Directorate of Laboratory Medicine

Manchester Cytology Centre
NHS Cervical Screening Programme
INFORMATION PACK FOR SAMPLE TAKERS

APRIL 2012

CPA
Accredited Medical Laboratory
Reference No. 0513
SUMMARY OF CHANGES

Page 4  Following the retirement of the laboratory manager we are waiting for a new appointment to this post. In the interim please contact Adanna Ehirim with any queries that need the attention of the laboratory manager

Page 23  Zero Tolerance protocol. The actions to be taken when a sample arrives with no source details

IMPORTANT REMINDER:

To ensure that eligible women have the benefit of the Test of Cure HPV test following treatment for CIN; please could all sample takers provide details of previous treatment i.e. the histological grade of CIN, the type of biopsy e.g. punch biopsy, LLETZ or cone biopsy and/or the type of treatment. This is important if the treatment was ablative as there will be no histology report available. The presence of CGIN or invasive disease is particularly important as this precludes Test of Cure.
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</table>
1 CONTACT US

The Manchester Cytology Centre is one of the largest units of its kind in the country. It accepts SurePath Liquid Based Cytology (LBC) samples as part of the NHS Cervical Screening Programme. The department is housed in a purpose-designed building with state-of-the-art facilities and is affiliated to the North West Cytology Training Centre, which is situated on the ground floor of Clinical Sciences Building 2.

FIND US

The Manchester Cytology Centre is located on the first floor of the Clinical Sciences Centre. All visitors should access the department via the reception area on the ground floor.

CONTACT US

Address
Manchester Cytology Centre
First Floor, Clinical Sciences Centre
Manchester Royal Infirmary
Oxford Road, Manchester
M13 9WL

Telephone enquiries
Urgent & general enquiries
Tel: 0161 276 5111
Fax: 0161 276 3258

Email enquiries
cyto.pathology@cmft.nhs.uk

Hours of opening
The department is open from 8.00 am – 5.00 pm, Monday to Friday (except bank holidays)

Consultant Cytopathologists

Dr M Desai, Head of Service & Director of the North West Cytology Training Centre
Tel: 0161 276 5099
Fax: 0161 276 5113

Dr M Holbrook
0161 276 6475
Dr M Perera
0161 276 5109
Dr D N Rana
0161 276 5108

Medical Secretaries
Tel: 0161 276 5115/5119/6727
Fax: 0161 276 5113

Consultant Biomedical Scientists

Mrs Viv Beavers 0161 701 0228
Mr Paul Hermansen 0161 276 5103
Mrs Janet Marshall 0161 701 0228
Mr Mike Palmer 0161 276 5103

Chief Biomedical Scientist
Adanna Ehirim 0161 276 5119

Hospital Based Programme Co-ordinator
Janet Marshall 0161 701 0228

Assistant Hospital Based Programme Co-ordinator
Viv Beavers 0161 701 0228
Medical secretariat

Mrs Annette Lawton (Manager)  0161 276 5115
Mrs Nicola Wood 0161 276 5116
Mrs Helen Wilson 0161 276 6727

Fax: 0161 276 5113

VISITING THE LABORATORY

The Manchester Cytology Centre has an ‘open access’ policy for any clinicians or other screening programme staff who may want to visit the department and speak with staff to discuss any aspect of the service we provide.

Visits by medical staff can be arranged by contacting:

Dr M Desai, Head of Service, Manchester Cytology Centre

0161 276 5099

Informal visits by other clinical staff can be arranged by contacting one of our chief biomedical scientists:

Sample Preparation Laboratory Lead

Sarah Ferris, Advanced BMS 0161 276 5111

Cytology Training Officer

Pam Atkinson, Chief BMS 0161 276 5122
2 MANCHESTER CYTOLOGY CENTRE

2.1 QUALITY STATEMENT

The Manchester Cytology Centre is a CPA accredited department and all cervical liquid based cytology (LBC) samples are processed and screened following NHS Cervical Screening Programme guidelines and the regional Quality Assurance Reference Centre recommendations.

The department participates in the regional gynaecological and technical EQA schemes and the performance of all screening staff is assessed quarterly as per NHSCSP guidelines.

The management and staff within the department are committed to providing a quality service to our users. We aim to continually improve our service through internal audit and feedback from users. If you do have a complaint or concern about any aspect of the service, this should be addressed to the laboratory manager on 0161 276 5119.

General enquiries Tel: 0161 276 5111 Fax: 0161 276 5149

A consultant cytopathologist or a consultant biomedical scientist is available to answer any ‘gynaecological queries’ and discuss any aspect of the cytology report as well as give advice on patient management.

2.2 TRANSPORT AND LBC KITS

Specimen collection and transport

The Manchester Cytology Centre processes and reports SurePath® cervical LBC samples. These should only be collected by trained sample takers. Training in sample collection for primary care staff is available on request from the cytology training leads at the local Primary Care Trust. The cytology training lead can also arrange for three-yearly update training for sample takers in order for them to remain aware of developments within the cervical screening programme and to maintain competence. Instruction sheets on sample collection are also available from the laboratory.

The laboratory will deliver a 12-month supply of kits to each practice/clinic. If there are any issues relating to the provision of LBC kits, please contact the laboratory manager on 0161 276 5119.

LBC kits

The laboratory uses a database to keep a record of the number of LBC kits used by each surgery and clinic to ensure that supplies are readily available. For any enquiry regarding LBC kits please contact the laboratory on 0161 276 5172

LBC stock rotation

Please be aware that LBC kits have an expiry date and it is the sample takers responsibility to ensure that there is stock rotation and to check that the vials they are using have not passed the expiry date.
2.3 REQUEST FORMS AND VIALS

Request form: The request form should be completed in full with all information PRINTED legibly. The Manchester Cytology Centre supports the use of the electronic HMR101 request form that can be downloaded from Open Exeter. Please print off the form and complete it paying particular attention to the provision of relevant clinical history. See Section 6.1 for more information.

Information relating to previous histology biopsies (punch, LLETZ/loop, cone etc) with histology grade and date of biopsy, as well as details of any treatment are ESSENTIAL to ensure correct patient management is given.

NHS number: The NHS number MUST be used whenever it is available as this is the unique patient identifier. In addition the full forename, surname and date of birth MUST be given.

PIN codes: The sample taker is required to print their name in block capitals in order for the laboratory to assign the correct PIN code. PIN codes are created by the laboratory office manager and recorded against each test. The laboratory is required to record sample taker details for clinical governance purposes. The GMC and NMC number will eventually replace the PIN code and the laboratory is currently working with PCTs to gather this information prior to the changeover.

Sample: The label on the sample vial must record the forename (or initial), surname and date of birth and ideally the NHS number (if known) to allow matching of the vial with the request form in the laboratory. After collection and labelling, the sample and request form should be placed in separate sections of the plastic specimen bag provided before dispatch to the laboratory.

Vaginal vault samples: Women who need vaginal vault cytology following surgery are no longer included in the NHS Cervical Screening Programme. The recommendation from the North West Cervical Screening Quality Assurance Reference Centre (March 2009) is that vault cytology should be performed at colposcopy and therefore women requiring this should be referred to colposcopy.

Report generation and distribution

Reports are made available to the sample taker (and the GP if the sample has been taken somewhere other than the GP surgery – as long as the GP details are given on the request form). The PCT screening agency also receives a copy of the report to update the cervical screening history on the Exeter system.

Currently the laboratory issues hard copy reports to GPs/sample takers and electronic reports to the screening agencies. Electronic reports are currently being rolled out to GP surgeries and this project continues to be rolled out.

Urgent referrals for further investigation

Any test reported as suspected invasive carcinoma or suspected glandular neoplasia requires urgent referral for further investigation. The laboratory will contact the sample taker by phone and arrange to fax the report through to a ‘safe haven’ fax so that the referral process can commence as soon as possible. A failsafe system is in place to ensure that the report has been received and the patient has been referred.

