Standard Operational Procedure: Ambulatory Gynaecology Unit (GYN-SOP-002)

Approval

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<th>Approval Group</th>
<th>Job Title, Chair of Committee</th>
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<tr>
<td>Gynaecology Clinical Governance Committee</td>
<td>Chair, Gynaecology Clinical Governance Committee</td>
<td>20th September 2019</td>
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Change History

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QUALITY PROCEDURE

The Ambulatory Gynaecology unit has been set up and running. The unit will start offering Hysteroscopic procedures under local anaesthetic

- Hysteroscopic polypectomy /sub mucous fibroid/directed biopsies resection
- Insertion of Mirena IUS following the above procedures
- Endometrial ablation

Prepared by: Dr Mayura Nisal, Consultant Obstetrics and Gynaecology
Date of first issue: 8th August 2019

This version checked by: Barbara Hutchens, Operational Director Obstetrics & Gynaecology

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1. Scope and purpose

This QMP describes the document for use of clinicians and nursing staff involved in running of the ambulatory Gynaecology unit. This document will facilitate a dedicated women centred outpatient service for procedures mentioned above.

2. Authorised staff

2.1 Nurses after suitable training in MyoSure© and Novasure©.
2.2 Maternity Care assistants after suitable training for MyoSure© and Novasure©.
2.3 Clinicians who are trained to do the procedure according to RCOG guidance.

3. Specimen requirements

3.1 Specimen retrieved during the procedure should be appropriately put in the specimen pot, labelled and sent for histopathology examination.

4. Equipment and special supplies

- The ambulatory Gynecology procedures 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, assisted by one scrubbed staff member with appropriate training for the service, one health care assistant as a runner for managing equipment and 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 direct supervision of a competent practitioner. Ideally they should be performing regular diagnostic outpatient hysteroscopies.
- The preparation of treatment room should be in line with cleaning of theatre guidelines regarding infection control.
- Reusable equipment is to be sent to the sterilization hub or the sterilization services department for offsite cleaning, in preparation for use again.
- Equipment is to be appropriately audited /wrapped/ bagged and labelled, then transported to the SSD hub for collection.
- 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.
5. Standards

5.1 Scheduling and listing

- Procedure referrals are to be accepted from Gynaecology outpatient, 2 week wait clinic or hysteroscopy clinics, on a standard referral letter which includes referral source, patient’s name, procedure, comorbidities and other relevant information.

- The referring consultant will have overall responsibility of reviewing results and making appropriate arrangements for follow up and treatment for patients.

- In the clinic, packs for Myosure as well as Novasure will be kept. Please follow the instructions. The pack will include leaflet and prescription for the patient.

5.2 Inclusion Criteria: Following criteria should be met at the time of initial referral.

Inclusion criteria: Myosure Resection of polyps, sub mucous fibroids and directed biopsies

- Patients should be listed for above named procedures only if they can tolerate vaginal examination, hysteroscopy in the outpatient setting.

- Patients with suspected polyps or sub mucous fibroids (confirmed site, size and consistency) at outpatient hysteroscopy or PMB clinic.

- Patients will have undergone a diagnostic procedure to confirm the presence of the intra cavity lesion and assess ability to tolerate an outpatient procedure

- Patients should not be listed for an ambulatory procedure on the basis of an ultrasound scan suggestive of polyp/fibroid.

5.3 Inclusion criteria: Novasure Endometrial Ablation

- Patients choosing this procedure should have heavy menstrual bleeding as main complaint. These patients should have undergone outpatient hysteroscopy and endometrial biopsy to rule out significant pathology.

- Diagnostic hysteroscopy should document that cavity is regular and cavity is not too small or too big so that procedure is successful.

- There should be no sub mucus fibroids in the cavity.
5.4 Inclusion criteria: Mirena IUS insertion/removal/replacement

- Mirena IUS may be fitted with specific consent from the patient following 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)
  - May be considered for high risk patients with recurrent endometrial polyps

5.5 Exclusion Criteria: The following patients will not be suitable for ambulatory procedures

General Exclusions:

- Unprotected intercourse 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 may precipitate seizure)
- Weight exceeding limits of couch (150kg) (BMI >40 may be booked if speculum was feasible and referrer was able to visualize the cervix)
- On occasions, procedures can be performed in spite of relative contraindications but please discuss with the ambulatory team.

