that ensures that women who have not responded to screening invitations are invited for screening again. This includes women who have moved out of the area.
- Providing failsafe arrangements for women who are referred to colposcopy.
- Keeping records of women who have signed disclaimers to opt out of the National Programme and ceasing women from the programme for the following reasons: no cervix or the provision of a disclaimer signed by the patient.

Cytopathology Laboratory

It is the responsibility of the Hospital Based Programme Co-ordinator (HBPC) to ensure that the laboratory operates failsafe procedures by the following failsafe actions;

- Works to ensure all results are reported within 5/6 days
- Notifying the GP (or responsible clinician) of test results that have required referral for colposcopy
- Confirming with the call/recall department the number of test results being transferred
- Provide 10% of all results in hard copy for cross-checking
- Sending reminders to sample takers in cases where a repeat test is not received within an appropriate timescale
• Logging all tests with an action code R or S where indicated
• Informing the sample taker and the GP of the result and recommendation to refer to colposcopy
• Recording all other colposcopy results or DNA appointment outcomes
• Allocating appropriate action codes for follow up tests taken while suspended form recall
• Recording responses to failsafe enquiries from sample takers and GPs
• Recording any further actions to failsafe enquiries form sample takers and GPs
• Reporting the details of women lost to follow up to the PCT screening lead
• Analysing the outcome of referrals on the KC 61 part C
• Setting up a failsafe system for women who require further investigation and treatment.

All laboratory failsafe systems should follow the guidance set out in NHSCSP Publication No 21 December 2004.

Colposcopy Services
Colposcopy clinics are responsible for:

• Sending invitation letters or appointments to women referred for colposcopy including information leaflets for colposcopy or treatment
• Notifying GPs and responsible clinicians of women who do not respond to invitation letters or appointments.
• Conducting an annual audit of women who do not attend for investigation or treatment
• Ensuring all results are received and documented from the laboratory for all women investigated and/or treated in the unit
• Informing women of the results of investigation or treatment within 4 weeks (best practice) or 8 weeks (minimum national standard) and discharging them back to their GP or the responsible clinician.
• Diagnosing and treating precancerous cervical conditions.
• Responding to and acting on failsafe enquiries from laboratories.
• Monthly checks of the colposcopy database for missing data and to investigate and complete the database where necessary
• Informing Primary Care Support Services (PCSS) of the outcomes to ensure that the next screening ‘test due’ date is updated.

PCT
The PCT should monitor that failsafe procedures are in place in the
• Laboratory
• Call and recall system
• Colposcopy clinic

and that all failsafe procedures are linked and co-ordinated. These systems
should be audited annually.

PCTs should satisfy themselves that GPs, or the responsible clinician and colposcopy staff have in place systems to ensure that all reasonable steps are taken to contact women who are the subject of laboratory failsafe enquiries.

The PCT undertakes to:

- to monitor the number of women signing disclaimer forms, and to raise, with GPs the issue of screening with women who have signed disclaimers on a regular basis.
- to monitor the number of women who are exception reported for cervical screening and to inform the primary care commissioner of the volume of exception reported women on a regular basis.

Failure of a GP or the responsible clinician to respond to laboratory failsafe enquiries is a clinical governance and patient safety issue and will be dealt with as such (NHSCSP publication 21).

All sample takers

Clinicians requesting tests are responsible for;

- Ensure all samples are sent to the laboratory on the day taken (essential to meet 14 day turn around time)
- Maintaining a register of tests taken and cross-checking that a result is received for every test sent to the laboratory
- Ensuring there is a system to notify women of their test result in writing. NB This can be devolved to the call/recall department in the case of negative results, but it is the sample taker’s responsibility to discuss an abnormal result with the woman if contacted
- Ensuring that arrangements are in place for women who request ‘no correspondence’ (also to include temporary residents and women not registered with a GP) to obtain their results
- Following up women who they have been advised are non-responders or who have not attended for an early repeat test
- Following up on women who they have been advised by the colposcopy clinic have been non-responders
- Responding immediately to failsafe enquiries by the laboratories.
- Refer women as appropriate if they have chosen a hospital other than CUH for colposcopy

Community Clinics

- The principal responsibility lies with the Consultant in Reproductive.

GUM clinics

Cervical smears are not taken in GUM clinic in Croydon
No Trace Cervical Sample Reports
When Primary Care Support Services have received a screening report and the patient’s details cannot be traced on the computer database, the details are checked with the laboratory and if necessary the NHS Spine Portal system. If Primary Care Support Services traces the patient the result is entered onto the Exeter system and a result letter is issued. If there is no trace of the patient, the details and result are entered on the system under a “dummy” GP code (e.g. Dr Cytology) and a result letter is produced and posted to the patient.

If a woman indicates she has had a screening either overseas or privately, an NHS screening may still be offered. If she does not wish to attend for this, on her written instructions, her recall date can be postponed.

Women who have had an abnormal result in the past should be retained in the programme until any necessary treatment and/or surveillance has been concluded. They can be returned to routine recall following the guidelines in the NHSCSP Publication 20 Colposcopy and Programme Management.

Women should remain in the programme beyond their 65th birthday if their screening histories indicate further recall is necessary.

13.0 Cervical Sample Taker Training Requirements

The aim of the cervical cancer-screening programme is to provide women with a comprehensive, high quality service that is acceptable, efficient and effective.

The delivery of this service in primary care is dependent upon having appropriately trained and experienced clinical practitioners.

