Colposcopy Services - Full Clinical Guideline

Reference No.: Colposcopy/GD/09:2022/Colp/C1

Contents

Definitions Used

- **Borderline Nuclear Abnormality:** minor changes seen within cells**.**
- **Colposcopy:** An examination of the cervix under magnification with a colposcope.
- **Dyskaryosis:** Abnormality in the cells
- **Glandular Neoplasia:** Abnormality in the glandular cells of the cervix
- **Adenocarcinoma in situ:** Pre-invasive cervical glandular lesions.
- **Cervical Glandular Intraepithelial Neoplasia (CGIN):** Abnormality in the glandular cells of the cervix
- **Cervical Intraepithelial Neoplasia (CIN):** Pre-cancerous changes of the cells in the cervix
- **Cytology:** The preparation of stained smears and microscopic examination of cells.
- **Inadequate/Unsatisfactory:** The laboratory has been unable to report a result on a cervical sample due to varying reasons
- **Intermenstrual:** The time between two menstrual periods
- **Knife Cone Biopsy:** Surgical removal of cone shaped cervical tissue
- **Large Loop Excision of the Transformation Zone:** Treatment to the cervix to remove abnormal cells using a diathermy loop
- **Laser:** Treatment to the cervix to destroy abnormal cells using a laser
- **Post Coital Bleeding:** Bleeding after intercourse.
- **Histology:** The preparation and microscopic examination of tissue.
- **HPV Primary screening:** a screening test to detect the presence of HR HPV and if detected a cytology triage test will be performed
- **HR-HPV:** High risk type of Human Papilloma Virus – a common infection usually cleared by the immune system but in 20-30% women that don't there is a higher risk of developing cervical abnormalities
- **LLETZ:** Large loop excision of the transformation zone
- **LMP:** Last menstrual period
- **Cervical Screening:** The call and recall invitation for women aged 25 – 64 to attend for a cervical smear every 3 years until aged 49 then every 5 years before 65.
- **Postpartum:** After delivery of the baby.
- **QHB:** Queens Hospital Burton
- **RDH**: Royal Derby Hospital
- **SRP:** Sir Robert Peel Hospital Tamworth
- **Trimester:** One of the three successive three-monthly periods into which a pregnancy may be divided
- **Hysterectomy:** The surgical removal of the uterus.
- **Sub-Total Hysterectomy:** The uterus is surgically removed but the cervix is left in place
- **Trachelectomy:** Surgical removal of the cervix leaving the uterus in situ thus preserving fertility
- **Post menopausal Bleeding:** Bleeding after periods have ceased
- **Menstruation:** Monthly bleeding - shedding of the endometrium throughout the reproductive period
- **West Midlands Colposcopy Database:** The computer software used to store and audit Colposcopy patient's details- known as MASEY
- **Lorenzo:** The computer software used to store patient details. And used as the Patient Administration System and for ordering and reviewing tests and investigations.
- **UHDB:** University Hospitals of Derby and Burton

C1: COLPOSCOPY CLINIC

C1a: Royal Derby Hospital Site

Purpose

This policy explains the process for setting up the clinic room for Colposcopy.

Aim and Scope

To provide a dedicated service for women who require investigation following abnormal cervical cytology
To meet the needs of women from all cultural and religious backgrounds
Achieve minimum standards set by National Health Service Cervical Screening Programme "Colposcopy and Programme Management" 3rd edition (February 2020)
Provision of a flexible, patient orientated Colposcopy service.

Advantages

Dedicated Colposcopy team may increase patient satisfaction, efficiency, streamlining and safety of the service
Opportunity for increase of audit and research

Implementation

Referral System to Colposcopy Clinic

As per Colposcopy Standard Operating Protocol 8: Management of Colposcopy Referrals.

Selection Criteria

As per Colposcopy Standard Operating Protocol 8: Guidelines for Prioritising/Triage of Colposcopy Referrals

Preparation of the Colposcopy Room

- Ensure patients notes, referral letter and cervical screening result are available
- Ensure Clinic list is available
- Cervical screening request form- use pre-populated form HMR101/histology request form and specimen log book.
- Form to record the transfer of specimens to histology/cytology laboratory
- Ensure drinks tokens available
- Ensure dressing gowns, sanitary towels, tampons are available in the patient changing room
- Switch on and check colposcope and monitor, diathermy machine (correct settings and leads and attachments) and suction machine (display, leads and diathermy plate).
- Check that all consumables are available and are within their expiry date.
- Obtain 5% Acetic acid, schillers iodine, monsels solution, silver nitrate sticks and 3% citenest and octapressin from locked drug cupboard.

Preparation of Trolley

- **Lower Shelf**
  - Jumbo Swabs
  - Cotton Buds
  - Silver nitrate sticks
  - Monsels solution
  - Cervex brush and endocervical brush and Thinprep LBC sample pots.
  - Culture swabs for taking high vaginal swab, endocervical swab and swabs for Chlamydia antigen detection
  - Extra cotton wool balls
- **Upper Shelf**
  - Diagnostic or Treatment pack
  - 5% acetic acid
  - Schillers Iodine
  - Eppendorf forceps (2)
  - Lubricating gel sachets
  - Specimen pot with patient ID label and histology form
  - Gloves

Clinic Protocol

- The colposcopist and a nurse practitioner and health care assistant will staff the clinic. If the clinic is being conducted by the Nurse colposcopist, there must still be one further nurse practitioner in addition to the HCA.
- The patient reports to the reception desk and confirms correct current details
- The HCA will collect the patient's case notes for the colposcopist to review, see the cytology result/referral and ensure the correct record is open on the colposcopy database.
- The HCA will collect the patient from the waiting area, checking their name, address and date of birth with the case notes. She will ensure that the patient is aware that a friend or relative can also be present throughout the consultation and examination for support if required
- The HCA will ask for consent for any visitor to be present such as medical student, practice nurse, student nurse or trainee colposcopist
- Introduction of all staff to the patient on entering the consultation room
- The colposcopist will establish the patient's knowledge of the reason for referral. An independent interpreter is good practice for history taking and counselling if English is not the patients first language – friends and family should not take this role unless absolutely necessary and the patient is agreeable. Language line is only to be used as a last resort.
- Provide any information the patient requires
- Explain all stages of Colposcopy and answer any questions
- Take an appropriate medical history, record on the colposcopy database and establish any relevant allergies (particularly iodine/latex/local anaesthetic)
- Obtain verbal consent and record in the patient's notes and on the database
- If the patient has had a previous uncomfortable experience, found the speculum or cervical biopsy painful discuss options available such as using a smaller speculum, use of Entonox or local anaesthetic if a biopsy is required.
- The nurse/health care assistant assists the patient to a changing room (ensuite toilet if required), advises them to remove their lower garments (use dressing gown if required) and escorts them into the examination room.
- The friend or relative is shown where to sit in the examination room if the patient requires their support
- The nurse/health care assistant provides information, reassurance and support throughout the procedure
- Once the patient is comfortable on the couch and has a cover sheet for dignity, the colposcopist gently inserts the speculum and assesses the cervix and vagina
- Take cervical screening sample if indicated ("inadequate" referral or where referral is for obtaining a cervical or vault smear)
- Take swabs if indicated by symptoms (post coital or intermenstrual bleeding, pain, discharge, "inadequate" referral)
- Perform Colposcopy- applies 5% acetic acid and Schillers iodine and takes a directed biopsy if appropriate - explaining actions to patient at each stage of the process – show and explain on the monitor if the patient requests this
- Use of monsels/silver nitrate if indicated to stop bleeding following a diagnostic biopsy
- At the end of the examination, allow the patient time to recover and then get dressed. Once back in the consultation room explain findings and likely future management and answer any questions
- Complete specimen forms
- Give advice regarding after effects of Colposcopy –slight bleeding/brown discharge and provide patient information leaflet with contact numbers if any problems occur or advice needed
- Explain how and when the patient will get their results
- Provide a contact number on the consultants letter advising to phone if not received a results letter within 6 weeks
- Enter all details on the Colposcopy Database - (if not entered the notes must be tracked to Sr Lowe's office to be entered by the colposcopy secretary). The following data should be recorded: reason for referral, grade of cytology abnormality and HPV results, the presence or absence of a cervix, whether examination adequate i.e. full cervix and squamo columnar junction must be seen, presence or absence of any vaginal and/or endocervical extension, the colposcopic features of any lesion, the colposcopic impression of lesion grade, the type of transformation zone 1, 2 or 3, the site of any biopsies and reasons for not performing any biopsies must also be recorded.
- Print the colposcopy report, draw findings and file in the patients case notes
- The nurse will enter all details of the procedure, samples taken, staff present and planned follow up in the colposcopy log book
- All samples taken are checked against the colposcopy log book and signed by two nurses at the end of the colposcopy list
- All samples are sent to histology reception with a specimen record sheet – this enables the lab staff to check when unpacking that all samples were correctly received

- A proforma is attached by the nurse to the case notes highlighting the consultant, date seen and samples taken. The case notes are sent to the consultant's secretary at the end of clinic. The proforma ensures that she knows what results are awaited and she will keep the notes until results received

Follow up Care

Patients will either:

- Receive a letter through the post from their consultant with their results and recommendations for management
- A letter with a contact number must be given at Colposcopy and the patient is advised to phone consultants secretary if not heard through the post within 6 weeks as a failsafe

Or

- Leave their Colposcopy appointment with a gynaecology clinic appointment for 2-4 weeks to review their results with the consultant.

Digital dictation is used if a letter is to be sent to the GP/cytology recall.

Medical Emergency Plan

Haemorrhage

- If bleeding settles after period of observation – discharge home with contact details and instructions to return to gynaecology ward if heavy bleeding occurs
- If bleeding persists, consider diathermy/suture +/- vaginal pack and admit to gynaecology ward for observation
- Document in the patient's notes and on the colposcopy database

Fainting / Collapse

- Transfer to couch/trolley
- Perform first aid as per Trust First Aid Policy
- Ensure oxygen/suction available
- Take and record observations
- Allow to rest for ½ hour, if recovered, discharge home
- If continues to feel unwell, admit to the gynaecology ward for observation
- Document in the patient's notes.

Anaphylactic Shock

- Alert Cardiac Arrest Team – 2222
- Initiate basic life support
- Obtain resuscitation trolley, oxygen, suction, and defibrillator.
- Adrenaline on the resuscitation trolley to be given IM 0.5mls

Adverse Drug Reaction

- If serious reaction treat as for anaphylactic shock
- Report any adverse drug reaction to medical staff and document in the patient's notes. Ensure an alert sticker is placed on the cover of the notes
- Inform the patients GP of the reaction
- Report to pharmacy as per Medicine policy.
- Any untoward incident should be reported to the lead colposcopist, the lead colposcopy nurse, the nurse in charge and Datix completed. Refer to "Management of Safety Incidents in the Screening Programme" (2017) to assess if it is a screening incident or safety incident.

Equipment

- Ensure clinic is fully stocked prior to each session
- All equipment should be checked prior to clinic to ensure it is in correct working order – if any items damaged or faulty, remove from use and report to Synergy or clinical engineering
- Regular servicing and maintenance checks are carried out and records kept according to Trust policy and record kept in colposcopy room
- Check colposcope regularly –keep on low power in between patients
- If bulb blows phone medical engineering and/or Opticlar rep.
- In all cases of equipment malfunction or failure, follow Trust Safety of Medical Devices Policy and Management of Safety incidents in Screening Programmes (2017).

Environment

- All areas cleaned as per Synergy Cleaning Contract
- Follow Trust Infection Control policy for cleaning spillages
- Sharps disposed of according to Trust Infection Control policy – ensure no more than 2/3 full
- Equipment stored and maintained as per Trust Provision and Use of Work Equipment policy
- Electrical equipment checked as per Trust Provision and Use of Work Equipment policy
- Drugs stored as per Trust Medicines policy
- Linen stored and laundered as per Trust policy
- Used instruments sent to Synergy at the end of each clinic for sterilisation as per Trust Infection Control policy
- Implementation of Trust Fire policy.
- Risk assessments performed/ recorded as per Trust policy.

Audit

- A record of every patient attendance/non attendance will be entered onto the colposcopy database by the colposcopist
- Audit reports (KC65, re-accreditation data) will be produced each quarter by the colposcopy secretary, lead colposcopist and lead colposcopy nurse
- Regular audit of performance will be undertaken according to standards outlined in the National Health Service Cervical Screening Programme "Colposcopy and Programme Management" (2020) such as non-attendance, waiting times for appointment, patient satisfaction.

Clinic Outcomes

- Adequacy of biopsies for histological interpretation >90%
- For those with an adequate colposcopic examination and upper extent of the lesion and SCJ visualised, the positive predictive value of a colpscopic diagnosis of a high grade lesion (CIN 2 or worse) should be at least 75% and 35% for all other referrals

Quality Outcomes

- Result of investigations should be communicated back to the patients within 4 weeks of her attendance (best practice 90%) or 8 weeks (minimum standard 100%)
- Results and management plans should be communicated to the referring practitioner within 4 weeks of her attendance (best practice 90%) or 8 weeks (minimum standard 100%)
- Patient satisfaction with the service
- Staff satisfaction
- Recording of colposcopy data – reason for referral (100%), grade of cytology abnormality (100%) and whether examination adequate and all of cervix seen (100%).

C1b Queens Hospital Burton Site

Daily Pre and Post Clinic Working Instructions

<u>Pre-Clinic</u>

- Before every colposcopy clinic session it is essential that all equipment is checked and in sound working order, in the interest of Health and Safety and patient comfort.

- Please refer to the checklist over the page entitled "Before every clinic we all ensure that" which catalogues a checklist, which must be followed.

- A clinic list must be placed into the Colposcopy Procedure Book and any patient intervention must be documented.

<u>During Clinic</u>

- Perform Colposcopy- applies 5% acetic acid and Schiller's iodine and takes a directed biopsy if appropriate - explaining actions to patient at each stage of the
- Hand the punch biopsy forceps when requested to the colposcopist (these are referred to as Schumachens)
- Prepare the Formalin specimen pot with appropriate labelling according to department policy (please refer to section on management of Histology/Cytology samples).

- Reassure the patient offering any support necessary
- Once the colposcopist has taken the biopsy the tissue needs to be transfered to the specimen pot, and then moved out of the room to the recovery room to be taken to the path lab at the end of the clinic.
- The colposcopist may ask for Silver Nitrate sticks to cauterise the bleeding area.
- Post procedure it is important to provide the patient with a sanitary pad and explain what to expect for the next few days (refer to patient leaflet). Encourage patients to ask any questions and support them appropriately.
- On discharge from the clinic ensure the patient is given a procedure information leaflet including named nurse details and telephone number for the department for any concerns. Ensure they are aware results will be posted within 4 weeks.
- If the patient feels unwell post biopsy encourage them to sit and recover primarily on the couch with a glass of water, offer paracetamol if in pain, and afterwards offer refreshments in the patient recovery room prior to discharge.
- Ensure the procedure is recorded in the procedure logbook and the procedure sheet is filled in so that this information can be order entered after the clinic.
- All specimens should be collected and checked according to the unit policy (please see section on management of Histology and Cytology samples) Once the specimen has been taken it must be moved out of the treatment room into to the recovery room. Once in the recovery room the specimen must be recorded in the Specimen Record Book, with the date, the Consultant and the nursing staff attending, and both must sign the Specimen Book. Under each heading, the following details must be recorded: patient's name, hospital number and details of each specimen taken.
- Ensure two members of nursing staff check the sample against the histology form, the patient's name, date of birth, address and write on the pot the specimen taken. In the case of a Cervical Sample, the pot label only contains the following details, patient's name, and date of birth, hospital. number and date taken. When checking please ensure that the person who wrote the details on the pot is not the person checking the pot. The patients name must be spelt out to the person holding the form to ensure that it is correct and exactly the same on both the form and on the pot, once this had been done put the pot into the bag and seal ready to take down to the pathology lab.
- All specimens should be collected and checked according to the unit policy (please see section on management of Histology and Cytology samples).
- Once the specimen has been taken it must be moved out of the treatment room into to the recovery room.
- Once in the recovery room the specimen must be recorded in the Specimen Record Book, with the date taken,
- The Consultant and the nursing staff attending must both sign the Specimen Book.

