Clinical Points Release as a meeting report of the National Colposcopy PAG meeting.

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1 Screening interval
The NHS Cervical Screening Programme (NHSCSP) offers screening at different intervals, depending on a woman’s age:

1.1 Age group (years) Frequency of invitation
- Under 24.5 No invitation
- 24.5 First invitation (to ensure that women can be screened for the first time by their 25th birthday)
- 25-49 Every three years
- 50-64 Every five years

65+ Invitation as required for women who have had recent abnormal tests. Women who have not had an adequate screening test reported since age 50 may be screened on request.

1.2 Unscheduled screening
Unscheduled cervical screening does not form part of the NHSCSP. Provided a woman has undergone screening within the recommended interval (depending on her age), she should not be re-screened:
- On taking, or starting to take, an oral contraceptive
- On insertion of an intrauterine contraceptive device (IUD)
- On taking or starting to take HRT
- In association with pregnancy (antenatally or postnatally)
- On being diagnosed with genital warts or pelvic infection
- Due to heavy cigarette smoking
- Due to having multiple sexual partners

Women with cervical symptoms, including persistent vaginal discharge that cannot be otherwise explained (e.g. by an infection), should be referred in a timely manner for further evaluation of the cervix. Specific management algorithms have been published to manage women under 25 who have symptoms of cervical cancer.

1.3 Cervical sampling in genitourinary medicine (GUM) clinics
The indications for performing cervical cytology in GUM clinics are no different to those for the rest of the NHSCSP. Cervical samples taken for screening
purposes in GUM clinics should be restricted to women who have not been screened in the previous routine screening interval. Cervical screening sample takers in GUM clinics should be able to demonstrate appropriate training. The criteria for referral to a designated colposcopy clinic for women requiring further assessment remain the same as for the rest of the NHSCSP.

The specificity and sensitivity of cervical cytology for the identification of sexually transmitted infections by cervical cytology is not high enough to permit this test to be used as a diagnostic tool.

1.4 Withdrawal from screening

1.4.1 Voluntary withdrawal

Women can withdraw from the programme via a written request. Reasons for voluntary withdrawal may include:

- Women at low risk of cervical cancer, for example women who have never had intimate contact with another person (male or female).
- Women with a physical or learning disability of a nature that makes taking a sample very difficult or distressing, who do not wish to receive further invitations.
- Women may not benefit from screening, for example those who are terminally ill.
- Women who for any reason (for example, circumcision) are unable to give an adequate sample. Alternative options such as gynaecological referral should be discussed and agreed with the woman.
- Women who do not want to participate at any point.

Health professionals must ensure that all women who express a wish to withdraw are provided with sufficient and accurate information to make an informed decision. Such women should never be ceased without their informed consent to withdraw. In all cases, the woman should be offered an appointment with an appropriate health professional to discuss their withdrawal.

1.4.2 ‘Best interests’ decisions

Rarely, a woman may be unable to make either an informed choice to accept a screening invitation or to withdraw from the screening programme permanently. Under the Mental Capacity Act (2005), decisions can be made on behalf of such women by a legally authorised representative.

A ‘best interests’ decision must be the least restrictive of all possible options and so, in most cases, it is preferable to continue with regular invitations at routine intervals, which can be accepted or declined individually.
1.4.3 Medical reasons for ceasing a woman

Women should be ceased from the programme where they do not have a cervix due to:

- Having undergone total hysterectomy (women with a subtotal hysterectomy remain at risk and should remain in the programme)
- Congenital absence of the cervix
- Being a male-to-female transsexual
- Women who have undergone radical trachelectomy for cervical cancer

1.4.4 Radiotherapy

It is difficult to report accurately samples from women who have undergone radiotherapy for cervical, bladder, rectal and other pelvic cancers. This group should be ceased from the programme, and instead referred for gynaecological follow-up.

All cases should be considered individually, and women who are unsuitable for screening can be ceased from the programme.

1.4.5 Cervical stenosis

It may not be possible to obtain a cytology sample that represents the whole transformation zone from women who have severe cervical stenosis (often a result of previous surgery). Cervical dilatation should be considered in all such cases, but for women with a history of high-grade cytology or CGIN, hysterectomy can also be considered. Involvement of the colposcopy MDT may be useful when making this decision. Where neither cervical dilatation nor hysterectomy is appropriate, the lead colposcopist should consult with the woman and a joint decision may be reached to withdraw her from the NHSCSP. Where the woman declines withdrawal, she should continue to receive invitations to screening.

1.4.6 Automatic ceasing

Women will be automatically ceased from the programme if their next test date falls after their 65th birthday and their last three tests (fewer if less than three in the screening history) were taken at the appropriate intervals, with adequate samples and normal results. Women who have not responded to invitations can also be ceased if their next test is due after their 65th birthday.

2 Screening strategies

2.1 Liquid-based cytology

The current standard screening modality within the NHSCSP is liquid-based cytology (LBC).
2.2 HPV testing

2.2.1 Background to HPV triage and test of cure: pilots and Sentinel Sites

In light of the evidence from the pilot and Sentinel Sites, national rollout of HR-HPV triage for women with borderline or low-grade cytology results and HR-HPV test of cure was completed in 2013.

2.2.2 HPV triage and test of cure

Under the HR-HPV triage protocol, women whose cervical samples are reported as showing borderline changes (of squamous or endocervical type) or low-grade dyskaryosis are given a reflex HR-HPV test. Those who are HPV positive are referred to colposcopy; those who are HR-HPV negative are returned to routine recall. Women whose cervical sample is reported as high-grade dyskaryosis or worse are referred straight to colposcopy without an HR-HPV test.

Under the HR-HPV ‘test of cure’ protocol, after treatment for all grades of CIN women are invited back 6 months after treatment for a repeat cervical sample in the community. A woman whose sample is reported as negative, borderline change (of squamous or endocervical type), or low-grade dyskaryosis are given an HR-HPV test. Those who are HPV negative are recalled for a screening test in three years (irrespective of age) and can be returned to routine recall if the subsequent test result is cytologically negative; those who are HR-HPV positive are referred back to colposcopy. Women whose cytology is reported as high-grade dyskaryosis or worse are referred straight to colposcopy without an HR-HPV test.

3 Cancer waiting times: national policy

The NHS Cancer Plan (2000) introduced a number of service standards related to cancer waiting times (CWT) for women referred or treated for cancer. Its provisions were amended and extended by the Cancer Reform Strategy (2007), which specified that women referred from the NHSCSP for colposcopy were included in the wait guidelines. The wider issue of hospital waiting times was tackled in the NHS Improvement Plan (June 2004),v which specified that no individual should wait longer than 18 weeks from GP referral to treatment, while The operating framework for the NHS in England 2012/13 (2011) controlled the interval between a positive primary screening test and a diagnostic test. Cancer waiting times are monitored by the Health and Social Care Information Centre.
3.1 Cancer wait and referral standards applicable to the NHSCSP

The standards applicable to the NHSCSP are:

- No more than two months (62 days) should elapse between receipt of a referral from a cancer screening service to first treatment for cancer (Target >85%).
- No more than one month (31 days) should elapse from diagnosis (decision to treat) to first treatment for all cancers (Target >96%).
- Women should wait no longer than 18 weeks between GP referral and treatment (or discharge) after cancer has been excluded.
- No more than 1% of patients should wait longer than six weeks for a diagnostic test (colposcopy qualifies as a diagnostic test).
- Waiting times are measured in calendar days, not working days, and the date of receipt of referral counts as day 0 in all calculations.

The NHSCSP also sets its own standards for the programme that are designed to ensure that all services meet these national requirements. These are outlined in the appropriate sections, below.

3.2 Cytological reports

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

3.2.1 Inadequate samples

3.2.1.1 Cytological management of inadequate samples

Where an initial LBC sample is reported as inadequate, cytology should be repeated. The repeat sample should not be taken less than three months after the previous test. In addition, a sample must be reported as inadequate if the sample-taker has not completely visualised the cervix, or if the sample has been taken in an inappropriate manner, for example with a sampling device that has not been approved by the NHSCSP.

Samples must not be reported as inadequate if they contain any evidence of borderline change or dyskaryotic cells.

Referral on the basis of consecutive inadequate samples

After three consecutive inadequate samples, a woman should be referred to colposcopy. She should be seen by the colposcopist within 6 weeks of referral.

3.2.2 Scanty samples

In some cases, a scanty sample will be sufficient to allow an abnormal cytology report to be issued, but inadequate to provide a reliable HR-HPV test result.
Scanty samples that show no abnormalities should not ordinarily be tested for HPV. When planning further action, however, it is important to be mindful of the effect of low cellularity on the reliability of cytology results.

3.2.3 Negative results
Adequate samples with no abnormal cells are classified as negative. Women who receive a negative report can be safely returned to routine recall.

