

COLPOSCOPY AND PROGRAMME MANAGEMENT

Guidelines for the NHS Cervical Screening Programme
Second edition

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Second Edition

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1. INTRODUCTION

1.1 The revised *Colposcopy and Programme Management*

Colposcopy and Programme Management: Guidelines for the NHS Cervical Screening Programme was first published in 2004. Since then the cervical screening programme has seen important changes, the most far-reaching being the introduction of liquid based cytology, which was completed in October 2008. This new edition is designed, in part, to ensure that the *Guidelines* fully reflect these changes.

The first edition focused on two key aspects of developing a colposcopy service: women at increased risk of cervical cancer and improving the quality of the colposcopy service overall. The NHS Cervical Screening Programme (NHSCSP)* has commissioned a small editorial group to update the account of these objectives, and to address issues that have arisen in the intervening years and affect current practice. New sections have been added to the document on patients awaiting treatment, the management of benign and atypical endometrial cytology, patients exposed to diethylstilbestrol in utero, and whether cytology should be repeated at the initial colposcopy visit. Also included are clarification of post-hysterectomy management, follow up after treatment, and further recommendations in relation to colposcopy multidisciplinary team meetings. There is new information on human papillomavirus (HPV) testing as a primary screen and for triage of low grade abnormality, although as yet no further practice recommendations have been added for these scenarios. A draft version of the updated guidelines was circulated to the National Quality Assurance Colposcopy Group (which includes the President of the British Society for Colposcopy and Cervical Pathology), the British Society of Clinical Cytology, the National Laboratory Quality Assurance Group and the National Primary Care Quality Assurance Group. All standards included in the *Guidelines* are summarised in Appendix 1.

The aim of these guidelines is to optimise available resources within the screening programme. This has not changed any of the data items required for the colposcopy minimum data set, which is designed to ensure accurate collection of data for the KC65 and for further audit and benchmarking of general colposcopic practice. New standards relating to colposcopy multidisciplinary teams (MDTs) have been added; other standards have been fine tuned, and a few removed.

1.2 Evidence-based guidelines

Guidelines are a means of setting standards for care. Ideally, guidelines for practice should be based on robust evidence. As in any developing area of health care, however, evidence may be patchy or incomplete and there remains a heavy reliance on professional consensus. In this publication we have used published evidence as far as possible, and have indicated where we have relied on consensus. This challenges the colposcopy and screening communities to generate the research that will enable successive editions to become ever more evidence based.

*See the NHS Cancer Screening Programmes website at <http://www.cancerscreening.nhs.uk/cervical/index.html>. For details of NHS Cervical Screening Programme publications see <http://www.cancerscreening.nhs.uk/cervical/publications/index.html>.

1.3 Content of these guidelines

Sections have been included to address areas that have generated constant query since the first edition was published.

The principal change to the core of the programme introduced in 2004 is a recommendation to refer after one mildly dyskaryotic sample. This might be seen as increasing workload and thus jeopardising one of the *Guidelines*' objectives. As a modelling study published in 2006 emphasises, however, it is important to take this change of practice in context.¹ A rapid return to community-based cytological surveillance has been recommended for all women who have normal colposcopy and low grade abnormalities. Taken together, the two elements of this strategy are judged to offer both safety and efficiency.

The value of training, audit and team working has been emphasised and standards have been set. Earlier standards relating to quality in the colposcopy clinic, such as privacy in changing facilities, have been made more stringent. This is part of a broader strategy to ensure that a modern colposcopy service is delivered in an environment that is not only well designed and equipped but also takes into account the views of the women who use it.

2. SCREENING PROGRAMME POLICY

2.1 Frequency of screening

2.1.1 Screening intervals

The age and frequency of screening are as follows

Age group (years)	Frequency of screening
25	First invitation
25–49	Three yearly
50–64	Five yearly
65+	Only screen those who have not been screened since age 50 or who have had recent abnormal tests

Evidence: The International Agency for Research on Cancer notes that ‘a three- to five-year interval used to be recommended in the United Kingdom, but recently a three-year interval was recommended for women aged 25–49 and five years for women 50–64 years old’.² These recommendations were based on an audit of screening histories by Sasieni et al,³ which concludes that ‘five-yearly screening offers considerable protection (83%) against cancer at ages 55–69 years and even annual screening offers only modest additional protection (87%). Three-yearly screening offers additional protection (84%) over five-yearly screening (73%) for cancers at ages 40–54 years, but is almost as good as annual screening (88%). In women aged 20–39 years, even annual screening is not as effective (76%) as three-yearly screening in older women, and three years after screening cancer rates return to those in unscreened women. This calls into question the policy of having a uniform screening interval from age 20 to 64 years and stresses the value of screening in middle-aged women.’

2.1.2 Invitations for routine screening and re-screening

All letters of routine invitation should be sent to women five to six weeks before the date on which their test is due, and in no case later than the test due date. Women under the age of 25 should be sent their first invitation at 24.5 years; women aged 25–49 should receive their invitation 34.5 months after a previous test; and those aged 50–64 should receive theirs 58.5 months after a previous test.

Evidence: There is evidence that a delay of several months may occur between the issuing of invitations to women and the date of their screening test.⁴

2.1.3 Monitoring the screening interval

The actual screening interval should be monitored.

Evidence: Good practice point. The numbers of women screened within the previous three and five years does not correspond with the number regularly screened at intervals of three and five years. As a proportion of women will not be screened in every screening round, looking at the number screened in the last three to five years would not correspond with the number undergoing regular screening. NHSCSP returns provide some data on the proportion of the population screened at different intervals,⁵ but more detailed research is needed.

2.2 Age at starting screening

Recently published research and experience from the cervical screening programme have shown that screening women under the age of 25 may do more harm than good.^{6,7} Cervical cancer is very rare in women under 25. In 2007, 56 cases of cervical cancer were registered among women aged 15–24 in England and Wales and a total of three deaths were reported.^{8,9}

Evidence: The incidence of cervical cancer in the under 25 age group is low^{6,10} and the prevalence of transient HPV infection after coitarche is high.¹¹ Almost one in six cervical cytology samples taken in this age group are abnormal.⁸ Much of this prevalent low grade disease would resolve spontaneously if screening were started at a later age.^{6,7,11} Screening may thus lead to unnecessary attendances at colposcopy, with the possibility of increased anxiety, overtreatment, and potentially negative consequences for women's childbearing.^{12,13} Screening has not been shown to be effective at reducing the incidence of invasive cancer in women under the age of 25.^{6,7}

The evidence confirms that women under 25 should not be screened in the context of a national programme with computerised call and recall. Women under 25 who are concerned about their sexual health or risk of developing cervical cancer should contact their GP or the local genitourinary medicine (GUM) clinic. (See section 4.11.)

2.3 Age at finishing screening

Routine screening ends at the age of 65 years. Although it may possibly be safe to withdraw well screened women with three consecutive negative cervical samples from the screening programme at age 50 years, there is at present insufficient robust evidence to warrant this.^{14,15}

In the interim, the effectiveness of screening women over the age of 50 will continue to be kept under review. It is clear that screening women aged 50–64 who have had fewer than three previous cervical cytology samples taken is an extremely effective policy.^{3,15}

Evidence: Ceasing screening at the age of 65 is the practice in the NHSCSP. However this is being kept under review by the Advisory Committee on Cervical Screening in the light of the most recent evidence and technology available.^{16,17} Setting the exit age at 65 has been questioned, particularly for women who have been well screened to 50 and have a satisfactory negative history.¹⁸ Cervical screening is less efficient at detecting cervical intraepithelial neoplasia 3 (CIN 3) in older women – more cervical cytology samples are required to detect a case of CIN 3 after the age of 50¹⁹ – but it is more efficient at preventing invasive cancer.³

The prevalence of CIN 3 and invasive cancer in women over the age of 50 is low:¹⁵ 11 in 100 000 in well screened women compared with a prevalence rate of 59 in 100 000 women in the population as a whole.²⁰ Women who were diagnosed with invasive cancer after the age of 50 had not participated adequately in the cervical screening programme.²¹ Evidence from the USA suggests that screening previously poorly screened women over the age of 65 still results in a reduction in the subsequent rate of cervical cancer.²²

Early withdrawal of women from the cervical screening programme could lead to a substantial reduction in the resources devoted to screening, and the resources released could be channelled effectively into other aspects of health care. However early withdrawal would be likely to increase the overall incidence of cervical cancer unless other steps were taken to compensate.²³

No study to date has shown that cervical cancer rates in women aged 60–70 would not increase dramatically if screening were offered only up to age 50.

2.4 Unscheduled cervical screening

Additional cervical screening is not justified in any of the following situations, providing the woman is in the age group to be screened and has undergone screening within the previous three to five years

- on taking or starting to take an oral contraceptive
- on insertion of an intrauterine contraceptive device (IUCD)
- on taking or starting to take hormone replacement therapy (HRT)
- in association with pregnancy – either antenatally or postnatally, or after termination unless a previous screening test was abnormal (see section 10.1.1)
- in women with genital warts
- in women with vaginal discharge
- in women with pelvic infection
- in women who have had multiple sexual partners
- in women who are heavy cigarette smokers.

In a mathematical simulation model, the practice of routinely taking a second cervical cytology sample one year after the first ever sample conferred no additional benefit in terms of person-years of life saved.²⁴ Providing the first sample was negative and was taken as part of a quality controlled programme this practice should not be pursued.

Evidence: There is no evidence available to suggest that social or behavioural risk factors reduce the length of the preclinical, cytologically detectable phase of cervical neoplasia. The strength of the association with socio-sexual correlates is not sufficient to predict women with high grade CIN.^{25,26} More intensive screening of women with a history of multiple sexual partners and early onset of first intercourse is not cost effective.²⁶

The risks and benefits of cervical screening for HIV positive women receiving antiretroviral treatment and for chronically immunosuppressed women have yet to be fully evaluated. (See section 11.)

2.5 Cervical sampling in genitourinary medicine clinics

Cervical sampling in GUM clinics should be reserved for women with a cytological indication or those who have not been screened in the previous routine screening interval (three years for women under the age of 50).

Evidence: A case–control study of women attending GUM clinics in the UK suggested that they were as likely to attend for routine screening as women in the general population.²⁷ Higher rates of cytological abnormality were due mainly to an excess of cervical samples containing low grade abnormalities. This has been confirmed in a survey of UK sexually transmitted infection clinics.^{28,29} Audits of cervical screening in GUM clinics suggest that a greater proportion of samples are reported as inadequate or exhibit inflammatory changes, owing to the presence of infection.^{30–32} A cervical cytology sample is an inappropriate test for the detection of genital infection.^{33–35}

2.6 Withdrawal from cervical screening

In women with severe cervical stenosis (usually as a result of previous surgery) it may not be possible to obtain a cytological sample that is representative of the whole transformation zone.

The options in such cases are

- hysterectomy
- cervical dilatation
- withdrawal from further recall in the NHSCSP.

Cervical dilatation should be considered in all cases. Cervical dilatation or hysterectomy is recommended for women with a history of high grade CIN, cervical glandular intraepithelial neoplasia (cGIN) or unexplained high grade cytology. Involvement of the colposcopy multidisciplinary team may be useful.

If neither of those options is appropriate the lead colposcopist may recommend withdrawal from the screening programme. If the woman agrees to withdraw, this should be managed in accordance with local ceasing protocols. The local call and recall service must be informed of the management decision in all cases. If a woman declines withdrawal, against the recommendation of the local colposcopy service, cervical screening should continue.

2.7 Summary of standards

1. Cervical screening should take place between the ages of 25 and 64, at intervals of three or five years depending on the woman's age. Women must be called six months before their 25th birthday, then recalled at three yearly intervals between the ages of 25 and 49 years and at five yearly intervals between the ages of 50 and 64 years.

3. SCREENING STRATEGIES

3.1 Liquid based cytology

Cervical sampling using liquid based cytology (LBC) was implemented throughout the UK by October 2008 and is the current standard method of screening in the NHSCSP.

Evidence: In 2003 the National Institute for Clinical Excellence (NICE) recommended that LBC be used as the primary means of processing samples in the cervical screening programme in England and Wales.³⁶ Its decision took into account a wide range of evidence and a number of factors – including the potential for increased sensitivity, reduction of inadequate smears and probable improvements in laboratory efficiency – and concluded that the LBC method was likely to be more cost effective than the Papanicolaou smear.

3.2 Colposcopic screening

There are a few circumstances where colposcopic screening should be considered in addition to cytology for routine cervical screening. Certain very high risk groups of women who are at increased risk of CIN could be considered for additional cytological and colposcopic screening; they include immunosuppressed women, such as transplant recipients or patients with renal failure requiring dialysis. (See section 11.) Women whose samples are repeatedly reported as inadequate should be referred for colposcopy as part of routine screening. (See section 4.)

Evidence: In other high risk groups, such as women with genital warts or cigarette smokers, there is no evidence to suggest that three yearly cervical cytology is less protective than it is for lower risk women. In HIV positive women, however, annual screening by cytology is recommended.

3.3 Other screening strategies

Among the other screening strategies under investigation are the following

- human papillomavirus (HPV) testing as a form of risk assessment
- immunoenhanced testing using antibodies to cell cycle proteins
- electro-optical technologies.

Only HPV testing is currently being evaluated for implementation in the NHSCSP.

3.4 HPV testing

3.4.1 HPV testing to triage low grade abnormalities and test of cure

The potential benefits of introducing HPV testing to triage women with borderline and mildly abnormal results are currently under investigation.

Evidence: NHSCSP Sentinel Site pilot studies of HPV triage and test of cure are in progress. The initial pilot triage study³⁷ showed HPV triage to be feasible and acceptable to women. However it involved a transient rise in colposcopy rates compared with historical data based on colposcopy for persistent cytological abnormalities. The positive predictive value (PPV) for the colposcopic diagnosis for CIN 2+ was 15–20%, and higher in women under 35 years. A major advantage is rapid diagnosis and, providing there is no abnormality, a rapid return to normal recall. There is also a reduction in cytology for follow up.

3.4.2 HPV testing for follow up of treated CIN

No changes are planned at present but the following should be considered. Further data from trials and pilots will become available. There is some evidence to suggest that all women who have had treatment for CIN should have an HPV (Hybrid Capture® or HC2) test after six months, as well as a combined cervical cytology and HPV test after 12–18 months.³⁸ If all three of these tests are negative the patient can be returned to routine three or (for those over 49) five yearly testing. There are currently no plans to introduce HPV testing into mainstream practice, and any decision to do so would need to be based on a full understanding of the health economics involved. Cervical cancer after treatment is uncommon.³⁹

The test of cure study¹⁷ revealed that if both cytology and HPV testing are negative at six months then the risk of CIN 2+ over the next two years was less than 0.5%. Returning these women to normal recall after six months would prevent the need for 10 annual cytology tests, with correspondingly reduced anxiety for the women involved and a potential saving of up to 400 000 cytology tests per year in England.

The results of pilots and the test of cure study were considered sufficiently strong to progress to the next tier of implementation with the establishment of six Sentinel Sites. The outcome of the Sentinel Sites Implementation Project will be known in 2010 and if it is successful HPV testing will be rolled out nationally. The NHSCSP would support the development of a laboratory infrastructure to permit its introduction as part of routine practice.

