Resources for Women's Health

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Endometrial Sampling Technologies for the Office or Clinic

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The health care provider working in private practice has a wide range of health care technologies from which to choose in diagnosing and managing obstetrical and gynecological problems. Access to a variety of technologies has the potential to help health care providers offer better, more appropriate reproductive health care; however, it can also lead to the overuse of some costly technologies, such as ultrasound, that may only be available from specialists or in hospital settings. Other technologies provide innovative applications that can be utilized in a wide range of settings. For example there are many occasions when endometrial biopsy is appropriate or requested for either diagnostic or sampling purposes. An endometrial sampling technique using vacuum aspiration can be performed in an office or simple clinic setting. This publication focuses on endometrial sampling: a useful technology for resolving some pathologies or circumstances related to a woman's health that can arise at different times during her life.

Endometrial sampling can be performed to determine the potential causes of infertility, to evaluate abnormal uterine bleeding, to diagnose endometrial cancer or hyperplasia, and to monitor the effects of hormone replacement therapy.

Vacuum aspiration is a simple, safe technology that can be used for endometrial sampling, and that, in many cases, can be used as an alternative to sharp curettage or dilation and curettage (D&C), a surgical procedure that requires facilities with operating rooms (Table 1). Using vacuum aspiration as an alternative to D&C offers advantages for both the patient and provider. A vacuum aspiration procedure, performed as an ambulatory procedure in an office or primary clinic (potentially by a non-physician provider), increases accessibility as well as acceptability for most women. By contrast, D&C requires an operating room which increases

Table 1: Comparison of Vacuum Aspiration and Sharp Curettage (D&C) for Endometrial Sampling

Vacuum Aspiration	Sharp Curettage
Uses flexible plastic or metal cannulae	Requires a sharp curette
Does not require cervical dilation	Mechanical dilation often performed
Anesthesia or analgesia optional, depending on patient's need	Paracervical anesthesia or parenteral analgesic often administered
More convenient for patient and provider	—
Lower rate of complications (uterine hemorrhage, infection and perforation)	—
Approximately 1/10 the cost of D&C per procedure	—
Specimens consist of strips of tissue with little blood	Specimens fragmented and mixed with blood
Office or outpatient procedure	Usually needs operating room

the cost of care; furthermore, the woman usually receives general anesthesia, increasing both her risk and recovery time.

Technologies Report

Endometrial sampling devices employing vacuum aspiration provide in-office, diagnostic and monitoring services minimizing the need for procedures requiring D&C.

The use of vacuum aspiration for endometrial biopsy has been well established since Grimes' 1982 analysis of 13,598 sharp curettage procedures and 5,851 procedures using the Vabra vacuum aspirator. By the early 90s, vacuum aspiration had become the standard technology for endometrial biopsy in the United States although sharp curettage is still used (Hulka, 1991).

Safety

The safety advantage of vacuum aspiration over sharp curettage is supported by research on vacuum aspiration for a variety of indications. This body of research spans 30 years, encompasses over 80 studies, and involves more than 500,000 patients (Greenslade et al., 1993). Vacuum aspiration removes less of the basal layer of the endometrium than sharp curettage (Hale et al., 1976; Suarez et al., 1983; Marik and Tatarun, 1984; Hulka, 1988), so that Asherman's syndrome (associated with intrauterine adhesions and traumatic amenorrhea) may be less likely following vacuum aspiration (Grimes, 1982).

Effectiveness

Histologic analyses of endometrial tissue provide health care providers with important information concerning adenocarcinoma, atypical hyperplasia, polyps, submucosal myomas, chronic inflammation, and progestational effect in anovulatory cycles (Baughan, 1993). Aspiration endometrial sampling devices can also be used to monitor the effect of hormone replacement therapy (Kaunitz, 1995).

Vacuum Sources

Endometrial sampling devices achieve suction in one of three ways: a vacuum syringe, an internal piston, or a vacuum pump (Table 2). The Ipas MVA syringe features a locking valve which allows the provider to establish a vacuum before beginning the aspiration procedure. Internal piston devices generate suction that draws a column of tissue into the tube when the piston is withdrawn. Both mechanisms may be manual or electrical and are reusable.