3.2.4 Borderline change in squamous or endocervical cells

3.2.4.1 Cytological management of borderline change in squamous and endocervical cells
When borderline change is reported in either endocervical or squamous cells on a cytology sample, a reflex HR-HPV test is performed. Women who have borderline change of either type and who test positive for HR-HPV must be referred for colposcopy. Women who are HR-HPV negative are returned to normal recall.

If a sample is scanty, HR-HPV testing may be attempted, but should only be considered reliable where the result is positive, or where the validity of a negative result is confirmed by an internal control. In case of scanty samples in which cytology is reported as borderline but the HR-HPV test result is negative, a further sample should be taken in six 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 who are positive for HR-HPV should be referred to colposcopy. Women who are negative for HR-HPV can be returned to routine recall.
- If the second screen is reported as high-grade dyskaryosis (moderate) or worse, the woman should be referred straight to colposcopy. An HR-HPV test is not necessary.

3.2.4.2 Referral wait time for borderline change in squamous and endocervical cells
All women who are HR-HPV positive and have borderline change in squamous and endocervical cells reported in their LBC cytology sample must be referred to colposcopy. They should be seen within six weeks of referral (99%).

3.2.5 Low-grade dyskaryosis

3.2.5.1 Management of low-grade dyskaryosis
When low-grade dyskaryosis is reported on a cytology samples, a reflex HR-HPV test will be performed.
If the HR-HPV test is positive, the woman must be referred for colposcopy. If the HR-HPV test is negative, the woman must be returned to routine recall. Women with a low-grade result who are also HPV positive and who attend for colposcopy should be seen and assessed. To prevent possible overtreatment, however, they should not be managed on a ‘See and Treat’ basis. For information on follow-up after treatment and on the surveillance of women who have not been treated.

3.2.5.1 Referral wait time for low-grade dyskaryosis
All women who are HR-HPV positive and have low-grade dyskaryosis reported in their LBC cytology sample must be referred to colposcopy. They should be seen within six weeks of referral (99%).

3.2.6 High-grade dyskaryosis (moderate)
3.2.6.1 Management of high-grade dyskaryosis (moderate)
Women must be referred for colposcopy after one test is reported as high-grade (moderate or severe) dyskaryosis. A HR-HPV test is not necessary.

3.2.6.2 Referral wait time for high-grade dyskaryosis (moderate)
Women whose liquid-based cytology samples are reported as high-grade dyskaryosis (moderate) are included in the 62-day standard introduced by the Cancer Reform Strategy. Since the clock for the 62-day period runs from receipt of the referral from the NHSCSP until the start of the first definitive treatment (should the woman be discovered to have cancer), prompt referral to colposcopy is necessary. If a woman is not referred directly to colposcopy, her GP must make an urgent referral through the ‘two week wait’ pathway. The woman should be seen by a colposcopist within 2 weeks (93%).
Receipt of this referral at the acute provider is the starting point for the 18-week commitment, should the woman receive a benign diagnosis.

3.2.7 High-grade dyskaryosis (severe)
3.2.7.1 Management of high-grade dyskaryosis (severe)
Women must be referred for colposcopy after one test is reported as high-grade dyskaryosis (severe).

3.2.7.2 Referral wait time for high-grade dyskaryosis (severe)
Women whose liquid-based cytology samples are reported as high-grade dyskaryosis (severe) are included in the 62-day standard introduced by the Cancer Reform Strategy. Since the clock for the 62-day period runs from receipt of the referral from the NHSCSP until the start of the first definitive
treatment (should the woman be discovered to have cancer), prompt referral to colposcopy is necessary. If a woman is not referred directly to colposcopy, her GP must make an urgent referral through the ‘two week wait’ pathway. The woman should be seen by a colposcopist within 2 weeks of referral (90%). Receipt of this referral at the acute provider is the starting point for the 18-week commitment, should the woman receive a benign diagnosis.

### 3.2.8 Invasive squamous cell carcinoma

#### 3.2.8.1 Cytological management of invasive squamous cell carcinoma

Women must be referred for colposcopy after one test is reported as invasive squamous cell carcinoma.

#### 3.2.8.2 Referral wait time for invasive squamous cell carcinoma

Women whose liquid-based cytology samples are reported as invasive squamous cell carcinoma are included in the 62-day standard introduced by the Cancer Reform Strategy. Since the clock for the 62-day period runs from receipt of the referral from the NHSCSP until the start of the first definitive treatment (should the woman be discovered to have cancer), prompt referral to colposcopy is necessary. If a woman is not referred directly to colposcopy, her GP must make an urgent referral through the ‘two week wait’ pathway. The woman should be seen by a colposcopist within 2 weeks of referral (>90%). Receipt of this referral at the acute provider is the starting point for the 18-week commitment, should the woman receive a benign diagnosis.

### 3.2.9 Glandular neoplasia

#### 3.2.9.1 Referral pathway for glandular neoplasia

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

In cases in which the abnormal glandular cells probably originated from the endocervix, or the source is not specified, the woman must be referred for colposcopy. If a woman is not referred directly, the GP must make an urgent referral through the ‘two-week wait’ pathway. In cases in which 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. If a woman is not referred directly, the GP must make an urgent referral through the ‘two-week wait’ pathway.

Referrals to gynaecology clinics are not part of the screening programme and may be managed according to local protocols. The following guidance should be followed to ensure appropriate management.
The woman’s individual circumstances must be considered holistically. A referral combining cervical and extra-cervical investigations may be feasible in some cases. Communication with the woman’s GP may be advisable to avoid causing distress if the woman is already under treatment for the suspected condition.

A member of the consultant medical staff at the cervical cytology laboratory must decide on the types and priorities of referrals required and ensure that each referral is made in a timely manner. Note that gynaecological referrals will not be covered by programme-wide failsafe systems.

Arrangements must be made to inform the woman of her diagnosis of non-cervical glandular neoplasia.

Such communications are particularly sensitive, as the woman may have received a screening result letter referring to a negative, borderline, or low-grade cytological abnormality.

In rare cases, a woman’s cytology test may reveal the co-existence of non-cervical glandular neoplasia with cervical abnormalities. Treatment of the former falls outside the scope of the screening programme; therefore it is the latter result that is recorded and sent to NHAIS to determine the woman’s management within the screening programme. This ensures that the woman is subject to NHSCSP failsafe systems.

### 3.2.9.2 Referral wait time for ?glandular neoplasia

Whatever the source of the abnormal glandular cells, if a woman is not referred directly to colposcopy or gynaecology services, she must be referred by her GP via the ‘two week wait’ pathway. The woman must be seen urgently, within two weeks of referral (90%).

### 3.3 Difficult cases

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 cytologist, colposcopist, and histopathologist at the colposcopy multi-disciplinary team meeting before future management is decided.
Summary of referral/waiting time standards

<table>
<thead>
<tr>
<th>Cytology/HPV</th>
<th>Wait/CWT pathway</th>
<th>NHSCSP standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 consecutive inadequate samples</td>
<td>18 week pathway, upgraded to 62 days if cancer subsequently suspected</td>
<td>Offered an appointment with a colposcopist within 6 weeks</td>
</tr>
<tr>
<td>Borderline change/ HR-HPV positive</td>
<td>18 week pathway, upgraded to 62 days if cancer subsequently suspected</td>
<td>Offered an appointment with a colposcopist within 6 weeks</td>
</tr>
<tr>
<td>Low-grade/ HR-HPV positive</td>
<td>18 week pathway, upgraded to 62 days if cancer subsequently suspected</td>
<td>Offered an appointment with a colposcopist within 6 weeks</td>
</tr>
<tr>
<td>High-grade (moderate)</td>
<td>62 day pathway / 2 week urgent GP referral; (move to 18 week pathway if cancer excluded)</td>
<td>Offered an appointment with a colposcopist within 2 weeks of referral</td>
</tr>
<tr>
<td>High-grade (severe)</td>
<td>62 day pathway / 2 week urgent GP referral; (move to 18 week pathway if cancer excluded)</td>
<td>Offered an appointment with a colposcopist within 2 weeks of referral</td>
</tr>
<tr>
<td>?Invasive squamous carcinoma</td>
<td>62 day pathway / 2 week urgent GP referral; (move to 18 week pathway if cancer excluded)</td>
<td>Offered an appointment with a colposcopist within 2 weeks of referral</td>
</tr>
<tr>
<td>?glandular neoplasia of endocervical type or not otherwise specified (NOS)</td>
<td>62 day pathway / 2 week urgent GP referral; (move to 18 week pathway if cancer excluded)</td>
<td>Offered an appointment with a colposcopist within 2 weeks of referral</td>
</tr>
<tr>
<td>?glandular neoplasia cells of other origin - referral outside NHSCSP</td>
<td>62 day pathway / 2 week urgent GP referral; (move to 18 week pathway if cancer excluded)</td>
<td>Offered an appointment with a gynaecologist within 2 weeks of referral</td>
</tr>
<tr>
<td>Abnormal cervix (outside the NHSCSP)</td>
<td>62 day pathway / 2 week urgent GP referral; (move to 18 week pathway if cancer excluded)</td>
<td>Offered an appointment with a gynaecologist within 2 weeks of referral</td>
</tr>
<tr>
<td>Symptomatic (outside the NHSCSP)</td>
<td>62 day pathway / 2 week urgent GP referral; (move to 18 week pathway if cancer excluded)</td>
<td>Offered an appointment with a gynaecologist within 2 weeks of referral</td>
</tr>
</tbody>
</table>

3.4 Benign endometrial cells in cervical samples

The significance of cytologically benign endometrial cells in cervical samples varies with the phase of the menstrual cycle, and with the drug, clinical history, and age of the woman. However, in a population based cervical screening programme, some, if not most, of the information listed above is often
unavailable. This should be reflected in the clinical management advice provided. There is now a considerable body of evidence suggesting that endometrial cells in a sample from a woman under the age of 40 do not indicate significant endometrial pathology. Therefore, normal endometrial cells found in a cervical sample from a woman of this age need not be reported.

