

GUIDELINES FOR THE MANAGEMENT OF CERVICAL CYTOLOGY SAMPLES SENT TO CELLULAR PATHOLOGY AT MAIDSTONE

Introduction

These guidelines have been drawn up to provide a working document for sample takers and replace all previous guidelines. They are based on the NHS Cervical Screening Programme: Guidelines for Colposcopy and Programme Management (3rd Ed. March 2016) with the addition of information from the NHS Cervical Screening programme Short term mitigation using primary HPV screening.

The guidelines are not intended to be prescriptive, or to cover every eventuality. Clinical judgement and the patient's medical history are also important. Any deviation from the guidelines may be at the discretion of the Cytopathologist and should be justifiable.

Cervical cytology is a screening tool. It aims at detecting precancerous conditions of the cervix, not cervical cancer. Precancerous conditions do not produce symptoms. If gynaecological symptoms exist (e.g. post menopausal or post coital bleeding etc) referral to gynaecologist should be considered especially in women over 40 years. Referral of younger women to GUM clinics should be considered.

Primary HPV screening

From 1st June 2018 a subset of the population screened at Maidstone laboratory will be initially tested for HR-HPV. If the result is negative no LBC cytology processing will be performed and a result recommending appropriate routine recall will be issued. If the HR HPV test is positive LBC cytology processing will take place and all the criteria below will apply. The remainder of the population screened will continue to be reported as below.

Adequate samples

An adequate sample will represent the cervix and contain sufficient number of squamous epithelial cells necessary to ensure acceptable squamous abnormality detection rates or, in the case of Primary HPV testing, sufficient cells to generate a valid result.

The sample taker is responsible for ensuring that the cervix has been visualised and fully sampled..

The technical quality, including cellularity of the sample, is assessed by the cytology laboratory in the LBC cytology processing population. For local quality control the cytology report should include a statement as to whether endocervical and/or metaplastic cells are present

Inadequate samples

A sample is never diagnosed as inadequate solely on the criteria of endocervical/ metaplastic cells being absent (except in follow up to glandular abnormalities), providing the slide has a good covering of well fixed squamous cells. A sample is reported as inadequate for the following reasons:-

- Cervix not / not fully visualised by sample taker
- Vial received unlabelled or mislabelled.
- The sample taker has not got a valid Sample Taker number.
- Insufficient squamous cells for assessment or to give a valid HR HPV test result.
- More than half the cellular material is obscured by blood, menstrual debris, polymorph exudate or bacteria.
- Excess lubricant blocking the filter.
- Only endocervical cells present.

- Sample quality too poor to give a valid HR HPV test result

The clinician ultimately determines what is adequate sampling for an individual patient based on integrating information from the clinical history, visual inspection of the cervix and the cytopathology report.

Further advice can always be obtained from the Cytopathology Consultants, Dr Ann Fleming or Dr Anna Bryant
or Clinical Cytologist, Paul Wallace. Phone 01622-224065/220132

RECOMMENDATIONS FOR MANAGEMENT

1. *Management categories*

Every cervical cytology report should carry a recommendation for subsequent management.

There are five categories:

- Routine recall (or automatic ceasing from recall after the age of 65).
- Repeat cytology (at a fixed interval, which may be earlier than routine recall).
- Colposcopy.
- Urgent referral.
- Gynaecological referral.

Inadequate samples and repeat cytology

Where an initial sample is inadequate, cytology should be repeated. The repeat sample **should not** be taken less than three months after the previous test. Women should be referred for colposcopy after three consecutive inadequate samples. Consideration should be given to investigating and treating any infections that are present after the second inadequate sample.

Primary HPV positive and LBC cytology processing negative

Samples from women found to be positive for HR HPV will have cytology performed. Those with normal cytology will be recalled in 12 months for a repeat test. Women recalled for a repeat test at 12 months will be HR HPV tested. If this test is negative women will be returned to routine screening. If the test is positive cytology will be performed. If Cytology is negative a further repeat in 12 months will take place. If the cytology is abnormal a referral to Colposcopy will be made.

If the final HR HPV test is negative women will be returned to routine screening. If the test is positive cytology will be performed but referral to Colposcopy will take place regardless of the cytology findings.

