

# UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST GYNAECOLOGY

Colposcopy UHL Gynaecology Guideline

Author: V Shesha and R Bowden Contact: L Matthews, Clinical Risk and Quality Standards Midwife Approved by: Gynaecology Governance Group Guideline Register No: C205/2016 NB: Paper copies of this document may not be most recent version. Page 1 of 55

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## COLPOSCOPY UHL GYNAECOLOGY GUIDELINE

Author: Miss V. Shesha (Consultant Gynaecologist & Colposcopy Lead Clinician) Rachelle Bowden (Gynaecology Matron)

**April 2019** 

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#### INTRODUCTION TO THE COLPOSCOPY SERVICE AT UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST

#### Geographical site of service and opening times

The Colposcopy Clinics are situated within 2 hospitals – the Leicester Royal Infirmary (LRI) and the Leicester General Hospital (LGH) in the Gynaecology out-patient departments. Future service developments include the Colposcopy service being wholly situated at LGH, Spring 2020.

#### **Opening Hours**

The Gynaecology clinics are open from Monday to Friday 8.30 to 5.30 pm.

#### **Contact Details:**

Colposcopy Service C/O Gynaecology Administration Level 1, RMO Building Women's Clinical Management Group Leicester University Hospitals NHS Trust, Infirmary Square Leicester Royal Infirmary LE1 5WW

Telephone: 0116 2585068

#### Service provision

Procedures performed in the Colposcopy Clinic include

- Smear taking
- Diagnostic Colposcopy
- LLETZ (large loop excision of the transformation zone)
- Diathermy to cervix
- Polypectomy
- Endometrial pipelle biopsy
- Vulval/vaginal biopsy

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#### **COLPOSCOPY SERVICE PERSONNEL**

The colposcopy team consists of medical and nursing staff performing colposcopy, health care assistants (HCA's) and administrative/secretarial staff, as follows:

Position	Name
Lead Colposcopist	Miss V Shesha
Hospital Based Programme Co-ordinator	Mrs S Vryenhoef
Consultant Colposcopists	Mr Q Davies
	Miss E Moss
	Mr S Chattopadhyay
	Mrs R Aravindan
	Mr A Banerjee
	Mr R Bharathan
Gynaecology Matron	Rachelle Bowden
Lead Nurse Colposcopy & Hysteroscopy	Hannah Ball
Colposcopy Clinical Nurse Specialists	Rachel Ellis
	Sara-Jane Mason-Birks
Colposcopy Staff Grade Doctors	Ilze Silina
	Obehioye Enabor (Trainee)
Health Care Assistants	Shireen Ali
	Louise Basten
	Vanessa Brown
	Margaret Cayless
	Tara Harris
	Sharon Smith
	Curinne Mcgonagle
	Amina Mulla
	Rachel Cousins
	Joanne Hector
	Nichola Owens
	Jane Everett
	Shahina Shaikh
	Rachel Wilson
Clinic Coordinators	Julie Spadaccini Julette Frost
	Fatima Murujani Julia Francis
	Rubina Ikram
	Narinder Singh
	Lucy Underwood
	Debbie Rawlinson
	Shirley Jackson
	Nicola Warner
	Khusnuma Safi
	Joanne Ellis
	Anna Chodnicka

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	Wendy Mcglinchey Harvinder Bhandal
Medical Secretaries	Mandy Priestley Rebecca Edmonds Daxa Mistry Cillian Waldan
Data & Audit Coordinators	Gillian Walden Sheena Purohit Elan Samatra

#### **CLINIC ACCOMMODATION**

#### • Reception area

The Colposcopy clinic is accessed from Welford Road (LRI) and Colman Road (LGH) and patients and visitors report to the Reception desk on arrival. There is seating for patients and friends/relatives and disabled access for wheelchair users. There is a coffee shop directly outside of the gynaecology clinics. The hospital restaurant is based within the Balmoral building (LRI) and near the main entrance at LGH.

#### • Interview rooms

At the LRI clinic there are 2 consultation rooms where patients consult with the doctor or nurse prior to changing for their procedures. At the LGH the consultation and treatment rooms are contained within 1 room.

#### • Treatment rooms

The 2 treatment rooms (in both clinics) are both equipped for colposcopy with adjustable couches, colposcopes, loop diathermy equipment and TV monitors (not all).

#### • Changing rooms

At LRI there are 2 private, lockable changing rooms for patients to change prior to their procedures. At LGH the changing accommodation is within the treatment room behind privacy screens / curtains. Gowns are provided.

#### • Recovery area

There is a recovery room with a reclining chair for patients to recover after their procedure if required (recovery room is used for other clinics including hysteroscopy). Hot drinks or water are available if required.

#### • WC

There is a WC and washbasin with disabled access and safety handrail.

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#### Clerical accommodation

The administrative/secretarial staffs are situated in offices off the clinic corridor at LGH and upstairs from the clinic at LRI. The audit and data co-ordinator is based within an office within the clinic at LGH and in the offices upstairs at the LRI.

#### MANAGEMENT OF REFERRALS

Referrals to the Colposcopy Service are received from the following sources:

#### **Direct referrals**

- The List of woman with abnormal cytology results are sent by the lab to the colposcopy direct referral mail box <u>CDReferrals@uhl-tr.nhs.uk.</u>
- Once the appointment is made the details of this are sent back to the lab to the Gynae cytology mail box <u>GynaeCytology@uhl-tr.nhs.uk.</u>
- The Direct referral mailbox is checked every day and arrangement are in place for admin staff that moves cross site, all appointments are made in accordance with the NHSCSP number 20 guideline specification.

#### **2week wait cancel referrals**

•If patient are referred by the GPs via PRISM pathway which is triage by the two week wait cancer admin team and this patients are booked into two week wait cervix clinic which are run by accredited colposcopist.

#### Symptomatic patients PCB

•The patients are referred via the PRISM PCB pathway. This is received by the Gynaecology admin team who book these patients into dedicated PCB clinics which are run by accredited Coloposcopist.

#### Gynaecology referrals

•Referrals for Women requiring colposcopy opinion or management are triaged by Lead colposcopist or Nurse colposcopists to book them into appropriate 2ww/colposcopy/PCB clinics.

#### Advice and Guidance

•The lead colposcopist also provides electronic advice and guidance to the GPs requesting appointments for colposcopy related issues. Where appropriate an appointment is requested to the colposcopy service.

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#### Fail Safe Procedure

Once referrals have been received form the laboratory the list of patients is printed and cross checked by the Direct Referrals Team to ensure that no patients have been missed. The copy of all patients and appointments are then passed to the gynaecology administration management team who keep a copy of all referrals and patient details.

#### Prioritisation of referrals

Appointments are prioritised as follows:

Reason for referral	Waiting time target
Clinical appearances suggestive of cervical cancer (2WW)	2 weeks
Post coital bleeding lasting more than 6 weeks in women >35 years with an abnormal looking cervix	2 weeks
Post coital bleeding in women < 35 years where infection and contraceptive methods have been eliminated as the cause	6 weeks
Query invasive carcinoma on screening test	2 weeks
Glandular abnormalities	2 weeks
High grade dyskaryosis – severe or moderate	2 weeks
Borderline nuclear change in squamous cells , High Risk HPV Positive	6 weeks
Borderline nuclear change in glandular cells, High Risk HPV Positive.	2 weeks
Low grade dyskaryosis, High Risk HPV Positive	6 weeks
Negative cytology, High Risk HPV Positive on Test of Cure	6 weeks
Persistent inadequate cytology	6 weeks
Clinical appearances not suggestive of cervical cancer, e.g. polyp	6 weeks
Clinical symptoms not suggestive of cervical cancer, e.g. discharge	6 weeks
Request for routine cytology	6 weeks
Referral for out of area follow up	6 weeks

#### Management of cancellations and DNAs

- In the event of a patient contacting clinic to cancel her appointment, a further date will be given over the telephone and confirmed in writing.
- If a patient defaults from her first appointment, a second appointment will be sent routinely. In the event of further default, no further appointment will be sent but a letter sent to the GP to advise that no further action will be taken unless the surgery or patient contacts the clinic to make a (new referral) further appointment.
- If the referral is for a high grade smear, suspected malignancy or other urgent indication, a telephone call will be made to the GP surgery to alert the GP to the fact that the patient has failed to attend. A further appointment will be given. It will also be documented in the colposcopy database.

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- If the default is for a treatment appointment following the diagnosis of CIN, a letter will be sent to the patient with a further appointment and copied to the GP. In the event of further default a letter will be sent to the GP to advise that no further action will be taken unless the surgery or patient contacts the clinic to make a further appointment. Patients list who have DNA for treatment will be produced by the data- co-ordinator every quarter and submitted to the lead nurse specialist who will then make another attempt to contact the patient if they have not already attended. A copy is sent to the lab as well.
- When the default is for a follow up cytology appointment a letter will be sent to the GP asking the surgery to follow up the patient with cytology in the surgery and no further appointment sent unless requested by the patient or the GP. This is documented in the GP discharge summary and CSAS(NHS Cervical Screening Administration Services) is notified.
- Following default from a follow up colposcopy appointment where there is concern that the patient may be lost to follow up, a letter will be sent to the GP asking the surgery to contact the patient. A further appointment will be offered following a request from the GP or patient.
- 2x DNA the patient is discharged back to the care of the GP. A letter is dictated to the GP stating that the patient has failed to attend on two separate occasions and as per hospital policy is discharged back to the care of the GP. We ask the GP to check that the patient is still at the address and to impress on the patient how important follow up is. If they have the reassurance of the patient that they will attend a further appointment the GP should make a re-referral back to the clinic. If the patient is due a follow up smear we advise that if the patient is not happy to be re-referred this smear can be taken at the GP surgery. A copy of this letter is sent to the patient, and a copy put in the patients notes.

#### **RESULTS MANAGEMENT AND FAILSAFE PROCEDURES**

The standards set by the NHSCSP (Document 20, 3rd edition, March 2016) state best practice is that 90% of patients and referrers to receive their results within 4 weeks of attendance at clinic. The minimum standard is 100% within 8 weeks.

The colposcopy database incorporates failsafe reports that indicate missing data and potential failure to meet these standards. Patient data are added to the database on once the first clinic examination has been completed. The system is updated with results and the date of communication to the patient and GP. The date of discharge and subsequent follow-up screening interval are included to enable to production of the spreadsheet which is sent monthly to CSAS(NHS Cervical Screening Administration Services), the call-recall centre.

#### Data input, Management of Results and Failsafe

- Patient referral details and demographics are entered into the database once the first clinic examination has been completed.
- Following attendance at clinic data regarding the examination and any investigations performed are entered in the database record.

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- Case notes remain in the Colposcopy office "awaiting results" box from the laboratories. If the notes are removed from clinic before the results are received, a tracer card is placed in the box to maintain the failsafe system.
- On receipt of results from the laboratories they are attached to the case notes and collated for review by the appropriate colposcopist. In the event of absence due to sick leave or annual leave, the nurse colposcopist will process the results, referring to another consultant in the event of a query. Historically this has only been done amongst nurses. Each clinician is sent a list of cases whose results review is outstanding more than 3 weeks to meet the target of 4 weeks.
- When a management plan has been decided, results letters are initiated to the patient and referrer (either standard format or dictated letters) and following typing and authorising, the results and date of communication of results are entered into the database.
- Failsafe reports on the database alerts the data input clerk to cases where no plans have been entered into the database. This report is run on a fortnightly basis.
- The case notes awaiting results are checked every 4 days by the nursing staff to highlight any outstanding results. This is only done when there is an opportunity. If a biopsy result or screening test result has not been received within 14 days of attendance at clinic, this is chased with the laboratory. Individual colposcopists may do this if they are awaiting a result and have an opportunity. Further chasing takes place if necessary.
- The database also has a failsafe to identify patients who have had the outcome "treatment appointment, "inpatient waiting list" or "day surgery waiting list" and have not been treated as an outpatient or admitted for their procedure within 3 months.
- A monthly spreadsheet is produced and sent to CSAS(NHS Cervical Screening Administration Services) to advise them of the screening interval for each patient following discharge from clinic.

