#### GUIDELINES FOR CERVICAL CYTOLOGY SPECIMENS CA1066 (V11)

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## **GUIDELINES FOR CERVICAL CYTOLOGY SPECIMENS CA1066 (V11)**

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OCT 2014	VIKI FREW	Update to incorporate changes to patient management following treatment for CGIN/ SMILE. Further information on NHSCSP inclusion criteria. Further information on follow-up tests after treatment of invasive cervical cancer. Added reference to ISO standard	
Nov 2014	XENIA TYLER	Exceptions: women who test negative cytology & HPV +ve at 6 months and then negative cytology & HPV –ve at 18 months are recalled in 3 years added	
Feb 2018	VIKI FREW	Added HPV Primary Screening algorithm Added new HPV Primary screening codes to Cytology reporting section Further information on inadequate samples Added conservative management to follow-up for women attending colp Added no vault samples should be taken in primary care Updated HPV testing in follow-up of women treated for cervical cancer Updated follow-up tests after treatment of 1A1 cervical cancer in line with NNUH clinical practice, Updated references, Amended page numbers	
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April 2021	GEOFFREY CURRAN	Vault follow up on page 13 corrected
Feb 2023	VIKI FREW	Page 7: HIV patients given A routine recall at 64/65yrs Page 8: NNUH recommendation to colposcopy clinics to biopsy atypical transformation zone irrespective of grade of referral Page 13: clarification on presence of endocervical cells required for post CGIN samples Page 14: clarification on vault follow-up

Clinical Guideline for: Cervical Cytology Specimens

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For Use in:	Cytology Laboratory, General Practice, Gynaecology Outpatients, Colposcopy Clinic, Community and Sexual Health (CaSH) clinic, Other NHS Community Clinics
Ву:	Cytology Staff, Practice Nurses, General Practitioners, Gynaecologists, Colposcopists,
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## Introduction

In England the NHS cervical screening programme is delivered from 8 centralised laboratories. The laboratory at Norfolk and Norwich University Hospital is the provider for the East of England. Throughout the UK the testing method is by molecular testing for high-risk HPV strains with reflex cytology for HPV high-risk detected cases; this method is known as HPV Primary Screening.

## **Quick Reference Guidelines to HPV Primary Screening**



## Rationale for the main recommendations

- Cervical screening is a multidisciplinary activity involving many groups of staff in both primary and secondary care.
- The screening, reporting and classification of cervical cytology samples is the responsibility of cytology laboratory staff, who also make a recommendation for future management based on supplied information, including high risk HPV status and including the screening history.
- The definitions of various cervical cytology results and their recommended management are constantly changing in the light of emerging evidence.
- These recommendations are based mainly on national guidance, which has been adapted for local use.



## Guideline development and approval

Amendments to local clinical guidelines are in line with the most recent changes to national guidelines.

## **Broad recommendations**

The aim of the NHS Cervical Screening Programme (NHSCSP) is to reduce the number of women who develop cervical cancer and improve morbidity outcomes. This is achieved by offering regular screening to women so that conditions which might otherwise develop into cervical cancer can be identified and treated. Cervical Intraepithelial Neoplasia (CIN) are pre-cancerous changes on the cervix and can be detected on the cervical cytology sample.

#### NHSCSP cervical screening inclusion criteria:

Age Group (Years)	Frequency
24.5	First Invitation
25 - 49	3 yearly
50 - 64	5 yearly
65+	Women are screened who have not been screened since the age of 50 or who have had recent abnormal tests

Women who fall outside of the national screening programme criteria are not eligible for cervical screening.

All primary care sample takers should have access to Open Exeter and check the patient's screening history prior to taking the sample.

Women receive their invitation and result letters direct from the NHSCSP Cervical Screening Administration Service (CSAS). These letters are sent to the woman's address as registered on the national Open Exeter database. The GP must inform NHSCSP call & recall of any change of address to enable the database to be updated.