In women over the age of 40, normal endometrial cells are significantly more likely to be found in the cervical sample up to the twelfth day of the menstrual cycle than in the remainder of the cycle, and need not be specifically reported by the laboratory.

In women aged over 40, who are beyond the twelfth day of the menstrual cycle, the finding of normal endometrial cells in a cervical sample may indicate endometrial pathology ranging from benign polyps to carcinoma. The association of normal endometrial cells in a cervical sample with significant pathology (endometrial hyperplasia and neoplasia) increases with age: it has been reported that endometrial disease may be found in up to 13% of women over the age of 60 with normal endometrial cells in their sample.

However, normal endometrial cells found beyond the twelfth day of the menstrual cycle in an individual over 40 may not indicate pathology if the woman is receiving oral contraceptives, hormone replacement therapy, or tamoxifen, or where an IUCD has been fitted.

Normal endometrial cells identified in a sample from a woman aged 40 or over should always be reported if the menstrual, drug, and contraceptive history are not known (see above). They should also be reported where they are found in any postmenopausal woman, accompanied by a comment similar to the following:

- ‘Endometrial cells are present in a woman aged over 40. Such cells may be associated with endometrial pathology, particularly if out-of-phase or after the menopause. Referral for a gynaecological opinion should be considered in light of the menstrual, drug, and clinical history.’

If the day of the menstrual cycle is not known, and the sample is otherwise negative, then it should be reported as negative, with a comment similar to the following: ‘Endometrial cells are present but menstrual history not stated. If there is any history of abnormal vaginal bleeding, referral for a gynaecological opinion should be considered.’

3.5 Abnormal cervix

Sample-takers must visualise a woman’s cervix when taking an LBC sample. If they notice abnormalities, the woman should be referred for gynaecological examination.
3.5.1 Referral guidelines for women an abnormal cervix
Women with an abnormal cervix must be seen urgently, within two weeks of referral.

3.6 Women with symptoms
3.6.1 Management of women with symptoms
The NHSCSP is a population-based screening programme, designed to reduce the incidence of, and mortality from, cervical cancer by detecting disease at an early stage of its development. Women presenting with symptoms of cervical cancer (e.g. postcoital bleeding, persistent vaginal discharge that cannot be explained by infection or other causes) are not suitable candidates for screening. If the common causes of these symptoms have been excluded in general practice e.g. infection, type of contraception usage, they must instead be referred for examination by a gynaecologist experienced in the management of cervical disease (for example a cancer lead gynaecologists). Gynaecologists may refer these women on for symptomatic colposcopic examination outside the NHSCSP if cancer is suspected.
Contact bleeding at the time of cervical sampling may occur, and is not an indication for referral to colposcopy in the absence of other symptoms.

3.6.2 Referral guidelines for women with symptoms
Women with symptoms of cervical cancer must be seen urgently, within two weeks of referral.

3.7 Previous treatment for CIN and ‘test of cure’
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 test of cure 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.
3.8 Previous treatment for CGIN

Women who undergo excision for CGIN are at risk of recurrence. If the CGIN has been completely excised, at the time of first excision or subsequent re-excision, a test of cure (TOC) sample should be taken 6 months after treatment. If negative for cytology (endocervical cells must be present) and negative for HR-HPV a second TOC sample is taken 12 months later (i.e. 18 months after treatment) - if this is also negative for cytology and HR-HPV the woman can be discharged to recall in 3 years. Further recall will depend on the result of this test and the age of woman. These samples can be performed in the community. If either cytology or HR-HPV, at six or 18 months after treatment, is positive the woman should be referred to colposcopy.

If the woman fails TOC at six months only because of a positive HR-HPV test and no abnormality is detected at colposcopic examination the woman should have a second TOC sample twelve months later, if this sample is negative for cytology and HR-HPV the woman can be discharged to recall in 3 years. Further recall will depend on the result of this test and the age of woman. If a positive cytology result is reported in either of the 6 or 18 months ‘TOC’ samples the woman must be referred to colposcopy and managed appropriately. If no colposcopic abnormality is present and re-excision is not appropriate the women should revert to 10 years of cytology follow up. Women who have incompletely excised CGIN and have declined re-excision should be followed up in the colposcopy clinic. Cytology should be performed 6 months after treatment and if negative repeated 6 months later (i.e. at 12 months after treatment) and then annually for the subsequent 9 years. Complex CGIN cases will benefit from discussion at the colposcopy MDT.

4. Quality standards for colposcopy clinics
4.1 Good working practices
4.1.1 Quality Assurance

Whether it is provided in a gynaecological or GUM clinic or in primary care, colposcopy should be organised as a Quality Assured service.

The service must be run by a team working to the protocols and quality standards outlined in this document. Any problems arising in connection with colposcopy practice should be addressed in a confidential and supportive manner.

4.2 Role of lead colposcopist

Each colposcopy team must have a lead colposcopist, whose role is to ensure that good practice is followed, that protocols are observed, and that the quality standards outlined in this document are attained. The lead colposcopist
must also ensure that the service collects data to meet the minimum dataset of the British Society for Colposcopy and Cervical Pathology (BSCCP). This will ensure that the requisite information is available to enable the completion of KC65 (the mandatory annual Department of Health return) and audits.

4.3 Role of hospital-based programme coordinator

A hospital-based programme coordinator must be identified, and must take responsibility for ensuring that non-attendance and other Quality Assurance targets are monitored.

4.4 Audit of invasive cervical cancers

The Audit of invasive cervical cancers aims to understand why cervical cancers occur in spite of the existence of the cervical screening programme. The overall purpose of the exercise is to identify modifications to the programme that might reduce the incidence of invasive cervical cancer. There is an educational element to the audit, since it offers an opportunity to review the original management of each case of invasive cancer, and to determine whether it was appropriate.

The Audit collates data from different sources: screening invitations, cytology results, colposcopy attendance, and histology. Since April 2013, colposcopy services participating in the NHS Cervical Screening Programme have been required to provide data on their performance. Any colposcopic examinations that predate the index referral by up to five years are reviewed since these examinations (and associated management) may have impacted on the development of cervical cancer. The reviewer will check whether the colposcopic management of the woman reflected the NHSCSP guidelines pertaining at the time. The aim is to improve education through assessment of potential errors, so any colposcopic examinations associated with the index referral cytology and made within 18 weeks of the subsequent diagnosis of cervical cancer does not require routine review.

In most cases, the lead colposcopist at the unit where the diagnosis of the cancer was made will undertake the review. She or he must include notes from other clinics where necessary. However, if the lead colposcopist participated in the management of the woman, another British Society for Colposcopy and Cervical Pathology (BSCCP) certified colposcopist from the same unit should undertake this task.

Women who have participated in the screening programme, but who have subsequently developed invasive cervical cancer, should be offered an opportunity to review the results of their previous tests (cytology and colposcopy). The local cancer team must decide how this disclosure is
managed, taking into account the principles for disclosure outlined in the *Audit of Invasive Cervical Cancers* (NHSCSP Publication No 28).

### 4.5 NHAIS

Decisions made by colposcopists directly influence a woman’s management, including the interval to any follow-up tests. If follow-up tests are managed by the colposcopy service, details of the test results should be added to the woman’s screening record on NHAIS to ensure that no premature or inappropriate recall invitations are produced by the failsafe system.

If follow-up tests are to be carried out in primary care, colposcopy services will need to communicate information on each woman’s screening recall due date to call/recall departments to allow the NHAIS system to produce an automatic invitation at the correct interval. In practice, it is preferable for these updates to be communicated electronically in a standard format and using a secure mechanism for the transfer of information.

