

Ipas U.S. Start-up Kit for Integrating Manual Vacuum Aspiration (MVA) for Early Pregnancy Loss into Women's Reproductive Health-care Services



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Ipas works globally to increase women's ability to exercise their sexual and reproductive rights and to reduce abortion-related deaths and injuries. We seek to expand the availability, quality and sustainability of abortion and related reproductive-health services, as well as to improve the enabling environment. Ipas believes that no woman should have to risk her life or health because she lacks safe reproductive-health choices.

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Center photo courtesy of R. Lord.

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I. Introduction

A. Ipas U.S. Start-up Kit for integrating manual vacuum aspiration (MVA) for early pregnancy loss into women's reproductive health-care services

Ipas is an international, nonprofit organization that is focused on increasing access and improving quality of reproductive health services for all women. Founded in 1973, we work in Africa, Asia, Latin America, Europe and the United States. We are a somewhat unique nonprofit organization because we are also the manufacturer of a hand-held, manual uterine-evacuation device that we disseminate worldwide, as well as donate to facilities and locations with great need. While we have not to date realized a profit on our product, if we did we would put that profit back into our programming, in the countries where we work.

Ipas strongly supports the integration of state-of-the-art uterine evacuation services into women's reproductive health-care services, including services for early pregnancy loss or miscarriage management (spontaneous or incomplete abortion). When manual vacuum aspiration (MVA) is introduced into a hospital, clinic or other type of health-care system, it very effectively improves quality, reduces costs, decreases client wait time and increases choices for clients around miscarriage management. This can include moving uterine evacuation services from an operating room to an outpatient area, redesigning a service-delivery area or starting a new service.

The Ipas U.S. Start-up Kit provides up-to-date guidance, tips, checklists, resources and sample medical protocols for incorporating MVA into women's reproductive health-care services. We have drawn from many sources to assemble this guide, and thank those sources for all the great work they have done and continue to do.

B. The Ipas woman-centered care approach

Woman-centered care is an important approach that Ipas promotes in the delivery of uterine-evacuation services for miscarriage management (incomplete or missed abortion), and is the underlying foundation for the information we are providing you on how to most effectively integrate manual vacuum aspiration (MVA) into uterine-evacuation services. The woman-centered approach takes into account the complex and varied factors that influence a woman's individual sexual and reproductive health needs, both physical and psychological, as well as her personal circumstances and her ability to access services. It actively involves the woman in her own care by forming open communication and a collaborative partnership with her health-care provider.

Positive outcomes, both clinical and psychological, are something that all health-care providers strive for. Utilizing a womancentered care approach helps to ensure positive outcomes by considering a woman, her medical needs and her individual (nonmedical) circumstances all together. In addition, by directly seeking and responding to women's perspectives on service delivery and quality, this approach helps to build communication and rapport between a woman and her health-care provider, further increasing the opportunity for positive outcomes. Research has shown that women who are satisfied with the communication and rapport that they've established with their health-care provider are more likely to comply with instructions, resulting in positive clinical outcomes (Shelton, 2000).

Ipas's woman-centered care approach for the provision of uterine-evacuation services can also be adapted for other types of women's health-care services. The Ipas model consists of three key components: choice, access and quality. These are all important considerations for you when you undergo planning for a service-delivery change, and their implications will vary depending on your individual service setting, staffing and resources.

- Choice. Because women have different needs when seeking miscarriage care, health-care providers need to offer as many options as possible. Finances, pain, confidentiality, time involved, length of recovery and ability to care for children during recovery all impact a woman's decision-making process. Having a choice between expectant management ("watch and wait"), medication or an aspiration procedure to complete the miscarriage process allows a woman to opt for the procedure that serves her best. To ensure that a woman makes the most informed choice, she must be informed with complete and accurate information and the opportunity to ask questions of, and express concerns to, knowledgeable health-care personnel.
- Access. Access to care is critical when providing miscarriage services. Having aspiration procedures, if that is the treatment of choice, offered only in an operating room can result in women waiting long periods of time because their procedures may be rescheduled to take care of persons with more critical medical needs. It is not uncommon for a woman who is having a miscarriage to wait up to 24 hours or longer for an operating room to become available.

Once a woman has made the decision to have medical or aspiration intervention for a miscarriage, she generally prefers to be seen in a timely manner. To increase women's access to services, it is important that the time between the initial request for an appointment and the appointment itself is as short as possible, also be sure to offer the widest range of services possible, to decrease having to refer women elsewhere.

• Quality. High-quality woman-centered care means carefully considering a woman's circumstances and needs. This includes providing accurate information and counseling; following your facility's protocols and standards; providing contraceptive counseling and services as needed; treating or referring her for related health services; ensuring confidentiality; and training and requiring staff to respect and support every woman they serve.

It is important to note that health-care workers who do not perform clinical services also have a role in ensuring that women receive high-quality services. It is essential that all staff members deliver services that are based on respect for each and every woman's situation and circumstances.

C. How to use the Ipas U.S. Start-up Kit

Providing high-quality, cost-effective services that ensure positive clinical outcomes and best meet client's needs is an important goal for all health-care providers. The Ipas U.S. Start-up Kit seeks to address this goal by presenting "how-to" information on integrating MVA for miscarriage management into women's reproductive health-care services.

Target Audience. The Kit targets clinicians, including obstetricians, gynecologists, family-medicine doctors, pediatricians and other health-care professionals involved in the delivery of women's reproductive health-care services, such as nurse managers, office/clinic managers and advanced practice clinicians (APCs). Individuals involved in important support services like billing and reimbursement and procurement will also find this manual useful.

Organization. The Kit is organized into four main parts:

- Checklist for integrating MVA into miscarriage management, including tips for ordering equipment. Lists general medical equipment and supplies, as well as specific items needed for miscarriage management with MVA. Also discusses pregnancy verification and estimating gestational age.
- Service-delivery considerations. Outlines important considerations around physical plant, equipment, staffing, scheduling appointments, counseling and referrals, billing and reimbursement, and marketing. Also presents considerations for providing culturally competent and youth-friendly services.
- Sample medical protocol. Presents miscarriage management overview, definitions, medical intake, and miscarriage management options including MVA, expectant and medical management.
- **Resources.** Contains information sources on a wide variety of topics including bibliographies on women's health, billing codes, embryo-fetal development, equipment recommendations (this is not an exhaustive list nor an endorsement for vendors or products), medication and supply vendors (again, not an exhaustive list nor an endorsement), and special considerations for working with diverse populations.

II. Checklist

For integrating MVA into miscarriage management, including tips for ordering equipment

A. Introduction

We know that starting or changing a service like miscarriage management can be a challenge within any health-care delivery setting. To help you successfully negotiate service-delivery change, we have compiled a checklist of our recommendations for medical equipment and supplies to assist you and make the process less complicated. We also identify some resources for equipment and supplies throughout the checklist. Keep in mind that these resources are suggestions (not endorsements) and are not inclusive of all equipment and supplies available in the United States. In Section VI. Resources (p. 101), you will find other sources for helping you integrate MVA into your services.

B. General medical equipment and supplies

Front desk supplies:	
☐ Phone scripts (to ensure that each woman who calls for information gets a thorough and standardized response that meets their needs)	
☐ Appointment book and/or computerized appointment grid	
☐ Pregnancy wheel (for doing an initial, quick estimate of gestational age from date of last menstrual period or LMP)	
☐ Insurance and fee information	
☐ Referral numbers (for both medical and related social services)	
Laboratory supplies:	
☐ Venipuncture and/or finger-stick supplies	
☐ Urine HCG supplies	
☐ Immune globulin and RH testing supplies	
☐ HemoCue machine or centrifuge to test hematocrit	

C. Miscarriage management with MVA

Nondisposable items for the examination, procedure and/or recovery room:
☐ Blood pressure cuff, medium and large, and stethoscope
☐ Light source, such as a gooseneck lamp
☐ Gynecologic examination table (ideally with automated position control, though not necessary) with knee stirrups and pillow
☐ Hot water bottles and/or heating pads, and ice bag (for women who prefer a cold pack)
☐ Thermometer
☐ Double-locking storage for narcotics, if applicable
☐ Art work that reflects the population you are serving and relaxing music
☐ Portable cart to store all equipment and forms relevant to abortion care (if you don't have a dedicated space to store your equipment and forms)
☐ Oxygen tank with breathing apparatus and oral airways
☐ Crash cart
☐ AmbuBag (as part of crash cart)
☐ Pulse oximeter, when using intravenous (conscious) sedation
☐ Ipas MVA Plus® (reusable) and/or Ipas Double-Valve/DVS (single use)
☐ Other instruments:
 Speculums – Pederson's, Graves medium (larger Graves for obese women)
• 9in single-tooth tenaculum, or 9in atraumatic tenaculum