#### Why are women under 24.5yrs not invited?

In women under the age of 25, invasive cancer is extremely rare, but cell changes in the cervix are common. Although lesions treated in very young women may prevent cancers from developing many years later, the evidence suggests that screening can safely start at age 25 and that it is relatively ineffective in younger women. Lesions that are destined to progress will still be screen detectable, and those that would regress will no longer be a source of anxiety. Younger women will not have to undergo unnecessary investigations and treatments. Women under the age of 25 with gynaecological symptoms should be managed according to Appendix A.



#### Why are women over 65 not invited?

Women aged 65 and over are taken out of the call recall system unless they need ongoing surveillance or follow up. Generally speaking, the natural history and progression of cervical cancer means it is highly unlikely that screened women of 65 and over will go on to develop the disease. Women aged 65 and over who have never had a test are entitled to one.

#### What about women who are not sexually active?

The evidence shows that if a woman has never been sexually active then her risk of developing cervical cancer is very low. We don't say 'no risk' just 'low risk'.

#### Abnormal looking cervix / gynaecological symptoms:

GPs are advised to refer women with an abnormal looking cervix / gynaecological symptoms (see Appendix A).

Women with cervical warts should be referred for colposcopy regardless of cervical cytology result.

Women with vulval warts do not require more regular cervical screening tests.

#### Immunosuppressed women:

- All HIV-positive women should be screened annually. CSAS will only invite these women for an annual smear if the laboratory are informed of the HIV status and indicate R12 on negative results. The record held on the call & recall database will not include the HIV status. At age 64/65 the laboratory will indicate A for normal recall to allow CSAS to cease recall.
- If immunosuppressed for any other reason, there is no indication for more frequent smears. Normal recall is appropriate.
- All women with renal failure requiring dialysis or transplantation should have a smear at diagnosis and colposcopy for any grade of abnormality.

#### Smears in pregnancy:

If an individual has been called for routine screening and they are pregnant, the test should be deferred until she is at least 12 weeks post natal.

An individual referred with an abnormal screening test should have colposcopy in late first or early second trimester unless there is a clinical contraindication.

If a previous colposcopy was abnormal and in the interim the individual becomes pregnant, then the colposcopy should not be delayed.

If a pregnant individual requires colposcopy or a screening sample after treatment (or follow up of untreated cervical intraepithelial neoplasia grade 1 (CIN1)), their assessment may be delayed until after delivery.

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## Cervical Cytology Reporting

Cervical cytology is the microscopic examination of cells removed from the surface layers of cervical epithelium during the cervical screening test. The cervical cytology result is an indicator for the presence of underlying pre-cancerous changes. In line with national screening guidelines the cytology laboratory will arrange the direct referral to colposcopy if abnormal cells are identified or persistent hrHPV is detected. Following referral, NNUH cervical cytology recommends that unless treatment excision is planned, a diagnostic biopsy is carried out when a recognisably atypical transformation zone is present irrespective of the cytology referral grade. This is to determine the presence and grade of Cervical Intraepithelial Neoplasia (CIN) and reduce the risk of progression to an invasive lesion if left under diagnosed and untreated.

## HPV Primary screening

**All samples** following the HPV Primary screening algorithms are analysed for the presence of molecular hrHPV DNA.

The results of HR HPV testing are recorded using standard infection codes:

High risk HPV DNA not detected (infection code 0)

High risk HPV DNA detected (infection code 9)

High risk HPV DNA unavailable (infection code U)

The HPV U code indicates that no HPV test result could be obtained from the sample.

## HPV not detected

Patients whose samples have no molecular hrHPV will not have reflex cytology performed.

#### Management recommendations

Routine recall will be recommended when hrHPV is not detected except in the following circumstances:

- If the test is a first test of cure following treatment for CIN or a second test of cure following CGIN a repeat in 3years is advised (R36).
- Patients on follow up after a diagnosis of cervical cancer will be repeated annually for 10 years (R12)
- Patients who are HIV+ve will be repeated annually (R12)

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• Patients on the conservative management pathway for untreated CIN2 will be referred to colposcopy for a management decision for the next test (S)

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### Valid result codes

X 0 A – routine recall X 0 R – early repeat X 0 S – conservative management pathway

## HPV detected

Samples with hrHPV detected are processed for microscope examination. Those patients with hrHPV present will receive a result indicating HPV and cervical cytology result using the reporting categories listed below.