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#### INDUCTION FOR TRAINEE/NEW COLPOSCOPISTS TO UHL

A trainee who is new to UHL will meet one of the Nurse Specialist for arranging orientation and meeting the team, work plans and training need are discussed with the clinical supervisor.

The trainees are oriented to the following:

- Colposcopy rooms both sites
- Colposcopy secretary offices
- Colposcopy offices
- Clinic coordinators
- •Histology and cytology labs
- •MDT meeting room
- •Stores clinical and stationary

#### Meet the team

- Colposcopists
- •Health care assistants
- Colposcopy secretaries
- Clinic coordinators
- •Cytology and histology lab staff

#### Access to

- ≻ICE
- ≻ILAB
- ≻DATABASE
- ≻HISS

#### Work plan

- •Observational opportunities in colposcopy clinic. gaining informed verbal consent from the patient when taking history and counselling and also for colposcopy examination/treatment.
- •Visits to the labs
- •Attendance of monthly MDT meeting
- Study time
- •Time with trainer reflection, log book, discussing results etc
- •Attending study days pre-osce day, osce, bsccp conference, colposcopy nurse conference, annual colposcopy study day
- •Colposcopy clinic guidelines
- •How to maintain colposcopy qualification

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#### **CLINIC STAFFING**

#### Nursing staff and their responsibilities

#### Nurse Colposcopist

- To manage a caseload of patients attending for colposcopy with all referral indications, performing both diagnostic and therapeutic interventions.
- To maintain accreditation with the British Society of Colposcopy and Cervical Pathology (BSCCP)
- To manage the Colposcopy Service and support the Lead Colposcopist in ensuring that standards are maintained, audit requirements met and monitoring reports produced promptly.
- To co-ordinate the monthly MDT meetings, present the cases and communicate management plans to patients and referrers
- To supervise trainee colposcopists (nursing and medical) and provide teaching to medical and nursing students attending clinic
- To collate laboratory results with patient case notes and ensure that they are reviewed by the colposcopist in a timely manner this is the colposcopy secretary's role we have done this only when there has been an opportunity within our working day.
- To undertake external teaching sessions to cytology sample takers

#### Health Care Assistants (HCA)

- To assist all members of the colposcopy team to deliver a high standard of care to patients.
- To maintain at all times a caring and professional attitude toward the needs of the patient.
- To liaise closely with medical and nursing staff to ensure that clinics are conducted effectively and efficiently.
- To ensure that all equipment and consumables are available for clinic and initiate ordering of stock where necessary to maintain adequate levels.
- To chaperone and support patients and assist colposcopists during all procedures
- To take responsibility for monitoring daily clinical checks of equipment and stock levels within the service and maintain high standards of infection control.

#### Data & Audit Coordinator

- To input patient referral data from the referral letter/direct referral summary onto the PHE MASEY colposcopy database prior to attendance in clinic
- To update the database with details of the patient attendance, laboratory results, management plan etc. colposcopists who are using the data system do this.
- To assist with production of the quarterly returns (including the KC65 data) to the West Midlands Cervical Screening QA Reference Centre and other national bodies.
- To operate the failsafe system in respect of overdue results, missing management plans, admission for inpatient procedures etc.

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#### Administrative staff

The Clinic coordinators/Administrators provide the administrative support for all the activity in the Colposcopy Clinic. They are responsible for booking all appointments, managing the clinic sessions to ensure optimal use of available slots, ensuring that the appropriate supportive paperwork is available for the patients' attendances and communicating results and management plans to patients and referrers. The individuals in the team have been trained to cover each other's roles if necessary in the event of absence.

#### **Clinic Reception Administrators**

The individual responsibilities are as follows:

- To undertake receptionist duties acting as first point of contact to welcome patients, colleagues and members of the public into the department.
- To manage telephone enquiries, referring to the nursing staff where appropriate.
- To make or change appointments where requested by patients
- To liaise with medical staff in respect of clinic cancellations, alterations etc. and to ensure that the nursing staff are aware of these events.
- To manage the Choose & Book referrals and ensure that requests for information or advice are answered promptly, referring to nursing staff where appropriate.
- To manage the clinic sessions to ensure efficient use of appointment slots and enable achievement of waiting time targets, notifying the Unit Manager over concerns regarding colposcopy capacity.
- To ensure that casenotes and referral information are always available when patients attend clinic appointments
- To provide administrative support to the colposcopy service by producing personalised data sheets and clinic lists.
- To assist the Direct Referral administrators and secretaries in providing administrative support to the nursing staff.

#### Direct Referral Administrators/Secretaries -

- To manage the Direct Referral system and allocate appointments to patients within the waiting time protocols
- To notify the Unit Manager of concerns regarding colposcopy capacity where relevant to ensure that waiting times are met
- To type letters to patients and referrers following attendance at clinic and when communicating results, management plans etc.
- To assist reception staff in providing support to nursing staff in respect of obtaining case notes, laboratory results etc.
- To assist the data input clerk where appropriate
- To assist with requesting case note for patients on the monthly colposcopy MDT meeting and the month Invasive Disease Audit. Disseminating these notes back to the appropriate clinician for result letters after the meeting.

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#### COLPOSCOPY CLINIC NURSING GUIDELINES

- All patients are chaperoned by a HCA during their examination and the role of the HCA is to assist the colposcopist and act as patient advocate. This role is of paramount importance in ensuring the safety of everyone in the examination room and giving reassurance and support to the patient.
- Training for use of all equipment is included in the induction programme for all new staff when they commence within the clinics.
- The nursing staffs are formally assessed as to their competency to assist with any procedure. New staffs are able to shadow an experienced member of the team during the induction period until they feel confident to carry out their duties under direct supervision initially and then independently.
- The patient is counselled by the colposcopist prior to the procedure and then invited to change ready for the procedure. At this stage the chaperoning HCA should introduce herself to the patient and explain that she will be with her during the examination (the HCA is present during the history taking and counselling and is introduced at the beginning of the appointment). If the HCA is concerned that the patient is worried about the procedure she should try to reassure her and bring this to the attention of the colposcopist before the procedure begins if necessary.
- Positioning the patient so that she is as comfortable as possible is important and explanations and reassurance given throughout the procedure are known to distract the patient, thereby helping to reduce anxiety.

#### Health & Safety

All staff should familiarise themselves with the Trust policies as follows:

- Control of Substances Hazardous to Health (COSHH) (B10/2002)
- Infection Prevention Management Guidelines of patients with known or suspected blood borne viruses (B4/2006)
- Safer Handling Policy (B56/2011)
- Cleaning and Decontamination for Infection Prevention (B5/2006)
- Infection Prevention and Control Policy (B4/2005)
- Hand Hygiene Policy (B32/2003)
- Waste Policy

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#### Checks

In order to ensure patient, staff and visitor safety, a number of checks are carried out by the nursing staff at the beginning of the day and before, during and after every procedure, as follows:

#### Start of day and pre-clinic

- In the interest of Health and Safety, Infection Prevention and patient safety and comfort all equipment is checked to ensure that it is clean and in sound working order before every clinic session.
- Environmental checks should be carried out to check that there are no potential hazards in the patient area using the daily checklists which should be kept for future reference. We do not have a checklist.

#### **During clinic**

- All patients must be chaperoned by a member of the nursing team
- All equipment must be checked before and after use with each patient. Any malfunction should be reported immediately and the equipment taken out of use.
- To avoid sample labelling errors, only the patient record relating to the patient being examined should be in the clinical room. Before the patient has left the room a verbal check is made between the patient and the nurse that the request form and the specimen have the correct ID labels in place.
- Patient details should be checked with the patient from the ID label before labelling of the specimen pots. Prior to placing specimens in the request envelope, it must be confirmed that correct matching labels are affixed to the specimen pot(s) and request form.
- A patient ID label should be placed on the specimen record sheet together with accurate details of the number and nature of specimen(s) sent to the laboratory.
- The request envelope should be placed in the pathology specimen collection box before the next patient is taken into the clinical room. See section on management of histology and cytology samples.
- A CSSD barcode sticker should be placed in the patient's notes following use of sterile instruments to facilitate traceability.
- The colposcope, couch, loop diathermy machine, suction machine, floor area and trolley should be thoroughly cleaned between patients. Any spillages should be cleaned in accordance with Trust policy.
- Single use instruments should be disposed of safely and correctly in clinical waste bags/bins in accordance with Trust policy.

#### **Post-clinic**

• The clinical treatment rooms should be thoroughly cleaned at the end of each session, including the couch, trolley, colposcope, loop diathermy machine, suction machine, floor and work surfaces.

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- Any necessary re-stocking of clinical equipment and stationery should be carried out to ensure that everything is in place for the next clinic session.
- All sterile supplies (CSSD) equipment for sterilisation should be placed in the sluice area according to Unit policy.
- All equipment should be checked in readiness for the next session and switched off/unplugged if it is the end of the clinic day.
- Suction equipment filters should be changed according to policy (*please refer to the diathermy loop excision section*).

#### Performing pregnancy testing

All staff must undertake training in the Alere HCg Easy Urine method of pregnancy testing. This should be recorded on the LocSSIP (local safety standards for invasive procedures) checklist.

#### Guidance for assisting with punch biopsy samples

- Ensure that biopsy forceps are readily available; open sterile packaging and hand to the colposcopist when requested.
- Prepare the formalin specimen pot with appropriate labelling according to department policy; having confirmed with the patient that the correct ID label has been affixed (*please refer to section on management of histology/cytology samples*).
- Reassure and support the patient during the procedure.
- Remove the biopsy from the forceps using a small needle, taking care not to damage the specimen or cause a needle stick injury, and place in the cell safe. Multiple biopsies can be placed in the same cell safe which should then be closed and placed in the correctly labelled formalin pot.
- A final check should be made to ensure that the labels on the pot and the request form are the same and are those of the patient before the specimen is removed to the pathology specimen collection box. This should be recorded on the LocSSIP checklist by the HCA.
- Post procedure, the patient should be counselled about what to expect following the biopsy, together with advice about avoiding infection. A written fact sheet should be given to reinforce the information and the patient advised to contact the clinic if they have any concerns. In the event of heavy bleeding the patient leaflet advises the patient to contact the Gynaecology Assessment Unit (GAU) at LRI.
- Patients should be advised that the results will be communicated to them and the GP in 4-6 weeks and that the clinic is unable to give results over the telephone.
- If any patient feels unwell during or post biopsy, she should be advised to lie flat on the couch until she recovers. In the event of vasovagal collapse the patient should be managed in accordance with nursing guidelines.

#### Assisting with LLETZ/diathermy

- All staff should familiarise themselves with the NHSCSP document "Guidance notes on the safe use of diathermy loop excision for the treatment of Cervical Intraepithelial Neoplasia" (NHSCSP Equipment Report 0401, December 2004) which is available in the nursing procedures file.
- The section entitled "Guidance notes for Colposcopy staff on safety procedures for cervical diathermy treatment." covers equipment settings and safety checks specific to the

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department policy. The trolley should be set up with the tray, cotton wool balls, sponge holder and solutions in the usual way.

