Title: **Outpatient endometrial biopsy results; a quality improvement project.**

Date: 4/11/2024

NCT06694246

CLINICAL AUDIT PROJECT PLAN

Please complete this project plan before starting your project.

1. **Short Title of Audit:** | **Outpatient endometrial biopsy results; a quality improvement project.**

2. **Details of Audit Lead**

Audit Lead:	**Name: Islam Elkhateb**	**Designation: Registrar**
Contact details:	**E-mail: islamtarekhamed@gmail.com**	**Phone: 99780408**

3. **Details of Audit Sponsor:**

Audit Sponsor:	**Name: Dr**	**Designation: Consultant**
	Name: Dr	**Designation: Head of department**

4. **Date plan completed:** | **27/10/2024**

5. **Rationale and objectives of the Audit:**

Pipelle is the most commonly used outpatient endometrial biopsy device.
Pipelle endometrial biopsy can diagnose 90% of endometrial cancer cases.
It is one of the first line diagnostic procedure for women presenting with abnormal peri- and post-menopausal vaginal bleeding.
Insufficient samples are obtained in 5-23% of cases.
In our hospital, a retrospective analysis of all outpatient endometrial samples sent to the histopathology department from April- to October 2024 study showed an insufficient sample percentage of 32%This maybe attributed to patients, equipment, and physicians factors.

Our project aims to improve the endometrial biopsy results by Identifying these factors in our hospital setting, Implementing measures to modify them, and finally e-auditing the endometrial biopsy results after six months.

6. **Based on your audit rationale how would you classify this audit?**

This is an external audit ☐ (e.g. National audit)	**This is an internal audit** ☐ (e.g arising from Trust objectives/ risks/ incidents / complaints/ NICE guidelines compliance etc)
This a Division/Service priority √ (e.g. part of Divisional or Team Service improvement priorities)	**This is an individual clinician interest** ☐ (e.g. personal interest, personal development or as part of an educational or training programme)

7. **Background and criteria that will be audited?**

Evidence:

- Blumenthal PD, Berek JS. A Practical Guide to Office Gynecologic Procedures. Lippincott Williams & Wilkins; 2013 Apr 8. Chapter 14, Endometrial Biopsy; P92-98

- Giuseppe Del Priore.Office-based endometrial sampling procedures. In: UpToDate, Connor RF (Ed), Wolters Kluwer. (Accessed on October 21, 2024.)

- Williams PM, Gaddey HL. Endometrial biopsy: tips and pitfalls. American Family Physician. 2020 May 1;101(9):551-6.

Suggested criteria (proforma items):

1. Place the patient in the dorsal lithotomy position.
2. Perform a bimanual examination, paying particular attention to the size, shape, and orientation of the uterus.
3. Insert a speculum and visualize the cervix.
4. Cleaning the cervix with antiseptic solution (eg, povidone-iodine) is performed by some clinicians, but not all. Sterile preparation in patients who are allergic to iodine is discussed separately.
5. If anesthesia is to be used, it is administered prior to any other manipulation.
6. In many patients, an endometrial sampling device can be inserted without grasping the cervix with a tenaculum. Use of a tenaculum increases patient discomfort.
7. A tenaculum should be used if the uterus is not close to axial in position. In such cases, place a tenaculum (with teeth in a horizontal position) on the anterior cervical lip and retract outwardly to straighten the cervicouterine angle. Straightening the uterine axis may reduce the risk of uterine perforation. If a tenaculum is required and a paracervical block has not been given, we may apply a local anesthetic (eg, 2% benzocaine gel or 20% benzocaine spray) to the intended site before placing the tenaculum. Directing the patient to cough while simultaneously applying the tenaculum may also decrease discomfort. Patients scheduled for sampling may be advised to take an NSAID prior to arriving at the clinic.
8. Using steady and moderate pressure, slowly insert the sampling device through the cervical os and on to the uterine fundus. Stop when resistance is met.
9. If the device will not pass through the cervix, attach a tenaculum (if not already in place), and use a series of small (1 to 4 mm) Hegar or similar dilators to gently dilate the canal. An Allis clamp rather than a single-tooth tenaculum may offer some advantages (eg, less bleeding).
10. Many devices are marked with centimeters, so the device can be used to measure the uterine depth. Average uterine length is 6 to 8 cm.
11. Stabilize the sheath with one hand and pull the piston out as far as possible to create suction.
12. Move the device tip along the endometrial surface using a corkscrew rotation combined with a repeating cephalic-caudal motion while maintaining suction.
13. Remove the device when the entire cavity has been sampled. Expel the specimen into a formalin container. If there appears to be insufficient tissue for diagnosis, perform a second pass with the device. The same device may be used if it has not been contaminated; it should not have touched the formalin.
14. Remove the tenaculum, if present. Most bleeding can be controlled with pressure via cotton swabs or a sponge stick. If bleeding persists, use ferric subsulfate (Monsel) solution or silver nitrate sticks to cauterize the site.