Prioritising the workload

The laboratory is a Phase 1 pilot site and has worked in collaboration with NHS Improvement and as part of a multidisciplinary team to achieve a 14-day turnaround time for cervical cytology reports. Introducing LEAN methodology and redesigning the service has brought significant improvements and we now apply a ‘first in, first out’ approach to all cervical cytology requests.
Audit

The department participates in the Trust audit programme and has a rolling programme of audit projects.

Feedback on inadequate cytology reports

The laboratory sends data to the regional Quality Assurance Reference Centre on a quarterly basis and samples takers can access the information on-line. To register for access to the sample taker database, contact QARC via their web site:

www.nwcsqarc.org.uk or telephone Michael Wall at NWCSQARC on 0151 702 4284

3 RESEARCH ACTIVITIES

3.1 HPV TRIAGE IN PRIMARY SCREENING & HPV ‘TEST OF CURE’

The Manchester Cytology Centre has been selected as one of six national sentinel sites to begin the controlled implementation of Human Papillomavirus (HPV) triage in primary screening and the use of HPV testing to determine if the treatment of Cervical Intraepithelial Neoplasia (CIN) has been successful i.e. as a ‘Test of Cure’. The detection of ‘high risk’ HPV is an indication for colposcopy referral whereas the absence of ‘high risk’ HPV means the woman can be returned to routine recall. All women whose sample is taken in primary care and shows a borderline or mild dyskaryosis result on cytology will be included and managed according to their HPV test result. Women who have had successful treatment of CIN will have a repeat cytology test at 36 months before returning to routine recall.

See Section 10 or visit our web page for more information and copies of the Sentinel Site protocols

www.cmmc.nhs.uk/directorates/labmedicine/departments/cytology/sentinel.asp

3.2 ADEQUACY TRIAL

A multistranded HTA funded study to determine the minimum cellularity required for the reliable assessment of Liquid Based Cervical (LBC) cytology samples. The trial uses archival samples.

Project Reference 05/41/02

Liquid Based Cytology (LBC) was approved as the recommended method for preparing cervical samples in 2003. National pilot studies showed that this method was superior to conventional spread smears and reduced the inadequate rate from 10% to 1-2%. However, the number of cells required for these samples to be deemed adequate remains the subject of debate. There is a risk that samples may be described as negative when they are really inadequate and that abnormalities could therefore be missed.

An adequate LBC sample is one in which sufficient numbers of cells are present to allow the detection of an abnormality were it to be present. This study aims to establish the threshold of cellularity which will minimise the risk of false negative reports.

The first part of the study surveys current practice in laboratories throughout mainland UK using LBC for cervical screening and establishes the cellularity of a large cohort of inadequate, negative and abnormal slides. The second part of the study evaluates the ability of screeners to detect abnormalities of differing type and relative abundance. This will be done by preparing sets of slides which vary in their total cellularity and in the total number, type and relative proportion of abnormal cells. These will be presented to a large number of laboratories for independent evaluation. The results will allow an estimate of a level of cellularity at which most abnormalities are likely to be detected and will hence determine a safe minimum cellularity.

This study is led by a team of national experts with many years of experience in cervical screening, liquid based cytology and the conduct and evaluation of clinical trials.

The first phase of the trial is completed and the samples are being assessed for the second phase.
4 CERVICAL SCREENING AND PATIENT MANAGEMENT PROTOCOLS

4.1 INDEPENDENT SECTOR CERVICAL CYTOLOGY SAMPLES

PCT colleagues have raised concerns regarding women undertaking cervical cytology testing at independent facilities i.e. “private smear tests”. Cervical cytology samples undertaken in the Independent Sector (IS) are not part of the national screening programme. Colleagues felt it would be helpful if GPs/practices were made aware of the issue.

All eligible women (aged from 25-64) will automatically receive their invitation letter from the Call/Recall Agency to attend for screening. Women who have cervical samples taken outside the NHS cervical screening programme may contact their GP to say that they have had cervical cytology done privately. The GP/practice should then advise the woman that her private cervical cytology test results are not captured in the NHS screening programme and that she is eligible and for her routine test and should attend for this.

Any sample taken in the IS will not be captured under the national screening programme, though GPs may be informed of the result. Through the NHS Cervical Screening Programme, women will be eligible to be invited for cervical screening and will still receive invitations to attend.
4.2 INAPPROPRIATE AND ‘OUT OF PROGRAMME’ SAMPLES

Recall intervals for cervical screening

- Routine 3 yearly recall between the ages of 24 years, 4 months to 49 years inclusive
- Routine 5 yearly recall between the ages of 50 to 64 years inclusive
- Cease cervical cytology at age 65 years, only screen those who are currently on follow-up for a previous cervical abnormality

Inappropriate and ‘out of programme’ samples

- Cervical cytology samples are NOT justified in any of the following situations:
  - WOMEN AGED UNDER 24YRS & 4MONTHS WHO HAVE NOT BEEN INVITED FOR SCREENING
  - WOMAN AGED 65YRS AND OVER WITH LAST TEST ROUTINE RECALL
  - WOMEN WITH AN ABNORMAL LOOKING CERVIX
  - On taking or starting to take an oral contraceptive
  - On insertion of an intrauterine contraceptive device (IUCD)
  - On taking or starting to take hormone replacement therapy (HRT)
  - In association with pregnancy – either antenatally or postnatally, or after termination unless a previous screening test was abnormal
  - In women with genital warts
  - In women with a vaginal discharge
  - In women with pelvic infection
  - In women who have had multiple sexual partners
  - In women who are heavy cigarette smokers

Symptomatic women

Women with symptoms of cervical cancer should be referred for gynaecological examination. Cervical cytology is not an appropriate investigation for:

- Postcoital bleeding
- Intermenstrual bleeding
- Postmenopausal bleeding
- Persistent vaginal discharge

Cervical screening in pregnancy

- If called for routine screening, test should be deferred
- If previous test was abnormal, then woman becomes pregnant, test should be taken mid-trimester unless clinically contraindicated
- If colposcopy or cytology after treatment (or follow-up of untreated CIN1) is required, delay assessment until after delivery
- If colposcopy or cytology, after treatment for CGIN or CIN2/3 with involved or uncertain margins is required, do not delay assessment
4.3 SAMPLES TAKEN IN PRIMARY CARE

Eligibility for HR-HPV triage
Samples taken from women within the NHSCSP screening age ranges that have adequate cellularity can be tested for high-risk human papillomavirus (HR-HPV). Women are ineligible if they are below the minimum age for screening or if their sample contains insufficient squamous cells as scanty samples may yield a false negative HR-HPV result.

<table>
<thead>
<tr>
<th>Cytology Report</th>
<th>Patient Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative</td>
<td>Routine recall</td>
</tr>
<tr>
<td>Inadequate because endocervical cells are absent with a history of CGIN</td>
<td>Repeat cytology in 3 months, ensuring ectocervical and endocervical sampling</td>
</tr>
<tr>
<td>1st Inadequate</td>
<td>Repeat in 3 months</td>
</tr>
<tr>
<td>2nd Inadequate</td>
<td>Repeat in 3 months</td>
</tr>
<tr>
<td>3rd Inadequate</td>
<td>Refer for colposcopy</td>
</tr>
</tbody>
</table>

Eligible for high-risk HPV (HR-HPV) triage

Borderline nuclear changes* HR-HPV detected
Refer for colposcopy

Borderline nuclear changes* HR-HPV not detected
Routine recall

*Includes BNC in endocervical cells

Not eligible for HR-HPV triage

<table>
<thead>
<tr>
<th>Cytology Report</th>
<th>Patient Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st Borderline</td>
<td>Repeat in 6 months</td>
</tr>
<tr>
<td>2nd Borderline</td>
<td>Repeat in 6 months</td>
</tr>
<tr>
<td>3rd Borderline</td>
<td>Refer for colposcopy</td>
</tr>
<tr>
<td>BNC in endocervical cells or BNC</td>
<td>Refer for colposcopy</td>
</tr>
</tbody>
</table>