- The dental syringe, loaded with the first anaesthetic cartridge should be placed on the trolley and additional cartridges placed with it. *It is the responsibility of the Colposcopist to check that the cartridge is the correct dosage and in date.*
- A variety of sizes of diathermy loop should be placed on the trolley, together with a diathermy ball.
- A formal in histology pot should be labelled with an ID label after checking the details with the patient as per Unit policy. This is documented on the LocSSIP checklist. The pot should be placed on the trolley until required.

#### Safety checks prior to commencing treatment include the following:

- Are there any metal prostheses, pins or plates in 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 the patient have a pacemaker? If yes, defer treatment and seek advice from her cardiologist.
- Are there any piercings in place from umbilicus downwards? If yes, advise removal due to small risk of diathermy burn. If this is not possible cover with micropore tape.
- Are there any tattoos in the area where the diathermy pad is to be placed? If so an alternative site should be used.
- If the patient has used moisturiser on the skin where the diathermy plate is to be attached, the area should be washed and dried with the patient's permission prior to affixing the plate to ensure adequate contact.
- An appropriate speculum with smoke evacuation tube should be available on the trolley.
- The suction tubing should be attached to the suction machine with the appropriate filter in place.
- Once the speculum has been inserted by the colposcopist, the suction tube should be firmly attached to the smoke evacuation tube.
- The patient should have been counselled by the colposcopist prior to the procedure regarding what to expect, any possible side effects and advice regarding restrictions post treatment. If there is any concern that the patient is not comfortable with the procedure or has not been adequately informed about what to expect, the colposcopist should be advised before the procedure commences.
- Prior to treatment, the patient should be placed on the examination couch and efforts made to ensure that she is as comfortable as possible.
- The diathermy and suction machines should be activated when requested by the colposcopist. Reassurance should be given to the patient regarding the noises and sensations she should expect.
- The patient should be reassured throughout the procedure. If she is particularly anxious a second nurse should be asked to be present solely to give reassurance whilst the first nurse assists the Coloposcopist.
- Once treatment is completed, the patient should be assisted to sit up. If she feels well enough she can be encouraged to return to the changing room. *In the event of the patient feeling unwell she should be placed in the recovery room.* Refreshments should be offered and one of the nurses should go through the post-treatment advice and provide the fact sheet to take home. Any questions raised by the patient should be answered appropriately and she should be advised that the results will be sent in writing to her and her family doctor as per current standards.

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- The specimen labels should be checked on the histology pot and request form prior to specimen being placed in the pathology specimen collection box. A label should be placed on the specimen record.
- A notification of treatment should be sent to the family doctor immediately after the clinic advising that the procedure has been carried out and advising the surgery that the patient has been asked to contact them in the event of post procedure infection. This is not on the letter template.

#### Performing Cervical Cytology

Nurses taking cervical cytology samples must have attended a foundation cytology training course and have completed cytology training as per NHS Cervical Screening Programme guidelines. They should also attend update sessions every 3 years and it is the responsibility of the individual to ensure that this takes place. The Lead Nurse should keep a record of all staff training.

Cascade training in the use of the Thin Prep Liquid-based Cytology technique must have been undertaken and competency. Staff should refer to the Quick Reference Guide to performing Thin Prep Cytology for advice if required.

#### Essential competencies prior to performing cytology

Nurses taking cervical cytology samples must be able to:

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

#### Prior to the procedure:

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

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- Before using the vial, it should be checked that the vial is in date.
- The liquid vial must be labelled with an ID sticker from the patient's notes showing her name, NHS number and date of birth. The date of the sample should be written on the label after the sampling has taken place. We have never documented the date on the label as it is documented on the form.

#### During the procedure:

- Every effort should be made to ensure that the patient is comfortable and well informed during the procedure.
- The Coloposcopist should introduce herself and the chaperone to the patient and explain that a cervical screening test ("smear") is going to be performed with the patient's consent.
- The procedure should be explained to the patient, giving her the opportunity to ask questions or express any concerns.
- The patient should be asked about the date of her last menstrual period, method of contraception, if there has been any unexpected bleeding or increased discharge, pain or other symptoms. Advice should be sought from the colposcopist if any suspicious symptoms are reported, e.g. post-coital bleeding, unusual discharge, pain or other symptoms.
- Samples should **not** be taken when the patient is menstruating
- In positioning the patient on the examination couch her dignity should be respected at all times.
- A full explanation of the procedure itself and the reason for performing it should be given, ensuring that the patient is happy to proceed.
- The patient should be advised that, if the examination is uncomfortable she should make this known and that the examination can be terminated at any stage.
- Prior to insertion of the speculum the external genitalia should be inspected to identify any abnormal appearances. Seek the advice of the colposcopist if necessary.
- Assessment should be made as to the correct size speculum for optimum patient comfort and satisfactory visualisation of the cervix. KY jelly is applied to the speculum before insertion to make the procedure more comfortable for the patient. This should be inserted gently, explaining to the patient what to expect at each stage. If the patient experiences discomfort the procedure should be halted until she is able to proceed or discontinued at the request of the patient.
- The position of the SCJ junction should be assessed and the appropriate sampler used to take the test. If the SCJ cannot be visualised fully, there is any doubt that the correct area is being sampled or the cervix looks abnormal, assistance should be requested from the colposcopist.
- If there is evidence of vaginal infection vaginal swabs should be considered after the screening test has been performed.
- Lukewarm water can be used to warm and lubricate the speculum, if desired, water-soluble gel lubricant can be applied sparingly on the posterior blade of the speculum but care should be taken to ensure than none is on the tip of the speculum in case the sample is contaminated.
- The broom sampler should be inserted as quickly as possible into the solution in the vial, pressing it into the bottom of the vial 10 times, forcing the bristles apart. Finally, swirl it vigorously to release further material. The sampler should then be discarded. **The brush head should not be placed in the vial**.
- If an endocervical brush is used, this should be inserted into the cervical os until the bottom-most fibres only are exposed. Slowly rotate one half of a turn in a clockwise

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direction. **Do not over-rotate.** The brush should then be rotated in the solution 10 times whilst pressing it against the wall of the vial. Discard the brush.

#### After the procedure:

- The lid must be secured appropriately and placed in the cytology specimen request envelope following checking that the patient's details and GP details are correct and correlate with the request form. A patient ID label should be placed on the specimen record as per Unit policy.
- The request envelope and specimen vial should be place in the pathology specimen collection box before the next patient enters the room.

#### MANAGEMENT OF COMPLICATIONS IN THE COLPOSCOPY CLINIC

All nursing staff should familiarise themselves with the following policies

- Trust Cardiorespiratory Resuscitation Policy (A14/2001)
- Statutory and Mandatory Training (B21/2005)

#### Post LLETZ haemorrhage

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

#### Fainting or vasovagal attack

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

- Immediately stop instrumentation /examination of the cervix.
- Reassure patient and calmly try to rouse them by talking to them.
- Place the patient in head-down position by lowering the backrest of the couch.
- Protect the patient's airway and turn onto her side if she is vomiting.
- Give oxygen.

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- Monitor pulse rate and blood pressure and record in the notes.
- Continue to assess patient and transfer to the Recovery Room or gynaecology ward if she is not able to be discharged home.
- In the event of collapse call the Resuscitation Team on 2222 and state ADULT resuscitation team required and give location including building and hospital
- Obtain the crash trolley located by clinic reception (LRI) or the clinic corridor (LGH).
- Maintain airway/basic life support until arrival.

#### Severe bronchospasm or other severe allergic reaction:

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

- Stop procedure and administer prescribed oxygen if appropriate.
- Call the Resuscitation Team on 2222 and state ADULT resuscitation team required and provide the exact location including building and hospital
- Obtain the crash trolley located by clinic reception (LRI) or the clinic corridor (LGH).
- Maintain airway/basic life support until arrival.

#### **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 lowest level possible and lower backrest
- In severe cases call the Resuscitation team on 2222 and maintain airway/basic life support until arrival.
- Obtain the crash trolley located by clinic reception (LRI) or the clinic corridor (LGH).
- Maintain airway/basic life support until arrival.

#### MANAGEMENT OF HISTOLOGY SPECIMENS AND CYTOLOGY SAMPLES

The correct labelling of all colposcopy specimens is essential in order to avoid the risk of incorrect processing and, most importantly, the hazard of incorrect diagnosis.

In the event of a specimen being unlabelled or wrongly labelled the specimen will not be processed and this could lead to the patient being subjected to a repeat examination; however, in the case of a LLETZ, this would not be possible and would lead to extreme distress for the patient and the absence of important histological information.

All specimens leaving the department must be clearly labelled and packaged appropriately for transportation after each clinic session by the portering staff.

#### Cervical cytology samples

- Liquid based cytology is now the sampling method as per NICE guidance. Thin Prep is used in this service.
- Before using the vial, checks should be made to ensure that the vial is in date. Directive from cytology lab is the pot must have at least 14 days left before expiring.

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- The liquid vial must also be labelled with an ID sticker from the patient's notes showing name, NHS number and date of birth. The date of the sample should be written on the label after the sampling has taken place.
- The lid must be secured appropriately and placed in the cytology specimen request envelope following checking that the patient's details and GP details are correct and correlate with the request form. A patient ID label should be placed on the specimen record as per unit policy.
- The request envelope and specimen vial should be place in the pathology specimen collection box before the next patient enters the room.
- In the instance of a pot spillage, gloves and eye protection must be worn. The area must be ventilated and all personnel warned within the clinical environment so that the area can be temporarily evacuated by the majority of staff.
- Disposal considerations: Absorb in inert material and place in separate clinical waste bag to be treated as special waste. Porters to be contacted.

#### Swabs for microbiology

- Swabs for microbiology must be labelled with a patient sticker ID and placed in the appropriate request envelope; following checks that the patient ID is correct as per unit policy and that labels on the specimen and request form are identical.
- Individual swab containers should be labelled as to their content (i.e. HVS, endocervical swab) if they are being sent in the same envelope. The swabs should be recorded on the specimen record by a patient ID label and placed in the pathology specimen collection box. If swabs are to be kept in the unit overnight they should be stored in the fridge and a note left to remind staff to place them in the collection box the next morning.

#### Histology specimens

- Before placing the formalin histology pots in the request form it is important to ensure that the lids are attached securely to prevent hazardous leakage (see COSHH file for use of formalin)
- Nursing staff should check that all histology pots and request forms are correctly labelled as per the Unit policy.
- Specimens and case notes must be removed from the treatment room before the next patient enters. The only case notes and specimen request forms in the treatment rooms should relate to the patient being examined at the time. The nurse chaperoning the patient should establish that the correct ID labels are being used as soon as the patient has been positioned on the examination couch.
- If more than one pot is used for a patient, both pots can be placed in the same envelope, following the usual ID checking procedure. If two envelopes are used the nursing staff should annotate "1 of 2", "2 of 2" etc. to ensure that the laboratory is aware that there is more than one request for the patient.
- The specimens should be placed in the pathology specimen collection box located on the clinic reception desk (LRI) or by the main clinic entrance at LGH for collection by the hospitals porters.

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#### PROTOCOL FOR MANAGEMENT OF STERILE SUPPLIES

#### **Relevant Trust policies**

Please refer to intranet for trust policies.