### 4.6 Certification

All colposcopists in the team must be certificated through the BSCCP/Royal College of Obstetricians and Gynaecologists (RCOG) scheme. They must undergo the recertification process every three years in order to maintain levels of expertise and ensure that individuals are completing a sufficient caseload.

To achieve recertification, a colposcopist must pursue continued medical education (CME) to ensure that they are abreast of developments in scientific knowledge and clinical practice. Suitable CME opportunities include attendance at regional educational meetings arranged by the colposcopy Quality Assurance teams, advanced colposcopy courses, and the BSCCP Annual Meeting.

Those who are actively engaged in providing colposcopic services should also be able to demonstrate, through audit activity, workload, attendance at meetings, and other educational events (such as general revalidation), that they are maintaining their knowledge base and competency.

It is the view of the NHS Cervical Screening Programme that independent colposcopy should be conducted in the NHS only by competent practitioners.

### 4.7 Clinic staffing and facilities

Every colposcopy service requires at least one colposcopy nurse whose duties are to ensure the smooth running of the clinic and the provision of support to the woman being screened.
A second trained member of staff will be needed to assist in making the necessary preparations for cervical sampling, biopsies, and treatment. Nurse colposcopists working in a clinic must receive the same level of support. All clinic staff must be familiar with the treatment method(s) used (100%).

The colposcopy service requires adequate clerical and secretarial support to ensure timely communication with patients and their GPs. In addition, administrative support is needed to ensure efficient data collection, effective communication with other agencies, and robust failsafe mechanisms.

4.8 Operational meetings
The colposcopy team should hold operational meetings.

Operational meetings should be arranged at least quarterly to discuss clinic policy, protocol problems, findings of audit and peer review visits, and any areas where the clinic falls short of quality standards.

4.9 Reducing anxiety for women
Information and communication

Effective information and communication are crucial to reducing anxiety.

Each woman should be offered verbal information and sent written information before and after cervical screening, and before colposcopy (95%). Women must be sent an appropriately worded invitation. This must contain the name of a contact at the clinic, a telephone number for the clinic, and the clinic’s times.

Information concerning the visit to the clinic and the results of investigations should be communicated to the patient within four weeks of her attendance (best practice 90%). All results must be communicated within eight weeks (minimum standard 100%).

In addition to the national information leaflets, information leaflets tailored to the needs of the local population should be available at each clinic. Counselling must be available as an integral part of colposcopy.

Results and management plans should be communicated to the GP or the referrer within four weeks of the patient’s attendance at the clinic (best practice 90%). All results must be communicated to these parties within eight weeks (minimum standard 100%).

4.10 Black and minority ethnic groups
Culturally appropriate information should be made available for members of minority ethnic groups.
Good practice dictates that patients should have their history taken and be counselled with an independent interpreter present. Friends or family members should not undertake this role.

4.11 Information given to women having outpatient treatment

Where a woman is considering outpatient treatment, providing relevant information can reduce the risk of harmful consequences. Women should be advised:

- To avoid using tampons for four weeks following treatment.
- To abstain from vaginal intercourse for four weeks following treatment.
- To avoid swimming for two weeks following treatment.
- That they may drive following loop excision or local treatment, unless advised otherwise by the examining colposcopist.
- That they may consume alcohol in moderation after treatment.
- That other normal activities, including light exercise, may continue.
- That, although there are no known health grounds for avoiding travel following treatment, overseas medical attention for complications arising from the treatment may not be covered by insurance.
- That there may be a temporary change in their menstrual pattern following loop excision.
- That single conisation, cervical diathermy, and loop excision measuring less than 10mm in length/depth is not associated with any increase in the incidence of preterm labour and preterm pre-labour rupture of membrane.
- That single conisation, cervical diathermy, and loop excision is not associated with any increased risk of infertility but may increase the risk of mid-trimester miscarriage.

4.12 ‘See and Treat’ clinics

Clinics operating a ‘See and Treat’ policy must ensure that women who are offered treatment at their first visit have been sent adequate and appropriate information in advance of their appointment (100%).

4.13 History taking

Appropriate and sensitive enquiries regarding sexual history may be made, but only under the auspices of an ethically approved study, or if the patient presents with a specific indication.
4.14 Clinic facilities
The clinic’s facilities must include:
- A private area with changing facilities.
- Toilet facilities.
- A permanently sited specific room for colposcopy (100%).
- Refreshment facilities.
- Separate waiting and recovery areas.

4.16 Visitors to the clinic
Women should be able to have a friend or relative present if they wish. The patient’s consent should be sought prior to colposcopy if anyone not essential for its performance is to be present (e.g. trainees, undergraduates, or visitors).

4.17 Equipping the colposcopy clinic
The clinic environment should be welcoming and protect the patient’s dignity. Patients should be given time to discuss their care both before and after the colposcopy examination and/or treatment.

The following equipment must be available in the colposcopy clinic:
- A permanent couch and colposcope.
- Suitable sterile instruments and/or sterilising facilities, compliant with local and national health and safety recommendations.
- Adequate and immediately accessible resuscitation equipment, and staff involved in the clinical care of patients who are familiar and trained in its use.
- Suitable IT equipment.
- Software to facilitate collection of data for the BSCCP minimum data set and for submission of the statutory quarterly KC65.

Where possible, television monitoring facilities should be made available for patients who wish to watch the procedure.

Additionally:
- If laser or diathermy equipment is in use, adequate safety guidelines should be in place, and all staff must be trained in the operation of this equipment. Clearly written and easily accessible emergency guidelines must also be available in each clinic. These must conform with local protocols.
- In units offering an exclusively diagnostic service, there must be automatic referral to a unit where treatment is available if needed.
4.18 Non-attenders
With respect to patient non-attendance:
- There must be written protocols for the management of non-attenders.
- Audit should include analysis of the records of defaulters to discern any patterns that could be addressed to reduce the default rate.
- The default rate should be less than 10%.

4.19 Multidisciplinary working
4.19.1 Liaison with other units
Effective liaison between units is an essential component of high-quality integrated patient care:
- Colposcopy clinics within GUM clinics must have established protocols for liaison with gynaecological services. (100%)
- Colposcopy clinics within gynaecology services should have established protocols for liaison with GUM services. (100%)
- Colposcopy clinics should have established protocols for liaison with cytology laboratories and the call and re-call service. (100%)
- Multidisciplinary audit must be an integral part of the service. (100%)
- There should be well-established clinical and computer links with cytological and histological services to support multidisciplinary working.
- Colposcopy clinics should have protocols describing failsafe mechanisms. (100%)
- Colposcopy clinics should have protocols describing the notification procedure for future community based cytological recall. (100%)

4.20 The Colposcopy Multidisciplinary Meeting
4.20.1 The primary purpose of the meeting is to plan the management of patients with discordant histology, cytology and colposcopic findings:
- All meetings must be attended by a minimum of one colposcopist and one person to present and discuss the histology and cytology.
- All histology must be reviewed prior to the meeting by a consultant histopathologist who undertakes the reporting of colposcopic histology. Advanced practitioners in cervical cytology (AP's) may then present histology after discussing it with a consultant histopathologist.
- The cytology must be reviewed prior to the meeting and may be reviewed and presented by an AP or consultant pathologist who reports cervical cytology routinely.
- All colposcopists must attend at least half the meetings.
- Lead cytopthologists should attend some of the meetings.
• Meetings must be held at least 6 times/year though monthly is best practice

4.20.2 Cases which should be discussed
There should be a clear local protocol. This is not an exhaustive list:

• All cases where high grade cytology has not been confirmed on colposcopy and/or histology
• Borderline change in endocervical cells, HPV+ with no abnormality on colposcopy and/or histology
• Any case where colposcopists wish to ask for an "off protocol" HPV test
• All cases of invasive cervical cancer
• There must be facilities for colposcopy, histology and cytology to add to the list any case where they have concerns they wish to discuss
• The outcome must be recorded in the patient notes and fed back to the managing clinician
• Outcomes should be recorded on the cytology computer system or other systems allowing access to cytology/histology in the future
• Regular audit is recommended

This guidance supersedes that given in NHSCSP document No.10

4.21 Training and certification of colposcopists
4.21.1 Training requirements
All practising colposcopists must be able to demonstrate that they have received an adequate training. The evidence required depends on when an individual’s training began:

• For those who began training after April 1998: BSCCP/RCOG Diploma in Colposcopy.
• For those who began training before April 1998 but had not completed training by April 1998: BSCCP Completion of Training Certificate.
• Self-certification is no longer permissible.

4.21.2 Training after April 1998
The joint BSCCP/RCOG training programme is currently the only recognised colposcopy training and certification programme for colposcopists who wish to practise within the NHSCSP and commenced training after April 1998.
The training can be undertaken as an Advanced Training Skills Module (ATSM) through the RCOG, but can also be taken via the BSCCP, since not all trainees will be affiliated with the RCOG (e.g. nurse colposcopists).