Table 2: Endometrial Sampling Devices for the Office or Clinic

	Vacuum Source		
	Locking-valve Syringe	**Internal Piston**	**Electric or Mechanical Pump**
Characteristics of Use	Flexible cannulae, reusable or disposable; reusable syringe	Entire device is disposable	Cannulae and collection chamber disposable
Sampling Cannulae (external diameter)	Plastic (2-7mm)	Plastic (2-3mm)	Plastic or stainless steel (2-7mm)
Endometrial Samples	60 cc syringe collects large, diagnostically adequate sample with a high ratio of endometrial tissue to blood clot.	Slim flexible device collects small but diagnostically adequate sample	Sample chamber collects specimen; compares favorably with those obtained by diagnostic D&C
Examples	Ipas Gynecologic Aspiration Kits with Cannulae & Syringe Curette	Pipelle, Z-Sampler, Gynosampler, Pipet	Tis-U-Trap, Vabra Aspirator, Masterson Endometrial Biopsy System

Cannula

Ipas 4mm flexible plastic cannulae for endometrial biopsy have two whistlecut apertures near the distal end. Novak's 2-4mm cannulae and Randall's 4mm cannula for endometrial biopsy are reusable and made of stainless steel. These cannulae attach to the syringe via Luer-Loks. Internal piston devices are plastic and usually 3mm in external diameter. Pump vacuum sources use stainless steel or plastic cannulae ranging from 2-7mm in diameter.

Endometrial Sampling with Ipas MVA Instruments

A number of studies evaluating endometrial biopsy performed with MVA demonstrate it to be an effective and safe technology for collecting endometrial samples (Hale et al., 1976; Ladipo, 1976; Suarez et al., 1983; Goldrath and Sherman, 1985; Mateo Sanez et al., 1994).

Tissue samples collected with MVA were consistently adequate for histologic diagnosis (Hale et al., 1976; Ladipo, 1976; Mateo Sanez et al., 1994). Hale found MVA superior to sharp curettage in sampling the cornual regions of the uterus. In Suarez' study, 82% of MVA samples were adequate for diagnosis compared to 76% of those obtained with sharp curettage. MVA samples were judged to be of better quality than sharp curettage samples, as there were larger strips of tissue and a higher ratio of tissue to blood clot in the specimen, facilitating pathologic diagnosis (Hale et al., 1976; Suarez et al., 1983).

Furthermore, MVA was found to be as good a diagnostic tool as sharp curettage in detecting endometrial cancer (Suarez et al., 1983) and, when performed with hysteroscopy, superior to sharp curettage (Goldrath and Sherman, 1985; Suarez et al., 1983).

Mateo Sanez et al. found 92.2% of samples obtained with MVA were adequate, as compared with 84.4% of samples obtained with Novak's cannula.

Endometrial samples obtained with MVA are particularly valuable for research because large samples can be obtained to prepare endometrial cells for tissue cultures. Examination of cell cultures derived from such samples yields valuable insights into various aspects of reproductive physiology, including certain types of infertility.

What is MVA?

MVA is a simple yet effective vacuum aspiration technique. This innovative technology consists of a flexible plastic cannula that is connected to a manual aspiration syringe with a locking valve to perform an endometrial biopsy or a uterine evacuation. MVA is a very effective method and safer than sharp curettage. With the MVA instruments, a qualified health care provider may perform a wide range of ambulatory surgical procedures using the capabilities already available in the office or treatment room. Thus, the patient is not forced to be admitted to a hospital and instead can undergo a safe and effective procedure in a private setting.

MVA Instruments Characteristics

- Manufactured with high quality standards.
- Easy to learn: Each instrument kit contains detailed and illustrated instructions to facilitate learning the operative technique.
- High level of effectiveness, safety and patient acceptability.
- Of practical use in the medical office, clinic and hospital.
- May be used with local anesthesia (paracervical block) so that the patient avoids the risk of epidural or general anesthesia.
- Of great application in ambulatory surgery.
- Portable, not electric.

Combining all these characteristics, MVA yields a significant benefit for both the provider and the patient.

What are the applications of MVA?

MVA's applications in gynecology and obstetrics include the following:

Endometrial Sampling

- Primary or secondary infertility
- Abnormal uterine bleeding
- Amenorrhea
- Hyperplasia
- Endometrial cancer screening
- Chronic endometrial infections
- Monitoring in hormone replacement therapy
- Intrauterine neoplasia

Uterine Evacuation

- Inevitable abortion
- Infected abortion
- Missed abortion
- Hydatidiform mole
- Incomplete abortion—retained products of conception
- early elective abortion through the first trimester

Use of MVA for endometrial biopsy requires little if any pain control medication. The procedure generally is completed in less than one minute (Ladipo, 1976; Suarez et al., 1983; Mateo Sanez et al., 1994), with women reporting minimal pain (Ladipo, 1976; Suarez et al., 1983; Goldrath and Sherman, 1985; Mateo Sanez et al., 1994). In Ladipo's study, no pain medication was administered, and 10% of the women experienced light or moderate discomfort. Mateo Sanez et al. found that the women reported less pain with MVA than with Novak's cannula. Studies with MVA also document its safety for endometrial biopsy, with no major complications reported. Ladipo (1976) reported some incidence of transient syncope.

