Directorate of Laboratory Medicine

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

2016

Accredited Medical Laboratory
Reference No. 0513

Compiled by Janet A Parker, Hospital Based Programme Co-ordinator, Manchester Cytology Centre
SUMMARY OF CHANGES

1. SERVICE PROVISION:
From 1st April 2016 Central Manchester University Hospitals NHS Foundation Trust (CMFT) will be the provider for cervical screening laboratory services throughout Greater Manchester, Lancashire and Cumbria.

2. ELECTRONIC REQUESTING OF CERVICAL SCREENING TESTS:
Electronic requesting for cervical screening tests will commence roll-out by 1st April 2016. This will require the sample taker to use their NMC or GMC number as a username for requesting cervical screening tests. Samples submitted via paper request form without a valid GMC/NMC number will be reported to the Screening & Immunisation Team as part of the laboratories sample acceptance policy.

3. CERVICAL SAMPLE TAKER DATABASE:
From 1st April 2016 the laboratory will take on the responsibility for managing the new Cervical Sample Taker Database (CSTD) for the local cervical screening programme. This has replaced the sample taker register that was previously held by the regional QA service and has been enhanced to also record details of sample taker training, both novice and update training. We have received notifications from the Screening and Immunisation teams throughout Greater Manchester, Lancashire and Cumbria of all sample takers working in GP practices and CASH services. This information has been used to populate the CSTD with sample taker name, GMC/NMC code, GP practice and details of sample taker training.

The new CSTD will allow you to view your inadequate rates and also give details of samples that have been rejected under the laboratory sample acceptance policy. All sample takers will be contacted prior to implementation with more information about the functionality of the CSTD and how to register to use the system.

4. DIRECT REFERRAL OF SUSPECTED CANCER CASES:
Women with suspected cervical cancer on cytology will be directly referred to colposcopy from 1st April 2016. This change only applies to Lancashire and Cumbria practices. This procedure is already in place for Greater Manchester practices.

5. SAMPLE ACCEPTANCE POLICY:
A recent audit has again shown that just under half of the samples rejected at specimen reception were unlabelled vials. Please check that all vials are labelled and match the request form before despatch to the laboratory.

6. EXPIRY DATES ON SAMPLE VIALS:
Please always check the expiry dates on LBC vials as the laboratory cannot be held responsible if an out-of-date vial is used. This is because the printed labels containing patient demographics may obscure the expiry date.
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1 CONTACT DETAILS

The Manchester Cytology Centre is one of six national pilot sites working with national office to introduce HPV testing as a primary screening test within the NHS Cervical Screening Programme. The department, which accepts SurePath LBC samples, is affiliated to the North West Cytology Training Centre, both are situated within the Clinical Sciences Centre at Manchester Royal Infirmary.

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 Holbrook, Clinical Lead & Director of the North West Cytology Training Centre
Tel: 0161 276 6475
Fax: 0161 276 5113

Dr D N Rana
0161 276 5108

Consultant Biomedical Scientists
Mrs Viv Beavers
0161 701 0228
Mr Peter Heptinstall
0161 276 5118
Mr Paul Hermansen
0161 276 5103
Ms Janet A Parker
0161 701 0228

Cellular Pathology Manager
Sally Wood
0161 276 6138

Lead Biomedical Scientist
Adanna Ehirim
0161 276 5119

Hospital Based Programme Co-ordinator (Cytology)
Janet A Parker
0161 701 0228

Assistant Hospital Based Programme Co-ordinator (Cytology)
Viv Beavers
0161 701 0228

Failsafe manager/Office manager
Wendy Mitchell
0161 276 5123

Pathway Manager
Antonia Tweed
0161 276 5111
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 Holbrook, Clinical Lead, Manchester Cytology Centre

0161 276 5099

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

Cytology lead

Adanna Ehirim, lead BMS in cytology 0161 276 5119

Pathway Manager & Screening Room Manager

Antonia Tweed, Senior BMS 0161 276 5111
2 MANCHESTER CYTOLOGY CENTRE

2.1 QUALITY STATEMENT

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

The department participates in the regional gynaecological and technical EQA schemes and the performance of all screening staff is assessed monthly and reported to quarterly to SQAS 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 annual feedback from users. If you do have a complaint, concern or compliment about any aspect of the service, this should be addressed to the lead biomedical scientist on 0161 276 5119 or the cellular pathology manager on 0161 276 6138.