Side effects and complications:

1. The most common side effect of endometrial sampling is cramping, which subsides rapidly after the procedure is completed. Cramping tends to be more severe with the higher pressure suction devices than low-pressure devices because the former is more rigid, the suction is greater, and larger samples are removed. Many patients will experience light vaginal bleeding or spotting for several days following the procedure.

2. Vasovagal reactions are not uncommon during endometrial sampling. Such reactions can generally be prevented by allowing the patient to eat and drink before the procedure and by minimizing pain through use of analgesics and, if necessary, local anesthesia. The risk of uterine perforation is approximately 1 to 2 per 1000 procedures.
3. Rare complications include excessive uterine bleeding (especially with undiagnosed coagulopathies), uterine perforation (risk, 0.1 to 1.3 percent), pelvic infection, and bacteremia (including sepsis and endocarditis).

Comtraindications:

1. The only absolute contraindication to endometrial sampling is the presence of a viable and desired pregnancy
2. A bleeding diathesis is a relative contraindication since bleeding may be excessive in such patients
3. In the presence of acute vaginal, cervical, or pelvic infection, the procedure should be deferred, if possible, until the infection has been treated. This does not apply to clinical situations in which the indication for the biopsy is to evaluate for a subclinical infection or perform microbiologic and histologic studies.
4. In rare instances, in which endometrial sampling needs to be performed in a patient with cervical cancer, an obstructing cervical lesion may be a relative contraindication in some patients due to increased risk of bleeding or uterine perforation. Imaging may obviate the need for endometrial sampling in this circumstance.
5. Sampling can be performed with an intrauterine device in place. In our practice, we have done so without complications

N.B.:

- **One approach to improving the tissue adequacy rate** is by using a technique that combines a corkscrew twisting motion and uterine curettage. When using this method, the device is inserted to the fundus and then withdrawn to the lower uterine segment, alternating between a corkscrew twisting motion and the motion usually used to curette the endometrium during a dilation and curettage (D&C). In a retrospective review with uniform pathology evaluation, use of a corkscrew twisting motion and uterine curettage yielded adequate tissue in 95 percent of cases, which was higher than the 77 percent success rate with a corkscrew technique alone
- When using a suction device, do not let the sheath come outside of the external os or you will lose the negative pressure. If you do, simply expel the contents of the sheath into the formalin container or onto a sterile nonadhesive bandage (eg, Telfa), taking care not to contaminate the device, and reinsert the sheath. Multiple passes are sometimes needed to assure specimen adequacy.
- **Anesthesia:** Office sampling procedures can usually be performed without significant pain. Discomfort can be minimized by reassuring the patient, explaining each step before doing it, and avoiding use of mechanical cervical dilators and/or a tenaculum, if possible. Some clinicians recommend an oral nonsteroidal anti-inflammatory drug (NSAID) 30 to 60 minutes prior to the procedure to decrease cramping
- **Cervical preparation and dilation:** Cervical preparation or dilation is not required in many patients, particularly premenopausal parous patients. For those in whom it may be difficult to pass the sampling device without cervical dilation, misoprostol (200 to 400 mcg) orally, per vagina, or both may be given the night before the procedure
- **Endometrial brush:** Several observational studies have compared endometrial sampling results from the endometrial brush with those of an endometrial suction sampling device. In a larger study, 526 pre- and postmenopausal patients were evaluated using both the Tao Brush and the Pipelle. In the postmenopausal patients, endometrial sampling with the brush resulted in a significantly higher proportion of adequate endometrial samples compared with the suction device