Borderline change (in squamous/endocervical cells) and HR-HPV triage (Primary LBC processing)

When borderline change in squamous or endocervical cells is reported on a cytology sample, a reflex HR-HPV test will be performed to assess the presence of HR-HPV DNA. Women who have borderline change of either type and who are positive for HR-HPV must be referred for colposcopy. Women who are HR-HPV negative are returned to routine recall. Where a sample is scanty, HR-HPV testing may be attempted, but should only be considered reliable where the result is positive, or when the validity of a negative result is confirmed by an internal control. In scanty samples where cytology is reported as borderline and the HR-HPV result is negative, a further sample should be taken in 6 months, and the woman should be managed as follows:

- If the cytology report from the second screen is negative, borderline, or low-grade, an

- HR-HPV test should be conducted. Women with a positive HR-HPV test should be
- referred to colposcopy. Women with a negative HR-HPV test return to routine recall.
- If this second screen is reported as high-grade dyskaryosis (moderate) or worse, the
- woman should be referred straight to colposcopy.

Low-grade dyskaryosis and HR-HPV triage (Primary LBC processing)

When low-grade dyskaryosis is reported on a cytology sample, a reflex HR-HPV test will be performed to assess the presence of HR-HPV DNA. Women who have low-grade dyskaryosis and who are positive for HR-HPV must be referred for colposcopy.

Women who are HR-HPV negative are returned to routine recall.

Where a sample is scanty (i.e. it fails to meet the criteria for adequate cellularity), HR-HPV testing may be attempted, but should only be considered reliable where the result is positive, or when the validity of a negative result is confirmed by an internal control. In cases involving a scanty sample where cytology is reported as low-grade and the HR-HPV result is negative and confirmed by an internal control, the woman can be returned to routine recall. However, if the HR-HPV test result is not confirmed by an internal control in this scenario, the woman should be referred straight to colposcopy.

Borderline change (in squamous/endocervical cells) or Low-grade dyskaryosis following Primary HPV positive test

Women who have borderline change of either type or low-grade dyskaryosis following a positive Primary HPV test must be referred for colposcopy.

High-grade dyskaryosis (moderate) – (Primary LBC or Primary HR HPV positive)

Women must be referred for colposcopy after one test is reported as high-grade (moderate) dyskaryosis. If women are not referred directly to colposcopy, the GP must make an urgent referral through the 'two week wait' pathway.

High-grade dyskaryosis (severe) - (Primary LBC or Primary HR HPV positive)

Women must be referred for colposcopy after one test is reported as high-grade (severe) dyskaryosis. If women are not referred directly to colposcopy, the GP must make an urgent referral through the 'two week wait' pathway.

High-grade dyskaryosis/ ? invasive squamous cell carcinoma - (Primary LBC or Primary HR HPV positive)

Women must be referred for colposcopy after one test is reported as high-grade dyskaryosis, ? invasive squamous cell carcinoma. If women are not referred directly to colposcopy, the GP must make an urgent referral through the 'two week wait' pathway.

Glandular neoplasia - (Primary LBC or Primary HR HPV positive)

When glandular neoplasia has been reported, the referral pathway will depend on the details provided about the source of the abnormal glandular cells.

- Where the abnormal glandular cells probably originated from the endocervix, or where the source is not specified, the woman must be referred for colposcopy. Where a woman is not referred directly, the GP must make an urgent referral through the 'two week wait' pathway.
- Where the source of the abnormal glandular cells is likely to be the endometrium or another gynaecological site, the woman should be referred to a gynaecology clinic.
- The GP must make an urgent referral through the 'two week wait' pathway.

Colposcopy

Colposcopy is a continuation of the screening process, providing further evidence about the nature of observed changes. The Colposcopist must therefore have sight of the cytology report at the time of the examination.

Those reporting abnormal cervical cytology samples should be aware that women with reports indicating high-grade dyskaryosis or worse (including ungraded dyskaryosis) may be treated by excision biopsy/Loop at first colposcopic examination, if an appearance consistent with a high-grade abnormality is seen. However, when colposcopic referral results from a report of low-grade dyskaryosis or borderline change (usually on first occurrence), or from an inadequate sample, treatment may well be deferred until results from a histological biopsy are obtained, particularly where the Colposcopist has not seen any cervical abnormality.

Those reporting abnormal cervical cytology samples may refer a woman for colposcopic assessment when cytological changes are difficult to interpret. In these instances, colposcopic appearances may also be non-specific, but a more accurate assessment is likely to be obtained by combining cytological review, colposcopic appearances, and histological biopsy of any abnormality seen. Ideally, such cases should be reviewed by a Cytopathologist, Colposcopist, and Histopathologist at the colposcopy multidisciplinary team meeting (MDTM) before future management is decided.