All staff should familiarise themselves with the following policy:

• Medical Devices Policy (B26/2005)

#### **Processing of used instruments**

- It is the Unit policy that single use instruments are used wherever possible. However, some instruments are reusable and are sent to the Central Sterile Services Department (CSSD) for processing.
- Single use instruments including specula, biopsy forceps and sponge holders are ordered directly from the suppliers. These should be disposed of in the designated clinical waste bins (yellow).
- Reusable items such as treatment or special size speculum, biopsy forceps, canal forceps, polyp forceps and dental syringes are processed in the CSSD. If urgent processing is required, the nursing staff should complete a Fast Track request and attach it to the instruments that are required urgently.
- After use the reusable items should be placed in the CSSD collection trolley. Care should be taken to dispose of sharps in the sharps bin attached to the trolley prior to clearing the instruments away after a procedure. Failure to do this could result in a needle stick injury (see Trust Sharps Procedure).

#### Recording and management of sterile supplies

• For every instrument used, the small sticker the bar code on the front packaging of every instrument must be removed and placed in the patient's colposcopy notes.

#### INFECTION CONTROL IN COLPOSCOPY

#### **Relevant Trust Policies**

All staff should familiarise themselves with the following Trust policies:

- Infection Prevention Management Guidelines of Patients with Known or Suspected Blood Borne Viruses (B4/2006)
- Safer Handling Policy (B56/2011)
- Cleaning and Decontamination for Infection Prevention (B5/2006)
- Infection Prevention and Control Policy (B4/2005)
- Hand Hygiene Policy (B32/2003)
- Latex allergy in patients (B29/2005)
- Waste management policy and guidance (A15/2002)

#### Use of gloves within the clinical area

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

#### Handling of used linen

• Used linen should be bagged as per the above Trust policies and taken to the refuse room located in the clinic (LRI) or at the end of the maternity corridor at LGH.

#### Waste disposal

#### Cardboard waste

• Flatten and dispose of in the refuse rooms.

#### **Domestic waste**

- Place in black plastic bag
- Waste bags should not be overfilled; <sup>3</sup>/<sub>4</sub> full only
- Tie bag securely using a *swan neck fastening*

#### **Clinical waste**

- Place in yellow plastic bag
- Waste bags should not be overfilled; 3/4 full only
- Tie bag securely using a *swan neck fastening*
- Place in refuse room if not collected by the clinic domestic
- Clinical waste must be destroyed by incineration

#### **Confidential waste**

 Place in the locked shredding bin located by the clinic reception (LRI) or in the Pre-Assessment office at LGH

#### HEALTH AND SAFETY / RISK MANAGEMENT

The health and safety of staff, patients and visitors is of the utmost importance to all who work within the colposcopy department. Risk assessments are undertaken and policies and procedures are written to underpin them. These can be found in the Risk Assessment file and on the DATIX system.

Whilst the Trust Chief Executive has overall responsibility for Health and Safety, it is the executive/clinical directors, directorate managers and line managers who have local day to day accountability. The directors and managers would also receive advice and support from the Trust Risk Manager.

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#### **Relevant Trust Policies**

All staff should familiarise themselves with the Trust Health & Safety related policies as follows:

- •Control of Substances Hazardous to Health (COSHH) (B10/2002)
- •Infection Prevention Management Guidelines of Patients with Known or Suspected Blood Borne Viruses (B4/2006)
- •Safer Handling Policy (B56/2011)
- •Cleaning and Decontamination for Infection Prevention (B5/2006)
- •Infection Prevention and Control Policy (B4/2005)
- •Hand Hygiene Policy (B32/2003)

#### Health & Safety related training

- All staff employed by the Trust must attend an annual mandatory training session. This training session includes Safeguarding of Adults (level 1 and 2) and Children (level 1 and 2).
- This training will include Resuscitation, Fire Safety and Manual Handling.
- Hand hygiene updates and assessments are performed annually via an e-learning module.

#### **Incident reporting**

Untoward incidents should be reported by the individual witnessing or involved in the incident using the DATIX incident reporting system. An incident log is also kept for frequently occurring admin error such as no notes, wrong patient notes/ref/results/result letters, wrong/inappropriate clinic, inappropriate referral, not prepped, documents missing, double booking of slots. The folder is monthly updated on to the excel document which is reviewed by the lead Coloposcopist to deal with common themes, all Health care assistants and clinical staff are aware of the folder.

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#### **RECORD KEEPING AND DOCUMENTATION**

#### **Relevant Trust Policies**

All staff should familiarise themselves with the following Trust policies:

- Policy for Documenting in Patients' Health Records (B30/2006)
- Information Governance Policy UHL (B4/2004)
- Data Protection Policy (A6/2003)

It is the responsibility of all staff to maintain accurate and appropriate records and documentation, maintaining patient confidentiality at all times.

#### **Colposcopy Documentation**

The Reception administration team should check that the correct clinical documentation is filed appropriately in the patient's notes ready for clinic sessions. The documentation includes:

- Direct Referral summary sheet or referral letter
- History and continuation sheets
- Colposcopy datasheet
- Patient ID labels (these should be replaced prior to the patient seeing the Coloposcopist if there is a change of details notified at the time of checking in); the Reception administrator should also advise the nursing staff if there is a change to the patient's registered GP practice

#### **Responsibility for documentation**

- At the time of preparing the patient records for clinic it is the responsibility of the nursing staff to ensure that all the above documentation is present and that the results of any known previous investigations relevant to the current referral are obtained and placed in the case notes. Any special requirements or conditions should be highlighted.
- All practitioners are responsible for keeping clear and accurate records of patient consultations. The colposcopy datasheets should be fully completed at the time of the examination to facilitate accurate data input and conversations with patients clearly documented in the case notes in accordance with the above policies.
- Patient confidentiality should be respected at all times and patient records stored securely in accordance with the Trust policies, as above.

#### Patient Information Leaflets

It is well known that providing information and communicating effectively with patients helps to decrease anxiety. The NHSCSP Document 20 standards are as follows:

- Each woman should be offered verbal information and should be sent written information before and after a cervical screening and before colposcopy (95%).
- Counselling must be available as an integral part of colposcopy.

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- Women must be sent an appropriately worded invitation with a contact name, telephone number, clinic times, clinic location and transport advice.
- Written information regarding the colposcopy examination should be provided to all women with their appointment invitation.

	Objective	Measure	Target
1	To ensure women are adequately	<ul> <li>All women referred for colposcopy should be offered verbal information and be sent written information before and after cervical screening and before colposcopy.</li> </ul>	95%
	informed about colposcopy and treatment.	<ul> <li>Women must be sent an appropriately worded invitation with a contact name, telephone number and clinic times.</li> </ul>	100%
	treatment.	<ul> <li>Counselling must be available as an integral part of colposcopy</li> </ul>	
		<ul> <li>All women needing treatment should be informed that treatment will be required and have that treatment explained. Their consent, either written or verbal, should be recorded.</li> </ul>	
		<ul> <li>Information concerning the visit and results of investigations should be communicated to the patient within fours week or eight weeks of her attendance</li> </ul>	90% within four weeks (best practice) or 100% within eight weeks (minimum standard).
2	To provide an	All clinics should have the following facilities:	
	adequate clinic	Permanently sited specific room for colposcopy (100%)	100%
	environment (see also 3.1).	Dedicated private area with toilet and changing facilities.	
		<ul> <li>A suitable couch, colposcope and other equipment necessary for diagnosis and treatment.</li> </ul>	
		<ul> <li>Appropriate sterilising facilities must be available in accordance with local and national health and safety recommendations.</li> </ul>	
		<ul> <li>At least one method of satisfactory treatment of CIN or automatic referral to a unit where treatment is available.</li> </ul>	100%
		<ul> <li>If laser or diathermy equipment is in use, there must be adequate safety guidelines in place with all staff trained in their operation.</li> </ul>	
		<ul> <li>Resuscitation equipment and the ability and training to use it correctly.</li> </ul>	
		<ul> <li>Written emergency guidelines with which all clinic staff are familiar.</li> </ul>	
3	To provide appropriate clinic staff (see also 3.1)	<ul> <li>All clinics should have a named colposcopist with appropriate skills who leads the service. The named lead colposcopist must have a job description.</li> </ul>	
		<ul> <li>All clinics should have a named clinic nurse with appropriate skills and without concurrent out-patients duties.</li> </ul>	

#### **Colposcopy Service Standards**

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		There must be at least two nurses for each clinic.	
		<ul> <li>Nurse colposcopists working in a clinic role must be supported by another registered nurse.</li> </ul>	
		There must be adequate dedicated clerical support for each clinic.	
		<ul> <li>Consent should always be obtained to the presence of non-essential clinic personnel e.g. trainees, undergraduates, visitors.</li> </ul>	
4	To ensure appropriate and accurate data	<ul> <li>There must be suitable information technology equipment and software to facilitate collection of data for the BSCCP minimum data set and for submission of the standard</li> </ul>	
	collection	<ul> <li>Appropriate and sensitive enquiries regarding sexual history should be made only when necessary.</li> </ul>	
I		<ul> <li>Multi-disciplinary audit must be an integral part of the service</li> </ul>	100%
5	To reduce default	<ul> <li>All clinics should have written protocols for the management of non- attenders</li> </ul>	
		<ul> <li>Minimal default rate at first appointment.</li> </ul>	<15% of women fail to attend for first appointment.
		<ul> <li>Minimal numbers of defaulters at follow up appointment.</li> </ul>	<15% of women fail to attend for follow up appointment.
6	To reduce the failure of diagnosis of early cancers	An excisional form of biopsy is recommended when:	95%
		- Most of the cervix is replaced with high grade abnormality	
		- Low colposcopic change is associated with severe dyskaryosis or worse	
		- A lesion extends into the canal (sufficient canal must be removed in these situations).	
		<ul> <li>Reasons for not performing a biopsy must be recorded</li> </ul>	100%
		<ul> <li>All women should have had histological diagnosis before destructive treatment</li> </ul>	100%         100%         <15% of women fait to attend for first appointment.
7	To improve the quality,	<ul> <li>Women should be referred to colposcopy after three consecutive inadequate samples within 6 weeks</li> </ul>	99%
	accuracy and timeliness of diagnosis	reported as porderline pulciear change in squamous cells and HPV	
		<ul> <li>Women should be referred for colposcopy after one test reported as borderline nuclear change in endocervical cells and HPV positive. Our local policy is to see them within 2 weeks.</li> </ul>	99%
		<ul> <li>A woman should be referred for colposcopy after one test is reported as low-grade dyskaryosis and HPV positive within six weeks</li> </ul>	99%
		<ul> <li>Women should be referred to colposcopy after one test reported as moderate dyskaryosis within two weeks.</li> </ul>	93%
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<ul> <li>Women should be referred to colposcopy after one test reported as severe dyskaryosis within two weeks.</li> </ul>	93%
<ul> <li>In England, women referred with a high grade cytological abnormality must enter a 62 day cancer pathway. Once cancer has been excluded these women must enter the 18 week pathway</li> </ul>	100%
<ul> <li>Women must be referred to colposcopy after one test reported as possible invasion.</li> </ul>	100%
They should be seen urgently, within two weeks of referral	93%
 <ul> <li>Women must be referred to colposcopy after one test reported as possible glandular neoplasia</li> </ul>	100%
They should be seen urgently, within two weeks of referral	93%
<ul> <li>Waiting time for colposcopic assessment for all referrals.</li> </ul>	≥90% in less than eight weeks
<ul> <li>Waiting time for women with a test result of moderate or severe dyskaryosis should be seen within two weeks of referral</li> </ul>	93%
<ul> <li>Women with moderately or severely dyskaryotic cytologys having a biopsy (i.e. material excised and sent for histological interpretation). Unless an excisional treatment is planned, biopsy should be carried out when cytology indicates moderate dyskaryosis or worse, and always when a recognisable atypical transformation zone is present. Pregnancy is an exception.</li> </ul>	≥90% 100%
<ul> <li>The proportion of women having definitive treatment for high grade CIN within four weeks of the colposcopy clinic receiving a diagnostic biopsy report.</li> </ul>	≥90%
<ul> <li>All women having definitive treatment for high grade CIN must be treated within eight weeks. Pregnant women are the exception to this. The reason for any delay should be specified.</li> </ul>	100%
Accurate recording of colposcopic findings to include:	
1. Reason for referral (100%)	
2. Grade of cytological abnormality (100%)	100%
<ol> <li>Whether the examination is satisfactory. This is defined as the entire squamocolumnar junction having been seen and the upper limit of any cervical lesion also being seen (100%)</li> </ol>	90% 100%
4. Presence or absence of a visible lesion	
<ol> <li>Colposcopic opinion regarding the nature of the abnormality and requirement for treatment</li> </ol>	
<ul> <li>Proportion of biopsies adequate for histological interpretation</li> </ul>	>90%
<ul> <li>If a colposcopically directed biopsy is reported as inadequate for histological interpretation, it should be repeated if there is a residual</li> </ul>	95%