Equipment/medical cart recommendations

Metro 1.800.323.4220 www.metrocarts.com Look at the Metro Basic 36.20 and Carts, Procedural

Armstrong Medical 1.800.323.4220 www.armstrongmedical.com Look at "Smart Carts" or "Narrow Carts"

Future Health Concepts 1.888.282.8644 www.futurehealthconcepts.com

Biz Chair 1.800.924.2472 www.BizChair.com

- 9.5in sponge/ring forceps
- Deniston dilators: plastic, ranging in size from 5mm to 14mm
- Pratt dilators: metal dilators, sizes 13/15, 17/19, 21/23, 25/27, 29/31, 33/35, 37/39
- Small metal cup or kidney bowl to empty products of conception (POC) into

	☐ Mayo tray and stand	
	□ Emesis basin	
	Biohazard containers	
	Sharps containers	
	Wheelchair	
	Ultrasound (not required)	
Disposable items for the examination, procedure and/or recovery room:		
	Table paper	
	Drape sheet or gown	
	Underpads	
	Tissues	
	Sanitary pads	
	Ultrasound supplies: gel, printer paper, probe covers (can use condoms)	
	Vaginal wipes	
	Exam and/or sterile surgeon's gloves (health-care provider preference)	
	Latex-free gloves for health-care providers and women with allergies to latex	
	Flexible Karman cannulae and/or Ipas EasyGrip® cannulae (come in a variety of sizes to accommodate up to 12-weeks gestation, as well as endometrial bioposy)	
	Ipas Double-Valve/DVS aspirator (single use)	
	Hypodermic needles (18gu to draw up lidocaine; 21 to 23gu for paracervical blocks)	
	Syringes (10cc and/or 20cc for paracervical blocks and smaller syringes if using IV sedation)	
	Cotton balls	
	Swabs	
	Large scopettes for visualizing the cervix and sterile cotton swabs for checking the os	

	Sterile 4x4 gauze
	Autoclave tape (¾ to 1in)
	Autoclave wrap or pouches
	Sterile drape non-fenestrated for instrument setup on Mayo tray, generally 18x26in
	Pap smear, wet prep and culture supplies
	Red biohazard bags
	Drinking cups (6 to 8oz)
	Water/juice and cookies/crackers (clear liquids generally produce less vomiting)
	Client information handouts (after-care instructions, contraceptive methods, emergency contraception)
	Client journal (are useful tools for women to record feelings and experiences)
	Paper lunch bags (for client take-home materials)
Solu	itions and medications:
	Betadine solution and an alternative (for women allergic to Betadine)
	Lubricating jelly
	Hurricane gel (provider preference)
	Lidocaine 1% or .5% with or without epinephrine (provider preference)
	Analgesic of choice like ibuprofen or Tylenol
	Immune globulin injection: HyproD or RhoGam in minidose
	Prophylactic antibiotics (you can dispense on-site or provide prescription)
	Autoclave cleaners
	PRN medications (Methergine PO and/or IM, misoprostol, Phenergan)
	Contraceptives, including emergency contraception (you can write a prescription or have on hand)

HyproD is the most economical and is available through HPSRx 1.800.850.1657 www.hpsrx.com RhoGam is available through Henry Schein

www.henryschein.com

Light Box Recommendation

Light Tracer Light Box 10 x12in or 12 x18in average price between \$35 and \$90; can be purchased at:

SuppliesNet – www.suppliesnet.com

Hobby Lobby – www.craftsetc.com

Michael's - The Arts and Crafts Store www.michaels.com

Joann's Fabric and Crafts www.joann.com

You can also buy a light box at most photography stores.

Products of conception (POC) examination:

☐ Light box (you can purchase from a medical supply company for about \$400, or you can go to a neighborhood craft store and pay less than \$100)	
☐ Small, clear glass Pyrex dish (8x8in square or 9in pie pan)	
☐ 6in-diameter (average size) strainer with small mesh	
☐ Scrub brushes for cleaning strainer	
☐ Metal/tin utensils holder	
☐ Tweezers or tissue forceps	
☐ Pathology cups with preservative (to transport POC to reference lab)	
☐ Running water	
☐ Hand-held magnifying lens	
A second information assumes on BOC avarations in articularly	

A good information source on POC examinations, particularly fetal-tissue books, is the Center for Choice www.centerforchoice.com.

A Guide to Fetal Development: The First Trimester – Center for Choice (Toledo, Ohio). Fax a request to 419.259.2644 or call for an order form at 419.225.7769. Book is \$75, including shipping. 1.800.589.6005

Cleaning supplies:

- ☐ Cleaning supplies and disinfectants
- ☐ Instrument cleaner for high-level disinfection/cold soak (Cidex®, CidexOPA® or Sporox II®; you do not need a ventilation hood with Sporox II)
- ☐ Autoclave cleaners (follow manufacturer's recommendations)

D. Pregnancy verification and estimating gestational age

Pregnancy verification and gestational age estimation are important steps in the provision of miscarriage-management services. Depending on your setting, you can do pregnancy testing on- or off-site. You can also utilize ultrasound, in your facility or from an outside source, to verify and estimate gestational age. Ultrasound is becoming more widely used in hospitals and outpatient health-care facilities partly due to the availability of smaller and less expensive ultrasound machines. Ultrasound is also very helpful if you are teaching health-care providers and residents how to perform uterine evacuation using MVA, as it allows for the visualization of the inside of the uterus.

III. Ipas MVA Plus® instrument processing

A. Introduction

The Ipas MVA Plus and adapters are multi-use devices that require either high-level disinfection or sterilization prior to initial use and between clients. They **do not** need to be high-level disinfected or sterile at the time of use. All Ipas cannulae are single-use devices. After use, you simply discard as infectious waste. Also, if you use the Ipas Double-Valve/DVS aspirator, it is important to remember that this device is for single use and needs to be disposed of as infectious waste after a procedure.

When using the Ipas MVA Plus, it is important to always clean and process the instrument according to the manufacturer's instructions and specifications. If you elect to autoclave the aspirator it is critical that you set the temperature on your autoclave to the settings Ipas recommends. Higher temperatures will, at a minimum, warp the cylinder of the syringe making it impossible for the plunger to slide easily. At worst, increased temperatures will melt the aspirator.

The Ipas EasyGrip cannulae and/or flexible Karman cannulae are single use and must be discarded as infectious waste immediately after use.

B. Cleaning and processing the Ipas MVA Plus

- Always wear gloves and face protection while processing the aspirator.
- As soon as the uterine-evacuation procedure is complete, immediately discard cannula and soak the aspirator and adapters to ease cleaning.
- Disassemble the aspirator completely and clean it by washing all surfaces thoroughly in warm water and detergent.
 Detergent is preferable to soap, which can leave a residue.
 As an alternative, an enzyme cleaner, a solution specifically designed to clean blood and tissue from surgical instruments, can be used.

• If using a high-level disinfectant soak, place all the parts in the soak for the amount of time directed on the bottle. Ipas recommends Cidex or Cidex OPA (Advanced Sterilization Products/Johnson & Johnson), or Sporox II (Sultan Chemists, Inc.) because both products achieve high-level disinfection (20 minutes for Cidex, 12 minutes for Cidex OPA and 30 minutes for Sporox II). Additionally, Sporox II does not require ventilation or a hood because there are no fumes. You can also completely sterilize instruments using Cidex or Sporox II, but you need to soak the instruments for a specified amount of time. To sterilize with Cidex, soak for 10 hours. Note that Cidex OPA cannot be used for sterilization. For sterilization with Sporox II, soak for six hours.

Through the manufacturer of Sporox II (Sultan), there is a handy ProSoak container available to soak instruments that has a cover and a carrying handle.Go to www.sultanintl.com for more detailed information.

If you elect to use glutaraldehyde for high-level disinfection, a good resource is www.osha.gov/SLTC/etools/hospital/hazards/glutaraldehyde/glut.html.

- When sterilizing aspirators by **autoclaving**, do not reassemble the device place all the parts in a wrap or instrument pouch and autoclave at 250 degrees Fahrenheit for 30 minutes.
- For STERRAD 100S systems, place the disassembled aspirator and adapters along with the chemical indicator strip inside each package. Place it in the STERRAD 100S chamber. Process for one cycle according to manufacturer's instructions. Visit www.sterrad.com for these instructions.
- Providers can choose the disinfectant/sterilization method that best suits their practice. As a guideline, the Ipas MVA Plus can be used between 25 and 50 times when following the Ipas processing instructions provided in its package insert. Whichever method of disinfection/sterilization is chosen, the Ipas MVA Plus needs to be inspected before next use. If the Ipas MVA Plus shows signs of damage or is not functioning properly, it should be discarded.