International Experience

Ipas has supported programs to introduce the use of MVA for endometrial biopsy in many countries. This experience shows that shifting from sharp curettage to MVA improves patient care and reduces resource use. In one country, for example, rather than admitting patients overnight for D&C, MVA was performed in an outpatient treatment area and the women were able to leave the hospital shortly afterwards.

Contraindications and Precautions

There are few contraindications to office endometrial aspiration. Endometrial biopsy is contraindicated with known or suspected pregnancy. If cervical, uterine or pelvic infection (e.g. acute pelvic inflammatory disease, chlamydial cervicitis) is present or suspected, the endometrial biopsy should be delayed until antibiotic cover is established. When cervical stenosis is present, dilation may be required. The procedure should not be done without emergency backup for women with a history of blood dyscrasia because of the risk of hemorrhage.

Conclusion

Modern vacuum aspiration technologies for endometrial sampling are valuable tools for diagnosis and monitoring. They can be used safely and effectively by trained health care providers, including nurses or nurse midwives, to provide care in office or clinic setting. Because typically no anesthesia or operating room facilities are needed, vacuum aspiration can be used in more decentralized settings that are more accessible to more women. A variety of technical approaches to in-office endometrial sampling are available and useful. Ipas MVA instruments provide a convenient, effective and safe alternative for delivering these important women's reproductive health services.

Examination and Assessment

Screening of patients should include a medical history, physical exam, and laboratory tests as indicated. In postmenopausal women, cervical stenosis may make outpatient sampling more difficult. If the working diagnosis is infertility, the patient should be in the premenstrual (luteal) phase of her cycle. It is preferable to perform endometrial biopsy when the patient is not bleeding. A Pap smear may also be done at the time of endometrial biopsy.

General Physical Exam

Check and record the patient's vital signs (temperature, pulse, respirations and blood pressure). Note the general health of the woman (whether she is malnourished, anemic, or in general poor health). Examine her lungs, heart, abdomen, and extremities, as indicated by the clinical presentation.

Bimanual Pelvic Exam

The purpose of the pelvic exam prior to endometrial biopsy is to establish the size, consistency, and position of the uterus, and to check for adnexal tenderness or other signs of infection. Careful assessment of the uterus and cervix is essential to the procedure. Prior to the bimanual exam, explain the purpose of the exam to the patient. She should empty her bladder and assume the lithotomy position on an examination table. Drape the patient to protect her privacy. The practitioner should wear clean, undamaged examination gloves.

Speculum Exam

Insert the speculum to expose the cervix. Note any abnormal-smelling discharge. Check for signs of cervical infection or sexually transmitted diseases as well as pelvic inflammatory disease (PID). Any suspected infection should be treated with appropriate antibiotics before aspiration.

Pain Control

Assess the woman's need for pain-control medication and administer as needed. Generally, because no cervical dilation is necessary for endometrial biopsy, analgesia and/or mild anti-anxiety medication is sufficient to ease uterine cramping during the procedure. If cervical dilation is required, paracervical block may ease the discomfort of dilation.

Patient Preparation

Extensive preparation of the perineal area is not necessary. Ask the patient about any allergic reactions to antiseptics before selecting an antiseptic solution. Swab the cervical and vaginal areas with a water-based (not alcohol-based) antiseptic solution, using sponge forceps and gauze or cotton wool. Wait 1-2 minutes before beginning the procedure, to allow the antiseptic to dry.

Preparing Ipas Cannulae and Syringes

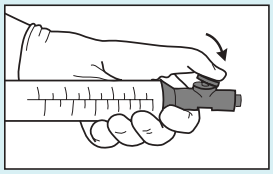
Instruments need to be sterile when they are inserted through the cervix. If sterility is not possible, high-level disinfection (HLD) is the only acceptable alternative. Before being inserted, the parts of dilators or cannulae that will enter the uterus should not touch objects or surfaces that are not sterile or treated with HLD, including the vaginal walls.

1. **Have ready a 4mm cannula** and a single-valve syringe.

2. **Inspect the syringe.** To be effective, a syringe must be able to hold a vacuum. Discard syringes with any visible cracks or defects, or ones that do not hold a vacuum.