Policy within Croydon requires that sample takers must attend a recognised cervical cytology course prior to taking cervical samples. All nurses are bound by the code of professional conduct, which clearly sets out that each nurse is personally accountable for their actions. A nurse is required to “acknowledge the limits of her professional competence and only undertake practice and accept responsibility for those activities in which she is competent” (NMC 2002).

The national programme states that, as a minimum, sample takers should update their knowledge and skills every 3 years. In Croydon sample takers are expected to attend an approved update day on a 3 yearly basis. A register of trained nurses is maintained by the Croydon Cancer Screening Co-ordinator.

Please see NHS Croydon sample takers policy 2012
14.0 Audit

All areas involved in the cervical screening programme have a responsibility to audit the quality and efficiency of their local service and local plans should exist, outlining these arrangements. Primary Care Support Services (PCSS), Laboratories and PCT Screening Commissioners are formally audited by the Quality Assurance Reference Centre.

All disciplines within the NHS cervical screening programme are required to participate in the NHSCSP Audit of Invasive Cancers, in line with national requirements laid out in the NHSCSP Publication 28 (2006).

15.0 Reporting and Management of Incidents

The reporting and management of incidents should follow the standard operating procedures set out in the following guidance:

- SWL NHS Incident Reporting system via Datix
- NHS Cervical Screening Programme Publication no11 Guidelines for Managing Incidents in the Cervical Screening Programme.
- London QARC Guidance on Reporting and Managing an Early Warning Arising out of a Suspected or Anticipated Problem Occurring within the Cervical Screening programme.

16.0 Cervical Screening Coverage

From 2010/11 the national target for cervical screening is that > 70% of eligible women aged 25-49 years of age will be screened at least once every three years and 75% of women aged 50 – 65 every five years. This level of coverage must be achieved and maintained to maximise the benefits of the programme to public health.

<table>
<thead>
<tr>
<th>Achieve</th>
<th>Underachieve</th>
<th>Fail</th>
</tr>
</thead>
<tbody>
<tr>
<td>25-49: &gt;= 70%</td>
<td>25 - 49: &gt;= 60%</td>
<td>25 - 49: &lt;60%</td>
</tr>
<tr>
<td>50 - 65: &gt;= 75%</td>
<td>50 - 65: &gt;= 65%</td>
<td>50 - 65: &lt; 65%</td>
</tr>
</tbody>
</table>

NHS Croydon must maintain, review and implement a cervical screening coverage action plan. The principal responsibility for this lies with the screening commissioners. The action plan should outline the various interventions, policies and working practices that will be adopted in order to reach and maintain the coverage minimum standard. Members of the Cervical Screening Committee should work collaboratively to implement the coverage action plan. Progress against the action plan is reviewed at quarterly committee meetings.
17.0 Confidentiality

Due to the nature of the cervical screening programme there will be occasions when it is necessary to share data between organisations. Access to patient identifiable information should be controlled by the owner of the system within each organisation and agreed with the organisation’s Caldicott Guardian. Access to such confidential information should be restricted to those staff that have a justifiable need to know in order to effectively pursue their role within the programme.

The Caldicott principles should guide any approaches taken by the organisations involved in sharing of confidential information:

- Justify the purpose for using confidential information
- Only use it when absolutely necessary
- Use the minimum that is required
- Access should be on a strict need to know basis
- Everyone must understand their responsibilities in regard to the use of such information
- Understand and comply with the law
- Information flows must be monitored and audited

NHS screening services have been granted exemption from the requirements of Section 60 of the Health and Social Care Act (2001) for explicit consent for the sharing of patient information. Exemption is awarded on an annual basis following application to the Patient information Advisory Group (PIAG). Each Trust and PCT must ensure that all those involved in the NHS Cervical Screening Programme comply with the NHSCSP Confidentiality Policy and the NHSCSP Information Security Policy (NHSCSP 2011). All members of PCT screening teams (including Primary Care Support Services) and all Trust employees involved in the NHSCSP are required to read both national policies and sign a declaration of compliance and view the London QARC video on PIAG and information security on an annual basis.

PCT Caldicott Guardians or Chief Executives are required to sign a declaration confirming that all sample takers have been sent copies of the national policies and receive annual updates on confidentiality and information security.
# Appendix 1: NHSCSP Quality Standards for Cervical Screening in the UK –2010-11

