Standard Operating Procedure: UHL Gynaecology Procedures for Diagnostic Outpatient hysteroscopy

University Hospitals of Leicester NHS Trust

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Contents

1. Introduction

This SOP is intended for the use of clinicians and nursing staff who are involved in providing diagnostic hysteroscopy services.
This document will facilitate a dedicated women-centred outpatient service for the patients requiring hysteroscopy as a Gynaecological investigation or on two weeks wait pathway.

Standard 1: Scheduling and listing

Procedure referrals are to be accepted from Gynaecology **outpatient**, on a standard peach referral form which includes referral source, patient's name, procedure, comorbidities and other relevant information (appendix 1) or **from primary care under two weeks wait referral pathway (appendix2)**

The referring consultant retains overall responsibility for the patient's ongoing care and responsibility for reporting results, arranging any subsequent treatment, intervention or follow up in case of clinic referrals.

For patients on a 2 week wait cancer pathway, the consultant performing the procedures retains the responsibility of the patients unless there is prior agreement with the head of the

service.

Inclusion criteria:

Patients should be listed for an outpatient hysteroscopy procedure only if they can tolerate vaginal examination, in the outpatient setting. They should have been offered the choice of having procedure in outpatient setting versus in theatre with sedation/regional/general anaesthetic as appropriate clinically.

Inclusion criteria: Mirena IUS insertion/removal/replacement

- IUCD /IUS may be fitted with specific consent from the patient following directed endometrial biopsies, resection of polyps or fibroids for the following indications
- Licensed indications for IUS:
    - Contraception
    - Treatment of heavy /problematic periods
    - For endometrial protection alongside estrogen hormone therapy
- Unlicensed uses of IUS include:
    - Treatment of Endometrial hyperplasia (recommended in RCOG GTG 67)
    - Endometriosis or Adenomyosis
    - May be considered for high risk patients with recurrent endometrial polyps
    - Confirmed or suspected endometrial cancer and atypical hyperplasia – on the advice of the oncology MDT

Exclusion Criteria: The following patients may not be suitable for outpatient hysteroscopy procedures

Please discuss extensively with the patient and document the consultation in the following situations

1. Difficult speculum and smear examination (vaginoscopy may still be possible)
2. Previous history of sexual abuse, perineal trauma, extreme dyspareunia (vaginoscopy may be possible)
3. History of fainting during menstrual period or previous smears or coil insertions
4. Unprotected intercourse with a fertile man within preceding 2 weeks of procedure date in a premenopausal woman (defined as <12 months amenorrhea). A negative pregnancy test in these circumstances does not exclude pregnancy and therefore the procedure must be deferred.

- Known uncontrolled epileptic (LA and pain may precipitate seizure)
- Severe mobility issues (unless pre-arranged with ward and operating clinician and double slot booked)
- Weight exceeding limits of couch (200kg)
- It may be feasible to perform the procedures even if there are some relative contraindications, but please ensure you document consent carefully with a nurse/HCA witness and pay

particular attention to patient experience and abandon the procedure if she is not coping.

Booking Process

1. The patient should be provided with the appropriate leaflets which will be posted to the patient along with their appointment.
2. The patient is encouraged to take pain killers prior to the appointment.
3. The patients should be encouraged to eat prior to the procedure to reduce the chance of fainting
4. The lists are to be scheduled in accordance with CMG policy of the waiting lists. The patient notes should be made available for the procedure and procedures should not be performed without a proper and sufficient record available.
5. A bridging plan for thromboprophylaxis is NOT REQUIRED for patients undergoing a diagnostic hysteroscopy and biopsy in theatre or in outpatient setting.
6. The list should be appropriately published including patient name, hospital number, procedure and any extra information as additional comments e.g. latex allergy or medical comorbidity.

