Colposcopy clinical guidance

University Hospitals of Leicester NHS Trust

Trust ref: C13/2025

Contents

1. Introduction and Who Guideline applies to

This guideline is for all clinical, administrative and management staff working within Gynaecology delivering service both at UHL and Allied Clinics part of the LLR Commissioning.

The purpose of this guideline is;

- to ensure all staff are aware of the process of results and referrals of cervical samples taken within the trust outside of colposcopy clinic. This includes opportunistic cervical sampling, service users who has previously defaulted or service users who have been invited for a routine screening test. These samples should only be taken by trained registered clinicians. Currently, the cervical screening laboratory is located at the University Hospitals of Derby.
- to ensure that all members of the colposcopy team and gynaecology are aware of the process of communicating results and referrals for cervical samples taken outside of the colposcopy clinic in an appropriate time frame.
- to ensure that all members of the colposcopy team are aware of the criteria for the selection of women for conservative management of CIN 2 and the follow up process.
- to ensure checklists are in place for every visit.
- to ensure that all women who have cervical samples taken outside of colposcopy are correctly managed in accordance with NHS CSP guidance (September 2024).
- Ensure an up to date database of clinicians performing cervical screening both in and outside of colposcopy services.

Related documents:

All staff should familiarise themselves with the following Trust policies:

Safer Handling UHL Policy (B56/2011)
Cleaning and Decontamination for Infection Prevention UHL Policy (B5/2006)
Infection Prevention UHL Policy.pdf (B4/2005)
Latex Allergy in Patients and Staff UHL Policy (B29/2005)
Hospital Linen - Infection Prevention UHL Policy (B14/2012)
Cardiopulmonary Resuscitation Policy UHL LLR Alliance LPT.pdf **(**E4/2015)
Core Training (Statutory and Mandatory) UHL Policy.pdf (B21/2005)
Medical Device UHL Policy (B26/2005)
Waste Management UHL Policy (A15/20020)
Sharps Management UHL Policy (B8/2013)

Associated patient information leaflet: The Colposcopy Service
(also found on YourHealth)

2. Colposcopy Standards and Procedures

2.1 Essential competencies prior to performing cytology

Clinicians taking cervical cytology samples must be able to:

- Demonstrate a sound understanding of the anatomy and physiology of the external female genitalia, vagina and cervix.
- Assess the type and size of speculum required to visualise the cervix fully whilst ensuring patient comfort.
- Position the speculum correctly to visualise the cervix and identify the squamocolumnar junction (SCJ)
- Assess normal and abnormal cervical appearances and request review by a Colposcopist if concerned
- Recognise symptoms and clinical indications of vaginal infection and manage appropriately, seeking advice from a Colposcopist where necessary
- Demonstrate an understanding of the possible results of the screening test and likely management plan in order to counsel the patient prior to taking the test
- Answer any questions the patient may have.
- Perform the screening test using the Thin Prep liquid based cytology (LBC) sampling technique, demonstrating the correct selection and use of sampler based on the position of the SCJ.
- Demonstrate full awareness and understanding of the policy for preparation of samples and comply with this
- Complete the request form with the relevant details, ensuring accuracy of patient details.
- Demonstrate an ability to interpret cytology test results and communicate them to the patient.

2.2 Prior to the procedure:

The Thin Prep vial should be prepared and labelled as follows:

- Before using the vial, it should be checked that the vial is intact and in date.
- The liquid vial must be labelled with an ID sticker from the patient's notes showing their name, NHS number and date of birth. The date of the sample should be written on the label after the sampling has taken place.

2.3 Consultation:

- Every effort should be made to ensure that the patient is comfortable and well informed during the procedure.
- The Coloposcopist should introduce themselves and the chaperone to the patient and explain that a cervical screening test is going to be performed with the patient's consent.
- The procedure should be explained to the patient, giving them the opportunity to ask questions or express any concerns.
- The patient should be asked about the date of their last menstrual period, method of contraception, if there has been any unexpected bleeding or increased discharge, pain or other symptoms. Advice should be sought from the Colposcopist if any suspicious

symptoms are reported, e.g. post-coital bleeding, unusual discharge, pain or other symptoms.

- During the procedure, the patient on the examination couch and their dignity should be respected at all times.
- A full explanation of the procedure itself and the reason for performing it should be given, ensuring that the patient is happy to proceed.
- The patient should be advised that, if the examination is uncomfortable they should make this known and that the examination can be terminated at any stage.
- Prior to insertion of the speculum the external genitalia should be inspected to identify any abnormal appearances. Seek the advice of the Colposcopist if necessary.
- Assessment should be made as to the correct size speculum for optimum patient comfort and satisfactory visualisation of the cervix.
- KY jelly is applied to the speculum before insertion to make the procedure more comfortable for the patient. This should be inserted gently, explaining to the patient what to expect at each stage. If the patient experiences discomfort the procedure should be halted until they are able to proceed or discontinued at the request of the patient.
- The position of the SCJ junction should be assessed and the appropriate sampler used to take the test.
- If there is evidence of vaginal infection vaginal swabs should be considered after the screening test has been performed.
- Lukewarm water can be used to warm and lubricate the speculum, if desired, water-soluble gel lubricant can be applied sparingly on the posterior blade of the speculum but care should be taken to ensure than none is on the tip of the speculum in case the sample is contaminated.
- The broom sampler should be inserted as quickly as possible into the solution in the vial, pressing it into the bottom of the vial 10 times, forcing the bristles apart. Finally, swirl it vigorously to release further material. The sampler should then be discarded. The brush head should not be placed in the vial.
- If an endocervical brush is used, this should be inserted into the cervical os until the bottom-most fibres only are exposed. Slowly rotate one half of a turn in a clockwise direction.
- Do not over-rotate. The brush should then be rotated in the solution 10 times whilst pressing it against the wall of the vial. Discard the brush.