4.21.2 Training content and assessment
Training involves supervised and unsupervised colposcopic assessments, as well completion of an electronic colposcopy logbook. Attendance at histopathological and cytopathological sessions is also required. The final assessment method used is Objective Structured Clinical Examination (OSCE). This is a quality-assured examination that has been validated.

4.22 Maintenance of clinical skill and continued medical education (CME)
Colposcopists practising within the NHSCSP must see at least 50 new abnormal cytology referrals per year. Possession of a current BSCCP certificate does not exempt a colposcopist from achieving this standard.

All colposcopists must attend at least one BSCCP-recognised colposcopy meeting every three years. The NHSCSP considers compliance with the BSCCP recertification process to be highly desirable. Continued practice should be quality assured, with continuing personal development and regular audit. Discussion of practice should be included in colposcopists’ annual general appraisals.

5 Diagnostic standards for colposcopy
5.1 Cytology results
The cytology result should be available to the colposcopist before the colposcopic examination begins.

5.1.1 Repetition of cervical cytology
Cervical cytology should not be repeated at the first colposcopy following a referral for cytological abnormality. Where an initial cytology sample is inadequate, the repeat cytology sample should be taken no less than three months after the date of the first sample. HPV testing should not be repeated in a colposcopy clinic except after discussion at the colposcopy MDM.

5.2 Colposcopic examination
The following data should be recorded at the colposcopic examination:

- Reason for referral. (100%)
- Grade of cytological abnormality. (100%)
- Whether the examination was adequate or inadequate. (For the examination to be adequate the entire cervix must be seen). (100%)
• The visibility of the squamocolumnar junction - completely visible, partially visible, not visible
• The presence or absence of vaginal and/or endocervical extension.
• The colposcopic features of any lesion.
• The colposcopic impression of lesion grade.
• The type of transformation zone, i.e. type 1, 2 or 3.
• The site of any colposcopically directed biopsies

5.3 Invasive disease
Care must be taken not to overlook invasive disease. An excisional form of biopsy is recommended in the following circumstances:
• When most of the ectocervix is replaced with high-grade abnormality.
• When low-grade colposcopic change is associated with severe dyskaryosis or worse.
• When a lesion extends into the endocervical canal, sufficient cervical tissue should be excised to remove the entire endocervical lesion.

In the situations mentioned above, punch biopsies are not considered to be reliably informative. The colposcopist should be aware of the small risk of inappropriate or inadvertent destruction of invasive or glandular lesions. These are most often encountered in association with high-grade cytological or colposcopic change (CIN3). There may be pressing reasons for delaying biopsy, for example pregnancy. Reasons for not performing a biopsy must be recorded (100%).

5.4 Accuracy of colposcopic diagnosis
Where an adequate colposcopic examination has been conducted, the positive predictive value of a colposcopic diagnosis should be at least 65% for a high-grade lesion (CIN2 or worse)

5.5 Colposcopically directed punch biopsy
Unless an excisional treatment is planned, biopsy should be carried out when the cytology indicates moderate dyskaryosis or worse, and always when a recognisably atypical transformation zone is present (100%). Cases occurring in pregnancy are an exception.

Low-grade cytological abnormality (mild dyskaryosis or less) and a low-grade or negative colposcopic examination do not require colposcopic biopsy if there is no atypical transformation zone present. In deciding on treatment (and especially if destructive methods are being considered) associated cytological and colposcopic findings are as important as the result of directed biopsy.
5.6 Adequacy of biopsies
Of all biopsies taken (directed and excisional) >90% should be suitable for histological interpretation. If colposcopically directed biopsy is reported as inadequate for histological interpretation, it should be repeated if there is a residual colposcopic lesion. (95%)

5.7 Adjunctive tests in colposcopy
5.7.1 The dynamic spectral imaging system
The dynamic spectral imaging system (DySIS) is a digital video colposcope that also uses dynamic spectral imaging to evaluate the blanching effect of applying acetic acid to the epithelium (acetowhitening). It produces a quantitative measurement of the rate, extent and duration of the acetowhitenning that is summarised in a graphical display, called a DySIS map. This can be overlaid on a colour image of the tissue to help the clinician determine the presence and grade of any lesion. DySIS can be used within the NHSCSP, as long as the standard colposcopic guidelines and process are followed.

DySIS colposcopy has a higher sensitivity than conventional colposcopy: it can detect high-grade lesions with 88% sensitivity, compared to the 55% achieved in conventional colposcopy. It has also been demonstrated to have 97% sensitivity and 100% specificity in detecting patients that are HPV16 positive and have CIN2+ lesions. Conventional colposcopy often misses the smaller, high-grade lesions that could be present in patients with low-grade cytology results. In this subgroup, the DySIS clinical trials demonstrated a sensitivity of 77% in comparison with 19% for conventional colposcopy. The sensitivity is particularly important, given the pivotal role of colposcopy in the current NHSCSP HPV triage and Test of Cure of protocol for selecting which women with low grade smears and who are HPV positive can return to normal recall. DySIS should be seen as an adjunct to standard colposcopic indicators, however, additional training is required to ensure that users understand the correct use and interpretation of a DySIS map. During the initial 2 to 4 week period of user familiarisation with the system, it may be necessary for clinics to reduce the number of patients seen. NICE has evaluated the DySIS system and have concluded that the technology is suitable for use in NHS colposcopy clinics. Clinical trials have demonstrated that, when combined with all other usual colposcopic indicators, DySIS colposcopy can detect high-grade lesions with 88% sensitivity, compared to the 55% achieved in conventional colposcopy.

5.7.2 ZedScan
ZedScan utilises electrical impedance spectroscopy (EIS) as an adjunctive real time test to colposcopy. EIS is independent of acetowhite changes on the
cervix. Studies using EIS technology in the UK and Europe have been published.
NICE has published a Medtech Innovation Briefing on ZedScan.

5.7.3. LuViva

LuViva utilises fluorescent and reflective spectroscopy to evaluate the cervix to identify CIN. The device is used prior to colposcopy and is not a replacement for colposcopy nor is it an adjunctive test at the time of colposcopy. There is currently no NICE evaluation or data from the UK available for LuViva.

6 Infections, cytology and colposcopy

Cervical cytology and colposcopy can identify a number of infectious agents, but appearances are not pathognomonic for any condition. For example, some colposcopic and naked-eye appearances, such as the ulcers of herpes and syphilis, are easily mistaken for squamous carcinoma. The poor sensitivity, specificity, and positive and negative predictive values of both cytology and colposcopy for infectious agents mean that neither cervical cytology nor colposcopy should be used solely for the diagnosis of infections.

6.1 Testing for infections in colposcopy clinics

To use a colposcopy visit to screen for the most common sexually transmitted infection, *Chlamydia trachomatis*, is neither-cost effective nor indicated. Similarly, evidence fails to support testing for gonorrhoea in asymptomatic women when a cytology sample is taken.

6.2 Management of infections found on cytology

The presence of some organisms on cytology may lead to variations in a woman’s clinical management. Specific drug therapies will not be detailed here; instead, the issues raised by specific infections noted on cytology reporting are considered. The following genital tract infections may be noted during microscopy of a conventional cervical smear, and results from liquid-based cytology samples have been having been shown to be equivalent:

- *Actinomyces*-like organisms (ALOs)
- *Trichomonas vaginalis*
- *Candida* species
- *Herpes Simplex Virus* (HSV)

6.3 Actinomyces-like organisms

ALOs are usually associated with an intrauterine contraceptive device (IUD). If the woman is symptomless, then neither removal of the device nor antibiotic treatment is indicated. If the woman has symptoms, the IUD may need to be
removed (after first determining that the patient has not had sexual intercourse during the preceding five days). If the IUD is removed, the device should be sent for culture testing, and the woman prescribed a course of appropriate antibiotics. A subsequent gynaecological referral may be necessary to ensure that symptoms and/or signs resolve. Alternative contraception should be arranged in the interim, as appropriate.

Due to the poor sensitivity and specificity and low positive predictive value of cervical cytology for the detection of ALOs, the prognostic significance of ALOs detected via this method is minimal in the absence of concomitant symptoms.

6.4 Candida species

Microscopy of a cytology sample is not sufficiently sensitive for a diagnosis of vaginal candidiasis to be made. The presence of spores indicates the reproductive activity of the organism, but such yeasts are common in symptomless women and in such cases treatment is not indicated. Even in symptomatic women, the presence of Candida does not necessarily indicate that Candida infection is the only cause of the complaint.

6.5 Bacterial vaginosis

Bacterial vaginosis is associated with the presence of ‘clue cells’ (squamous cells coated with a layer of coccal bacilli along the cell membrane) and a conspicuous absence of normal lactobacilli. LBC samples offers opportunities for accurate diagnosis, with a false positive rate of less than 1% when compared to wet mount and DNA probe technologies.