Evidence: Of women who develop cancer in the UK, 16% have had previous treatment for CIN.³⁹ A number of non-randomised studies have been reported which suggest that HPV testing can improve the prediction of treatment failure.⁴⁰ This may be due to the fact that HPV testing will have a high negative predictive value for residual disease, the commonest cause of treatment failure. One of the published studies controlled for margin status, and the presence of HPV was still significantly associated with treatment failure.⁴¹ HPV testing using HC2 is the most sensitive test of cure and is superior to either cytology or colposcopy.^{40,42,43} The addition of cytology to HPV testing improves the sensitivity of sampling. The optimum time for the double test (cytology and HC2) is probably at 18–24 months³⁸ but testing at 12–18 months represents a pragmatic fit with the current timing of follow up cytology. The high negative predictive value of HPV testing combined with cytology is useful.⁴⁰ There is currently insufficient evidence to allow firm recommendations about the choice of sampling method after 18 months.

3.4.3 *Population screening with HPV testing*

Primary screening with high risk HPV DNA testing generally detects more than 90% of all CIN 2/3 or cancer cases, and is approximately 25% more sensitive than cytology at a cut-off of borderline dyskaryosis or worse. However it is about 6% less specific.⁴⁴ The reduced specificity of HPV DNA testing may be improved by adding HPV typing, for example, or by detecting the presence of biomarkers such as p16 and mRNA coding for viral E6 and E7 proteins. The ARTISTIC trial of 24 510 women aged 25–64 within the NHS Cervical Screening Programme¹⁷ compared HPV DNA testing combined with LBC against LBC alone over two screening rounds approximately three years apart. Its findings suggest that the combination of LBC with additional HPV testing over two screening rounds is no more sensitive than cytology alone for the detection of CIN 3+ or CIN 2+. While LBC is highly effective as primary screening, however, HPV testing has the twin advantages of a high negative predictive value, which should allow longer screening intervals, and automated platforms to optimise throughput.⁴⁵ Moreover no significant adverse psychosocial effects were detected. While the trial indicated that it would not be cost effective to screen with cytology and HPV combined, it highlights the potential of HPV DNA testing as the sole screening modality with cytology reserved for triage of HPV positive women and a longer screening interval for those who are negative.^{44,45}

In a Dutch randomised controlled study comparing HPV polymerase chain reaction based testing with conventional cytology (POBASCAM), type specific differences in clearance rates indicate the potential value of high risk HPV genotyping in screening programmes that maintain close surveillance of women with HPV 16. A more conservative approach may be suitable for other high risk HPV types.⁴⁶

Longer term follow up of screened cohorts will provide further evidence of the effectiveness of HPV testing, particularly its negative predictive value. It is likely that HPV testing will prove sufficiently cost effective to play a role in the NHSCSP. However any introduction into the national programme requires rigorous evaluation and a convincing evidence base. HPV testing is not currently recommended for routine use.

4. REFERRAL GUIDELINES FOR COLPOSCOPY

4.1 Cancer waiting times

The management of women with cervical cytology showing high grade changes or worse should conform with the waiting time standards set out in the Department of Health's *Going Further on Cancer Waits* initiative. As context for the guidance that follows, these standards are summarised below.

- Where women are referred from the screening programme to colposcopy services they will be included within the 62 day standard introduced by the Cancer Reform Strategy. Unless direct referral is active, women referred from primary care with **moderate dyskaryosis or worse** should therefore be fast-tracked as Urgent GP Referral for Suspected Cancer ('priority Type 3'/'Two-Week-Wait'). This includes women with a cytology result of **?invasive or ?glandular** if the local service protocol requires cytology results to be sent back to the patients' own GP for action. **In all such cases, direct referral to colposcopy is strongly recommended.** The receipt of the 'priority Type 3' referral will be the starting point of both the two week wait period and the 62 day referral to treatment period. The receipt of this referral at the acute provider will also be the starting point for the 18 week commitment, if cancer is later excluded by colposcopic opinion or in the light of a biopsy.
- Patients subsequently diagnosed with cancer should receive their first definitive treatment within 31 days of agreeing their care plan (the date of decision to treat) or by the 62nd day on their pathway, whichever is sooner. However it is acknowledged that it will not be clinically appropriate to treat all patients within this time, and that patients may wish to take time to consider their treatment before agreeing their care plan.
- All clinical procedures should be in the best interest of the woman and should not be influenced by waiting time commitments. Where ordinarily a biopsy or other excisional technique would not be judged appropriate, then clinical practice should not be changed. Where a histological specimen is available, then this report should be used to judge whether cancer can be excluded and to determine the woman's future pathway.

The following are recommended as good practice

4.1.1 ?invasive cancer or ?glandular neoplasia

Women with a cytology result of ?invasive cancer or ?glandular neoplasia should be seen urgently, within two weeks of referral (90%).

Evidence: Good practice point.

4.1.2 *Moderate or severe dyskaryosis*

Women who have been referred with a cytology result of moderate or severe dyskaryosis, and who are therefore on the 62 day pathway, should be seen in a colposcopy clinic within four weeks of referral (90%).

Evidence: Good practice point.

4.1.3 *Borderline nuclear change or mild dyskaryosis*

Women who have been referred with a cytology result of borderline change or mild dyskaryosis and who are on the 18 week pathway should be seen within eight weeks of referral (90%).

Evidence: Good practice point.

4.2 **Inadequate samples**

Women should be referred for colposcopy after three consecutive inadequate samples.

Evidence: Good practice point. Invasive cancers may be associated with inflammatory processes and bleed on contact. Women with persistent inadequate samples should undergo colposcopy to exclude invasive cancer, as inadequate results may be associated with lesions that are not exfoliating.

4.3 **Borderline nuclear change**

Repeat tests are recommended for the first occurrence of borderline changes. A second repeat may be requested for borderline changes, but after three such samples colposcopy is expected. The interval recommended for repeat tests (usually six months) takes into account the time needed for resolution of such changes.

Borderline changes will occasionally be seen in endocervical cells, or there may be a suspicion of high grade disease. In such cases the cytopathologist should refer the woman immediately to colposcopy rather than waiting for repeat tests.

When cytological surveillance is recommended, there should be no more than three borderline samples over any 10 year period without a recommendation for colposcopy.

Following mild dyskaryosis or borderline nuclear change, a woman should be returned to routine recall only after a minimum of three negative tests each at least six months apart or colposcopic assessment indicating no abnormality.

Before recall is ceased for reasons of age, at least three negative follow up tests should be reported after borderline nuclear change.

Changes in borderline dyskaryosis are reported and are assessed according to the severity of those changes. The cytologist or histopathologist providing the report may request colposcopic assessment when cervical changes are difficult to interpret, such as when borderline nuclear changes in endocervical cells are reported. In these instances, colposcopic appearances may also be non-specific, but a more accurate assessment is likely to be obtained by a combination of cytological review, colposcopic appearances and histological biopsy of any abnormality seen. Ideally such cases should be reviewed by a cytopathologist, a gynaecologist and a histopathologist before future management is decided.

If there is concern that the abnormality requires urgent referral then the cytological abnormality must be classified as high grade. Reclassification of the borderline grade may cause confusion and the colposcopist will be guided by the cytological recommendations ahead of the publication of the results of the Sentinel Sites Implementation Project.⁴⁷

As part of the Sentinel Sites Implementation Project, six cytology laboratories are currently piloting HPV triage to assist in the management of women with borderline and mild test results. (See section 3.4.)

4.3.1 *Squamous cell changes*

Women should be referred for colposcopy after three tests in a series reported as borderline nuclear change in squamous cells without the woman being returned to routine recall.

Evidence: In a randomised trial performed in the USA, of women with cytology showing atypical squamous cells of undetermined significance (ASCUS), the incidence of high grade CIN after a single sample reporting borderline nuclear change was low (11%).⁴⁸ In a UK prospective series, the incidence of CIN 2/3 was 36%.⁴⁹ Women with persistent borderline nuclear change are at increased risk of developing high grade CIN over time.⁵⁰

4.3.2 *Endocervical cell changes*

Women should be referred for colposcopy after one test reported as borderline nuclear change in endocervical cells.

Evidence: Case series showing that women with cervical cytology samples reported as borderline glandular cells have increased rates of malignant (4–16%) and preinvasive disease (17–40%).^{51–54}

4.4 **Abnormal results of any grade**

Women should be referred for colposcopy if they have had three tests reported as abnormal at any grade in a 10 year period, even if returned to routine recall on one or more occasions in that period.

Evidence: Good practice point.

4.5 Mild dyskaryosis

Women should be referred for colposcopy after one test reported as mild dyskaryosis, but it remains acceptable to recommend a repeat test. Women must be referred after two tests reported as mild dyskaryosis without a return to routine recall.

Evidence: A randomised trial in the hospital based management of mild dyskaryosis comparing four periods of surveillance, which included immediate colposcopy, found 68% of women with high grade CIN after a single mild or moderately dyskaryotic cervical cytology sample.⁵⁵ Other case series have shown the percentage of women found with high grade CIN after a mild dyskaryotic sample to be around 40%.^{49,56} Retrospective case series of women followed in the community report varying rates of referral to colposcopy (14–64%) and that these women are at increased risk of developing invasive cancer.⁵⁷ There is a high non-attendance rate for women who are followed up for more than 24 months.⁵⁸ An economic model suggested that immediate colposcopy was more cost effective than cytological follow up.⁵⁹ Since that publication, the recommendations for cytological follow up after a mild dyskaryotic sample have changed: three normal results, rather than two, are now required before return to routine screening.⁶⁰ This change will make cytological surveillance more expensive and immediate colposcopy comparatively cheaper. In two studies, only 25% of women with a cervical cytology sample showing mild dyskaryosis achieved regression to a normal sample.^{58,61}

The TOMBOLA study randomised 4439 women with low grade cytological abnormalities to immediate colposcopy or community based cytological surveillance. Of these, 1476 had mild dyskaryosis.⁶² The cumulative incidence of CIN 2+ was lower in the borderline group than in the mild dyskaryosis group. More cases of CIN 2+ were detected at immediate colposcopy and this group had a lower rate of CIN 2+ on exit from the study. Compared with women in the surveillance group, more women who underwent immediate colposcopy reported adverse effects.

Women with a mild dyskaryotic result should be seen and assessed but not necessarily treated. To prevent possible overtreatment, they should not be managed on a 'See and Treat' basis.

Following a mild dyskaryotic result, a woman should be returned to routine recall only after a minimum of three negative tests each at least six months apart or colposcopic assessment indicating no abnormality.

Before recall is ceased for reasons of age, at least three negative follow up tests should be reported after mild dyskaryosis.

As part of the Sentinel Sites Implementation Project, six cytology laboratories are currently piloting HPV triage to assist in the management of women with borderline and mild test results. (See section 3.4.)

4.6 Moderate dyskaryosis

Women must be referred for colposcopy after one test reported as moderate dyskaryosis (**100%**).

In England, women referred with a high grade cytological abnormality must enter a 62 day cancer pathway. Once cancer has been excluded these women must enter the 18 week pathway (**100%**).

Evidence: A randomised trial of the management of women with a moderately dyskaryotic cervical cytology found 74% of women to have CIN 2/3.⁵⁵ Case series also report a high incidence (74–77%) of CIN 2/3 at time of colposcopy.^{56,63}

4.7 Severe dyskaryosis

Women must be referred for colposcopy after one test reported as severe dyskaryosis (100%).

In England, women referred with a high grade cytological abnormality must enter a 62 day cancer pathway. Once cancer has been excluded these women must enter the 18 week pathway (**100%**).

Evidence: Case series report a high incidence (80–90%) of CIN 2/3 at colposcopy.^{57,63}

4.8 Possible invasion

Women must be referred for colposcopy after one test reported as possible invasion (**100%**). Where the local service protocol dictates that all cytology results are sent back to the patient's own GP for consideration and/or action, patients with ?invasive results should be referred by their GPs to the appropriate secondary care service as an Urgent GP Referral for Suspected Cancer ('priority Type 3'/'Two-Week-Wait').

Evidence: The correlation between a cervical cytology sample showing features of invasion and the histological diagnosis of invasive cancer is high. The PPV in one series was 56% for all cancers.⁶⁴

4.9 Glandular neoplasia

Women must be referred for colposcopy after one test reported as possible glandular neoplasia (**100%**). Where the local service protocol dictates that all cytology results are sent back to the patient's own GP for consideration and/or action, patients with ?glandular results should be referred by their GPs to the appropriate secondary care service as an Urgent GP Referral for Suspected Cancer ('priority Type 3'/'Two-Week-Wait').

Evidence: The natural history of this condition remains unclear. Case series of women referred to colposcopy with a single cervical cytology sample reporting glandular neoplasia are associated with high levels of invasive (40–43%) and preinvasive (20–28%) disease.^{51,65}

4.9.1 Benign endometrial cells in cervical samples

There is evidence of a higher prevalence of benign endometrial cells in cervical samples taken using LBC.⁶⁶ In women under 40 their presence has no significance and should not be reported or acted upon.

In women over 40, their significance varies with the phase of the menstrual cycle, the use of some hormones and the patient's clinical history. After the 14th day of the menstrual cycle, the presence of normal endometrial cells in a cervical sample may indicate endometrial pathology. Exceptions are when women are receiving oral contraceptives, hormone replacement therapy or tamoxifen, or are fitted with an IUCD. If this information is provided on the request form, an annotation or educational note should be made in the free text section of the report. Provided there is no other clinical symptomatology to suggest endometrial disease, no further clinical action is required.⁶⁶

Normal endometrial cells identified in a sample from a woman 40 years or older should always be reported if the menstrual, drug and contraceptive history is unknown (see above) or if the woman is postmenopausal. If the sample is otherwise negative it should be reported as negative but the report should include a note to the effect that

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 the light of the menstrual, drug and clinical history.

If this history suggests that an opinion is necessary, such cases should be seen urgently, within two weeks of referral.

Evidence: Compared with conventional cytology, LBC may be associated with a higher prevalence of normal endometrial cells (NECs) but these are less likely to be associated with endometrial pathology. This prevalence might be explained by more consistent use of sampling instruments for LBC with better access to the endocervical canal, or by changing technology and improved reporting standards with an apparent increase in the presence of normal endometrial cells in cervical cytology. In women with NECs who have been followed up, most endometrial pathology is accompanied by symptoms, implying that a relatively smaller number of additional cases are identified through follow up of asymptomatic women.⁶⁶

4.10 Abnormal cervix

Women with an abnormal cervix should be referred for gynaecological examination and onward referral for colposcopy if cancer is suspected. They should be seen urgently, within two weeks of referral.

Evidence: Good practice point. An abnormal cervix may be associated with invasive cancer.

4.11 Women with symptoms

Women presenting with symptoms of cervical cancer – such as postcoital bleeding (particularly in women over 40 years), intermenstrual bleeding and persistent vaginal discharge – should be referred for gynaecological examination and onward referral for colposcopy if cancer is suspected. Examination should be performed by a gynaecologist experienced in the management of cervical disease (such as a cancer lead gynaecologist). They should be seen urgently, within two weeks of referral.