2.4 After the procedure:

- The lid must be secured appropriately and placed in the cytology specimen request envelope following checking that the patient's details and GP details are correct and correlate with the request form.

- A patient ID label should be placed on the specimen record as per the Units Policy.

- The request envelope and specimen vial should be place in the pathology specimen collection box before the next patient enters the room.

3. MANAGEMENT OF COMPLICATIONS IN THE COLPOSCOPY CLINIC

3.1 Post Procedure bleeding.

The Colposcopy Clinics now have 2 'Emergency boxes each containing basic resuscitation equipment with IV fluids, cannula, syringes and specific haemostatic equipment including long needle holders, sutures, vaginal pack and Fibrillar.
Monsell's solution is also available and staff will undergo training to use it.
This box has to be checked every day to ensure all components are present and in date.
The box must be re-stocked immediately after use.

- A vaginal pack and catheter should be available in each clinic room in case of primary haemorrhage at the time of the procedure or whilst the patient is still in the Unit. **Medical staff should be asked to remain in the Unit until patients undergoing treatment have recovered fully.**
- Patients are advised to contact GAU at the LRI in the event of heavy bleeding in the post procedure period. They are given an information leaflet with instructions and contact details.
- In the event of the patient bleeding heavily and not responding to haemostatic procedures, they may need to go to theatre. In this event the on-call Gynaecology Registrar should be contacted via switchboard to attend the Unit.
- Observations should be carried out to ensure that the patient is stable and the findings documented in the case notes.
- IV access should be gained as soon as possible.
- Staff should liaise with the ward regarding bed availability if the patient is to be admitted
- Porters should be booked to transfer the patient.
- A trained member of the colposcopy nursing staff should accompany the patient to theatre or to the ward and give an effective handover to the receiving nurse.
- Patient should not be transferred to LRI Gynaecology emergency assessment unit while actively bleeding, this needs to be managed at LGH. On Call consultant should be informed.

3.2 Fainting or vasovagal attack

This may occur as a result of a vagal reflex due to cervical stimulation (vasovagal attack)

- Immediately stop instrumentation/examination of the cervix.
- Reassure patient and calmly try to rouse them by talking to them.
- Place the patient in head-down position by lowering the backrest of the couch.
- Protect the patient's airway and turn onto their side if they are vomiting.
- Give oxygen via a face mask; 5-10 litres.
- Monitor pulse rate and blood pressure and record in the notes.
- Continue to assess patient and transfer to the Recovery Room or Gynaecology Ward if they are not able to be discharged home.
- In the event of collapse **call the Resuscitation Team on 2222 and state ADULT resuscitation team required and give exact location including building and hospital**
- Obtain the crash trolley located in the clinic corridor.
- Maintain airway/basic life support until arrival.

3.3 Severe bronchospasm or other severe allergic reaction:

This may occur rarely in response to injection of a local anaesthetic.

- Stop procedure and administer oxygen via a face mask, if appropriate.
- **Call the Resuscitation Team on 2222 and state ADULT resuscitation team required and provide the exact location including building and hospital.**
- Obtain the crash trolley located in the clinic corridor.
- Maintain airway/basic life support until arrival.

3.4 Epileptic seizures

These may occur as a result of injection of a local anaesthetic or spontaneously in a susceptible patient.

- Make the environment around the patient as safe as possible by making maximum space in close proximity. **Do not restrict the patient in any way.**
- Lower the couch to lowest level possible and lower backrest
- In severe cases **call the Resuscitation team on 2222** and maintain airway/basic life support until arrival.
- Obtain the crash trolley located in the clinic corridor.
- Maintain airway/basic life support until arrival.

In all of the above events Nurse in charge should be contacted and available to coordinate the treatment and transfer of patient.

4. MANAGEMENT OF HISTOLOGY SPECIMENS AND CYTOLOGY SAMPLES

The correct labelling of all colposcopy specimens is essential in order to avoid the risk of incorrect processing and, most importantly, the hazard of incorrect diagnosis.
In the event of a specimen being unlabelled or wrongly labelled the specimen will not be processed and this could lead to the patient being subjected to a repeat examination; however, in the case of a LLETZ, this would not be possible and would lead to extreme distress for the patient and the absence of important histological information.
All specimens leaving the department must be clearly labelled, checked with the patient, and packaged appropriately for transportation after each clinic session by the portering staff.

Histology samples must be checked by 2 members of staff and recorded on Colposcopy LocSSIP checklist.

4.1 Cervical cytology samples

- Liquid based cytology is now the sampling method as per NICE (2023) guidance (nice.org.uk guidance-on-the-use-of-liquidbased-cytology-for-cervical-screening-pdf) Thin Prep is used in this service.
- Before using the vial, checks should be made to ensure that the vial is in date. Directive from cytology lab is the pot must have at least 14 days left before expiring.
- The liquid vial must also be labelled with an ID sticker from the patient's notes showing name, NHS number and date of birth.