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colposcopic lesion	
<ul> <li>For those with a satisfactory colposcopic examination, the predictive value of a colposcopic diagnosis of a high grade lesion (CIN2 or worse)</li> </ul>	<u>≥</u> 65%
Evidence of CIN on histology	>85%
<ul> <li>Biopsy should be undertaken in women with moderate or severe dyskaryosis (high grade) on their test result</li> </ul>	>95%
<ul> <li>Women referred with moderate dyskaryosis or worse cytological abnormalities who have a colposcopically low grade lesion and who are not treated should have multiple biopsies</li> </ul>	90%
<ul> <li>All patients who are immunosuppressed must be managed in a centre with demonstrable skill and expertise, with sufficient access to patient numbers to maintain that expertise</li> </ul>	
<ul> <li>All women aged 25-65 years with renal failure requiring dialysis must have cervical cytology performed at, or shortly after diagnosis</li> </ul>	
<ul> <li>Reporting of any abnormal glandular sample must be supplemented with a written description report</li> </ul>	100%
<ul> <li>Women with atypical endometrial cells on a sample, with or without irregular vaginal bleeding and regardless of menopausal status, should be seen urgently, within two weeks of referral, by a gynaecologist</li> </ul>	
<ul> <li>The investigation of abnormal bleeding after the menopause must include direct visual inspection of the cervix</li> </ul>	100%
<ul> <li>Colposcopic assessment is essential in the presence of cytological glandular abnormality</li> </ul>	100%
<ul> <li>If colposcopy has been performed during pregnancy, postpartum assessment of women with an abnormal cytology or biopsy proven CIN is essential</li> </ul>	100%
<ul> <li>If invasive disease is suspected clinically or colposcopically in a pregnant woman, a biopsy adequate to make the diagnosis is essential</li> </ul>	100%
<ul> <li>All patients in the cervical screening age range undergoing a hysterectomy for other gynaecological reasons should have a negative cytology sample within the screening interval or as part of their preoperative investigations</li> </ul>	100%
<ul> <li>All patients being considered for hysterectomy who have an undiagnosed abnormal cytology sample or symptoms attributable to cervical cancer should have diagnostic colposcopy and an appropriate biopsy</li> </ul>	100%
<ul> <li>The MDT should meet once each month (best practice) or at least once every two months (minimum standard)</li> </ul>	
<ul> <li>All colposcopists should attend at least 50% of MDT meetings to ensure the timely management of difficult cases and discordant results (minimum standard).</li> </ul>	50%
Attendance at MDT meetings should be recorded (minimum standard)	
<ul> <li>The MDT outcome documented in the patients proforma that is filed in the patients notes, these are sent to the responsible clinicians by the Coloposcopist secretary for actions to be taken as per recommendation. The minutes and action of the MDT are</li> </ul>	

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	documented, stored on the shared drive and also emailed to the colposcopy team.	
8 To ensure appropriate selection for and quality of	<ul> <li>All women needing treatment should be informed that treatment will be required and their consent, either written or verbal, recorded. *Written consent labels – are placed into the patient's notes; the patient reads signs and prints her name and dates the consent label.</li> </ul>	100%
treatment	<ul> <li>All treatments should be recorded.</li> </ul>	100%
	<ul> <li>All women should be treated in properly equipped and staffed clinics.</li> <li>Clinic staff must always be familiar with the treatment method(s) used</li> </ul>	100%
	<ul> <li>Biopsy should be carried out unless an excisional treatment is planned, when the cytology indicates moderate dyskaryosis or worse, and always when a recognisably atypical transformation zone is present. Pregnancy is an exception</li> </ul>	100%
	<ul> <li>All women should have had their histological diagnosis established prior to destructive therapy.</li> </ul>	100%
	<ul> <li>All women needing treatment must have had a colposcopic assessment</li> </ul>	100%
	<ul> <li>The proportion of women treated at the first visit who have evidence of CIN 2/3 or CGIN on histology</li> </ul>	<u>≥</u> 90%
	<ul> <li>Proportion of women managed as outpatients under local analgesia.</li> </ul>	>80%
	<ul> <li>Proportion of treatment associated with primary haemorrhage that requires a haemostatic technique in addition to the treatment method applied.</li> </ul>	<u>≤</u> 5%
	<ul> <li>The proportion of cases admitted as in-patients due to treatment complications</li> </ul>	<u>&lt;</u> 2%
	<ul> <li>Proportion of treated women with no dyskaryosis on cytology at six months.</li> </ul>	<u>&gt;</u> 90%
	<ul> <li>Ablative techniques are only suitable when:</li> </ul>	
	<ul> <li>the entire transformation zone is visualised</li> </ul>	100%
	<ul> <li>there is no evidence of glandular abnormality (100%)</li> </ul>	100%
_	<ul> <li>there is no evidence of invasive disease (100%)</li> </ul>	100%
	<ul> <li>Cryo-cautery should only be used for low grade CIN and a double freeze-thaw-freeze technique must be used</li> </ul>	100%
	<ul> <li>When excision is used, at least 80% of cases should have the specimen removed as a single sample</li> </ul>	80%
	<ul> <li>For ectocervical lesions, excisional techniques should remove tissue to a depth of greater than 7 mm</li> </ul>	95%
	<ul> <li>Treatment at first visit for a referral of borderline or mild dyskaryosis should be used only in exceptional cases, and only when audit has identified that CIN 2/3 or * borderline in endo are treated on the first visit due to high risk of CGIN/cancer</li> </ul>	90%
		1
	<ul> <li>All women over the age of 50 years who have CIN 3 at the lateral or deep margins and in whom satisfactory cytology and colposcopy</li> </ul>	100%
	appropriate selection for and quality of	colposcopy team.           To ensure appropriate selection for and quality of treatment should be informed that treatment will be required and their consent, either written or verbal, recorded. "Written consent labels – are placed into the patient's notes; the patient reads signs and prints her name and dates the consent label.           • All women should be treated in properly equipped and staffed clinics.           • Clinic staff must always be familiar with the treatment method(s) used           • Biopsy should be carried out unless an excisional treatment is planned, when the cytology indicates moderate dyskaryosis or worse, and always when a recognisably atypical transformation zone is present. Pregnancy is an exception           • All women needing treatment must have had a colposcopic assessment           • The proportion of women treated at the first visit who have evidence of CIN 2/3 or CGIN on histology           • Proportion of treatment associated with primary haemorrhage that requires a haemostatic technique in addition to the treatment method applied.           • The proportion of cases admitted as in-patients due to treatment complications           • Proportion of treated women with no dyskaryosis on cytology atsix months.           • Ablative techniques are only suitable when:           • there is no evidence of invasive disease (100%)           • Croy-cautery should only be used for low grade CIN and a double freeze—thaw—freeze technique must be used           • When excision is used, at least 80% of cases should have the specimen removed as a single sample           • For ectocervical lesions, excisional techniq

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		cannot be guaranteed must have a repeat excision performed to try to obtain clear margins	
		<ul> <li>Women with adenocarcinoma in situ or CGIN can be managed by local excision for those wishing to retain fertility. Incomplete excision at the lateral or deep margins requires a further excisional procedure to obtain clear margins and exclude occult invasive disease</li> </ul>	95%
9	To ensure	<ul> <li>All women are at risk following treatment and must be followed up</li> </ul>	100%
	appropriate and adequate follow up	<ul> <li>All women who do not have negative cytologys after treatment should be re-colposcoped at least once within 12 months</li> </ul>	100%
		<ul> <li>Proportion of treated patients having a follow up cytology within six to eight months following treatment.</li> </ul>	90%
		<ul> <li>The proportion of treated women with no dyskaryosis six months following treatment</li> </ul>	<u>≥</u> 90%
		<ul> <li>Proportion of confirmed (histological) treatment failures within 12 months of treatment</li> </ul>	<u>&lt;</u> 5%
		<ul> <li>If at follow up a high grade cytological abnormality persists, excisional treatment is recommended</li> </ul>	90%
		<ul> <li>If a low grade lesion has not resolved within two years of referral to colposcopy, at least a biopsy is warranted</li> </ul>	>90%
10	To ensure adequate communications with referring practitioner	<ul> <li>Proportion of results and management plans communicated to the referring practitioner</li> </ul>	>90% within four weeks (best practice) or eight weeks (minimum standard 100%) of patient's attendance at clinic
11	To maintain skill levels	<ul> <li>All practising colposcopists must be able to demonstrate that they have received an adequate training</li> </ul>	
		<ul> <li>All colposcopists in the team should be certificated through the BSCCP/RCOG scheme and should comply with the re-certification process every three years</li> </ul>	
		<ul> <li>All colposcopists must attend one BSCCP recognised colposcopy meeting every three years</li> </ul>	
		<ul> <li>Number of new abnormal cytology referrals managed by an individual colposcopist per annum</li> </ul>	<u>&gt;</u> 50
		<ul> <li>If training unit, number of cases directly supervised by an individual colposcopist per annum</li> </ul>	<u>≥</u> 50

- Information concerning the visit and results of investigations should be communicated to the patient within four weeks (best practice 90%) or eight weeks (minimum standard 100%) of her attendance.
- Clinics operating a 'Select and Treat' policy must ensure that women who are offered treatment at their first visit are sent adequate and appropriate information in

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advance of their appointment, including the possible after effects and restrictions, so they are able to decide whether Select and Treat is appropriate for them.

- Results and management plans should be communicated to the referring practitioner within four weeks of the patient's attendance at the clinic (best practice 90%) or eight weeks (minimum standard 100%).
- Information leaflets should be individualised to each clinic and procedure and should be in an easily readable format.

The Colposcopy Clinic complies with the above standards and has written fact sheets for patients in respect of the following:

- The colposcopy examination
- Advice following a punch biopsy
- LLETZ & Diathermy procedures (these are sent this with their first appointment or when secretary books them for a LLETZ)
- Post LLETZ/Diathermy advice
- Advice following vulval/vaginal biopsy
- Advice following cervical polypectomy
- Insertion of IUS
- HPV testing (this is sent with their first appointment)

#### **Telephone counselling**

- Patients are advised in the written information provided that the clinic staff are unable to discuss individual cases over the telephone due to the Trust patient confidentiality policy
- In the event of a patient being distressed and wishing to discuss the results of investigations, the Nurse Colposcopist (or Lead Nurse in her absence) should be contacted and asked to deal with the situation. However, general enquiries about the examination and issues surrounding colposcopy should be answered as fully as possible, giving reassurance and information in order to reduce anxiety.
- Any qualified member of the nursing team can advise patients over the telephone, and if necessary forward queries to the nurse colposcopists for further advice.
- Any advice or specific anxieties should be documented in the case notes for future reference. It is important to record dates and times as well as any points of discussion.
- In the event of arrangements being made for the patient to return to the department for further examination/management, it is important that this is communicated to senior colleagues and reception staff so that they are aware and can obtain the case notes prior to her arrival.