Standard 2: Procedure: Personnel and equipment

- Outpatient hysteroscopies are to be performed in a dedicated area appropriately staffed with trained practitioners or supervised trainees.
- There is a minimum of three personnel during the procedure. These include one skilled practitioner(Hysteroscopist) , assisted by one staff member with appropriate training for assembling and handling hysteroscope , and one health care assistant as patients' advocate and support.
- The procedure should be performed by a competent practitioner adequately trained to perform these procedures or a trainee under the supervision of a competent practitioner. The preparation of the treatment room should be in line with cleaning of theatre guidelines regarding infection control.

Standard 3: Pre-procedure checks

- Appropriate skill mix of workforce is to be confirmed prior to the start of the list. The patient notes, appropriate sets of adequate hysteroscopes and devices, vaginal trays, prepacked drapes and supplies need to be confirmed prior to the list commencing. An extra hysteroscope should be available on standby for the list.
- BMI will be calculated for all new patients
- Pregnancy/risk of pregnancy has been excluded:

Healthcare practitioners can be reasonably certain that a woman is not currently pregnant if any one or more of the following criteria are met and there are no symptoms or signs of pregnancy:

- She has not had intercourse since the start of her last normal (natural) menstrual period, since childbirth, abortion, miscarriage, ectopic pregnancy or uterine evacuation

for gestational trophoblastic disease.

- She has been correctly and consistently using a reliable method of contraception. (For the purposes of being reasonably certain that a woman is not currently pregnant, barrier methods of contraception can be considered reliable providing that they have been used consistently and correctly for every episode of intercourse.)
- She is within the first 5 days of the onset of a normal (natural) menstrual period.
- She is less than 21 days postpartum (non-breastfeeding women). She is fully breastfeeding, amenorrhoeic AND less than 6 months postpartum.
- She is within the first 5 days after abortion, miscarriage, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease.
- She has not had intercourse for >21 days AND has a negative high-sensitivity urine pregnancy test (able to detect hCG levels around 20 mIU/ml).

- A team briefing should be completed prior to the start of each procedure in accordance with the LocSSIP checklist. (Appendix). Additional procedures will be discussed to ensure equipment availability (e.g. smears, swabs, IUS)
- The patient's name, date of birth and address will be confirmed with the patient prior to labeling the specimen pot and histology form.
- Throughout the procedure, patient's privacy and dignity is to be maintained. It should always be remembered that patient is awake and all the conversation should be appropriate and confidentiality is to be maintained all the time. At any time, the procedure should be abandoned if patient is unable to tolerate the procedure or becomes unwell and concerns may be raised by any member of the team.
- The patient's name, date of birth and address will be confirmed with the patient prior to labelling the specimen pot and histology form.

Standard 4: Patient pathway:

1. Meet and greet. Height, weight and BMI are recorded for new patients and urine sample taken for a pregnancy test on all women who are sexually active with a man unless she has at least 12 months amenorrhoea (post-menopausal).(see pre-procedure checks above) Patients with latex allergy will be highlighted and preparations to the treatment room will be in accordance with the Latex Allergy Policy (appendix4)
2. The patient is seen in clinic by HCP and consented
3. The setup of all equipment for the procedure should be completed prior to the arrival of the patient in the treatment room.
4. Patient is taken to the changing area to change into a hospital gown
5. The team will be introduced.
6. Patient will be invited into the treatment area and her name date of birth and address are confirmed for the histology sample pot and form. The procedure is confirmed with the patient including any additional procedures. Patients may bring a friend or relative into the treatment room for support at the operator's discretion.
7. The patient will be seated on the procedure couch and the couch adjusted into the best

position for the doctor and patient, maintaining her dignity.

8. The perineum and/or cervix are cleaned with antiseptic/saline solution if necessary.
9. A vaginoscopic approach should be performed whenever possible and local anaesthetic is not routinely required unless dilatation is needed. Choice of the anesthetic agent is at the individual preference of the operating practitioner and dependent upon comorbidities.
    a. Lignospan/Cytonest with a dental syringe provides easier administration and higher volumes of local Lidocaine can be used with adrenaline.
    b. Adrenaline can increase the risk of unwanted side effects. Lidocaine without adrenaline is available for use with a standard syringe and blue/orange needle and allows for aspiration to avoid inadvertent intravascular injection.