- The lid must be secured and placed in the cytology specimen request envelope following checking that the patient's details and GP details are correct and correlate with the request form. A patient ID label should be placed on the specimen record as per the Units Policy.
- The request envelope and specimen vial should be place in the pathology specimen collection box before the next patient enters the room.
- In the instance of a pot spillage, gloves and eye protection must be worn. The area must be ventilated and all personnel warned within the clinical environment so that the area can be temporarily evacuated by the majority of staff.
- Disposal considerations: Absorb in inert material and place in separate clinical waste bag to be treated as special waste. Porters to be contacted.

For Guidance on cervical screening samples taken outside the Colposcopy clinic. Please refer to appendix 2

5. MANAGMEMENT OF ABNORMAL CYTOLOGY RESULTS

The Colposcopy service follows the guidelines in the NHSCSP Publication 20 "Colposcopy and Programme Management"
(September 2024 Update gisci.it/documenti/altri/guidelines_nhs.)

Public Health England (NHS Cancer Screening Programmes) published Screening Protocol Algorithms for managing patients with abnormal cytology results following the introduction of Primary HPV screening and Test of Cure. These are available in all of the Colposcopy Clinics.

The aim of this guideline is to ensure appropriate management and follow up for patients with abnormal cytology results following assessment and to provide a robust process for ensuring that all women who are undergoing conservative management of CIN 2 follow the strict process of follow up and management.

5.1 Management of abnormal glandular abnormalities

Borderline changes in endocervical cell samples
Individuals who have a positive primary hrHPV test and subsequently have a borderline endocervical screening result should be referred to colposcopy clinic and have appropriate assessment. They should be seen within 2 weeks.
Following a UHL audit a local policy suggests to offer LLETZ to women referred with Borderline changes in Endocervical cells. All cases should be discussed at colposcopy MDT

Suspected Glandular abnormality of endocervical type
Refer patients to colposcopy for further investigation. At least 93% of patients should be seen within 2 weeks of referral.

Suspected Glandular abnormality of non-cervical type.
Refer patients to gynaecology for further investigation. At least 93% of patients should be seen within 2 weeks of referral.

5.2 The role of colposcopically directed or punch biopsy in the management of Suspected Glandular abnormality and borderline changes in endocervical cells samples

Punch biopsy in the management of Suspected Glandular abnormality and borderline changes in endocervical cell samples is not appropriate.

Investigate and diagnose CGIN/stratified mucin producing intraepithelial lesion of the cervix (SMILE) through colposcopy and histopathological assessment of an excisional biopsy (including the endocervical canal) in order to distinguish between CGIN and invasive adenocarcinoma.

Endometrial biopsy
Endometrial sampling is indicated in individuals referred to colposcopy with suspected glandular neoplasia or not otherwise specified (NOS).

5.3 Management of cytology reported as suspected glandular neoplasia of endocervical type (CGIN)

For individuals with suspected CGIN or early invasive adenocarcinoma, the extent of the cervical excision should be tailored to each case. In younger individuals and or individuals who wish to conserve their fertility who have a colposcopically visible squamocolumnar junction (SCJ), a cylindrically-shaped cervical excisional biopsy including the whole transformation zone (TZ) and at least 10mm of endocervix above the SCJ is appropriate.

In older individuals (age 50 or over), or where the SCJ is not visible at colposcopy, a cylindrical biopsy should be taken that includes all of the visible TZ and 20mm to 25mm of the endocervical canal.

5.4 Management of confirmed CGIN

CGIN often occurs in young individuals. Excisional treatment is recommended for those wishing to retain fertility. Individuals can be managed conservatively if, following excisional treatment, the margins of the excisional specimen are negative and invasion is excluded. They should be counselled that the expected programme of management appears safe as long as follow up tests and appointments are attended.

5.5 Management of incompletely excised CGIN

If the margins of an initial excision are not free from CGIN, a further attempt at excision should be offered in order to confidently exclude invasion and obtain negative margins. For individuals who decline a repeat excision or if a repeat excision is not possible, primary hrHPV testing should be performed 6 months after treatment. If negative, it should be repeated 6 months later (12 months after treatment), and then annually for the subsequent 9 years. If hrHPV test is positive at any point in follow up and the sample was performed in the community, a direct referral to colposcopy is required regardless of the cytology result, or because of persisting HPV positivity and negative cytology.
All Cases of CGIN / Borderline in Endocervical Cells should be discussed at Colposcopy MDT.

5.6 Stratified mucin producing intraepithelial lesion of the cervix (SMILE)

SMILE is a histological entity usually found in conjunction with CIN and CGIN, but it can occur in the absence of these. The cytological appearance of SMILE is poorly understood. Individuals with SMILE should be managed according to guidance for CGIN.

5.7 Hysterectomy for cervical glandular neoplasia

Simple hysterectomy may be considered if:

- fertility is not required
- there are positive margins after an adequate excisional procedure
- treatment by excision is followed by further high grade cytological abnormality
- the patient is unwilling to undergo conservative management
- adequate screening follow up has not been possible, for example because of cervical stenosis
- the patient has other clinical indications for the procedure
- invasive disease has been confidently excluded

5.8 Management of suspected malignancy/ Smear with invasive features.

- If frank carcinoma is suspected on clinical grounds a biopsy should be taken by appropriate means. This may be a punch biopsy or small LLETZ.
- The sample should be sent as an urgent 2WW sample in an orange bag to the histology laboratory.
- If cancer is confirmed on biopsy, the patient should be given the diagnosis by consultant clinician with a Gynae-oncology Nurse Specialist in attendance.
- The Gynae-oncology MDT should be informed and the initial staging investigation and follow-up arranged.
- In UHL the pathology lab flags up all cases of cervical cancer to the Gynaecology MDT as a failsafe.
- If screening suggest invasion, an excisional biopsy is recommended.