<table>
<thead>
<tr>
<th>Objective</th>
<th>Measurement</th>
<th>Acceptable Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>To minimise the incidence of invasive cancer of the cervix</td>
<td>Women aged 20-64 should be screened at least once every 5 years</td>
<td>&gt;80% coverage of women aged 25-64</td>
</tr>
<tr>
<td></td>
<td>Ascertainment of screening history of all women with cancer of the cervix</td>
<td>100% of women with invasive cancer of the cervix audited</td>
</tr>
<tr>
<td>To ensure effective sampling of the Transformation Zone</td>
<td>Cytological evidence of sampling the Transformation Zone in women aged 20-50</td>
<td>&gt;80% of smears contain metaplastic and/or endocervical cells</td>
</tr>
<tr>
<td>All women to receive result in writing</td>
<td>Proportion of women to receive result within 14 days from the date of smear taking</td>
<td>98%</td>
</tr>
<tr>
<td></td>
<td>Sensitivity of primary screening with respect to final report after rapid review of all negative and inadequate smears</td>
<td>85-95%</td>
</tr>
<tr>
<td>To ensure accuracy of smear reporting</td>
<td>Laboratory report profile: Moderate/severe</td>
<td>0.7-1.3%</td>
</tr>
<tr>
<td></td>
<td>Mild/borderline</td>
<td>3.6 – 7.4%</td>
</tr>
<tr>
<td></td>
<td>Inadequate</td>
<td></td>
</tr>
<tr>
<td></td>
<td>PPV for moderately/severely dyskaryotic smears</td>
<td>77% - 90% CIN2 or worse</td>
</tr>
<tr>
<td>To ensure that all staff screening or reporting smears are competent</td>
<td>Participation in UK proficiency testing scheme.</td>
<td>100% of staff to have acceptable performance</td>
</tr>
<tr>
<td>To maintain and improve recommended standards and skills</td>
<td>Number of screening programme slides processed/reviewed annually by: Laboratory</td>
<td>&gt;15,000 slides</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt; 3000 per primary screener, 7,500 per WTE maximum</td>
</tr>
<tr>
<td></td>
<td>Individual screeners</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Individual medical staff</td>
<td>&gt; 750 cases reported</td>
</tr>
<tr>
<td>To ensure that appropriate action taken for all women with other than routine recall schedule</td>
<td>Proportion of women with unknown outcome within 12 months</td>
<td>&lt; 5%</td>
</tr>
<tr>
<td>To ensure prompt colposcopic assessment for women referred</td>
<td>Waiting time for colposcopic assessment for all referrals</td>
<td>&gt; 90% seen in &lt; 8 weeks</td>
</tr>
<tr>
<td></td>
<td>Waiting time for colposcopic assessment for women with moderately/severely dyskaryotic smears</td>
<td>&gt; 90% seen in &lt; 4 weeks</td>
</tr>
<tr>
<td>To ensure the colposcopy service is of high quality</td>
<td>No dyskaryosis on cytology in treated women at 6 months</td>
<td>&gt;90%</td>
</tr>
<tr>
<td></td>
<td>Number of women managed by each colposcopist</td>
<td>&gt; 50 new cases per year</td>
</tr>
<tr>
<td>To minimise unnecessary treatment of women referred for colposcopy</td>
<td>Proportion of women treated at the first visit that have evidence of CIN on histology</td>
<td>&gt; 90%</td>
</tr>
</tbody>
</table>
### Appendix 2 – NHS Cervical Screening Programme Publications

<table>
<thead>
<tr>
<th>NHSCSP Publication number</th>
<th>Title</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Achievable Standards, Benchmarks for reporting, and Criteria for evaluating cervical cytopathology.</td>
<td>June 2012</td>
</tr>
<tr>
<td>10</td>
<td>Histopathology Reporting in Cervical Screening</td>
<td>Apr 1999</td>
</tr>
<tr>
<td>11</td>
<td>Guidelines for managing incidents in the Cervical Screening Programmes</td>
<td>Nov 1999</td>
</tr>
<tr>
<td>15</td>
<td>External Quality Assessment Scheme for Gynaecological Cytopathology</td>
<td>May 2011</td>
</tr>
<tr>
<td>16</td>
<td>Bench aid for the reporting of cervical histological samples</td>
<td>Sep 2003</td>
</tr>
<tr>
<td>17</td>
<td>Ergonomic Working Standards for Personal Engagement in the Preparation Scanning and Reporting of Cervical Screening Slides.</td>
<td>Sep 2003</td>
</tr>
<tr>
<td>18</td>
<td>Cervical Screening Call and Recall: A guide to Administrative Good Practice</td>
<td>Feb 2004</td>
</tr>
<tr>
<td>19</td>
<td>External Quality Assessment Scheme for the Evaluation of Papanicolaou Staining in Cervical Cytology, Protocol and Standard Operating Procedures</td>
<td>Apr 2004</td>
</tr>
<tr>
<td>20</td>
<td>Colposcopy and Programme Management: Guidelines for the NHS Cervical Screening Programme</td>
<td>May 2010</td>
</tr>
<tr>
<td>21</td>
<td>Guidelines for Failsafe Actions for the Follow-up of Cervical Cytology reports</td>
<td>Dec 2004</td>
</tr>
<tr>
<td>22</td>
<td>The Aetiology of Cervical Cancer</td>
<td>Sep 2005</td>
</tr>
<tr>
<td>23</td>
<td>Taking Samples for Cervical Screening – A Resource Pack for Training</td>
<td>Apr 2006</td>
</tr>
<tr>
<td>25</td>
<td>Cervix Chart for Sample Takers in Primary Care</td>
<td>Apr 2006</td>
</tr>
<tr>
<td>NHSCSP Publication number</td>
<td>Title</td>
<td>Date</td>
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<tr>
<td>26</td>
<td>Improving the Quality of Written Information Sent to Women about Cervical Screening: Evidence based criteria for the content of letters and leaflets</td>
<td>Dec 2006</td>
</tr>
<tr>
<td>27</td>
<td>Improving the Quality of Written Information Sent to Women about Cervical Screening: Guidelines on the content of letters and leaflets</td>
<td>Dec 2006</td>
</tr>
<tr>
<td>28</td>
<td>Audit of Invasive Cervical Cancers</td>
<td>Dec 2006</td>
</tr>
<tr>
<td>29</td>
<td>Time Dependent Response to Invitation to Screening</td>
<td>March 2007</td>
</tr>
<tr>
<td>30</td>
<td>Guidelines for Quality Assurance Visits</td>
<td>Oct 2008</td>
</tr>
<tr>
<td>31</td>
<td>The Impact of Cervical screening on young women: Literature Review</td>
<td>Feb 2009</td>
</tr>
<tr>
<td>Guide no. 1</td>
<td>Ceasing Women from the NHS Cervical Screening Programme</td>
<td>Feb 2004</td>
</tr>
<tr>
<td>Series 2</td>
<td>Equal Access to Breast and Cervical Screening for Disabled Women</td>
<td>Mar 2006</td>
</tr>
</tbody>
</table>