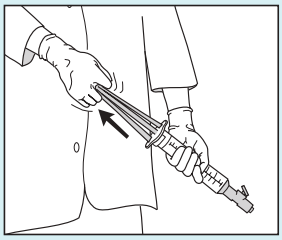
3. **Check the plunger and valve.** The plunger should be positioned all the way into the barrel and the pinch valve should be open, with the valve button out.

4. **Close the pinch valve** by pushing the button down and forward toward the syringe tip. When closed, the valve will lock into place.



Closing the Pinch Valve

5. **Prepare the syringe** by grasping the barrel and pulling back on the plunger until the arms of the plunger snap outward at the end of the syringe barrel, holding the plunger in place. Check the stable positioning of the plunger arms. Both plunger arms must be fully extended to the sides and secured over the edge of the barrel. With the arms snapped in this position, the plunger will not move forward and the vacuum is maintained.



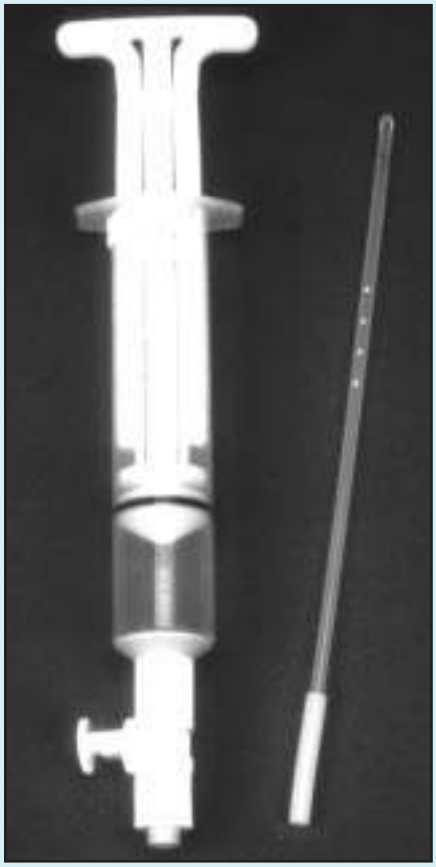
Creating the Vacuum

Incorrect positioning of the arms could allow them to slip back inside the barrel, possibly pushing the contents of the syringe or air into the uterus. *Never grasp the syringe by the plunger arms.*

6. **Check the syringe for vacuum tightness before use.** Leave the syringe for several minutes with the vacuum established. Open the pinch valve by releasing the button. Air will rush into the syringe, indicating that there was a vacuum in the syringe. If there is not a rush of air, lubricate the o-ring with silicone and test the vacuum again. Replace the o-ring or use another syringe if the syringe still will not hold a vacuum.

7. **Repeat steps 3 through 6** to reestablish the vacuum at the time of the procedure.

Steps for Endometrial Biopsy

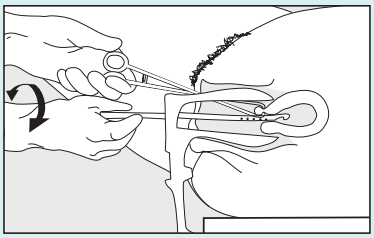


Any instruments or parts of instruments that enter the uterus must be sterile or high-level disinfected. Observe a No-Touch Technique throughout the procedure: do not contaminate the cannula or allow the tip to touch objects or surfaces before being inserted through the cervical canal.

1. With speculum inserted, **hold the cervix steady** with a tenaculum and gently apply traction to straighten the cervical canal.

2. **Dilate the cervix (if required).** When performing endometrial biopsy, cervical dilation is rarely necessary to allow passage of the 4mm cannula, although it may be required in some instances. In some older women, particularly postmenopausal patients, the cervix may be so stenotic that dilation and passage of a cannula may not be possible in the outpatient setting.

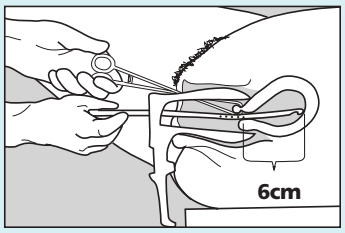
3. **Insert the cannula** gently through the cervix into the uterine cavity just past the internal os, while holding the cervix steady. Rotating the cannula with gentle pressure often helps ease insertion.