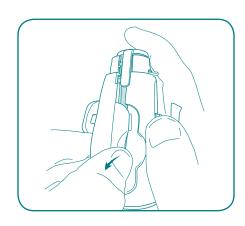
Processing tips:

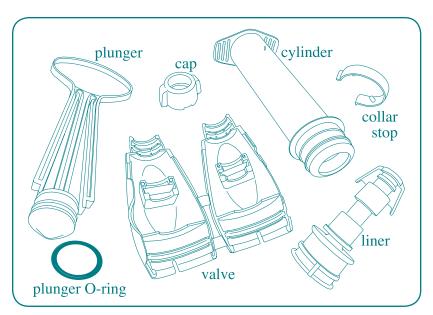
- You will find Ipas's *Tips for Using the Ipas MVA Plus* at this address: http://ipas.org/Library/Other/Tips_for_Using_the_Ipas_MVA_Plus.pdf.
- Keep several "spare-parts kits" handy, so that you have extra
 O-rings, collar stops and lubricant always available. Ipas has
 accessory kits, available through its distributor HPSRx, called
 AK-PLUS.
- Aspirators need to be stored in dry, covered containers or packages, protected from dust and other contaminants.
- Reassemble the disinfected/sterilized aspirator before you
 plan to use it. You can make sure it is operating properly and
 that all of its parts are accounted for before the woman you
 are serving is on the examination table.

C. Disassembly and reassembly of the Ipas MVA Plus

Disassembly:

- Remove the cannula from the valve by twisting the cannula base and pulling it out of the valve. The wings of the cannula can be gripped to aid in this task. **Do not attempt to remove the base of the cannula;** it is permanently attached.
- Pull the cylinder out of the valve.
- Press down the cap-release tabs to remove the cap. Open the hinged valve body by pulling open the clasp. Remove the valve liner.
- Disengage the collar stop by sliding it sideways under the retaining clip or removing it completely from the cylinder.
- Pull the plunger completely out of the cylinder.
- Displace the plunger O-ring by squeezing its sides and rolling it down into the groove below. It is **not** necessary to completely remove it.





MVA parts disassembled

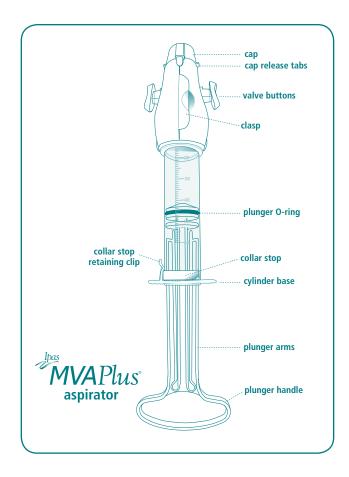
Reassembly:

- Place the valve liner in position inside the valve by aligning the internal ridges. Close the valve until it snaps in place.
- Snap the cap into place on the end of the valve.
- Push the cylinder into the base of the valve.
- Place the plunger O-ring in the groove at the end of the plunger and lubricate it by spreading one drop of lubricant around the O-ring with a fingertip. Silicone, which is nonsterile, is provided; other nonpetroleum-based lubricants can also be used.

Caution: Excessive lubrication can cause the aspirator to lose vacuum. **Do not** over lubricate the plunger O-ring. **Do not** lubricate other parts of the aspirator.

- Squeeze the plunger arms and fully insert the plunger into the cylinder.
- Move the plunger in and out to lubricate the cylinder.
- Insert the tabs of the collar stop into the holes in the cylinder so that the plunger cannot be pulled out of the cylinder.

Always check that the aspirator retains a vacuum before using it. If the aspirator does not retain a vacuum, check that it is properly assembled and inspect the O-ring for foreign particles and proper lubrication.



IV. Service-delivery considerations

A. Introduction

When you are integrating miscarriage management using MVA into an existing service, you will need to make decisions about many important items, including physical plant, equipment, staffing, scheduling appointments, counseling and referrals, billing and reimbursement, and advertising and marketing. You will also need to provide services that are culturally competent and youth friendly. If you choose to provide local anesthesia only, you will need to be knowledgeable and comfortable in supporting a woman through an aspiration procedure using local anesthesia. This section provides guidance on these considerations, plus tips for helping you to get started. While the Ipas U.S. Start-up Kit does not focus on how to establish and set up a free-standing clinic or health center, this section will help assist those providers and institutions that are doing so with some basic information and tips.

B. Physical plant

One of the most important issues you will need to consider when integrating MVA for miscarriage management into your services is the physical space at your facility. One key physical plant-related question you will face is whether or not you will need to reconfigure your space to accommodate the new service. When providing services in an outpatient setting, it is always important to organize your service/facility in a way that facilitates smooth client flow.

It is also critical that you determine if there are any state regulations that will affect your facility. Some states require facilities to meet ambulatory surgical-center regulations, some have less restrictive regulations and a few states have no physicalplant regulations at all.

Another extremely important consideration is the physical appearance of a facility. Your facility's appearance, level of comfort and cleanliness will certainly influence a woman's impression of her overall care.

Here are some other important considerations:

- Waiting room and registration area Is your space adequate or will you need to expand? If you can't expand, one option might be to offer MVA services on less busy days. Be sure your registration area allows for easy access, yet provides women the opportunity to have private conversations with staff.
- Medical intake, consent, education and counseling Some facilities have separate rooms for intake, consent, education and counseling. Depending on your client volume and space, you can use one room or area for all of these functions. What is important to ensure, though, is having space that allows for the privacy of the woman. It is also important to have a space that also allows for easy entry and exit of both the counselor or other staff and the woman, in the event of medical emergency.
- **Ultrasound equipment** If you plan to offer ultrasound, where will you perform the scan? If the entire MVA procedure will happen in one room, you will need to plan for the necessary space to be sure you can fit in an ultrasound machine and have an appropriate place to store it.
- Laboratory testing If you will be performing your own laboratory testing, you will need to be Clinical Laboratory Improvement Amendments (CLIA) certified at the Moderate Complexity level. CLIA has specific requirements for laboratory testing, such as having a sink available. Fees for CLIA certification and renewal are based on volume and vary from state to state. For more information on CLIA, visit the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services at www.cms.hhs.gov/CLIA.
- Examination/procedure room Make certain you have an examination or procedure room that will comfortably hold between three and four people: the provider, nursing assistant, client and significant other (if permitted). If remodeling is required, pay attention to the location of your procedure room within the facility.

When using MVA for miscarriage management in a hospital setting, you have the flexibility of offering this service outside of a procedure or operating room if your facility permits and this meets your needs. Some hospitals, for example, use MVA for resolving miscarriages in the emergency department, ob-gyn triage, and labor and delivery. When working with women experiencing miscarriage, you might expect more counseling issues surrounding the loss of a wanted or planned pregnancy. You cannot assume, however, that all miscarriages are unwelcome events. The woman's partner is also more likely to want to be included in her care, particularly if the pregnancy was a planned one.

• MVA equipment – Keep in mind that there is no large equipment required for MVA – simply your standard tray of instruments and supplies as listed in *Section II. Checklist* (p. 8). Contact information for the vendor of the Ipas manual vacuum aspirators, HPSRx, is included in *Section VI. Resources* (p. 79). For miscarriage management, HPSRx carries the Ipas WomanCare™ Kit, a single-use, fully disposable uterine-evacuation kit containing a sterile, single-use aspirator, cannulae and dilators. You will only need to supply a speculum, tenaculum, sponges, a needle and a numbing agent (for a paracervical block if required). This saves you the staff, time and money associated with cleaning, processing, inventorying and tracking instruments. Particularly useful for emergency departments, the Ipas WomanCare Kit is available at www.ipaswomancare.org.

You will need to think about where you want to clean your instruments, keeping in mind that this area will be considered a "dirty" area. You will also need to consider where you will sterilize your instruments. Some hospitals and health-care centers utilize a central sterile service, while others have autoclaves or trays for cold processing on-site in a special area. Be aware that some cold soaks require ventilation hoods.

- Products of Conception (POC) examination When offering MVA for miscarriage management, be sure to set aside a space for gross tissue evaluation and specimen preparation for those samples being sent for microscopic evaluation. Some providers do only gross tissue examination when using MVA. If you are going to be transporting tissue samples from the procedure room to another part of your facility for evaluation, you will need to develop a system for doing so. You can use a cart on wheels or hand-carry specimens, but be sure to always transport them in a covered container.
- Recovery area You will need to determine where the women receiving MVA procedures will recover. When using a paracervical block and analgesics only, the typical woman will require an average of 10 to 15 minutes of rest and basic monitoring before leaving your facility. The woman might be able to recover in the procedure room itself, depending on your client flow and physical plant layout. A dedicated recovery space is typical in facilities offering intravenous sedation or general anesthesia. If you have a separate recovery area, be sure to have staff that are prepared to accompany each woman to that area she may be a bit unsteady when she first gets up from the examination table and you need to prevent any potential falls.
- Emergency evacuation Consider the evacuation route through your facility should a woman require emergency transport in the unlikely event a complication occurs when using MVA. When possible, locate the procedure/ examination room near an external door to give emergency medical technicians (EMTs) easy access.
- Medication technologies For women who are receiving medication technologies for miscarriage management, you will need a typical examination room or you can even use the ultrasound room to avoid moving from room to room (exam room to ultrasound room) for this type of visit. If you are allowing a woman's significant other to be present during this type of visit, be sure you have enough space to accommodate this request.
- Ambience It can be very calming to have low lighting
 (without interfering with adequate light for exams and MVA
 procedures), music (piped in or a portable cassette/CD
 player), and posters or artwork that is population appropriate
 – these all contribute to good ambience.