Follow-up after borderline changes:

<table>
<thead>
<tr>
<th>Cytology Report</th>
<th>Patient Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st Negative (taken at 6 months)</td>
<td>Repeat in 6 months</td>
</tr>
<tr>
<td>2nd Negative</td>
<td>Repeat in 12 months</td>
</tr>
<tr>
<td>3rd Negative</td>
<td>Routine recall</td>
</tr>
</tbody>
</table>

Note: there should be no more than 3 borderline results in any 10-year period without referral for colposcopy

Eligible for HR-HPV triage

Mild dyskaryosis HR-HPV detected
Refer for colposcopy

Mild dyskaryosis HR-HPV not detected
Routine recall

Not eligible for HR-HPV triage

Mild dyskaryosis
Refer for colposcopy

Moderate dyskaryosis
Refer for colposcopy

Severe dyskaryosis
Refer for colposcopy

Suspected invasive carcinoma
Urgent colposcopy referral

Suspected glandular neoplasia
Urgent colposcopy or gynaecological referral depending on cell type
## Eligibility for HR-HPV Test of Cure

Only women who have had biopsy proven CIN that has also been treated are eligible for Test of Cure. Women are ineligible if the CIN has not been treated. Women are ineligible if they have had biopsy proven CGIN.

### Follow-up after referral to colposcopy for mild dyskaryosis or less (normal colposcopy & no treatment)

<table>
<thead>
<tr>
<th>Follow-up</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st follow-up smear is negative</td>
<td>Return to routine recall</td>
</tr>
<tr>
<td>1st follow-up smear is borderline or mild dyskaryosis</td>
<td>Repeat HR-HPV test and manage as per HPV triage</td>
</tr>
<tr>
<td>1st follow-up smear shows moderate dyskaryosis or worse</td>
<td>Refer back for colposcopy</td>
</tr>
</tbody>
</table>

### Follow-up after treatment of CIN 1

<table>
<thead>
<tr>
<th>Eligible for HR-HPV Test of Cure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative, borderline or mild dyskaryosis &amp; HR-HPV detected</td>
</tr>
<tr>
<td>Negative, borderline or mild dyskaryosis &amp; HR-HPV not detected</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Not eligible for HR-HPV Test of Cure</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st Negative</td>
</tr>
<tr>
<td>2nd Negative</td>
</tr>
<tr>
<td>3rd Negative</td>
</tr>
<tr>
<td>Any abnormal grade on cytology (borderline or worse)</td>
</tr>
</tbody>
</table>

### Follow-up after treatment of CIN 2 and CIN 3

<table>
<thead>
<tr>
<th>Eligible for HR-HPV Test of Cure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative, borderline or mild dyskaryosis &amp; HR-HPV detected</td>
</tr>
<tr>
<td><strong>If colposcopy is satisfactory &amp; normal, return to routine recall</strong>*</td>
</tr>
<tr>
<td><strong>Otherwise, follow-up to be determined by colposcopist</strong></td>
</tr>
<tr>
<td>Negative, borderline or mild dyskaryosis &amp; HR-HPV not detected</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Not eligible for HR-HPV Test of Cure</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st Negative (taken at 6 months)</td>
</tr>
<tr>
<td>2nd Negative</td>
</tr>
<tr>
<td>3rd Negative</td>
</tr>
<tr>
<td>Subsequent negative smears</td>
</tr>
<tr>
<td>Any abnormal grade on cytology (borderline or worse)</td>
</tr>
</tbody>
</table>

### Follow-up after treatment of CGIN

**NOT ELIGIBLE FOR HR-HPV TEST OF CURE**

<table>
<thead>
<tr>
<th>Follow-up</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st Negative (taken at 6 months)</td>
<td>Repeat in 6 months</td>
</tr>
<tr>
<td>2nd Negative</td>
<td>Repeat in 6 months</td>
</tr>
<tr>
<td>Subsequent negative smears</td>
<td>Repeat at 6 monthly intervals for 5 years, then annually for 5 years, then routine recall</td>
</tr>
</tbody>
</table>

### Follow-up after treatment for invasive cervical cancer - women with residual cervix

| Stage 1a1 (without radiotherapy) | Repeat in 6 and 12 months, then annual smears for total of 10 years and then routine recall until 65 years. **Not eligible for Test of Cure.** |

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April 2012

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### 4.4 FOLLOW-UP AFTER TOTAL HYSTERECTOMY

**FOLLOW UP AFTER TOTAL HYSTERECTOMY**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Follow-up Plan</th>
</tr>
</thead>
<tbody>
<tr>
<td>Where there is no CIN or invasive cervical cancer on histology</td>
<td>For women on routine recall. Suggest cancel recall.</td>
</tr>
<tr>
<td></td>
<td>For women not on routine recall.</td>
</tr>
<tr>
<td></td>
<td>Take vault sample at 6 months, then suggest cancel recall if negative.</td>
</tr>
<tr>
<td>For fully excised CIN/CGIN</td>
<td>Suggest cancel recall after 2 subsequent negative cytology tests at 6 months</td>
</tr>
<tr>
<td></td>
<td>and 18 months after surgery.</td>
</tr>
<tr>
<td>For incomplete or uncertain excision of CIN 1</td>
<td>Follow-up vault cytology at 6 and 12 and 24 months.</td>
</tr>
<tr>
<td></td>
<td>Follow-up continues until age 65 or until 2 years after surgery (whichever is</td>
</tr>
<tr>
<td></td>
<td>later)</td>
</tr>
<tr>
<td>For incomplete or uncertain excision of CIN 2, CIN 3 or CGIN</td>
<td>Follow-up vault cytology at 6 and 12 months.</td>
</tr>
<tr>
<td></td>
<td>Follow-up continues until age 65 or until 10 years after surgery (whichever is</td>
</tr>
<tr>
<td></td>
<td>later)</td>
</tr>
<tr>
<td>For incomplete, unspecified, uncertain or unknown excision of CGIN</td>
<td>Follow-up vault cytology at 6 and 12 months, then 6 monthly cytology</td>
</tr>
<tr>
<td></td>
<td>for a total of 5 years. Then annual cytology for a further 5 years. If all are</td>
</tr>
<tr>
<td></td>
<td>negative, return to routine recall.</td>
</tr>
<tr>
<td>For invasive cervical carcinoma (no radiotherapy)</td>
<td>Follow-up to be determined by the gynaecologist or oncologist</td>
</tr>
<tr>
<td>Follow-up after radiotherapy</td>
<td>No need for follow-up vault cytology unless specialist opinion indicates other</td>
</tr>
<tr>
<td>For endometrial/ovarian carcinoma</td>
<td>Suggest cancel recall unless specialist opinion indicates otherwise.</td>
</tr>
</tbody>
</table>

**References**

- NHSCSP Publication No 8, Guidelines for Clinical Practice and Programme Management, December 1997
- ABC 2 - A Regional Guide to Implementation
- NHSCSP Publication No 20, Colposcopy and Programme Management 2004

In July 2005, the North West Regional Quality Assurance Reference Centre issued additional guidance for follow-up cytology after radical hysterectomy and radiotherapy for the treatment of cervical cancer:

- **Women who have undergone radical hysterectomy for cervical cancer:**
  
  *In general, cytological follow-up is not recommended in the assessment of these women but decisions regarding this small group of patients should be determined by the gynaecological oncologist who carries out the procedure*

- **Women who have undergone radiotherapy for the treatment of cervical cancer:**
  
  *Cervical or vaginal vault cytology should not be performed on women who have undergone radiotherapy as part of their treatment*
4.5 POST-HYSTERECTOMY FLOWCHART

Samples to be taken with at colposcopy

If vault cytology is required it should not be taken in primary care. The woman should be referred to colposcopy (North West Cervical Screening Quality Assurance Reference Centre Guidelines, March 2009)