5.6 MyoSure exclusions:

- Sub mucus fibroids larger than 3cm may not be suitable to be done in outpatients. For polyps there will be no limitations on size.
- Patients with congestive cardiac failure which is uncontrolled.(concerns about fluid overload)

5.7 Novasure Exclusions:

- ≥ 3 Previous caesarean sections or any upper segment uterine incision (Transmural myomectomy or Classical CS). Please discuss with the team.
- Significant uterine cavity distortion – by fibroids or uterine anomalies
- Cavity length {sound length MINUS cervical length} is less than 4cm {risk of cervical thermal damage} and greater than 8cm {only top 6.5cm of cavity will be treated}
- Cavity width <2.5cm at the fundus
- Less than 3 months failed medical therapy
- Previous ablation
- Family not complete
- Suspected or confirmed uterine malignancy or hyperplasia within 5yrs
- Proven endometrial hyperplasia
- Untreated CIN
- Symptomatic endometriosis and/or suspected adenomyosis
- Active or suspected sexually transmitted pelvic infection or PID or evidence of systemic infection (e.g. pyrexia)
- Failure rate is higher in women under 40yrs so should be avoided
- Mirena insertion at Novasure not recommended as subsequent removal will not be possible

### 6. Procedure

#### 6.1 Pre-procedure checks

- Appropriate skill mix of workforce is to be confirmed prior to the start of the list. The appropriate set of adequate hysteroscopes and devices, vaginal trays, pre packed drapes and supplies need to be confirmed prior to the list commencing. An extra operative hysteroscope and diagnostic hysteroscope should be available on standby for the list.
- A team briefing should be completed prior to the start of each patient to discuss additional procedures and to ensure equipment availability (e.g. smears, swabs, Mirena IUS)
- 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.
- Procedure should be abandoned if patient cannot tolerate or feel unwell or any of the staff member has concerns.
- The patient’s name, date of birth and address will be confirmed with the patient prior to labeling the specimen pot.
6.2 Patient pathway

- Patient is greeted by member of the staff and accompanied. Urine pregnancy test is performed prior to the procedure unless postmenopausal (amenorrhea for over 1 year).
- Patient is then consented by medical staff and procedure explained.
- The setup of all equipment for the procedure should be completed prior to the arrival of the patient in the treatment room.
- Patient is taken to the changing room to change into a hospital gown.
- Patient will be made comfortable on the couch and identity checks done. Patient can bring partner or a friend to support during the procedure.
- Sterile drapes are used (operator preference) and plastic water collection bag is used for Myosure procedures. The perineum and/or cervix are cleaned with antiseptic solution as necessary.
- The procedure is carried out under local anesthesia (Intra cervical or Para cervical block) for both procedures where dilatation is required. Local anesthetic may not be required if dilatation is not needed.
- Entonox may be available for all patients requiring additional analgesia as required.
- Operating practitioner will select appropriate instrument.
- 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.
- Digital photographs will be taken, clearly marked with the patient details and date uploaded securely on EPR.
- The specimen should be labeled and sent for histology.
- The traceability stickers for the device and operating sets are attached to the consent form.
- Documentation of the procedure will be done on viewpoint and EPR.
- Once patient is ready and changed into own clothes, she will be seen by the clinician again.
- The clinician will explain the findings and if any future recommendation.
- The letter will be dictated to GP, patient and original referring Consultant.
7. Post-operative care

- Post operatively women will rest on the recliners for around 30 minutes before leaving.
- They should not drive back home on the day.
- They can resume normal activities after the procedure.
- They should be made aware of light bleeding for few days and possibility of infection and to contact the GP if develop fever, foul discharge, heavy bleeding, or persistent pain.

8. Potential risks/complications

- Please refer to Outpatient hysteroscopy protocol CG601

9. Dissemination/Circulation/Archiving

- The standard operating procedure will be reviewed by the Gynaecology clinical governance team and any amendment will be made.

8. Training

- There is no mandatory training associated with this procedure but appropriate training for handling the equipment will be provided. If staff have queries about its operation, they should contact their lead consultant the first instance.