Contact bleeding at the time of cervical sampling may often occur and is not an indication for referral for colposcopy in the absence of other symptoms or an abnormal result.

The Advisory Committee on Cervical Screening is currently developing guidance on the management of young women with gynaecological symptoms such as pain or bleeding on intercourse or between periods. This will involve primary care, GUM, gynaecology and cervical screening experts.

Evidence: Good practice point. A case series reported a high incidence of cervical neoplasia in women with postcoital bleeding.⁶⁷

Although postcoital bleeding is a cardinal sign of cervical neoplasia, the majority of cases are not malignant. In younger women, chlamydial infection and problems with family planning are more likely causes. These women require appropriate assessment and referral for colposcopy if cancer is suspected.

4.12 Previous treatment for CIN

Women should be referred for colposcopy if they have been treated for CIN, have not been returned to routine recall, and a subsequent test is reported as mild dyskaryosis or worse (**100%**).

Evidence: Women treated for CIN are at increased risk of developing cervical cancer.⁶⁸

4.13 Summary of standards

1. Women should be referred for colposcopy after three consecutive inadequate samples. At least **90%** of women should be seen in a colposcopy clinic within eight weeks of referral.
2. Women should be referred for colposcopy after three tests reported as borderline nuclear change in squamous cells in a series, without the woman being returned to routine recall. At least **90%** of women should be seen in a colposcopy clinic within eight weeks of referral.
3. Women should be referred for colposcopy after one test reported as borderline nuclear change in endocervical cells. At least **90%** of women should be seen in a colposcopy clinic within eight weeks of referral.
4. Women should be referred for colposcopy if they have had three tests reported as abnormal at any grade in a 10 year period. At least **90%** of women should be seen in a colposcopy clinic within eight weeks of referral.
5. Ideally, women should be referred for colposcopy after one test reported as mild dyskaryosis, but it remains acceptable to recommend a repeat test. Women must be referred after two

tests reported as mild dyskaryosis without a return to routine recall. At least **90%** of women should be seen in a colposcopy clinic within eight weeks of referral.

6. Women must be referred for colposcopy after one test reported as moderate dyskaryosis (**100%**). They should be seen within four weeks of referral (**90%**).
7. Women must be referred for colposcopy after one test reported as severe dyskaryosis (**100%**). They should be seen within four weeks of referral (**90%**).
8. In England, women referred with a high grade cytological abnormality must enter a 62 day cancer pathway. Once cancer has been excluded these women must enter the 18 week pathway (**100%**).
9. Women must be referred for colposcopy after one test reported as possible invasion (**100%**). They should be seen urgently, within two weeks of referral (**90%**).
10. Women must be referred for colposcopy after one test reported as possible glandular neoplasia (**100%**). They should be seen urgently, within two weeks of referral (**90%**).
11. Women should be referred for colposcopy if they have been treated for CIN and have not been returned to routine recall and a subsequent test is reported as mild dyskaryosis or worse (**100%**).

5. QUALITY STANDARDS FOR COLPOSCOPY CLINICS

5.1 Good working practices

5.1.1 Quality assurance

Colposcopy should be organised as a quality assured service whether it is provided in a gynaecological or GUM clinic or in primary care. Guidance on good working practices for colposcopy clinics appears at Appendix 2. The service should be run by a team, using protocols based on the *Colposcopy and Programme Management Guidelines*, and should aim to meet the quality standards defined here. Any problems arising in connection with colposcopy practice should be addressed in a confidential and supportive manner.

The team must be led by a lead colposcopist. The role of the lead colposcopist is to ensure good practice, observance of protocols, and data collection that complies with K65 (the mandatory Department of Health return) and audit. It is also a responsibility of the lead colposcopist to ensure that the quality standards outlined in this document are attained. A sample job description for lead colposcopists appears at Appendix 3.

The attainment of quality assured colposcopy in the NHS has been a considerable achievement and continued efforts are needed to ensure that standards remain uniformly high. Completion of form KC65 is one task that underpins this process. This return is required quarterly but is likely to become an annual return in the future. It requires clinics to have and to maintain computerised data based on the minimum data set of the British Society for Colposcopy and Cervical Pathology (BSCCP).

A hospital based programme coordinator must be identified. He or she should take responsibility for ensuring that non-attendance and other quality assurance targets are monitored.

Disclosure of the results of previous cytology and colposcopy should be offered to women who have taken part in the screening programme and have subsequently developed cervical cancer. The local cancer team will decide how this disclosure is managed, taking into account the principles for audit and disclosure described in the *Audit of Invasive Cervical Cancers* (NHSCSP Publication No 28).⁶⁹

5.1.2 Certification (see section 5.7)

All colposcopists in the team must be certificated through the BSCCP/Royal College of Obstetricians and Gynaecologists (RCOG) scheme and should undergo the re-certification process every three years. This will help them to maintain their expertise and indicate continued practice of a sufficient caseload. Those who are actively engaged in providing colposcopic services should 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 NHSCSP that independent colposcopy should be conducted in the NHS only by competent practitioners.

It is a requirement of re-certification that continued medical education (CME) is pursued by all colposcopists to keep them abreast of developments in scientific knowledge and clinical practice. Suitable CME opportunities include attending advanced colposcopy courses and the BSCCP Annual Meeting. (See section 5.7.)

5.1.3 *Clinic staffing and facilities*

The service requires at least one colposcopy nurse whose duties are to ensure the smooth running of the clinic and provision of support to the patient. A second nurse will be needed to assist, between patients, in preparations for cervical sampling, biopsies and treatment. (See section 5.4.)

The colposcopy service requires adequate clerical and secretarial support to ensure timely communication with patients and the GP. In addition, this support is needed for data collection and to ensure effective failsafe mechanisms.

The clinic facilities should protect the patient's dignity, and patients should be given time to discuss their care both before and after the colposcopy examination and/or treatment.

5.1.4 *Team meetings*

The colposcopy team should have operational and multidisciplinary clinical meetings. Operational meetings should be arranged at least quarterly to discuss clinic policy, protocol problems that arise, the findings of audit and peer review visits, and shortcomings against quality standards. Multidisciplinary meetings involving cytopathology, histopathology and colposcopy staff should be held at least every two months, and the agenda should include relevant clinical issues. (See section 5.6.2.)

5.2 **Reducing anxiety for women**

5.2.1 *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%**)
- counselling must be available as an integral part of colposcopy
- women must be sent an appropriately worded invitation with a contact name, telephone number and clinic 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%**) or eight weeks (**minimum standard 100%**)
- in addition to the national information leaflets, individualised information leaflets should be available at each clinic
- results and management plans should be communicated to the referring practitioner within four weeks of the patient's attendance at the clinic (**best practice 90%**) or eight weeks (**minimum standard 100%**).

Evidence: There is compelling evidence^{70–76} that many women suffer significant negative psychological effects from receiving an abnormal cervical cytology result and being called for further investigation; the psychological sequelae may discourage compliance with subsequent screening and follow up. The provision of accurate and clear information reduces anxiety and improves the patients' experience.

5.2.2 *Information given to women having outpatient treatment*

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
- 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 the menstrual pattern following loop excision
- that single conisation, cervical diathermy and loop excision are each associated with a small but significant increase in the incidence of preterm labour and preterm prelabour rupture of membranes.

Evidence: Evidence suggests that treatment of the cervix prior to childbearing may increase the risk of preterm delivery in young women.^{6,7} All other recommendations are good practice points. Menstrual bleeding following loop excision may be more sustained, heavier (19–48%) and more painful (15–41%).^{77,78} Vaginal intercourse, vaginal douches and tampon use should be avoided for four weeks after loop electrical excision procedure (LEEP) or cryotherapy.⁷⁹ Swimming should be avoided for two weeks following loop excision.⁸⁰ Driving is acceptable immediately after minor procedures involving local analgesia without sedation (eg dental block).⁸¹ The main risk of driving after loop excision arises from the analgesia rather than the surgery; there is no need for patients to be driven home. They can return to work the next day,⁸² although some may need another day or two to recover.⁷⁹ There are no restrictions on normal activities, other than intercourse.⁸³

Meta-analyses of long term observational data suggest that cone biopsy or radical diathermy significantly increases the risks of preterm delivery and perinatal mortality. Loop excision is associated with preterm delivery but not with increased perinatal mortality.^{12,13,84} Loop excision does not appear to be a cause of infertility or mid-trimester miscarriage.⁸⁵

5.2.3 *Minority ethnic groups*

Culturally appropriate information should be made available for members of minority ethnic groups.

Evidence: Coverage is low in many minority ethnic and refugee communities. There are significant differences in awareness about cervical cancer across different ethnic groups. Promoting informed choice and effective understanding of risk in a diverse community can help to improve understanding of and participation in cancer screening.⁸⁶

5.2.4 *'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%**).

Evidence: Anxiety is greater in women attending 'See and Treat' clinics if they are not adequately informed of the potential for treatment at their first visit.⁸⁷⁻⁸⁹

5.2.5 *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.

Evidence: Questions regarding sexual history may cause embarrassment, resentment and distress to some women. This may result in poor compliance if the woman feels she is being judged.^{71,90}

5.2.6 *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.

Evidence: Good practice point.

5.2.7 *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 (such as trainees, undergraduates or visitors).

Evidence: Women may have strong negative reactions to the intrusiveness of a gynaecological examination. Those attending for colposcopy are often particularly anxious. Being sensitive to these concerns helps to improve their experience of the service.^{71,74}

5.3 Equipping the colposcopy clinic

The following equipment must be available in the colposcopy clinic

- a permanent couch and colposcope
- suitable 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 with its use
- suitable information technology equipment
- software to facilitate collection of data for the BS CCP 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.

The following information and facilities must be in place

- adequate safety guidelines if laser or diathermy equipment is in use, with all staff trained in their operation. Clearly written and easily accessible emergency guidelines must also be available in each clinic and should conform with individual Trust recommendations⁹¹
- in units offering an exclusively diagnostic service there must be automatic referral to a unit where treatment is available if needed.

Evidence: Good practice point.

5.4 Clinic staffing

The colposcopy unit requires the following staffing

- all clinics must have a named colposcopist with appropriate skills who leads the service, supported by a specialist team specific to the colposcopy unit. The named lead colposcopist must have a job description
- there must be at least two nurses for each clinic in addition to the colposcopist or colposcopists. The primary nurse should be a registered nurse trained in counselling. This should be the named nurse dedicated to the unit, without other concurrent outpatient duties. The second nurse should be for the support of the patient, and need not be a registered nurse. These roles are

interchangeable: the second nurse could be the clinic assistant, while the primary nurse could work outside the colposcopy room but remain available where needed for supporting activities

- nurse colposcopists working in a clinic role must be supported by another registered nurse and a second nurse or clinic attendant (as described above)
- all colposcopists need support staff in the colposcopy room throughout the session
- clinic staff must be familiar with the treatment method(s) used (**100%**)
- there must be adequate dedicated clerical support for the clinic.

Evidence: Having a specialist team specific to the colposcopy unit provides continuity of care and allows women to gain confidence in individual members of staff.⁷¹ This in turn helps reduce their anxiety and improves both attendance and their satisfaction with the service. The extended role of the nurse colposcopist may be of particular benefit here.^{88,92}

5.5 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 **15%**.

Evidence: Twenty per cent of women fail to attend for their appointment. Their reasons may include one or more of the following: fear of cancer or the procedure; forgetting the appointment; menstruation; work or childcare commitments; transport constraints; lengthy waiting times.

Wasted appointments represent an administrative cost to departments. Following reminders, most women will eventually be seen within a year of their first non-attendance. Strategies to improve patterns of attendance should be explored.^{93–98} Patient focused booking may reduce patient default and cancellation rates in the non-colposcopy setting.^{99–101} However its role in the colposcopy setting is unclear.

5.6 Multidisciplinary working

5.6.1 Liaison with other units

Effective liaison between units is an essential component of high quality integrated patient care

- colposcopy clinics in GUM must have established protocols for liaison with gynaecological services¹⁰² (**100%**)
- multidisciplinary audit must be an integral part of the service
- there should be well established clinical and computer links with cytological and histological services to support multidisciplinary working
- details of the referral cytology report (if performed) should be available at time of colposcopy
- colposcopy clinics in gynaecology should have established protocols for liaison with GUM services.

5.6.2 *Multidisciplinary teams*

Multidisciplinary team (MDT) meetings help to ensure high quality care and local peer review of the screening programme

- although the outline structure and objectives of MDTs must conform with national policy, their organisation and management should be determined locally
- the colposcopy MDT should either hold separate meetings or be a distinct part of the gynaecological cancer MDT meeting
- there should be one MDT for each Trust, with caseloads to be decided locally
 - inclusion of all mismatches is likely to result in a large MDT caseload
 - the MDT should define what a mismatch is and who selects appropriate cases for discussion
 - difficult cases, borderline glandular and glandular cytology as well as cGIN should be included.

Membership

Members of the MDT should include cytologists, histopathologists and colposcopists. The chair of the meeting should be an MDT member with a management role in the local screening programme: for example, the hospital based coordinator, lead colposcopist, lead cytologist or lead histopathologist.

Frequency of MDT meetings

The MDT should meet often enough to allow timely care of women: once each month (**best practice**) or no less than once every two months (**minimum standard**).

Attendance at meetings

All colposcopists should attend at least 50% of MDT meetings to ensure the timely management of difficult cases and discordant results (**minimum standard**). Attendance at the MDT meeting should be recorded (**minimum standard**).

Recording of MDT discussions

Decisions on each case must be recorded in patients' medical records (**minimum standard**). The minutes of each meeting, including the outcome of any discussion, should be recorded and a letter describing the recommendation for future care must be sent to the colposcopist responsible for the patient (**minimum standard**). All cases of cervical cancer must be reviewed by a gynaecological cancer centre MDT (**minimum standard**).

Evidence: Good practice point.

5.7 Training and certification of colposcopists

5.7.1 Training requirements

All practising colposcopists must be able to demonstrate that they have received an adequate training. The evidence required depends on when their 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 it by April 1998 – BSCCP Completion of Training Certificate
- for those completing training before April 1998 – self-certification. There will be no self-certification after 1 January 2010. The support of a professional society is required (**best practice**).

Training must be conducted according to the requirements established by the BSCCP Certification and Training Committee. The 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. It is the view of the NHSCSP that independent colposcopy should be conducted in the NHS only by BSCCP certificated practitioners.

5.7.2 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 re-certification process to be highly desirable. Continued practice should be assured with continuing personal development and regular audit. Discussion of practice should be included in colposcopists' annual general appraisals.