5.9 Endometrial sampling

This is indicated in the Colposcopy Clinic when there is

- A high grade glandular smear
- Abnormal vaginal bleeding > 40 years of age

5.10 Colposcopy in Pregnancy

- An individual who meets the criteria for colposcopy should be examined in the colposcopy clinic even if they are pregnant.
- In UHL, pregnant women suspected of an abnormal cervix are referred by an email to Gynaecology referral mailbox stating their stage of pregnancy, due date and their symptoms.
- This is prioritised and triaged by the Lead Nurse colposcopist or Clinician. All these women are booked into a consultant colposcopy clinic.

- The primary aim of colposcopic examination of a pregnant individual is to exclude invasive disease and to defer biopsy or treatment until the individual has given birth.

- Individuals seen in early pregnancy may require a further assessment in the late second trimester at the clinician's discretion. If excision for diagnostic purposes is clinically indicated it is feasible and acceptable to individuals. This is usually reserved for individuals with colposcopic high grade disease and concerns about cancer. If an

individual declines treatment in early pregnancy they should be seen for postpartum colposcopy.

Colposcopy follow up after pregnancy

- Clear follow up arrangements should be made for postpartum assessment of individuals whom have been referred with an abnormal screening test or suspicious looking cervix who have had an abnormal colposcopy. This is between 6-8 weeks post partum.

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If CIN1 or less is suspected

The individual should be managed as per the screening algorithm (see the cervical screening pathway requirements guidance).

If CIN2 or CIN3 is suspected

Repeat colposcopy at the end of the second trimester. If the pregnancy has already advanced beyond that point, repeat 3 months following delivery.

If invasive disease is suspected

If invasive disease is suspected, clinically or colposcopically, an adequate biopsy to make the diagnosis is essential. Studies published in 2013 and 2017 showed that excisional treatments are safe in pregnancy in the first and second trimester. In those women above second trimester, MDT team would be involved and input from Obstetric team.

All excisions are associated with a risk of haemorrhage and such biopsies should be taken only where appropriate facilities to deal with haemorrhage are available. Punch biopsy suggesting CIN only cannot reliably exclude invasion.

5.11 Management of Immune Suppressed Women

In UHL patients with immunosuppression, multifocal disease and HIV positive women are referred to specialised clinics with the necessary expertise. There are 2 specialist clinics per month to manage women post-transplant and long term immunosuppressive therapy with multifocal disease. There is multidisciplinary input involving oncologists and colorectal surgeons with special interest in anal intraepithelial neoplasia.

5.12 Management and Treatment of Cervical Ectropion

- Patients with symptomatic ectropion e.g. postcoital bleeding or excessive mucous discharge, where CIN has been excluded, may benefit from silver nitrate cautery, diathermy cautery or shallow Lletz to the ectropion.
- Infection must be ruled out prior to treatment of ectropian.
- A biopsy should be taken prior to diathermy being performed if there has been abnormal cytology or colposcopy.

5.13 Management of Infections

In UHL we do not recommend routine infection screening before any colposcopic procedure. If infection is suspected or in those that are at high risk of infection (poorly controlled diabetes, immunosuppression etc) we recommend appropriate antibiotic treatment.

5.14 Management of Patients with Concurrent Gynaecological Problems

Some patients will present in the colposcopy clinic with an abnormal smear and a concurrent gynaecological problem. The colposcopy clinic is not the ideal setting in which to undertake general gynaecological assessments. There are of course exceptions to this rule and clinical judgement should be exercised. If the problem requires minimal investigation and can be dealt with easily then this should be done while the patient is in the clinic. If more protracted investigation is envisaged i.e. infertility, vulval problem, pelvic pain, etc. then the GP is requested to make an appropriate assessment and referral.
In other situations, the actual management of the smear may be influenced by concurrent gynaecological problems. An example of this would be a patient with menorrhagia and CIN. This patient might be more effectively managed by total abdominal or vaginal hysterectomy. If such a case arises counselling can be dealt with in the colposcopy clinic.
There are also circumstances where patients will have been referred to the colposcopy clinic from one of the other clinics as a result of having had an abnormal cervical smear. In general, these patients should be managed as for any new referral. One special instance is in those who are awaiting hysterectomy. Colposcopy in this situation is used to define the limits, if any, of vaginal extension of a lesion. Secondly if invasion is suspected, this should be confirmed or excluded prior to proceeding with hysterectomy as a more radical procedure may be indicated.

5.15 TREATMENT OF CIN AND CGIN

Treatment Standards (NHSCSP Document 20 September 2024))

Consent and Counselling

- A pre colposcopy leaflet is sent out to the women prior to their colposcopy appointment.
- On arrival the patient should be given further verbal information at the time their history is taken and given the opportunity to discuss their feelings and anxieties. It is important that this phase of counselling is very positive and supportive.
- It is standard practice to take E consent using Concentrix for LLETZ. A verbal consent is sufficient for punch biopsies of the cervix, vagina or vulva.
- After any procedure, an explanation of what was found, undertaken and what may or may not be planned should be given to the patient and this should be re-enforced with written information in the case of women who have had an invasive procedure (treatment or directed biopsy).
- Information should be given to the patient about how and when the results will be communicated to them and their GP.
- In all cases the woman should be given a contact name and number where they can get additional advice once they have left the clinic. Colpscopy Cards are given to all patients.