Gynaecological queries
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

Cervical samples should only be collected by trained sample takers. Details of update training courses are available from the local Screening and Immunisation team.

Instruction sheets on sample collection are available from the laboratory.

Posting LBC vials

Occasionally it may be necessary to post a sample vial to the laboratory. If this is the case then please be aware that:

Royal Mail will only transport UN3373 diagnostic specimens if they are packaged following packaging instruction P650, and,

- Sent by first class post or special delivery to an inland address only
- The packet is marked with the sender's name, telephone number and address

LBC kits

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

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 general enquiries 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 their expiry date as printed labels containing patient details often obscure the expiry date once attached to the vial.
2.3 REQUEST FORMS AND VIALS

Request form: The request form should be completed in full with all information PRINTED legibly or a printed label containing patient demographics can be used. 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.

Electronic requesting: cervical screening tests can be requested electronically via a system called ICE allowing the sample taker to provide all the relevant mandatory information.

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

PIN codes: The laboratory uses the GMC and NMC numbers as the unique sample taker identifier. This information MUST be provided. The sample taker name should also be printed clearly. When electronic requesting has been introduced, the GMC or NMC code will be a mandatory field. The laboratory will check that the sample taker is validated to take samples i.e. is up-to-date with their training requirements.

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

2.4 VAGINAL VAULT SAMPLES

Women who need vaginal vault cytology following surgery are no longer included in the NHS Cervical Screening Programme. The latest national recommendation supported by the North West SQAS is that vault cytology should be performed at colposcopy and therefore women requiring this should be referred to colposcopy or remain at colposcopy until all necessary vault samples have been taken.

The laboratory will reject any vault samples taken in primary care as part of the sample acceptance policy.

Cervical screening reports: 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). Primary Care Support Services (Preston) also receive a copy of the report to update the cervical screening history on the Exeter system.

The laboratory issues electronic reports to GPs/sample takers and electronic reports to the screening agencies. By the end of 2016 we intend to phase out paper copy reports for all but CASH services.

Urgent referrals for further investigation

Any test reported as suspected invasive carcinoma or suspected cervical glandular neoplasia requires urgent referral to colposcopy via the direct referral process. The laboratory will contact the sample taker by phone to discuss the result. A fail-safe system is in place to ensure that the report has been received prior to the patient appearing on the direct referral notification to PCSS (Preston) and colposcopy.

14-day turnaround

The laboratory aims to report at least 98% of tests within 7 days from receipt of the sample. This in turn supports the 14-day turnaround standard.
Audit

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

Feedback on inadequate cytology reports and rejected samples

The laboratory is now responsible for giving feedback to practices on the inadequate rates for the practice and their individual sample takers as well as the number of samples rejected under the sample acceptance policy. Reports will be issued at 6-monthly intervals.

3 RESEARCH ACTIVITIES

3.1 HPV PRIMARY SCREENING PROJECT

The Manchester Cytology Centre is one of the six national sentinel sites currently working with the national office of the NHSCSP to introduce HPV testing as the primary screening test within the cervical screening programme. Approximately 40% of the laboratory workload from the Cumbria and Lancashire area has been converted to HPV primary screening with the remainder using traditional cytology primary screening.

The Hospital Based Programme Co-ordinator sends data at regular intervals to the national team to inform progress within the pilot study.