6.6 Chlamydia trachomatis

The sensitivity (31%) for the detection of chlamydial infection by cytology is low. Therefore, diagnosis of this organism by this method cannot be relied upon. The fluid used for liquid-based cytology, however, preserves the DNA of Chlamydia trachomatis. Many commercial tests are available to test for Chlamydia in this specimen type. Although not part of the cervical screening programme this could form part of clinical investigation.

6.7 Neisseria gonorrhoea

The presence of intra-cytoplasmic diplococcii is not diagnostic as other organisms (including common and non-pathogenic species of Neisseria) are morphologically indistinguishable. Confirmatory testing before giving the woman this diagnosis is mandatory, however, liquid-based samples preserve Neisseria gonorrhoea DNA. Many commercial tests are available to test for
gonorrhoea in this specimen type. Although not part of the cervical screening programme this could form part of clinical investigation.
6.8 Genital herpes
LBC samples may show features that are indicative of herpes simplex virus infection. The specificity of LBC samples is high for this organism.

6.9 Communicating results with the woman
It should be recognised that the potential for harming a relationship and the requirement to notify a partner of the existence of certain infections mitigate against relying on screening samples for diagnosis of sexually transmissible agents. Highly accurate testing modalities exist and should be used where there is any suspicion of infection in women attending for cytology screening and/or colposcopy. Good liaison with local GUM services is beneficial along with appropriate protocols for referral and treatment when indicated.

7 Treatment of CIN
7.1 Surgical techniques
There is no obviously superior conservative surgical technique for treating and eradicating cervical intraepithelial neoplasia (CIN). However ablative techniques are only suitable when:
  - The entire transformation zone is visualised. (100%)
  - There is no evidence of glandular abnormality. (100%)
  - There is no evidence of invasive disease. (100%)
  - There is no major discrepancy between cytology and histology.

Only in exceptional circumstances should ablative treatment be considered for women over 50 years of age.

7.2 Local destruction
All women must have an established histological diagnosis before undergoing destructive therapy (100%).

7.3 Cryocautery
Cryocautery should only be used for low-grade CIN and a double freeze-thaw-freeze technique must be used (100%).

7.4 Excision
7.4.1 Removal of specimen
When excision is used, at least 80% of cases should have the specimen removed as a single sample. Removing the transformation zone in multiple fragments can increase the difficulties encountered in histopathological assessment. Furthermore, if microinvasive disease is present, it may be
impossible to allocate a substage or define completeness of excision in fragmented excisional specimens.

7.4.2 Histology report
The histology report should record the dimensions of the specimen and the status of the resection with regard to intraepithelial or invasive disease.

7.4.3 Depth/Length of excision
The goal of excision is to remove all the abnormal epithelium.
Type I cervical transformation zone:
- For treating ectocervical lesions, excisional techniques should remove tissue to a depth/length of more than 7mm (95%), though the aim should be to remove <10 mm in women of reproductive age.
Type II cervical transformation zone:
- Excisional techniques should remove tissue to depth/length of 10-15 mm, depending on the position of the squamocolumnar junction within the endocervical canal.
Type III cervical transformation zone:
- Excisional techniques should remove tissue to a depth/length of 15-25 mm.

When excisional treatment is used for CIN associated type 1 and type 2 TZ lesion the depth/length of the reported specimen should be ≤15mm. (85%)

7.5 ‘See and treat’ policy
Treatment at first visit to colposcopy for a referral of borderline or low-grade dyskaryosis should not be offered.
The proportion of women treated at the first visit who have evidence of CIN2, CIN3, or CGIN on histology must be >90%.

7.6 Repeat excision
7.6.1 CIN3 extending to margins
CIN3 extending to the lateral or deep margins of excision (or uncertain margin status) results in a higher incidence of recurrence but does not justify routine repeat excision provided:
- There is no evidence of glandular abnormality
- There is no evidence of invasive disease
- The woman is under 50 years of age.

7.6.2 Women over the age of 50
All women over the age of 50 years who have CIN3 at the lateral or deep margins and in whom satisfactory cytology, HR-HPV typing and colposcopy cannot be guaranteed must have a repeat excision performed to try to obtain clear margins (100%).

7.7 Local excision

7.7.1 Microinvasive squamous cancer FIGO stage Ia1

Microinvasive squamous cancer FIGO stage Ia1 can be managed by local excisional techniques if:

- the excision margins are free of both CIN and invasive disease
- the gynaecological cancer centre pathologist and MDT have reviewed the histology.

If the invasive lesion is excised but CIN extends to the excision margin, then a repeat excision should be performed to confirm complete excision of the CIN and to exclude further invasive disease. This should be performed even in those cases where a hysterectomy is planned to exclude an occult invasive lesion requiring radical surgery.

7.8 Anaesthesia

Treatment should be performed with adequate pain control and should include pre-treatment counselling.

Treatment should be offered with local analgesia; where this is inappropriate, general anaesthesia should be offered. Reasons for treating under general anaesthesia should be recorded in the colposcopy record.

The proportion of women managed as out-patients with local analgesia should be ≥80%.

8 Management of glandular abnormalities

8.1 Cervical glandular epithelial abnormalities

Cervical screening with cytology can predict the presence of cervical glandular intraepithelial abnormalities.

8.2 Reporting of abnormal glandular samples

Samples should be reported as ‘?glandular neoplasia of endocervical type’ if they show cytological features suggestive of cervical glandular intraepithelial neoplasia (CGIN) or endocervical adenocarcinoma.

8.3 Colposcopic assessment

Colposcopic assessment is essential when glandular abnormality is observed on cytology (100%).
8.4 Further investigation of ‘glandular neoplasia of endocervical type’

8.4.1 ‘glandular neoplasia of endocervical type’

Women with samples reported as ‘glandular neoplasia of endocervical type’ on cytology should be referred for colposcopic investigation within two weeks to exclude significant cervical and endometrial neoplasia.

8.4.2 Borderline glandular samples

When borderline changes are reported in endocervical on a cytology sample, a reflex HR-HPV test is performed. Women who have borderline changes of either type and who test positive for HR-HPV must be referred for colposcopy. Women who are HR-HPV negative are returned to normal recall.

Women referred with borderline nuclear change in glandular cells and are positive for HR-HPV should undergo colposcopy, any appropriate cervical biopsy.

8.4.3 Glandular neoplasia (Non-cervical)

Patients should be referred to gynaecology for further investigation. They should be seen urgently, within two weeks of referral.

8.5 Colposcopically directed/punch biopsy

Colposcopic punch biopsy is of low sensitivity for diagnosis of intraepithelial glandular lesions. Furthermore, it has no role in precise diagnosis as it cannot exclude the presence of invasive disease. Expert opinion indicates that a reliable diagnosis of high-grade CGIN and distinction from invasive adenocarcinoma can be achieved only in the histopathology laboratory, and an excisional biopsy including the endocervical canal is required for this purpose.

8.6 Endometrial biopsy

Where a woman’s cervical sample indicates ‘glandular neoplasia of endometrial type’, with or without irregular vaginal bleeding and regardless of menopausal status, she should be seen urgently for further investigations, within two weeks of referral. She should be referred for gynaecological assessment, but not to colposcopy. Repeat cervical cytology is not recommended. Although it is accepted that cervical assessment may be needed in such cases, the majority of women do not have cervical disease and should have an endometrial assessment in the first instance.
8.7 Endocervical curettage in the assessment of ‘?glandular neoplasia of endocervical type’

There is no clear role for endocervical curettage in the assessment of ‘?glandular neoplasia of endocervical type’

8.8 Clinical management of cervical glandular neoplasia

8.8.1 Management of cytology reported as ‘?glandular neoplasia of endocervical type’

Expert opinion supports a primary excisional procedure for initial management of all cases of high-grade atypical glandular cytology, with further management decisions based on a thorough histological assessment, including margin status. For women with suspected CGIN or early invasive adenocarcinoma, the extent of the cervical excision can be individualised. In younger women and/or women who wish to conserve their fertility who have a colposcopically visible squamocolumnar junction (SCJ), a cylindrically-shaped cervical excisional biopsy, including the whole transformation zone (TZ) and at least 1 cm of endocervix above the SCJ is appropriate. In older women, or where the SCJ is not visible at colposcopy, a cylindrical biopsy should be taken that includes all of the visible TZ and 20–25mm of the endocervical canal. Expert histopathological opinion favours techniques that either avoid or minimise thermal artefact to improve assessment of the excision margins. In women with high-grade atypical glandular cytology, where cervical pathology has been excluded, an endometrial biopsy, +/- pelvic imaging should be considered.