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 sub-stage or define completeness of excision in fragmented excisional specimens. The histology report should record the specimen dimensions and the resection margin status (100%)

See and treat’ policy

Clinics can offer treatment at first visit to colposcopy for a high grade referral.
Treatment at first visit to colposcopy for a referral of hrHPV positive and cytology negative, borderline squamous changes or low grade dyskaryosis should not be offered except where the abnormality is known to be long-standing.

Destructive Treatment (Diathermy)

The only destructive method of treatment used in the UHL colposcopy clinic is diathermy.
It is acceptable to use diathermy to treat symptomatic biopsy proven negative ectropions, persistent HPV and inflammation but NOT CIN.
There **MUST** be no suspicion of invasive disease.

Loop Diathermy Excision (LLETZ)

- Loop excision under local anaesthesia is the usual and most common method for treating and eradicating CIN.

Local Anaesthesia

- Treatment should be performed with adequate pain control and should include pre-treatment counselling. Treatment should be offered with local analgesia. The proportion of individuals managed as out-patients with local anaesthesia should be at least 85%, with an achievable target of 90%.
- Local anaesthesia may be administered under Patient Group Directive.
- Colposcopy is performed using unlicensed medicines including acetic acid, Iodine, Monsells solution and silver nitrate. These are all documented on UHL trust protocols.

Treatment under General Anaesthesia

- A small proportion of women may require general anaesthesia.
- Reasons for treating under general anaesthesia should be recorded in the colposcopy record.
- Patients should be listed for a Day Surgery Unit. Arrangements should be made for the patient to attend for pre-operative assessment prior to being given an admission date.
- All listed patients should be informed to the data co-ordinator for failsafe.
- The case notes should be returned to the Colposcopy Secretaries after coding has taken place in order to ensure that follow up is arranged and the results communicated to the patient and GP.
- The colposcopy database will be updated when the patient is listed and an alert will be issued if no admission has taken place within 3 months.

Depth of excision

The goal of excision is to remove all the abnormal epithelium in accordance with the type of transformation zone.

<u>Type I cervical transformation zone</u>

For treating ectocervical lesions, excisional techniques should remove tissue to a depth of more than 7mm, though the aim should be to remove <10mm in individuals of reproductive age

<u>Type II cervical transformation zone</u>

Excisional techniques should remove tissue to a depth of 10 to 15mm.

<u>Type III cervical transformation zone</u>

Excisional techniques should remove tissue to a depth of 15 to 25 mm.

5.16 Conservative management of CIN 2.

(See Appendix 1)

- UHL do offer a Conservative Management pathway for CIN 2 only.
- **All** Cases must be carefully selected as per protocol (see Appendix 2) and discussed at Colposcopy MDT.
- Conservative management requires strict colposcopy follow up at 6 monthly intervals with cervical screening / Colposcopy +/- biopsy.
- Cases are logged on CIN 2 database and audited annually.

5.17 Repeat excision

High grade CIN extending to margins

- High grade CIN extending to the deep lateral or endocervical margins of excision (or uncertain margin status) results in a higher incidence of recurrence but does not justify routine repeat excision if:
    - there is no evidence of glandular abnormality
    - there is no evidence of invasive disease
    - the individual is under 50 years of age
- All individuals over the age of 50 years who have CIN 3 at the deep lateral or endocervical margins, and in whom satisfactory screening samples and colposcopy cannot be guaranteed, must have a repeat excision performed to try to obtain clear margins.
- Repeat excisions should be entered into the MASEY database as 'return for treatment' rather than follow up otherwise these cases are included in the individual performance data as recurrence of CIN within 12 months of initial treatment.

5.18 Hysterectomy

- A minority of patients with CIN will be treated by hysterectomy. It is an acceptable form of treatment of persistent abnormal cytology provided all measures to exclude occult invasion have been applied and fertility issues are resolved.
- All women having a hysterectomy should have had a smear within three years.
- All women with abnormal cytology who are being considered for hysterectomy should undergo a diagnostic colposcopy to exclude cervical and vaginal abnormalities and appropriate biopsies pre-operatively.
- The clinician in charge (Gynaecologist or GP) will be responsible for failsafe mechanisms for this small group of women.
- Women who undergo subtotal hysterectomy, the GP should be advised of this in writing including future cervical screening interval.

6. TREATMENT COMPLICATIONS

6.1 Primary Haemorrhage (within 48 hours of treatment)

- There is no agreed definition but, in the context of outpatient treatment, it can be defined as bleeding experienced during or within 48 hours of treatment sufficient to warrant the patient to be hospitalised.
- If significant bleeding is encountered that cannot be controlled using diathermy or Monsells solution the vagina should be packed and the patient admitted to Gynaecology ward at LGH.

6.2 Patients on Oral Anticoagulants

- Patients on warfarin should have their INR ideally between 2 and 2.5. These patients should be identified in the clinic and should be referred to the pre assessment team for a bridging plan.
- Patients on edoxiban or Rivoroxaban will need to omit medication for 48 hours prior to procedure.

6.3 Patients within 3 Months of Venous Thromboembolism

- Unless cancer is suspected, treatment should not be performed within 3 months of venous thromboembolism.
- If cancer is suspected local surgical guidelines should be consulted

6.4 Patients with a Pacemaker Fitted.

- Women with a pacemaker fitted need to be discussed with a consultant and will be performed under a local anaesthetic in theatre.