C. Equipment

Your biggest consideration regarding equipment will be cost, which will impact whether you decide to perform certain tests within your facility or refer out. In Section VI. Resources (p. 79), we give you information on suggested vendors for equipment and supplies. The most common equipment considerations include:

- **Ultrasound** If you decide to perform the ultrasound in your facility, plan to spend around \$15,000 to \$35,000 for an ultrasound with vaginal probe and abdominal transducer. You can also explore purchasing a used/refurbished ultrasound if your budget is small.
- **POC examination** You will need to purchase a light source, and you can spend \$300 to \$400 at a medical-supply company or \$50 to \$100 at a craft or photo shop.
- IV sedation If you plan to offer IV sedation, you will need a pulse oximeter to monitor vital signs during the procedure. A portable pulse oximeter ranges from \$200 to \$1,000.
- **Autoclave** If your facility does not have an autoclave or if you are choosing to autoclave in your area versus a central sterile arrangement like in a hospital, you can plan to spend about \$2,000 to \$5,000 for a countertop model.
- **Examination tables/chairs** Having a comfortable examination table/chair is important, particularly when doing aspiration procedures with local anesthesia. Tables with knee crutches versus stirrups are a great option, such as Midmark/Ritter at www.midmark.com.
- Other items You may want to have a wheelchair in the facility for women who are unable to ambulate easily. Wheelchairs average between \$100 and \$200.

D. Staffing

Along with the physical appearance of your facility, your staff will also play a critical role in how a woman experiences the services you are delivering. Staffing in any health-care delivery setting is always important — not just the number and type of staff you need — but also staff attitudes and how they treat the consumers of your services. You will not only need to focus on staffing your service, but providing regular training as well.

Tasks that require staffing. Depending on your facility, the number and type of staff required to provide miscarriage-management services will vary — the number of projected clients and the types of services you will offer will help guide your staffing decisions. That said, there are basic tasks associated with providing this service, regardless of the setting:

- **Telephone contact** information and appointment scheduling and initial triage during office hours.
- **Insurance/payment options** information and verification.
- **Intake** medical history.
- **Pregnancy diagnosis** urine test and/or ultrasound dating.
- **Laboratory testing** at a minimum, hemoglobin or hematocrit and Rh type.
- Counseling, education and informed consent a private conversation to discuss the woman's emotional status and needs for support and guidance, as well as a review of the procedure and any medications. Contraception can be discussed if appropriate or at a later point in time, such as at the follow-up visit. The woman's signature is always required on all consent forms.

- **Procedure** performing first-trimester abortion using MVA, using MVA for miscarriage management or using medication technologies to complete a miscarriage.
- Recovery and discharge you may need to have a licensed health-care provider, registered nurse (RN) or licensed practical nurse (LPN), in your recovery area, depending on your state and/or facility regulations.
- After-hours calls either nursing triage followed by physician call, or physician only, depending on your state and/or facility regulations.

To find out if your state has regulations that specify staffing requirements, contact your state department of health, department of professional regulations and/or board of nursing. It is very helpful to cross-train staff on as many of the above tasks as possible, particularly if you are a small facility. Cross-training also helps to contain overall service-delivery costs.

Suggested staffing complement. In terms of types of staffing, what follows is a suggested staffing complement for uterine evacuation using MVA for miscarriage management in a free-standing clinic or service site. Counselors, for example, can be hired part-time or be volunteer. If you are in a hospital, you can sometimes utilize social-service staff to provide counseling. You may not also need this full complement if you are referring out for ultrasound and/or laboratory testing. Note that these staff persons don't always have to be your dedicated staff.

If you are adding miscarriage management to an existing service, you will most likely not need all of the staff listed on the next page. If you are planning to utilize existing staff, be sure to select staff who want to do this type of work. If you compel your staff to take on early pregnancy loss work when they don't want to, their displeasure will certainly be felt all around the service setting and by the women seeking care, comfort and support in your facility.

- Nurse RN or LPN depending on state or institutional regulations.
- **Reception/intake person** this person can generally answer phones, process insurance information (not billing), and staff the reception desk for intake.
- **Counselor** licensed, degreed, or appropriately lay trained - to provide education, counseling and informed consent.
- **Ultrasound person** you will typically need one person to perform sonograms - this can be the physician/clinician, a trained ultrasonographer, or a clinic staff person trained to do basic ultrasonography.
- **Laboratory person** if you are performing lab tests on-site, you will need an appropriately trained staff person. CLIA guidelines state that a moderately complex laboratory can use lay-trained staff with appropriate supervision. See www. fda.gov./cdrh/CLIA for more information. This site includes information on everything you need to know about setting up a small laboratory in your facility.
- Advocate/procedure assistant this can be a nurse or medical assistant depending upon state or institutional regulations. This also can be the same person who does ultrasounds, lab tests, or even counseling, education and informed consent.
- Recovery and discharge person this may need to be a nurse depending upon state or institutional regulations.
- After-hours calls person this can be a nurse, a well-trained counselor or medical assistant, along with the clinician/provider.

Other staffing considerations. When receiving miscarriage-management services, a woman usually interacts with a number of staff before she enters into consultation with the clinician. She often, in fact, interacts longer with staff than with the clinician throughout her service experience. How your staff interacts with your clients will directly impact each woman's satisfaction with your service. Skillful hiring and a commitment to training are key components of quality care in any medical service. Be sure to employ staff who convey both professional integrity and a caring attitude. Negative, judgmental attitudes have no place in the provision of women's reproductive health services. It is very helpful to have written standards outlining professional behavior, as well as personnel policies that you can use when evaluating performance.

Staff training and supervision. Standardized training will ensure consistency among your staff in the services you provide to women. Standardization is an important part of any quality assurance protocol in a health-care delivery setting. It is important to customize your training to meet the needs of your staff and to do so on a regular basis, to accommodate for staff changes. Aligning your training program with areas that have been identified as important to the women you serve is also helpful for ensuring high-quality services. Training topics, besides the basics about the services you are providing, can include customer service, woman-centered care, cultural competency and values clarification. It is also very helpful to provide ongoing staff supervision, whether this is on an individual or a group basis. Setting aside time to discuss challenges and new ideas, and share information is a very worthwhile activity that often gets overlooked in busy health-care settings.

Be aware that your medical malpractice carrier offers free risk-management training for your staff. This type of training highlights charting and documentation, confidentiality, telephone etiquette and processing chart/records requests. Pharmaceutical representatives often have training and food allowances built into their marketing budgets and you can request informal lunch trainings for your staff, as appropriate.

E. Scheduling appointments

Setting up a workable, efficient system for telephone appointments is always challenging. There are two important initial decisions you will have to make, whether you are setting up a brand new system or modifying your current system to accommodate a new miscarriage-management service.

- Decide where calls will come for these appointments will you have a dedicated line/number for appointments? Or, will these calls come through your routine appointment system?
- Determine who will take these calls will it be your general receptionist and appointment person/people? Will you train a specific person(s) to handle these calls?
- Determine whether the person taking the calls needs to know a language other than English – do you need bilingual staff or will you make other arrangements to handle non-English speakers?

Service-delivery decisions. Once you identify the "where and who" of appointment scheduling, you will next need to make specific service-delivery decisions to guide your telephone staff in assisting women and responding to them with standardized information. The following table outlines key information your telephone staff will need to collect from women seeking your services, with questions for you to consider.