#### Notes:

Samples are not reported as inadequate if they contain any abnormal cervical cells.

## **Negative**

Negative indicates that no abnormal cells have been identified even though hrHPV is has been detected.

The presence or absence of transformation zone cells will be recorded in the laboratory for feedback to sampler-takers for audit purposes, but will not be part of the cytology report.

#### Notes

Negative tests may also show:

- Specific organisms (which should not be an indication for an early repeat sample *per se*).
- Non-specific inflammatory and benign reactive changes.
- Abundant leucocytes and/or blood. Providing the cells can be seen the sample can be reported as negative rather than inadequate.

#### Management recommendations

- Repeat in 12 months
- Refer to colposcopy at the third consecutive hrHPV detected with negative cytology
- Refer to colposcopy if the test of cure test is hrHPV detected with negative cytology
- Repeat in 3 years if two hrHPV detected cytology negative tests follow a histological diagnosis of CIN1 or less

#### Valid result codes

2 9 R12 – repeat in one year 2 9 R36 – repeat in three years 2 9 S – refer to colposcopy

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## Low grade Abnormal Tests

These samples will have tested positive for hrHPV, the presence of abnormal cells and hrHPV will indicate a referral to colposcopy.

All low grade dyskaryosis / borderline squamous changes will be direct referred for colposcopy.

### Valid result codes

8 9 S – borderline changes in squamous cells, refer to colposcopy

3 9 S – low grade dyskaryosis, refer to colposcopy

## High Grade Abnormal Tests

These samples will have tested positive for hrHPV, the presence of abnormal cells and hrHPV will indicate a referral to colposcopy

Borderline changes in endocervical cells

- Features suggestive of atypical endocervical epithelium and cannot exclude diagnosis of endocervical intraepithelial neoplasia (CGIN).
- Direct referral for colposcopy will be arranged

High grade dyskaryosis (moderate)

- Features support diagnosis of high grade squamous intraepithelial neoplasia (CIN 2/3)
- Direct referral for colposcopy will be arranged

High-grade dyskaryosis (severe)

- Features support diagnosis of high grade squamous intraepithelial neoplasia (CIN 2/3)
- Direct referral for colposcopy will be arranged

High grade dyskaryosis/ ? invasive squamous cell carcinoma

- Features support diagnosis of squamous cell carcinoma
- Urgent direct referral for colposcopy will be arranged

? Glandular neoplasia of endocervical type

- Features support diagnosis of endocervical intraepithelial neoplasia (CGIN) or endocervical adenocarcinoma.
- Urgent direct referral for colposcopy will be arranged



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Glandular neoplasia (non-cervical)

- Features support diagnoses of adenocarcinoma of endometrial, ovarian or metastatic lesions from beyond the genital tract
- Urgent direct referral for gynaecology will be arranged

### Valid result codes

- 99 S borderline changes in endocervical cells, refer to colposcopy
- 7 9 S moderate dyskaryosis, refer to colposcopy
- 49 S severe dyskaryosis, refer to colposcopy
- 5 9 S severe dyskaryosis suggesting squamous cancer, refer to colposcopy
- 6 9 S dyskaryosis in endocervical cells suggesting CGIN, refer to colposcopy
- 0 9 S glandular neoplasia of non-cervical origin, refer to gynaecology

## **Reporting and coding multiple diagnosis**

In rare circumstances coexisting cervical and non cervical abnormalities may be detected. It is the cervical abnormality which is recorded and sent to CSAS, and will determine the patient management in the NHS CSP. It is essential that the woman also receives an urgent gynaecological referral, and communication to the woman must be sensitive as she may have already received a letter referring only to a non urgent cervical cytology abnormality.

## Endometrial cells

Endometrial cells are a normal finding in the first 12 days of the menstrual cycle but may be seen throughout, particularly with hormone and IUCD use. If present at other times of the cycle:

Normal endometrial cells:

- in women <45 years; can usually be disregarded and will not normally be reported.
- in women >45 year; their presence and possible significance should be reported. The GP should consider referral if there are clinical symptoms suggestive of endometrial pathology.