![Flowchart Diagram]

- **Total Hysterectomy (entire cervix removed)**
  - Yes
    - Evidence of cervical disease on histology?
      - No
        - **Part or all of the cervix remains?**
        - Yes
          - Follow-up/recall as for cervical screening
        - No
          - **Evidence of cervical disease on histology?**
            - Yes
              - **Invasive cervical cancer**
            - No
              - **CIN or CGIN**
                - **CIN or CGIN completely excised?**
                  - Yes
                    - Suggest cancel recall after 2 subsequent negative cytology tests at 6 and at 18 months
                  - No
                    - Incomplete, unspecified, uncertain or unknown excision of CIN or CGIN
                      - **Without radiotherapy**
                        - Suggest cancel recall
                      - **With radiotherapy**
                        - Suggest cancel recall
                - Not on routine recall
                  - Vault cytology at 6 months then suggest cancel recall
              - On routine recall
                - Suggest cancel recall

- **Invasive cervical cancer**
  - With radiotherapy
    - Suggest cancel recall
  - Without radiotherapy
    - Vault cytology at 6 & 12 months then annual cytology for 9 years. If all negative, routine recall
IMPORTANT NOTICE

*If the broom head is not present in the vial the sample will be reported as inadequate*

**COLLECT**... an adequate sample from the cervix using a broom-like device. Insert the central bristles of the broom into the endocervical canal deep enough to allow the shorter bristles to fully contact the ectocervix. Push gently, and rotate the broom in a **CLOCKWISE** direction **FIVE TIMES**

**DETACH THE BROOM HEAD**... by placing your thumb against the back of the broom head. Push the broom head from the stem into the SurePath preservative vial

**THE BROOM HEAD MUST BE PRESENT IN THE VIAL**

**CAP THE VIAL**... securely so that it does not leak

For further copies please contact the Manchester Cytology Centre on: 0161 276 5111
www.surepath.com
6 THE CERVICAL CYTOLOGY REQUEST FORM

6.1 ELECTRONIC HMR101 FORM

The Manchester Cytology Centre supports the use of the electronic HMR101 request form that can be downloaded from Open Exeter. Please print off the form and complete it paying particular attention to the provision of relevant clinical history.

Information relating to previous histology biopsies (punch, LLETZ/loop, cone etc) with histology grade and date of biopsy, as well as details of any treatment are ESSENTIAL to ensure correct patient management is given.

The version to use is HMR101 form A5 PDF (2009). This document will be pre-populated with the forename, surname, date of birth and NHS number, as well as the date of the previous test. Also printed on the form is the cervical cytology history for the woman.

If you require any support in accessing the request form on Open Exeter, please contact LASCA:

Head of Contractor & Patient Services
Elaine Jones 01772 221 340

Screening development manager
Pauline Fisher 01772 221 345

HMR101 form A5 PDF (2009)

IF YOU DO NOT HAVE ACCESS TO THE ELECTRONIC FORM THE LABORATORY WILL PROVIDE PAPER REQUEST FORMS AS SHOWN BELOW
### 6.2 CERVICAL CYTOLOGY PAPER REQUEST FORM, MANCHESTER CYTOLOGY CENTRE

*Use this form if you do not have access to Open Exeter forms or electronic requesting.*

<table>
<thead>
<tr>
<th>THE MANCHESTER CYTOLOGY CENTRE</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>CERVICAL CYTOLOGY REQUEST FORM</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>NHS NUMBER</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surname</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Forename(s)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Previous Surname</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date of test</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date of LMP (1st day)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Previous test date</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>PRINT PATIENT INFORMATION CLEARLY TO PREVENT ERRORS</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date of birth</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospital/Clinic number</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lab use only</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient's Address</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Post code</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Specimen Site</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sampling Device</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Condition</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Appearance of cervix</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cervix fully visualised</td>
<td></td>
<td></td>
</tr>
<tr>
<td>360° X5 sweep of cervix</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Haemorrhage</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TOTAL Hysterectomy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CINIC/NMC number (enter in boxes below)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Visit our website: [www.manlab.co.uk](http://www.manlab.co.uk)
# The Cervical Cytology Request Form

Due to the number of years between cervical screening, the woman's surname may change. The previous surname helps us to link previous records to the current test.

<table>
<thead>
<tr>
<th>Field</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td>First name of the patient</td>
</tr>
<tr>
<td>Middle Name</td>
<td>Middle name of the patient if any</td>
</tr>
<tr>
<td>Surname</td>
<td>Last name of the patient</td>
</tr>
<tr>
<td>Reason for Test</td>
<td>Reason for the cervical cytology test (e.g., first test, routine recall, abnormal test)</td>
</tr>
<tr>
<td>Sampling Device</td>
<td>Type of sampling device (e.g., Cervex-Brush® (Broom), Endocervical sampler)</td>
</tr>
<tr>
<td>Condition</td>
<td>Condition of the cervix (e.g., normal, erosions, polyps)</td>
</tr>
<tr>
<td>Appearance of Cervix</td>
<td>Appearance of the cervix (e.g., normal, erosion, polyps)</td>
</tr>
<tr>
<td>Cervix Visualised &amp; Sampled 360 Degrees X5</td>
<td>This is the only indication that the cervix has been adequately sampled.</td>
</tr>
<tr>
<td>Total Hysterectomy</td>
<td>Total hysterectomy means the woman has no cervix</td>
</tr>
</tbody>
</table>

**Clinical Details:**

- **Printed Clearly:** Provide details of previous abnormal cytology, biopsy type, and grade.
- **Date, Type of Biopsy/Treatment, Grade of CIN:**

**Note:**

- The NHS number is the unique patient identifier and should be used on all request forms. This will be a mandatory field for electronic requesting.
- The post code ensures that the correct call/recall agency sends the result letter.
- The name of the GP the patient is registered with must be given to ensure that the test result reaches the correct clinician.
- The sample taker's forename & surname must be printed to correctly identify the person taking the sample. This is a clinical governance requirement.
- The date of test ensures the correct recall date for the next invitation letter from the call/recall agency.
- The date of previous test allows us to match the current test with previous samples from this patient.
- The standard sampler is the Cervex-Brush® (Broom). If only an endocervical sampler is used, the test is technically inadequate.

**Details of Biopsy & Treatment Given Here:**

To ensure correct patient management.

DATE, TYPE OF BIOPSY/TREATMENT, GRADE OF CIN
The flowchart shows the estimated maximum number of days between each step in the patient/sample pathway to achieve a 14-day turnaround from sample collection to receipt of the result letter.

- Woman attends for screening test at GP or clinic: Up to 3 days
- Sample received by cytology lab: 1 day
- Sample processed & LBC slide prepared: 1 day
- Slide screened and reported: 1 day
- Samples requiring HPV testing are sent to virology: Up to 3 days
- HPV results received back in cytology: Same day
- Test result sent to Call/recall & sample taker. GP receives a copy if the GP is not the sample taker: 1 day
- Result: routine screening: Call/recall process result and send letter to woman by 1st class post Mon – Fri. Woman receives result letter: Up to 3 days
- Result: colposcopy advised: Direct referral list sent to call/recall from cytology laboratory. Call/recall process result and send letter to woman by 1st class post Mon – Fri. Woman receives result letter: 1 day
- Result: suspected non-cervical cancer: Laboratory contacts GP or sample taker to advise contacting woman & urgent referral under two week wait rule. Call/recall process result and send letter to woman by 1st class post Mon – Fri. Woman receives result letter and advised to contact GP to discuss the result: Up to 3 days
- Woman receives result letter and COLPOSCOPY appointment is made as per local protocol: 1 day
- Woman attends COLPOSCOPY
- Woman attends GYNAECOLOGY
- GP makes urgent referral to GYNAECOLOGY

KEY
PATIENT
LAB
CALL/RECALL
GP
8  DIRECT REFERRAL TO COLPOSCOPY
8.1  QARC MODEL

**Lab**
- Lab - report test result
- Lab - Direct Referrals

**LaSCA**
- LaSCA - record test results and print result letters for women.
- LaSCA - check result letters produced for all women on Direct referral list
- LaSCA - send Direct Referral letters to women by first class post on the day of receipt of result, advising them to telephone colposcopy clinic to make appointment. Letter also advises on times they can ring colposcopy clinic and to contact GP if they prefer to attend a different clinic

**Colposcopy Clinic**
- Colposcopy Clinic - wait 3 working days, and if no telephone call from woman send her an appointment.
- Colposcopy Clinic - receive telephone calls from women listed on Direct Referral list to book appointments

**GP**

**Patient**
8.2 DIRECT REFERRAL TO COLPOSCOPY

Manchester Cytology Centre (MCC) has well-established systems and several years of experience with direct referral to colposcopy. We operate a protocol for direct referral for all the colposcopy units in Cumbria and Lancashire.