- Under each heading, the following details must be recorded, patient's name, hospital and details of each specimen taken.
- Ensure two members of the nursing staff check the sample against the histology form, the patient's name, DOB, address and write on the pot the specimen taken. In the case of a Cervical Sample, the pot label only contains the following details, patient's name, and date of birth, hospital number and date taken. When checking please ensure that the person who wrote the details on the pot is not the person checking the pot. The patient's name must be spelt out to the person holding the form to ensure that it is correct and exactly the same on both the form and on the pot, once this had been done put the pot into the bag and seal ready to take down to the pathology lab.
- All equipment used must be recorded in the patients' notes by sticking the white instrument tracking label into them. The equipment must be labelled with the patient hospital number and placed in the sluice ready for collection by HSSU (please see section on HSSU management).

Post Clinic

- The clinical treatment room should be thoroughly cleaned at the end of each session, including the couch, trolley and surfaces.

- All patient procedures must be entered onto the HISS order entry and the patient procedure sheet must be placed into the folder at the nurse's station which will be collected by Clinic Coding.

- Any necessary re-stocking of clinical equipment and stationary should be carried out to ensure that everything is in place for the next session.

- The Computer must be switched off at the end of the day.

- All equipment should be checked ready for the next session or switched off if it is the end of the clinic day. Suction equipment filters should be changed according to manufacturer's recommendations (please refer to the diathermy loop excision section).

C1c: Sir Robert Peel Hospital

Daily Pre and Post Clinic Working Instructions

Pre-Clinic

- Before every colposcopy clinic session it is essential that all equipment is checked and in sound working order, in the interest of Health and Safety and patient comfort.
- Please refer to the checklist over the page entitled “Before every clinic we all ensure that” which catalogues a checklist, which must be followed.
- A clinic list must be placed into the Colposcopy Procedure Book and any patient intervention must be documented.

During Clinic

- All specimens should be collected and checked according to the unit policy (please see management of Histology and Cytology samples)
- The two members of the nursing staff assisting in clinic must both sign the procedure sheet verifying that the samples are correctly labelled and match the request bag they are attached to.
- All re-usable equipment used must be recorded in the procedure book by sticking the white instrument label into them. The equipment must be labelled with the patient NHS number and placed in the sluice ready for collection by HSSU (please see section on HSSU management).
- Single use equipment label to be put into colposcopy record book alongside patient name, Equipment is then disposed of in the appropriate grey collection box, kept in the colposcopy room.

Post-Clinic

- The clinical treatment room should be thoroughly cleaned at the end of each session, including the couch, trolley and surfaces.
- All patient procedures must be entered onto the patient procedure sheet must be placed into the folder at reception which will be sent to Clinic Coding at Queens Hospital Burton.
- Any necessary re-stocking of clinical equipment and stationary should be carried out to ensure that everything is in place for the next session.
- The Computer must be switched off at the end of the day.
- All equipment should be checked ready for the next session or switched off if it is the end of the clinic day. Suction equipment filters should be changed according to manufacturer’s recommendations (please refer to the diathermy loop excision section).

Colposcopy Clinic: Nurses Checklist

- Check resuscitation equipment prior to session
- Ensure adequate supply of all single use items is available in the treatment room.
- Check colposcope working and spare bulb available
- Ensure couch is working.
- Check diathermy machine and attach diathermy lead and handle.
- Check suction is working, attach tubing.
- Ensure supply of instruments/equipment – sponge holders, cuscoes, cotton wool, Q-tips, lubricant gel, iodine, acetic acid, Monsel's, silver nitrate sticks, local anaesthetic, histology pots, smear pots, biopsy forceps – NB this is not an exhaustive list.

C2a. TREATMENT TO THE CERVIX (LARGE LOOP EXCISION OF THE TRANSFORMATION ZONE) UNDER LOCAL ANAESTHETIC

Royal Derby Hospital Site

Purpose

This policy explains the process for treatment to the cervix. They are guidance and not intended to be rules for practice and are based on the NHS Cervical Screening Colposcopy and Programme Management Publication No 20 (Update February 2020), NHSCSP Good Practice Guide and NHSCSP safety for Electrosurgery Procedures 2004.

Aim and Scope

To ensure a colposcopist has the skills and competence to treat women following abnormal cervical histology using local anaesthetic

To achieve standard of >85% (with a target of 90%) of patients treated under local anaesthetic set by National Health Service Cervical Screening Programme "Colposcopy and Programme Management" (2020).

Achieve minimum standards set by National Health Service Cervical Screening Programme "Colposcopy and Programme Management" (2020)

Provision of a flexible, patient orientated Colposcopy service.

Advantages

- May decrease waiting times for appointment
- Patient preference
- Outpatient procedure
- Opportunity for increase of audit and research
- Cost effective
- Safer for patients by avoiding general anaesthesia

Disadvantages

- Patients may prefer general anaesthetic
- Area may be too large to treat under local anaesthetic or access may be difficult thus increasing risks of inadvertent injury to vaginal walls

Implementation

Referral System to Treatment Clinic

- Colposcopist may opt to see and treat at first visit in selected cases if appropriate and patient agreeable- potential suitable patients are sent patient information literature regarding treatment in addition to their colposcopy leaflet with their appointment details.
- Following diagnostic Colposcopy the consultant writes to or reviews the patient explains the Colposcopy result and why treatment is recommended. This is supported with written LLETZ information leaflet
- Colposcopist's determine if patient's suitable for treatment under local anaesthetic

Selection Criteria and management options

Patients to be included in the treatment clinic caseload:

- Patients referred with High Grade abnormalities on smear (moderate dyskaryosis, severe dyskaryosis, severe ? invasive, glandular abnormalities categories) who are suitable on colposcopic findings, have no contraindication to treatment and are agreeable to treatment after appropriately being counselled and preferably having had appropriate pre clinic literature regarding treatment.
- Patient's whom the consultant has recommended treatment to the cervix following a Colposcopic biopsy showing CIN2 or 3, glandular abnormalities, or persisting CIN1.
- In the majority patients with confirmed High Grade disease will require treatment, however there are circumstances where conservative management of High grade disease no worse than CIN2 may be appropriate. This group will include young women with predominantly low grade disease with focal high grade changes, or women who have had 1 or more treatments with an already shortened cervix but who are desirous of pregnancy but care in these circumstances needs to be individualized with appropriate follow up and confidence that the patient will comply with the required follow up. Discussion at MDT is required in all cases of conservative management of high grade CIN. Patients with biopsy proven high grade CIN who are pregnant are also managed conservatively, reassessed and treated 3 months postnatal.
- The majority of patients with low grade changes will be managed conservatively with follow up cytology, however in select cases where low grade change is persistent or where the patient wishes to proceed

with treatment it may be appropriate to offer excisional treatment for low grade disease especially in older women (due to less likelihood of spontaneous regression) and who have completed their family.

Patients to be excluded:

- Pregnant women
- Patients who poorly tolerate diagnostic Colposcopy/biopsy
- Patients who request or require a general anaesthetic
- Patients whose abnormality extends onto the vaginal wall.
- Patients with poor/difficult access to the cervix
- Patients with an allergy to local anaesthetic

Preparation of the Colposcopy room

- All staff should be familiar with NHSCSP "Electro safety in Electrosurgical Procedures 2004" guidelines
- Ensure patients notes, histology report and smear/swab results are available if taken at Colposcopy
- Ensure clinic list is available
- Histology request form
- Form to record the transfer of specimens to histology/cytology laboratory Ensure drinks tokens available
- Ensure dressing gowns, sanitary towels, tampons are available in the patient changing room
- Switch on and check colposcope (and white balance), image capture stack, diathermy machine (correct settings and leads) and suction machine.
- Check that all consumables are available and are within their expiry date.

Preparation of Trolley

Lower Shelf

- Jumbo Swabs
- Cotton Buds
- Silver nitrate sticks
- Monsel's solution
- Cotton wool balls
- Diathermy electrode abrasive pad

Upper Shelf

- Colposcopy treatment pack
- 5% acetic acid
- Schillers Iodine
- Dental syringe (1)
- Citenest/Xylonest 3% with Octapressin ampoules
- Dental needles
- Diathermy loops (different sizes) and single use diathermy pencils
- Diathermy balls
- Diathermy plates
- Suction tubing
- KY jelly
- Specimen pot with patient ID label and histology form
- Gloves
- Available sanitary towels and tampons

Ensure Available

- Vaginal pack
- Colposcopy suture pack
- Resus trolley
- Long nosed spencer wells
- Thread retriever
- Mirena and copper coils and IUCD insertion pack

Clinic Protocol

New Patients

- The Consultant or nurse colposcopist, a nurse practitioner and health care assistant will staff the clinic
- The patient reports to the reception desk and confirms correct current details
- The HCA will collect the patient's case notes for the colposcopist to review, see the cytology result/histology result and ensure the correct record is open on the colposcopy database.
- The HCA will collect the patient from the waiting area, checking their name, address and date of birth with the case notes. She will ensure that the patient is aware that a friend or relative can also be present throughout the consultation and examination for support if required

- The HCA will ask for consent for any visitor to be present such as medical student, practice nurse, student nurse or trainee colposcopist
- Introduction of all to the patient on entering the consultation room
- Seen by the colposcopist who discusses the Colposcopy results, explains the LLETZ procedure and ensures that the patient has read the information leaflet
- Check that the patient is not going on holiday or getting married within the following 4 weeks as an alternative date may be required
- Provide any information the patient requires and answers any questions
- Take an appropriate focused medical history (LMP) and establish any relevant allergies (particularly iodine/latex) An independent interpreter is good practice for history taking and counselling if English is not the patients first language – friends and family should not take this role unless absolutely necessary and the patient agreeable.
- Obtain spoken agreed consent and document in the patient's notes and on the colposcopy database
- The nurse/health care assistant assists the patient to a changing room (ensuite toilet if required), advises them to remove their lower garments (use dressing gown as required) and escorts them into the examination room.
- The friend or relative is shown where to sit in the examination room if the patient required their support
- The nurse/health care assistant provides information, reassurance and support throughout the procedure
- Once the patient is comfortable on the couch and has a cover sheet for dignity, the colposcopist gently inserts the speculum and assesses the cervix and attaches suction tubing, uses 5% acetic acid and Schillers iodine to highlight the area of abnormal cells
- Infiltrate each quarter of the cervix with Citenest/Xylonest 3% with Octapressin using a dental syringe and needle to a depth of ¼ inch –allow time to take effect.
- Before fixing the diathermy plate, safety checks for treatment (WHO checklist completed) include questioning:
- Does she have metal prosthesis, pins or plates in the area adjacent to treatment area i.e. Hips or Knees? (An alternative site for the diathermy plate must be used if this is the case).
- Does she have a pacemaker? (If yes defer treatment and seek advice from her cardiologist).
- The HCA will apply the diathermy plate to the patients thigh muscle ensuring good contact all round
- Perform LLETZ according to local safety rules, explaining actions to patient at each stage of the process
- At the end of the treatment, allow the patient time to recover and then get dressed. Once back in the consultation room explain findings and likely future management and answer any questions
- Document treatment, type and dose of anaesthetic and any additional top up required in the patients case notes and on the colposcopy database
- Antibiotics (amoxicillin and metronidazole providing the patient is not allergic to penicillin) may be prescribed for the patient to take home at the discretion of the colposcopist
- Complete histology specimen form if appropriate
- Give advice and provide patient information leaflet with contact numbers if any problems occur or advice needed regarding after effects –slight bleeding/discharge for up to 4 weeks is normal but must report any heavy bleeding
- Explain how and when the patient will get their results
- Provide a contact number on the consultants letter advising to phone if not received a results letter within 6 weeks
- Escort patient back to the reception area then allow to sit and have a drink for ½ hour before leaving
- Enter all details on the Colposcopy Database - (if not entered the notes must be tracked to Sr Lowe's office to be entered by the secretary).
- Print the colposcopy report, draw findings and file in the patients case notes
- The nurse will enter all details of the procedure, samples taken, staff present and planned follow up in the colposcopy log book
- All samples taken are checked against the colposcopy log book and signed by two nurses at the end of the colposcopy list
- All samples are sent to histology reception with a specimen record sheet – this enables the lab staff to check when unpacking that all samples were correctly received
- A proforma is attached by the nurse to the case notes highlighting the consultant, date seen and samples taken. The case notes are sent to the consultant's secretary at the end of clinic. The proforma ensures that she knows what results are awaited and she will keep the notes until results received

Advice following Treatment

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 (offer advice regarding any other sport or exercise)

- That they may drive following loop excision or local treatment, unless advised otherwise by the treating colposcopist
- That they may consume alcohol in moderation after treatment,
- That other normal activities, including light exercise, may continue
- That, although there are no known health grounds for avoiding travel following treatment, overseas medical attention for complications arising from the treatment may not be covered by insurance
- That there may be a temporary change in the menstrual pattern following loop excision
- There is no clear evidence that a single loop excision (less than 10mm in depth) are associated with any increase in the incidence of preterm labour and preterm pre-labour rupture of membranes
- Excisional treatment is not associated with any increase risk of infertility but may increase the risk of mid trimester miscarriage
- Treatment has to be tailored to individual circumstances and may require more that 10mm in depth

Follow up Care

- At the discretion of the consultant, patients will either leave with a further appointment made or the consultant will await results and arrange a follow up appointment to be posted with the results letter if required at hospital. Most patients will be discharge to primary care for a follow up hrHPV test in 6 months.

Digital dictation is used if a letter is to be sent to the GP/cytology recall.

Patient notes will be returned to the consultant's secretary.

Medical Emergency Plan

Haemorrhage

- If bleeding settles after period of observation – discharge home with contact details and instructions to return to gynaecology ward if heavy bleeding occurs
- If bleeding persists, consider suture +/- vaginal pack and admit to gynaecology ward for observation
- Document in the patient's notes and on colposcopy database.

Fainting / Collapse

- Transfer to couch/trolley
- Perform first aid as per Trust First Aid Policy
- Ensure oxygen/suction available
- Take and record observations
- Allow to rest for ½ hour, if recovered, discharge home
- If continues to feel unwell, admit to the gynaecology ward for observation
- Document in the patient's notes.