Publications list reviewed and updated October 2012
Appendix 3 – Croydon Programme Reporting and Governance Process

NHSWL Joint Boards
*Receive annual reports*

CCG management team, clinical leadership group & CCG Board
*Receive performance reports and serious incident reports*

Croydon cervical screening committee*

SWL cervical screening committee
*Discussion with other PCT cervical screening leads*

SWL acute unit
*Manages PCSS contract and hospital contracts*

*Membership: public health, cytology, histology, colposcopy, PCSS, primary care (2 x LMC reps) For minutes: Community sexual health clinic, ACU, London QA*

This governance chart agreed at CCG SMT October 2012
Appendix 4 – Croydon District Committee Terms of Reference 2012-13

Aim

The group will ensure that the cervical screening programme contributes cost-effectively to the goal of reducing morbidity and mortality associated with cervical cancer in the area.

Objectives

1. **The group will meet quarterly**

2. **To set the strategic direction for the Cervical Screening Programme**
   - Oversee implementation of national and regional policy on Cervical Screening within the Croydon programme.
   - To use epidemiological data and service user views to inform the programme
   - To identify issues requiring external liaison with NHS Croydon commissioners and Acute Trust service managers where appropriate.
   - To encourage the recognition of the importance of all the contributors to the programme within Croydon.

3. **To monitor the quality of the Cervical Screening Programme & its components**
   - To monitor cervical screening activity and outcomes and to receive clinical audit reports.
   - To maintain an overview of significant risks attached to the programme and monitor action to reduce these risks.
   - To produce an annual report for consideration by NHS Croydon and Mayday NHS Hospital Trust, incorporating the annual report of the Hospital Based Screening Coordinator.
   - To provide reports for the NHS Croydon Governance Committee and SWL Cancer Network as required.

4. **To ensure that programme activity is co-ordinated and mutually supported**
   - To agree an action plan aimed at optimising programme coverage for women in the target age group and reducing health inequalities.
   - To determine a co-ordinated approach to training aimed at ensuring good practice and to minimise the number of inadequate smears taken.
   - To ensure there is a fail-safe system for follow up of women with abnormal smears.
• To encourage good communication between members of the screening programme.

5. Communications Policy

• To ensure all those involved in the Cervical Cytology Screening Programme are provided with clear, accurate and timely information through agreed channels. These include:
  - Quarterly statistical information (including KC61/65)
  - Quarterly updates from Commissioning, Screening Manager (PCT), Cytology Laboratory, Colposcopy Clinic
  - Annual Report
  - Changes in policy or protocols

• To ensure the programme is effectively promoted to local women in the target age group

6. List of members

• HBPC / Consultant Pathologist, Mayday Hospital
• Lead Clinical Scientist, Mayday Hospital
• Consultant Gynaecologist/Lead Colposcopist, Mayday Hospital
• 2 Nurse Practitioners, Colposcopy Clinic, Mayday Hospital
• Cancer Screening Co-ordinator, NHS Croydon
• 2 General Practitioner representatives
• Consultant and Lead Nurse, Family Planning, NHS Croydon
• Public Health Consultant, NHS Croydon (Chair)
• Commissioning Manager, (receives minutes)
• Screening Manager, PCSS
• QA representative, London Cancer QA Team
• Service User

The committee is quorate if there is a representative from 1) primary care 2) public health 3) Mayday cytology and 4) Mayday colposcopy

7. Accountability

The group is accountable to:
  - The London Regional NHS Quality Assurance Team
  - The National Health Service Cervical Screening Programme

Locally the group is accountable to the NHS Croydon Board via the NHS Croydon Governance Committees

Agreed September 2012
Review December 2013
Appendix 5 – NHS Cervical Screening Programme Croydon Ceasing Guidelines

Introduction
This information is taken from the NHSCSP national guidance on ceasing, good practice publication no. 1, and Consent to Cancer Screening NHSCSP national guidance second edition series no 4 January 2009.

Ceasing a woman from the NHS Cervical Screening Programme (NHSCSP) has the effect of stopping all invitations being sent to a woman and removing her name permanently from prior notification list (PNL). There are two clear categories where this takes place (age and no cervix), but there are also a number of other reasons why a woman is ceased.

Informed dissent
Some women may choose not to be invited for future cervical screening test. If this is the case, the women may ask to have her name removed from the list of eligible women. Before this request can be implemented, the following conditions must be satisfied:

- The woman must be provided with sufficient information to enable her to make an informed decision about withdrawing from the cervical screening programme – this must be in format which is accessible to her. It should include information on the condition being screened for, the screening process (including risk and benefits) and the consequences of attending or ceasing. ‘Sufficient’ is defined by the woman herself.
- The woman should be informed that withdrawing from the programme will prevent her from receiving any future invitations or reminders about the cervical screening.
- It must be made clear to the woman that she can be returned to the programme at any time at her request.

The woman should put her request to withdraw from the programme in writing to confirm that she has made an informed decision. The template letters in the appendix (form B for cervical screening) have appropriate wording for this purpose. If a woman is unable to sign a standard form, for example because of a severe physical disability, then the alternative methods of communication are acceptable according to individual circumstances. A copy of the confirmation letter stating that the woman should has been withdrawn (ceased) from the cervical screening programme should be sent to her GP.