    Adrenaline should be avoided in patients with cardiac arrhythmia or epilepsy.
10. The maximum volume of local anaesthetic which may be administered is dependent on the weight of the patient, the concentration of the anaesthetic and whether or not adrenaline is used.

Drug	Concentration (mg/ml)	Maximum dose (mg/kg)	Maximum volume (ml)								
			35 kg	40 kg	45 kg	50 kg	60 kg	70 kg	80 kg	90 kg	100 kg
Lidocaine **1%**	10 mg/ml	**3 mg/kg**	10.5	12	13.5	15	18	20ml (200mg)			
Lidocaine **2%**	20 mg/ml		5.25	6	6.75	7.5	9	10ml (200mg)			
Lidocaine **1%** *with Adrenaline (1:200000)*	10 mg/ml	**7 mg/kg**	24.5	28	31.5	35	42	49	50ml (500mg)		
Lidocaine **2%** *with Adrenaline (1:200000)*	20 mg/ml		12.25	14	15.75	17.5	21	24.5	25ml (500mg)		
Prilocaine **1%**	10 mg/ml	**6 mg/kg**	21	24	27	30	36	40ml (400mg)			

11. Entonox should be readily available should patient need or request it.
12. Smallest diameter hysteroscopes should be used as far as possible. Use of operative hysteroscope if available is recommended for targeted biospies or retrieval of coils.
13. Standard operating pressures for outpatient hysteroscopy are between 80-100mmHg. **Occasionally pressure may need to be increased to reduce bleeding but should never exceed 140mmHg**. The practitioner will be mindful of the pain experienced by the patient and if excessive at higher pressures, either reduce the pressure, give Entonox or abandon the procedure.
14. All the specimens are appropriately labeled with the patient sticker. The patient details will be confirmed with her by the HCA (runner) before attaching the sticker to the pot and verified with the operating practitioner. The operating practitioner completes all histology forms and addresses them to the patient's original referring Gynaecology consultant who will maintain overall responsibility for the patient's ongoing care.

15. Digital photographs will be taken, clearly marked with the patient details and date and attached securely in the patient notes in accordance with CMG policy.
16. The traceability stickers for the device and operating sets are attached to the documentation sheet.
17. Documentation of the procedure will be completed on the pro forma and will include any abnormalities, concerns or recommendations.
18. Once the patient is ready, she will be escorted back to the changing area to re-dress and thence to the consultation area.
19. The operating practitioner will debrief the patient following the procedure along with any further management plans and need for further procedures e.g. Polypectomy or ablation procedures.
20. The discharge letter is dictated by the operating practitioner along with a letter to the originating consultant where necessary. The originating consultant retains overall responsibility for the ongoing care of the patient and will write to the patient with her results. However, the operating practitioner has their own duty of care to ensure the results are actioned where necessary. In case of 2WW clinic, person undertaking the clinic responsibility for the day is responsible for results and further correspondence.
21. The HCA will escort the patient back to the waiting room prior to the patient leaving the department. Refreshment may be offered depending upon need. The patient will wait for 10-15 mins before leaving the department to ensure she is fully recovered from the procedure.
22. The patient can be discharged anytime when she feels ready.

Standard 5: Monitoring During Anaesthesia

Most diagnostic hysteroscopy patients do not need routine local anaesthesia. However following guidance is available where needed.

All patients undergoing a local anaesthetic procedure are monitored according to the Royal Association of Anaesthetist and Department of Anaesthetist guidelines.

	ACTION	**RATIONALE**
(a)	All patients will have vital signs recorded prior to commencement of procedure	To ensure the patient does not have any adverse reactions and following the Association of Anaesthetist guidelines.
(b)	Patients undergoing **Local anaesthetics and Endoscopy procedures** will have the following parameters measured: • Blood Pressure • Pulse oximetry • Height • Weight All of the above must be available within the department	All patients undergoing local and regional anaesthesia will require the same standard of care and monitoring, ensuring any adverse reactions are identified and acted upon immediately.