The direct referral policy documents produced by MCC in collaboration with the colposcopy clinics incorporate a protocol for the allocation of appointments based on the cytology result. This information is provided to the colposcopy clinic by the MCC, via the screening agencies and allows efficient use of appointments to ensure women at highest risk get the earliest appointments.

Women who are suspected of having cancer as a result of their cervical cytology test are fast-tracked through the referral process. The laboratory notifies the woman’s GP immediately of any cases reported as possible invasive carcinoma or possible glandular neoplasia. Patient and test result details appear on the direct referral notification from the laboratory. With regard to possible glandular neoplasia, the direct referral notification will indicate if colposcopy or referral for gynaecological assessment has been advised. Hence the clinician is aware of all urgent referral cases.

MCC failsafe procedures ensure that we are notified of any delays in referral as we request urgent notification of the name of the hospital and clinician that the patient has been referred to. The failsafe procedures that surround these urgent referrals ensure that we get confirmation of referral in all cases.

Failsafe procedures for colposcopy

Colposcopy failsafe procedures are triggered if the patient does not make an appointment, or keep an appointment. A second appointment is offered by the colposcopy unit and if the patient DNA’s, she is referred back to her GP or the sample taker.

Laboratory failsafe for colposcopy referrals

All colposcopy referrals are covered by laboratory failsafe procedures and an enquiry letter is generated in the event that a colposcopy outcome is not notified to the laboratory within the predetermined timescales. It is important that sample takers are aware that they still have overall responsibility for ensuring the patient attends colposcopy, even when direct referral is in operation. Any cases where an outcome is not available are notified to the screening lead at the PCT and the Hospital Based Programme Co-ordinator at the Manchester Cytology Centre.

Laboratory failsafe

The laboratory has a dedicated failsafe manager who liaises with the colposcopy clinics and the histology departments to ensure that all relevant information is received by the Manchester Cytology Centre to complete the outcome enquiries for all women referred for colposcopy or gynaecological investigation.

Failsafe manager/Office manager

Wendy Mitchell 0161 276 5123
8.3 REFERRAL OF SUSPECTED CANCER CASES

**CYTOLOGY LABORATORY REPORTS THE SCREENING TEST AS SUSPICIOUS OF CANCER AND RECOMMENDS URGENT REFERRAL FOR FURTHER INVESTIGATION**

- **SUSPECTED INVASIVE SQUAMOUS CARCINOMA**
  - COLPOSCOPY IS ADVISED (CODE 5)
  - Same day

- **SUSPECTED CERVICAL GLANDULAR NEOPLASIA**
  - COLPOSCOPY IS ADVISED (CODE 6)
  - Same day

- **SUSPECTED NON-CERVICAL GLANDULAR NEOPLASIA**
  - GYNAECOLOGICAL ASSESSMENT ADVISED (CODE 6)
  - Same day

**Result: URGENT COLPOSCOPY ADVISED**

- Laboratory contacts GP or sample taker to discuss cytology result and the need for an urgent appointment under the 2 week rule
- Laboratory advises GP to contact the patient urgently to discuss the cytology result
- Laboratory explains that direct referral applies and a colposcopy appointment will be arranged

- **Same day**
  - Direct referral list sent to call/recall from cytology laboratory

**Result: URGENT GYNAECOLOGICAL ASSESSMENT ADVISED**

- Laboratory contacts GP or sample taker to discuss cytology result and the need for an urgent appointment under the 2 week rule
- Laboratory advises GP to contact the patient urgently to discuss the cytology result
- Laboratory informs GP or sample taker that **DIRECT REFERRAL IS NOT IN OPERATION** for this patient & the GP must make an urgent appointment for gynaecology

- **Same day**
  - Call/recall process result and send letter to woman by 1st class post Monday – Friday

**KEY**

- LAB
- CALL/RECALL
- PATIENT
- GP

**CALL/RECALL**

- Woman receives result letter which advises her to contact her GP to discuss the result
- Call/recall notify colposcopy unit as per direct referral protocol

**GP**

- Makes urgent referral to COLPOSCOPY

- Woman attends COLPOSCOPY

**GYNÆCOLOGY**

- Woman attends GYNÆCOLOGY

**Women**

- Same day
- Call/recall process result and send letter to woman by 1st class post Monday – Friday
- Woman receives result letter which advises her to contact her GP to discuss the result
- GP makes urgent referral to GYNÆCOLOGY
- Woman attends GYNÆCOLOGY
9 ZERO TOLERANCE AT SPECIMEN RECEPTION

A Zero Tolerance policy for discrepancies found at sample reception was implemented on 1st December 2010. This will ensure that:

1. The correct test result is issued to the correct women who attends for cervical screening
2. There are no concerns about the identity of the woman from whom the sample has been collected
3. There is a reduction in the number of phone calls and returned samples currently occurring as a direct result of errors made by the sample taker
4. The laboratory is able to comply with the 14-day turn around standard for all samples

ESSENTIAL PATIENT DATA

- Surname
- Forename
- Date of birth
- NHS number

At least 3 of the 4 patient data items must be provided – this makes allowances for family planning clinics who may not have access to the NHS number.

<table>
<thead>
<tr>
<th>Completing the cervical cytology request form</th>
<th>Labelling the vial</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surname</td>
<td>Surname</td>
</tr>
<tr>
<td>Full forename</td>
<td>Forename or initial</td>
</tr>
<tr>
<td>Date of birth</td>
<td>Date of birth</td>
</tr>
<tr>
<td>NHS number</td>
<td>NHS number</td>
</tr>
</tbody>
</table>

Errors in request form and sample vial labelling are categorised into minor or major discrepancies as these are handled differently within the laboratory.

9.1 MINOR DISCREPANCIES

Minor discrepancies will be accepted.

1. Spelling error in patient name
2. Transposition of digits within the date of birth or NHS number
3. Specimen without form, or vice versa – contact the sample taker to seek an explanation following local protocol and SOP
4. Request form without sender (source) details

Spelling error or transposed digit - The laboratory will check Open Exeter to confirm the correct patient data. Open Exeter is regarded as the “gold standard”.

Specimen without form or vice versa – If only the vial has been received; the office will call the GP to check where the sample was taken. If this can be confirmed then a request form should be sent or faxed to the laboratory and the sample processed as normal. The appropriate zero tolerance audit code is entered on the patient record. If the GP does not know where the sample was taken, retain the sample for 4 weeks then discard the vial and send a ‘sample discarded’ letter to GP and request that he discusses the matter with the woman.