Ceasing Policy
Women should only be ceased from the cervical screening Call and Recall as follows:

- Following the first test after their 60th birthday only when their last three consecutive test have all been negative.
- Persistent non-responders should be ceased from the recall on their 65th birthday.
- Women making an informed choice that they do not want to have future screening.
- Women who have undergone radiotherapy for cervical cancer.
- The ‘absence of cervix’ marker is used for
  1. women with a total hysterectomy
  2. male to female transsexuals
  3. congenital absence of cervix.
The following women **should not** automatically be ceased from cervical screening call and recall:

- women who have never had sex with a man
- terminally ill women
- women who have been circumcised
- women with physical disabilities (including severe arthritis and obesity)
- women with learning disabilities
- when ‘clinical’ or ‘medical’ reasons alone are cited.

The law states that only the woman herself can consent to withdraw from the programme, and that no other person can give or withhold consent to treatment on behalf of a mentally incapacitated patient. Therefore these women should remain in the cervical screening programme and as they become due for screening a decision should be taken as to whether their invitation should be postponed.

Women who are mentally competent yet have a disability that prevents them from having regular screening can make an informed decision to be ceased from the programme, but only at their expressed wish. Some of these patients are unable to sign the written withdrawal form, in these circumstance it is acceptable to cease if the patient has given verbal instruction that has been witnessed by 2 members of staff. In this situation please ensure a copy of the form is sent to the screening team at the PCSS.

Practices requesting to cancel a patient’s recall must be submitted on the relevant documentation with an authorised signature.

**Practice Staff Signatures**

It is the policy of NHS Croydon that a doctor should sign documents relating to screening. The NHS Croydon will however accept a signature of a member of practice staff on behalf of the patient’s registered general practitioner, but only on completion of a signed mandate form. The mandate form now includes a section that covers electronic prior notification list which can be obtained from the screening team.

**Disclaimers - women who do not want to attend screening**

Wherever possible, patients should remain on the Call/Recall system as ‘Non Responders’. If a patient insists that she does not wish to attend for cervical screening she can be invited to read and sign a disclaimer form. Only women making an informed choice not to participate in the screening programme should sign a disclaimer. The original disclaimer should be retained in the medical record, a copy sent to the screening section at NHS Croydon and a copy given to the woman. Women should be encouraged to read the national cervical screening leaflet and should be counselled as part of their decision making process.

The wording of the disclaimer form is taken from the published guidance ‘Consent to cervical screening’. The wording has been approved and considered appropriate by the legal advisors to the NHS screening programme. If you have a letter within the practice that has previously been used, you should use the standard version currently issued by the PCSS.
Please remember to send a copy of the signed disclaimer form to NHS Croydon or the PCSS otherwise the woman will not be taken out of the recall programme. It should be noted that despite the women’s name being withdrawn from Call/Recall, she remains part of the eligible population.

The national guidance, issued in 2008, Cancer screening publication no 4 indicates that Call/Recall programmes are unable to cease a patient due to women’s choice without their written consent.

1. If a woman reaches the ‘Final Non-responder’ stage, she may be automatically ceased if:

   a) She has been called but never attended and her next test due date is after her 65th birthday, the woman will automatically be ceased from recall even though she has no screening history.

   b) The woman is on routine recall and her previous test is Negative with a normal recall and she has no abnormal tests in her last 3 adequate tests and her next test due date is after her 65th birthday she will automatically be ceased from recall ‘due to age’. Should a further negative with normal recall test be received the woman will remain ceased.

Manual Ceasing
A woman may be ceased ‘due to age’ manually via the electronic PNL, amendment forms etc as long as she is aged more than 65 regardless of her screening history.

CANCER SCREENING FOR PEOPLE WHO LACK THE MENTAL CAPACITY TO CONSENT

Mental capacity
The decision whether or not to participate in cancer screening involves consideration of the benefits and disadvantages of the screening process. Some people who lack mental capacity may not be able to make an informed decision about this. Lack of mental capacity means the inability to make a particular decision at a particular time. This may be because of, for example, a stroke or brain injury; a mental health problem; dementia; a learning disability; or confusion, drowsiness or unconsciousness because of an illness or the treatment for it; or substance misuse. A person who cannot do one or more of the following things is deemed unable to make a decision:

- understand the information provided that is relevant to the decision
- retain that information long enough to be able to make the decision
- use or weigh up the information as part of the decision-making process.
- communicate his or her decision – this could be by talking or using sign language and includes simple muscle movements such as blinking an eye or squeezing a hand.

The provisions of the Mental Capacity Act 2005 (www.dca.gov.uk/menincap/legis.htm) came fully into force in October 2007. Under the provisions of the Act, people must be assumed to have capacity to make their own decisions unless it is proved otherwise. Individuals must be given all practicable help to make their own decisions before anyone treats them as not being able to do so.
People with learning difficulties may benefit from information materials in more accessible formats. The NHS Cancer Screening Programmes have produced picture leaflets entitled An Easy Guide to Breast Screening, An Easy Guide to Cervical Screening, An Easy Guide to Bowel Cancer Screening and An Easy Guide to Having a Colonoscopy which may be helpful in explaining the screening process and enabling people to make their own screening decisions.21–24 The leaflets are available to download or order via the NHS Cancer Screening Programmes’ website at www.cancerscreening.nhs.uk.

Some people may have a condition whereby their capacity to consent fluctuates. In such circumstances, the decision regarding screening should be delayed until the person is able to make his or her own choice.