5.8 Summary of standards

1. Each woman should be offered verbal information and be sent written information before and after cervical screening and before colposcopy (**95%**).
2. Counselling must be available as an integral part of colposcopy.
3. Women must be sent an appropriately worded invitation with a contact name, telephone number and clinic times.
4. Information concerning the visit and results of investigations should be communicated to the patient within four weeks of her attendance (**best practice 90%**) or eight weeks (**minimum standard 100%**).
5. Results and management plans should be communicated to the referring practitioner within four weeks of the patient's attendance at the clinic (**best practice 90%**) or eight weeks (**minimum standard 100%**).
6. Clinics operating a 'See and Treat' policy must ensure that women who are offered treatment at their first visit are sent adequate and appropriate information in advance of their appointment (100%).
7. There must be a private area with changing facilities. There must also be toilet facilities.
8. There must be a permanently sited specific room for colposcopy (**100%**).
9. Refreshments must be available.
10. There must be separate waiting and recovery areas.

11. There must be a permanent couch and colposcope.
12. Appropriate sterilising facilities must be available in accordance with local and national health and safety recommendations.
13. In units offering a diagnostic service, there must be automatic referral to a unit where treatment is available if required.
14. Clinic staff must always be familiar with the treatment method(s) used (**100%**).
15. If laser or diathermy equipment is in use, there must be adequate safety guidelines in place with all staff trained in their operation; emergency guidelines must be available in each clinic.
16. Adequate resuscitation equipment must be immediately available and staff involved in the clinical care of patients must be familiar with its use.
17. There must be suitable information technology equipment and software to facilitate collection of data for the BSCCP minimum data set and for submission of the statutory quarterly KC65.
18. All clinics must have a named colposcopist with appropriate skills who leads the service, with a specialist team specific to the colposcopy unit. The named lead colposcopist must have a job description.
19. There must be at least two nurses for each clinic.
20. Nurse colposcopists working in a clinic role must be supported by another registered nurse and a second nurse or a clinic attendant.
21. There must be adequate dedicated clerical support for the clinic.
22. There must be written protocols for the management of non-attenders.
23. The default rate should be less than **15%**.
24. Colposcopy clinics in GUM must have established protocols for liaison with gynaecological services (**100%**).
25. Multidisciplinary audit must be an integral part of the service.
26. The MDT should meet once each month (**best practice**) or at least once every two months (**minimum standard**).
27. All colposcopists should attend at least 50% of MDT meetings to ensure the timely management of difficult cases and discordant results (**minimum standard**). Attendance at MDT meetings should be recorded (**minimum standard**).
28. Decisions on each case must be recorded in patients' medical records (**minimum standard**). The minutes of each meeting, including the outcome of any discussion, should be recorded and a letter describing the recommendation for future care must be sent to the colposcopist responsible for the patient (**minimum standard**).
29. All cases of cervical cancer must be reviewed by a gynaecological cancer centre MDT (**minimum standard**).
30. All colposcopists in the team should be certificated through the BSCCP/RCOG training scheme and compliance with the re-certification process every three years is highly desirable.
31. All 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.
32. All colposcopists must attend at least one BSCCP recognised colposcopy meeting every three years.

6. DIAGNOSTIC STANDARDS FOR COLPOSCOPY

6.1 Cytology results

The cytology result should be available to the colposcopist before the colposcopic examination begins. (See section 5.6.1.)

Evidence: Knowledge of the cytological result improves the identification of colposcopic images of high grade CIN;¹⁰³ when combined with colposcopic findings it improves the sensitivity of diagnosis of high grade CIN.^{104,105}

6.2 Repetition of cervical cytology

Cervical cytology should not be repeated at first colposcopy following referral for cytological abnormality.

Cytology may be taken if the referral is for persistently inadequate sampling, or if a patient's cervical cytology is due.

Evidence: Both prospective observational and retrospective data suggest that management may be changed in up to 9% of referrals^{106–114} if a 'See and Treat' approach is not used in this setting. Additional cytology may detect further high grade lesions requiring treatment. If cytology is repeated at an interval of less than three months,^{115–117} however, the sensitivity of the repeat cytology for unspecified or high grade CIN is lower than the sensitivity of screening.^{115,116} This may be because a short interval between cytology samples does not allow time for the cervical epithelium to heal, or for small dysplastic lesions to recur between tests. Repeat cytology may adversely affect the quality of the subsequent colposcopy. Potentially, 6.4% of high grade referrals could have had their treatment prevented with cytology at the time of colposcopy; and 3.7% of low grade referrals could have had their management altered in a retrospective study of 6595 new referrals. However 14% of high grade disease was missed at cytology taken at the time of the first visit for all referrals, and the figure was 18% where the referral cytology was high grade.¹¹⁶

6.3 Colposcopic examination

The following data should be recorded at the colposcopic examination

- reason for referral (**100%**)
- grade of cytological abnormality (**90%**)
- whether the examination is satisfactory (this is defined as the entire squamocolumnar junction having been seen and the upper limit of any cervical lesion also being seen) (**100%**)
- the presence or absence of vaginal and/or endocervical extension

- the colposcopic features
- the colposcopic impression of lesion grade.

6.4 Invasive disease

Care should be taken not to overlook invasive disease. An excisional form of biopsy is recommended **(95%)** 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 canal. Sufficient canal must be removed with endocervical extension of abnormality.

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. This situation is most often encountered in association with high grade cytological or colposcopic change (CIN 3).

There may be pressing reasons for delaying biopsy, such as pregnancy. Reasons for not performing a biopsy must be recorded **(100%)**.

Evidence: The evidence sources are one systematic review¹¹⁸ and subsequent retrospective reviews^{119,120} of cases of invasion identified through cervical screening and colposcopic examination. The relevant findings were that 56% of microinvasive and 30% of invasive lesions are missed by colposcopy.¹¹⁸ The retrospective reviews^{119,120} suggest that approximately two-thirds of missed cancers are due to colposcopist error, while one-third are due to the limitations of technique. There is evidence that the likelihood of cancer is related to the size of the lesion as described by the proportion of the ectocervical transformation zone involved with a high grade abnormality. A small observational study looked at lesion length and the association with cancer and suggested that women with microinvasive cervical carcinoma had CIN 3 occupying most of the surface of the transformation zone. However comparisons of lesion size were with historic controls with CIN 3.¹²¹ Common cytological and colposcopic findings in cases of missed disease included one or more of the following

- high grade cytological abnormality
- endocervical extension of lesions, even when examination was 'satisfactory'
- large, complex lesions with raised irregular surfaces
- underevaluation of lesions by colposcopically directed biopsy.¹²²⁻¹²⁴

Systematic review has shown that unsatisfactory colposcopy is a more frequent finding in invasive disease (61% of microinvasive, 71% of invasive disease) than in CIN (14% of CIN). Atypical vessels are found in 44% of microinvasion and 84% of invasion.^{118,125}

6.5 Local destruction

All women must have had histological diagnosis established before destructive therapy **(100%)**.

Evidence: Accepted practice dictates that the decision to perform destructive treatments should be reached only after the available cytological, colposcopic and directed biopsy evidence indicates a high degree of confidence that invasion is absent. Retrospective studies of invasive disease presenting after destructive treatments indicate that failure to exclude invasive carcinoma prior to treatment is the most important aetiological factor.^{126,127} Nevertheless, large observational studies of local destructive therapies conducted in regional centres with rigorous colposcopic assessment indicate high success rates with only a small risk of inadvertent or inappropriate treatment of invasive and glandular lesions.^{128–130}

6.6 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%**). Pregnancy is an exception.

Low grade cytological abnormality (mild dyskaryosis or less) **and** a low grade or negative colposcopic examination may not require colposcopic biopsy.

Evidence: A retrospective study¹³¹ showed that in women with low grade cytological abnormalities and a normal colposcopic examination, only 7.8% had CIN 2 or 3 on loop excision.

6.6.1 Treatment decisions

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.^{118,122,132}

Evidence: Colposcopically directed biopsy (CDB) can be considered only as a sampling of the lesion, by convention the most atypical area, and thus can give only a provisional histological diagnosis. Systematic review¹¹⁸ of studies comparing CDB with reference histology from cones or hysterectomy specimens shows a lower PPV for CIN 1 and 2 (16%, 32%) than for CIN 3 (86%). PPV for microinvasion was 59% and for invasion was 83%. Additional retrospective studies show that while CDB may correctly 'overestimate' the grade of lesion compared with reference histology when the lesion is small, CDB has been shown frequently to underestimate the severity of the lesion. High grade CIN is underestimated in 4.3–57.1% of cases.^{104,133–136} Cases of early invasive disease have been underevaluated as CIN 3.^{120,122,133} Subjectivity in colposcopic opinion is also reflected in selection of site for biopsy.¹³⁷

6.6.2 Destructive treatment

Of all biopsies taken (directed and excisional) **>90%** should be suitable for histological interpretation.

The colposcopist should analyse the results of cytology, colposcopy and biopsy before selecting a destructive method for treatment.

Evidence: Good practice dictates that the decision to perform destructive treatments should be reached only after the available cytological, colposcopic and directed biopsy evidence indicates a high degree of confidence that invasion is absent.

If colposcopically directed biopsy is reported as inadequate for histological interpretation, it should be repeated if there is a residual colposcopic lesion (**95%**).

Evidence: Good practice point.

6.7 Accuracy of colposcopic diagnosis

For those with satisfactory colposcopic examination, the predictive value of a colposcopic diagnosis of a high grade lesion (CIN 2 or worse) should be at least **65%**.

It is desirable that colposcopists should be able to differentiate high grade (CIN 3 and CIN 2) lesions (intraepithelial or otherwise) from low grade lesions in order to avoid missing advanced disease and to reduce overtreatment for low grade lesions. A variety of factors influence the precision of colposcopic diagnosis.

Specific colposcopic appearances such as acetowhite epithelium, punctation and mosaicism, and glandular cuffing have been related to histology in few studies¹¹⁸ and any statistical analysis is unreliable. Furthermore, punctation and mosaicism are noted in benign circumstances.¹¹⁸ Scoring systems have been published but these are not recommended for routine clinical use. They do not readily facilitate the confirmation or exclusion of high grade disease, which is the most important and reproducible colposcopic criterion (see below). Among experienced colposcopists, there is a lower level of agreement when diagnosing low grade lesions (CIN 1) compared with high grade lesions,^{103,137} and for low grade abnormalities agreement is poor.¹⁰³ Not all CIN lesions may demonstrate colposcopic abnormality.¹³⁸

There is an association between increasing severity of CIN and lesion size. Furthermore, the accuracy of colposcopic diagnosis in women with proven high grade CIN is related to lesion size.¹⁰⁵ Invasive cancer and high grade CIN are usually accepted as reproducible end points for significant disease in assessing cervical screening and diagnosis. Although it has been noted that there is considerable subjectivity and interobserver variability in the grading of CIN by expert pathologists, this is less marked for high grade lesions. The histological presence or absence of high grade CIN seems the most valid way of assessing the performance of colposcopic diagnosis (colposcopic impression).

For guidance in relation to cervical glandular intraepithelial neoplasia, see section 12.

Evidence: One meta-analysis¹³⁹ of the ability of colposcopy to differentiate high grade lesions (CIN 2/3) from all others (normal and low grade). Additional retrospective studies were identified from which sensitivity and PPV for high grade lesions could be calculated.^{104,122,140} One systematic review calculated the PPV of colposcopic impression.¹¹⁸ Meta-analysis suggests high sensitivity of colposcopy, with average weighted sensitivity 85%, but low specificity, with average weighted specificity 69%, confirming a high rate of false positive diagnosis of high grade lesions. Further analysis showed that high grade lesions had colposcopic characteristics that allowed them to be reasonably accurately separated from low grade lesions. However attempting to distinguish low grade lesions from benign was much less accurate.¹³⁹ Analysis of three other retrospective studies indicated broadly similar results. One study showed improvement in diagnostic sensitivity of 8%¹⁰⁴ by considering the cytology result, at the expense of a similar reduction in specificity. The systematic review demonstrated a PPV of a colposcopic impression of CIN 3 of 78%. PPV declined as severity of CIN decreased.¹¹⁸

6.8 Summary of standards

1. The following data should be recorded at the colposcopic examination
 - reason for referral (100%)
 - grade of cytological abnormality (90%)
 - whether the examination is satisfactory. This is defined as the entire squamocolumnar junction having been seen, and the upper limit of any cervical lesion also being seen (100%).
2. An excisional form of biopsy is recommended (**95%**)
 - 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 canal. Sufficient canal must be removed with endocervical extension of abnormality.
3. Reasons for not performing a biopsy must be recorded (**100%**).
4. All women must have had histological diagnosis established before destructive therapy (**100%**).
5. 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%**). Pregnancy is an exception.
6. Of all biopsies taken (directed and excisional) **>90%** should be suitable for histological interpretation.
7. If colposcopically directed biopsy is reported as inadequate for histological interpretation, it should be repeated if there is a residual colposcopic lesion (**95%**).
8. For those with satisfactory colposcopic examination, the predictive value of a colposcopic diagnosis of a high grade lesion (CIN 2 or worse) should be at least **65%**.

7. INFECTIONS AND COLPOSCOPY

7.1 Asymptomatic women

There is no indication to routinely test for *Chlamydia* and other infections in asymptomatic patients when attending colposcopy. If a patient complains of vaginal discharge or soreness then high vaginal and endocervical sampling is indicated after gaining verbal consent for *Chlamydia/Gonococcus* testing.

Evidence: Screening for *Chlamydia* has been recommended for women attending GUM clinics (prevalence 16%), having termination of pregnancy (prevalence 8%), for sexually active women under 25 years of age or those with a new partner or more than two partners in the previous year. Prevalence of asymptomatic infection in general practice and family planning clinics is 5%.^{141,142} Colposcopy clinics have not been included as a high risk group but a prevalence rate of 3–10% has been quoted in studies of women attending for cervical cytology in general practice in Wales and a low risk urban population in the USA.^{143,144} Similarly evidence fails to support testing for *Gonococcus* in asymptomatic women.¹⁴⁴

7.2 *Actinomyces*-like organisms

Actinomyces-like organisms (ALOs) require no specific intervention in the vast majority of patients and are usually seen in patients using an intrauterine contraceptive device (including the Mirena IUS).

If asymptomatic then

- the coil does not need to be removed and antibiotics are not required (see section 10.2.2)
- the patient should have an abdominal and pelvic examination
- the patient should be warned of the small possibility of developing pelvic actinomycosis and advised to return should she develop symptoms
- repeat cytology is not required unless the cervical cytology sample was graded inadequate or abnormal and is due for an early repeat
- if the asymptomatic patient wishes the device to be removed or it is due for removal then it need not be sent for culture
- no follow up is required.

If the patient complains of specific symptoms the device may need to be removed, after first ensuring that the patient has not had sexual intercourse in the preceding five days. These symptoms include

- pelvic pain
- deep dyspareunia
- intermenstrual bleeding (after six months of a device being in situ)
- vaginal discharge, dysuria or significant pelvic tenderness.

If the device is removed because the woman has any of the above symptoms

- the device should be sent for culture and alternative contraception advised
- a course of antibiotics (such as amoxicillin 250mg three times daily for two weeks, or erythromycin 500mg three times daily for two weeks in penicillin sensitive patients) should be given and a gynaecological opinion arranged to ensure that the symptoms or signs have resolved.¹⁴⁵

Evidence: Good practice point.

7.3 Incidental infections

Incidental infections may be detected in cervical samples. Some may require specific treatment or defined management.