8. How will you implement changes and recommendations?

- **A proforma/ checklist maybe put in the procedures room and included with the endometrial biopsy histopathology request. This shall outline the precautionary measures and instructions, as well as the steps of endometrial biopsy procedure.**

- **The topic will be mentioned in the morning meeting.**
- **The topic maybe covered and illustrated in one of the biweekly scientific meetings.**
- **An emai/ message maybe sent to all teams on the OBGYN department group.**

9. Do the audit standards cover the practice of one or more professional groups?

This is a Multi-disciplinary audit	☐	This is an Uni-disciplinary audit	√

10. What data collection method will be used?

Retrospective and concurrent data collection: endometrial biopsy results over the previous six months (April- September 2024) were extracted from the computer system and alaysed.

After drawing receommendations and implementing changes, endometrial biopsy results over the next six months (November 2024- April 2025) will be monitored and audited.

11. What is your sample size?

Name of Service or Team and Division
Interval sampling was the method used for sample size calculation of this audit, in which all results in the specified time periods (April- Septmeber 2024) and (November 2024- April 2025) were included. **429 cases were available for the previous 6 months (April- September 2024). Twhich is more than the sample size required for any prevalence study assuming a 50% prevalence rate and an infinite population (n=384).**

12. What is your planned project timetable

Project Activity	Estimated Completion Date
Date of completiomn of data collection, inputting, and analysis	**31/10/2024**
Proposed date for presentation of results and recommendations for the modification of practice	**4/11/2024**
Proposed date for start of implementation of modifications	**5/11/2024**
Proposed date for re-auditing the results	**May 2025**

13. How will service users or carers be involved in this audit?

Service users are not be involved in this audit since they cannot modify/ control patient factors for insufficient endometrial biopsy results (example: nullipara, menopausal, .. etc)

Project lead: **Project supervisor:**

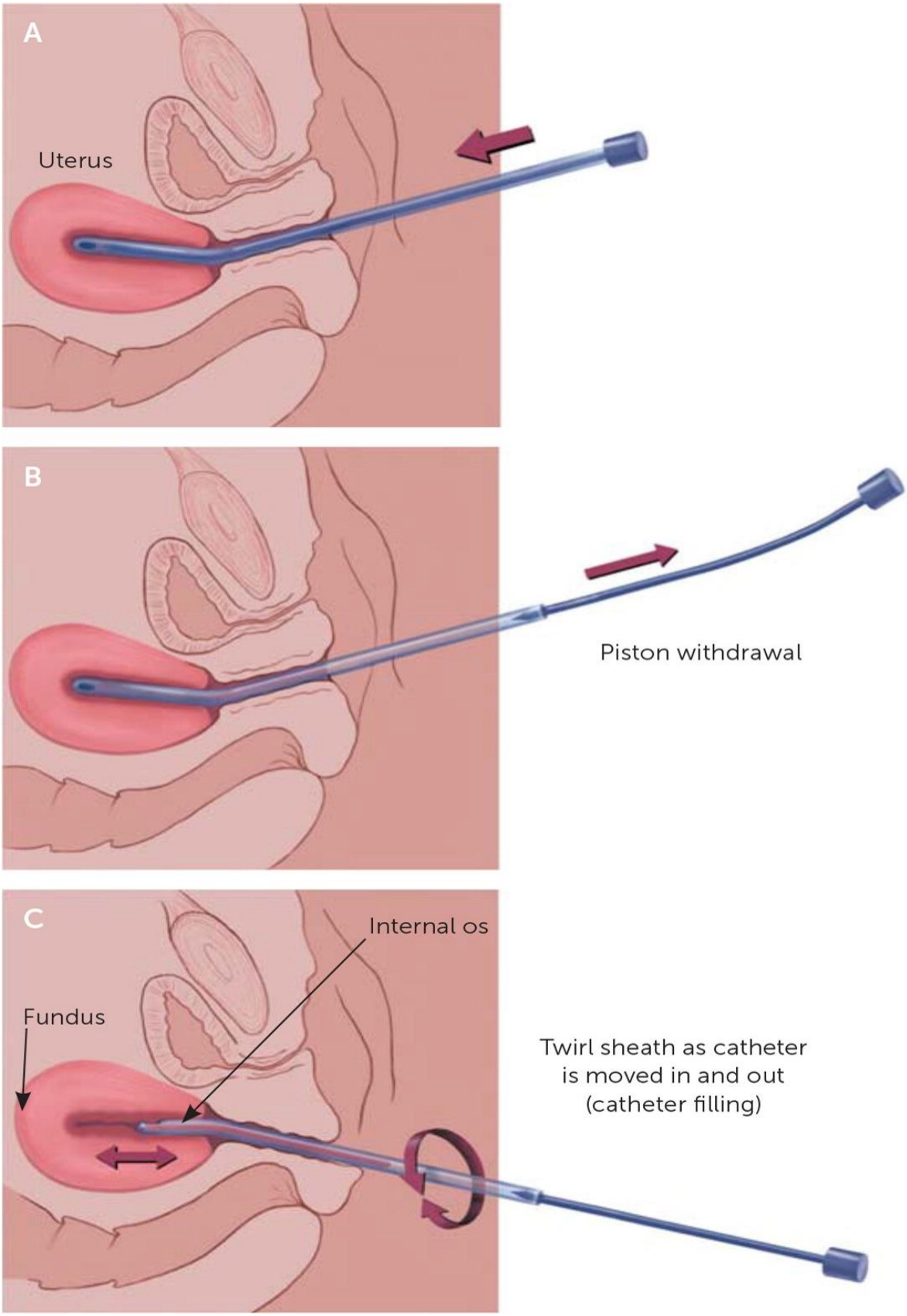
Department head:

Outpatient endometrial sampling checklist

	Before starting the procedure:	√
1.	Patient identity checked Informed consent obtained Equipment checked Proper lithotomy position and exposure.	
2.	No contraindications: pregnancy, acute PID, bleeding diathesis, or obstructing cervical lesion	
3.	Bimanual examination performed with non-sterile gloves, paying particular attention to the position of the cervix, and size and orientation of the uterus.	
	During the procedure:	√
4.	Insert an appropriate-size speculum to visualize and center the cervix	
5.	Optional: Cervix cleansed with antiseptic solution (especially if profuse vaginal discharge)	
6.	Optional: Tenaculum applied in horizontal orientation (especially if cervix is very mobile or cervicouterine angle is very marked (uterus not axial), or dilation/ sounding is needed). **An Allis/ Vulsellum is a better alrenative** (less pain and bleeding)	
7.	Pipelle slowly inroduced through the cervical os on to the uterine fundus using moderate and steady pressure. Stopped when resistance is met. **Pipelle should be inserted 6-8cm to ensure that it is properly placed isnide the uterus**	
8.	Sheath stabilized the with one hand and piston pulled out as far as possible to create suction	
9.	Device tip moved along the endometrial surface using a corkscrew (360’) rotation combined with a repeating cephalic-caudal motion while maintaining suction. **Combining corkscrew motion with the motion usually used to curette the endometrium during D&C improves the sample adequancy**	
10.	Contents expelled into formalin container once the sheath comes out of the external os, taking care not to contaminate the device tip with non-setrile fomalin or container.	
11.	**Second or multiple passes done to ensure sample adequacy**	
	After the procedure:	√
12.	Check side effects: Vasovagal attacks are self-limiting, keep in supine. Painful uterine cramps usually resolve in 12 hours. Bleeding points in cervix controlled with cotton pressure or silver nitrate sticks.	
13.	Patient counselled about red flags: come back if persistent pain, heavy vaginal bleeding, offensive vaginal discharge, fever, and chills.	

Name:

Date:



(A) Endometrial biopsy catheter is inserted into the uterine fundus until resistance is felt. (B) The internal piston is fully withdrawn once the catheter is in the uterine cavity. (C) A 360-degree rolling or twirling motion is used as the catheter is moved between the uterine fundus and the internal os of the cervix