3.2 CINTEC PLUS

The department is one of three sites using CINtec PLUS Cytology® which is an advanced combination of biomarkers that can help identify women who are HPV positive with borderline or low-grade cytological abnormalities that may have underlying high-grade disease.

4 CERVICAL SCREENING AND PATIENT MANAGEMENT PROTOCO LS

4.1 INDEPENDENT SECTOR CERVICAL SCREENING SAMPLES

Primary care 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 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 for her routine test and should attend for this.

However, please be aware that there should be a 3 month interval between any private sample and one taken as part of the NHSCSP to ensure an adequate sample has been taken.
4.2 INAPPROPRIATE AND ‘OUT OF PROGRAMME’ SAMPLES

Recall intervals for cervical screening

- Routine 3 yearly recall between the ages of 24 years, 6 months to 49 years inclusive
- Routine 5 yearly recall between the ages of 50 to 64 years inclusive
- Cease cervical screening at age 65 years, only screen those who are currently on follow-up for a previous abnormality

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. Note, this includes women under the age of 20 years.

Other inappropriate tests

- 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

1 The first invitation letter is sent at 24 years, 6 months. Women are invited by the Scottish and Welsh cervical screening programmes at age 20 years.
2 Women over 64 years should only be screened if they are currently on follow-up for previous abnormal cytology or follow-up after treated CIN/invasive cervical cancer.
3 Women with an abnormal looking cervix should be referred for gynaecological examination and onward referral to colposcopy if cancer is suspected.
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, the 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 is required after treatment (or follow-up of untreated CIN1) delay assessment until after delivery
- If colposcopy or cytology is required after treatment for CGIN or CIN2/3 with involved or uncertain margins do not delay assessment
### 4.3 FOLLOW-UP AFTER TOTAL HYSTERECTOMY

**VAULT CYTOLOGY TO BE TAKEN IN COLPOSCOPY – NOT PRIMARY CARE**

<table>
<thead>
<tr>
<th>Follow-up after total hysterectomy</th>
<th>For women on routine recall. Suggest cancel recall.</th>
</tr>
</thead>
<tbody>
<tr>
<td>For fully excised CIN/CGIN</td>
<td>Suggest cancel recall after 2 subsequent negative cytology tests at 6 months 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. Follow-up continues until age 65 or until 2 years after surgery (whichever is 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. Then annual follow-up for a total of 10 years. Follow-up continues until age 65 or until 10 years after surgery (whichever is later)</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 otherwise.</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 20, Colposcopy and Programme Management 2010

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
4.4 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)
PREPARING A SUREPATH LBC SAMPLE

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 REQUESTING A CERVICAL SCREENING TEST

6.1 ELECTRONIC REQUESTING

Electronic requesting for cervical screening tests is available to all GP practices via a system called ICE. This will eliminate the need to complete paper copy request forms and ensure all mandatory information is provided. If ICE is unavailable at any point, sample takers will have the option to complete a paper request form or download and print a form directly from Open Exeter.

6.2 OPEN EXETER REQUEST FORM

The electronic HMR101 request form can be downloaded from Open Exeter for those sample takers who have been trained in the use of this form. Training guidance can be provided by contacting PCSS (Preston). 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)**