7.3.1 *Bacterial vaginosis*

If the patient does not complain of a vaginal discharge and is not pregnant then treatment is not required.

7.3.2 *Candidiasis (Monilia)*

This should be treated if symptomatic.

7.3.3 *Herpes simplex*

Patients with a herpes simplex virus infection may present with symptoms long before the cervical cytology report is available. All patients should be referred to a local GUM clinic. Acyclovir (200 mg five times daily for five days) is started if active infection is suspected. There is no evidence that this drug is teratogenic, so it can be safely prescribed in pregnancy.¹⁴⁶

7.3.4 *Trichomonas vaginalis (TV)*

Asymptomatic detection of this protozoon merits treatment in all cases. All patients should be referred to a local GUM clinic. The patient and her partner should be treated with metronidazole (400 mg three times daily for one week). Cervical samples with *Trichomonas* present may often be unsatisfactory because of the marked inflammation. TV should be first treated if a repeat test is required.

Evidence: Good practice point.

8. TREATMENT OF CERVICAL INTRAEPITHELIAL NEOPLASIA (CIN)

8.1 Treatment standards

- All women needing treatment must be informed that treatment will be required and their consent, either written or verbal, recorded (**100%**).
- All women needing treatment must have had a colposcopic assessment (**100%**).
- All treatments must be recorded (**100%**).
- All women must be treated in properly equipped and staffed clinics (**100%**).
- The proportion of women treated at the first visit who have evidence of CIN 2/3 or cGIN on histology must be **≥90%**.
- The proportion of women having definitive treatment for high grade CIN within four weeks of the colposcopy clinic receiving a diagnostic biopsy report should be **≥90%**.
- All women having definitive treatment for high grade CIN must be treated within eight weeks (**100%**). Pregnant women are excepted from this. The reason for any delay must be specified.
- The proportion of treatment associated with primary haemorrhage that requires a haemostatic technique in addition to the treatment method applied must be **<5%**.
- The proportion of cases admitted as inpatients because of treatment complications must be **<2%**.

8.2 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.

Evidence: Cochrane review of 28 randomised controlled trials comparing seven surgical techniques: knife cone biopsy, laser conisation, large loop excision of the transformation zone (LLETZ), laser ablation, cryocautery, cold coagulation, and radical diathermy.¹⁴⁷ One prospective randomised trial of excision versus destruction has indicated a lower rate of moderately dyskaryotic cervical cytology samples after excision.¹⁴⁸ Occasionally women under 25 years of age are seen with CIN 3. Management of these unusual cases should be discussed with the local lead colposcopist, preferably with the assistance of the local colposcopy MDT.

CIN 1 does not necessarily require treatment. If CIN 1 is not treated, cytological follow up should be performed until cytological regression occurs or treatment is undertaken.

8.3 Cryocautery

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

Evidence: The rate of clearance of CIN 3 is poor.^{149,150} The double freeze technique has a lower incidence of residual disease compared with a single freeze technique.^{151,152}

8.4 Excision

8.4.1 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.

Evidence: Good practice point.

8.4.2 Histology report

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

Evidence: Good practice point.

8.4.3 Ectocervical lesions

For ectocervical lesions, excisional techniques should remove tissue to a depth of greater than 7 mm (**95%**).

Evidence: Histological assessment of the depth of crypt involvement by CIN 3 has shown a mean depth of 1–2 mm with a maximum of 5.22 mm and a mean +3 standard deviations (99.7%) of 3.80 mm.^{153,154}

8.5 Select and treat policy

Treatment at first visit for a referral of borderline or mild dyskaryosis should be used only in exceptional cases, and only when audit has identified that CIN 2/3 or cGIN is present in **≥90%** of the excised specimens.

Evidence: It is inappropriate to adopt 'See and Treat' if the proportion of specimens with no CIN is high, as these women will have received unnecessary treatment. From a randomised controlled trial of 1983 women aged 20–59 years referred with borderline or mild dyskaryosis, punch biopsy and selective treatment detected as much CIN 2+ over three years as immediate loop excision. Sixty per cent of loop excisions contained in the immediate treatment arm had no CIN.⁶² Clinics undertaking treatment at the first visit must audit the proportion of cases with high grade CIN or cGIN. A target of $\geq 90\%$ can be achieved with a selective policy.¹⁵⁵

8.6 Repeat excision

8.6.1 *CIN 3 extending to margins*

CIN 3 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.

Evidence: CIN extending to the resection margins of a LLETZ has been shown to be a risk factor for recurrent CIN in both the short and the long term.^{156–158} This risk appears predominantly due to the presence of CIN at the endocervical margin.¹⁵⁹ Despite the increased incidence of recurrence, the majority of women in the above studies had no evidence of residual disease, and the recommendation is that these women have colposcopy and cytology at first follow up.

8.6.2 *Women over the age of 50*

All women over the age of 50 years who have CIN 3 at the lateral or deep margins and in whom satisfactory cytology and colposcopy cannot be guaranteed must have a repeat excision performed to try to obtain clear margins (**100%**).

Evidence: In a series of 3426 LLETZ procedures, women aged ≥ 50 with CIN at the margins of excision constituted a minority high risk group. It was suggested that these women be offered retreatment rather than surveillance.¹⁵⁹

8.7 Local excision

8.7.1 Women with adenocarcinoma in situ or cGIN

Women with adenocarcinoma in situ or cGIN who wish to retain fertility can be managed by local excision. Incomplete excision at the lateral or deep margins requires a further excisional procedure to obtain clear margins and exclude occult invasive disease (**95%**). (See sections 12.3 and 12.4.)

Evidence: Several studies have shown that women with adenocarcinoma in situ with negative margins can be managed conservatively.^{160–163} One study has suggested that up to 15% of these women will require further treatment within four years because of recurrent cytological abnormalities.¹⁶²

8.7.2 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 excision of the CIN and to exclude further invasive disease. This should be performed even in those cases planned for hysterectomy to exclude an occult invasive lesion requiring radical surgery.

Evidence: Several studies have suggested that FIGO stage Ia1 disease can be managed conservatively.^{155,164} Variation in histological diagnosis of microinvasive disease is well recognised and all cases should be reviewed by an independent pathologist with an interest in gynaecological oncology.

8.8 Anaesthesia

Treatment should be performed with adequate pain control and should include pretreatment counselling. Treatment should be offered with local analgesia but 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 outpatients with local analgesia should be **≥80%**.

8.9 Summary of standards

1. All women needing treatment must be informed that treatment will be required and their consent, either written or verbal, recorded (**100%**).
2. All women needing treatment must have had a colposcopic assessment (**100%**).
3. All treatments must be recorded (**100%**).
4. All women must be treated in properly equipped and staffed clinics (**100%**).

5. The proportion of women treated at the first visit who have evidence of CIN 2/3 or cGIN on histology must be **≥90%**.
6. The proportion of women having definitive treatment for high grade CIN within four weeks of the colposcopy clinic receiving a diagnostic biopsy report should be **≥90%**.
7. All women having definitive treatment for high grade CIN must be treated within eight weeks (**100%**). Pregnant women are excepted from this. The reason for any delay must be specified.
8. The proportion of treatment associated with primary haemorrhage that requires a haemostatic technique in addition to the treatment method applied must be **<5%**.
9. The proportion of cases admitted as inpatients because of treatment complications must be **<2%**.
10. 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%**).
11. Cryocautery should be used only for low grade CIN and a double freeze–thaw–freeze technique must be used (**100%**).
12. When excision is used **≥80%** of cases should have the specimen removed as a single sample.
13. For ectocervical lesions, excisional techniques should remove tissue to a depth **> 7 mm (95%)**.
14. Treatment at first visit for a referral of borderline or mild dyskaryosis should be used only in exceptional cases, and only when audit has identified that CIN 2/3 or cGIN is present in **≥90%** of the excised specimens.
15. All women over the age of 50 years who have CIN 3 at the lateral or deep margins and in whom satisfactory cytology and colposcopy cannot be guaranteed must have a repeat excision performed to try to obtain clear margins (**100%**).
16. Women with adenocarcinoma in situ or cGIN who wish to retain fertility can be managed by local excision. Incomplete excision at the lateral or deep margins requires a further excisional procedure to obtain clear margins and exclude occult invasive disease (**95%**).
17. The proportion of women managed as outpatients with local analgesia should be **≥80%**.

9. FOLLOW UP OF WOMEN ATTENDING FOR COLPOSCOPY

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.^{68,165} 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.³⁹ Thorough compliance should be encouraged.

There is no obviously superior conservative surgical technique for the treatment of cervical intraepithelial neoplasia.¹⁴⁷ Excisional treatments permit histological assessment of a biopsy and can determine risk factors for residual disease. Women at increased risk of residual or recurrent disease should be considered for more intensive surveillance following treatment.

Evidence: Several retrospective studies^{152,159,166–174} of residual disease rates after LLETZ or knife cone biopsy have demonstrated that negative excision margins are associated with lower risk of residual disease and positive excision margins are associated with higher risk of residual disease. Studies have demonstrated that disease at the endocervical resection margin is associated with increased risk of residual disease compared with involved ectocervical margins.^{152,156,173,175,176} Women aged 50 or more^{159,177} are particularly at risk of persistent/recurrent disease.

9.2 Standards for follow up of treated women

- Follow up should start at six months following treatment and not later than eight months following treatment (**>90%**).
- Cytology alone is recommended for follow up and samples should be taken by appropriately trained staff.
- Initial follow up cytology (six month test) may be performed in the colposcopy or gynaecology clinic. Alternatively, it may be performed in the community.
- All women who do not have negative test results after treatment should be re-colposcoped at least once within 12 months (**100%**).
- The proportion of treated women with no dyskaryosis six months following treatment should exceed **90%**.
- The proportion of confirmed histological treatment failures should not exceed **5%** within 12 months of treatment.

9.3 Duration of follow up

Women should have annual follow up for at least 10 years after the treatment of CIN 2 or worse before returning to the routine screening interval. Women treated for CIN 1 can be returned to routine recall after two years of negative post-treatment cytology.

Evidence: The majority of persistent/recurrent disease is detected within the first 24 months.^{159,178} However there is clear evidence that there is persistent long-term risk of invasive cancer for at least 10 years after treatment and possibly for 20 years.^{68,179} Annual follow up cytology is therefore justified after the treatment of CIN 2 or worse. While the risk of invasive recurrence is likely to be greater after treatment of high grade disease, there are no reliable data that examine the relative risks for different grades of CIN. Annual cytological follow up is not to be extended beyond 10 years, but work is in progress on test of cure. Recommendations will become available in due course to guide management.

9.4 Frequency of follow up

Recommendations for follow up protocols are currently determined by expert consensus opinion

- women treated for high grade disease (CIN 2, CIN 3, cGIN) require six and 12 month follow up cytology and annual cytology for the subsequent nine years at least before returning to screening at the routine interval (high risk follow up)
- women treated for low grade disease require six, 12 and 24 month follow up cytology. If all results are negative, then women may be returned to screening at the routine interval (low risk follow up)
- if a woman has not attended for all the specified cytology for her high risk follow up, she should be allowed to return to routine screening provided her samples are normal at least 10 years after treatment.

Evidence: There is no clear evidence suggesting that diagnostic performance of cytology in combination with colposcopy for the detection of persistent disease after treatment for CIN is superior to cytology alone.

Current opinion is mixed on the value of cytology combined with colposcopy for follow up. Some authors suggest that colposcopy does not increase the detection of disease.^{179,180} Other authors^{181–184} suggest that an initial follow up colposcopy marginally enhances early detection of disease and reduces the false negative rate.

Women treated for cGIN are at somewhat higher risk of developing recurrent disease than those with high grade CIN.¹⁶² In addition, recurrent disease is more difficult to detect cytologically. Cytology should continue for the same duration with the same frequency as after treatment of CIN 2 and CIN 3 (**minimum standard**). Ideally, six monthly samples would be taken for five years followed by annual samples for a further five years (**best practice**).

9.5 Cervical samples for follow up cytology

Brush devices such as the Cervex-Brush® or EndoCervex Brush® should be used for liquid based samples

- after surgical treatment, particularly excisional treatment, the squamocolumnar junction can retract into the cervical canal. Care should be taken to sample the endocervical canal

- after treatment for cGIN, follow up samples must contain endocervical cells. (See section 12.3.) Paired samples should be taken and supplied in the same pot.

9.6 Follow up after 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
- women who undergo hysterectomy and have **completely excised CIN** should have vaginal vault cytology at six and 18 months following their hysterectomy
- for 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)
 - as women who have undergone hysterectomy have no cervix, and so are no longer eligible for recall within the NHSCSP, their vault cytology following treatment of CIN must be managed outside the programme
- responsibility for implementing these follow up policies will rest with the 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
- follow up will be dealt with by the general practitioner. This excludes cases of incomplete excision, a high risk group that will be dealt with by the colposcopy clinic
- follow up arrangements for women who need vault cytology after hysterectomy will be agreed locally, along with any failsafe arrangements. There is no national guidance on how this should be achieved. It will be based on consultation with the local screening service, local screening leads, the lead colposcopist and local GPs
- 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
- there is no clear evidence that colposcopy increases detection of disease on follow up.

Evidence: The incidence of vaginal intraepithelial neoplasia (VaIN) following hysterectomy diagnosed with CIN is in the order of 1% in a series of 341 women¹⁸⁵ with no subsequent cases of invasive disease. In a similar series of 177 women,¹⁸⁶ 4% developed VaIN with 0.6% developing subsequent invasive disease. A meta-analysis of long term results suggests that while recurrent intraepithelial disease is less common after hysterectomy for CIN than after local treatments of the cervix (522 vs. 1587 per 100 000 woman-years), the risk of invasive recurrence is similar in both groups (57 vs. 67 per 100 000 woman-years).³⁹

It is accepted that, even after hysterectomy, there is a risk of developing cancer similar to that after conisation or local destruction. It is not clear whether this is due to incomplete treatment or recurrent disease, although the latter would seem unlikely if the whole cervical transformation zone (along with the cervix) has been removed. Although supporting evidence is lacking, professional consensus suggests that if there is complete excision with no transformation zone remaining and two follow up cytology tests confirm no dyskaryosis, then the risk of developing cancer must be very small indeed and does not justify surveillance beyond the suggested 18 months.

HPV testing may become available in the future; it is **not** recommended until further data become available from trials and pilots.

9.7 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.

Follow up of stage Ia1

If conservative treatment for cervical cancer has been performed, leaving a residual cervix, cytological follow up is identical to that for high grade preinvasive disease. 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.

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. (See section 9.6.)

Total hysterectomy where patient has invasive or early invasive carcinoma of cervix

The patient will receive further follow up determined by her gynaecologist or oncologist. This might include subsequent vault cytology and/or colposcopy. It is the responsibility of the clinician to ensure that the patient is properly followed up; she will not be subject to further recall by the NHSCSP.

Total hysterectomy for carcinoma of the cervix also treated by radiotherapy

The patient will receive further follow up, to be determined by her gynaecologist or oncologist. This might include colposcopy. It is the responsibility of the clinician to ensure that the patient is properly followed up; she will not be subject to further recall by the NHSCSP.