Cytological follow-up of women treated for CIN and 'test of cure (TOC)'

NOTE – for HPV primary screening the TOC will be a HPV test (replacing the cytology test), with cytology performed only on detection of abnormal cells. All HPV positive TOC results will result in colposcopy referral irrespective of cytology findings

Women who have been treated for CIN should be returned to community-based routine recall, irrespective of their excision margin status. A cervical cytology sample should be taken six months after treatment.

- Where the cytology sample is reported as negative, borderline or low-grade, a reflex HR-HPV test will be undertaken. Women who are positive for HR-HPV will be referred for colposcopy. Women who are negative for HR-HPV will be recalled for a repeat cytology sample in three years, irrespective of their age. The three-year repeat is managed according to standard HR-HPV triage protocols.
- Where the cytology sample is reported as high-grade dyskaryosis or worse, women must be referred for colposcopy. An HR-HPV test is not necessary.

If the TOC cytology sample is performed in a hospital setting instead of the community, it should be taken in a cytology clinic, as a formal colposcopic examination is not required.

In the primary HPV testing pathway the negative tests result in a 3 year recall for patients and positive tests are referred to Colposcopy irrespective of cytology results

Follow-up management of women adequately treated for CGIN (complete excision margins)

- All follow-up samples must contain endocervical cells.

Where the cytology sample is reported as negative, a reflex HR-HPV test will be undertaken. Where cytology shows, borderline or low-grade or above the women is referred for colposcopic assessment, followed up for 10 years with cytology only or HPV tests depending on pathway. Women who are positive for HR-HPV will be referred for colposcopy. Women who are negative for HR-HPV will be recalled for a repeat cytology sample in one year.

A further test of cure is then carried out before returning to 3 year recall.

Follow-up management of women treated for CGIN (Incomplete excision margins)

These women are managed as previous cytological follow-up. The first sample should be taken six months after treatment. If it is negative, then cytology should be repeated six months later (i.e. at 12 months after treatment) and then annually for the subsequent nine years (minimum standard). All follow-up samples must contain endocervical cells.

Follow-up management of women referred to colposcopy as part of HR-HPV triage or test of cure

Where women are referred to colposcopy as part of HR-HPV triage, and their colposcopic examination is satisfactory and normal, they should be returned to community-based routine recall. Subsequent samples will be taken at 3- or 5-yearly intervals, depending on their age. Where women are referred to colposcopy as part of 'test of cure', and their colposcopic examination is satisfactory and normal; their next sample will be taken in three years, irrespective of their age. Where this subsequent sample is negative, the woman will return to routine recall (at 3- or 5-yearly intervals, depending on her age).

Use of HR-HPV testing outside of HPV triage and TOC

The aim of HR-HPV testing is to identify those women who can be discharged from colposcopy to appropriate recall in the community. However, the use of HR-HPV testing outside of the HR-HPV triage and test of cure protocols may assist with the management of some clinical scenarios. To prevent the overuse of HR-HPV testing, it is recommended that all such cases are discussed at the colposcopy MDTM before an HR-HPV test is administered.

HR-HPV testing may be of use in the following clinical scenarios:

1. Women undergoing long term colposcopic surveillance for low-grade CIN or unresolved abnormal cytology, who have not previously been tested for HR-HPV.
1. This could include women with cervical stenosis where colposcopy is non-contributory.
2. Women who have undergone hysterectomy for CIN, or whose hysterectomy specimens have been found to contain CIN, who subsequently present with abnormal vault cytology but no evidence of high-grade vaginal intraepithelial neoplasia (VAIN).
3. Women who experience difficulty tolerating colposcopy, whose examinations are therefore unsatisfactory.
4. Women with a persistent mismatch between high-grade cytology and low-grade histology, which has been discussed at the colposcopy MDTM, with the result that a decision not to treat has been reached.

A negative HR-HPV sample in the above scenarios may guide appropriate management, which may include discharge to appropriate recall, or avoidance of clinical intervention.

Follow-up after treatment for invasive cervical cancer

Guidance on the follow-up of women after treatment for early stage cervical cancer has been issued by the NHS CSP.

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Cytology NHSCSP 20 Colposcopy and Programme Management, section 9.7