Abnormal / atypical endometrial cells; Glandular neoplasia (non-cervical) code 0 - urgent gynaecological referral

It should be remembered that well differentiated carcinomas may shed morphologically normal cells and the GP should always refer post menopausal women to a gynaecologist if the presence of endometrial cells is noted in the report.

## Inadequate Samples (result code and infection codes X U or 1 9)

Inadequate samples may arise when HPV testing is not possible or may follow a hrHPV detected test.

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Reasons for inadequacy:

- HPV test not possible
- insufficient epithelial cells as determined by laboratory staff
- epithelial cells are obscured by an abundance of polymorphs or blood
- epithelial cells are cytolysed
- only endocervical cells are present
- no endocervical cells during the follow-up of an endocervical abnormality when hrHPV test is detected.
- head of the Cervex brush has been left in the vial
- the cervix was not completely visualised
- sample taken with inappropriate sampling device
- vial expiry date exceeded
- sample contaminated with lubricant

## Management recommendations

- Repeat in 3 months (see report for sampling recommendations)
- Refer to colposcopy at the second consecutive hrHPV detected with inadequate cytology
- Refer to colposcopy at the second consecutive hrHPV not available or inadequate screening test in any combination

## Valid result codes

X U R – no cytology, HPV test not possible, repeat no sooner than 3 months

- X U S no cytology, HPV test not possible, refer to colposcopy
- 19 R cytology inadequate, repeat no sooner than 3 months

19 S – cytology inadequate, refer to colposcopy

## Cytology follow-up for women attending colposcopy:

Quick reference to follow for women with an abnormal cervix on examination

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# Cytology follow-up of women with untreated CIN1 or colposcopic impression of low grade changes (punch biopsy):

All women should undergo cytological follow-up at 12months with a hrHPV test.

If hrHPV is not detected the patient is recalled in 3 year (R36), otherwise she is recalled in 12 months. Repeat in 3 years is recommended after two hrHPV detected cytology negative tests.

The rationale for returning women to 3years is these patients have been seen in colposcopy to exclude high grade abnormality and in follow up patients may not have cleared the virus but their cytology is now negative.

# Cytology follow-up of women with untreated CIN2+ following conservative management:

All women under conservative management for untreated CIN2 continue to remain under the care of colposcopy up to the time they are discharged. Cervical screening reports will indicate refer to colposcopy in the patient management advice.

## Cytology follow-up of women treated for CIN and HPV Test of Cure (ToC):

Women who have been treated for CIN 1, 2, or 3 have a six month follow-up test usually in primary care. If HPV is detected they will be referred back to colposcopy, and if HPV is not detected they will be recalled in 3 years (R36) followed by routine recall (A). If the HPV test is unavailable a repeat cytology plus HPV test will be arranged in 3 months.

## Cytology follow-up of women treated for CGIN with clear excision margins:

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for every patient Trust Guideline for the Management of: Cervical Cytology Cases of treated CGIN with clear excision margins have an HPV Test of Cure. The first sample is taken six months after treatment (best practice with colposcopy examination) and if negative for HPV a further 12 month repeat is recommended.

- hrHPV positive samples in either of the 6 or 18 month ToC or any subsequent annual follow-up samples must contain endocervical cells to be considered adequate.
- If at either 6 or 18 month ToC follow-up there is any HPV positivity or abnormal cytology the patient is referred back to colposcopy and complete 10 year annual follow-up

Exceptions: women who test negative cytology & HPV +ve at 6 months and then negative cytology and HPV –ve at 18 months are recalled in 3 years

• If at both 6 and 18 month ToC follow-up the HPV test is negative a repeat at 3 years is recommended.

# Cytology follow-up of women treated for cervical cancer (who still have a cervix) or CGIN with incomplete excision margins:

Minimum follow-up at 6 & 18 months post treatment, then complete 10 year annual follow-up using hrHPV testing.

The presence of endocervical cells is not required for a negative report.

Women are referred back to colposcopy if any sample in follow-up is HPV detected.

#### Vault smears following Total Hysterectomy:

Vault smears are no longer part of the NHS Cervical Screening Programme and vault followup <u>should not be undertaken in primary care</u>.