7. FOLLOW UP

7.1 After Treatment for CIN

Individuals who have been treated for CIN1, CIN2, or CIN3 should be invited 6 months after treatment for a test of cure repeat cervical sample in the community. The date for the next recall should be 6 months after their treatment. The colposcopy clinic is responsible for notifying the call and recall service with the due date for the next screen.
Patient compliance with follow up must be encouraged. The nature and timing of follow up depends on their screening result, that is:

- individuals with a sample that has been reported as hrHPV negative should be recalled in 3 years, whatever their age; where the 3 year test is negative, individuals can return to routine recall
- individuals with a sample that has been reported as positive for hrHPV should be referred to colposcopy; reflex cytology is performed as it helps to inform colposcopic examination
- individuals whose hrHPV result is unavailable should have repeat testing at 3 months
- individuals who reach the age of 65 must continue to be invited for follow up tests and or be referred for further investigations as necessary until they have completed all follow up protocols and satisfy the requirements for being ceased from the programme

7.2 After treatment for CGIN/SMILE

Individuals who undergo excision for CGIN are at risk of recurrence. If the CGIN has been completely excised at the time of first excision or subsequent re-excision, a test of cure (TOC) sample should be taken 6 months after treatment. If negative for hrHPV a second TOC sample is taken 12 months later (18 months after treatment or the subsequent re-excision). If this is also negative for hrHPV the individual can be recalled for screening in 3 years. These samples can be performed in the community.

Both 6 month and 12 month screening will be carried out in colposcopy clinic.

7.3 After a Diagnosis of Carcinoma

- If conservative treatment for early stage cervical cancer Squamous (1A1) has been performed, leaving a residual cervix, follow up is recommended. A TOC primary hrHPV sample should be taken 6 and 12 months after treatment in the colposcopy clinic, followed by annual sampling for the next 9 years in primary care before returning to routine recall (if still within the screening age range). The cervical screening programme continues to provide recall arrangements.

- If patient has had 1A1 Adenocarcinoma all of their follow up samples will be performed in colposcopy clinic.

- If at any point in follow up a sample performed in the community is hrHPV positive, a direct referral to colposcopy is required regardless of the cytology result

- For follow up of cervical cancers (Ia2 and above) will be followed up according to local protocol.

7.4 Follow up of untreated individuals

Individuals referred with low grade cytology
Individuals referred with low grade dyskaryosis or less and who have an adequate and normal colposcopic examination are at low risk of developing cervical cancer. These individuals are returned to community-based 3 year recall.

Individuals referred with a result of low grade dyskaryosis or less and who have a colposcopically low grade CIN1 or biopsy proven CIN1 should have a further screen at 12 months in the community.

Colposcopic biopsy at initial assessment is not essential to confirm or exclude low grade CIN. If the lesion has not resolved within 2 years of referral to colposcopy, a biopsy should be considered. Persistent low grade CIN is not considered to be a significant precursor to high grade disease and women can be offered further annual surveillance. Women can be offered treatment at this point as persistent surveillance risks default and women might prefer this option. Options should be discussed with women and informed choice documented.

Excisional treatments in this setting are not expected to contain high grade disease and should be excluded from audits of high grade cytology management pathways.

Management of women with persistent HR HPV + Negative cytology / Bline squamous and LG Dysk and unsatisfactory colposcopy.

In the absence of any national guidance for management of these women. Following a local audit that has shown significant levels of HG CIN, it is reasonable to offer diagnostic lletz for these women.

Women who have declined Lletz or have normal colposcopy appearance should refer for a 12 month follow up.

After Conservative Management of CIN 2 – see Appendix 1

- Follow up for conservative management of CIN2 must be in colposcopy clinic at 6 monthly intervals. If no resolution of the lesion after 2 years, Woman must be offered a LLETZ.

- In selected women with HR HPV + HG dyskaryosis and normal colposcopic appearance, consider cytology review in colposcopy MDT before treatment.

7.5 After Hysterectomy.
Individuals who have had a hysterectomy with CIN present are potentially at risk of developing vaginal intraepithelial neoplasia (VaIN) and invasive vaginal disease.

The recommended follow up is that:

- for individuals on routine recall and with no CIN in their hysterectomy specimen, no further vaginal vault sample is required
- individuals who undergo hysterectomy and have completely excised CIN should have vaginal vault sample at 6 months following their hysterectomy; if they have a negative HPV result they can be discharged
- individuals who undergo hysterectomy and have completely excised CIN, and are hrHPV positive cytology negative at 6 months, should be referred to colposcopy; if there is no evidence of VaIN at colposcopy the individual can be discharged
- for individuals who undergo hysterectomy and have incompletely excised CIN (or uncertain excision), primary HPV screening follow up should be;
    - CIN 1: vault sample at 6, 12 and 24 months
    - CIN 2/3: vault samples at 6 and 12 months followed by 9 annual vault samples
- follow up for incompletely excised CIN continues to 65 years or until 10 years after surgery (whichever is later)
- the clinician in charge (gynaecologist or GP) is responsible for failsafe mechanisms for this small group of individuals
- individuals who undergo subtotal hysterectomy still have their cervix in situ, and so must remain within the cervical screening programme

7.6 CEASING FROM CERVICAL SCREENING

This may need to be considered if screening is difficult or impossible due to

- Clinical reasons include cervical stenosis, insufficient cervical epithelium, patient immobility or very difficult access. In women with severe **cervical stenosis** it may not be possible to obtain a cytological sample that is representative of the whole transformation zone.
- Patient anxiety or inability to tolerate screening test

The case should be discussed at the MDT Meeting and the management options include

- HPV testing
- Hysterectomy
- Cervical dilatation
- Ceasing from screening
- Cervical dilatation should be considered in all cases where there is a history of high grade CIN, cervical glandular intraepithelial neoplasia (CGIN) or unexplained high grade cytology. If this is not successful, hysterectomy should be considered.