Specimen with no source details – The office call the GP to check where the sample was taken. If this is confirmed then the sample is processed as normal and the zero tolerance audit code is recorded in the patient record. If the GP does not know where the sample was taken, retain the sample for 4 weeks then discard the vial and send a ‘sample discarded’ letter to GP and request that he discusses the matter with the woman.
9.2 MAJOR DISCREPANCIES

Major discrepancies constitute a serious risk to an individual

1. Absence of two or more essential data items
2. Mismatch between the vial and the form
3. Two or more minor discrepancies
4. Unlabelled vial

Action: The appropriate action is determined by the type of discrepancy as follows;

1. Absence of essential data – correct patient cannot be identified; dispose of the sample and send a letter to the sample taker*
2. Mismatch between the vial and the form – if correct patient can be identified, allocate a laboratory number and report as inadequate.
3. Two or more minor discrepancies - if correct patient can be identified allocate a laboratory number and report as inadequate. If correct patient cannot be identified; dispose of the sample and send a letter to the sample taker*
4. Unlabelled vial – dispose of the sample and send a letter to the sample taker*

*Letters to the sample taker - A letter will be sent to the sample taker describing the problem and requesting that they contact the woman and request a repeat test.

Designated individual
The designated individual who deals with the major discrepancies and decides on the action to be taken must be a senior biomedical scientist

Auditing discrepancies
Regular audit of discrepant cases should be carried out by the laboratory and a report sent to the PCT and Public Health leads for cervical screening via the commissioners of the cytology service.

DISCREPANCY CODES USED BY THE LABORATORY

<table>
<thead>
<tr>
<th>Code</th>
<th>Type of discrepancy</th>
<th>Letter sent to sample taker OR Code is recorded:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Z1</td>
<td>Minor discrepancy: spelling</td>
<td>Code is recorded in laboratory notes</td>
</tr>
<tr>
<td>Z2</td>
<td>Minor discrepancy: DOB</td>
<td>Code is recorded in laboratory notes</td>
</tr>
<tr>
<td>Z3</td>
<td>Minor discrepancy: NHS number</td>
<td>Code is recorded in laboratory notes</td>
</tr>
<tr>
<td>Z4</td>
<td>Minor discrepancy: missing vial/form</td>
<td>Code is recorded in laboratory notes</td>
</tr>
<tr>
<td>ZF</td>
<td>Minor discrepancy: no sender details</td>
<td>Code is recorded in the report or sample is rejected &amp; letter sent to the GP</td>
</tr>
<tr>
<td>ZA</td>
<td>Major discrepancy: missing essential data</td>
<td>Rejection letter sent</td>
</tr>
<tr>
<td>ZB</td>
<td>Major discrepancy: mismatch vial/form. Include NHS number for a different patient</td>
<td>Rejection letter sent</td>
</tr>
<tr>
<td>ZC</td>
<td>Major discrepancy: 2 or more minor errors</td>
<td>Rejection letter sent or, code is recorded in report</td>
</tr>
<tr>
<td>ZD</td>
<td>Major discrepancy: unlabelled vial</td>
<td>Code is recorded in report</td>
</tr>
<tr>
<td>ZE</td>
<td>Major discrepancy: under 25, new info received &amp; sample processed</td>
<td>Code is recorded in report</td>
</tr>
<tr>
<td>ZG</td>
<td>Major discrepancy: sample unsuitable for processing</td>
<td>Rejection letter sent</td>
</tr>
<tr>
<td>RPL</td>
<td>SAMPLE RETAINED IN PREP LAB</td>
<td>Record code as a request flag</td>
</tr>
</tbody>
</table>
## 9.3 LABORATORY ACTIONS IN CASE OF A DISCREPANCY

<table>
<thead>
<tr>
<th>MINOR DISCREPANCIES</th>
<th>SAMPLE RECEPTION</th>
<th>OFFICE</th>
<th>REPORTER</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SPELLING ERROR</strong></td>
<td>In the margin of the request form, make a note of the Z code &amp; spelling on the vial</td>
<td>Check Open Exeter for the correct details. Allocate the request as usual</td>
<td>Record the Z code in request notes &amp; describe the minor discrepancy in the report</td>
</tr>
<tr>
<td><strong>TRANSPOSED DIGIT</strong> - Date of birth</td>
<td>In the margin of the request form, make a note of the Z code &amp; date of birth or the NHS number given on the vial</td>
<td>Check Open Exeter for the correct details. Allocate the request as usual</td>
<td>Record the Z code in request notes &amp; describe the minor discrepancy in the report</td>
</tr>
<tr>
<td><strong>VIAL WITHOUT FORM</strong> or <strong>FORM WITHOUT VIAL</strong></td>
<td>Keep the vial or form in the sample reception area for maximum of one month.</td>
<td>No action</td>
<td>Record the Z code in request notes &amp; describe the reason for delay in the report</td>
</tr>
<tr>
<td><strong>NO SOURCE DETAILS</strong></td>
<td>Write the Z code for ‘no source details’ on the form.</td>
<td>Check Open Exeter for GP details. Contact GP to ascertain where sample was collected. Allocate the request as usual</td>
<td>If source known, record the Z code in request notes &amp; the report</td>
</tr>
<tr>
<td></td>
<td>Follow office protocol then; after 4 weeks – discard of vial and send letter to GP</td>
<td>If source unknown, record phone call in patient incident and return to reception to retain for 4 wks</td>
<td></td>
</tr>
</tbody>
</table>

---

April 2012  
[CYT GEN 029 Version 004]  
25
## MAJOR DISCREPANCIES

<table>
<thead>
<tr>
<th>ESSENTIAL DATA IS MISSING</th>
<th>SAMPLE RECEPTION</th>
<th>OFFICE</th>
<th>REPORTER</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Surname</td>
<td>Pass the case to the designated individual for checking</td>
<td>Make photocopy of request form for audit</td>
<td>(i) Use the Z code in the report. Code the sample as inadequate and request a repeat test in 3 months</td>
</tr>
<tr>
<td>- Forename</td>
<td>Designated individual to decide:</td>
<td>(i) Allocate a laboratory number and pass to designated individual for reporting</td>
<td></td>
</tr>
<tr>
<td>- DOB</td>
<td>(i) If patient can be identified: Accept request and record as inadequate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- NHS No.</td>
<td>Record the Z code on the margin of the form &amp; a brief description of the error. DO NOT PROCESS THE SAMPLE</td>
<td>(ii) Make photocopy of request form. Send standard letter and photocopy of request form to sample taker</td>
<td></td>
</tr>
</tbody>
</table>

| MISMATCH BETWEEN VIAL & FORM | | |
|-----------------------------| |

| TWO OR MORE MINOR DISCREPANCIES | | |
| E.g. spelling mistake and transposed digit in DOB &/or NHS No. | | |

| UNLABELLED VIAL | | |
|-----------------| | |

- Record reason for disposal on request form and keep for audit | | |
9.4 ‘OUT OF PROGRAMME’ AND INAPPROPRIATE SAMPLES

As well as rejecting discrepant samples, from 1st December 2010, the laboratory no longer accept samples that have been taken outwith the NHS cervical screening programme.

Out of programme samples

Out of programme samples are those taken from women outwith the screening age range i.e. under 24 years and 4 months, unless on follow-up for a previous abnormality or if invited for screening by the Welsh or Scottish screening programmes.

Inappropriate samples

Inappropriate samples are those taken from women with an abnormal looking cervix. If there is a clinical suspicion of cervical disease, cytology is not the appropriate test to investigate the symptoms. The woman should be referred urgently to colposcopy for investigation under the two-week-wait rule.

Young women with abnormal bleeding

Women below the screening age range who present with symptoms such as postcoital bleeding or intermenstrual bleeding should be managed as per the latest recommendations in “Clinical Practice Guidance for the Assessment of Young Women aged 20-24 with Abnormal Vaginal Bleeding”. Cervical cytology does not form part of this management pathway.