8.8.2 Conservative management of confirmed HG-CGIN

High-grade cervical glandular intraepithelial neoplasia (HG-CGIN) often occurs in young women. Conservative management is recommended for those wishing to retain fertility, if the margins of the excisional specimen are negative and invasion is excluded. Women who are to be managed conservatively following cone biopsy should be counselled that the expected programme of management appears safe if careful follow up is carried out (see below).

8.8.3 Management of incompletely excised CGIN

When advising expected management for CGIN, the clinician should be satisfied that the specimen submitted has been thoroughly sampled in the laboratory and that the margins of the specimen are free of disease. If the margins of an initial, conservative excision are not free, it is reasonable to offer a further attempt at conservative excision in order to confidently exclude
invasion and obtain negative margins. The colposcopy or gynaecological cancer MDT should help to guide further management.

8.8.4 Follow-up of conservatively treated CGIN

Women who undergo excision for CGIN are at risk of recurrence. If the CGIN has been completely excised, at the time of first excision or subsequent re-excision, a test of cure (TOC) sample should be taken 6 months after treatment. If negative for cytology (endocervical cells must be present) and negative for HR-HPV a second TOC sample is taken 12 months later (i.e. 18 months after treatment) - if this is also negative for cytology and HR-HPV the woman can be discharged to recall in 3 years. Further recall will depend on the result of this test and the age of woman. These samples can be performed in the community. If either cytology or HR-HPV, at six or 18 months after treatment, is positive the woman should be referred to colposcopy.

If the woman fails TOC at six months only because of a positive HR-HPV test and no abnormality is detected at colposcopic examination the woman should have a second TOC sample twelve months later, if this sample is negative for cytology and HR-HPV the woman can be discharged to recall in 3 years. Further recall will depend on the result of this test and the age of woman. If a positive cytology result is reported in either of the 6 or 18 months ‘TOC’ samples the woman must be referred to colposcopy and managed appropriately. If no colposcopic abnormality is present and re-excision is not appropriate the women should revert to 10 years of cytology follow up. Women who have incompletely excised CGIN and have declined re-excision should be followed up in the colposcopy clinic. Cytology should be performed 6 months after treatment and if negative repeated 6 months later (i.e. at 12 months after treatment) and then annually for the subsequent 9 years. Complex CGIN cases will benefit from discussion at the colposcopy MDT.

8.9 Hysterectomy for cervical glandular neoplasia

Simple hysterectomy might be considered if:

- Fertility is not required
- There are positive margins after an adequate excisional procedure
- Treatment by cone biopsy is followed by further high grade cytological abnormality
- The patient is unwilling to undergo conservative management
- Adequate cytological follow up has not been possible, e.g. because of cervical stenosis
- The patient has other clinical indications for the procedure
- Invasive disease has been confidently excluded.
8.10 Cervical screening for women exposed in utero to diethylstilbestrol

Women exposed in utero to diethylstilbestrol (DES) should have an initial colposcopic examination. In the absence of an abnormality at the first examination, only routine cervical screening is required. For women whose initial examination shows an abnormality or stigmata of DES exposure, annual colposcopic examination of the vagina and cervix is required, possibly for life, in specialist centres.

Management should be considered on an individual basis by the woman concerned and the colposcopist.

9 Follow-up of women attending for colposcopy with CIN and early stage cervical cancer

9.1 Treated women

All women remain at risk following treatment and must be followed up (100%). Treated women are between two and five times more likely than the general population to experience cervical cancer. Much of this increased risk may result from poor compliance with long-term follow up; several case series demonstrate that over 50% of cancers develop in women who are lost to follow up. Thorough compliance should be encouraged.

9.1.1 Duration and frequency of follow-up after treatment for CIN under the HPV 'test of cure' protocol:

- Women who have been treated for all grades of CIN should be invited 6 months after treatment for ‘test of cure’ repeat cytology. Patient compliance with follow-up protocols should be encouraged.
- Women with a sample that has been reported as negative, or as showing borderline changes or low-grade dyskaryosis, and whose HR-HPV test is negative should be recalled in 3 years, whatever their age.
- Where the 3-year test is negative, women over 50 can return to 5 yearly routine recall.
- Women with a sample that has been reported as negative, or as showing borderline changes or low-grade dyskaryosis, and whose HR-HPV report is positive should be referred to colposcopy.
- Women with a sample that has been reported as showing high-grade dyskaryosis should be referred for colposcopy. No HR-HPV test is required.
- Women with a sample that has been reported as negative, or as showing borderline changes or low-grade dyskaryosis, and whose HR-HPV test result is unavailable should undergo repeat cytology at 3 months.
• Women who reach 65 must still complete the protocol and otherwise comply with national guidance.
• Women in annual follow up after treatment for CIN are eligible for the HPV test of cure at their next screening test.

9.2 Management for women following treatment for early stage cervical cancer

The treatment of early invasive cervical cancer (FIGO stage Ia1, Ia2, Ib1 and IIa1) lies outside the responsibility of the NHSCSP. However the following guidance is provided for the sake of completeness.

9.2.1 Follow up of stage Ia1

If conservative treatment for cervical cancer has been performed, leaving a residual cervix, cytological follow up is recommended. Cervical cytology should be taken six and 12 months after treatment, followed by annual cytology for the next nine years before return to routine recall to 65 years. The NHSCSP will continue to provide recall arrangements. The “Test of Cure” utility of HPV testing has not been applied to cases of stage Ia1 and Ia2 cervical cancer. Until such evidence becomes available the current standard of annual cytology should remain.

9.2.2 Follow up of stage Ia2/Ib1

If conservative management for Ia2/Ib1 disease was by simple or radical trachelectomy, cytological follow up is determined by the management policy of the gynaecological oncologist. If the woman has undergone hysterectomy for early stage cervical cancer, follow-up will as per the local cancer network guidelines. Women who receive pelvic radiotherapy either as primary or adjuvant treatment will be followed up according to the local cancer network guidelines.

9.3 Follow-up after a hysterectomy

Women who have had a hysterectomy with CIN present are potentially at risk of developing vaginal intraepithelial neoplasia (VaIN) and invasive vaginal disease. There is no clear evidence that colposcopy increases the detection of disease on follow-up.

Expert consensus opinion recommends that:

• For women on routine recall and with no CIN in their hysterectomy specimen, no further vaginal vault cytology is required
• Women not on routine recall, and with no CIN in their hysterectomy
  specimen, should have vaginal vault cytology at six months following their
  hysterectomy and then ceased if the cytology is negative.

• Women who undergo hysterectomy and have completely excised CIN
  should have vaginal vault cytology at six and 18 months following their
  hysterectomy.

• Women who undergo hysterectomy and have incompletely excised CIN
  (or uncertain excision), follow up should be as if their cervix remained in
  situ
  – CIN 1: vault cytology at six, 12 and 24 months
  – CIN 2/3: vault cytology at six and 12 months, followed by nine annual
    vault cytology samples – follow up for incompletely excised CIN continues
    to 65 years or until 10 years after surgery (whichever is later)

Responsibility for implementing these follow up policies will rest with the
  treating gynaecologist and will be informed by the local lead colposcopist

Any gynaecologist discharging a patient who requires further vault cytology
  should ensure that the GP receives specific written guidance for follow up

The clinician in charge (gynaecologist or GP) will be responsible for failsafe
  mechanisms for this small group of women:

• Women who undergo subtotal hysterectomy will still have their cervix in
  situ, and so must remain within the NHSCSP

• Women who have radical trachelectomy, as part of conservative
  management of cervical cancer, should remain under the care and
  guidance of their treating gynaecologist or gynaecological oncologist.
  Follow up is recommended with colposcopy and cytology; owing to the
  limited information on outcome, however, all cases should be subject to
  local audit. As these women have cancer they are under the individual
  care of a gynaecologist and are no longer within the NHSCSP.

The role of HPV testing in the post-hysterectomy scenario has not been
  addressed in any trials. Given that women who have had a hysterectomy are a
  small proportion of the total population at risk, it seems unlikely that guidance
  will be based on clinical trials in the near future. Whilst logic would suggest that
  HPV testing would be informative in this group, cytology should continue to be
  performed. HPV testing in parallel is recommended as this may facilitate the
  development of guidance for the management of these women.
10 Pregnancy, contraception, menopause, hysterectomy

10.1 Pregnant women

10.1.1 Cervical screening during pregnancy

If a woman has been called for routine screening and she is pregnant, the test should be deferred:

- A woman referred with abnormal cytology should undergo colposcopy in late 1st or early 2nd trimester unless there is a clinical contraindication. However for low-grade smear changes triaged to colposcopy on the basis of a positive HPV test, the woman’s assessment may be delayed until after delivery.

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

- If a pregnant woman requires colposcopy or cytology after treatment (or follow up of untreated CIN1), her assessment may be delayed until after delivery. Unless there is an obstetric contraindication, however, assessment should not be delayed if the first appointment for follow-up cytology or colposcopy is due following treatment for CGIN. The ‘test of cure’ appointment should not be delayed after treatment for CIN2 or CIN3 with involved or uncertain margin status.