Information to Collect When Scheduling Appointments

Key Questions	Comments
Who will you allow to make the appointment? The woman only? Her partner or parent (if she is an adolescent)?	If you permit others to make the appointment for a woman, be sure to obtain all of the medical information needed. You can also have them call back with any information they do not know. If the person making the appointment is a minor, be familiar with your facility's policies and legal obligations.
What medical information will you require when a woman is making an appointment?	Determine what (if any) conditions you want to screen for on the phone. Have a standardized list of questions you want asked of every caller, including LMP, prior ultrasound, blood type, list of current medications, medical conditions, allergies to medications.
What will be your process for referring out?	Determine all contraindications to treatment within your facility. Your appointment schedulers will need to know what these are and why a woman needs to be referred. Also have referrals ready for these contraindications — it is always helpful to have a name, not just a number to share.
What type of pre-procedure information do you want to convey?	Have a list of pre-procedure instructions for your service, if applicable. Remind the woman to bring in her insurance card, if applicable. If a woman is requesting IV sedation or medication that will prevent her from driving herself home, be sure to explain this to her and also let her know that the clinician will need to evaluate her to make sure she can receive sedation or other medication. IV sedation typically requires up to one hour in recovery. If your facility has a website, you can consider adding this information to it.
How quickly do you want to make appointments?	Keep in mind that you will need to pay attention to the amount of time between a woman's call and her actual appointment date. For miscarriages, you will need to set up a system to determine how urgently the woman needs to be seen and a back-up system to refer to an emergency room. Remember, though, that women experiencing miscarriage can often have anxiety and fear, so being seen as soon as possible is always best.
What will you do to support women who are calling your facility to make an appointment?	The woman calling you to inquire about or make an appointment may be nervous, afraid and upset with herself or her partner. She needs empathy, patience, support and information delivered in a way she can understand. Remember this call will be her first experience with your facility.

Training for appointment staff. Comprehensive staff training is a critical component that will help to ensure a smooth appointment-making system in your facility. It is important that all telephone staff receive an initial orientation, as well as ongoing training to update them on changes in your facility or new developments in the field that affect their work. Here are some areas that are important to consider when training your appointment staff:

- a complete understanding of the services being provided in your facility — your staff must be able to answer most of the caller's questions about miscarriage management, pain management, aftercare and know general contraception information
- basic telephone-counseling training to allow the staff person to address each caller's concerns and fears
- familiarity with screening procedures
- knowledge of confidentiality principles and practices both inside and outside your facility
- charting requirements particularly relating to callers with emotional and/or medical issues
- knowledge of your facility's appointment grid
- making appropriate referrals
- how to effectively and compassionately handle callers who are in crisis

F. Counseling and referrals

Effective counseling is an integral part of high-quality miscarriage care, as it provides an opportunity to assess a woman's ability to cope and helps her explore her feelings and fully understand the information she needs to make informed decisions. It is essential to provide complete, accurate and easy-to-understand information that assists the woman in understanding and considering her medical options. It is also important to understand that women may be anxious about their visit to your facility. Through effective counseling, anxiety can be reduced and women are better able to to develop appropriate expectations about the service they are about to experience.

Counseling also helps you to identify other issues that affect a woman's sexual and reproductive health and are critical to her well-being not just while she is in your facility, but after she leaves. The level of partner support, issues of sexual violence and contraceptive choices are areas where counselors can be sensitive to a woman's needs and help identify areas in which a woman may need more information, a referral or simply someone to listen to and support them.

Every health-care facility will vary on how counseling is done: some facilities will have social workers and other trained professionals, some will have lay counselors or a combination of both. In some facilities the clinician may be the counselor. If you are located in a hospital setting, you might want to consider having medical residents learn the counseling piece, as well as the medical procedure – this will strengthen their understanding of the issues women face and the choices they make, which will help them to deliver more effective services.

Checklist for providing woman-centered counseling and education. The following checklist has been developed to aid you in offering a nonjudgmental, women-centered education and counseling session for uterine evacuation services. ☐ Treat women with respect and dignity and always in a nonjudgmental manner. ☐ Identify yourself by name and state the purpose of the interaction and your role. ☐ Help the woman clarify her thoughts and decisions about her pregnancy loss and her options. ☐ Explain the procedure in a manner that reflects the woman's level of understanding. Do not, for example, use complicated medical terms and keep your delivery short. It does not help to overwhelm someone with unnecessary information. Be sure that the woman is making a voluntary, informed choice about the procedure. The counselor can explain that there are many reasons women bleed during pregnancy and that the clinician will need to examine them to make sure they are having a miscarriage. ☐ Encourage the woman to ask questions and address any concerns she may have. Avoid yes or no questions. To verify understanding, have the woman tell you in her own words what she knows about the procedure. ☐ Ask if the woman wishes for her partner or a support person to accompany her to the procedure and/or recovery room, if your facility permits. With miscarriage, it is not uncommon for a woman's partner or support person to want to be part of the process. ■ Explain the range of feelings a woman is likely to experience after losing a pregnancy and help the woman to identify a support network to process her feelings during and after the event. Do not make assumptions about what women are feeling — for example, a woman having a miscarriage may be in fact happy or relieved that she is having a miscarriage while another woman might be sad or angry. ☐ Discuss any follow-up or additional visits that may be required, when they will take place and what to expect

during the visit(s).

Identify measures that can be taken to prevent possible complications and give directions for managing complications if they do occur, such as contacting the facility after hours, pain relievers, etc.
Offer information about sex/intercourse after the procedure.
Ask the woman if she has birth-control needs and discuss appropriate options with her.
When handing a woman a written list of instructions or information on contraceptives, be sure to review verbally with her. This will help to facilitate her understanding and give her an opportunity to raise any questions or concerns. To verify understanding, you can ask her to tell you in her own words how she needs to take care of herself after an aspiration procedure, how she needs to take her birth control pills, etc.

Referrals. Every facility needs to be prepared with an up-to-date referral list, in order to effectively address all of a woman's needs. Keep in mind that, for some women, this might be the first time they are seeking medical care, giving you a great opportunity to help them with other health-care or social-service needs.

Types of referrals and resources to consider include:

- family planning
- domestic violence
- HIV/AIDS treatment and prevention services
- substance abuse (detoxification and outpatient services)
- housing/shelters
- mental health
- home health
- food and nutrition

- protective services
- · legal services
- · day-care programs
- insurance and prescription-drug assistance
- employment assistance
- · financial assistance
- transportation

After you have developed your resource and referral list, be sure to update your list with new contact names, phone numbers, websites and e-mail addresses at least every six months.

When making a referral, remember it is always preferable to give a woman the name of a contact person rather than just a phone number. You might want to consider following up with women after making referrals to make sure that a referral was appropriate, that service was in fact received and to obtain information about what the woman's experience was with the service. If you find women are having difficulty accessing a particular service or were dissatisfied with a service, you can use this as an opportunity to conduct awareness raising and education with that particular service provider.

G. Supporting women through an MVA procedure with local anesthesia

When using MVA for uterine evacuation for miscarriage, neither conscious sedation nor general anesthesia is required, particularly if the opening to the cervix is already dilated. MVA has been used successfully with women using local anesthesia for many years and in many different settings. Pain management is discussed in more detail in Section V. Sample Medical Protocol for Miscarriage Management (p. 49). Local anesthesia is a good option for women who have transportation issues or need to return to work or care for their children and other family members as soon as possible. It is also a good option for women who do not want anesthesia.

It is not uncommon that clinicians and other health-care personnel think that IV sedation and/or general anesthesia is required or is the norm for uterine evacuation. Many facilities, however, successfully provide uterine evacuation for miscarriage using only local anesthesia and oral analgesic. This option allows women to remain awake during their procedure; shortens their recovery time; and reduces possible anesthesia complications. Women can expect uterine evacuation for miscarriage using MVA to take less than five minutes. During that time, a medical assistant, counselor or nurse can be at the woman's side as her advocate to lend support to help her through the procedure.

Here are some tips for how to work with women who are having local anesthesia for uterine-evacuation services:

- Your attitude and energy, for both the advocate and the clinician, are key in setting the tone during a procedure. Being respectful, calm, reassuring and direct will go a long way toward relaxing the woman. When women are relaxed, they tend to experience less discomfort.
- Advocates and clinicians will need to establish a routine for getting started with a woman. Introductions are necessary if the clinician is just meeting the woman. The clinician can ask if the woman has any further questions and also may want to do a final chart review. The advocate or the clinician will then set the women in position, placing her feet/knees in the stirrups to begin her procedure.

- Have an advocate stationed at the head of the table, solely focused on the woman. The advocate can offer physical comfort during the procedure, including touching a shoulder or holding a hand. Be aware that sometimes a woman's emotions might not fully surface until she is on the table undergoing a procedure. Being focused will help you to better respond to her needs during the procedure.
- Ask the woman how you can help her get through the procedure this includes both the advocate and the clinician. Some women will want to know everything that is happening, while others prefer to be distracted with conversation about something else. If a woman does want to know what is happening technically, be sure to tell her before it happens. Alert her that she may feel a slight pinch if a paracervical block is administered. When the clinician starts to suction the uterus, let her know that it is normal and natural to feel anything from mild to strong cramping.
- Don't be afraid of acknowledging and normalizing discomfort and pain. If a woman is fearful, remind her that everyone's response to pain is different and ask her what you can do to help her through it. It can also help to let the woman know that cramping serves an important function and can signal that the procedure is proceeding properly. Cramping is a natural reaction when a uterus is emptied it is normal and supposed to happen.
- A very effective way to help with pain management is to utilize the basic breathing technique. Get close to the woman's face and have her focus on your face. Instruct her to take a deep breath through her nose and hold it for a count of five. Then have her slowly exhale through pursed lips — exhaling the entire breath. Repeat as needed.
- When the procedure is complete, be sure to cover the woman
 after all instruments are removed and before you are ready to
 take her legs out of the stirrups. This simple gesture is
 very respectful.