Anaphylactic Shock

- Alert Cardiac Arrest Team –2222
- Initiate basic life support
- Obtain resuscitation trolley, oxygen, suction, and defibrillator.
- Adrenaline 0.5ml to be given IM (on resuscitation trolley)

Adverse Drug Reaction

- If serious reaction treat as for anaphylactic shock
- Report any adverse drug reaction to medical staff and document in the patient's notes. Ensure an alert sticker is placed on the cover of the notes
- Inform the patients GP of the reaction
- Report to pharmacy as per Medicine policy.
- Any untoward incident should be reported to the lead colposcopist, the lead colposcopy nurse, the nurse in charge and Datix completed. Refer to "Management of Safety Incidents in the Screening Programme" (2017) to assess if it is a screening incident or safety incident.

Equipment

- Ensure clinic is fully stocked prior to each session
- All equipment should be checked prior to clinic to ensure it is in correct working order - if any items damaged or faulty, remove from use and report to Synergy or clinical engineering
- Regular servicing and maintenance checks are carried out and records kept according to Trust policy and record kept in colposcopy room

- Check light source on colposcope regularly and white balance prior to use and keep on low power in between patients
- Check the suction machine and primary and secondary filters – change as per ERBE Manual
- In all cases of equipment malfunction or failure, follow Trust Safety of Medical Devices Policy and Management of Safety incidents in Screening Programmes (2017).

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Environment

- All areas cleaned as per Synergy Cleaning Contract
- Follow Trust Infection Control policy for cleaning spillages
- Sharps disposed of according to Trust Infection Control policy – ensure no more than 2/3 full
- Equipment stored and maintained as per Trust Provision and Use of Work Equipment policy
- Electrical equipment checked as per Trust Provision and Use of Work Equipment policy
- Drugs stored as per Trust Medicines policy
- Linen stored and laundered as per Trust policy
- Used instruments sent to Synergy at the end of each clinic for sterilisation as per Trust Infection Control policy
- Implementation of Trust Fire policy.
- Risk assessments performed/ recorded as per Trust policy.

Audit

- A record of every patient attendance/non-attendance will be entered onto the Colposcopy Database
- Audit reports (KC65, re-accreditation data) will be produced each quarter by the colposcopy secretary, the lead colposcopist and the lead colposcopy nurse
- Regular audit of performance will be undertaken according to standards outlined in the National Health Service Cervical Screening Programme "Colposcopy and Programme Management" (2016) such as waiting time for treatment, treatments performed under local anaesthetic and patient satisfaction.

Clinic Outcomes

- >90% of patients will have no dyskaryosis on their smear at 6 months
- >90% of women treated at the first visit should have evidence of CIN2/3 or CGIN on histology
- At least 85% (with a target of 90%) of women should be treated as out patients with local anaesthetic
- >80% of patients should have their sample removed as a single piece
- Depth of excision – type 1 transformation zone greater than 7mm, type 2 transformation zone 10-15mm and type 3 transformation zone 15-25mm

Quality Outcomes

- Result communicated back to the patients within 2-4 weeks Results of investigations should be 4 weeks of her attendance (best practice 90%) or 8 weeks (minimum standard 100%)
- Results and management plans should be communicated to the referring practitioner within 4 weeks of her attendance (best practice 90%) or 8 weeks (minimum standard 100%)
- Patient satisfaction with the service- through annual patient satisfaction survey
- Staff satisfaction.

C2b. Queens Hospital Burton Site

Diathermy Loop Excision

- Make sure you are familiar with the NHSCSP document "Guidance notes on the safe use of diathermy loop excision for the treatment of Cervical Intraepithelial Neoplasia" which is available in the treatment room.
- Read the document over the page entitled Guidance notes for Colposcopy staff on safety procedures for cervical diathermy treatment. This covers equipment settings and safety checks specific to BHNHSFT policy. MAKE SURE EQUIPMENT IS READY AND SET APPROPRIATELY IN ACCORDANCE WITH GUIDELINES.
- As the Patient's advocate under the NMC Code of Professional Conduct ensure that the patient has given verbal consent to the procedure and is aware of the after effects, and any implications such as holiday/weddings etc.
- Also ensure that the patient has been informed that the local anaesthetic to be used is Prilocaine 3%, as this is an unlicensed drug for loop excision treatment and in accordance with the agreement of its use by UHDB Drugs and Therapeutics Committee.

- Prior to the treatment make sure the patient is as comfortable as possible.
- Before fixing the diathermy plate, safety checks for treatment include questioning:
- Does she have metal prosthesis, pins or plates in the area adjacent to treatment area i.e. Hips or Knees? (An alternative site for the diathermy plate must be used if this is the case).
- Does she have a pacemaker? (If yes defer treatment and seek advice from her cardiologist).
- Are there any piercings from umbilicus downwards? (If yes advice removal due to small risk of diathermy burn).
- Ensure suction tubing is connected and ready for attachment to speculum by colposcopist.
- Pass the local anaesthetic to the colposcopist when requested checking date on cartridge and correct loading of dental syringe. 2 extra cartridges should be placed on the trolley for the colposcopist to ensure complete cervical anaesthesia.
- Ensure Formalin histology pot is ready on the trolley and labelled as per policy.
- Offer choice of loop sizes and attach it to diathermy lead.
- Reassure patient of the noise they are about to hear.
- After switching on the machine, check the cut and coag blend are appropriate. Switch on the suction machine.
- Support and reassure patient throughout the procedure holding their hand if needed.
- Once the biopsy has been taken pass the diathermy ball to the colposcopist to insert into the diathermy lead. Monsel's is kept in the back cupboard if required to stop the bleeding.
- All specimens should be collected and checked according to the unit policy (please see section on management of Histology and Cytology samples) Once the specimen has been taken it must be moved out of the treatment room into to the recovery room. Once in the recovery room the specimen must be recorded in the Specimen Record Book, with the date, the Consultant and the nursing staff attending, and both must sign the Specimen Book. Under each heading, the following details must be recorded: patient's name, hospital number and details of each specimen taken.
- Ensure two nursing staff check the sample against the histology form, the patient's name, date of birth, address and write on the pot the specimen taken. In the case of a Cervical Sample, the pot label only contains the following details, patient's name, and date of birth, hospital number and date taken. When checking please ensure that the person who wrote the details on the pot is not the person checking the pot. The patients name must be spelled out to the person holding the form to ensure that it is correct and exactly the same on both the form and on the pot, once this had been done put the pot into the bag and seal ready to take down to the pathology lab.
- If patient feels unwell post treatment encourage them to sit and recover primarily on the couch with a glass of water, and afterwards offer refreshments in the patient counselling/recovery room.
- Post procedure it is important to offer the patient a sanitary pad and explain what to expect for the next few days (refer to the patient leaflet). Encourage patients to ask any questions and support them appropriately.
- On discharge from the clinic ensure the patient is given a procedure information leaflet including the named nurse details and telephone number for the department for any concerns. Ensure they are aware they will get their results directly and also a copy will be sent to their G.P.
- Ensure the procedure is recorded in the procedure logbook and the procedure sheet is filled in so that this information can be entered into the database after the clinic.

Management of Post Treatment Haemorrhage

- In case of an excessive amount of bleeding after Loop Diathermy, an emergency vaginal packing pack should be obtained. These are located in the clinic room where the colposcopy sets are kept.
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- The nursing staff must liaise with the Colposcopist to ensure all the relevant people have been contacted, in case the patient needs to transfer to a ward or theatre. If patient's need to be transferred to a Ward permission should be sought from the Matron and a Ward Transfer document should be filled out and sent with the patient.

- Call the Porters so they can send a wheelchair/bed to transfer the patient.

- Before the patient is moved from the Colposcopy Department ensure that their observations have been carried out and documented on the Gynae sheet in their notes.
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  Finally make sure the patient has a safe transfer from the Department to either the Ward or Theatre. A trained member of the colposcopy nursing staff should accompany the patient and give effective handover to a member of staff on the ward.

Management of Non-Surgical Complications of Colposcopy

Vaso-vagal attacks

- This may occur as a result of a vagal reflex due to cervical stimulation.
- 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 back rest of the couch.
- Remove any pillows to ensure patient lies flat on the couch.
- Connect and administer oxygen if indicated by the Colposcopist.
- Monitor pulse rate and blood pressure and record in notes.
- Continue to assess patient and if she is not able to be discharged from outpatients, contact the bed manager and make arrangements for a ward transfer.

Severe Bronchospasm or other Severe Allergic Reaction

- May occur rarely in response to injection of local anaesthetic.
- STOP PROCEDURE and administer prescribed oxygen if appropriate
- Call the CRASH TEAM on 2222 and maintain airway/basic life support until arrival.
- Get the CRASH TROLLEY from the clean utility room

Epileptic Seizures

- These may occur as a result of injection of 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 the lowest level possible and lower back rest if appropriate for patient's comfort.
- In severe cases CALL CRASH TEAM and maintain airway/basic life support until arrival.

C2c. Sir Robert Peel Hospital Site

Management of Post Treatment Haemorrhage

In case of an excessive amount of bleeding after Loop Diathermy, a vaginal pack can be obtained from Theatre, if the colposcopist is still present, alternatively, an admission to Queens Hospital will need to be arranged by the Colposcopist and nursing staff.

Management of Non-Surgical Complications of Colposcopy

Vaso-vagal attacks

This may occur as a result of a vagal reflex due to cervical stimulation.
If the patient is still on the couch

- 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 back rest of the couch.
- Remove any pillows to ensure patient lies flat on the couch.
- Collect and administer oxygen if indicated by the Colposcopist.
- Monitor pulse rate and blood pressure and record in notes.

Severe Bronchospasm or other Severe Allergic Reaction

- May occur rarely in response to injection of local anaesthetic.
- STOP PROCEDURE and administer prescribed oxygen if appropriate
- Initiate CPR if required and dial 9-999 for emergency assistance.

Epileptic Seizures

- These may occur as a result of injection of 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 the lowest level possible and lower back rest if appropriate for patient's comfort.

TREATMENT TO THE CERVIX (LARGE LOOP EXCISION OF THE TRANSFORMATION ZONE) UNDER GENERAL ANAESTHETIC

Patients may require treatment under general anaesthetic for a variety reasons as listed below.

- Pregnant women (bleeding risk)
- Need for Cold Knife Cone biopsy
- Patients who poorly tolerate diagnostic Colposcopy/biopsy
- Patients who request or require a general anaesthetic
- Patients whose abnormality extends onto the vaginal wall or large area to treat (at the discretion of the colposcopist)
- Patients with poor/difficult access to the cervix
- Invasive disease suspected and outpatient biopsy not considered appropriate
- Patients with an allergy to local anaesthetic

The process of organising this will depend on whether the patient is seen at RDH site or at QHB/SRP colposcopy clinic.

C2d. Royal Derby Hospital Site

1) If the patient is seen as a first visit in the nurse led smear clinic with a high grade abnormality but deemed unsuitable for local anaesthetic treatment the a representative biopsy should be taken and documented on the patient record that general anaesthetic treatment will be needed so that when the histology result is available then the relevant arrangements can be made. A treatment information leaflet should be given to the patient if one was not already enclosed with the invitation letter.

2) If the patient is seen in a consultant clinic and findings are in keeping with a high grade lesions then the consultant can either complete a waiting list form and give a date at the time or complete a waiting list form with specified urgency and a date allocated by the waiting list clerks.

3) If treatment is required following availability of biopsy results, then the responsible consultant must dictate a letter to the patients, with the histology result, proposed treatment plan and the relevant patient information leaflet along with completing a waiting list form with specified urgency+/- surgeon and the waiting list team will make the appropriate arrangements thereafter including any pre-op assessment deemed necessary based on the patients overall medical history.

C2e. Queens Hospital Burton and Sir Robert Peel Tamworth

1) A minority of patients will require treatment as inpatients. The most frequent reasons are listed above.
2) In such situations the urgency of the situation should first be assessed. The admission should be booked by liaising with the appropriate surgeon or consultant.
3) The patient should be informed that she will receive a letter informing her of her admission if not arranged in clinic.

Documentation of In-Patient Treatment

In order that the colposcopy clinic database is well maintained and that timely communication occurs, it is necessary to complete a colposcopy data sheet KC65 on all patients undergoing in-patient treatment both NHS and private patients.

C3. FOLLOW UP AFTER TREATMENT TO THE CERVIX FOR CERVICAL PRE-CANCER

Purpose

This policy explains local and national recommendations for follow up after treatment to the cervix for cervical precancer.

Aim and Scope

The purpose of this policy is to ensure that all women are given appropriate follow up after treatment to the cervix for cervical precancer according to national recommendations from the NHS Cervical Screening Programme.

Implementation

Communication of Results

The named Consultant responsible for the patient will write to the patient once the histology report is available, detailing the findings and recommended follow up. The letter will also be copied to the patient's GP. In addition, on a monthly basis a spreadsheet is submitted to cytology recall informing them of the outcome of all patients seen in colposcopy and where (community or hospital based clinic) and when the next cervical screening test will be required.

In certain circumstances (ie complex patients or where a diagnosis of invasive disease is suspected) a follow up appointment to clinic may be made at the time of the original colposcopy/treatment.

Follow up Following Treatment of CIN

If the patient has had treatment to the cervix for any grade of CIN, the first cervical screening sample should be taken 6 months following treatment in **Primary care (default option)** or at hospital nurse led cervical screening clinic (using a cervex with or without endocervical brush thus ensuring adequate transformation zone sampling) – the consultant will advise when writing to the patient and her GP with treatment results. The latter option (hospital nurse led screening clinic) should be predominantly for patients where sampling is thought to be difficult or where excision at endocervical +/- radial margins is incomplete. Women under the age of 25 who have received treatment for CIN will have their cervical screening sample taken at hospital nurse led cervical screening clinic to avoid the possibility that they do not have a smear performed due to being under 25. A HPV test of cure will be performed on all first cervical screening after treatment to assess a women's risk of having residual or recurrent disease. (see Appendix 2)

If the test for high risk HPV is negative the women can be discharged and will not need to be recalled for cervical screening for 3 years with her GP regardless of her age. (If at 3 years her HR HPV result is negative, women over 50 years should revert to their normal recall pattern – every 5 years).

If the HPV test of cure is positive, a cytology slide will be prepared and analysed. If this is negative or abnormal (any grade) the patient will be referred back to colposcopy (within 2 or 6 weeks as per referral guidelines based on grade of cytological abnormality) for further evaluation and management as indicated by the colposcopic findings and biopsies.

If Colposcopy is satisfactory/adequate and findings are negative, she can be discharged and be recalled for further cervical screening in 3 years with her GP. The patient will be informed of all test results in writing.

If the cytology report is returned as unsatisfactory or the HR HPV test is unavailable, the patient will be sent a further appointment for repeat cervical screening in 3 months.

Women who have been treated for stage 1a1 invasive disease (who still have a cervix) are included in HPV primary screening test of cure protocol and will be given annual HPV testing (instead of cytology) for 10 years in the hospital setting.

Follow up of CGIN

1) Incomplete excision

Women treated for CGIN should be discussed at MDT and those with incompletely excised CGIN further excision could be offered where appropriate to confidently exclude invasion and obtain negative margins. Incomplete excision margins for CGIN or SMILE require annual HPV testing for 10 years.

With incomplete excision where a further excision is not possible or declined and a conservative approach is adopted then primary hrHPV screening should be undertaken at 6 and 12 months and then annually for a further 9 years. If HR HPV positive at any point in follow up a direct referral to colposcopy is required regardless of the cytology result.