The Mental Capacity Act also makes it clear that making a decision that might be considered unwise should not be taken to mean that the individual lacks the capacity to make that decision.

A person lacking the mental capacity to consent may have made an advance decision to refuse participation in a screening programme or associated tests or treatment at a time when he or she did have mental capacity. A valid and applicable advance decision must be followed in the same way as a contemporaneous refusal made by a person with capacity.

**Screening under a best interests decision**

- the opinions of people that know the individual well (including family, friends, and other carers) as to what they feel the individual would want.

A best interests decision must not be based on what the person making the decision would necessarily do, and it must not be based on what is easiest for the carer or screening staff. It should be remembered that the person responsible for making the decision to proceed with (or withhold) screening in a person’s best interests must be able to justify the decision. A carer who has made a best interests decision should have considered all the relevant factors, and may benefit from speaking to screening staff in order to be fully informed about the screening process and its implications for the individual concerned. Even if a carer has decided in favour of screening as a best interest decision, the screening practitioner should be able to debate that decision if he or she feels that there are valid reasons why the screening procedure may not be in the individual’s best interests.

Screening practitioners should adhere to the requirements of the Mental Capacity Act 2005. Further guidance about all aspects of the Act can be found in the Code of Practice, available on the Office of the Public Guardian (OPG) website at www.publicguardian.gov.uk/mca/code-ofpractice.htm.25 A copy of the OPG guidance for health care practitioners needing to make best interests decisions can also be found on the OPG website (www.publicguardian.gov.uk) and at www.cancerscreening.nhs.uk/publications/making-decisions-opg603-1207.pdf

Any best interests decision to screen or withhold screening should be clearly documented, including detailed information about who made the decision, and why the decision was considered to be in the individual’s best interests.

**Ceasing in a person’s best interests**

It is important for screening staff to recognise that a person who lacks the mental capacity to consent to screening should not be permanently removed from a screening recall programme unless a best interests decision to do so has been taken on his or her behalf. In most cases, the least restrictive option is for that person to remain in call/recall and receive screening invitations at routine intervals. The invitations can be considered and accepted or declined on each occasion.
In exceptional circumstances, a care team may decide that it is in the best interests of a person who lacks mental capacity to withdraw from a cancer screening programme. Screening staff should be satisfied that the best interests decision has been reached in accordance with the Code of Practice (see section 5.2). The person making the best interests decision to cease a person from screening should be aware that the person can be reinstated onto the screening list at any time (if still within screening age) if circumstances change and screening is then considered to be in the person’s best interests.

**Lasting Power of Attorney**
The Mental Capacity Act provides for decisions about the health care (including participation in screening) of a person who lacks mental capacity to be made by a legally accountable decision maker only if he or she has been authorised to do so. This may be someone nominated under a Lasting Power of Attorney, or a deputy appointed by the Court of Protection. Decisions made by them must be accepted as if they were made by the person lacking capacity. However, those decisions must be made in accordance with the same processes of any other person acting in the individual’s best interests.

**Additional guidance: bowel cancer screening**
Some people who need help to make an informed decision about bowel cancer screening; for example, people with a learning difficulty may also need additional help to use the FOBt kit, because the test is completed by the individual at home rather than screening being carried out by a screening practitioner.

If a carer is making a best interests decision for a person who lacks the mental capacity to make his or her own decision about bowel cancer screening, the carer must have received and understood information relating to the entire screening process, including the possibility of further investigations. A best interests decision must not be based on the completion of the FOBt kit alone, but must also consider the implications and risks of colonoscopy should the screening participant receive an abnormal screening test result. If it seems likely that an individual will be unable to tolerate or comply with the colonoscopy procedure, an alternative method of investigation, such as imaging, may be offered. A carer should seek advice from the NHS Bowel Cancer Screening Programme free phone helpline (0800 707 60 60) before making a best interests decision about bowel cancer screening. A statement to this effect is included in the screening invitation letter.

**The following documents are contained in the full ceasing policy document**

- Informed Consent document
- Informed Consent document no 2
- Disclaimer Information Pack Guide
- Disclaimer by GP
Appendix 6 – Royal College of Nursing Cervical Screening Guidance


\wpct.local\shared\Public Health\General
INTRODUCTION

Due to a number of widely publicised incidents which have occurred within the Cervical Screening Programme the Quality Assurance Reference Centre (QARC) have developed guidance for cervical screening personnel on the steps to be taken if a “suspected problem” within the cervical screening programme is identified.

This guidance document:

- Outlines some of the mechanisms by which a suspected problem might be revealed
- Describes the stages of investigation if a “suspected problem” arises
- Recommends the sequence of steps to be taken if an “early warning” is necessary.

A Suspected Problem

A “suspected problem” is an interpretation of a possible system failure arising from the occurrence of certain events, patterns or trends.

An Early Warning

An “early warning” would be initiated where a suspected problem has arisen which if by further examples resulting from data collection could compromise the quality of the screening services (see appendix 1 for examples of Early Warnings).

QA Process

Quality Assurance is an integral part of the NHS Cervical Screening Programme and is the process by which a local cervical screening programme identifies and avoids potential risks. Occasionally, problems occur that have not been identified at an earlier stage or have not been dealt with adequately at the time of first identification.
The cervical screening service at any level may be alerted to a suspected problem through the following e.g.

Internal mechanisms:

- Auditing of performance statistics against national minimum standards and targets
- Auditing of IT systems and links to external organisations
- Assessment of professional performance over a period of time
- Monitoring of systems or specialities or personnel by trust management as part of its clinical governance activities
- Staff/patient/community concerns
- Complaints.