H. Billing and Reimbursement

Billing is an important aspect of service delivery and service sustainability. Below, you will find billing codes and alternatives to billing insurance carriers that can assist you as you add new services to your facility. Keep in mind that this is not an exhaustive list of billing codes.

Billing insurance carriers. To assist you with billing for miscarriagemanagement services, here are billing codes that you can use.

We list the:

- International Statistical Classification of Diseases and Related Health Problems, or ICD-9 codes. For more information on ICD-9 provider and diagnostic codes go to www.hhs.gov/ ICD9ProviderDiagnosticCodes. ICD-9 codes are diagnostic codes and are also referred to as Level 3 codes.
- American Medical Association's Current Procedural Terminology, or CPT codes. For more information on CPT codes go to www.ama-assn.org/ama/pub/category/3113.html.
 - CPT codes are used to bill for procedures and are also referred to as Level 1 codes. CPT codes are revised annually and you can obtain information about purchasing a CPT book via the link to the American Medical Association above. You can also purchase and download the book from this site.
- U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services Healthcare Common Procedure Coding System, or HCPCS codes. For more information go to www.hhs.gov/MedHCPCSGenInfo.
 - HCPCS codes are used to bill for drugs or medical supplies and are also referred to as Level 2 codes.

ICD-9 diagnosis codes to use for MVA for miscarriage:

V72.42	positive pregnancy
634.91	spontaneous abortion; incomplete
634.92	spontaneous abortion; complete
632	missed abortion
634.00	threatened abortion
V07.2	RhoGam
787.02	nausea alone
787.01	nausea and vomiting
787.03	vomiting alone
V67.00	post-surgical care
V25.9	contraceptive management; unspecified
V25.01	initiation of oral contraceptives (OCs)
V25.02	initiation of other contraception
V25.41	contraceptive-pill management
V25.49	other contraceptive management
V25.09	family-planning advice
V72.42	special pregnancy examination or test, positive result (can use for first visit if no procedure is done)

CPT procedure codes for uterine evacuation:

36415	venipuncture
36416	finger stick
57401	pelvic exam
58300	IUD insertion (includes Mirena)
58301	IUD removal (includes Mirena)
59812	surgical intervention for incomplete abortion
59820	missed miscarriage in first trimester or missed abortion in first trimester
64435	paracervical block
64450	injection, nerve block
76801	transabdominal ultrasound, obstetric
76815	limited ultrasound, obstetric
76817	transvaginal ultrasound, obstetric (pregnant uterus)
81025	pregnancy test; urine
81205	urine HCG
84702	pregnancy test; blood
85018	hemocue
85108	hemoglobin
86901	Rh typing
88304	fetal tissue exam
90385	microRhogam
90782	therapeutic injection
99000	specimen handling
99402	counseling and informed consent (performed by a physician)

HCPCS drug and medical supply codes for miscarriage:

A4550	surgical tray
J1885	Ketorlac (for nausea)
J2001	lidocaine
J2210	methergine (for heavy bleeding)
J2550	Phenergan (for vomiting)
J2788	half dosage of Rhogam
J2790	full dosage of Rhogam
J3490	unclassified drug
J8499	prescription drug, oral, nonchemo, NOS
S0191	misoprostol

Alternatives to billing insurance. For women without insurance or who choose not to use their insurance, alternative payments include cash, personal checks, credit cards or delayed payments.

I. Advertising and marketing

Not all facilities will elect to advertise their miscarriage management services. Many hospitals, for example, do not advertise, other than within their different departments, to make other medical and social-service staff aware of a new service or procedure. If you do plan to actively advertise, here are some things for you to consider:

- It is important to develop an advertising and marketing budget and a marketing plan.
- Some "tried-and-true" advertising strategies include: online provider listing through the local telephone book; print telephone books; brochures; business cards; and referral notes. Don't forget to factor printing and postage costs into your advertising budget.
- Develop a web site for your facility that describes your services, including MVA for miscarriage management. If you already have a website, add information on your new service to your site.

J. Providing culturally competent services

It is important to take into consideration the individual experiences and needs of women who come to your facility for miscarriage-management services. The loss of a wanted or planned pregnancy can stir varied and sometimes strong emotions in any woman, yet women from particular groups may need closer attention and support. Keep in mind that there is a wide diversity of experiences between women from different racial/ethnic groups, lesbian, gay, bisexual and transgendered (LGBT) groups, women living with HIV and women with disabilities.

To provide culturally competent services, your facility and staff will need to:*

- Have a defined set of professional values and demonstrate behaviors and attitudes that enable you to work effectively with women of different cultures other than your own;
- Have the capacity to value diversity, conduct continuous self-assessment or monitoring, acquire and institutionalize cultural knowledge and adapt to diversity and the cultural contexts of the communities you serve;
- Incorporate the above into all aspects of service delivery, including involving input from the women you serve.

Special considerations. As you plan for your service-delivery change, consider the training needs for your current staff or the staff you will hire to become culturally competent. We list some key issues here for you to consider that your staff might also need training in. We identify some resources to assist you in the following text and have a more extensive list in *Section VI. Resources*.

^{*}Adapted from Georgetown University's National Center for Cultural Competence, www11.georgetown.edu/research/gucchd/nccc/

- **Stigma**. Stigma around miscarriage can affect service delivery in a facility. Many women feel unable to talk about miscarriage, even with close female friends, partners and family members, and experience isolation and guilt. Women may face stigma from their community, particularly if they don't already have children and have struggled with having a successful pregnancy. Feelings about being infertile and childless can be extremely overwhelming, as can the common myth that a woman "did something wrong" to cause her miscarriage. Latinas can be influenced by their religion (Catholic or Evangelical) and experience heightened guilt with miscarriage, and African-Americans may feel unable to talk openly about miscarriage because of the importance their community places on the family. Women from these population groups, as well as women in general, may not feel comfortable sharing their experiences and will need support from you and perhaps a referral for further counseling.
- Sexual orientation/gender identity. Cultural sensitivity needs to be applied when providing services to women who identify themselves as being part of the lesbian, gay, bisexual, and transgender (LGBT) community. It is important not to assume that a woman who identifies herself as a lesbian doesn't have sex with a male partner or is a victim of sexual abuse.
- Women living with HIV. Not making assumptions is key when
 working with women living with HIV. Like with any woman,
 the pregnancy may be unplanned or planned and wanted or
 unwanted. Also do not assume that women living with HIV
 are only interested in learning about condoms they often
 want information about other methods of contraception
 as well. You will also need referrals to a local HIV/AIDS
 organization or information line.

- Women with disabilities. Not making assumptions toward
 women with disabilities is also key, particularly regarding
 their ability to have sex or desire to have children. Be aware
 that women with disabilities can tend to experience violence
 and abuse over long periods of time, and that a pregnancy
 may be the result of sexual abuse.
- Language. Being culturally competent includes taking into consideration that English may not be the language spoken by some of the women you serve. If you serve a particular language group, having bilingual staff is highly recommended. You can also serve women well by using trained interpreters (avoid using family members because you will not get unbiased information). One resource is the ATT Language Line with 24-hour access to interpretation of over 140 languages at 1.800.628.8486. You can also make non-English speaking women feel safe, secure and more at ease by having information and posters in languages other than English.

K. Providing youth-friendly services

It is important to include a youth-friendly approach in your practice if you currently or plan to provide services to adolescents. Young women are less comfortable accessing reproductive health services than adult women. They are also likely to have fewer resources and are more likely to have less accurate information about their bodies, pregnancy and contraception.

Providing youth-friendly services does not have to mean radically changing your facility, but rather making some changes or additions to make your practice friendlier to adolescents. It is key, for example, that all of your staff think about their own beliefs about adolescent sexuality because negative attitudes towards youth can become a major barrier to service provision.

What are youth-friendly services?

- Respectful and nonjudgmental provider and staff attitudes
- Services are offered at hours that are convenient for adolescents
- Staff are trained in counseling young people
- Involve young people in the planning and implementation of services
- Clients are given the assurance of confidentiality and privacy
- Provide services for free or on a sliding scale
- Have materials available that focus on adolescents
- Separate space set aside for young people

To help you make your services more youth friendly, we have listed materials and organizations you can access in Section VI. Resources (p. 79).