Cervical samples should be avoided, but will be accepted and subject to audit if they are taken in the following circumstances:

- Women who present earlier than should since last test
- Women who present for annual cytology with a previous HR-HPV negative virology result
- Women who present for annual cytology who have been assessed at colposcopy as colposcopy NAD, biopsy NAD and/or cytology negative at 6 month follow-up
- Women who have had double negative Test of Cure i.e. cytology negative/HR-HPV negative
10 SENTINEL SITE IMPLEMENTATION PROJECT – HPV TESTING

10.1 SUMMARY

Cervical Cancer
- Over 2,200 women were diagnosed with cervical cancer in England in 2004
- Cervical cancer causes over 1,000 deaths each year in the UK
- The twelfth most common cancer in women in the UK and the second most common cancer in women younger than 35

The Cervical Screening Programme
- Aims to reduce the number of women who develop invasive cervical cancer and the number of women who die from it
- Saves approximately 4,500 lives per year in England
- Prevents up to 3,900 cases of cervical cancer per year in the UK
- Screens almost 3.5 million women in England each year
- Eligible population: all women between the ages of 25 and 64
- Screening is offered every 3 or 5 years depending on age

HPV
- There are approximately 100 subtypes of HPV (human papilloma virus)
- Certain subtypes (high risk) are known to cause cervical cancer e.g. types 16 and 18
- HPV infection is common and in most cases transient
- Infection persists in approximately 20 to 30% of women putting them at risk of cervical intraepithelial neoplasia (CIN) and in some cases cervical cancer

HPV Test
- Performed on the sample of cells taken at the screening appointment
- Results sent with the cytology report, including management recommendations

HPV Triage
- Women with mild or borderline test results who have no evidence of high risk HPV infection are very unlikely to develop cervical cancer
- HPV testing women with mild or borderline test results can speed up referral to colposcopy and avoid referral when HPV is not found

HPV Test of Cure
- Follow up of women treated for CIN currently involves annual screening for 10 years
- Women found to be HPV negative at six months following treatment and who also have no abnormal cells found in their sample can return to a three year recall period

Sentinel Sites
- Six cytology laboratories introducing HPV triage of borderline and mild test results and HPV test of cure
- Building upon experience gained in previous NHS pilot studies

Key issues for women to understand
- HPV is a very common infection amongst people who have ever been sexually active
- The virus is asymptomatic
- The infection may have been present and undetected for many years
- A male partner may have acquired the infection many years ago and passed it on unwittingly
- A positive HPV test should not imply infidelity or promiscuity by either partner
10.2 HPV TRIAGE OF BORDERLINE & MILD DYSKARYOSIS & HPV TEST OF CURE

INFORMATION FOR SAMPLE TAKERS

This information is intended to inform sample takers and to help them advise and counsel women who are having an HPV test as part of the sentinel sites implementation project. It is important to note that 95% of screened women will not require an HPV test.

What is Human Papilloma Virus (HPV)?

There are around 100 subtypes of HPV. Most do not cause significant disease in humans. However, some subtypes (most notably type 16 and 18) have been confirmed as agents causing cervical cancer. These so called ‘high risk’ types do not cause symptoms such as visible genital warts (these are caused by types 6 and 11).

Almost all cervical cancers contain HPV DNA. Looking at cases of CIN, we find the number of cases with high risk HPV infection increases with increasing grade of CIN.

From this evidence we can say that women with no evidence of infection with high risk HPV are extremely unlikely to develop cervical cancer in the short to medium term. Even if they do have abnormal cytology, it is unlikely to reflect CIN2 or 3 and most will be mild abnormalities which regress without treatment.

Infection with high risk HPV is common, especially in young women (under 35 years old). In most cases the infection is transient. However, for reasons that are not yet known, around 20 to 30% of women do not clear the infection. It is this group who are at most risk of CIN, some of whom would eventually develop cervical cancer in the absence of screening.

How do women get the virus?

It is anticipated that this will be one of the main concerns for women. As far as we know, most cases are sexually transmitted; there are two important considerations:

- The infection is asymptomatic, so may have been present and undetected for many years. It may therefore have nothing to do with their current relationship
- A male partner may have acquired an asymptomatic infection with no visible lesions many years ago and passed it on unwittingly

Women can therefore be reassured that a positive test result for high risk HPV types should not imply infidelity or promiscuity by either partner.

Why are we using HPV testing?

The aim of HPV testing is to speed up referral to colposcopy, avoid referral for those who do not need it, and allow treated women to proceed to a three year recall period after just six months.

It is well known that some women with CIN3 have tests that show only low grade abnormalities. At the moment persistent borderline or mild abnormalities trigger referral to colposcopy, but this takes time. Returning women to routine screening can take two years after a single abnormal test result.

HPV testing aims to identify those women with cytology tests showing borderline changes or mild dyskaryosis who may have significant disease and refer them to colposcopy immediately. Women who are HPV negative are very unlikely to have significant disease, they can be reassured, avoid the anxiety of repeat screening tests and possible colposcopy referral before going back to routine recall.

The follow up of treated women currently involves annual screening for 10 years prior to them returning to routine recall. HPV testing at six months following treatment will allow HPV negative women with normal cytology to proceed to a three year recall period.
**How is the test done?**
The test is performed on the sample taken for the cytology test, so there is no need for the woman to be recalled for a second test.

Samples will be processed at the laboratory and all results will be issued as part of a single cytology report. As at present, each cytology report will have a result and a management recommendation. Where an HPV result is available, it will be included in the report and taken account of in the management recommendation.

**How will HPV testing affect women?**
Women whose cytology test shows moderate dyskaryosis or worse will not have an HPV test and will be referred to colposcopy as before.

Women whose cytology test result is negative will not have an HPV test and will be advised to return to routine recall or early repeat in view of previous history as at present.

Women whose cytology test shows borderline change or mild dyskaryosis will have an HPV test. If this test is positive they will be referred to colposcopy. If negative they will return to routine 3 or 5 year recall, depending on age.

All women who have been treated for CIN regardless of excision status will have an HPV and cytology test at six months following treatment. Women who are HPV negative with normal cytology will proceed to a three year recall period. Women who are either HPV positive or have abnormal cytology will be referred back to colposcopy.

**Does the HPV test affect colposcopy?**
The HPV test only considers which women will go to colposcopy, which can go back to routine screening, or which can proceed to a three year recall period following treatment. At colposcopy the women will be managed according to the colposcopist’s opinion on examination of the cervix as happens now.
10.3 HPV TESTING - INFORMATION FOR WOMEN

What is HPV?
HPV stands for Human Papilloma Virus.

HPV is a very common infection of the cervix. Most women get the virus at some time in their life. In most cases it does not need treatment and the body will clear it on its own.

There are lots of types of HPV and most are harmless. Some types can cause cervical abnormalities. These types are known as 'high risk' HPV types. If left these abnormalities can go on to develop into cervical cancer. However, cervical abnormalities often clear up when the virus clears. In some women the virus persists and these women are at greater risk of developing cervical abnormalities (CIN) which may require treatment.

How do people get HPV?
HPV is a very common infection amongst people who have ever been sexually active. HPV is easily transmitted during sex between both men and women and partners of the same sex. As the virus shows no symptoms it is therefore possible that:

- Someone may have had the infection for many years without knowing about it.
- A partner may have been infected many years ago and again not know.

Why might I be tested for HPV?

HPV testing in women with borderline or mild dyskaryosis
HPV tests will be carried out on samples from women whose screening result shows mild abnormalities called borderline or mild dyskaryosis.

Women with borderline or mild dyskaryosis have only a 15-20% chance of having a significant abnormality that needs treatment. The HPV test is important because it is effective at identifying which women may need treatment.

If HPV is found the woman will be invited to go for colposcopy. Colposcopy is a way of looking closely at the cervix to see whether any treatment is needed. If treatment is needed the woman will usually be seen in an outpatients clinic which means that they will not need to stay overnight.

HPV testing in women who have received treatment for CIN
HPV tests will be carried out on samples from women whose screening result is normal six months after having treatment for CIN. If HPV is not found these women do not need to return for further screening until three years later.

If HPV is found or the screening result is abnormal then these women will be invited to go for colposcopy again and will be followed up in the usual way.

How is the HPV test done?
The test is done using the sample of cells taken during the screening test so there is no need for the woman to come back for a second test. Samples are tested in a laboratory and results are sent to the woman in writing.