Following hysterectomy NHSCSP recall should be ceased. Vault samples are not recorded on the CSAS data base and CSAS do not send screening invite or result letters.

If the hysterectomy was subtotal, the cervix remains and therefore cervical screening should continue.

Hysterectomy containing no CIN - prior to hysterectomy patient on routine recall

no further vaginal vault cytology required

Hysterectomy containing no CIN - prior to hysterectomy patient not on routine recall

- vault hrHPV test at 6 months; then cease if negative
- If HPV positive or abnormal cytology, refer to colposcopy

exclude VaIN; discharge - no further vault sample required

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Hysterectomy containing completely excised CIN1, CIN2, CIN3 or CGIN

- vault hrHPV test at 6 months then cease if negative
- If HPV positive or abnormal cytology, refer to colposcopy

   exclude VaIN; discharge no further vault sample required

Hysterectomy containing incompletely excised CIN1

- vault hrHPV test at 6, 12 and 24 months; then cease if negative
- If HPV positive or abnormal cytology, refer to colposcopy
  - exclude VaIN; discharge at 24 months no further vault sample required

Hysterectomy containing incompletely excised CIN2, CIN3 or CGIN

- vault hrHPV test at 6 and 12 months and then annually for 9 years then routine
- If HPV positive or abnormal cytology, refer to colposcopy
  - exclude VaIN; discharge at 65 years or 10 years whichever is later

## Follow-up tests after treatment of invasive cervical cancer:

Vault sampling is not part of the routine screening programme and vault samples are not recorded on the CSAS data base.

Stage 1a1 (and any CIN) completely excised by loop/cone biopsy

- hrHPV test at 6 and 12 months then 9 annuals then routine screening. If abnormal cytology or HPV positive, refer to colposcopy.
- Stop age 64 or at 10 years whichever is later.
- NHSCSP will continue to provide recall arrangements.

Stage 1a1 (and any CIN) completely excised by total hysterectomy

- hrHPV vault tests at 6 and 18 months, if negative no further follow-up is required
- ceasing recall and informing CSAS is a clinical decision to be made by the clinical team.

## **Trachelectomy**

• Patients undergoing radical trachelectomy should remain under the care and guidance of gynaecology. Follow up is recommended by colposcopy and hrHPV testing. Cervical screening reports will indicate refer to colposcopy in the patient management advice.

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# <u>No cervical or vault cytology follow-up after radical surgery (Wertheim's hysterectomy) or radiotherapy</u>

- The follow up of patients 1a2 or greater should be through the Gynaecological Oncology team.
- Vault cytology can be difficult to interpret after radiotherapy and should be avoided.
- There is no evidence to support earlier detection of recurrence using cytology compared with clinical evaluation alone.
- There is no evidence to determine the frequency or length of follow up but this is typically 3-5 years.
- Patients and GPs need to be aware of symptoms of recurrence such as vaginal bleeding and pain.

## Distribution list / dissemination method

These guidelines will be made available on the Trust's Intranet site.

## **Clinical Audit**

- 1. Reasons for inadequate samples are audited within the laboratory. Inadequate rates and evidence of transformation zone sampling are fed back to smear takers on request.
- 2. All samples should carry an appropriate management recommendation this is continuously monitored by the follow-up and failsafe systems within the laboratory and the call and recall agency.
- 3. Invasive cancers are discussed and reviewed at the gynaecological cancer weekly multidisciplinary team meeting (MDM) and the laboratory takes part in the National Invasive Cancer Audit. Mismatch cases are discussed at the monthly colposcopy MDM.
- 4. Quarterly and annual KC61 returns monitor performance indicators and correlation with histology.
- 5. Performance figures for screeners, biomedical scientists, consultant biomedical scientists and pathologists are produced on a quarterly basis.