Inserting the Cannula

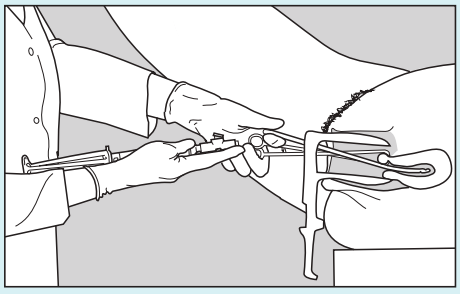
4. **Push the cannula slowly into the uterine cavity** until it touches the fundus. Note the uterine depth by the dots visible on the cannula. The dot nearest the tip of the cannula is 6cm from the tip, and the other dots are at 1cm intervals.

After measuring the uterine size, withdraw the cannula slightly.



Measuring Uterine Depth with Cannula

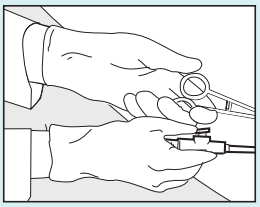
5. **Attach the prepared syringe** (vacuum established) to the cannula. With the index and thumb of one hand, hold the end of the cannula, and with the other fingers the tenaculum. Hold the syringe with the other hand. Make sure that the cannula does not move forward into the uterus as you attach the syringe.



Attaching the Syringe to the Cannula

Some providers prefer to attach the syringe to the cannula before inserting the cannula through the cervical os.

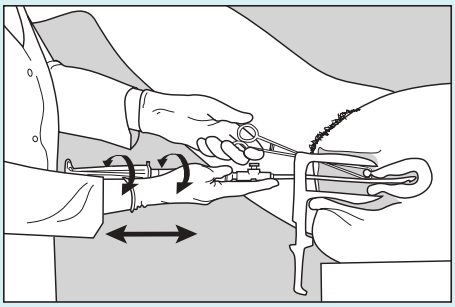
6. **Release the pinch valve** on the syringe to transfer the vacuum through the cannula to the uterus. Blood, tissue and bubbles should begin to flow through the cannula into the syringe.



Releasing the Pinch Valve

7. Movement of the cannula inside the uterus may vary according to the purpose of the biopsy. Aspirate tissue sample by moving the cannula gently and slowly back and forth within the anterior uterine cavity, without going beyond the internal os. Then rotate the cannula and reinsert it until it touches the uterine fundus and aspirate the tissue sample from the posterior cavity in the same manner. In the case of hemostatic curettage (biopsy), move the cannula gently and slowly back and forth within the entire uterine cavity, rotating the syringe as you do so.

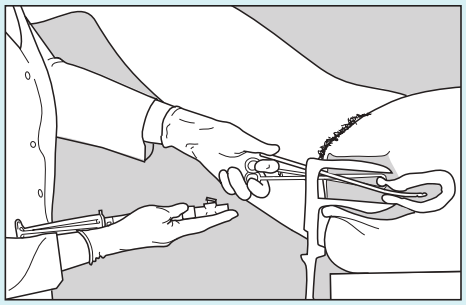
It is important not to withdraw the cannula apertures beyond the cervical os during the procedure.



Aspirating Endometrial Tissue Sample

While the vacuum is established and the cannula is in the uterus, **never grasp the syringe by the plunger arms** to ensure that they do not move from their locked position on the rim of the barrel. Accidentally allowing the plunger to slip back into the syringe may push tissue or air back into the uterus, possibly causing complications.

8. **Complete the procedure.** The procedure may be quicker and produce less discomfort than biopsy with metal curettes, and is complete as soon as an adequate amount of tissue is obtained for pathological examination. Withdraw the cannula from the uterus.



Detaching Syringe

If the cannula is detached from the syringe immediately following withdrawal, empty the contents of the syringe into a fixitive solution by opening the valve and pushing the plunger to eject aspirated tissue. If the cannula is not detached immediately following withdrawal from the uterus, the cannula may be used to draw fixative into the syringe, mixing the fixative with the aspirated tissue. Then the cannula is detached from the syringe and the aspirated tissue is emptied into a specimen bottle containing fixative.

Prepare and deliver specimen in accordance with local laboratory requirements. *(Do not reinsert the cannula into the uterus after flushing with fixative.)*

9. **Decontaminate and process all instruments appropriately.**

Manual vacuum aspiration is a procedure that involves minimal trauma to the uterus and cervix. However, in a small percentage of cases, one or more of the following complications may occur: uterine or cervical perforation, hypotension, vagal reaction, pelvic infection, or air embolism. Some of these conditions can lead to secondary infertility or other serious injury, or, in some cases, death.

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- to improve services through increasing availability of appropriate reproductive-health-care technologies.

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