Don’t forget to print your full name and your GMC or NMC code

Printing the HMR101 form – if possible please print in ‘portrait format’ to facilitate use in the laboratory.
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>NHS NUMBER</th>
</tr>
</thead>
<tbody>
<tr>
<td>CERVICAL SCREENING REQUEST FORM</td>
<td><strong>PRINT PATIENT DETAILS CLEARLY TO PREVENT ERRORS</strong></td>
</tr>
<tr>
<td><strong>SURNAME</strong></td>
<td><strong>REASON FOR TEST</strong></td>
</tr>
<tr>
<td><strong>FORENAME(S)</strong></td>
<td>1 First ever test</td>
</tr>
<tr>
<td><strong>PREVIOUS SURNAME</strong></td>
<td>2 Routine recall</td>
</tr>
<tr>
<td><strong>DATE OF BIRTH</strong></td>
<td>3 Other</td>
</tr>
<tr>
<td><strong>HOSPITAL / CLINIC NUMBER</strong></td>
<td>4 Prev abnormal test</td>
</tr>
<tr>
<td><strong>PATIENT’S ADDRESS</strong></td>
<td>5 Follow-up after treatment</td>
</tr>
<tr>
<td><strong>SAMPLER</strong></td>
<td>6 Annual follow-up</td>
</tr>
<tr>
<td><strong>SPECIMEN SITE</strong></td>
<td>7 Last test inadequate</td>
</tr>
<tr>
<td><strong>HAEMORRHAGE</strong></td>
<td>8 Opportunistic test</td>
</tr>
<tr>
<td><strong>TOTAL Hysterectomy?</strong></td>
<td>9 Other</td>
</tr>
<tr>
<td><em>If no previous test tick box [ ]</em></td>
<td><strong>CONDITION</strong></td>
</tr>
<tr>
<td><strong>APPEARANCE OF CERVIX</strong></td>
<td>1 Pregnant</td>
</tr>
<tr>
<td></td>
<td>2 Postnatal (&lt;12 weeks)</td>
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<tr>
<td></td>
<td>3 IUCD</td>
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<td></td>
<td>4 Other hormones (specify)</td>
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<td></td>
<td>5 Oral contraceptives</td>
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<tr>
<td></td>
<td>6 Postmenopausal</td>
</tr>
<tr>
<td></td>
<td>7 Abnormal, this test is not appropriate</td>
</tr>
<tr>
<td><strong>TOTAL Hysterectomy?</strong></td>
<td><strong>CLINICAL DETAILS</strong></td>
</tr>
<tr>
<td><strong>GP NAME AND FULL POSTAL ADDRESS</strong></td>
<td>(PREVIOUS REPORT OR CLINIC)**</td>
</tr>
<tr>
<td></td>
<td><strong>HISTORICAL CART</strong></td>
</tr>
<tr>
<td><strong>FORM</strong></td>
<td><strong>GMC/NMC NUMBER</strong></td>
</tr>
<tr>
<td></td>
<td>(ENTER IN BOXES BELOW)**</td>
</tr>
</tbody>
</table>

Visit our website @ www.cmft.nhs.uk
6.3 THE CERVICAL CYTOLOGY REQUEST FORM

- 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 previous surname helps us to link previous records to the current test.
- The GP NAME & ADDRESS must be given to ensure that the test result reaches the correct clinician. **MUST**
- The POST CODE ensures that the correct Call/Recall Agency sends the result letter.
- 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.
- Total hysterectomy means the woman has NO CERVIX.
- The sample taker’s FORENAME & SURNAME must be PRINTED to correctly identify the person taking the sample. This is a clinical governance requirement. **PRINT GMC OR NMC NUMBER CLEARLY**
- Any information given in this section of the form **MUST BE ACCURATE.** Any discrepancies must be resolved before the sample can be reported and will lead to a delay in the report being sent out.
7  PATIENT PATHWAY THROUGH CERVICAL SCREENING

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.

- **Sample received by cytology lab**
- **Sample processed & cytology slide prepared**
- **Slide screened & reported**
- **Samples requiring HPV testing are sent to virology**
- **HPV results received back in cytology**
- **Test result sent to Call/recall & sample taker. GP receives a copy if the GP is not the sample taker**
- **Result: routine screening**
  - Call/recall process result and send letter to woman by 1st class post Mon – Fri
  - Woman receives result letter
- **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
  - Call/recall notify colposcopy unit as per direct referral protocol
  - Woman receives result letter and advised to contact GP to discuss the result
- **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
  - GP makes urgent referral to GYNAECOLOGY
  - Woman attends GYNAECOLOGY
- **Up to 3 days**
- **1 day**
- **Same day**
- **1 day**