2) Complete excision

Women treated for completely excised cervical glandular intraepithelial neoplasia found either on diagnostic or therapeutic biopsy require a test of cure cervical screening sample at 6 months after treatment using a cervix and endocervical brush. If negative for HR HPV a second test of cure cervical screening sample is taken 12 months later (i.e. 18 months after treatment). If this is also negative for HR HPV the women can be discharged for recall in 3 years. Further recall will depend on the result of this test and the age of the women.

If the HR HPV test, at 6 or 18 months after treatment is positive, a cytology slide will be prepared and analysed. The women should be referred back to colposcopy whether the cytology is negative or abnormal.

If the woman has a positive HR HPV test/cytology negative test and no abnormality is detected at colposcopic examination the women should have a second HR HPV test of cure 12 months later.
If this sample is negative for HR HPV the women can be discharge to recall in 3 years. Further recall will depend on the result of this test and the age of the women.

If a positive cytology test (abnormal cytology) is reported in either of the 6 or 18 month samples, the woman must be referred to colposcopy and managed appropriately. If no colposcopic abnormality is present and re-excision is not appropriate, the women should revert to 10 years of cytology follow up – 6 monthly for the first 2 years and then annually for 8 years.

Follow up of SMILE lesions

Stratified Mucinous Intraepithelial Lesion (SMILE) shows a similar spectrum of nuclear morphology to CGIN but in this variant, mucin production is preserved with vacuoles distributed throughout the whole height of the dysplastic epithelium. In most instances, SMILE is associated with HG CIN or HG-CGIN. If seen on directed biopsy, presence of SMILE should be an indication for further sampling of the cervix in the form of LLETZ or Knife Cone biopsy. If SMILE is identified in an excisional biopsy then it is important that complete excision has been achieved (similar to HG CGIN) and the case should be reviewed at colposcopy MDT. Follow up of SMILE lesions needs to be along the same pathway as HG CGIN as discussed above.

Follow Up arrangements Following Hysterectomy

Women who have undergone a subtotal hysterectomy still have their cervix in situ so must remain within the National Screening Programme and be followed up as per guidelines in NHSCSP no. 20 Colposcopy and Programme Management (2016).

For women who were on routine recall prior to their hysterectomy and no CIN was identified in the histology specimen at hysterectomy, no further vaginal vault sample testing is required.

Women with completely excised CIN at hysterectomy require vaginal vault sample for HR HPV testing at 6 months following surgery and cease screening if negative. Vault sampling needs to be done in the hospital setting.

Women with completely excised CIN at hysterectomy and are HR HPV positive and cytology negative at 6 months, should be referred to colposcopy. If there is no evidence of VAIN at colposcopy they can be discharged.

For women with incomplete or uncertain excision of CIN follow up should be conducted as if the cervix is still in situ (See Guidelines for Follow up After Treatment To The Cervix For Cervical Precancer).

For CIN1 this is vault HPV test at 6, 12 and 24 months and for CIN2 or 3 this is vault HPV test at 6 and 12 months, followed by 9 annual vault HPV test samples. The vault sample needs to be done in the hospital setting.

Follow up for incompletely excised CIN at hysterectomy continues to 65 years or until 10 years after surgery (whichever is later).

The responsibility for implementing and undertaking follow-up after a hysterectomy resides with the treating gynaecologist. If discharging to GP, the gynaecologist must ensure they receive specific written guidance as to future follow-up and if requires further vault sampling these need to be arranged to be done in secondary care.

The clinician in charge (Gynaecologist pre discharge, GP post discharge) will be responsible for fail safe mechanisms for these women.

Women who have had radical trachelectomy as part of conservative management for cervical cancer should remain under the care and guidance of their treating oncologist, Follow up is recommended with colposcopy and cytology and this is no longer within the NHSCSP.

C4. SPECIALIST NURSE COLPOSCOPY SERVICE- ROYAL DERBY HOSPITAL SITE

Purpose

This policy explains the process for the specialist nurse Colposcopy service.

Aim and Scope

To provide a nurse colposcopist led clinic for women who require investigation following abnormal cervical screening
To provide a specialist contact person to meet the psychological needs of women referred – for advice, counselling and support
To provide a female led clinic to meet the needs of women from all cultural and religious backgrounds
To provide the patient with continuity of care – see the same person on subsequent visits
To assist managing waiting times for appointments – achieve standards set by National Health Service Cervical Screening Programme "Colposcopy and Programme Management" (2020).
Provision of a flexible, patient orientated Colposcopy service.

Advantages

- A female colposcopist may increase patient satisfaction
- Extra, qualified personnel as a resource to reduce cancellation of Colposcopy clinic if medical staff unavailable
- Increased flexibility of clinic sessions as nurse colposcopist has fewer fixed commitments
- Opportunity for increase of audit and research
- Opportunity for nurses' professional development and expansion of scope of practice.

Disadvantages

- Patients may prefer to see a doctor
- Inability to deal with other coexisting medical problems
- Necessity for medical availability if emergency situation arises.

Implementation

Referral System to Nurse Colposcopist Clinic

- Follow Colposcopy Standard Operating Protocol 8 Management of Colposcopy Referrals
- Consultants allocate if patient's suitable for nurse colposcopist clinic when prioritising referral letters
- Each patient in the Nurse colposcopist clinic has already a named consultant assigned at the point of triage of the referral to ensure appropriate chain of responsibility and identified clinician for advice and support to the nurse colposcopist.
- Caseload comprises of new colposcopies/follow-up colposcopies.
- 6/7 patients per clinic, 30 minute slots.

Selection Criteria

Patients to be included in the nurse colposcopist's caseload:

- Patients' who the cytology laboratory have recommended referral for Colposcopy following a smear showing inadequate smears, High Risk HPV detected and borderline, low grade or high grade dyskaryosis, abnormal symptoms and follow up colposcopies.

Clinic Protocol

New Patients

- The nurse colposcopist, a nurse practitioner and Health Care Assistant will staff the clinic
- The patient reports to the reception desk and confirms correct current details
- The HCA will collect the patient's case notes for the nurse colposcopist to review, see the cytology result/referral and ensure the correct record is open on the colposcopy database.
- The HCA will collect the patient from the waiting area, checking their name, address and date of birth with the casenotes. She will ensure that the patient is aware that a friend or relative can also be present throughout the consultation and examination for support if required
- The HCA will ask for consent for any visitor to be present such as medical student, practice nurse, student nurse or trainee colposcopist
- Introduction of all staff to the patient on entering the consultation room
- Establish the patient's knowledge of the reason for referral
- Provide any information the patient requires An independent interpreter is good practice for history taking and counselling if English is not the patients first language – friends and family should not take this role

unless absolutely necessary and the patient is agreeable. Language line should only be used as a last resort

- Explain all stages of Colposcopy and answer any questions
- Take an appropriate medical history, enter on the colposcopy database and establish any relevant allergies (particularly iodine/latex)
- Obtain spoken agreement and record in the patient's notes and on the colposcopy database If the patient has had a previous uncomfortable experience, found the speculum or cervical biopsy painful discus options available such as using a smaller speculum, use of Entonox or local anaesthetic if a biopsy is required.
- The nurse/health care assistant assists the patient to a changing room (ensuite toilet if required), advises them to remove their lower garments (use dressing gown if required) and escorts them into the examination room.
- The friend or relative is shown where to sit in the examination room if the patient required their support
- The nurse/health care assistant provides information, reassurance and support throughout the procedure
- Once the patient is comfortable on the couch and has a cover sheet for dignity, the nurse colposcopist gently inserts the speculum and assesses the cervix
- Take cytology sample if indicated ("inadequate" referral)
- Take swabs if indicated by symptoms (post coital or intermenstrual bleeding, pain, discharge, "inadequate" referral)
- Nurse colposcopist performs colposcopy- applies 5% acetic acid and Schillers iodine and takes a directed biopsy if appropriate - explaining actions to patient at each stage of the process – show and explain on the monitor if the patient requests this
- Although not normally required, if indicated an image can be saved to the colposcopy database to enable discussion with consultant/lead colposcopist e.g. suspicious lesion, vaginal extension
- Use of Monsel's/silver nitrate if indicated to stop bleeding following a diagnostic biopsy
- At the end of the examination, allow the patient time to recover and then get dressed. Once back in the consultation room explain findings and likely future management and answer any questions
- Complete specimen forms
- Give advice regarding after effects of Colposcopy –slight bleeding/discharge and provide patient information leaflet with contact numbers if any problems occur or advice needed
- Explain how and when the patient will get their results
- Provide a contact number on the consultants letter advising to phone if not received a results letter within 6 weeks
- Enter all details on the Colposcopy Database - (if not entered the notes must be tracked to Sr Lowe's office to be entered by the secretary). The following data should be recorded: reason for referral and HPV result, grade of cytology abnormality, the presence or absence of a cervix, whether examination adequate i.e. full cervix and squamo columnar junction must be seen, presence or absence of any vaginal and/or endocervical extension, the colposcopic features of any lesion, the colposcopic impression of lesion grade, the type of transformation zone 1, 2 or 3, the site of any biopsies and reasons for not performing any biopsies must also be recorded.
- Print the colposcopy report, draw findings and file in the patients case notes
- The nurse will enter all details of the procedure, samples taken, staff present and planned follow up in the colposcopy log book
- All samples taken are checked against the colposcopy log book and signed by two nurses at the end of the colposcopy list
- All samples are sent to histology reception with a specimen record sheet – this enables the lab staff to check when unpacking that all samples were correctly received
- A proforma is attached by the nurse to the case notes highlighting the consultant, date seen and samples taken. The case notes are sent to the consultant's secretary at the end of clinic. The proforma ensures that she knows what results are awaited and she will keep the notes until results received

Follow up Care

Patients will either:

- Receive a letter from their consultant with their results and recommendations for management
- Contact number given at Colposcopy – advised to phone consultant's secretary if not heard by letter within 6 weeks

Or

- Leave clinic with a follow up gynaecology clinic appointment for 2-4 weeks to review their results with the consultant.

Any cases will be discussed with the named consultant if clinically indicated.

Referral to Medical Staff
If at any stage of the consultation the nurse colposcopist believes the patient's condition is beyond the scope of her expertise, she will refer her to the patient's consultant or the consultant on call in their absence or another consultant who may be in clinic at the time.

Medical Emergency Plan

Haemorrhage
- If unable to settle with Monsel's solution/silver nitrate sticks alert the nearest appropriate member of medical staff or the consultant on call
- If bleeding persists, consider diathermy/suture +/- vaginal pack and admit to gynaecology ward for observation
- If bleeding settles after period of observation – discharge home with contact details and instructions to return to gynaecology ward if heavy bleeding occurs
- Document in the patient's notes and on colposcopy database

Fainting / Collapse
- Transfer to couch/trolley
- Perform first aid as per Trust First Aid Policy
- Ensure oxygen/suction available
- Take and record observations
- Allow to rest for ½ hour, if recovered, discharge home
- If continues to feel unwell, admit to the gynaecology ward for observation
- Document in the patient's notes.

Anaphylactic Shock
- Alert Cardiac Arrest Team 2222
- Initiate basic life support
- Obtain resuscitation trolley, oxygen, suction, and defibrillator
- 0.5mls adrenaline to be given IM (on resuscitation trolley)

Adverse Drug Reaction
- If serious reaction treat as for anaphylactic shock
- Report any adverse drug reaction to medical staff and document in the patient's notes. Ensure an alert sticker is placed on the cover of the notes
- Inform the patients GP of the reaction
- Report to pharmacy as per Medicine policy.
- Any untoward incident should be reported to the lead colposcopist, the lead colposcopy nurse, the nurse in charge and Datix completed. Refer to "Management of Safety Incidents in the Screening Programme" (2017) to assess if it is a screening incident or safety incident.

Equipment
- Ensure clinic is fully stocked prior to each session
- All equipment should be checked prior to clinic to ensure it is in correct working order - if any items damaged or faulty, remove from use and report to Synergy or clinical engineering
- Regular servicing and maintenance checks are carried out and records kept according to Trust policy and a record kept in the colposcopy room
- Check light source on colposcope regularly – white balance prior to each use and keep on low power in between patients
- If bulb blows – change lead to alternative bulb – phone medical engineering to change the bulb that has blown at the end of clinic
- In all cases of equipment malfunction or failure, follow Trust Safety of Medical Devices Policy and Management of Safety incidents in Screening Programmes (2017)

Environment
- All areas cleaned as per Synergy Cleaning Contract
- Follow Trust Infection Control policy for cleaning spillages
- Sharps disposed of according to Trust Infection Control policy- ensure no more than 2/3 full
- Equipment stored and maintained as per Trust Provision and Use of Work Equipment policy
- Electrical equipment checked as per Trust Provision and Use of Work Equipment policy
- Drugs stored as per Trust Medicines policy
- Linen stored and laundered as per Trust policy

- Used instruments sent to Synergy at the end of each clinic for sterilisation as per Trust Infection Control policy
- Implementation of Trust Fire policy.
- Risk assessments performed/ recorded as per Trust policy.

Audit

- A record of every patient attendance/non-attendance will be entered onto the Colposcopy Database
- Audit reports (KC65, re-accreditation data) will be produced each quarter by Colposcopy secretary, lead colposcopist and lead nurse colposcopist
- Regular audit of performance will be undertaken by the nurse colposcopist according to standards outlined in the National Health Service Cervical Screening Programme "Colposcopy and Programme Management" (2020) such as non-attendance, waiting times for appointment, patient satisfaction.

Clinic Outcomes

- Adequacy of biopsies for histological interpretation >90%
- For those with an adequate colposcopic examination and upper extent of the lesion and SCJ visualised, the positive predictive value of a colposcopic diagnosis of a high grade lesion (CIN 2 or worse) should be at least 65%

Quality Outcomes

- Result of investigations should be communicated back to the patients within 4 weeks of her attendance (best practice 90%) or 8 weeks (minimum standard 100%)
- Results and management plans should be communicated to the referring practitioner within 4 weeks of her attendance (best practice 90%) or 8 weeks (minimum standard 100%)
- Patient satisfaction with the service
- Staff satisfaction
- Recording of colposcopy data – reason for referral (100%), grade of cytology abnormality (100%) and whether examination adequate and all of cervix seen (100%).
- Significant correlation between the colposcopic appearance and histology >70%.

C5. NURSE LED CERVICAL SCREENING SERVICE- ROYAL DERBY HOSPITAL SITE

Purpose

This policy explains the process for the nurse led cervical screening service.

Aim and Scope

To provide a nurse led clinic for women who require cervical screening follow up after treatment to the cervix
To provide a female led clinic to meet the needs of women from all cultural and religious backgrounds
Provision of a flexible, patient orientated follow up service.

Advantages

- Free clinic slots in the Consultant's gynaecology clinics and Colposcopy clinics
- Dedicated cervical screening clinics – streamlined service
- Increased flexibility of clinic sessions
- Opportunity for increase of audit and research into patient follow up
- Opportunity for nurses' professional development and expansion of scope of practice.
- Ensures that the first post treatment cervical sample is performed within the time span recommended by the National Health Service Cervical Screening Programme "Colposcopy and Programme Management" (March 2020)
- Provides a source of information regarding any post treatment complications
- Ensures that the cervical screening samples are taken appropriately and the opportunity is taken to discuss the importance of follow up with patients.
- Training opportunity for junior medical staff

Implementation

Referral System to Nurse Led Cytology Clinic

- Consultants specify if patient requires cervical screening follow up in the nurse led clinic when communicating results after treatment to the cervix or diagnostic colposcopy. The secretary sends the letter to the appointments office for an appointment to be booked and sent with the letter.
- 12 - 15 patients per clinic, 15 minute slots.