Standard 6: Care of equipment and treatment room

- Reusable equipment is to be sent to the sterilization hub or the sterilization services

department (SSD) for offsite cleaning, in preparation for use again.

- Equipment is to be appropriately audited (completed information sheet allocated to the item) /wrapped/ bagged and labeled, then transported to the SSD hub for collection.
- Clean items are to be collected from SSD from the allocated shelving
- Single use items are disposed of according to hospital policy
- All hard surfaces used are to be cleaned with the chlorclean between each case
- Camera head and light leads are cleaned with high grade disinfectant wipes between each case. Separate light leads to be used where possible.

Standard 7: Transport of Specimens from the Hysteroscopy clinics to histopathology laboratory

HCA Runner must ensure that:

- The tissue sample pot is correctly labeled after demographics verification with the patient (or her representative if does not have mental capacity), confirming that this correlates with the label on the pathology request form.
- The details of all the samples sent are recorded in the clinic book
- Ensure the pathology pot contains sufficient preservative (formalin) to preserve the tissue sample. This must cover all the tissue.
- Secure containers with fluid and tissue tightly for transportation to avoid leaks.
- Place label on the container and not on the lids
- Use a bio hazard label on any container that may be potential harmful to the laboratory team
- Mark pathology request forms for urgent (2WW) processing with red “2WW” ink stamp and place in ORANGE bag
- Ensure samples are collected by UHL porter service.

Standard 8: Management of unexpected events

A Hysteroscopy is a very safe procedure. However, complications can and do occur which include:

A. Fainting or dizziness (vasovagal reaction)

B. Extreme pain discomfort while performing the procedure

C. Confirmed or suspected uterine perforation, bowel, bladder or blood vessel injury

A. Vasovagal Episode

1. Cervical manipulation or dilation can result in vaginal stimulation of the parasympathetic system. This results in bradycardia and vasodilatation causing fall in blood pressure and fainting.

Vasovagal rates are approximately 1-1.7% & during OPH.

2. Remove scope immediately reassure patient. Most patients recover in a few seconds. Lower head and raise legs to increase venous return from the legs

3. Call for additional assistance

4. Check BP, Pulse, Respiratory Rate and oxygen saturation

5. Consider oxygen, IV access and a 12 lead ECG if effects of vasovagal prolonged.

6. Look for adverse signs:

- Systolic BP<90
- Heart rate<40
- Ventricular arrhythmia

7. If persistent adverse signs present: Start oxygen

8. Obtain IV access

9. Medical Staff to administer Atropine 500mcg IV stat and start IV fluids

10. If no satisfactory response call Resuscitation Team and follow algorithm

11. In rare cases where effects of vasovagal are profound or prolonged follow:

Adult Bradycardia Algorithm

B. Extreme pain

- If patient experiences severe pain during administration of local anaesthetic, stop injection and allow pain to settle as the injection takes effect. Reassure patient. Further injections are likely to be less painful. If patient continues to find this excessively painful – offer patient Entonox or abandon the procedure.
- If patient finds cervical dilatation painful stop dilatation – infiltrate further LA into the cervix up to maximum dose – See chart in main guideline. Allow time for the LA to take effect
- If the patient finds the pressure of the saline painful (cramping pain) – consider reducing the intrauterine pressure. Standard operating pressures are between 80-100 mmHg. Occasionally pressure may need to be increased to reduce bleeding but should never exceed 140mmHg. The practitioner will be mindful of the pain experienced by the patient and if excessive at higher pressures, either reduce the pressure, give Entonox or abandon the procedure.
- If at any point the patient requests for the procedure to stop – the practitioner will do so.