**KEY**

- PATIENT
- CYTOLOGY
- VIROLOGY
- CALL/RECALL
- GP
8 DIRECT REFERRAL TO COLPOSCOPY
8.1 DIRECT REFERRAL FLOWCHART

Lab: report test result

Lab: direct referrals

Test results

LASCA – record test result and print result letters for women

LASCA – check result letters produced for all women on direct referral list

LASCA – email colposcopy clinic on day letters are being sent to women confirming names of women included in direct referral

LASCA – send direct referral letters to women by first class post on the day of receipt of result – advising them that an appointment will be arranged (appointment sent, or they need to contact colposcopy to book and appointment – depending on local policy). They are advised they can contact their GP if they prefer to attend a different clinic.

Test results

Direct Referral List

Colposcopy clinic – wait 3 working days and if no telephone call from woman send her an appointment

Colposcopy clinic
1. Receive telephone calls from women listed on direct referral list to book appointments

OR

2. Colposcopy sends an appointment asking woman to confirm or rearrange

Patient

GP
8.2 DIRECT REFERRAL TO COLPOSCOPY & FAILSAFE

The laboratory has well-established systems of direct referral to all the colposcopy units in Lancashire and Cumbria. It provides details of the test result to allow efficient allocation of appointments based on the cytology grade to ensure women at highest risk get the earliest appointments.

Women who are suspected of having cancer as a result of their cervical screening 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 cervical glandular neoplasia and the patient is directly referred from the laboratory.

Suspected non-cervical glandular neoplasia

The department has a separate protocol for the referral of suspected glandular abnormalities of non-cervical origin. This involves contacting the GP or sample taker prior to authorising the report to discuss the result and explain that an urgent referral to gynaecology is required. Referral is to be made by the GP as the patient will receive a ‘normal result’ letter from the call/recall agency. Actions are audited on a proforma.

![Audit Proforma for Non-Cervical Glandular Neoplasia Referrals]

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 and they should respond accordingly when a failsafe enquiry letter is sent. Any cases where an outcome is not available are notified to the Screening and Immunisation Team and the Hospital Based Programme Co-ordinator at the Manchester Cytology Centre.
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)
- Test result sent to call/recall from cytology laboratory
- Same day

**SUSPECTED CERVICAL GLANDULAR NEOPLASIA**
- Colposcopy is advised (code 6)
- Test result sent to call/recall from cytology laboratory
- Same day

**SUSPECTED NON-CERVICAL GLANDULAR NEOPLASIA**
- Routine cervical screening [referral to gynaecology by GP] (code 0)
- Test result sent to call/recall from cytology laboratory
- Same day

**Result: URGENT COLPOSCOPY ADVISED**
- Laboratory contacts GP or sample taker to discuss cytology result and the need for an urgent colposcopy appointment under the 2 week rule
- Laboratory advises GP to contact the patient urgently to discuss the cytology result. The report is then authorised and sent to PCSS (Preston)
- Patient is directly referred from the laboratory

**Result: URGENT GYNAECOLOGICAL ASSESSMENT ADVISED**
- Laboratory contacts GP or sample taker to discuss cytology result and the need for an urgent gynaecology 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

**KEY**
- **CYTOLOGY**
- **CALL/RECALL**
- **PATIENT**
- **GP**

**Call/recall process result and send letter to woman by 1st class post Monday – Friday**
- Up to 3 days
- Woman receives result letter which advises her of the need for an urgent hospital appointment

**Direct referral from the laboratory to COLPOSCOPY**
- Same day
- Woman attends COLPOSCOPY

**Call/recall process result and send letter to woman by 1st class post Monday – Friday**
- 1 day
- Woman receives result letter which advises her to contact her GP to discuss the result

**GP makes urgent referral to GYNAECOLOGY**
- Up to 3 days
- Woman attends GYNAECOLOGY
9 SAMPLE ACCEPTANCE

The laboratory has implemented a system for rejecting samples that fail to meet the sample acceptance criteria. This will ensure that:

1. The correct test result is issued to the correct women who attend 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 to resolve discrepancies
4. The laboratory is able to comply with the 7-day turn around standard for all samples

**Essential patient data are surname, forename, date of birth & NHS number**

At least 3 of the 4 patient identifiers must be provided – this makes allowances for Contraceptive & Sexual Health services as they may not have access to the NHS number.