# Trust Guideline for the Management of: Cervical Cytology

NHSCSP documentation is now only available as electronic versions

- 1. Cervical screening Guidance for Laboratories <u>https://www.gov.uk/government/publications/cervical-screening-laboratory-hpv-testing-</u> <u>and-cytology-services/cervical-screening-guidance-for-laboratories-providing-hpv-testing-</u> <u>and-cytology-services-in-the-nhs-cervical-screening-programme</u>
- Colposcopy and Programme Management. <u>https://www.gov.uk/government/publications/cervical-screening-programme-and-</u> <u>colposcopy-management</u>.
- 4. Guidance for acceptance of cervical screening samples in laboratories <u>https://www.gov.uk/government/publications/cervical-screening-accepting-samples-in-laboratories?utm\_source=b93a64cc-77c9-413f-9f61-673da1574353&utm\_medium=email&utm\_campaign=govuk-notifications&utm\_content=daily</u>
- 5. Managing safety incidents in NHS screening programmes

Managing safety incidents in NHS screening programmes - GOV.UK (www.gov.uk)

6. Cervical screening: Programme Specific Operating Model for Quality Assurance of Cervical Screening Programmes

https://www.gov.uk/government/publications/cervical-screening-programme-specific-operating-model/cervical-screening-programme-specific-operating-model

- NHS Cervical Screening Programme: laboratory quality control and assurance for human papillomavirus testing <u>https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment</u> <u>\_data/file/773338/Appendix\_1\_cervical\_screening\_protocol.pdf</u>
- European guidelines for quality assurance in cervical cancer screening: recommendations for clinical management of abnormal cervical cytology. Cytopathology 2008, 19 (6), 342 – 354.
- 9. Clinical Practice Guidance for the Assessment of Young Women aged 20 -24 with abnormal vaginal bleeding.

https://www.gov.uk/government/publications/abnormal-vaginal-bleeding-in-women-under-25-clinical-assessment

10. NHS cervical screening website for England.

https://www.gov.uk/topic/population-screening-programmes/cervical

11. Guidelines for the management of gynaecological cancer. Anglia Cancer Network 2019

https://www.nnuh.nhs.uk/publication/download/anglia-gynae-cancer-networks-network-guideline-july-2019/



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## <u>Guidance on Management of Women with Gynaecological Symptoms</u>

Cervical cytology is a useful screening tool for the detection of pre-cancerous changes. It is not however useful in the investigation of women with symptoms, not least because of the high false positive rate associated with inflammatory cellular changes but also because precancerous changes (Cervical Intraepithelial Neoplasia / CIN) are asymptomatic.

Visual inspection of the cervix and vagina and pelvic examination is encouraged. If a suspicious growth is identified this should prompt urgent referral to a Gynaecologist through the two-week wait system. Do not take a cytology sample.

### Vaginal Discharge

Sexually transmitted infections should be considered and chlamydia testing is advised. Referral to GU medicine should be considered if symptoms are persistent. CIN does not cause these symptoms and so cervical cytology is not appropriate. If on examination a suspicious growth is identified this should prompt urgent referral to a Gynaecologist through the two-week wait system. Do not take a cytology sample.

### Post-coital bleeding (PCB)

Sexually transmitted infections should be considered and chlamydia testing is advised. Referral to GU medicine or Gynaecology should be considered if symptoms are persistent. CIN does not cause these symptoms and so cervical cytology is not appropriate. If on examination a suspicious growth is identified this should prompt urgent referral to a Gynaecologist through the two-week wait system. Do not take a cytology sample.

#### Inter-menstrual bleeding (IMB)

Sexually transmitted infections should be considered and chlamydia testing is advised. Other causes include hormonal contraceptives, dysfunctional uterine bleeding, cervical and endometrial polyps and fibroids. Referral to GU medicine or Gynaecology should be considered if symptoms are persistent.

CIN does not cause these symptoms and so cervical cytology is not appropriate. If on examination a suspicious growth is identified this should prompt urgent referral to a Gynaecologist through the two-week wait system. Do not take a cytology sample.

## Post menopausal bleeding (PMB)

Urgent referral to a gynaecologist is advised. Do not take a cytology sample.

#### For management of abnormal vaginal bleeding in women under 25 years, consult the Department of Health publication: 'Clinical Practice Guidance for the Assessment of Young Women aged 20 – 24 with Abnormal Vaginal Bleeding'

#### https://www.england.nhs.uk/south/wp-content/uploads/sites/6/2016/10/guidance-20to24.pdf