9.8 Follow up of untreated women

9.8.1 Women referred with moderate or severe dyskaryosis

Women referred with moderate or severe dyskaryosis (high grade) on their test result are at significant risk of CIN 2 or 3 even in the presence of normal colposcopy. Biopsy should be undertaken in **>95%** of women with moderate or severe dyskaryosis (high grade) on their test result. (See section 6.4.) If treatment is not undertaken, close surveillance with colposcopy and cytology every six months is advised. If at follow up a high grade cytological abnormality persists, excisional treatment is recommended (**90%**).

Evidence: The overall specificity for distinguishing normal from abnormal tissue at colposcopy in a meta-analysis was only 48%.¹⁸⁷ The specificity of high grade cytology is over 90% in several studies.^{188,189} This evidence suggests that high grade cytological abnormalities have a high likelihood of being associated with CIN 2 or CIN 3. Follow up studies^{190,191} also support the relatively high likelihood of CIN 2 or CIN 3 in this group. Therefore the presence of persistent high grade abnormalities, even in the face of normal colposcopy, warrants treatment.

9.8.2 Women referred with moderate dyskaryosis or worse

Women referred with moderate dyskaryosis or worse cytological abnormalities who have a colposcopically low grade lesion, whose colposcopy is satisfactory and who are not treated should have multiple biopsies (**90%**). If CIN 1 or less is confirmed, close colposcopic and cytological follow up is advised. Cases with unexplained severe dyskaryosis should be discussed at multidisciplinary meetings.

Evidence: The PPV of colposcopy for distinguishing low grade from high grade lesions is only 57%.¹⁸⁷ As the specificity of high grade cytology is over 90%, the likelihood of an underlying high grade lesion in this situation is extremely high. If treatment is not undertaken as a result of colposcopic diagnosis of a low grade lesion, histological assessment is recommended by way of multiple directed biopsies.^{189,192} If there is high grade cytology at follow up, treatment is recommended.

9.8.3 Women referred with mild dyskaryosis or less

Women referred with mild dyskaryosis or less who have a satisfactory and normal colposcopic examination are at low risk of developing cervical cancer. Their management is best determined by repeat cytological assessment six months after the referral sample

- if this is normal they can be returned to recall
- if this is borderline, repeat test in 12 months
- if this is mild dyskaryosis, a colposcopy with another test within 12 months is recommended
- any other test result warrants further colposcopy with or without biopsies
- the local call/recall service must be informed.

There is no new evidence to suggest that a colposcopically directed punch biopsy from a normal transformation zone is of any benefit following a low grade referral.¹⁹³ (See section 6.6.)

Evidence: Three studies^{190,191,194} indicate that the risk of significant disease is extremely small when low grade cytology (mild dyskaryosis or less) is associated with normal colposcopy. The risk probably does not warrant intensive surveillance with its attendant costs and anxieties. In each of these studies, follow up cytology identified women with significant disease and this should form the main part of follow up. In one study¹⁹⁴ the cervical cytology sample at first colposcopy visit distinguished those who were at risk. If this repeat sample was normal or borderline, the risk was minimal and referral back to community screening was advised. There is evidence to suggest that the routine practice of repeating cervical cytology sampling at first attendance at the clinic does not add significantly to management, and certainly repeating it within three months of an index sample is unlikely to be helpful. However in the face of a low grade referral there is a 50% chance of normal colposcopy. If it is satisfactory and normal the cytology should be repeated six months later at a colposcopy clinic or in the community.

9.8.4 *Women referred with a report of mild dyskaryosis or less*

Women referred with a result of mild dyskaryosis or less who have a colposcopically low grade lesion may be treated or followed up at 6–12 months in the colposcopy clinic or the community. Colposcopic biopsy at initial assessment is not essential.

If the lesion has not resolved within two years of referral to colposcopy, at least a biopsy is warranted (>90%). In practice, many women are offered treatment at this point as persistent surveillance risks default.

Evidence: Approximately 50% of women with a low grade cytological abnormality who are not treated at first visit will eventually revert to normal cytology and colposcopy.¹⁶ Those who are identified as having a colposcopically low grade lesion may be followed up.¹ Prospective randomised data suggest that such a policy does not alter the number of women with high grade lesions who are treated but does reduce the number of low grade lesions treated.⁶¹ However in this study over one-fifth of women defaulted from follow up. Therefore, the decision to follow up rather than treat in the presence of an apparent low grade lesion must incorporate analysis of the likelihood of default. Furthermore the PPV for distinguishing low grade from high grade lesions is only 57%.¹⁸⁷ Therefore follow up is warranted as a result of the inherently poor colposcopic discrimination between high and low grade lesions. The ongoing management decisions for this group will often be influenced by the woman's choice.

9.8.5 *Management of inadequate cytology*

Where cytology taken immediately prior to colposcopy remains inadequate, if the colposcopy is satisfactory and normal the patient should be invited for routine recall.

9.9 **Summary of standards**

1. All women remain at risk following treatment and must be followed up (**100%**).

2. Follow up should start at six months following treatment and not later than eight months following treatment (**>90%**).
3. Cytology alone is recommended for follow up and samples should be taken by appropriately trained staff.
4. Initial follow up cytology (six month test) may be performed in the colposcopy or gynaecology clinic. Alternatively, it may be performed in the community.
5. All women who do not have negative test results after treatment must be re-colposcoped at least once within 12 months (**100%**).
6. The proportion of treated women with no dyskaryosis six months following treatment should exceed **90%**.
7. The proportion of confirmed histological treatment failures should not exceed **5%** within 12 months of treatment.
8. Biopsy should be undertaken in **>95%** of women with moderate or severe dyskaryosis (high grade) on their test result.
9. If at follow up a high grade cytological abnormality persists, excisional treatment is recommended (**90%**).
10. Women referred with moderate dyskaryosis or worse cytological abnormalities who have a colposcopically low grade lesion, whose colposcopy is satisfactory and who are not treated should have multiple biopsies (**90%**).
11. If a low grade lesion has not resolved within two years of referral to colposcopy, at least a biopsy is warranted (**>90%**).

10. PREGNANCY, CONTRACEPTION, MENOPAUSE AND HYSTERECTOMY

10.1 Pregnant women

10.1.1 Cervical screening in pregnancy

- If a woman has been called for routine screening and she is pregnant, the test should be deferred.
- If a previous test was abnormal and in the interim the woman becomes pregnant, then the test should not be delayed but should be taken in mid-trimester unless there is a clinical contraindication.
- If a pregnant woman requires colposcopy or cytology after treatment (or follow up of untreated CIN 1), her assessment may be delayed until after delivery. Unless there is an obstetric contraindication, however, assessment should not be delayed if a first follow up cytology or colposcopy is required following treatment for cGIN, or treatment for CIN 2/3 with involved or uncertain margin status.

The colposcopist may wish to perform only colposcopy at a follow up appointment in pregnancy.

If repeat cytology is due, and the woman has missed or defaulted her appointment prior to pregnancy, consideration should be given to her having the cytology or colposcopy during pregnancy.

10.1.2 Colposcopy in 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 colposcopy for pregnant women 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.

Evidence: The safety of delaying treatment of pregnant women has been shown in a number of cohort and retrospective uncontrolled studies.^{195–197} The incidence of invasive cervical cancer in pregnancy is low and pregnancy itself does not have an adverse effect on the prognosis.¹⁹⁸

If colposcopy has been performed during pregnancy, postpartum 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 colposcopy post partum. This requires a system to ensure that women are given an appointment after delivery.

Evidence: Regression rates for preinvasive cervical disease during pregnancy and following delivery are low from retrospective uncontrolled studies and regression is not related to mode of delivery.¹⁹⁹ A retrospective study of pregnant women treated by cone biopsy for high grade CIN and microinvasion reported high rates of disease persistence.²⁰⁰

10.1.3 Colposcopic evaluation of the pregnant woman

Colposcopic evaluation of the pregnant woman requires a high degree of skill

- if CIN 1 or less is suspected, repeat the examination three months following delivery
- if CIN 2 or 3 is suspected, repeat colposcopy at the end of the second trimester or, if the pregnancy has already advanced beyond that point, 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 where appropriate facilities to deal with haemorrhage are available. Punch biopsy suggesting only CIN cannot reliably exclude invasion.

Evidence: Case series of biopsies taken by diathermy loop in pregnancy have shown that the risk of haemorrhage is in the order of 25%.²⁰¹

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. An abnormal result should not influence the choice of contraception.

Evidence: Nested case-control studies indicate a small increase in the relative risk of CIN after compensating for HPV infection with long term use of the OCP.²⁰²⁻²⁰⁴ However we do not have evidence that stopping OCP use will alter the natural history of the disease. A large prospective cohort study confirms no significant association between past or present users of OCP and cervical cancer.²⁰⁵ A systematic review found no significant effect for studies controlled for HPV status for up to 10 years of use.²⁰⁶

10.2.2 Women with an IUCD (see section 7.2)

Women with an intrauterine contraceptive device (IUCD) should be given clear information on the clinic's management policy regarding whether her IUCD 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.

Evidence: Good practice point.

10.3 Menopause and use of hormone replacement therapy

10.3.1 *Postmenopausal women*

The incidence of abnormal cytology is low in postmenopausal women with previous normal results. The use of systemic HRT is not known to alter the risk of cervical disease.

Evidence: One randomised controlled trial and two case–control studies demonstrated no increase in relative risk from the use of systemic HRT.^{207–209}

10.3.2 *Postmenopausal bleeding*

In an adequately screened woman, postmenopausal bleeding (PMB) 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.

Evidence: Good practice point.

10.4 Hysterectomy

10.4.1 *Women undergoing a hysterectomy for other reasons*

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

Evidence: Good practice point.

10.4.2 *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 biopsy²¹⁰ (**100%**).

Evidence: Professional consensus suggests that the nature and extent of cervical neoplasia be defined in such a way as to avoid inadvertent non-radical treatment of cervical cancer or inadvertent inadequate excision of VaIN.^{210,211}

10.4.3 *Hysterectomy as treatment for histologically proven CIN*

Hysterectomy is a recognised treatment for histologically proven CIN if there are coexisting conditions appropriately treated by hysterectomy.

Evidence: Good practice point.

10.4.4 *Hysterectomy as treatment of persistent abnormal endocervical cytology*

Hysterectomy is an acceptable form of treatment in cases where abnormal endocervical cytology persists despite a prior excisional biopsy of adequate size. This is provided that all measures to exclude occult invasion have been applied.²¹²

Evidence: Good practice point.

10.4.5 *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.²¹²

Evidence: Observational data.

10.4.6 *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.

Evidence: Good practice point.

10.4.7 *Follow up after hysterectomy*

After hysterectomy, follow up is advised as suggested in section 9.6.

Evidence: Good practice point.

10.5 Summary of standards

1. If colposcopy has been performed during pregnancy, postpartum assessment of women with an abnormal cervical sample or biopsy proven CIN is essential **(100%)**.
2. If invasive disease is suspected clinically or colposcopically in a pregnant woman, a biopsy adequate to make the diagnosis is essential **(100%)**.
3. The investigation of abnormal bleeding after the menopause must include direct visual inspection of the cervix.
4. All patients in the cervical screening age range undergoing a hysterectomy for other gynaecological reasons should have a negative test result within the screening interval or as part of their preoperative investigations **(100%)**.
5. All patients being considered for hysterectomy who have an undiagnosed abnormal sample or symptoms attributable to cervical cancer should have diagnostic colposcopy and an appropriate biopsy **(100%)**.

11. SCREENING AND MANAGEMENT OF IMMUNOSUPPRESSED WOMEN

11.1 Immunosuppressed women

This includes women on immunosuppressing medication, transplant recipients and all other forms of immunosuppression. The screening and management of the immunosuppressed woman is a complex area of assessment and management. All patients who are immunosuppressed must be managed in a centre that has demonstrable skill and expertise and sufficient access to patient numbers to maintain that expertise. Such a centre must have colposcopists who are familiar with the frequency of screening required for women who are immunosuppressed for various reasons. They must be able to recognise and manage VaIN, VIN and widespread condylomata. Close cooperation is advised with renal, autoimmune and sexual health physicians to ensure that women are not overtreated if there is a possibility of enhancing immunocompetence (eg by raising CD4 counts following improved compliance with antiretroviral therapy). 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 to the comorbidity of the underlying disease process.

11.2 Women with renal failure requiring dialysis

All women aged 25–64 years with renal failure requiring dialysis, and older women with this condition if they have never been screened, must have cervical cytology performed at or shortly after diagnosis.

Colposcopy should be performed if resource permits. Any cytological abnormality should be treated as a high grade abnormality requiring prompt colposcopic referral. All women about to undergo renal transplantation should have had cervical cytology performed within a year. Coexisting CIN should be managed according to national guidelines.

Evidence: There is good evidence that women who have renal failure requiring dialysis or renal transplantation are at an increased risk of CIN and cervical cancer.^{213,214} The range of incidence of abnormal cervical cytology in the renal transplant population has been quoted as between 8.7% and 70%; a realistic figure of around 15% represents a fivefold increase from the normal population.²¹⁵ There is some evidence that cervical cytology is relatively insensitive and coexisting CIN could be missed, hence early recourse to colposcopy.^{216,217} Most publications inform on cytology taken in a research/colposcopy clinic setting, and thus there is no information regarding cytology obtained on routine screening.

11.3 Women taking maintenance immunosuppression medication post transplantation

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

Any abnormal cervical cytology result should prompt colposcopic referral. Women with a previous history of CIN should have routine follow up as recommended for the immunocompetent population.

Evidence: There are insufficient data on the long term assessment and management of these patients. With one exception, all studies were cross-sectional and the only published longitudinal study has insufficient numbers to form a basis for national guidelines.²¹⁸ As there is no evidence that women who are immune suppressed following renal transplantation have an accelerated natural history of CIN, decreasing the screening interval currently has no demonstrable benefit.

11.4 Women with multifocal disease

Patients with multifocal disease (histologically proven lower genital tract precancer of squamous epithelium at more than one site occurring simultaneously or at intervals²¹⁹) will require specialist assessment and management in a centre with expertise in this area. The patients should be assessed by cytology, colposcopy, vulvoscopy and biopsy where indicated at least six monthly.

Evidence: In renal patients the risk of intraepithelial disease, and therefore cancer, appears to increase with time. There is little information in the literature regarding multifocal disease and renal transplantation. The only longitudinal study demonstrated the presence of 'high risk' oncogenic HPV type infection in all patients with VIN.²¹⁸ There is good evidence that infection with 'high risk' HPV types and the persistence of viral infection increase the risk of subsequent CIN and cervical cancer.²²⁰⁻²²² However the value of HPV screening has yet to be determined.

11.5 Women receiving cytotoxic drugs for rheumatological disorders

Women receiving long term cytotoxic drugs for rheumatological disorders should have regular cytological screening in accordance with national guidelines.

If the screening history is incomplete at the commencement of cytotoxic drugs, then a cervical sample should be taken with referral to colposcopy for any cytological abnormality.

Evidence: There is an increased incidence of CIN in women with systemic lupus erythematosus treated with long-term chemotherapy.^{223,224} The data in other rheumatological disorders are lacking but safe practice dictates adequate screening histories as a minimum requirement.