C. Confirmed or suspected uterine perforation, bowel, bladder or blood vessel injury

- If uterine perforation is suspected the procedure will be abandoned, a full assessment undertaken and set of observations and consideration will be given to the need for admission for observation/further investigation
- If there was no evidence of bowel, bladder or blood vessel injury at the time of the perforation, the patient is well and reasonably comfortable, she will be prescribed oral broad spectrum antibiotics and analgesia as required
- Where vaginal or cervical injury occurs, this may be managed conservatively if minor or with

sutures or packing of the vagina and admission with antibiotic cover or transfer to theatre as appropriate.

- Where visceral damage is suspected or confirmed – admit for observation and discuss further management with the on call general surgical or urological team.
- Where vascular damage is suspected or confirmed – admit for resuscitation, observation and treatment as required, liaising with the vascular or interventional radiology team if necessary.

Standard 9: Privacy and Dignity

Staff must respect a patient's privacy and dignity at all times. All patients have the right to individualised care when undergoing treatment.

	ACTION	RATIONALE
(a)	• Local Anaesthetic Patients may retain dentures, spectacles, wigs, false limbs etc. All information regarding the above must be documented on the patient care plan and the procedure team informed.	• This protects patient's dignity when they are feeling vulnerable. The team will be made aware of any potential hazards.
(b)	Patient's religious and ethnic culture must be respected and their wishes granted when practicable.	All patients are to be treated equally irrespective of their religion or ethnic culture.
(c)	Patients will not be left unattended in the treatment and resting area.	To provide support and protect the patient from any misadventure.
(d)	In Treatment Room • The patient's clothing and / or sheet is to remain in place until the last possible moment. • Skin exposure must be kept to a minimum but sufficient to allow appropriate skin preparation and draping.	To protect the patient's dignity when they are unable to do so for themselves.

2. Monitoring Compliance

It is recommended that the service undertake regular audit, service evaluation and patient satisfaction questionnaires to assist in assessing the quality of the service.

3. Education & Training

None

4. Supporting References

1. Best Practice in outpatient hysteroscopy RCOG/BSGE joint guidelines March 2011 (accessed December 2023)

https://www.rcog.org./gtg59hysteroscopy.pdf

2. UHL theatre guidelines
3. UHL infection prevention guidelines

For all procedures include reference to NatSSIPs and the UHL Safer Surgery Policy:

National Safety Standards for Invasive Procedures, NHS England 2015:
https://www.england.nhs.uk/patientsafety/wp-content/uploads/sites/32/2015/09/natssips-safety-standards.pdf
UHL Safer Surgery Policy: B40/2010
UHL Sedation Policy: Safety and Sedation of Patients Undergoing Diagnostic and Therapeutic Procedures B10/2005
UHL Consent to Treatment or Examination Policy A16/2002
UHL Delegated Consent Policy B10/2013
UHL Guideline: Anticoagulant Bridging Therapy for Elective Surgery and Procedures B30/2016