External mechanisms

- QA monitoring
- QA visits
- CPA visits
- Litigation
- Media reporting
- IT links failures.
“SUSPECTED PROBLEM” IDENTIFIED
(Evidence based)

Who Should Notify the QARC

If a suspected problem is identified within the cervical screening service the QARC should be informed.

If a suspected problem is identified within an Acute Trust

The HBPC is the point of focus for communication within a Trust concerning the cervical screening programme.

The Hospital Based Programme Co-ordinator (HBPC) should therefore be made aware of any “suspected problems” that arise. They are responsible for notifying the QARC and the Primary Care Organisation (PCO) Screening lead of the suspected problem.

If a suspected problem is identified within a Primary Care Organisation

It is the responsibility of the PCO Screening lead to notify the QARC of a “suspected problem”.

Notification should be confirmed in writing to the QARC within five working days following the identification of a “suspected problem” and should include accurate information characterising the “suspected problem” (see appendix 2 for template).
The Initial Investigation

An investigation team should be established with the appropriate personnel (see appendix 3).

The initial investigation team should include as a minimum:

<table>
<thead>
<tr>
<th>Within the Hospital Trust</th>
<th>Within Primary Care</th>
</tr>
</thead>
<tbody>
<tr>
<td>HBPC</td>
<td>PCO Screening Lead</td>
</tr>
<tr>
<td>Senior Trust Management</td>
<td>Laboratory Medical/Non-medical Lead</td>
</tr>
<tr>
<td>Representative</td>
<td>Clinical Governance Lead</td>
</tr>
<tr>
<td>Colposcopy Lead (only if required)*</td>
<td>Exeter Administrator (only if required)*</td>
</tr>
<tr>
<td>QA Manager/Facilitator</td>
<td>QA Manager/Facilitator</td>
</tr>
</tbody>
</table>

(The above list should be used as guidance. Membership of the initial investigation team may vary)

The aim of the initial investigation team is to review early evidence and establish some facts in order to confirm whether there is a clinical risk to women and whether if the situation is left unattended, implications for the screening programme may arise.

It is important to be clear that this is all that the initial investigation is trying to achieve. Communication should be limited to those who need to know, and the investigation should not be referred to as 'an incident'.

The initial investigation team should also consider what safeguards or additional quality assurance checks should be introduced on a temporary basis to prevent continuation or repetition of the suspected problem. These temporary measures should remain in place until the suspected problem is either confirmed or the team is satisfied that the suspicion has not been substantiated.
## Findings of the Initial Investigation

<table>
<thead>
<tr>
<th>No Problem</th>
</tr>
</thead>
<tbody>
<tr>
<td>The initial suspicions have not been confirmed.</td>
</tr>
<tr>
<td>Record the methodology and the basis of the conclusion reached.</td>
</tr>
<tr>
<td>Report the outcome to the Trust Management, Director of Public Health of the Commissioning PCO, SHA Director of Public Health and the QARC.</td>
</tr>
<tr>
<td>The QARC will notify the National Co-ordinator and the Regional Director of Public Health if required.</td>
</tr>
</tbody>
</table>

## Minor Problem Identified (Early Warning)

<table>
<thead>
<tr>
<th>Minor Problem Identified (Early Warning)</th>
</tr>
</thead>
<tbody>
<tr>
<td>There is a problem identified with the system but does not have consequences for the clinical management or follow-up of the woman.</td>
</tr>
<tr>
<td>Produce a chronological order of events leading up to the identified problem.</td>
</tr>
<tr>
<td>Map the process of the problem identified. This should highlight possible weaknesses in the provision of the service and what steps should be taken to resolve these issues. (Refer to NHS Modernisation Agency Improvement Leaders’ Guide to Process Mapping, Analysis and Redesign)</td>
</tr>
<tr>
<td>Make recommendations for action(s) to remedy weaknesses within the service.</td>
</tr>
<tr>
<td>A final report should be produced and distributed to: all members on the investigation panel, Trust Management, Commissioning PCO, SHA Director of Public Health and the QARC.</td>
</tr>
<tr>
<td>Following closure of the early warning and as a point of good practice, the final report should include lessons learnt in identifying the potential risks to the service providing the screening programme. The QARC will facilitate the sharing of the lessons learnt with other service providers.</td>
</tr>
<tr>
<td>QARC will notify the National Co-ordinator and the Regional Director of Public Health.</td>
</tr>
</tbody>
</table>
ACTION REQUIRED IF AN EARLY WARNING IS CONFIRMED

Chronological Order of Events
A chronological order of events leading up to the identified problem should be maintained by the initial investigation team and submitted with the final report (see appendix 4 for template).

Action Plan
If an early warning is confirmed, the investigation panel should agree an action plan with agreed timescales.

A copy of the action plan should be sent to the QARC. (see appendix 5 for template).

Closure of the Early Warning
Once the investigation is complete and there is no further cause for concern the early warning may be closed with the distribution of the final report to the investigation team and appropriate key cervical screening personnel.

A copy of the final report should be sent to the QARC.

Monitoring of the Early Warning
The early warning should be monitored through various mechanisms, i.e. clinical governance, cervical screening policy group meetings.