11.6 Other women who are immunosuppressed

There is no indication for increased surveillance in the following situations

- women receiving cytotoxic chemotherapy for non-genital cancers
- women receiving long term steroids
- women receiving oestrogen antagonists such as tamoxifen.

Such women should have cytological screening in accordance with national guidelines.

Evidence: There is a theoretical risk that folate deficiency acts as a co-carcinogen during the initiation of cervical dysplasia. Folic acid supplements do not alter the course of established disease nor decrease the risk of developing CIN.²²⁵ There is no evidence to suggest that women who receive chemotherapy with cytotoxic drugs or tamoxifen are at increased risk of CIN.^{226–228}

11.7 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 cytological 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 CIN 2 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 preinvasive cervical lesions.

Evidence: There is evidence that in HIV positive women there is an increased risk of false negative cytology.²²⁹ The estimated prevalence of cervical disease in HIV seronegative women is approximately 3%.²³⁰ By contrast, a number of reports, including cross-sectional, case-control and cohort studies, have indicated a greatly increased prevalence of squamous intraepithelial lesions, ranging between 20% and 40%,^{231–234} and increased incidence in HIV infected women.²³⁵ Furthermore, regression of low grade lesions is rare and high grade lesions may respond poorly to standard therapies.^{236,237} In one study, the recurrence rate in women with CD4 counts <200/mm³ was 87%,²³⁷ compared with <10% in immunocompetent women.

The reason for this high incidence of CIN and recurrence following treatment is thought to be the lack of immune activity against HPV. Even cohorts using HAART are at increased risk of abnormal cytology, although HAART may increase the regression of low grade lesions.²³⁸ Early data from a European cohort study show a 33% prevalence of abnormal cytology, ASCUS or worse among the 859 women recruited so far, although a large proportion were receiving HAART.²³⁹

11.8 Summary of standards

1. All patients who are immunosuppressed must be managed in a centre that has demonstrable skill and expertise and sufficient access to patient numbers to maintain that expertise.
2. All women aged 25–65 years with renal failure requiring dialysis, and older women with this condition if they have never been screened, must have cervical cytology performed at or shortly after diagnosis.

12. MANAGEMENT OF GLANDULAR ABNORMALITIES

12.1 Cervical glandular epithelial abnormalities

Cervical screening with cytology can predict the presence of cervical glandular intraepithelial abnormalities, including cervical adenocarcinoma and high grade intraepithelial glandular neoplasia.

Evidence: Observational studies of women with abnormal glandular cytology with histological correlation. The data indicate that premalignancy and malignancy account for a variable proportion of pathology; high grade CIN, cervical adenocarcinoma, endometrial cancer and high grade glandular intraepithelial neoplasia are the pathological conditions most commonly diagnosed.^{51,65,240,241}

12.2 Reporting of abnormal glandular samples

Written reports

Reporting of any abnormal glandular sample must be supplemented with a written descriptive report (**100%**).

Evidence: Wherever possible, the written report should indicate the likely source of the glandular cells. Although not expected to be 100% accurate, the finding of abnormal endometrial cells can facilitate the diagnosis of endometrial carcinoma.

12.2.2 Colposcopic assessment

Colposcopic assessment is essential in the presence of cytological glandular abnormality (**100%**).

Evidence: There is a high prevalence of invasive adenocarcinoma, cGIN and CIN in this population.^{51,52} Although there are no specific colposcopic indicators of glandular abnormality, villous fusion and acetowhite changes proximal to the squamocolumnar junction have been noted.^{51,242} However colposcopy lacks sensitivity for the diagnosis of glandular lesions²⁴³ and punch biopsy has no role in their precise diagnosis. Colposcopy demonstrates concomitant CIN in 50% of cases, provides an assessment of the anatomy of the cervix and vagina, and helps to determine the most appropriate method and extent of biopsy.

12.2.3 Further investigation of ?glandular neoplasia

Women with samples reported as ?glandular neoplasia should be referred for investigation urgently within two weeks by colposcopy to exclude significant cervical and endometrial neoplasia. (See section 4.9.)

Evidence: For high grade glandular cytological abnormality, reports suggest variations in PPV of 17–96% for premalignant or malignant pathology.^{51,65,240,241,244} Furthermore, the predictive value of abnormal glandular cytology is compromised by the occurrence of several benign conditions which mimic cervical glandular neoplasia cytologically.²⁴⁵ Endocervical brush artefact can give rise to such samples.²⁴⁶ Other non-cervical/endometrial neoplastic lesions of the genital tract and intraperitoneal organs may also present in this way. Although larger data sets are needed, expert opinion and the limited data available support a rigorous investigative protocol for this grade of abnormality.^{51,61,240,241}

12.2.4 Borderline glandular samples

Women referred with borderline nuclear change in glandular cells should undergo colposcopy, any appropriate cervical biopsy and selective use of endometrial biopsy.

Evidence: For more tentative predictions of glandular neoplasia, the borderline classification is used. However most available studies follow the Bethesda convention²⁴⁷ (which differs from the UK in respect of glandular samples) and report atypical glandular cells of unknown significance (AGUS). While the data are somewhat unreliable, high grade squamous intraepithelial lesions are those most commonly diagnosed, in 27–37 % of cases.^{246,248} However invasive lesions have also been noted to present in this way.²⁴⁹ Limited UK data indicate that a borderline classification of abnormal glandular cells is associated with a low, but still significant, incidence of pathology (33–57%). Intraepithelial glandular lesions rarely present with this grade of abnormality.^{51,52}

The above guideline conforms with the suggestions of a Joint College working party²⁵⁰ which did not suggest a need for radical excision of the endocervix.

12.2.5 Atypical endometrial cells in cervical samples (see section 12.2.7)

The term ‘borderline changes’ should not be used for endometrial cells. Sometimes cells may be present which do not suggest endometrial carcinoma, but are not definitely negative. Such cells should be described in the text of the cytology report as ‘atypical endometrial cells’, and the cytology result should be recorded as ‘?glandular abnormality (code 6)’.

These cells may be associated with

- endometrial polyp
- chronic endometritis
- intrauterine contraceptive device (IUCD)
- endometrial hyperplasia
- endometrial carcinoma.

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

Evidence: *Normal endometrial cells* in the cervical cytology of asymptomatic postmenopausal women have been reported with a low prevalence of (pre)malignant uterine disease.²⁵¹

Diagnosis of *atypical endometrial cells* is clinically significant, with more than one-third of women with histological follow up having significant uterine disease. In postmenopausal women, the majority of lesions (80%) are endometrial in origin: 13–18% of these are endometrial carcinoma; 6–7% of cases are high grade dyskaryosis and squamous carcinoma.^{252,253}

12.2.6 Punch biopsy

Punch biopsy is of no value in the assessment of suspected cGIN. In such cases it is important to involve the MDT. (See section 5.6.2.)

Evidence: Invasive neoplasia cannot be excluded on the basis of a punch biopsy.²⁵⁴ Punch biopsy is of low sensitivity for diagnosis of glandular lesions.^{255,256} 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. Asymptomatic endometrial carcinoma has been detected through the screening process, particularly following abnormal glandular cytology.^{51,52,249}

12.2.7 Endometrial biopsy

Where a woman's cervical cytology indicates atypical cells of endometrial origin, with or without irregular vaginal bleeding and regardless of menopausal status, she should be seen urgently, within two weeks of referral. She should be referred to an appropriate agency, such as a gynaecologist, 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 do not have cervical disease and should have an endometrial assessment in the first instance.

Women under 40 with normal endometrial cells do not need referral to colposcopy or gynaecology. Repeat cervical cytology is not recommended.

Evidence: Good practice point.

12.2.8 Endocervical curettage

Endocervical curettage is unhelpful in diagnosing the endocervical extension of CIN or the identification of cGIN. The samples are often unsatisfactory, lesion depth cannot be assessed and the procedure may be painful. It is not recommended in any circumstance.

Evidence: Good practice point.

12.3 Clinical management of cervical glandular intraepithelial neoplasia (cGIN)

12.3.1 Conservative management of cGIN lesions

Cervical glandular intraepithelial neoplasia often occurs in young women who wish to retain fertility. The weight of expert opinion has moved from radical towards conservative methods. In selected cases, a conservative cone type excision (removing a cylindrical rather than a conical specimen) is considered appropriate. Expert histopathological opinion²⁵⁴ favours techniques that either avoid or minimise thermal artefact to improve assessment of the excision margins.

For women with suspected cGIN or early invasive adenocarcinoma, the extent of the cervical excision can be individualised. In younger women and/or women desirous of 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 20–25 mm of the endocervical canal.

Evidence: Retrospective and prospective clinical studies^{243,255–260} and histomorphometric studies^{256,260} support the use of cone biopsy for the management of cGIN provided the conditions outlined below are met.

Despite columnar cell origins, cGIN lesions are found in the TZ in 85% of cases.^{257,261} TZ involvement is usually accompanied by endocervical columnar disease. Bertrand et al²⁵⁷ emphasise that deep clefts up to 5 mm from the margin of the canal may be involved with disease. While, theoretically, any site within the endocervix may be affected, multifocal disease is found in only 13–17% of cases; the lesion is usually unicentric, contiguous with the SCJ, and extends up the canal for a variable distance. A similar distribution of early invasive adenocarcinoma has been described.²⁶² Ninety-five per cent of cGIN extends within 25 mm of the anatomical external os.²⁵⁷ Further data²⁶³ show a relationship between age and proximal linear extent of disease, suggesting that more limited excision of the endocervix, ie 1 cm above the SCJ, may be reasonable in women aged <36 years. Such an approach would also allow accurate diagnosis of early invasive adenocarcinoma.²⁶² Glandular disease tends to be more extensive in older women.¹⁶¹ Moreover, it is well established that the SCJ retreats into the canal with increasing age so that older women require deeper excisions. Colposcopic examination may help to individualise the extent of the excisional specimen needed.

In advising expectant management for cGIN, the clinician should be satisfied that

- the margins of the specimen are free of disease; if the margins of the first 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 specimen submitted has been thoroughly sampled in the laboratory.

Women to be managed conservatively following cone biopsy should be counselled that expectant management appears safe if careful follow up is carried out (see below). Data indicate a recurrence rate of 15% at four years, although a slightly higher proportion will require further surgical investigation for abnormalities detected during follow up.¹⁶² (See section 8.7.1.) Follow up of conservatively

treated cGIN should consist of cytology and is best managed in the colposcopy clinic. (See section 9.4). The colposcopy or gynaecological cancer MDT should guide management. (See section 5.6.2.)

Evidence: Follow up cytology must include endocervical cells.²⁵⁶ (See section 9.5.) Such samples can detect the presence of residual glandular lesions.²⁵⁶ There are recognised difficulties in assessing atypical glandular cells in samples after cone biopsy for cGIN. Lower segment sampling has been misinterpreted as glandular abnormality, leading to further surgical intervention.²⁶³ The increased awareness of the possibility of glandular neoplasia introduces bias into the diagnosis with increased risks of false positive reporting as a result of benign mimics.²⁶⁴

Although evidence is lacking, colposcopy may be indicated because of the need to monitor the possible recurrence of cGIN, CIN and invasion. However the need for some form of heightened surveillance and easy access to cytologists seems clear.

If cervical histology is negative, other gynaecological and non-gynaecological conditions that might yield abnormal glandular cells should be considered.

Evidence: Observational retrospective studies.^{51,65,162,240,241,265}

12.4 Hysterectomy for cervical glandular intraepithelial 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, eg because of cervical stenosis
- the patient has other clinical indications for the procedure
- invasive disease has been confidently excluded. (See section 8.7.1.)

However colposcopy is required to assess the cervix for recurrent abnormal cytology after treatment.

12.5 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.

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

Evidence: Epidemiological evidence has shown that women exposed to DES are at increased risk of clear cell carcinoma of the vagina.²⁶⁶ They appear not to be at high risk of developing other cancers. A review of 4536 women exposed to DES revealed a twofold increased risk of developing high grade CIN but no increase in the incidence of cervical cancer. However the increased detection of CIN may have been a result of intensive follow up.

12.6 Summary of standards

1. Reporting of any abnormal glandular sample must be supplemented with a written descriptive report (**100%**).
2. Colposcopic assessment is essential in the presence of cytological glandular abnormality (**100%**).
3. Women with atypical endometrial cells on a sample, with or without irregular vaginal bleeding and regardless of menopausal status, should be seen urgently, within two weeks of referral, by a gynaecologist.

APPENDIX 1: SUMMARY OF STANDARDS

1. To ensure women are adequately informed about colposcopy and treatment
 - Each woman should be offered verbal information and be sent written information before and after cervical screening and before colposcopy (95%) (section 5.2.1).
 - Counselling must be available as an integral part of colposcopy (section 5.2.1).
 - Women must be sent an appropriately worded invitation with a contact name, telephone number and clinic times (section 5.2.1).
 - Information concerning the visit and results of investigations should be communicated to the patient within four weeks (**best practice 90%**) or eight weeks (**minimum standard 100%**) of her attendance (section 5.2.1).
 - Clinics operating a 'See and Treat' policy must ensure that women who are offered treatment at their first visit are sent adequate and appropriate information in advance of their appointment (**100%**) (section 5.2.4).
 - All women needing treatment must be informed that treatment will be required and their consent, either written or verbal, recorded (**100%**) (section 8.1).
2. To provide an adequate clinic environment
 - There must be a private area with changing facilities. There must also be toilet facilities (section 5.2.6).
 - There must be a permanently sited specific room for colposcopy (**100%**) (section 5.2.6).
 - Refreshments must be available (section 5.2.6).
 - There must be separate waiting and recovery areas (section 5.2.6).
 - There must be a permanent couch and colposcope (section 5.3).
 - Appropriate sterilising facilities must be available in accordance with local and national health and safety recommendations (section 5.3).
 - In units offering a diagnostic service, there must be automatic referral to a unit where treatment is available if required (section 5.3).
 - If laser or diathermy equipment is in use, there must be adequate safety guidelines in place with all staff trained in their operation; emergency guidelines must be available in each clinic (section 5.3).
 - Adequate resuscitation equipment must be immediately available and staff involved in the clinical care of patients must be familiar with its use (section 5.3).
3. To provide appropriate clinic staff
 - All clinics must have a named colposcopist with appropriate skills who leads the service, with a specialist team specific to the colposcopy unit. The named lead colposcopist must have a job description (section 5.4).
 - There must be at least two nurses for each clinic (section 5.4).
 - Nurse colposcopists working in a clinic role must be supported by another registered nurse (section 5.4).
 - There must be adequate dedicated clerical support for the clinic (section 5.4).
4. To ensure appropriate and accurate data collection
 - There must be suitable information technology equipment and software to facilitate collection of data for the BS CCP minimum data set and for submission of the statutory quarterly KC65 (section 5.3).
 - Multidisciplinary audit must be an integral part of the service (section 5.6).