<table>
<thead>
<tr>
<th>On the form</th>
<th>On 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>

A senior biomedical scientist oversees the sample rejection process. All rejections are coded with the relevant error code. This provides the laboratory with a means of auditing rejected samples.

**Minor discrepancies**

Minor discrepancies will be accepted as the patient identity is known

1. Spelling error in patient name but the name sounds the same (homonyms)
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
4. Request form without sender details – check Open Exeter and phone GP to confirm

**Major discrepancies**

Major discrepancies constitute a serious risk as the patient identity is uncertain and the sample must be rejected.

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
9.1 DISCREPANCY CODES USED BY THE LABORATORY

<table>
<thead>
<tr>
<th>Code</th>
<th>EXPLANATION</th>
<th>COMMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>E1</td>
<td>Vial received without form</td>
<td>Contact sender and ask for form. If no form, discard sample and request repeat test to be taken in three months</td>
</tr>
<tr>
<td>E2</td>
<td>Form received without vial</td>
<td>Contact sender and check sample was taken. If no vial, request repeat test to be taken in three months</td>
</tr>
<tr>
<td>E3</td>
<td>Vial is unlabelled</td>
<td>Inform sender. Discard sample and request new sample to be taken in three months</td>
</tr>
<tr>
<td>E4</td>
<td>Vial only partially labelled</td>
<td>Follow guidance for minor/major labelling discrepancies</td>
</tr>
<tr>
<td>E5</td>
<td>Patient details on form and vial do not match</td>
<td>Significant data inconsistencies require a repeat sample. Inform sender. Discard sample and request new sample to be taken in three months</td>
</tr>
<tr>
<td>E6</td>
<td>Insufficient patient details on form</td>
<td>Depends on severity. Inform sender. Discard sample and request new sample to be taken in three months</td>
</tr>
<tr>
<td>E7</td>
<td>Patient details differ from cytology records</td>
<td>Reject if major labelling discrepancy. If minor discrepancy, check Open Exeter and process but inform sender of error</td>
</tr>
<tr>
<td>E8</td>
<td>Valid PIN not provided</td>
<td>Inform Screening &amp; Immunisation co-ordinator to verify sample taker is trained &amp; updated. If not verified, report sample as inadequate unless sample is abnormal. If verified, record PIN and report sample in the usual way</td>
</tr>
<tr>
<td>E9</td>
<td>Vial split in transit/ incorrect or out of date container/ brush inappropriately missing or present</td>
<td>Process sample and report as inadequate unless sample is abnormal. Inform sender</td>
</tr>
<tr>
<td>E10</td>
<td>Form/vial details illegible</td>
<td>Depends on severity. Inform sender. Discard sample and request new sample to be taken in three months</td>
</tr>
<tr>
<td>E11</td>
<td>Out of programme sample (age, too early repeat, inappropriate vault)</td>
<td>Inform sender and discard sample</td>
</tr>
<tr>
<td>E12</td>
<td>Out of date vial</td>
<td>Discard sample. Inform sender. Ask sender to check stock and return any out of date vials to the laboratory for safe disposal</td>
</tr>
</tbody>
</table>

10 HPV TESTING WEBSITES

For more information

- Visit the Cancer Research UK website at [www.cancerresearchuk.org](http://www.cancerresearchuk.org)
- Visit the Jo’s Cervical Cancer Trust website at [www.jostrust.org.uk](http://www.jostrust.org.uk)
11.1 CYTOLOGY PRI00MARY SCREENING PROTOCOL (July 2014)