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#### QUALITY ASSURANCE

The clinic follows the guidance in the NHSCSP Publication 20 (2016) as below:

#### MONITORING AGAINST PERFORMANCE STANDARDS

The following audits are carried out to ensure that the Colposcopy Clinic is achieving the standards set out in Document 20 (NHSCSP, 2016):

#### Colposcopy database audit reports:

The database includes reports as follows:

- Waiting times
- Evaluation strategy reports such as adequate biopsies, untreated CIN and no treatment within 3 months
- Attendance details: Figures for attendance for all procedures during specified dates
- Performance data: Procedures performed in the clinic and figures for the number of new colposcopies performed by each individual colposcopist during specified dates
- BSCCP audit data
- Diagnostic accuracy figures by colposcopist
- Incomplete records: Alert to incomplete data relating to attendance, procedures performed results, plans and notification of results. Also alerts to non-admission for planned inpatient procedure within 3 months of decision to list for surgery.
- These are available through the data system and accessed by the audit and data coordinator

#### Validation of quarterly KC65 return

- The quarterly KC65 is validated and checked for errors before submission to the Regional QA Office.
- Discussion regarding the performance takes place at the monthly colposcopy meeting to feed back the analysis of the data and any necessary recommendations made.

#### Patient satisfaction surveys

- All patients are invited to complete a "Friends & Family Test" on the electronic tablets. This
  asks "How was your Care?" and whether the patient would recommend our service to
  friends and family if they were to need similar care or treatment. There is also a section for
  suggestions as to how the visit could have been made better. There is a tick box for
  anonymity if required.
- The results are collated in the Trust and a summary is published on the Trust Intranet for every area giving details of comments and scores. This information is fed back to staff on a regular basis and any issues raised are discussed and escalated if appropriate. If an issue

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is raised and a change in practice results, a notice is placed on the patient information board to this effect.

• Annual Patient Satisfaction surveys are also carried out. A sample of 100 patients is surveyed and the results collated and shared with the service.

# Environment

• Regular cleaning and environmental audits are carried out by the Estates and Domestic Services departments.

#### **Review and monitoring**

Monthly colposcopy department meetings are held to discuss any issues regarding the service. Planned 3 monthly meetings

Audit of areas of clinical interest

Staff are encouraged to undertake audit and research related to the colposcopy service. Audit proposals are discussed at the monthly colposcopy meeting

# **Multidisciplinary Team meetings**

These are held monthly between the colposcopy teams at the Leicester Royal Infirmary. The meeting is chaired by the Hospital Based Programme Co-ordinator. Colposcopists are required to attend 50% of the meetings annually.

A pathologist and cytopathologist are either present at the meetings or take part via video or phone link.

# Colposcopy MDT referral criteria.

- Smear histology discrepancy
- Smear /Colposcopy discrepancy
- Histology/Cytology review
- All HGCGIN
- TOC with high grade abnormalities
- Difficult management cases

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# CLINICAL GUIDANCE

The Colposcopy service follows the guidelines in the NHSCSP Publication 20 "Colposcopy and Programme Management" (2016)

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

# GENERAL PRINCIPLES

# Accreditation of Colposcopists

Colposcopists must complete their training and satisfy the requirements of the joint body of the British Society for Colposcopy and Cervical Cytology (BSCCP) and the Royal College of Obstetricians and Gynaecologists (RCOG) in order to become accredited colposcopists. Once accredited, 3-yearly application for reaccreditation and attendance at a colposcopy-related course or conference is required in order to remain on the BSCCP register of colposcopists.

It is the responsibility of the individual to ensure that they remain accredited and the Lead Colposcopist should maintain records for all colposcopists working in their department.

# Performance of diagnostic and therapeutic colposcopy

• Colposcopy must be performed by a BSCCP certified colposcopist or a BSCCP registered trainee under direct or indirect supervision.

#### Colposcopy is a subjective test that has a number of recognised limitations

- It is only satisfactory if the whole the cervical TZ is visible
- It is unreliable when there has been previous treatment

#### Documentation should be adequate

The following data should be recorded at the colposcopic examination:

- Reason for referral.
- Grade of cytological abnormality.
- Whether the examination is satisfactory. This is defined as the entire squamo-columnar junction being seen, and the upper limit of any cervical lesion also being seen.
- The presence or absence of vaginal and or endocervical extension
- The colposcopic features should be recorded.
- The colposcopic impression of lesion grade.

#### Care should be taken not to overlook invasive disease

- The most recent cytology result should be available to the colposcopist prior to commencing the colposcopic examination
- In the following situations, *excisional* form of biopsy is recommended:
- Colposcopy UHL Gynaecology Guideline

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- High grade cervical glandular changes on cytology
- Low grade Colposcopic change is associated with severe dyskaryosis or worse
- The Coloposcopist should be aware of the small risk of occult invasive or glandular lesions which are more likely when there is high grade cytological or colposcopic change (CIN 3)
- When a lesion extends into the canal (sufficient canal should be removed in these situations)
- Reasons for not performing an excisional biopsy in these circumstances should be recorded
- Biopsy should be carried out when cytology indicates persisting moderate dyskaryosis or worse, and always when a recognisably atypical transformation zone is present.

# *NB: Pregnancy is an exception – please refer to section on pregnancy*

# Colposcopic positive predictive value for high-grade disease (CIN 2 or worse) should be at least 65%

• Colposcopist should be able to differentiate high-grade (CIN 3 and CIN 2) lesions (intraepithelial or otherwise) from low grade in order to avoid missing advanced disease and to reduce over-treatment for low-grade lesions.

# Biopsy is not indicated in every case of cytological abnormality

- Biopsy not needed when there is LG cytology and negative colposcopic findings.
- When there are LG cytological and low grade colposcopic findings then biopsy should be considered but is dependent on clinical situation.
- When there are HG cytology and abnormal colposcopic findings, biopsy is mandatory.

# Directed punch biopsy

- Colposcopist should be mindful that punch biopsy may miss high grade disease. Associated cytological and colposcopic findings are as important as the result of directed biopsy.
- Correlation is indicated when there is a discrepancy between the index screening result, colposcopy and/or biopsy. Discussion at MDT is recommended.
- Punch biopsy is contra indicated when there is suspected glandular cancer or during pregnancy
- All patients with abnormal cytology must have punch biopsies taken prior to local destructive treatment and the result of the biopsy should be available.
- The Colposcopist should analyse the results of cytology, colposcopy and biopsy before selecting a destructive method for treatment.
- If a biopsy is inadequate for histological interpretation, it should be repeated
- Destructive treatment should not be used in the presence of CIN or CGIN

# Excisional cervical biopsy (loop biopsy) using loop diathermy (LLETZ)

• LLETZ aims to remove cervical abnormality by excising the visible abnormality and the cervical TZ to a depth of at least 7mm.

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- It can be performed in the colposcopy clinic using loop diathermy or under general anaesthetic in theatre using either a knife or loop diathermy
- It is not necessary to remove an IUS/IUD to perform treatment.
- It is essential to ensure there is no risk of pregnancy prior to LLETZ.
- It is indicated when:
  - Biopsy proven HG CIN
  - o Select & Treat: HG Smear and HG CIN clinically at 1st visit
  - High grade smear & whole TZ is not visible
  - Failure of previous treatment for HG disease
  - Is contra indicated when the patient is pregnant and presents with suspicions of glandular disease

# Management of abnormal glandular abnormalities

- Screening samples reported as showing a glandular abnormality (atypical glandular cells of endocervical origin) are prioritised as urgent referrals requiring colposcopy within 2 weeks.
- Glandular abnormalities suggestive of an *endometrial* abnormality should generate an urgent referral to gynaecology.
- In women over the age of 40 or those with risk factors for endometrial pathology, an endometrial pipelle biopsy should also be taken at the time of the colposcopy/treatment. NB: not al colposcopists are trained to take pipelles.
- CGIN/SMILE can be managed by local excision, particularly if retention of fertility is an issue, as long as excision is complete.
- Incomplete excision at the endocervical margin requires a further excisional procedure to obtain clear margins and exclude occult invasive disease (95%).
- Hysterectomy may be considered if fertility conservation is not an issue.
- Incomplete excision at the ectocervical margin may be managed conservatively following discussion at the MDT Meeting.
- All cases of CGIN or SMILE are routinely discussed at the Colposcopy MDT Meeting.

# Management of suspected malignancy

- If frank carcinoma is suspected on clinical grounds a biopsy should be taken by appropriate means. This may be a punch biopsy or small LLETZ.
- The counselling process should begin in clinic and it may be helpful to inform the patient that a cancer is a possibility. *However, if the patient is unaccompanied this may not be appropriate.*
- The patient should be given a review appointment within 7-10 days. This does not happen, the histology results may not be back within 7 days even if send as urgent.
- If cancer is confirmed on biopsy, the patient should be given the diagnosis by the initial clinician with a Gynae-Oncology Nurse Specialist Nurse in attendance.
- The Gynae-oncology MDT should be informed and the initial staging investigation and follow-up arranged by the CNS.
- If a screening test suggests invasion an urgent colposcopy within should be performed within 2 weeks.
- If, at colposcopy, there is no obvious cancer but an abnormal area is seen and the SCJ completely visible, a LLETZ should be performed. If the SCJ or lesion is not completely visible then a deep LLETZ can be performed if feasible. A cone biopsy or LLETZ under GA should be considered if difficulties. This should be arranged urgently.

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# **Endometrial sampling**

This is indicated in the colposcopy clinic when there is

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

# Management of abnormality in pregnancy

- A pregnant woman with a clinically suspicious cervix should be referred for urgent colposcopy
- Cytology in pregnancy: If an asymptomatic woman on *routine* call/recall has been called for screening and she is pregnant the smear should be deferred until 3 months postpartum.
- Colposcopy in pregnancy: Women referred for colposcopy and then found to be pregnant should be advised to have colposcopy, pregnancy notwithstanding.
- The primary aim of colposcopy for pregnant women is to exclude invasive disease and to defer biopsy/treatment until the woman has delivered. Women seen in early pregnancy may require a further assessment in the late second or third trimester at the clinician's discretion.
  - If CIN 1 or less is suspected, the examination should be repeated 3 months following delivery
  - If CIN 2 or 3 is suspected, repeat colposcopy around 26-32 weeks gestation; if the pregnancy has already advanced beyond that point repeats 3 months following delivery.
  - If invasive disease is suspected at colposcopy and the patient has not been seen by a consultant colposcopist, arrangements should be made for consultant review as soon as possible.

#### Management of Immune suppressed women

This section includes women on immune suppressing medication, transplant recipients and all other forms of immunosuppression *excepting those with HIV infection* 

- Standard: All patients who are immune suppressed should be managed in a centre with demonstrable skill and expertise, with sufficient access to patient numbers to maintain that expertise (100%).
- The screening and management of the immune suppressed woman is a complex area of assessment and management. There must be a compromise between the increased risk of CIN and the additional psychological and physical trauma of assessment and treatment, with due consideration to the co-morbidity of the underlying disease process.
- Standard: All patients with renal failure requiring dialysis should have cervical cytology performed at or shortly after diagnosis (100%).
- Colposcopy should be performed if resource permits. Any cytological abnormality should be treated as a high-grade abnormality requiring prompt colposcopic referral.
- Standard: All women about to undergo renal transplantation should have had cervical cytology performed within a year (100%)
- Co-existing CIN should be managed according to National Guidelines.