- If a woman chooses to withdraw from screening, the case should be discussed at the colposcopy MDT meeting. The local call and recall services, the Hospital Co-ordinator, and the GP must be informed on the management decision. It is advisable that the decision is fully discussed with the woman which should be documented in the notes. A letter is sent to the woman summarising the decision and the relevant factors.

8. PROTOCOL FOR MANAGEMENT OF STERILE SUPPLIES

Processing of used instruments

- It is the Unit's Policy that single use instruments are used wherever possible. However, some instruments are reusable and are sent to the Central Sterile Services Department (CSSD) for processing.
- Single use instruments including specula, biopsy forceps and sponge holders are ordered directly from the suppliers. These should be disposed of in the designated clinical waste bins (yellow/orange).

9. INFECTION CONTROL IN COLPOSCOPY

Room and equipment cleaning

All clinical staff are responsible for the cleaning and decontamination of clinical areas and equipment.
With reference to UHL Policies, 2 cleaning schedules have been compiled; general consultation rooms and Colposcopy & Hysteroscopy treatment rooms.

General Consultation Room Decontamination and Cleaning Schedule			
Item	**Decontamination Method**	**Frequency**	**Other checks**
Examination Couch	Clinell® wipe	After each patient	Visual check of couch vinyl covering
Operators Chair/Stool	Clinell® wipe	After each patient	Visual check of chairs' vinyl covering. Daily cleaning of wheels.
Examination lamp	Clinell® wipe	After each patient	Daily cleaning of wheels
Equipment Trolley – drawers	Cline®ll wipe	Weekly	Including visual check of intact packing and expiry dates
Equipment Trolley – TOP shelf	Clinell® wipe	After each patient	Daily cleaning of wheels
Staff chairs	Clinell® wipe	Start and end of each clinical session	Visual check of fabric covering. Daily cleaning of wheels.
Patient / Visitor chairs	Clinell® wipe	After each patient	Visual check of fabric/vinyl covering
Clinicians desk (including computer, Dictaphone and telephone)	Clinell® wipe	Start and end of each clinical session	

Colposcopy & Hysteroscopy Room Decontamination and Cleaning Schedule			
Item	**Decontamination Method**	**Frequency**	**Other checks**
Colposcope	Clinell® wipe	After each patient	Wheels daily
Colposcope eye piece	Clinell ®wipe	After each patient	
Operators Chair/Stool	Chlor-clean	After each patient	Visual check of chairs' vinyl covering
Examination lamp	Clinell®	After each patient	Wheels daily
Surgical Diathermy machine	Clinell® wipe	daily	Including wheels
Diathermy Pencil	Clinell® wipe	After each patient	Change at end of each clinic
Smoke Extractor	Clinell® Wipe	Daily	Including wheels
Smoke extractor – elephant tubing	Single use	Dispose after each patient	
Smoke extractor - clear tubing	Dispose	After each patient	
Smoke extractor filter		Change daily	
Light lead / Camera	Clinell® wipe	Daily	
Clinical waste (at end of couch)	Swan neck clinical waste sack	After each patient	
Procedure trolley (top shelf)	Chlor-clean	After each patient	Wheels daily

If patient is identified as infected then all equipment to be disposed of / decontaminated after procedure is complete.

Use of gloves within the clinical area

- Gloves should always be worn when indicated in a clinical setting. However, it is important that the correct type of glove be worn in order to protect both the wearer and the patient. This is also to minimise the risk of allergies and other complaints. Hands should always be washed when gloves are removed.
- UHL routinely stock Latex free gloves

Handling of used linen

- Used linen should be bagged as per the above Trust Policies and taken to the refuse holding room located at the end of the maternity corridor at LGH.

Waste disposal:

Cardboard waste

- Flatten and dispose of in the refuse holding room in the appropriate cage.

Domestic waste

- Place in black plastic bag
- Waste bags should not be overfilled; ¾ full only
- Tie bag securely using a *swan neck fastening*

Clinical waste

- Place in yellow plastic bag
- Waste bags should not be overfilled; ¾ full only
- Tie bag securely using a *swan neck fastening*
- Place in refuse holding room if not collected by the clinic domestic
- Clinical waste must be destroyed by incineration

Confidential waste

- Place in the locked shredding bin located by the clinic sluice.

10. Education and training

All new consultants and Trainees have training at induction with the SOP included for reference. Reminders for Cervical smear update through local deanery and NEPSEC.

11. Monitoring Compliance:

What will be measured to monitor compliance	How will compliance be monitored	Monitoring Lead	Frequency	Reporting arrangements
Use of Correctly completed request forms	Derby lab data	Colp Lead	Quarterly	Screening board
Location code on the forms	Derby Lab Data	Colp Lead	Quarterly	Screening board.
Abnormal cytology - Conservative management cases	Audit		as per audit schedule	Colposcopy Operational meeting Colposcopy Business meeting

12. Supporting References:

NHS CSP guidance September 2024 Cervical screening: programme and colposcopy management - GOV.UK

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13. Key Words

Carcinoma, Cervical, CIN, CGIN, Cytology, Ectropion, Endometrial, Excision, Histology, Hysterectomy, Malignancy, Punch Biopsy, Stratified mucin producing intraepithelial lesion (SMILE), Smear

The Trust recognises the diversity of the local community it serves. Our aim therefore is to provide a safe environment free from discrimination and treat all individuals fairly with dignity and appropriately according to their needs.
As part of its development, this policy and its impact on equality have been reviewed and no detriment was identified.