V. Sample medical protocol for miscarriage management

A. Miscarriage management overview and definitions

Overview: Fifteen to 20 percent of clinically recognized pregnancies end in miscarriage (Hemminki, 1998).

Historically, miscarriage was primarily managed with sharp curettage and later, with vacuum aspiration. Other treatment options exist and are increasingly used throughout the world, including expectant management and medical management with prostaglandins. Clinicians need to be familiar with the indications for, advantages and disadvantages of each option in order to appropriately counsel patients. The woman's preferences and expectations must also be factored into the management plan, using the concept of woman-centered care (Herrick, 2004; Hyman, 2005).

1. Miscarriage definitions

- a. Definition of miscarriage: A spontaneous pregnancy loss at less than 20-weeks gestation based upon last menstrual period. Guidelines for miscarriage management in this document will refer to either incomplete abortion or missed abortion, defined as follows:
 - i. **Incomplete abortion** refers to when a pregnant woman has an open cervix and has passed some, but not all of the pregnancy tissue (Castleman, 2002).
 - ii. Missed abortion refers to when a pregnant woman has a closed cervix and a uterus that does not increase in size, as would be expected in early pregnancy. The pregnancy is still in the uterus but is not viable. If an ultrasound is performed, it shows either an anembryonic pregnancy or embryonic demise.

- Anembryonic pregnancy: If a transvaginal ultrasound is performed no signs of an embryonic pole in a gestational sac with a mean sac diameter greater than 20mm (Ngai, 2001; Bagratree, 2004; Levi, 1988).
- Embryonic demise: no embryonic cardiac activity in an embryonic pole greater than 5mm (Goldstein,1992; Brown, 1990; Zhang, 2005; Creinin, Moyer, 1997; Bagratree, 2004; Ngai, 2001; Grieble, 2005; Chen, 2007).
- b. Evidence from large, randomized controlled trials supports the use of different misoprostol regimens for "incomplete abortion" versus "missed abortion" (Shaw, 2007; Zhang, 2005; Weeks, 2005; Ngoc, 2005; Ngoc, 2004; Tang, 2003).

B. Medical intake

Overview: The clinical assessment needs to take place in a safe and private setting, so a woman is given the opportunity to speak alone with the provider. A complete medical intake for miscarriage consists of the following steps:

1. Client history

- a. Details of current pregnancy:
 - i. last menstrual period, date of conception, if known
 - ii. signs and symptoms of pregnancy (especially bleeding or pain)
 - iii. most recent birth control method
 - iv. Is this pregnancy desired?

b. General medical history:

 Ask about general medical history, with a focus on conditions that may impact management, including: severe hypertension, active seizure disorder, severe anemia, blood-clotting disorders, uncontrolled diabetes, symptomatic or severe heart disease, or uncontrolled asthma.

- ii. surgical history (particularly cervical/uterine, reactions to anesthesia)
- iii. current or recently taken medications (prescription, over-the-counter or OTC or herbal remedies)

c. Drug allergies:

i. specific medications that have relevance to miscarriage care, such as prostaglandins, antibiotics, betadine, latex, ibuprofen and other analgesics

d. Pregnancy history:

- i. number of total pregnancies and method of delivery
- ii. any pertinent medical history related to previous pregnancies

e. Contraceptive history:

- i. methods used; side effects or complications; reasons for stopping/restarting
- ii. preliminary plans or questions regaring post-procedure contraception

Sexual history:

- i. as pertinent
- ii. HIV status and presence of sexually transmitted infections (STIs)

g. Social history:

- i. education.
- ii. employment and occupationiii.
- iii. support network (partner, family, friends, church, etc.)
- iv. tobacco, alcohol or drug use
- v. Is the woman subject to violence/forced sex?

2. Counseling and informed consent

General considerations: Counseling is a structured interaction through which the woman voluntarily receives emotional support and guidance from a trained person in a caring, nonjudgmental manner regarding her early pregnancy loss. Effective counseling is structured completely around the woman's needs and concerns. Active listening is key and it is best to ask open-ended questions and to also pay attention to nonverbal communication. Counseling must be done in order to obtain voluntary, informed consent.

- Solicit the woman's initial and current feelings towards the pregnancy. Do not make assumptions that the pregnancy was or was not desired.
- b. Tailor counseling based upon the woman's feelings towards the pregnancy. Emotions ranging from sadness, relief, anger or guilt are common.
- c. Address any feelings of guilt that the woman and/or her partner may have about "causing" the miscarriage. Inform the woman and her partner that the majority of miscarriages are a result of random events arising from chromosomal abnormalities.
- d. Inform the woman regarding the miscarriage diagnosis and likely outcome. Provide her with all treatment options and discuss the advantages and disadvantages of each option within the context of her situation.
- e. Reassure that the success rate for a subsequent successful pregnancy is good (at least 70 percent) following a miscarriage (Simpson, 2007).
- f. For recurrent pregnancy loss (defined as two or more consecutive miscarriages), a referral for further evaluation is indicated. Earlier evaluation may be warranted for older women (older than 35 years of age) or younger women with other clinical indications (Simpson, 2007).

- Establish voluntary, informed consent (for whatever course of action is chosen to magage the miscarrage):
 - i. Determine if the woman is capable of listening to and understanding information provided.
 - ii. Explain the options and procedure(s) available to her in nontechnical, clear language, including benefits, risks and alternatives. Provide written information to her, as well as referrals as appropriate.
 - iii. Provide accurate information about the woman's medical condition and test results, and how these may affect her options.
 - iv. Always ask her in private if she wishes to include others in the counseling session.
 - v. Encourage the woman to ask questions.
 - vi. Verify the woman's understanding of information provided.
 - vii. Obtain written consent when appropriate.

3. Physical examination

- a. Check vital signs: including pulse and blood pressure.
- b. Perform focused medical examination as indicated.
- c. Perform pelvic examination:*
 - i. Examine external genitalia: Note any lesions, signs of trauma.
 - ii. Perform bimanual exam: Assess uterine size, consistency and position of uterus and adnexa assess for cervical motion tenderness or adnexal tenderness.
 - iii. Perform speculum exam: Note bleeding, vaginal discharge. Perform wet prep and other STI testing as indicated.

- d. Laboratory testing:
 - i. Hemoglobin or hematocrit to detect anemia
 - ii. Rh status**
 - iii. STI screening, as indicated (including HIV)***
 - iv. cervical cytology, as indicated***
- e. Pregnancy diagnosis and gestational age determination:
 - i. LMP, date of conception
 - ii. pelvic examination (see details above)*
 - iii. urine pregnancy test(s), as indicated (see Box 1, p. 55)
 - iv. serum β -hCG level, as indicated (see Box 1, p. 55)
 - v. ultrasound, as indicated (see Box 2, p. 55)

*Ideally, the woman should undergo only one pelvic exam. This can be done just before the MVA procedure, which is nicer for the woman. If the pelvic exam is being performed immediately before MVA, then the clinician would do the bimanual exam first followed by the speculum exam (then immediately into the procedure). Alternatively, if the pelvic is to be repeated, then generally in the first pelvic exam the speculum exam and related tests/cultures are done before the bimanual exam.

**The need for routine Rhesus isoimmunization has not been proven by clinical studies (WHO Technical and Policy Guidelines for Safe Abortion, 2003). In areas where Rh immunoglobin is routinely provided to Rh-negative women, it should be administered at the time of the procedure.

*** Facilities that offer STI and cervical cancer screening should be prepared to inform women of positive results and treat or refer accordingly. Cervical cancer screening and other relevant reproductive health-care services can be offered to women at the time of miscarriage care.

Box 1. Use of urine pregnancy tests, serum β -hCG level

Often the information obtained from a woman's history and physical examination may confirm pregnancy, especially if it is advanced beyond approximately eight weeks and therefore advanced enough to determine uterine growth on exam. If the pregnancy is early, or if the typical signs of pregnancy are unclear and the provider is unsure about whether the woman is pregnant, laboratory tests are helpful.

Qualitative highly sensitive urine pregnancy tests (HSPTs) may be used to confirm pregnancy. Quantitative serum pregnancy tests are not costeffective for pregnancy diagnosis/confirmation.

Box 2. A note about ultrasound

While ultrasound is a helpful diagnostic tool, it is not a requirement for the provision of uterine evacuation services (WHO, 2003). It has been shown that experienced clinicians can accurately diagnose pregnancy and determine gestational age based upon the client's history and pelvic examination alone (Fielding, 2002). Clinical situations that may warrant ultrasonographic evaluation include:

- a. discrepancy between gestational age, as assessed by uterine size and LMP;
- b. suspicion of ectopic pregnancy, such as irregular vaginal bleeding, pelvic pain, or adnexal mass or tenderness;
- c. provider uncertainty with exam or inability to measure uterine size due to obesity, pelvic discomfort, or an uncooperative client.