ACTION REQUIRED IF A SERIOUS UNTOWARD INCIDENT (SUI) IS CONFIRMED

<table>
<thead>
<tr>
<th>A Clinical Risk to Women is Confirmed</th>
<th>There is a Problem (SUI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>The possibility of clinical under-performance or failure of systems which have consequences for the clinical management of women.</td>
<td>Inform Trust Chief Executive.</td>
</tr>
<tr>
<td>Inform Trust Chief Executive to set up formal investigation team.</td>
<td>Inform Strategic Health Authority.</td>
</tr>
<tr>
<td>The investigation team should refer to: “Guidelines for Managing Incidents in the Cervical Screening Programme” November 1999 No 11.</td>
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</tbody>
</table>

Serious Untoward Incident (SUI)
The definition of a SUI is open to interpretation but it is usually triggered by a recognition of increased clinical risk to women; adverse media attention and/or risk of litigation.
### Examples of ‘Early Warnings’

<table>
<thead>
<tr>
<th>Call/Recall Service (Exeter System)</th>
<th>The Call/Recall system is based upon a recurring protocol of Call/Recall notifications that have been designed to ensure that the maximum number of women deemed to be at risk i.e. those in a specified age group - receive cervical screening. This operates by inviting women for smear tests on a regular three or five yearly basis, depending on local policy.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Problem Identified</td>
<td>Failure in the electronic transfer of data between the laboratory and the Exeter database, resulting in inappropriate Call/Recalls being sent out and failure to re-invite some women on early recall.</td>
</tr>
<tr>
<td>Primary Care</td>
<td>Primary Care incorporates the General Practitioners, Family Planning and Genito-Urinary Medicine (GUM) clinics. Responsibility for the woman lies ultimately with the smear taker for following up smear results.</td>
</tr>
</tbody>
</table>
| Problems Identified                | - A trained smear taker with a high inadequate rate continuing to take smears. Smear takers should take responsibility for auditing their own work, using the current national rate 9.2% as a benchmark  
- A trained smear taker taking smears using incorrect/inappropriate instruments. |
| Laboratory Service                 | The cytology laboratory is responsible for reading and reporting the smear and ensuring that an effective failsafe system is in place for the management of women. |
| Problems Identified                | - Errors in result file transmissions to the Call/Recall centre  
- A failsafe system is not in place-operationally effective  
- The appearance of a laboratory backlog greater than 10 weeks. |
| Colposcopy Service                 | The colposcopy service is responsible for the investigation and treatment of abnormal smears. |
| Problems Identified                | - A failsafe system is not in place/operational  
- The appearance of a colposcopy waiting time in excess of 10 weeks for any category of colposcopy referral of new patients. |
REPORTING THE SUSPECTED PROBLEM TO THE QUALITY ASSURANCE REFERENCE CENTRE

This form needs to be completed as soon as a problem has been identified.

<table>
<thead>
<tr>
<th>Organisation(s) concerned:</th>
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<tr>
<td>Reported to QARC by:</td>
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<tr>
<td>Name, Job Title &amp; Contact Details: (i.e. telephone, email address)</td>
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<tr>
<td>Name of PCO Screening Lead:</td>
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Description of “Suspected Problem”:

Date of when problem was reported:

A copy of this form needs to be kept by either the Acute Trust or PCO and a copy sent to the:

London Quality Assurance Reference Centre,
4th Floor, 50 Eastbourne Terrace, London, W2 6LG
Main Office: 020 7725 5577 Main Fax: 020 7725 3484
www.londonqarc.nhs.uk

Sonya Narine
QA Manager (Cervical)
DDI: 020 7725 5676
sonya.narine@bartsandthelondon.nhs.uk

Steve Dixon
Head of QA – Cancer
DDI: 020 7725 5579
s.dixon@bartsandthelondon.nhs.uk
Appendix 3

MEMBERSHIP OF THE INITIAL INVESTIGATION GROUP

<table>
<thead>
<tr>
<th>Name</th>
<th>Job Title</th>
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Dates of all meetings of group.

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<th>Date</th>
<th>Details</th>
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sonya.narine@bartsandthelondon.nhs.uk

Steve Dixon
Head of QA – Cancer
DDI: 020 7725 5579
s.dixon@bartsandthelondon.nhs.uk
Appendix 4

**CHRONOLOGICAL ORDER OF EVENTS**

The following events took place that led to the identification of the Early Warning.

<table>
<thead>
<tr>
<th>Dates</th>
<th>Events</th>
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<table>
<thead>
<tr>
<th>Sonya Narine</th>
<th>Steve Dixon</th>
</tr>
</thead>
<tbody>
<tr>
<td>QA Manager (Cervical)</td>
<td>Head of QA – Cancer</td>
</tr>
<tr>
<td>DDI: 020 7725 5676</td>
<td>DDI: 020 7725 5579</td>
</tr>
<tr>
<td><a href="mailto:sonya.narine@bartsandthelondon.nhs.uk">sonya.narine@bartsandthelondon.nhs.uk</a></td>
<td><a href="mailto:s.dixon@bartsandthelondon.nhs.uk">s.dixon@bartsandthelondon.nhs.uk</a></td>
</tr>
</tbody>
</table>
Appendix 5

**ACTION PLAN**

If an early warning/minor problem is identified, the PCO Screening lead should agree an action plan with agreed time scales with members of the investigation team.

*List the problem (s) identified and the action (s) required to resolve the Early Warning.*

<table>
<thead>
<tr>
<th>Problem (s) identified</th>
<th>Action (s) required</th>
<th>Person responsible for the action required and deadline allocated</th>
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Copies of the action plan should be submitted to the following: Trust Management Commissioning PCO, SHA Director of Public Health and the QARC.