Selection Criteria

Patients to be included in the nurse's cytology caseload:

- Patient's who have had large loop excision of transformation zone for cervical intraepithelial neoplasia and the consultant specifies a follow up smear would be preferable in the nurse led clinic (most are discharged to primary care)
- Patient's who have had incomplete excision of CIN at LLETZ at more than the ectocervical margin (ie involving more than one margin)
- Patient's who have had treatment for adenocarcinoma in situ / cervical glandular intraepithelial neoplasia
- Patients who require follow up with a vault sample following hysterectomy

Patients to be excluded from the nurse caseload:

- Those who also require follow up Colposcopy as well as a cervical screening sample
- Patients with limited mobility who may find it easier to access the colposcopy couch,
- Patients whose cervix is technically difficult to access and may require the assistance of the colposcope/colposcopy couch

Preparation of Clinic Room

- Ensure patients case notes, cytology and histology results available
- Ensure clinic list available
- Ensure cervical screening request forms and clinic record log book are available
- Ensure sanitary towels, tissues, paper sheets available next to the couch
- Check lamp and couch are working correctly
- Check the LBC vials are within expiry date

Equipment

- Range of speculums including VI and Winterton's
- Thinprep vials
- Cervix and endocervical brushes
- Gloves
- Culture swabs

- Silver nitrate
- Sample taker folder and consultant letters

Clinic Protocol

- The registered nurse (who is trained and assessed to take cervical samples) and a health care assistant will staff the clinic
- The registered nurse will print the pre populated HMR101 cervical cytology request form from Open Exeter
- The patient reports to the reception desk and confirms correct current details
- The HCA will collect the patient's case notes for the nurse to review, see the cytology/histology result and ensure the correct record is open on the colposcopy database.
- The HCA will collect the patient from the waiting area, checking their name, address and date of birth with the case notes. She will ensure that the patient is aware that a friend or relative can also be present throughout the consultation and examination for support if required
- The HCA will ask for verbal consent/agreement for any visitor to be present such as junior doctor or trainee colposcopist
- Introduction of all staff present to the patient
- Establish the patient's knowledge of why follow up is required - An independent interpreter is good practice for history taking and counselling if English is not the patients first language – friends and family should not take this role unless absolutely necessary and the patient is agreeable. Language line is only to be used as a last resort.
- Provide any information the patient requires – explain about the national HPV primary screening programme and give patient information leaflets about this. It is not possible for women to request a cytology test instead – all samples will be tested using primary hrHPV testing.
- Explain cervical sample and answer any questions
- Establish whether any problems since the last visit
- Establish whether any IMB/PCB/discharge
- Obtain verbal consent and record in the patient's notes
- Confirm the patients correct details are recorded on the HMR101 form
- Explain to the patient how to prepare for the cervical screening examination and ensure that they have a cover sheet for dignity
- Once the patient feels comfortable on the couch the nurse takes the cervical screening sample using a cervex brush (and an additional endocervical brush if previous CGIN, invasive or incomplete endocardial margins at LLETZ), explaining actions to the patient and ensuring vial is within 2 weeks of the expiry date
- The HCA also provides reassurance and support at all stages throughout the procedure
- Take triple swabs if indicated by symptoms (post coital or intermenstrual bleeding, pain, discharge)
- At the end of the examination, allow the patient time to recover, then get dressed, provide sanitary towel if required
- Document all details in the case notes and correctly complete HMR101 request form. All samples for HPV Primary screening are placed in a <u>green</u> cytology specimen bag
- Both nurses check correct specimen and request form and sign the record in the specimen log book
- Give advice regarding after effects –slight bleeding/discharge
- Discuss the likely management and follow up. For example, explain what will happen if hrHPV negative or if hrHPV positive
- Explain how and when the patient will get their results (by letter) and confirm correct address
- A letter with a contact number must be given and the patient is advised to phone consultants secretary if not heard through the post within 6 weeks
- Follow local guidelines regarding future cervical screening
- Enter visit on the Colposcopy database
- A proforma is attached to the case notes by the HCA recording date, samples taken and consultant
- Patient notes/proforma returned to the consultant's secretary following clinic who will keep and show the results to the Consultant then send a results letter to the patient once dictated

Referral to Medical Staff

If at any stage of the consultation the nurse Colposcopist believes the patients' condition is beyond the scope of her expertise, she will refer her to the patient's consultant or the consultant on call in their absence.

Medical Emergency Plan

Fainting / Collapse

- Transfer to couch/trolley
- Perform first aid as per Trust First Aid Policy
- Ensure oxygen/suction available
- Take and record observations

- Allow to rest for ½ hour, if recovered, discharge home
- If continues to feel unwell, admit to the gynaecology ward for observation
- Document in the patient's notes.

Equipment

- Ensure clinic is fully stocked prior to each session
- All equipment should be checked prior to clinic to ensure it is in correct working order
- Regular servicing and maintenance checks are carried out and records kept according to Trust policy
- In all cases of equipment malfunction or failure, follow Trust Safety of Medical Devices Policy and Management of Safety incidents in Screening Programmes (2017).

Environment

- All areas cleaned as per Synergy Cleaning Contract
- Follow Trust Infection Control policy for cleaning spillages
- Sharps disposed of according to Trust Infection Control policy
- Equipment stored and maintained as per Trust Provision and Use of Work Equipment policy
- Electrical equipment checked as per Trust Provision and Use of Work Equipment policy
- Drugs stored as per Trust Medicines policy
- Linen stored and laundered as per Trust policy
- Used instruments sent to Synergy at the end of each clinic for sterilisation as per Trust Infection Control policy
- Implementation of Trust Fire policy.
- Risk assessments performed/ recorded as per Trust policy.

Audit

- Regular audit of performance will be undertaken by the nurse Colposcopist according to standards outlined in the National Health Service Cervical Screening Programme "Colposcopy and Programme Management" (2020) such as attendance for follow up, negative result after treatment
- Regular audit of own inadequate cervical screening rates will be undertaken by the sample taker to ensure it falls within the national acceptable range. 2-3% is advised but there is no definitive standard since implementation of liquid based cytology – under development nationally at present.
-

Service Outcomes that can be monitored

- The proportion of women with no dyskaryosis at 6 months after treatment should exceed 90%
- First follow up cytology performed 6 months after treatment should exceed 90%.
- The proportion of histological treatment failures within 12 months of treatment should not exceed 5%

Quality Outcomes

- Result communicated back to the patients within 4 weeks of her attendance (best practice 90%) or 8 weeks (minimum standard 100%)
- Results and management plans should be communicated to the referring practitioner within 4 weeks of her attendance (best practice 90%) or 8 weeks (minimum standard 100%)
- Patient satisfaction with the service
- Staff satisfaction.

C6. CLINIC NON-ATTENDANCE OF PATIENTS WITH SUSPECTED OR PREVIOUSLY TREATED CIN

C6a- Royal Derby Site

Purpose

This policy explains what action to take when a patient does not attend their Colposcopy (initial or follow up), appointment for discussion of results, or follow up smear appointment.

Aim and Scope

The purpose of this policy is to ensure that all women are given a second appointment if they fail to attend their first appointment.
This guidance is to ensure consistency throughout the Colposcopy service and minimise wasted clinic slots.
This guidance is to ensure that ultimately the patient understands that it is their responsibility to attend appointments.
This guidance is to ensure that endless appointments are not sent to a non current address or to patients who show no intention to attend thus avoiding unnecessary wastage of clinic slots.

Implementation

1st Stage

If a patient fails to attend for her a new or follow up appointment for Colposcopy, appointment for discussion of results or follow up cervical screening, a 2nd appointment is sent to the patient by the consultant's secretary with a standard letter (S12 if a colposcopy appointment, S14 if a cytology appointment) explaining that she has failed to attend. This directly reiterates the importance of attending with the offer of a final appointment.
A copy of this letter is sent to the GP.

The colposcopist must enter the non-attendance on the Colposcopy Database and document in the case notes.

The non-attendance rate per clinic should be less than 10% for new referrals and individuals returning for treatment and less than 15% for follow up appointments.

A 3 monthly audit of the records of non-attenders should be performed to discern any patterns that could be addressed to reduce the non-attendance rate.

2nd Stage

If the patient defaults a second consecutive appointment, the consultant's secretary should check the patient's address with the Finance and Patient Services Department.

If this address is verified, the consultant will review the case notes.

A letter will be sent to the GP/patient and either:

Ask the patient to see the GP for follow up cervical screening or,

Ask the GP to see the patient and counsel them to assess any indication of willingness to attend then request a further appointment or,

A further appointment will only be sent if the patient indicates a willingness to attend. Clinical responsibility will not continue if the patient fails to attend two consecutive appointments.

Enter the non-attendance on the Colposcopy Database and document in the case notes.

Women who default from follow up Colposcopy following untreated CIN1 (who are High risk HPV positive) should be referred again when they have their next cytology test if the latter is positive for HR HPV. If the subsequent test is negative for HR HPV they return to routine recall as per national guidance.

C6b Queens Hospital Burton and Sir Robert Peel Site

Default Policy

Defaulting from scheduled appointments is a frequent occurrence in the colposcopy clinics. The National Guidelines have also set targets for default rate and local socio-economic status is likely to be the major contributing factor.
Patients defaulting an appointment will be sent two further new appointments and patients receiving follow up appointments who default will be sent one further follow up appointment (standard letters enclosed - Example 2a).

The default rate should be less than 10% for new referrals and individuals returning for treatment and less the 15% for follow up appointments. Default will be audited through the KC65 returns and data sheets.
The procedures for managing default are detailed in the accompanying algorithm Figure 9. The basic management of these patients is summarised in the following table:

First default but patient contacted clinic to rearrange	Schedule a further appointment within 4 weeks
First default and patient did not contact clinic to rearrange	Default letter (1) together with further appointment letter
Second default but patient contacted clinic to rearrange	Schedule a further appointment inside 4 weeks
Second default and patient did not contact clinic to rearrange	Default letter (2)

Default letter (1) **EXAMPLE 1**

Dear Mrs …….

You did not attend the colposcopy clinic on . It is important that you attend this clinic and I have therefore arranged to see you on . An appointment letter is enclosed.

Dear Dr ……..

Further to your referral of this patient to my Colposcopy clinic I am writing to advise that she failed to attend. I have arranged another appointment for her on .

Default letter (2)

Dear Mrs …….

You did not attend the Colposcopy clinic again today. This can have serious consequences for your health and I would therefore be grateful if you would go to your own doctor to discuss this with him/her.

Dear Dr ……

You referred to the Colposcopy clinic on account of . She has not attended two appointments, nor have we heard from her. I would be grateful if you would investigate the situation and let me know and I will happily send out a further appointment. I have written to her asking her to attend you.

C7. LABELLING AND REMOVAL OF SPECIMENS FROM THE COLPOSCOPY ROOM

C7a: Royal Derby Hospital Site

Purpose

This policy explains the correct procedure for labelling and removing specimens from the Colposcopy room.

Aim and Scope

The purpose of this policy is to ensure that all women have their specimens correctly labelled and sent to the laboratory allowing the process to be traceable.
It aims to minimise the risk of mislabelling / loss of specimen and ensure consistent practice.

Implementation

The specimen pots/containers are to be labelled by the colposcopy nurse with the patient's details at the time of the colposcopy examination prior to the specimen being taken. The containers must be within expiry date (minimum 2 weeks within expiry date for cervical screening).

The Colposcopist must be shown the specimen pot/container with the patient's label on it by the colposcopy nurse, at the time of placing the specimen in the pot and both confirm the specimen details to be written on the pot,

The patient's name, address and date of birth should be verbally confirmed with the patient by the colposcopy nurse,

The pathology forms must be fully labelled at the same time and placed in a clear transport bag with the specimen (green transport bag if cervical screening),

The Colposcopist is responsible for writing clinical details regarding the specimen on the sample request form,

A record of all specimens must be entered in the colposcopy record log book in the colposcopy room which is kept locked when not in use,

The specimens must be placed in the transport bag in the Colposcopy room at the end of the colposcopy procedure,

At the end of the Colposcopy clinic two staff must check all specimen details and contents of the pot and sign the colposcopy record log book and take the transport bag to the pathology/cytology Department at the end of clinic.

An additional list containing all patients and the specimens sent must also be placed with the specimens in the transport bag so pathology staff can check on unpacking that all have been correctly received at the laboratory,

C7b Queens Hospital Burton and Sir Robert Peel Hospital Sites

Procedure for Management of Histology/Cytology/Microbiology Samples

The correct labelling of all Colposcopy specimens is essential in order to avoid the risk of incorrect processing, and indeed most importantly the hazard of incorrect diagnosis. All specimens should be collected and checked according to the unit policy.

All specimens leaving the department must be clearly labelled and packaged appropriately for transportation after each clinic session. The specimens must be taken to the Porters lodge and placed into the box for Burton courier collection (for specimens being sent before midday), for later samples, courier will collect from the designated room within the outpatient department

Cervical Cytology Samples

Liquid based cytology is now the sampling method as per NICE guidance. Burton Hospital uses Thin Prep LBC. The preservative vial must be within expiry date, labelled with the patient's name, hospital number and date of birth. The sampling brush must be pushed into the bottom of the vial 10 times and then swirled in the solution in the vial and ensure that the lid is secured tightly. The cytology specimen request form must be completed accurately, with all relevant details completed; the patient should verbally confirm their name address, DOB and GP. The form must also contain a Consultant's LBC number, indicate when two brushes have been taken, and complete relevant areas on the HMR101 form. The pot should be placed into the bag and sealed ready to go to the pathology lab.

Histology Specimens

The patient label should be placed onto the Formalin histology pot after the patient has verbally confirmed their address. The specimen/biopsy taken must be written onto the patient's label and ensure the pot is secured tightly. After the department checking procedure has been followed the pot and completed histology form must be placed into the plastic envelope and sealed securely, ready for sending to the laboratory

Microbiology samples

All swabs must be labelled with a patient sticker and the specimen site i.e. HVS or endocervical for chlamydia ELISA, must be clearly written onto the sticker. A microbiology request form giving all relevant details must be filled in. After following the department's checking procedure the swabs must be sealed securely into the plastic envelope.

The Colposcopy checking procedure is outlined below

2 members of the nursing team must check to ensure that the patients NAME, DOB and HOSPITAL NUMBER correspond exactly with the specimen and the cytology envelope, histology/microbiology form. This can either take place during the clinic session if time permits or at the end of each session.

C8. MANAGEMENT OF ABNORMAL CERVICAL SCREENING DURING PREGNANCY

Purpose
This policy explains local and national recommendations for management of abnormal cervical screening during pregnancy.

Aim and Scope
The purpose of this policy is to ensure that all women are managed appropriately if they have abnormal cervical screening during pregnancy according to national recommendations from the NHS Cervical Screening Colposcopy and Programme Management (2020)

Overview

Pregnant patients should undergo colposcopy based on the same criteria applied to non-pregnant patients. Colposcopy in the pregnant patient, especially with advancing pregnancy, may be more technically challenging in terms of access. Colposcopic evaluation of the pregnant cervix is also harder and these patients should be seen by a colposcopist with experience in assessing the pregnant cervix. Biopsies can be taken from the pregnant cervix but are likely to be associated with considerably more bleeding than is the case with non-pregnant patients. If high grade disease is identified colposcopically and on biopsy, the patient should undergo colposcopic surveillance during pregnancy approximately every 10-12 weeks till around 32-34 weeks and subsequently be seen at 6-8 weeks post natal for definitive treatment. Treatment should not be performed in pregnancy. Low grade lesions diagnosed in pregnancy do not require repeat colposcopic assessment in pregnancy and should be reviewed some 3 months postnatally.