Screening test result

- Inadequate
  Repeat in 3/12

- Negative or
  or non-cervical glandular neoplasia
  Routine recall

- Borderline (squamous or endocervical)
  or low-grade dyskaryosis
  HPV tested

- High-grade dyskaryosis or worse or
  Endocervical glandular neoplasia
  (CGIN)
  Colposcopy referral

- HPV negative
  Routine recall

- HPV inadequate/unreliable
  Cytology = borderline
  Repeat in 6/12 with HPV test only if Neg/BNC/low-grade

- HPV inadequate/unreliable
  Cytology = low-grade dyskaryosis
  Colposcopy referral

- HPV positive
  Colposcopy referral

Repeat test result

- Cytology
  Neg/BNC/low-grade
  HPV negative
  Routine recall

- Cytology
  Neg/BNC/low-grade
  HPV positive
  Colposcopy referral

- High-grade or worse
  (No HPV test required)
  Colposcopy referral

- High-grade or worse
  (No HPV test required)
  Colposcopy referral

- High-grade or worse
  (No HPV test required)
  Colposcopy referral

- <CIN1
  Cytology Neg/BNC/low-grade
  Routine recall

- Untreated CIN1
  Cytology follow-up
  SEE UNTREATED CIN1 PROTOCOL

- CIN 1/2/3 -> Treatment
  Next test in 6/12
  SEE TOC PROTOCOL

- CGIN -> Treatment
  Next test in 6/12
  SEE CGIN PROTOCOL
11.2 CYTOLOGY PRIMARY SCREENING PROTOCOL – UNTREATED CIN1 (July 2014)

Untreated CIN1
Cytology follow-up

Follow-up test

Cytology Borderline/Low-grade
HPV inadequate/unreliable
Repeat in 3/12

Cytology Normal
(No HPV test required)
Repeat in 12/12

Cytology Borderline/Low-grade
HPV positive
Colposcopy referral

Cytology Borderline/Low-grade
HPV negative
3 year recall

Follow-up test

Cytology Borderline/Low-grade
HPV inadequate/unreliable
Repeat in 3/12

Cytology Borderline/Low-grade
HPV negative

Follow-up test

Cytology Normal
(No HPV test required)
Repeat in 12/12

Cytology High-grade or worse
(No HPV test required)
Colposcopy referral

Cytology Normal
(No HPV test required)
Routine recall

Restart screening protocol algorithm
11.3 CYTOLOGY PRIMARY SCREENING PROTOCOL – TEST OF CURE PROTOCOL (July 2014)

CIN 1/2/3 -> Treatment
For TOC in 6 months

Test of Cure

- Cytology Neg/BNC/low-grade
  - HPV negative
    - 3 year recall
    - Colposcopy referral
  - HPV inadequate
    - Repeat in 3/12
    - Follow-up test
    - Restart screening protocol algorithm

- Cytology High-grade or worse
  - (No HPV test)
  - Colposcopy referral

(ii) Women referred back to colposcopy (at TOC following treatment for CIN) due to borderline, low-grade dyskaryosis or negative cytology, who are HR-HPV positive, and who then have a satisfactory and negative colposcopy, can be recalled in 3 years.
11.4 CYTOLOGY PRIMARY SCREENING PROTOCOL – CGIN PROTOCOL after adequate treatment (July 2014)

(iii) Women who have been adequately treated (complete excision margins) for CGIN or SMILE will follow the management in this protocol algorithm. Women receiving annual surveillance tests following treatment for CGIN or SMILE in the past may also be tested in line with this policy at their next two tests. Women treated for cervical cancer are excluded from this management policy.
12.1 HPV PRIMARY SCREENING PILOT PROTOCOL ALGORITHM (January 2015)