EDI Statement

We are fully committed to being an inclusive employer and oppose all forms of unlawful or unfair discrimination, bullying, harassment and victimisation.

It is our legal and moral duty to provide equity in employment and service delivery to all and to prevent and act upon any forms of discrimination to all people of protected characteristic: Age, Disability (physical, mental and long-term health conditions), Sex, Gender reassignment, Marriage and Civil Partnership, Sexual orientation, Pregnancy and Maternity, Race (including nationality, ethnicity and colour), Religion or Belief, and beyond.

We are also committed to the principles in respect of social deprivation and health inequalities.

Our aim is to create an environment where all staff are able to contribute, develop and progress based on their ability, competence and performance. We recognise that some staff may require specific initiatives and/or assistance to progress and develop within the organisation.

We are also committed to delivering services that ensure our patients are cared for, comfortable and as far as possible meet their individual needs.

CONTACT AND REVIEW DETAILS			
Guideline Lead Dr Vishanthi Shesha Consultant Hannah Ball Lead Nurse Colposcopist & Hysteroscopist			**Executive Lead** **Chief Nurse**
Date	**Issue Number**	**Reviewed By**	**Description Of Changes (If Any)**
January 2025	1	Dr Neveen Khan Dr Vishanthi Shesha H Ball	New document

Appendix 1: Conservative management of CIN 2

Criteria for selection of women

- Referred with HR HPV + LG Dyskaryosis or less
- Nulliparous
- Adequate colposcopy to exclude CIN3 or an invasive lesion
- Low Grade colposcopic opinion
- Lesion not occupying more than two quadrants of the cervix
- Non Smoker
- No previous history of High Grade CIN or previous LLetz.

Process

- Punch Biopsy is taken and confirms CIN 2.
- Histology and notes checked by colposcopist.
- All cases of potential conservative management to be discussed at colposcopy MDT to exclude an undercall or overvall.
- If Conservative management agreed patient is informed and options are discussed
- Women require strict colposcopy follow up with smears six monthly for 2 years and repeat biopsy as appropriate.
- If lesion has resolved and smear HR HPV negative and normal colposcopy at 2 year interval woman can be discharged to 3 year recall.
- If progression of the lesion to CIN 3 or persistent abnormal screening test.
- All cases must be entered into the conservative management spreadsheet as per UHL Colspcospy protocol
- Regular audit of these cases should be carried out.

Appendix 2: Process of results and referrals of cervical samples taken outside of colposcopy

Process:

- Cervical samples should only be obtained by an adequately trained clinician who has a valid sample taker code or PIN (personal identification number) with the local cervical screening laboratory in line with NHSCSP Guidance for the training of cervical sample takers.
- All cervical cytology sample takers working for the UHL and LLR allied Services must be registered on the East Midlands Sample Taker Database in order the University Hospitals of Derby and Burton NHS Foundation Trust's Cytology Laboratory to accept samples.
- Registration is obtained by attending the appropriate training session which is then valid for three years.
- Once training is complete, the sample taker must fill the registration form using an NHS email and GMC/NMC number. (Appendix 1)
- The form should be signed by the appropriate doctor in colposcopy/gynaecology department.
- The form is then emailed to uhdb.cytologystdatabase@nhs.net or posted to Cytology Department, Level 5 Pathology, Royal Derby Hospital, Uttoxeter Road, Derby, DE22 3NE
- Once registration is complete, the sample taker must use their GMC/NMC number for sample taking.
- Cervical sampling may be opportunistic, for those who have defaulted and those with an invitation to screening.
- Prior to offering the cervical smear test, review patient's cervical smear history on ICE (Open Net Report) where possible and enquire about their last test and any invitation letters received.
- Do not take a sample UNLESS patient is due/overdue a test. This will ensure unnecessary rejection of the test by the laboratory.
- Ensure that sample and patient details are completed correctly and match. Incorrect or insufficient information will result in rejection of the sample by the laboratory. See below the rejection criteria.
- Ensure the correct location of where the sample is taken including the post code and clinician responsible cervical on the HMR 101 form.
- At the end of the clinic, the cervical screening sample is taken and placed in a green plastic bag with pre-printed labels from the Derby laboratory.
- RBS card should be filled correctly and attached to the notes.
- For samples reported as HR HPV negative / HR HPV positive negative cytology clinician who has taken the sample is to communicate result with patient with appropriate recall information.
- For any abnormal cytology results, a direct referral from University Hhospitals of Derby will be made to colposcopy and appointment made within the appropriate time frame.

Non-acceptable cervical sample by the cytology laboratory:

- Unlabeled samples
- Incorrect forms/unmatched patient details
- Uninvited women <24.5yrs of age

- Women age 65yr (unless missed last invitation, unscreened or part of follow up from previous abnormal results)
- Less 3 months from last rejected or inadequate sample
- Taken at inappropriate period after a HPV negative test
- Vault samples following a total hysterectomy for non-cervical malignancy or benign conditions

If a sample is rejected by the laboratory, then it is the responsibility of the sample taker to inform the patient of the reasons for rejection and arrange for a repeat sample three months from the last test.