Implementation

- Cervical screening during pregnancy on a woman with negative screening history should only be performed if beyond 3 years since the last test.

- If a woman has been called for routine screening and she is pregnant then the test should be deferred. If repeat cytology is due, and the woman has missed or defaulted her appointment prior to pregnancy, cytology or colposcopy during pregnancy can be considered

- If a previous test was abnormal, and in the interim the woman becomes pregnant, then the test should not be delayed and should be taken unless there is a clinical contraindication or the woman declines.

- A woman who meets the criteria for Colposcopy still needs Colposcopy if she is pregnant. The primary aim is to exclude invasive disease and defer treatment until after the woman has delivered. A diagnostic biopsy may be taken at the discretion of the colposcopist.

- If Colposcopy has been performed during pregnancy, postpartum assessment of women with an abnormal cytology or biopsy proven CIN is essential and a follow up appointment should be arranged at this point for 10-12 weeks postnatal based on the woman's estimated date of delivery.

- At Colposcopy, if CIN1 or less is suspected, the examination should be repeated 3 months following delivery a follow up appointment should be arranged at this point for 10-12 weeks postnatal based on the woman's estimated date of delivery.

- At Colposcopy, if CIN 2 or 3 is suspected, Colposcopy should be repeated at the end of the second trimester and 3 months following delivery for assessment and definitive treatment .A follow up appointment should be arranged at the time of the final colposcopy performed during pregnancy for 10-12 weeks postnatal based on the woman's estimated date of delivery .

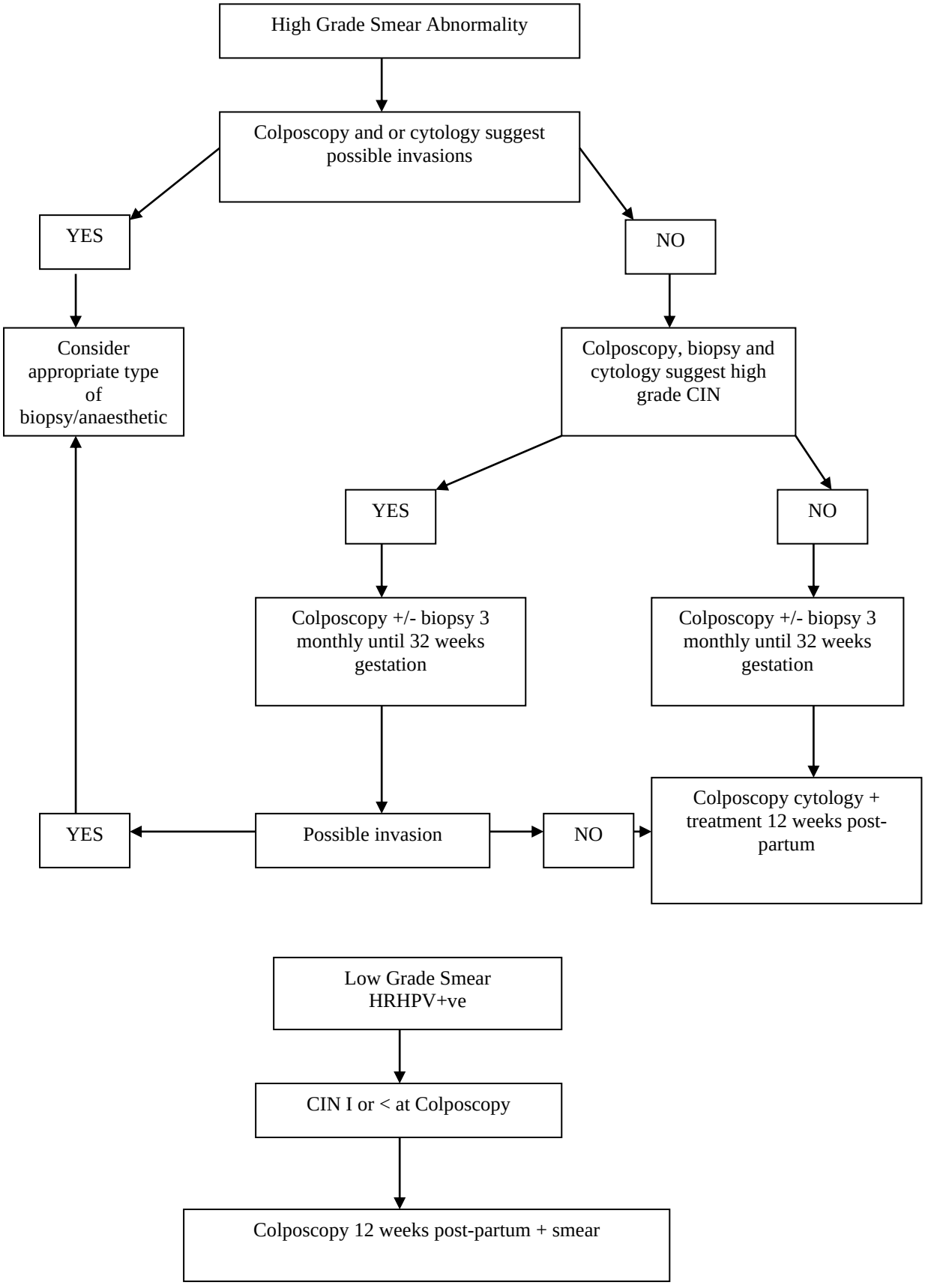
- If invasive disease is suspected clinically or colposcopically, a biopsy adequate to make the histological diagnosis is essential (cone, wedge or diathermy loop biopsy are all associated with a risk of haemorrhage).

- If a pregnant woman requires Colposcopy or cervical screening after treatment to the cervix, this should not be delayed if it is a first follow up cervical screening or Colposcopy following treatment for HGCGIN or CIN2/3. A cervex brush only should be used, no endocervical brush is needed.

- If a pregnant woman requires Colposcopy or cervical screening following treatment for CIN1 or follow up for untreated CIN1, her assessment may be delayed until 3 months post-partum a follow up appointment should be arranged at this point for 10-12 weeks postnatal based on the woman's estimated date of delivery.

- If a pregnant woman declines to have the Colposcopy or cervical screening, she should be given an appointment 3 months post partum and discussion documented in her casenotes.

Management of abnormal smears in pregnancy



C9. VAULT SAMPLING FOLLOW UP AFTER HYSTERECTOMY FOR NON MALIGNANT CONDITIONS

Purpose

This policy explains local and national recommendations for vault sampling follow up after hysterectomy for non-malignant conditions.

Aim and Scope

The purpose of this policy is to ensure that all women are given appropriate follow up after hysterectomy according to Colposcopy and Programme Management Document 20 and periodic updates.(2020)

Implementation

Women who have undergone a subtotal hysterectomy still have their cervix in situ so must remain within the National Screening Programme and be followed up as per guidelines in NHSCSP no. 20 Colposcopy and Programme Management (2020)

For women on routine recall and no CIN in the histology specimen at hysterectomy, no further vaginal vault sampling is required.

Women with completely excised CIN at hysterectomy require vaginal vault sampling at 6 months following surgery and recall can be ceased if they have a HR HPV negative result. Vault sampling needs to be done in the hospital setting.

Women with completely excised CIN at hysterectomy and are HPV positive with cytology negative at 6 months should be referred to colposcopy. If no evidence of VAIN at colposcopy the individual can be discharged.

For women with incomplete or uncertain excision of CIN primary HPV screening follow up should be conducted as if the cervix is still in situ (See Guidelines for Follow up After Treatment To The Cervix For Cervical Precancer).

For CIN1 this is vault sampling at 12 and 24 months and for CIN2 or 3 this is vault sampling at 6 and 12 months, followed by 9 annual vault samples. The vault sampling needs to be done in the hospital setting.

Follow up for incompletely excised CIN at hysterectomy continues to 65 years or until 10 years after surgery (whichever is later).

The responsibility for implementing and undertaking follow-up after a hysterectomy resides with the gynaecologist whose care the patient was under. If discharging to GP, the gynaecologist must ensure they receive specific written guidance as to future follow-up and if requires further vault sampling these need to be arranged to be done in secondary care.

The clinician in charge (Gynaecologist pre discharge, GP post discharge), will be responsible for fail safe mechanisms for these women.

Women who undergo radical trachelectomy as part of conservative management of cervical cancer should remain under the care and guidance of the treating gynaecological oncologist. Follow up is recommended with colposcopy and HR HPV testing. Future follow up will be determined by the treating gynaecological oncologist and the woman will no longer be deemed to be within the National Screening Programme.

C10: GUIDELINES FOR MANAGEMENT OF CONFIRMED OR SUSPECTED CERVICAL INTRAEPITHELIAL NEOPLASIA AND CERVICAL GLANDULAR INTRAEPITHELIAL NEOPLASIA, SMILE LESIONS and SUSPECTED CERVICAL CANCER.

Ref.No: GD/2015/colpXX

Purpose

These guidelines are a form of guidance and not intended to be rules for practice and are based on the NHS Cervical Screening Programme NHS CSP Publication No 20 March 2016 and February 2020 PHE update along with the NHSCSP Good Practice Guide. This policy explains local and national recommendations for treatment for cervical precancer including special circumstance such a pregnancy, immunosuppressed individuals and in the presence of IUCDs or IUSs.

Aim and Scope

The purpose of this policy is to ensure that all women are given appropriate treatment to the cervix for cervical precancer according to national recommendations from the NHS Cervical Screening Programme.
Please see Appendix attached with guidance illustrated with a flow chart current national guidance following HPV primary screening implementation

Definitions Used

- **Colposcopy:** An examination of the cervix under magnification with a colposcope.
- **Cytology:** The preparation of stained Liquid Based Cytology smears and microscopic examination of cells.
- **Cervical Intraepithelial Neoplasia (CIN):** Precancerous changes on the cervix
- **Cervical Glandular Intraepithelial Neoplasia (CGIN);** Abnormality in the glandular cells of the cervix.
- **Histology:** The preparation and microscopic examination of tissue.
- **HPV Primary screening:** a screening test to detect the presence of HR HPV and if detected a cytology triage test will be performed
- **HR-HPV:** High risk type of Human Papilloma Virus – a common infection usually cleared by the immune system but in 20-30% women that don't clear the HPV infection, there is a higher risk of developing cervical pre-cancer and cervical cancer.

Implementing the policy

These guidelines for the Management of CIN and CGIN need to be considered in conjunction with NHSCSP Colposcopy Programme Management Document 20 (and its periodical updates) and provides guidance for management together with Cervical Screening: Implementation Guide for Primary HPV Screening (2019).

Principles

The clinical setting of each individual patient needs to be considered in determining the most appropriate management for each patient and this is the overriding principle that should be paramount in determining the most appropriate individualized management.

The following should be recorded at the colposcopy examination:

- Reason for referral
- Grade of cytological abnormality and HPV result
- The presence or absence of a cervix,
- Whether examination is adequate (the entire scj must be seen)
- The presence or absence of vaginal and/or endocervical extension
- Colposcopic features should be recorded of any lesion
- The colposcopic impression of the lesion grade
- The type of transformation zone (type 1,2 or 3)
- The site of any colposcopic directed biopsies.

An excisional form of biopsy is recommended (>95%) in cases where:

- When most of the cervix is replaced with high grade abnormality
- When low grade colposcopic change is associated with high grade (severe) dyskaryosis or worse
- When a lesion extends into the endocervical canal, sufficient cervical tissue should be excised to remove the entire endocervical lesion
- Where cytology is suggestive of invasive disease or ?glandular neoplasia

Punch biopsies may not always be considered to be reliably informative. Reasons for not performing a biopsy (e.g. pregnancy) must be recorded.

As a minimum a colposcopically directed punch biopsy should be carried out unless an excisional treatment is planned when the cytology indicates a high grade abnormality (pregnancy is an exception). Of all the biopsies taken, directed and excisional, more than 90% should be suitable for histological interpretation and the colposcopists should analyse the results of cytology, colposcopy and biopsy before selecting a destructive method of treatment. If the directed biopsy is reported as inadequate for histological interpretation it should be repeated if there is a residual colposcopic lesion.

Patients will have been sent some written information on their original invitation to the clinic and may have been counselled by their own general practitioner or practice nurse prior to or at the time referral is made. On arrival the patient should be given further verbal information at the time her history is taken and given the opportunity to discuss her feelings and anxieties. It is important that this phase of counselling is very positive and supportive. She should be advised of what may be found and what may be necessary.

It is not necessary, in the conscious patient, to obtain written consent for colposcopy or indeed for outpatient treatment. This clinic however feels that verbal consent for treatment under local analgesia should be obtained and documented on database as part of good practice or a consent form completed.

After any procedure, an explanation of what was found, what was 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). In all cases the woman should be given a contact name and number where she can get additional advice once she has left the clinic.

The main modality of treatment of CIN in the Colposcopy clinic at UHDB (Royal Derby Hospital, Queens Hospital Burton, Sir Robert Peel- Tamworth, Ilkeston Community Hospital and Buxton Hospital) is Large Loop Excision of Transformation Zone (LLETZ) under LA. The size and depth are determined by the size of the lesion to be treated, and the type of squamo columnar junction and the recommended depth to be aimed for is at least 7mm. The required depth is likely to be greater where the SCJ is type 2 or type 3 or where the lesion visibly extends up the cervical canal or treatment is undertaken for glandular abnormalities. A loop removed as single specimen is preferable; however, this should not be at the expense of safety or more complete excision which in some circumstance may be better achievable with an additional trimming bite or a LLETZ in two halves, aiming to preserve the external os intact.

Destructive treatment such as cryocautery (freeze/thaw/freeze cycle) or ball diathermy under LA are only suitable for confirmed low grade lesions or treatment of symptoms of PCB/excessive discharge and only after a representative biopsy (preferably biopsies) must have been taken from the area before destructive treatment is performed unless biopsies have already been performed and the patient has returned for planned treatment. Patients should not have destructive treatment without prior biopsy if referred with a smear abnormality or as treatment for presumed CIN.

Management of Inadequate cytology of HPV Unavailable referrals

Following 2 consecutive tests with either HPV unavailable or Inadequate cytology patients should be referred to colposcopy. If colposcopy is normal and adequate follow up should be repeat screening in the community at 12 months and if they are then HPV negative should be returned to routine recall. Where colposcopy is inadequate then a repeat colposcopy and HPV testing should be performed at 12 months and if HPV negative then discharged to routine recall.

Management of Borderline Changes in Endocervical Cells

BNA in endocervical cells need to be seen in colposcopy within 2 weeks in 93% of cases. Even where colposcopic examination is negative such patients MUST NOT be discharged to 3 years but should be followed up in colposcopy at six months. All cases of BNA in endocervical cells should be discussed at colposcopy MDT and only where the original referral smear is downgraded to negative should they be discharged to three year recall after a negative colposcopy.