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- Women taking maintenance immunosuppression medication post-transplantation who have no history of CIN should have cervical screening as per the National Guidelines for the non-immune suppressed.
- Any abnormal cervical cytology in women taking maintenance immunosuppression medication post-transplantation result should prompt colposcopic referral.
- Any woman with a previous history of CIN should have routine follow-up as recommended immunocompetent population.
- At present this should conform to the recommendations for high-grade CIN.
- Patients with multifocal disease will require expert assessment and management in a centre with expertise in this area.
- The patients should be assessed by cytology, colposcopy, vulvoscopy and biopsy where indicated at least six monthly.

# **HIV positive women**

- All women newly diagnosed with HIV should have cervical surveillance performed by, or in conjunction with the medical team managing the HIV infection.
- Annual cytology with an initial colposcopy if resources permit
- Subsequent colposcopy for cytological abnormality should follow national guidelines
- Age range screened should be same as for HIV negative women.

# Management and Treatment of Cervical Ectropion

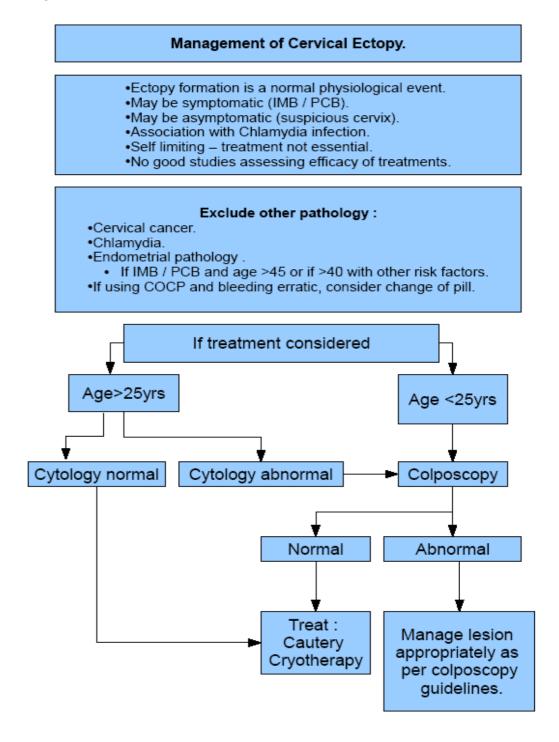
- Patients with symptomatic ectropion e.g. postcoital bleeding or excessive mucous discharge, where CIN has been excluded, may benefit from diathermy cautery to the ectropion.
- A biopsy should be taken prior to diathermy being performed if there has been abnormal cytology or colposcopy.

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#### See algorithm below



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# Management of infections

**Chlamydia:** There is no indication to test routinely for chlamydia and other infections in asymptomatic patients attending colposcopy.

If a patient complains of vaginal discharge or soreness then high vaginal and endocervical sampling is indicated after gaining verbal consent for Chlamydia / gonococcal testing. All women presenting with PCB should be offered chlamydia screening.

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

If asymptomatic then the coil does *not* need to be removed and antibiotics are *not* required If the asymptomatic patient wishes the device to be removed or it is due for removal then it need not be sent for culture. NB: ask about recent sexual activity and DO NOT remove if possibility of recent conception. Repeat cytology is *not* required unless the smear was graded inadequate/ abnormal

If the patient complains of specific symptoms the device may need to be removed, after first ensuring the date of the patients last LMP and that the patient has not had sexual intercourse in the preceding 5 days. These symptoms include:

- pelvic pain
- deep dyspareunia
- intermenstrual bleeding (after 6 months of a device being in situ)
- vaginal discharge, dysuria or significant pelvic tenderness
- Following removal the device should be sent for culture and alternative contraception advised
- A course of antibiotics (such as amoxicillin 250mg tds for 2 weeks in non penicillin sensitive patients or erythromycin 500mg tds for 2 weeks in penicillin sensitive patients) should be given and a gynaecological opinion arranged to ensure that the symptoms or signs have resolved
- Incidental infections:
  - **Bacterial Vaginosis**: if the patient does not complain of a vaginal discharge and is not pregnant then treatment is not required.
  - **Candidiasis (Monilia):** this should be treated if symptomatic.
  - Herpes Simplex: patients with a Herpes Simplex Virus (HSV) infection may already have sought advice/treatment before the screening test was reported. If not, refer to local GUM clinic.
  - Trichomonas Vaginalis (TV): Asymptomatic detection of this protozoon merits treatment cases. Refer to GUM clinic. If screening sample is inadequate it should be repeated.

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# Management of patients with concurrent gynaecological problems

Some patients will present in the colposcopy clinic with an abnormal smear and a concurrent gynaecological problem. The colposcopy clinic is not the ideal setting in which to undertake general gynaecological assessments. There are of course exceptions to this rule and clinical judgement should be exercised. If the problem requires minimal investigation and can be dealt with easily then this should be done while the patient is in the clinic. If more protracted investigation is envisaged i.e. infertility, vulval problem, pelvic pain, etc. then the appropriate referral should be made with an explanation to the patient that as further more specialised investigation will be required, a different clinic visit will be necessary.

In other situations, the actual management of the smear may be influenced by concurrent gynaecological problems. An example of this would be a patient with menorrhagia and CIN. This patient might be more effectively managed by total abdominal or vaginal hysterectomy. If such a case arises counselling can be dealt with in the colposcopy clinic.

There are also circumstances where patients will have been referred to the colposcopy clinic from one of the other clinics as a result of having had an abnormal cervical smear. In general, these patients should be managed as for any new referral. One special instance is in those who are awaiting hysterectomy. Colposcopy in this situation is used to define the limits, if any, of vaginal extension of a lesion. Secondly if invasion is suspected, this should be confirmed or excluded prior to proceeding with hysterectomy as a more radical procedure may be indicated.

# Management of patients with other medical problems

If other medical problems are identified while patients are being assessed in the colposcopy clinic these should be referred back to the 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 GP contacted as soon as possible.

# Consent and Counselling

- Patients will have been given 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 outpatient treatment. However, any risks and side effects should be explained to the patient in order to allow informed consent. If written consent is not taken, verbal consent for treatment under local analgesia should be obtained and documented on the data sheet.
- After any procedure, an explanation of what was found, undertaken and what may or may not be planned should be given to the patient and this should be re-enforced with written information in the case of women who have had an invasive procedure (treatment or directed biopsy).
- Information should be given to the patient about how and when the results will be communicated to her and her general practitioner.
- 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.

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# TREATMENT OF CIN AND CGIN

# Treatment Standards (NHSCSP Document 20)

- Written consent should be taken prior to performing treatment. The consent box should be ticked on the datasheet. .
- When excision is used >80% of specimens should be removed as a single sample
- The histology report should record the specimen dimensions and the resection margin status (100%)
- First visit treatment ("select and treat") should have CIN 2+ in >90% of the excised specimens
- Treatment at first visit for a referral of borderline or low grade dyskaryosis should only be in exceptional cases.
- CIN extending to the margins of excision does NOT justify routine repeat excision providing there is no evidence of glandular abnormality or invasive disease.
- Microinvasive squamous cancer FIGO stage 1a1 can be managed by local excisional techniques if the excision margins are free of CIN or invasive disease
- If the invasive lesion is excised but CIN extends to the excision margin then a repeat excision should be performed to confirm excision of the CIN and to exclude further invasive disease. This should be performed even in those cases planned for hysterectomy to exclude an occult invasive lesion requiring radical surgery.

# **Destructive Treatment (Diathermy)**

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

# Loop diathermy excision (LLETZ)

- Loop excision is the usual and most common method for treating and eradicating (CIN), and is the standard mode of treatment in the colposcopy clinic.
- The procedure should usually be carried out under local anaesthetic (preferably Citanest with Octapressin) wherever possible.
- The area to be treated should be determined using acetic acid and iodine. Usually a medium (15mm or 18mm) loop should be used with view to excising the abnormal area and the TZ.
- Following excision the treated area may receive diathermy ball fulguration.
- If the TZ is large, loop diathermy can be combined with ablative diathermy.
- Single use items are used to perform the excision wherever possible.
- Extended loop diathermy involves a deeper excision of the cervix with view to excising at least 15mms of the endocervical canal. A combination of large, medium and small loops may be needed.

# Knife conisation/cone biopsy

This is performed under general anaesthetic with view to performing either local or extended cervical excision as required. It should be performed either by a BSCCP registered colposcopist or a trainee under supervision by a BSCCP registered Colposcopist.

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# "Select & Treat" (treatment at first visit for patients with likely high grade CIN/CGIN)

- Select and treat is recommended for high grade colposcopic appearances in the presence of a high grade screening abnormality or with patients who are considered likely to default from follow up.
- Treatment at first visit for borderline nuclear change HR HPV Positive or low grade dyskaryosis HR HPV positive should only be performed if there are convincing high grade changes at colposcopy. NB: borderline in ENDO are treated at first visit unless there are no abnormalities seen, scj is visible must be put on MDT to discuss management.

# Inpatient Treatment

- A minority ≤ 15% of patients will require treatment as inpatients, either for clinical reasons or because of patient preference.
- The NHSCSP Document 20 states that the proportion of women managed as outpatients with local analgesia should exceed 80%.
- Patients should be listed for day case on the ward rather than Day Surgery Unit. Arrangements should be made for the patient to attend for pre-operative assessment prior to being given an admission date.
- The case notes should be returned to the Colposcopy Clinic after coding has taken place in order to ensure that follow up is arranged and the results communicated to the patient and GP.
- The colposcopy database will be updated when the patient is listed and an alert will be issued if no admission has taken place within 3 months.

# **Repeat Excision**

This should be reserved for

- Incomplete excision of micro invasive squamous cancer
- Incomplete excision of CIN 3 at the endocervical margin. All women over the age of 50 who have CIN 3 at the endocervical margin and in whom there is doubt about satisfactory cytology and colposcopy follow up should be considered for repeat excision or possible hysterectomy.
- Incomplete excision of CGIN
- Incomplete excision of CGIN at the endocervical margin
- Glandular abnormalities or micro invasive disease with incomplete excision of CIN.
- Incomplete excision managed conservatively with subsequent further abnormal cytology,

# Hysterectomy

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

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• Women who undergo subtotal hysterectomy. The GP should be advised of this in writing including future screening interval.

# TREATMENT COMPLICATIONS

# Primary haemorrhage (within 48 hours of treatment)

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

# Patients on oral anticoagulants

• The patient's INR should be checked the day before the procedure – if it is >2 advice should be requested from the Anticoagulation Clinic.