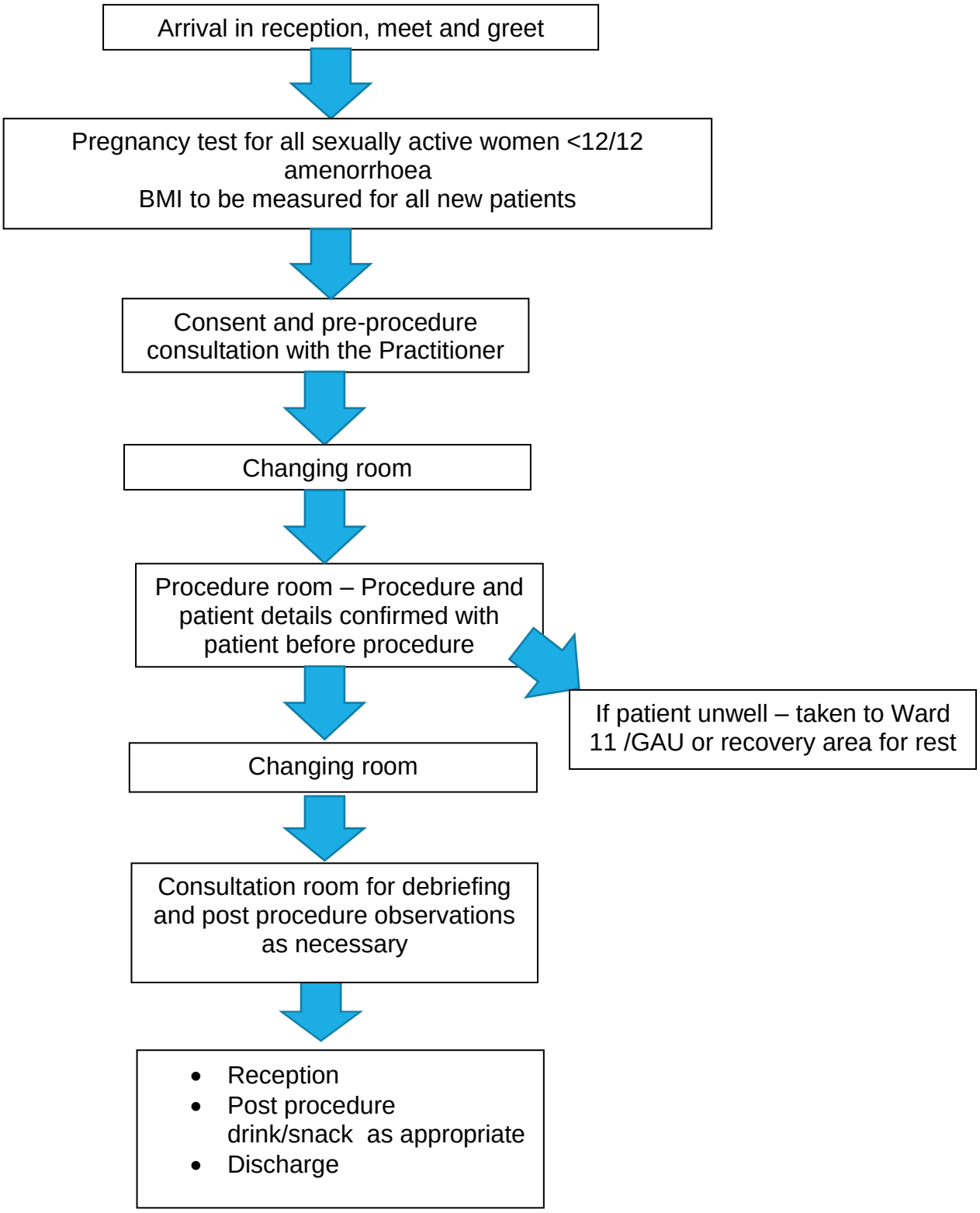
5. Key Words

Vaginal examination

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

CONTACT AND REVIEW DETAILS			
SOP Lead (Name and Title) Olivia Barney - Consultant			**Executive Lead** Chief Nurse
Details of Changes made during review:			
Date	**Issue Number**	**Reviewed By**	**Description Of Changes (If Any)**
November 2019	**1**		**New document**
December 2023	**2**	**Olivia Barney Gynaecology Governance Committee UHL Women's Quality & Safety Board**	Changed referral form colour from green to peach. Added sedation and regional to anaesthetic options in hospital. Added Endometriosis or Adenomyosis as criteria for unlicensed use of IUS Added pregnancy exclusion criteria Added record BMI for new patients Added LA weight related dosing Added consent to be taken by HCP Added Where vaginal or cervical injury occurs, this may be managed conservatively if minor or with sutures or packing of the vagina and admission with antibiotic cover or transfer to theatre as appropriate.

Appendix 1: Patient flow pathway



Appendix 2: Referral form
(PEACH PAPER)

Women's & Children's Clinical Management Group

DIAGNOSTIC HYSTEROSCOPY CLINIC REFERRAL FORM

CONSULTANT: **URGENT / ROUTINE*** **LRI / LGH / CCH / Melton / Hinckley / L'borough / Lutterworth***

Please note the ongoing care of the patient will remain with the referring consultant to whom all results will be returned to be actioned.