The colposcopist may wish to perform colposcopy only at a follow-up appointment scheduled during pregnancy.

If repeat cytology is due, and the woman has missed or defaulted her appointment prior to pregnancy, cytology or colposcopy during pregnancy can be considered.

10.1.2 Colposcopy during pregnancy

A woman who meets the criteria for colposcopy should be examined in the colposcopy clinic even if she is pregnant. The primary aim of colposcopic examination of a pregnant woman is to exclude invasive disease and to defer biopsy or treatment until the woman has delivered. Women seen in early pregnancy may require a further assessment in the late second trimester at the clinician’s discretion.

10.1.3 Colposcopy follow-up after pregnancy

If colposcopy has been performed during pregnancy, post-partum assessment of women with an abnormal cytology or biopsy-proven CIN is essential (100%). Excision biopsy in pregnancy cannot be considered therapeutic and these women should be seen for post-partum colposcopy. A system must be in place to ensure women are given an appointment after delivery.
10.1.4 Colposcopic evaluation of the pregnant woman
Colposcopic evaluation of the pregnant woman requires a high degree of skill:

- If CIN1 or less is suspected, repeat the examination three months following delivery
- If CIN2 or CIN3 is suspected, repeat colposcopy at the end of the second trimester. If the pregnancy has already advanced beyond that point, repeat three months following delivery
- If invasive disease is suspected clinically or colposcopically, a biopsy adequate to make the diagnosis is essential (100%). Cone, wedge, and diathermy loop biopsies are all associated with a risk of haemorrhage and such biopsies should be taken only where appropriate facilities to deal with haemorrhage are available. Punch biopsy suggesting CIN only cannot reliably exclude invasion.

10.2 Use of contraceptives
10.2.1 Women with abnormal cervical screening results
Women with abnormal cervical screening results should not be advised to change from the oral contraceptive pill (OCP) if it is a successful method of contraception for them. An abnormal result should not influence the choice of contraception.

10.2.2 Women with an IUD
Women with an intrauterine contraceptive device (IUD) should be given clear information on the clinic’s management policy regarding whether her IUD will be removed or not. She will need to know if she has to use alternative methods of contraception and if she has to schedule her treatment to coincide with the first half of her cycle. It is not necessary to remove an IUCD to perform local treatment.

10.2.3. The use of condoms
Condom use may promote HPV clearance and CIN1 regression in conservative management, but this depends on their consistent use for at least 3 months.

10.4 Menopause and use of HRT
10.4.1 Post-menopausal women
The incidence of abnormal cytology and HPV positivity is low in post-menopausal women with previous normal results but HPV triage has a higher positive predictive value for high-grade CIN in older women.
The use of systemic HRT is not known to alter the risk of cervical disease. Colposcopic examination and adequacy can be improved by the use of topical HRT.

10.4.2 Post-menopausal bleeding
In an adequately screened woman, post-menopausal bleeding is not an indication to take a cervical sample. The investigation of abnormal bleeding after the menopause must include direct visual inspection of the cervix. A cervical sample is not an appropriate test for investigating PMB. All unexplained bleeding should be referred to a gynaecologist.

10.5 Hysterectomy
10.5.1 Women undergoing a hysterectomy for reasons other than cervical cancer
All patients in the cervical screening age range undergoing a hysterectomy for other gynaecological reasons than a diagnosis of cervical cancer should have a negative test result within the screening interval. Otherwise, a cervical sample should be taken as part of their preoperative investigations (100%).

10.5.2 Women being considered for hysterectomy
All patients being considered for hysterectomy who have an uninvestigated abnormal test result or symptoms attributable to cervical cancer should have diagnostic colposcopy and an appropriate biopsy (100%).

10.5.3 Hysterectomy as treatment for histologically-proven CIN
Hysterectomy is a recognised treatment for histologically proven CIN if there are co-existing conditions appropriately treated by hysterectomy.

10.5.4 Hysterectomy as treatment for persistent ‘?glandular neoplasia of endocervical type’
Hysterectomy is an acceptable form of treatment in cases where ‘?glandular neoplasia of endocervical type’ cytology persists despite a prior excisional biopsy of adequate size. This is provided that all measures to exclude occult invasion have been applied.

10.5.5 Mapping vaginal abnormalities
Patients with CIN should have any abnormality on the vagina mapped by colposcopy or Lugol’s iodine at the time of surgery to ensure that any coexisting VaIN is recognised and excised at the time of the hysterectomy.
10.5.6 Correlation of histology with cytology
The histology of the resected uterus should be correlated with prior cervical cytology as part of the quality assurance process.

10.5.7 Follow up after hysterectomy
After hysterectomy, follow up is advised.

11 Screening and management of immunosuppressed women
11.1 Definition of immunosuppression
This chapter includes guidance for the management of women on immune suppressing medication, transplant recipients of any organ, and all other forms of immunosuppression.

11.2 Women with renal failure requiring dialysis
All women aged 25 to 65 years with renal failure requiring dialysis or any other disease with a high chance of needing organ transplantation must have cervical cytology at or shortly after diagnosis.

Women with an abnormal result should be referred to colposcopy as described previously. All women about to undergo organ transplantation should have had cervical cytology performed within the previous year. Co-existing CIN should be managed according to national guidelines.

11.3 Women taking maintenance immunosuppression medication post transplantation
Women taking maintenance immunosuppression medication after transplantation who have no history of CIN should have cervical screening in accordance with the national guidelines for the non immunosuppressed.

Any abnormal cervical cytology result should prompt colposcopic referral. Any woman with a previous history of CIN should have routine follow-up, in accordance with the guidelines for the immunocompetent population.

There should be effective education of both organ transplant recipients and their carers about the need for regular cervical cytology and HPV testing, with the production of leaflets and other educational materials targeted at this group.

11.4 Women with multifocal disease
The screening and management of the immunosuppressed woman is a complex area of assessment and management. This is especially true for those with multifocal disease, which is why these patients must be managed in a
centre with demonstrable skill and expertise and sufficient access to patient numbers to maintain that expertise.

There must be a compromise between the increased risk of CIN and the additional psychological and physical trauma of assessment and treatment, with due consideration paid to the co-morbidity of the underlying disease process. These patients should be assessed by cytology, HPV testing (within the context of the NHSCSP), colposcopy, vulvoscopy, and biopsy where indicated at least every six months.

11.5 HPV vaccination

All women who have never been sexually active prior to the diagnosis of their condition and commencement of immunosuppressive therapy should be offered HPV vaccination. After vaccination the women should remain in the screening programme.

11.6 Women receiving cytotoxic drugs for rheumatological disorders

Women receiving cytotoxic drugs for rheumatological disorders over the long-term should have regular cytological screening according to national guidelines.

If the woman’s cervical screening history is incomplete at the time that she commences a course of cytotoxic drugs, then a screening test should be performed with immediate referral to colposcopy for any screening abnormality.

11.7 Other women who are immunosuppressed

There is no indication for increased surveillance of the following groups:
- Women receiving cytotoxic chemotherapy for non-genital cancers.
- Women receiving long term biologic agents.
- Women receiving oestrogen antagonists such as tamoxifen.

These women should have cytological screening according to the national guidelines for the general population.

11.8 Women who are HIV positive

All women newly diagnosed with HIV should have cervical surveillance performed by, or in conjunction with, the medical team managing the HIV infection. Annual cytology should be performed with an initial colposcopy if resources permit. Subsequent colposcopy for screening abnormality should follow national guidelines. The age range screened should be the same as for HIV negative women.
Despite the higher cervical treatment failure rate, high-grade CIN should be managed according to national guidelines. Lesions less severe than CIN2 should probably not be treated as these are likely to represent persistent HPV infection of the cervix which responds poorly to treatment and may clear spontaneously. Regular cytological surveillance will detect progression.

Use of highly active antiretroviral therapy (HAART) reduces HIV viral load, and may reduce HPV viral load. As a consequence, the prevalence and incidence of cervical abnormality may also be reduced.

However, the evidence for this is inconsistent to date and thus there is a need for more intense surveillance of these women to detect pre-invasive cervical lesions.

Close cooperation is advised between colposcopists and HIV physicians to ensure that women are not over-treated if there is a possibility of enhancing immunocompetence (e.g. by raising CD4 counts following compliance with antiretroviral therapy). Women who are HIV positive can cease cervical screening at age 65 if they fulfil the criteria for ceasing.

11.9 Screening for HIV in colposcopy clinics

All colposcopists should be cognisant of the increased risk of HIV infection in women with multifocal disease and early recurrence of disease. Consideration should be given to offering HIV testing in this setting.

The routine screening of women attending colposcopy clinics is under review by the Advisory Committee on Cervical Screening and further advice from will follow in due course.