Where can I find out more information?
If you would like more information about HPV testing or anything else mentioned in this factsheet you can talk to your practice nurse, or visit the NHS Cancer Screening Programmes website at www.cancerscreening.nhs.uk
10.4 PATIENT MANAGEMENT FOLLOWING HPV TESTING

For samples taken in primary care

<table>
<thead>
<tr>
<th>Cytology result</th>
<th>Current management</th>
<th>HPV triage management</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>HPV -ve</td>
</tr>
<tr>
<td>Borderline</td>
<td>Repeat in 6 months</td>
<td>Routine recall</td>
</tr>
<tr>
<td>Mild dyskaryosis</td>
<td>Colposcopy referral</td>
<td>Colposcopy referral</td>
</tr>
<tr>
<td>Negative, borderline or mild dyskaryosis</td>
<td><strong>Negative</strong>: annual cytology for up to 10 years depending on grade of CIN</td>
<td></td>
</tr>
<tr>
<td>Women on cytology surveillance after treated CIN (completely or incompletely excised)</td>
<td>Borderline or mild dyskaryosis: refer back to colposcopy</td>
<td></td>
</tr>
<tr>
<td>Women with CGIN or cervical cancer are excluded</td>
<td>Routine recall</td>
<td>Colposcopy referral</td>
</tr>
</tbody>
</table>

Follow-up after treatment for biopsy proven CIN

All women who have biopsy proven CIN which has been treated are eligible for a ‘Test of Cure’ HR-HPV test if any of their post-treatment follow-up samples is negative, borderline or mild dyskaryosis on cytology.

If the HR-HPV test shows high-risk HPV is **not detected**, then a repeat cytology test is taken at 36 months. If this cytology test is also negative the woman is discharged back to routine recall.

Cytology surveillance is no longer required for women who test ‘double negative’ after treatment.

Inclusion of women on long term follow-up after treatment

From 1st April 2011, the HR-HPV testing protocol has been updated to include all women who are currently on cytology surveillance in primary care after treatment for CIN. These women are now eligible for an HR-HPV test if their next cytology sample is negative or shows borderline nuclear changes or mild dyskaryosis as long as there is no history of moderate dyskaryosis or worse on any follow-up sample taken between their treatment for CIN and the current cytology test. Their sample will be sent for HR-HPV testing and if they are HR-HPV negative they can be screened again in 36 months before a return to routine recall.
10.5 PATIENT MANAGEMENT FLOWCHART– HPV TRIAGE & HPV TEST OF CURE
HPV triage and Test of Cure protocol for women aged from 24 years, 4 months up to 64 years

**PRIMARY CARE: CYTOMETRY**

**TRIAGE**: all borderline changes & mild dyskaryosis from women on recall (and early repeats for untreated CIN)
**TEST OF CURE**: Negative, borderline or mild dyskaryosis & on cytology surveillance after treated CIN (1)(7)

- HPV negative
- HPV test failed or insufficient cells in sample (2)
- HPV positive

**COLPOSCOPY** (cytology test at colposcopy not required)

- Colposcopy normal
  - No biopsy OR biopsy no CIN(3)(5)
- Biopsy = CGIN
- Biopsy = Invasive ca.
- Biopsy = CIN 1
- Biopsy = CIN2
- Biopsy = CIN3

- Not eligible for Test of Cure

**TREATMENT**

- No treatment

- Cytology at 12 months (with or without colposcopy, depending on local practice) (4)

- Follow-up as per national protocols

- HPV negative
- HPV failed
- HPV Positive

**COLPOSCOPY**: FOLLOW-UP CYTOMETRY

- Cytology Normal or low-grade (8) TEST OF CURE
- Cytology High-grade (9)

- HPV negative
- HPV failed
- HPV Positive

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(1) EXCLUDES previous CGIN & microinvasive/invasive cervical cancer
(2) If sample unreliable/inaequate for HPV test, refer mild & recall BNC for 6 month repeat cytology. At repeat cytology, HPV test if Neg/BNC/Mild. If HPV negative return to routine recall, refer if HPV positive. Refer moderate or worse cytology
(3) Includes HPV, and basal abnormality of undetermined significance falling short of CIN
(4) Untreated C1N should be managed as per untreated CIN1 following BNC or mild dyskaryosis & are eligible for HPV testing if patient referred back to community cytology screening
(5) WOMEN REFERRED DUE TO BORDERLINE/MILD CYTOMETRY OR NORMAL CYTOMETRY/HPV POSITIVE, WHO THEN HAVE A SATISFACTORY AND NEGATIVE COLPOSCOPY CAN BE RECALLED IN THREE YEARS
(6) Unless immunosuppressed and on an annual cytology
(7) With no high-grade cytology between treatment and this test
(8) Low-grade = borderline nuclear changes or mild dyskaryosis. (9) High-grade = moderate dyskaryosis or worse
10.6 FREQUENTLY ASKED QUESTIONS:

Q What is Human Papilloma Virus (HPV)?
A This is a small virus which comprises about 100 types, some of which cause non-genital lesions such as common warts and some of which cause genital lesions, including genital warts. Those that cause genital warts (type 6) are not linked with cervical cancer but around 20 or so are, particularly types 16 and 18, and it is these that we are testing for. The virus replicates within the epithelium or mucosa of the cervix and sheds in exfoliated cells in cytology samples where it can be detected.

Q Why test for HPV?
A It is now very clear that when women have low grade abnormalities, only the HPV positive lesions are likely to have CIN. This means HPV negative women need not be referred to colposcopy and HPV positive women should be referred without the need for repeat cytology follow-up, which delays the final diagnosis.

Q How do we test for HPV?
A HPV is tested for by probing the same cervical sample used in cytology for viral DNA. This means that when a borderline or mild dyskaryosis is reported, the residual material left after the cytology slides have been prepared is used to test for HPV. The remaining cervical cells are processed such that any viral DNA in the cells can be detected.

Q How is HPV acquired?
A It is generally accepted that cervical HPV infection is acquired through sexual contact. The epidemiology of cervical cancer has for many years indicated increased risk in women with multiple partners and early onset of sexual activity. This fits with a sexually transmitted agent being involved in the process of cervical carcinogenesis.

It is common for women to state that their partner is their only ever sexual partner and that their partner states that the woman is his only sexual partner. Theoretically, if two virgins form a faithful sexual relationship there ought not to be the opportunity to acquire HPV. Yet we know that women in some such relationships test HPV positive. When questioned about this, it is impossible to reconcile. HPV infections can persist for many years and it is not possible to be sure about when the infection took place or what is the true “provenance” of the infection. Certainly the commonest HPV types of relevance in cervical cancer are usually symptomless in both partners.

This can be a difficult area but usually a gentle explanation of the facts as we understand them suffices. Do not be tempted to say that if the woman has only had a single sexual partner that this means her acquiring cervical HPV is a sign of infidelity.

Q How long does HPV infection last?
A HPV infection of the cervix usually occurs earlier in the sexual lives of women. We know this because HPV positive rates are around 50% in women around the age of 20. In the majority of women the infection clears usually within a year and indeed protective antibodies may develop to prevent future infection by the same type. This does not always occur however, and it is not uncommon to acquire new HPV infections of a different type. In some women, probably around 20 to 30%, the infection persists, and it may do so for years. The longer the infection persists the greater the risk of subsequent abnormality.

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

Q Can HPV infection be treated?
A There is no currently effective treatment for HPV infection, but as stated the immune system clears most infections.
**Q What role will HPV vaccines have?**

**A** The two vaccines which have been developed by international pharmaceutical companies have been reported to be very effective at preventing infection with the two most common virus types which cause cervical cancer. But these types are only responsible for about 75% of cases. The government has announced the introduction of an HPV immunisation programme to routinely vaccinate girls aged 12 to 13 years from September 2008. There will also be a two year catch up campaign from autumn 2009 for girls up to 18 years. Vaccines are ineffective in women who are already infected, so screening will still be needed in the future.