PATIENT DETAILS:	INDICATION(S):	PROCEDURE(S) REQUESTED:
INSERT ID LABEL Telephone number: Patient able to come in at short notice: Yes / No Does patient live alone: Yes / No Transport required: Yes / No Translator required: Yes / No Language	Tick all that apply: o PMB o IMB o HMB o PCB o Suspected polyps / SMF o Suspected Malignancy / ↑ET o Follow up for Hyperplasia o Infertility o Other ..... DIAGNOSIS/REMARKS/COMMENTS	Tick all that apply: o Diagnostic Hysteroscopy o Endometrial biopsy o Insertion* / Removal* of IUS* / Cu IUCD* Assessment for: o Myosure o Ablation to check cavity size/shape/exclude intra-cavity lesions o Other ..... ☐ HOIST REQUIRED ☐ DOUBLE SLOT REQUIRED BMI Patient's weight.....kg Please confirm you have: ☐ ensured adequate contraception before OPH

ADMISSION DETAILS:		Previous Surgery
Holiday dates:		Co-morbidities:
Dates Offered to Patient:	Reasons For Decline:	• Hypertension
1.	1.	• Diabetes
2.	2.	• Cardiac condition
3.	3.	• Arthritis
Date of Procedure:		Current Medications including Warfarin/Heparin (ANTICOAGULANTS DO NOT NEED TO BE STOPPED)
		Allergies

FORM COMPLETED BY CON / REG / SHO* SIGNED ..... PRINT ..... DATE: .....

If not booked by Consultant – was this discussed with referring Consultant? Yes / No - if not; why not .....

PLEASE ENSURE ADEQUATE CONTRACEPTION FOR SEXUALLY ACTIVE PREMENOPAUSAL OR PERIMENOPAUSAL WOMEN (<12/12 amenorrhoea)

Booked by Medical Secretary entering information on HISS within 24hrs of CON/REG/SHO date.

Name:.....

Signature: .....

Today's Date: .....

BREACH DATE

Waiting List Form April 2021

Appendix 3: LocSipps check list
– on all hysteroscopy pro formata

LocSSIP: TO BE COMPLETED BY RUNNER BEFORE COMMENCING PROCEDURE
Confirm pregnancy test performed: YES / N/A
Confirm patient details with patient: YES
Affix same checked sticker to sample pot and histology form: YES
Written consent confirmed: YES **Sign_____**

Appendix 4: Care of Patients with Latex Allergy

Latex allergy patients will receive optimal care within a latex free environment.

	ACTION	RATIONALE
(a)	All staff caring for a patient with latex allergy will be made aware This information will be included on the procedure list	To allow preparation of the peri-operative environment for this patient.
(b)	Staff involved with patients with a latex allergy will have access to information in the following areas: • Latex free folder OPD There should be a nominated latex advisor in each area.	All staff are to have access to latex free information and product guidelines.
(c)	Latex allergy patients should be first on the procedure list. If this is not possible then the area must be prepared following the guidelines below.	To allow for the preparation of the area environment reducing the risk of latex particles being present.
(d)	It is not necessary to empty the treatment room (TR) of fixtures and fittings. During preparation of the TR staff must wear latex free gloves. Preparation must include: • Removal of any visible latex products e.g. gloves or items to be covered with a latex free sheet. • TR should be cleaned in the approved manner. • Damp dust trolleys and bed. • Operating table pads and patient supports that contain latex (or when it is not certain that items are latex free) must have a latex free cover such as bubble wrap. This should be secured with a latex free tape. • Access to TR should be restricted and latex allergy awareness notices must be placed around the area.	To provide a latex free environment in compliance with the Trust's latex allergy policy. To inform staff that the TR is designated latex free.
(g)	Following procedure Patient to resting area prepared for the patient's latex allergy status.	All staff involved to be aware of allergy.