# Patients within 3 months of venous thromboembolism

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

# Patients with a pacemaker fitted.

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

# FOLLOW UP

# After treatment for CIN

- Women who have been treated for any grade of CIN are offered test of cure 6 months post treatment. This is performed in the community irrespective of the margin status. Exceptions will need to be discussed with Consultant colposcopists.
- A woman will be referred to colposcopy if test of cure shows borderline changes or mild dyskaryosis or normal cytology and she is HR-HPV positive. If the colposcopy is satisfactory and negative she can be recalled in three years
- If test of cure shows high grade abnormalities manage as per high grade abnormalities.
- If a low grade lesion has not resolved within two years of referral to colposcopy, at least a biopsy is warranted.
- Patients > 50 years with incomplete excision of CIN 3 at the endocervical margin should have a repeat excision
- Where there is a discrepancy between the LLETZ result and the previous biopsy result and/or clinical impression the patient will be seen for a repeat colposcopy and screening test (including Test of Cure) 6 months after treatment

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# After treatment for CGIN/SMILE

- Patients with complete excision (or conservative management of incomplete excision) will be followed up 6 months after treatment in the Colposcopy Clinic with colposcopy and ectocervical and endocervical LBC samples.
- HPV Test of Cure will be carried out on these samples.
- If the colposcopy was normal and the cytology is negative, HPV positive *or* negative, the patient will be seen again in the Colposcopy Clinic for a further colposcopy and LBC sampling 12 months later (18 months after treatment).
- At the 12 month appointment, if the colposcopy is normal and the cytology is negative, HR HPV positive, a further 12 month appointment will be given.
- At the second 12 month visit, if the colposcopy and cytology is negative, *HR HPV negative*, the patient will be returned to 3 year recall.
- At any stage of follow up, if the colposcopy and/or cytology is *abnormal*, 10 year follow up should be initiated with further appointments at 6 month intervals initially.

# After a diagnosis of carcinoma

- Patients with 1a1 squamous cell carcinoma which is completely excised will be seen in the clinic in 6 monthly for a colposcopy and smear for 2 years. If all negative for annual smears up to 10 years post treatment with GP.
- Patients with >1a1 squamous cell carcinoma or adenocarcinoma will be managed by the gynae oncology team

# After conservative management of CIN

- Patients with CIN 1 on histology which correlates with the screening result and colposcopic appearances can be managed conservatively. They can be discharged to the community for screening in 12 months.
- Non-correlating cases where there is high grade abnormality on screening or biopsy should be discussed at the Colposcopy MDT Meeting with review of the cytology and histology.
- Patients with non-correlating screening and biopsy and/or colposcopic opinion can be managed conservatively if no high grade lesion is suspected. A repeat colposcopy and LBC sampling will be arranged 6 or 12 months later. Treatment should be considered for persistent low grade change managed conservatively as there may be high grade disease present.

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# After hysterectomy

For women on routine recall and with no CIN in their hysterectomy specimen, no further vaginal vault cytology is required.

Women with less than 10 years recall and no CIN in their hysterectomy specimen, require a single vault smear at 6 months post hysterectomy.

Women with completely excised CIN require vault smears at 6 & 18 months post hysterectomy. Women with incomplete or uncertain excision of CIN should be followed up as if the cervix were still in situ, in the colposcopy clinic.

The responsibility for implementing these follow up policies will rest with the Gynaecologist concerned.

The Gynaecologist should advise the GP in writing that the patient has had a hysterectomy and whether vault screening is required. If it is required the GP should be advised that this will be done in the colposcopy clinic.

# **CEASING FROM CERVICAL SCREENING**

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

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

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

- HPV testing
- Hysterectomy
- Cervical dilatation
- Ceasing from screening
- Cervical dilatation should be considered in all cases where there is a history of high grade CIN, cervical glandular intraepithelial neoplasia (CGIN) or unexplained high grade cytology. If this is not successful, hysterectomy should be considered.
- If a woman chooses to withdraw from screening, the case should be discussed at the colposcopy MDT meeting. The local call and recall services, the Hospital co-ordinator, and the GP must be informed on the management decision. It is advisable that the decision is fully discussed with the women and that this is full documented in the notes, as well in a letter to the women summarising the decision and the relevant factors.

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# DISCHARGE FROM THE COLPOSCOPY CLINIC

Patients will be discharged from the colposcopy service when they have:

- undergone successful treatment for CIN and have been referred back to the community for screening follow up 6 months later
- had conservative management of low grade CIN and have had a follow up negative colposcopy and screening test
- completed the follow up regime for CGIN and have been referred back to the community for routine recall
- been diagnosed with cancer and referred to the Gynae Oncology team for ongoing management
- repeatedly defaulted (see management of default)

At the time of discharge it is essential that GP be fully informed of the patient's current status and what further follow up is required. The summary should also clearly state that if a further cytological abnormality arises, the patient should be referred back for reassessment.

The patient should be advised by letter that she is being discharged from the clinic and advised where and when the next screening test is due.

The call-recall service (CSAS) should be informed monthly of all patients being discharged, with full details of the required screening follow up.

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# **DISCHARGE SUMMARY PROCESS**

This process is for all patients discharged from Colposcopy clinic requiring follow-up smear tests in the community/GP practices. Colposcopy discharge information is sent on a monthly basis to the call and recall service as per the guidelines outlined in the national recommendation. The template provided by the Screening QA Service (Midlands and East) has been adopted and implemented to ensure that only the required and minimum patient information is exchanged and so that unnecessary information is not provided (screenshot below of spreadsheet being used).

The process of obtaining details of discharged patients and preparing the discharge summary is outlined below.

- 1) Clinician/Nurse Specialist to affix patient ID sticker to the Colposcopy Result/Future Management Form and complete procedures/results information.
- 2) Clinician/Nurse Specialist to include following information on the form:
  - •Date patient last seen in clinic
  - •Date next smear due in dd/mm/yy format
  - •Recall interval (e.g. 6/12, 12/12 RR-3yr, RR-5yr) as per NHSCSP protocol algorithm for HPV triage and TOC.
- 3) Colposcopy Result/Future Management Form to be provided to Data & Audit Coordinator.
- 4)Data & Audit Coordinator to input the patient information onto colpsocopy discharge summary excel spreadsheet for given month. Following fields to be completed:
  - •NHS number
  - •Surname
  - •Fist Name
  - •DOB
  - •Last seen in clinic date (day/month/year)
  - •Next smear due date (day/month/year)
  - •Recall Interval (e.g. TOC 6/12, SMEAR 12/12, RR 3yr, RR 5yr)
- 5) Completed discharge summary to be sent to Lead nurse colposcopist for validation.
- 6)Once validated the Data & Audit Coordinator to email the discharge summary for the month to the call and recall centre (CSAS and the CSPL via nhs.net in the first few days of the next month. Confirmation emails for the receipt of the discharge summary from the CSAS(NHS Cervical Screening Administration Services) are saved in the Colposcopy drive.
- 7) A copy of the spreadsheet is saved to the cytology shared hard drive.
- 8) A paper copy is printed and stored in the GP discharge data folder.

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# Protocol for the Safe use of Diathermy in Colposcopy Procedures

# Electrosurgery equipment manufacturers' operating instructions and literature

Manufacturers' operating instructions, educational booklets and video programmes should be read or viewed and thoroughly understood by all personnel, before use of the equipment.

# Patient electrical isolation

When the active electrode is energised in contact with the patient, the whole of the patient's body is available to serve as a return path. Electrical isolation of the patient from the earthed metal parts of the couch and leg supports by means of insulating mattresses is essential. The patients hands must not be allowed to touch any earthed metal when diathermy is in progress and contact with the patient by touching should be avoided. Special care should be taken to safeguard patients who are subject to involuntary movement. A burn occurs when the energy cannot be safely dissipated over a large area. If staff have to touch the patient, contact with the patient using the whole hand may be harmless but fingertip contact could result in a painful burn.

# Preparation of the patient

Colposcopy procedures carried out in outpatient clinic generally involve removal of only the patient's undergarments below the waist. Body piercings, particularly around the operating site, and any metal item nearer than the return electrode should be removed where possible; if this in impracticable, they should be covered with adhesive tape in cross form. Items of large metal jewellery which may prejudice the electrical isolation of the patient by making contact with an earthed object should also be removed.

#### Pacemakers, defibrillators and neurostimulators

Where a patient has an implanted pacemaker, defibrillator or neurostimulator, it is advised to carry out the procedure in theatres as an inpatient under a local so that safety procedures are in place. Where necessary an anaesthetic opinion should be seeked.

#### Attachment of return electrode

Diathermy equipment manufacturers' instructions on attachment and positioning of the return electrode must be followed. To reduce the risk of heat being generated at the point of contact with the patient, the pad should provide a large low impedance contact area on conductive tissue that is close to the operative site. Consequently, the whole area of the return electrode must be in contact with the patient without wrinkles. Surface area impedance can be compromised by excessive hair, adipose tissue and scar tissue. The return electrode should not be attached in the area of prosthetic inserts. If the alternative limb is also not available, use an area nearer to the excision site.

# **Connection of the active electrode**

Where a choice of length of active electrode lead is available from the supplier, choose the shortest length that will allow the lead to run from the diathermy electrode to the connection on the generator. Any surplus lead must NOT be coiled, neither should the lead be looped to clip it to the patient's couch or the generator trolley. Unlooped attachment to support the lead to prevent undue strain on the surgeon's hand and generator connection plug is acceptable. Particular care should be taken to keep the lead away from the colposcope and in no case should it be looped around the surgeon's arm to support it.

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# Inspection and storage of the cutting loop

Before use, the cutting loop should be carefully inspected and not used if the insulation is impaired. A holster of non-conducting material placed within easy reach of the surgeon should be used to house the active electrode when not in use. It should be kept clean and dry. Under no circumstances should the diathermy loop or coagulation ball be energised away from the excision site.

#### Electrical isolation of the nursing staff and clinician when the electrode is energised Nursing staff

As a general rule, nursing staff should avoid touching the patient when the electrode is energised. If contact is essential, this should be by firm whole hands not tips of fingers. Care must be taken not to allow contact with the earthed couch frame while touching the patient.

# <u>Clinicians</u>

The wearing of surgical gloves does not provide an effective means of isolation for the clinician during electrosurgery. Consequently, clinicians should isolate their arms, head and feet from the earthed couch and base and supporting column of the colposcope. A range of insulated electrosurgical accessories is available from appliance manufacturers to assist in providing effective isolation. The unused hand should not touch the patient when at rest. Although the eyepiece of the colposcope is plastic, the metal supporting tube should not be touched. If a teaching arm is fitted to the colposcope, the observer must take similar isolation measures to the clinician.

#### Smoke evacuation

A dedicated filtered evacuation system should be used to remove surgical smoke in order to allow clear observation of the excision site and removal of the potential health risk to personnel. The hospital vacuum system should not be used for this purpose. Recent research quoted in the *Archives of Dermatology* claims that viral transmission via surgical smoke had been demonstrated.

#### Precautions in the use of swabs and solutions

During electrosurgery it is normal for sparking to occur at the active electrode. These sparks are easily able to ignite fluids which have low ignition temperatures, and dry swabs and drapes. It is therefore important that spirit based fluids are not used for skin cleaning, disinfection or preparation of patients, particularly when other easily ignited materials such as dry swabs or drapes are used. When lubrication is required, use lubricants that are water based.

#### References:

Guidance Notes on the Safe Use of Diathermy Loop Excision for the Treatment of Cervical Intraepithelial

Neoplasia. NHS Cervical Screening Programme, 2004 (NHSCSP Publication No 4)

MDA Safety Notice SN 2000(17) Use of Spirit-based Solutions During Surgical Procedures Requiring the Use of Electrosurgical Equipment.

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August 2019	3	Vishanthi Shesha	<ul> <li>Management of Borderline nuclear changes in endocervical ells.</li> <li>Management of women over 50 with deep and lateral margins involved with CIN2 and above.</li> <li>SOP for induction of new colposcopists and trainees.</li> <li>Safe use of diathermy in Colposcopy.</li> <li>Discharge summary process.</li> </ul>			
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