Management of High Grade CIN

For patients referred with high grade cytological abnormalities, a ‘select and treat’ approach is recommended thus avoiding unnecessary delay in treatment (thus minimizing anxiety) and repeat visits (travel/parking cost, clinic capacity issues, inconvenience with time off work and childcare for appointments, delay in time to treatment from

time of referral). In making a decision to treat it is important to consider the following points (but this is not an exhaustive list)

- LMP/Contraception/Exclusion of Pregnancy
- Any plans for travel abroad in the following 2-3 weeks and if so what impact treatment may have ie inability to use Tampons for 4-6 weeks, implications for on holidays/swimming etc, medical care availability should complications such as infection arise while abroad.
- Suitability of lesion- size of lesion in conjunction with ease of access and confidence/experience of treating colposcopist.
- Patient wishes and tolerance of colposcopy procedure
- Evidence of current vaginal infection
- Relevant co existing medical conditions/treatment e.g. warfarin.

The proportion of individuals treated at their first visit who have evidence of CIN2, CIN 3 or CGIN on histology must be over 90%.

Depth of Excision - The goal of excision is to remove all the abnormal epithelium and this is dependent on the type of transformation zone whilst minimizing impact on future cervical function. Therefore for Type 1 transformation zone with ectocervical lesions, excision should aim to remove >7mm but less than. 10mm depth in reproductive age patients. For type 2 transformation zone, the aim should be to remove tissue to a depth of 10-15mm depending on the position of squamocolumnar junction within the endocervical canal whilst in Type 3 Transformation zone, the aim should be to remove tissue to a depth of 15 to 25 mm depending again on the position of the squamocolumnar junction within the endocervical canal.

Individuals who have a diagnosis of high grade CIN must receive treatment promptly. The proportion offered definitive treatment for high grade CIN within 4 weeks of the colposcopy clinic receiving a diagnostic biopsy report should be >90%. This should be monitored and recorded. All individuals having definitive treatment for high grade CIN must be treated within 8 weeks with the exception of those who are pregnant.

Women treated for CIN will require a follow up hrHPV test 6 months post treatment, mostly in primary care. Early attendance should be discouraged and samples taken less than 3 months post treatment should not be tested. Women testing negative for hrHPV will be recalled for screening in 36 months when they will restart the screening protocol for primary hrHPV testing. Women who test positive will have cytology performed but will all be referred back to colposcopy regardless of the cytology result. (See appendix 2)

High grade CIN extending to the margins does not justify repeat excision if there is no evidence of glandular abnormality, no evidence of invasive disease or if the individual is under 50.

If over 50, the presence of CIN3 at the deep radial and endocervical margins requires repeat excision to try to obtain clear margins if subsequent satisfactory screening and colposcopy cannot be guaranteed

In selected cases of CIN2 it may be justified to adopt a conservative approach especially in younger women with predominantly low grade abnormalities and focal areas of high grade change or women with small areas of high grade change who have a shortened cervix from previous treatment(s) but who are still desirous of pregnancy. Care should be individualized in such patients and the colposcopist needs to be confident that invasive disease has been excluded and the patient will comply with what may be a prolonged period of follow up. There must be close colposcopic follow up and if any screening samples are taken during this time they will be hrHPV tested with cytology performed if hrHPV positive. Such cases should be discussed at the colposcopy MDT to rule out CIN3. If during follow up CIN3 disease develops or CIN2 is persistent for 24 months or more, treatment should be recommended.

Management of Patients referred with Glandular abnormalities on smear

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

i) In cases in which the abnormal glandular cells probably originated from the endocervix, or the source is not specified, the woman must be referred for colposcopy. If a woman is not referred directly, the GP must make an urgent referral for colposcopy and 93% of such patients should be seen within two weeks.

ii) In cases in which the source of the abnormal glandular cells is likely to be the endometrium or another gynaecological site, the woman should be referred through the 2 week wait (2WW pathways at RDH or the UCR- Urgent Cancer Referral clinic pathway at QHB). These patients will also require a colposcopy if they came through the primary HPV screening as this needs to have been positive for HR HPV in the first instance if a cytology slide was made.

Occasionally cervical screening test reports include a reference to atypical or dysplastic glandular cells. These may have originated in the endocervical canal or the endometrium or may represent Lower Uterine Segment sampling (very rarely even higher in the genital tract e.g. ovary/fallopian tube). There is some recent evidence that such smears are associated with a high incidence of genital tract pathology, particularly in older women. For this reason, not only the cervix but the uterus must be assessed in any woman over the age of 40 yrs who has dysplastic glandular cells in her smear by means of a transvaginal scan and endometrial sampling. In women below the age of 40 years where there are no accompanying features that suggest endometrial pathology with normal endometrial cells on smear do not need further investigations. Features that may increase the risks of endometrial pathology that should be considered in stratifying risk and directing further management include

- History of unopposed oestrogen exposure
- Known polycystic ovarian syndrome and prolonged amenorrhoea
- Obesity
- Menstrual irregularity and intermenstrual and postcoital bleeding
- Post-menopausal bleeding

At colposcopy, the patients should undergo the same assessment as patients with suspected High grade dyskaryosis. For women with suspected CGIN or early invasive adenocarcinoma, the extent of the cervical excision must 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 or alternatively a knife cone biopsy may be an option. The most appropriate mode of excision needs to be determined by the colposcopist after consideration of both the colposcopic findings and patient characteristics. In selected patients (age over 40, irregular bleeding, high BMI, DUB) there may be a role foe selective endometrial sampling (pipelle biopsy)

In cases where excision of CGIN is incomplete a repeat excision is required. If repeat excision is not feasible or declined then follow up with primary HR HPV screening should be undertaken at 6 and 12 months in the colposcopy clinic and then annually for 9 years. In a small minority of patients, a hysterectomy may be considered where local excision is not feasible or additional clinical/patient related factors make this a more appropriate option.
All CGIN cases should be discussed at the colposcopy MDT.

Management of Patients with SMILE lesions on histology

Stratified Mucinous Intraepithelial Lesion (SMILE) show a similar spectrum of nuclear morphology to CGIN but in this variant, mucin production is preserved with vacuoles distributed throughout the whole height of the dysplastic epithelium. In most instances, SMILE is associated with HG CIN or HG-CGIN. If seen on biopsy, this should be an indication for further sampling of the cervix in the form of LLETZ or Knife Cone biopsy. If SMILE is identified in an excisional biopsy then it is important that complete excision has been achieved (similar to HG CGIN) and the case should be reviewed at colposcopy MDT. Follow up of SMILE lesions needs to be along the same pathway as HG CGIN.

Management of local excision of microinvasive squamous cancer FIGO stage 1A1

Microinvasive squamous cancer 1A1 can be managed by local excisional techniques if:

- The deep and lateral excision margins are free of both CIN and invasive disease (re excision is not required when only the ectocervical margin is involved by CIN)
- The Gynae cancer centre pathologist and MDT have reviewed the histology

If the invasive lesion is excised but CIN extends to the deep and lateral excision margin then a repeat excision should be performed to confirm complete excision of the CIN and exclude further invasive disease.

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 there is no clear evidence that ablative or excisional treatment measuring less than 10mm in depth is associated with any increase in the incidence of preterm labour and preterm prelabour rupture of membranes.
- Ablative or excisional treatment is not associated with any increased risk of infertility but may increase in the risk of mid trimester miscarriage
- Treatment has to be tailored to the individual circumstances and may require more than 10mm in depth.

FU for CGIN and SMILE lesions

Women adequately treated for CGIN or SMILE with complete excision margins are followed up with screening at 6 and 18 months post treatment, All samples will initially be tested for hrHPV and those women testing negative will be recalled for a second test in a further 12 months. Cytology is not required in hrHPV negative women to confirm the presence of endocervical cells.

Women testing hrHPV positive at the first follow up test will have cytology performed and all will be referred to colposcopy. The cytology samples from these hrHPV positive women must contain endocervical cells to be considered adequate for cytology (unless they contain abnormal cells).

Women who have negative cytology and normal colposcopic appearance will be recalled for the second follow up test in a further 12 months.

At the second follow up test women testing hrHPV negative will be recalled for further testing in 36 months when they will restart the screening protocol for hrHPV primary testing. Women testing hrHPV positive at the second follow up test will have cytology performed and all will be referred to colposcopy. Women who have negative cytology and normal colposcopic appearance will continue to be called at 12 monthly intervals for hrHPV testing and managed according to protocol for CGIN/SMILE follow up.

Women with abnormal cytology at either of the first 2 follow up tests will be re-referred to colposcopy. In those women where colposcopy is found to be normal or re-excision does not occur, 10 years follow up should be completed with annual hrHPV testing.

All women re-referred to colposcopy due to a hrHPV positive result will be eligible to enter the CGIN post treatment follow up pathway again if they have further re-excision with complete excision margins.

Management of Patients referred with low grade abnormal cytology,

In the main these patients, should undergo a diagnostic colposcopy and biopsy as appropriate. If however there is an unequivocal area of high grade disease a ‘select and treat’ approach may be appropriate. Treatment may also be appropriate where there is a distinct low grade lesion in older patients who may prefer treatment to longer term follow up or where there are concerns regarding patient compliance to future follow up. These judgements need to be made by the individual colposcopist in conjunction with other clinical features and after discussion of the options with the patient and what her informed preference may be..

Management of Untreated CIN 1

The management recommendation for women who have a colposcopic appearance consistent with CIN1 or CIN1 confirmed on biopsy is recall for screening in 12 months with hrHPV testing in primary care. At the clinicians discretion this may be performed in the hospital based nurse led cytology clinic (NOT the colposcopy clinic). Women testing hrHPV negative at this repeat test will be recalled in 36 months at which point they will restart the screening protocol for primary HPV testing.

Women testing hrHPV positive at the 12 months repeat test will have cytology performed on their sample and if this is abnormal (any grade) they will be referred to colposcopy again. Women with negative cytology will be recalled for screening again in a further 12 months' time.

At the second repeat test of the women who were followed up for CIN 1 and had HPV +ve negative cytology at first follow up and are hrHPV negative can be recalled in 36 months. Those who are hrHPV positive will have cytology performed. Those testing negative for cytology will also be recalled at 36 months when they will restart the screening protocol for primary HPV testing. Women with abnormal cytology will be referred to colposcopy.

At the discretion of the colposcopist/ consultant or following discussion at MDT it may be warranted that a small number of patients with untreated CIN1 need a follow up colposcopy and HPV test rather than just a HPV test ie where there remains discrepancy between cytological, histological and colposcopic findings or where histology was deemed upgradeable but favoured low grade. **See Appendix 1 for PHE – HPV primary screening colposcopy management recommendations algorithm.**

Follow–up of untreated high grade referrals

Individuals referred with HG dyskaryosis with an adequate colposcopy and normal or low grade findings on colposcopy should be discussed at MDT. If no treatment is carried out close surveillance with colposcopy and cervical samples every six months is advised and if at follow up there is persistent high grade cytology or CIN2/3 is present on biopsy, excisional treatment is recommended in 90% of cases.

Individuals referred with HG dyskaryosis on their test who have an adequate colposcopy and a colposcopically low grade lesion and who are not being treated should have multiple biopsies taken. If CIN1 or less is confirmed colposcopic and HPV screening should be performed at 6 months and only if these are negative should revert to 3 year recall.

Summary of Key Standards in relation to Treatment of CIN/CGIN (For more details see Colposcopic diagnosis, treatment and follow up www.gov.uk)

- All women must have had their histological diagnosis established prior to destructive therapy for CIN.
- The proportion of women treated at first visit that have evidence of CIN on histology must be greater than 90%
- Proportion of patients requiring additional haemostatic methods at the time of treatment must be less than 5%
- The proportion of patients admitted as inpatients due to treatment complications should be less than 2%
- All women having definitive treatment for high grade CIN should have been treated within 8 weeks (100%) pregnant women are exception.
- At least 80% of cases should have the specimen removed in a single sample.
- Histology report should record the dimensions of the specimen plus status of resection margins
- Ectocervical lesions should endeavour to remove tissue to a depth of greater than 7 mms (95%)
- See and Treat Policy
    - Treatment at first visit for a low grade smear should only exceptionally be used and supported by audit showing CIN II/III or CGIN present in more than 90% of excised specimens.
    - See and treat is recommended for high grade abnormalities and patients who are considered likely to default follow up (see Fig 1 p. 9).

Repeat Excision - should be reserved for incomplete excision with further abnormal cytology, glandular abnormalities or microinvasive disease with incomplete excision of CIN.

Follow up

The named Consultant responsible for the patient will write to the patient once the histology report is available, detailing the findings and recommended follow up. The letter will also be copied to the patient's GP. In addition, on a monthly basis a spreadsheet is submitted to cytology recall informing them of the outcome of all patients seen in colposcopy and where (community or hospital based clinic) and when the next screening test will be required.

In certain circumstances (ie complex patients or where a diagnosis of invasive disease is suspected) a follow up appointment to clinic may be made at the time of the original colposcopy/treatment.
See colposcopy guideline C6

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C11 GUIDANCE REGARDING COLPOSCOPY IN SUSPECTED CERVICAL CANCER, IMMUNOCOMPROMISED PATIENTS AND POSTMENOPAUSAL PATIENTS. GUIDANCE IN RELATION TO MISCELLANEOUS COLPOSCOPY RELATED ISSUES (Use of antibiotics, Treatment with IUCD/IUS in situ, Concurrent gynaecological/medical issues, Management of VAIN/VIN, Cervical stenosis, Infections in Colposcopy).

Suspected Cervical Cancer

Where cervical cancer is suspected at colposcopic assessment (ie frankly invasive disease) an appropriate biopsy should be taken and sent for urgent histology. It would be inappropriate to attempt a LLETZ with the view of removing the entire lesion. The biopsy should be labelled for attention of one of the specialist Gynae pathologist such as Dr Van Schalkwyk or Dr Hawari. It may in some circumstance be necessary to use a small loop to take an adequate biopsy and stop subsequent bleeding. The patient should then be brought back to clinic in 2 weeks to allow for histological assessment and oncology MDT review.

Women being followed up following treatment of early cervical cancer (Stage 1A1) and who still save a cervix will be followed up with hrHPV testing at 6 and 12 months and then annual follow up for a further 9 years. Any hrHPV positive result must be re-referred to colposcopy regardless of the cytology result.

Postmenopausal Patients

Referral criteria for postmenopausal women are the same as for premenopausal women. Colposcopy however may be more challenging as a higher proportion may be associated with an incomplete colposcopy due to postmenopausal atrophy which also may contribute to additional discomfort being associated with the procedure. The main challenges can be attributed to low oestrogen levels leading to

1. Atrophic vaginitis: May impair adequate visualisation of cervix
2. Atrophic cervicitis: Distorts the recognition of epithelial patterns, renders Schaller's test inaccurate, results in poor cytology, contact bleeding and epithelial stripping
3. Cervical inversion: The squamocolumnar junction (SCJ) becomes endocervical and not accessible for direct visiualization or biopsy

In selected cases there may be justification for a brief (2-3 months) treatment with topical oestrogens and repeating the colposcopy thereafter. Where there is a high grade abnormality in the presence of an incomplete colposcopy with nothing on the cervix or vaginal walls to account for the cytological abnormality, the case should be reviewed at MDT and if the cytological abnormality confirmed, consideration given to a diagnostic LLETZ. For low grade abnormalities and incomplete colposcopy the options between a diagnostic LLETZ or conservative follow up with colposcopy and cytology after a course of vaginal oestrogens.