HR-HPV TEST

HR-HPV NEGATIVE
Routine recall

HR-HPV POSITIVE
Cytology triage

Cytology normal #
Repeat in 12/12

Cytology abnormal
Colposcopy referral

HR-HPV NEGATIVE
Routine recall

HR-HPV POSITIVE
Cytology triage

Cytology normal or abnormal
Cytology triage

Cytology abnormal
Colposcopy referral

Notes
1. Inadequate tests at any screening episode in the pathway will be repeated in 3 months. Three inadequate tests in a row will lead to colposcopy referral
2. Women entering the pilot under follow-up for treated CIN will be given a 3 year recall if HR-HPV negative & will be referred to colposcopy if HR-HPV positive/any grade of cytology
3. Women entering the pilot under follow-up for treated CGIN or SMILE (complete excision margins) will follow the protocol for CGIN at their next two tests (see colposcopy management algorithm)
4. Women under follow-up for cervical cancer (who still have a cervix) & CGIN/SMILE (without complete excision margins) at a pilot site will be given annual HPV testing (instead of cytology) for 10 years.

# HPV 16/18 recorded where available. Women testing HPV 16 or 18 positive/cytology normal at baseline & again at their first 12 month follow-up test can be referred to colposcopy without further repeat tests
12.2 HPV PRIMARY SCREENING PILOT COLPOSCOPY MANAGEMENT ALGORITHM (January 2015)

Colposcopy inadequate or normal & adequate

**COLPOSCOPY EXAMINATION**

- **INADEQUATE COLPOSCOPY**
  - Index cytology HR-HPV +ve & Cytology ≤ Low-grade
    - REPEAT COLPOSCOPY IN 12 MONTHS
    - CONSIDER LLETZ (PATIENT CHOICE)
  - Index cytology HR-HPV +ve & Cytology High-grade or worse
    - LLETZ

- **NORMAL & ADEQUATE COLPOSCOPY**
  - No biopsy or biopsy <CIN1
  - Biopsy CIN1+
    - Manage according to ‘abnormal colposcopy’ examination
  - Index cytology HR-HPV +ve & Cytology ≤ Low-grade
    - REPEAT IN 36 MONTHS
  - Index cytology HR-HPV +ve & Cytology High-grade or worse
    - DISCUSS AT MDT WITHIN 2 MONTHS
**12.3 HPV PRIMARY SCREENING PILOT COLPOSCOPY MANAGEMENT ALGORITHM (January 2015)**

**Colposcopy abnormal**

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**COLPOSCOPY EXAMINATION - ABNORMAL**

- **CIN1 untreated**
  - Repeat in 12/12
  - HR-HPV –ve
    - Repeat in 36 months
  - HR-HPV +ve
    - Cytology +ve
      - Colposcopy referral
    - Cytology –ve
      - Repeat in 12/12
      - Repeat in 36 months

- HR-HPV –ve
  - Repeat in 36 months

- HR-HPV +ve
  - Cytology –ve
    - Repeat in 12/12
  - Cytology abnormal
    - Colposcopy referral

- **>= CIN2**
  - Treatment
  - Repeat in 6/12
  - HR-HPV –ve
    - Repeat in 36 months
  - HR-HPV +ve
    - Cytology –ve
      - Repeat in 12/12
    - Cytology +ve
      - Colposcopy referral
      - Repeat in 12/12
      - Repeat in 36 months

- **CGIN***
  - Treatment
  - Repeat in 6/12
  - HR-HPV –ve
    - Repeat in 36 months
  - HR-HPV +ve
    - Cytology abnormal
      - Refer to colposcopy.
        - Complete 10-yr cytology follow-up
    - Cytology normal or abnormal
      - Colposcopy referral

*Women who have been adequately treated (complete excision margins) for CGIN or SMILE. Women without complete excision margins will receive annual HPV testing for 10 years.
**After 36 months (three years) women will begin a new screening episode according to the HPV Primary Screening Protocol Algorithm*