5. To reduce default
 - There must be written protocols for the management of non-attenders (section 5.5).
 - The default rate should be less than **15%** (section 5.5).
6. To reduce failure of diagnosis of early cancers
 - An excisional form of biopsy is recommended (**95%**) (section 6.4)
 - when most of the cervix is replaced with high grade abnormality
 - when low grade colposcopic change is associated with severe dyskaryosis or worse
 - when a lesion extends into the canal (sufficient canal must be removed in these situations).
 - Reasons for not performing a biopsy must be recorded (**100%**) (section 6.4).
 - All women must have had histological diagnosis established before destructive therapy (**100%**) (section 6.5).
7. To improve the quality, accuracy and timeliness of diagnosis
 - Cervical screening should take place between the ages of 25 and 64 at intervals of three or five years depending on the woman's age. Women must be called six months before their 25th birthday, then recalled at three yearly intervals between the ages of 25 and 49 years and at five yearly intervals between the ages of 50 and 64 years (sections 2.1.1, 2.1.3).
 - Women should be referred for colposcopy after three consecutive inadequate samples (section 4.2).
 - Women should be referred for colposcopy after three tests in a series reported as borderline nuclear change in squamous cells without the woman being returned to routine recall (section 4.3.1).
 - Women should be referred for colposcopy after one test reported as borderline nuclear change in endocervical cells (section 4.3.2).
 - Women should be referred for colposcopy if they have had three tests reported as abnormal of any grade in a 10 year period (section 4.4).
 - Ideally, women should be referred for colposcopy after one test reported as mild dyskaryosis, but it remains acceptable to recommend a repeat test. Women must be referred after two tests reported as mild dyskaryosis without a return to routine recall (section 4.5).
 - Women must be referred for colposcopy after one test reported as moderate dyskaryosis (**100%**) (section 4.6).
 - Women must be referred for colposcopy after one test reported as severe dyskaryosis (**100%**) (section 4.7).
 - In England, women referred with a high grade cytological abnormality must enter a 62 day cancer pathway. Once cancer has been excluded these women must enter the 18 week pathway (**100%**) (section 4.7).
 - Women must be referred for colposcopy after one test reported as possible invasion (**100%**). They should be seen urgently, within two weeks of referral (**90%**) (section 4.8).
 - Women must be referred for colposcopy after one test reported as possible glandular neoplasia (**100%**). They should be seen urgently, within two weeks of referral (**90%**) (section 4.9).
 - Women should be referred for colposcopy if they have been treated for CIN and have not been returned to routine recall and a subsequent test is reported as mild dyskaryosis or worse (**100%**) (section 4.12).
 - At least **90%** of women with a test result of moderate or severe dyskaryosis should be seen in a colposcopy clinic within four weeks of referral (section 4.1.2).
 - At least **90%** of women with an abnormal test result should be seen in a colposcopy clinic within eight weeks of referral (section 4.1.3).
 - The proportion of women having definitive treatment for high grade CIN within four weeks of the colposcopy clinic receiving a diagnostic biopsy report should be **≥90%**. All women

having definitive treatment for high grade CIN must be treated within eight weeks (**100%**). Pregnant women are excepted from this. The reason for any delay must be specified (section 8.1).

- The following data should be recorded at the colposcopic examination (section 6.3)
 - reason for referral (**100%**)
 - grade of cytological abnormality (**90%**)
 - whether the examination is satisfactory. This is defined as the entire squamocolumnar junction having been seen, and the upper limit of any cervical lesion also being seen (**100%**).
- Of all biopsies taken (directed and excisional) **>90%** should be suitable for histological interpretation (section 6.6.2).
- If a colposcopically directed biopsy is reported as inadequate for histological interpretation, it should be repeated if there is a residual colposcopic lesion (**95%**) (section 6.6.2).
- For those with satisfactory colposcopic examination, the predictive value of a colposcopic diagnosis of a high grade lesion (CIN 2 or worse) should be at least **65%** (section 6.7).
- Biopsy should be undertaken in **>95%** of women with moderate or severe dyskaryosis (high grade) on their test result (section 9.8.1).
- Women referred with moderate dyskaryosis or worse cytological abnormalities who have a colposcopically low grade lesion and who are not treated should have multiple biopsies (**90%**) (section 9.8.2).
- All patients who are immunosuppressed must be managed in a centre with demonstrable skill and expertise, with sufficient access to patient numbers to maintain that expertise (section 11.1).
- All women aged 25–65 years with renal failure requiring dialysis must have cervical cytology performed at, or shortly after, diagnosis (section 11.2).
- Reporting of any abnormal glandular sample must be supplemented with a written descriptive report (**100%**) (section 12.2.1).
- Women with atypical endometrial cells on a sample, with or without irregular vaginal bleeding and regardless of menopausal status, should be seen urgently, within two weeks of referral, by a gynaecologist (section 12.2.7).
- The investigation of abnormal bleeding after the menopause must include direct visual inspection of the cervix (section 10.3.2).
- Colposcopic assessment is essential in the presence of cytological glandular abnormality (**100%**) (section 12.2.2).
- If colposcopy has been performed during pregnancy, postpartum assessment of women with an abnormal cytology or biopsy proven CIN is essential (**100%**) (section 10.1.2).
- If invasive disease is suspected clinically or colposcopically in a pregnant woman, a biopsy adequate to make the diagnosis is essential (**100%**) (section 10.1.3).
- All patients in the cervical screening age range undergoing a hysterectomy for other gynaecological reasons should have a negative cytology sample within the screening interval or as part of their preoperative investigations (**100%**) (section 10.4.1).
- All patients being considered for hysterectomy who have an undiagnosed abnormal cytology sample or symptoms attributable to cervical cancer should have diagnostic colposcopy and an appropriate biopsy (**100%**) (section 10.4.2).
- The MDT should meet once each month (**best practice**) or at least once every two months (**minimum standard**) (section 5.6.2).
- All colposcopists should attend at least 50% of MDT meetings to ensure the timely management of difficult cases and discordant results (**minimum standard**). Attendance at MDT meetings should be recorded (**minimum standard**) (section 5.6.2).
- The MDT's decisions on each case must be recorded in patients' medical records (minimum standard). The minutes of each meeting, including the outcome of any discussion, should be recorded, and a letter describing the recommendation for future care must sent to the

colposcopist responsible for the patient (minimum standard). All cases of cervical cancer must be reviewed by a gynaecological cancer centre MDT (minimum care) (section 5.6.2).

8. To ensure appropriate selection for and quality of treatment
 - All treatments must be recorded (**100%**) (section 8.1).
 - All women must be treated in properly equipped and staffed clinics (**100%**) (section 8.1).
 - Colposcopy clinics in GUM must have established protocols for liaison with gynaecological services (**100%**) (section 5.6).
 - Clinic staff must always be familiar with the treatment method(s) used (**100%**) (section 5.4).
 - Biopsy should be carried out unless an excisional treatment is planned, when the cytology indicates moderate dyskaryosis or worse, and always when a recognisably atypical transformation zone is present (**100%**). Pregnancy is an exception (section 6.6).
 - All women must have had histological diagnosis established before destructive therapy (**100%**) (section 6.5).
 - All women needing treatment must have had a colposcopic assessment (**100%**) (section 8.1).
 - The proportion of women treated at the first visit who have evidence of CIN 2/3 or cGIN on histology should be $\geq 90\%$ (section 8.1).
 - Proportion of treatment associated with primary haemorrhage that requires a haemostatic technique in addition to the treatment method applied ($<5\%$) (section 8.1).
 - The proportion of cases admitted as inpatients because of treatment complications should be $<2\%$ (section 8.1).
 - Ablative techniques are only suitable when (section 8.2)
 - the entire transformation zone is visualised (**100%**)
 - there is no evidence of glandular abnormality (**100%**)
 - there is no evidence of invasive disease (**100%**).
 - Cryocautery should only be used for low grade CIN and a double freeze–thaw–freeze technique must be used (**100%**) (section 8.3).
 - When excision is used, at least **80%** of cases should have the specimen removed as a single sample (section 8.4.1).
 - For ectocervical lesions, excisional techniques should remove tissue to a depth of greater than 7 mm (**95%**) (section 8.4.3).
 - Treatment at first visit for a referral of borderline or mild dyskaryosis should be used only in exceptional cases, and only when audit has identified that CIN 2/3 or cGIN is present in $\geq 90\%$ of the excised specimens (section 8.5).
 - All women over the age of 50 years who have CIN 3 at the lateral or deep margins and in whom satisfactory cytology and colposcopy cannot be guaranteed must have a repeat excision performed to try to obtain clear margins (**100%**) (section 8.6.2).
 - Women with adenocarcinoma in situ or cGIN can be managed by local excision for those wishing to retain fertility. Incomplete excision at the lateral or deep margins requires a further excisional procedure to obtain clear margins and exclude occult invasive disease (**95%**) (section 8.7.1).
 - The proportion of women managed as outpatients with local analgesia should be $>80\%$ (section 8.8).
9. To ensure appropriate and adequate follow up
 - All women are at risk following treatment and must be followed up (**100%**) (section 9.1).
 - Follow up should start at six months following treatment and not later than eight months following treatment ($>90\%$) (section 9.2).
 - Cytology alone is recommended for follow up and samples should be taken by appropriately trained staff (section 9.2).

- Initial follow up cytology (six month test) may be performed in the colposcopy or gynaecology clinic. Alternatively, it may be performed in the community (section 9.2).
 - All women who do not have negative test results after treatment must be re-colposcoped at least once within 12 months (**100%**) (section 9.2).
 - The proportion of treated women with no dyskaryosis six months following treatment should exceed **90%** (section 9.2).
 - The proportion of confirmed histological treatment failures should not exceed **5%** within 12 months of treatment (section 9.2).
 - If at follow up a high grade cytological abnormality persists, excisional treatment is recommended (**90%**) (section 9.8.1).
 - If a low grade lesion has not resolved within two years of referral to colposcopy, at least a biopsy is warranted (**>90%**) (section 9.8.4).
10. To ensure adequate communications with the referring practitioner
- Results and management plans should be communicated to the referring practitioner within four weeks of the patient's attendance at the clinic (**best practice 90%**) or eight weeks (**minimum standard 100%**) (section 5.2.1).
11. To maintain skill levels
- All practising colposcopists must be able to demonstrate that they have received an adequate training (section 5.7.1).
 - All colposcopists in the team should be certificated through the BS CCP/RCOG scheme and should comply with the re-certification process every three years (section 5.7.1).
 - Colposcopists practising within the NHSCSP should see at least 50 new abnormal cytology referrals per year (section 5.7.2).
 - All colposcopists must attend one BS CCP recognised colposcopy meeting every three years (section 5.7.2).

APPENDIX 2: GUIDANCE ON WORKING PRACTICES FOR COLPOSCOPY UNITS

The following guidance has been agreed by the NHSCSP Colposcopy Quality Assurance Group.

1. There needs to be a clear structure for managing NHS colposcopy services whatever the setting. There should be a designated lead colposcopist, ideally at consultant level, who is a practising colposcopist certificated through the BSCCP/RCOG scheme.
2. The lead colposcopist will be required to ensure that the defined standards are being met, and to maintain data collection that will allow audit to be conducted against these standards. The agreed national minimum data set and the required quarterly return should be prepared. The required annual return will be the responsibility of the lead colposcopist.
3. The data collected will enable performance to be compared between colposcopy units. All colposcopic practice, whether in Trusts or in the community, needs to be measured against uniform national standards. Regional arrangements should be in place to ensure that colposcopy clinics are running effectively. A scheme of regular visits (eg every 3–4 years) may provide an effective means of encouraging good practice and identifying deficiencies before problems arise.
4. Where there are concerns about colposcopic practice, these need to be openly discussed between colleagues. The best way of ensuring this is a culture of audit within the unit. This should include regular multidisciplinary meetings. Quality assurance is a means of ensuring that standards are improved, where necessary, using a constructive approach rather than a critical one.
5. Where concerns arise about an individual's clinical performance in colposcopy, these need to be handled sensitively and should be the responsibility of the lead colposcopist. There must be a speedy resolution; if this fails, or the lead colposcopist is under scrutiny, the medical director (or equivalent) should take responsibility. The regional QA colposcopy representative should also be involved at this stage.
6. Individual practice often cannot be judged on the basis of a small sample of cases with poor outcomes, unless these are extreme. Large and truly representative samples may be required, using valid data on outcomes, to reach reliable conclusions. Only when matters cannot be satisfactorily resolved internally should consideration be given to the need for external review. The external reviewer should assist in determining the scope and nature of the review. Under these circumstances the regional QA director will be informed.
7. All NHS colposcopy units must comply with the nationally agreed QA measures, and Trusts and Primary Care Trusts should regard maintenance of quality in colposcopy as an essential part of the framework of clinical governance.

APPENDIX 3: SAMPLE JOB DESCRIPTION FOR LEAD COLPOSCOPISTS

Introduction

The NHS Cervical Screening Programme (NHSCSP) requires each hospital Trust providing colposcopy services to have a named lead colposcopist. In Trusts where more than one colposcopy unit provides services, there should be one lead colposcopist to coordinate the KC65 statutory return, although there may be lead clinicians in separate colposcopy clinics within a single Trust.

The National Quality Assurance Group in Colposcopy of the NHSCSP and the Royal College of Obstetricians and Gynaecologists (RCOG) have published joint guidance on the roles and responsibilities of lead colposcopists.

The National Quality Assurance Group has devised this job description for lead colposcopists. Both the RCOG and the NHSCSP Quality Assurance Group believe that the roles and responsibilities of the lead colposcopist should be recognised by a sessional commitment of at least one notional half-day per week (or programmed activity). The lead colposcopist should be supported by at least one session of designated administrative/secretarial time for the tasks associated with the position.

Responsibilities of the post

The lead colposcopist is responsible for

- ensuring that written protocols are in place for the service and that these include recommended national guidelines
- ensuring that the protocols are regularly reviewed so that the needs of the users of the service and the commissioners of the services are met. The lead colposcopist will be required to ensure that the defined quality assurance standards are being met. The agreed national minimum data set and the required quarterly KC65 return should be collected
- ensuring that regular audit of the service takes place to compare practice with the local protocols and national targets
- liaising with the Trust staff responsible for providing the facilities needed to ensure that the service is adequately staffed by appropriately trained individuals (medical and non-medical), so that service needs can be met in a timely and consumer sensitive fashion
- coordinating training and liaising with the BSCCP Certification and Training Committee as appropriate
- facilitating the maintenance of continued certification of practising colposcopists within the unit
- working with the Trust management to ensure that procedures are in place to facilitate care and rapid communication with patients, other hospital departments, primary care agencies, cytopathology and histopathology services
- liaising with the hospital based programme coordinator, convening regular multidisciplinary meetings including cytology and histology services for case discussion and protocol review
- working with the hospital based programme coordinator to alert the Primary Care Trust screening commissioner to any shortcomings that might compromise the ability of the colposcopy services to respond to issues in primary care

- conducting regular dialogue with users, providers and purchasers of care to ensure that service and development are both appropriate and meet the needs of the local population.

Person specification

Essential

- BSCCP/RCOG certification
- Commitment to the colposcopy service and readiness to take responsibility for it
- Organisational skills
- Team management skills
- Training skills

Desirable

Experience of

- information technology
- data analysis
- conducting research.

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