Immunocompromised patients

Women on immunosuppressing medication including cytotoxic treatment for Rheumatoid Arthritis and rheumatological disorders, cytotoxic chemotherapy or oestrogen antagonists should have regular cervical screening according to the national guidelines and there is no indication for increased surveillance.

Women who are HIV positive should have annual cervical screening with initial colposcopy assessment if resources permit. . Despite higher cervical treatment failure rate, high grade CIN should be treated in accordance with national guidelines. Lesions less than CIN2 should generally be managed conservatively as they are likely to represent HR HPV infection of the cervix which responds poorly to treatment and may clear spontaneously especially with enhanced immunocompetence following antiretroviral treatment and rising CD4 counts. Screening can cease at age 65 if standard cessation criteria as per national guidance are met.

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.

The principle of treatment for immunocompromised patients is based on the same criteria for immune competent patients but it is important to bear in mind that persistent low grade change on the cervix and/or vagina may have to be tolerated in immunocompromised patients who may be less efficient at clearing the HPV.

DES exposure

Daughters of individuals exposed to DES are at increased risk only of clear cell cancer of the cervix and the vagina but not other forms of cervical cancer therefore routine call and recall is appropriate.

For individuals who are daughters of DES exposed patients **who have stigmata of DES exposure** follow up should be by annual colposcopy and may be appropriate to follow up with cytology even if the individuals are HR HPV positive (local service agreements required).

Granddaughters of those exposed to DES are not at any increased risk of cervical or vaginal cancer.

Miscellaneous Queries

Use of Antibiotics

Antibiotics are not routinely prescribed post treatment. These should however be considered where there are good clinical reasons to use them. Patients with risk factors for infections such as previous pelvic infections/STI, immunocompromised patients, patients requiring antibiotic prophylaxis for dental treatment may represent groups where it is worth considering whether post treatment prophylactic antibiotics may be of value.

Treatment of patients with IUCD or IUS in situ

In general it is possible to adequately and safely treat patients by LLETZ who have an IUCD or IUS in situ. After the diagnostic colposcopy is completed and local anaesthetic has been infiltrated to the cervix prior to treatment, the IUCD/IUS threads should be pushed up high into the cervical canal prior to the LLETZ being performed and subsequently retrieved after the treatment has been completed using a plastic thread retriever if required. Patients must be warned that the IUCD/IUS threads may be cut and the latter being the case the IUCD should be replaced. If the IUCD or IUS is imminently due a change it is not unreasonable to remove the IUCD/IUS and then replace it once treatment is complete. If the IUCD/IUS is removed at the patient's request, they should be alerted to the need of alternative contraception having ensured and also that they are not mid cycle or have had sexual intercourse in the last 7 days.

Concurrent Gynaecological problems

In the majority of patients attending colposcopy following abnormal cytology, concurrent gynaecological problems should be directed to primary care so that primary care practitioners can undertake initial assessments/investigations and to determine whether referral is appropriate. In some circumstances it may be appropriate to carry out minor investigations or procedures such as an endometrial pipelle or organise a transvaginal scan where the patient has been referred with intermenstrual or postcoital bleeding. In addition at the discretion of the colposcopist, if IUCD or IUS threads are not visible and the patient has an IUCD /IUS in situ it may be appropriate to organise a transvaginal ultrasound. Similarly if a patient requests removal of an IUS or IUD it may be reasonable to do so. Other gynaecological issues such as menstrual problems, pain, pelvic floor related issues, endocrine or subfertility issues should prompt advice to the patient to see their own GP for further investigation and onward referral as appropriate.

Concurrent Medical Problems

If other medical problems are identified whilst patients are being assessed in the colposcopy clinic these should be referred back to their general practitioner for appropriate referral or management. In some situations the concurrent medical problem may have a bearing on their gynaecological management or be of such severity as to

warrant a hospital appointment and the woman's general practitioner contacted as soon as possible. A typical example of the later categories would be referral to anaesthetic preoperative assessment clinic for patients with medical problems that require colposcopic treatment under anaesthesia.

Cervical Stenosis

It may not be possible to obtain a cytology sample that represents the entire transformation zone from women who have severe cervical stenosis (often as a result of previous surgery). Cervical dilatation should be considered in all such cases, but for women with a history of high grade dyskaryosis or cervical glandular intraepithelial neoplasia (CGIN), hysterectomy can also be considered. Involvement of the colposcopy multi-disciplinary team may be useful when making this decision. Where neither is appropriate the responsible consultant should consult with the women and a joint decision may be reached to withdraw her from the NHSCSP. If she declines, she should continue to receive invitations to screening and re-evaluated at each subsequent episode.

VAIN/VIN

Management and follow up of VAIN and VIN will depend on the extent, treatment history, clinical factors specific to a given patient and should be individually determined by the consultant responsible for the patient's care.

INFECTIONS AND COLPOSCOPY

Routine chlamydia screening is not indicated, however in the case of postcoital bleeding, vaginal discharge or dyspareunia high vaginal and endocervical sampling after gaining verbal consent should be undertaken. It should be explained to the patient that the GUM department may initiate patient contact directly following the result of the infection screen and best practice is to record this in the case notes.

Actinomyces-like organisms – this is usually seen in women using the IUCD and if identified on a smear performed in the colposcopy clinic or nurse led smear clinic (RDH only) then a recommendation should be made for a an IUS or IUCD review in primary care to ensure that the patient is not symptomatic of pelvic infection. The IUCD need not be removed, and antibiotics are not required. The patient should be warned of small possibility of developing pelvic actinomycosis. If the patient wants the IUCD to be removed it does not need to be sent for C&S and either the IUCD can be replaced immediately or an interval replacement arranged. If the IUCD/IUS is removed the patient needs to be alerted to use contraception.

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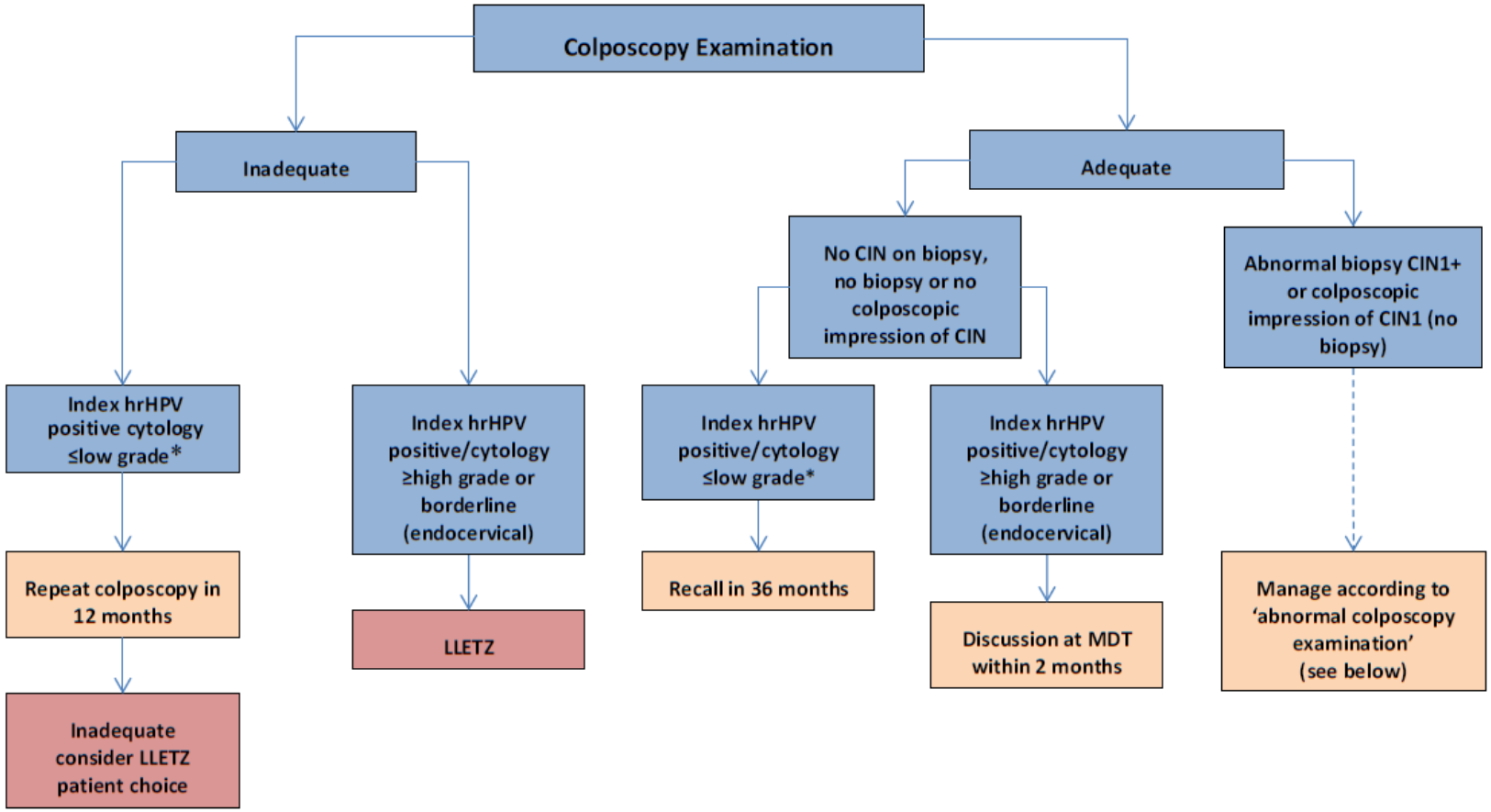
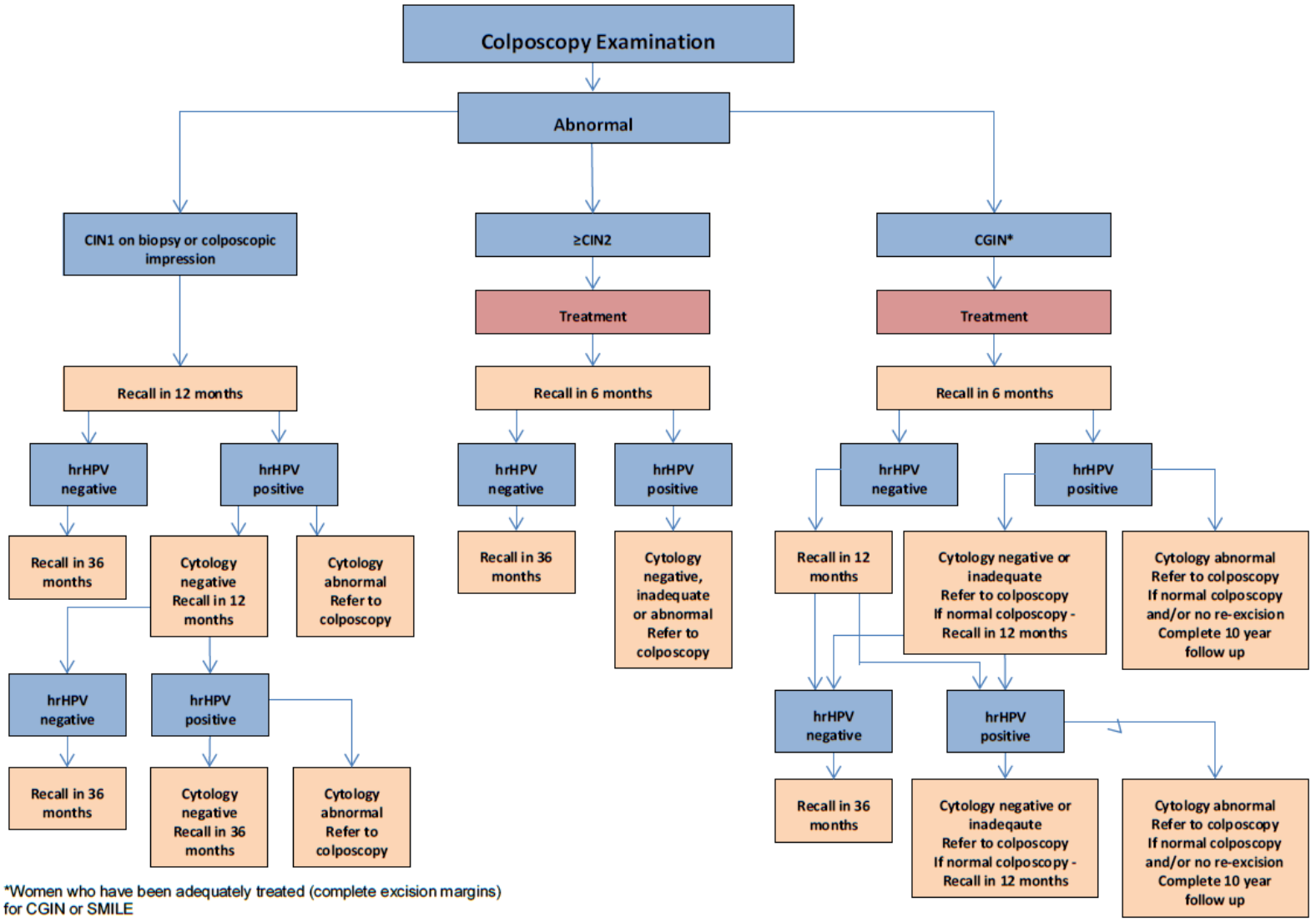
Appendix 2: cervical screening colposcopy management recommendations



*excludes borderline change in endocervical cells

Implementation guide: primary HPV screening



*Women who have been adequately treated (complete excision margins) for CGIN or SMILE

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Version / Amendment	Version	Date	Author	Reason
	1	2008	Onnig Tamizian, Colposcopist Gaynor Lowe, Specialist nurse Colposcopist	
	2	Nov 2012	Onnig Tamizian, Colposcopist Gaynor Lowe, Specialist nurse Colposcopist	3 Year update and merge of guidelines
	3	2015	Onnig Tamizian, Colposcopist Gaynor Lowe, Specialist nurse Colposcopist	3 Year update and merge of guidelines
	4	Mar 2017	Onnig Tamizian, Colposcopist Gaynor Lowe, Specialist nurse Colposcopist	Update with QA recommendations
	5	July 2018	Onnig Tamizian, Colposcopist Gaynor Lowe, Specialist Nurse Colposcopist	Incorporating move to HPV primary screening
	6	May 2019	Onnig Tamizian, Colposcopist Gaynor Lowe, Specialist Nurse Colposcopist	Following QA visit
	7	Dec 2019	Onnig Tamizian, Colposcopist Gaynor Lowe, Specialist Nurse Colposcopist	Formation of UHDB Trust
	8	April 2020	Onnig Tamizian, Colposcopist Gaynor Lowe, Specialist Nurse Colposcopist	Incorporating updated version of "Colposcopy and Programme Management" guidelines Feb 2020
	9	August 2022	Onnig Tamizian, Colposcopist Gaynor Lowe, Specialist Nurse Colposcopist	Review of guidelines
Intended Recipients: All staff with responsibility for caring for Colposcopy patients				
Training and Dissemination: Cascaded through lead sisters/doctors, Published on Intranet, Email circulation list,				
To be read in conjunction with: Supporting Patient information				
Consultation with:				
Business Unit sign off:	12/09/2022: Gynaecology Guidelines Group: Miss B Purwar – Chair (Virtual sign off) 27/09/2022: Gynaecology Development & Governance Committee: Mr J Dasgupta			
Divisional sign off:	27/09/2022			
Implementation date:	04/10/2022			
Review date:	September 2025			
Key Contact:	Cindy Meijer			