- f. Considerations for diagnosing ectopic pregnancy:
 - i. Women may be completely asymptomatic.
 - ii. Suspicious signs and symptoms: uterine size smaller than expected; sudden intense or persistent one-sided lower abdominal pain; irregular vaginal bleeding or spotting; palpable adnexal mass; no products of conception after aspiration procedure; no intrauterine pregnancy seen on ultrasound; and a serum β-hCG and/or low sensitivity UPT indicate the discriminatory threshold has been reached.
 - iii. Suspected ectopic pregnancy requires urgent followup and treatment. An ectopic pregnancy can be lifethreatening; the woman should be treated or transferred as soon as possible to a facility that can confirm diagnosis and begin treatment.

Ectopic Pregnancy

It can be challenging to diagnose ectopic pregnancies. Uterineevacuation methods, whether vacuum aspiration or medication methods using misoprostol and mifepristone, cannot terminate an ectopic pregnancy. A woman with an early ectopic pregnancy may be asymptomatic. Sometimes a clinician may note:

- uterine size that is smaller than expected;
- sudden, intense and persistent lower abdominal pain or cramping, usually one sided, that may be accompanied by irregular vaginal bleeding or spotting or palpable adnexal mass;
- Fainting or dizziness that persists more than a few seconds, possibly indicative of internal bleeding; internal bleeding is not necessarily accompanied by vaginal bleeding;
- No products of conception visualized after a vacuum-aspiration procedure.

When ectopic pregnancy is suspected or diagnosed, it must be followed up urgently. An ectopic pregnancy can be life-threatening; the woman should be treated or transferred as soon as possible to a facility that can confirm diagnosis and begin treatment.

C. Miscarriage Management Options

Three different options for miscarriage management are presented: 1)uterine evacuation using MVA; 2) expectant management; and 3) medical management with misoprostol.

1. Uterine evacuation using manual vacuum aspiration (MVA)

Overview: Aspiration abortion is a safe and effective method of uterine evacuation and is becoming a preferred technique for uterine evacuation, including for miscarriage management, up to 12-completed weeks of pregnancy (WHO, 2003). An aspiration procedure is commonly performed on an outpatient basis in a clinic or ambulatory setting using local anesthesia, oral analgesics and/or light sedation.

a. Uterine-evacuation procedures in miscarriage management

- Compared to vacuum aspiration, sharp curettage is associated with higher rates of bleeding, pain and longer duration procedures (Forna, 2001). Vacuum aspiration (MVA and EVA) can be performed safely in the outpatient setting and is recommended over sharp curettage (WHO, 2003).
- ii. Potential benefits of vacuum aspiration: a high success rate (higher than 98 percent); rapid resolution of symptoms; anesthesia and/or analgesia can be provided. MVA provides extra benefits allowing more decentralized care (Dalton, 2002; Dalton, 2005).
- iii. Potential disadvantages: risks of anesthesia and/ or analgesia, very low but reported surgical risks of: infection, uterine perforation (from 0 to 0.3 percent), cervical trauma, excessive bleeding or infection, patient anxiety and fear of a "procedure" (Hyman, 2005; Mahomed, 1994).

Traditionally, uterine evacuation for miscarriage management was referred to as dilatation and curettage (D&C), or sharp curettage, and was performed in the operating room under general or regional anesthesia or moderate sedation. Uterine evacuation can also occur via "aspiration" using an electric pump machine or a 60cc hand-held manual vacuum aspirator (syringe).

 iv. Prompt uterine evacuation is indicated in hemodynamically unstable patients experiencing heavy bleeding and/or septic abortion.

Box 3 compares two uterine aspiration methods, manual vacuum aspiration (MVA) and electric vacuum aspiration (EVA).

Box 3. Manual vacuum aspiration (MVA) compared to electric vacuum aspiration (EVA)

MVA EVA

Very portable Less portable Relatively inexpensive Expensive

Does not require electricity Requires electricity

Less fragmentation of POC
Slightly slower procedure
Quiet

More fragmentation of POC
Slightly faster procedure
Often loud "vacuum" sound

POC = products of conception

Ipas MVA Plus	lpas MVA Plus				
Intended use/indications	All Ipas aspirators and cannulae are intended for uterine aspiration/uterine evacuation in obstetrics and gynecologic patients. Clinical indications for uterine aspiration with this product are: treatment for incomplete abortion for uterine sizes up to 12 weeks from last menstrual period (LMP), first-trimester abortion (menstrual regulation) and endometrial biopsy. Applications for endometrial biopsy may include cases of fertility, abnormal uterine bleeding, amenorrhea, and screening for endometrial cancer or screening for endometrial infections.				
Contraindications	Endometrial biopsy should not be performed in cases of suspected pregnancy. There are no known contraindications for treatment of incomplete abortion for uterine sizes up to 12-weeks LMP or first-trimester abortion (menstrual regulation).				
Warnings	As with any invasive procedure, there is risk of infection to providers, patients and support staff through contact with contaminants. To minimize the risk, universal precautions must be observed at all times. These include using appropriate barriers (such as gloves and masks), handling waste carefully and taking precautions to prevent injuries. Uterine aspiration/uterine evacuation are procedures that involve minimal trauma to the uterus and cervix. However, in a small percentage of cases, one or more of the following complications may occur during or after procedures: uterine or cervical injury/perforation, pelvic infection, vagal reaction, incomplete evacuation or acute hematometra. Some of these conditions can lead to secondary infertility, other serious injury or death.				
Precautions	Before performing uterine evacuation or endometrial biopsy, any serious medical conditions that are present should be addressed immediately. These include: shock, hemorrhage, cervical or pelvic infection, sepsis, perforation or abdominal injury, as may occur with incomplete abortion or with clandestine abortion. Uterine aspiration/ uterine evacuation is often an important component of definitive management in these cases and once the woman is stabilized, the procedure should not be delayed. History of blood dyscrasis may be a factor in the woman's care. In cases where the woman has a history of a blood-clotting disorder, Ipas cannula and aspirators should be used only with extreme caution and only in facilities where full emergency backup care is available.				

b. Pain-management plan

- i. Discuss with the woman prior to the procedure.
- ii. Include verbal reassurance before, during and after the procedure.
- iii. Some clinicians feel that enabling the woman's support person to accompany her can be helpful.
- iv. Administer a non-steroidal anti-inflammatory (NSAID) of choice one hour before the procedure, if no allergies or contraindications.
- v. Any peri-procedural anxiolytic or analgesic medications (e.g. narcotics) should be offered.
- vi. Perform a paracervical block during the procedure.

c. Cervical preparation

- i. There is insufficient evidence to recommend routine cervical priming before an aspiration procedure in the first trimester (Society of Family Planning, 2007).
- ii. Cervical preparation should be considered for adolescents, for pregnancies greater than 12-weeks gestation (WHO, 2003; SFP, 2007), or for other situations in which the risk of perforation is increased due to either factors or provider experience (RCOG, 2000; SFP, 2007).
- iii. When misoprostol is used prior to an aspiration procedure, the optimal dose and timing are 400μg vaginally , 3–4h, orally 8–12h or sublingually 2–4h before the procedure (SFP, 2007). Vaginal administration may provide fewer systemic side effects (Carbonell, 2001, Carbonell, 2006).

d. Equipment

(See Section II. Checklist for integrating miscarriage management into outpatient service delivery, including tips for ordering equipment, C. Miscarriage management with MVA)

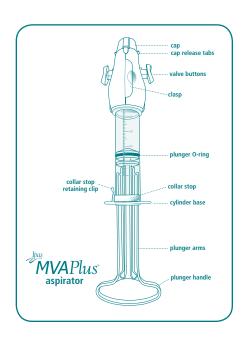
- i. emergency equipment (oxygen, crash cart)
- ii. instrument tray
- iii. equipment for POC viewing, specimen processing and disposal
- iv. documents (consents, education forms, instructions)

e. Prophylactic antibiotics

- Routine use of antibiotics just prior to or following uterine evacuation is recommended. Doing so is associated with a 42 percent reduction in post-procedure upper genital tract infection, regardless of the woman's risk status (Sawaya, 1996).
- ii. It is unclear which antibiotic regimen is most effective.
- iii. Commonly used regimens include doxycycline 100mg PO BID for three (Lichtenberg, 2003) or seven days (Lichtenberg, 2001).

f. Steps for performing MVA

- a. Clinician preparation:
 - i. Prepare the aspirator.
 - ii. Check the aspirator for vacuum retention (See Box 4).
 - iii. Wash hands and put on appropriate barriers, including gloves* (may be sterile or nonsterile).
 - iv. Select the correct cannula size (see Table 1).



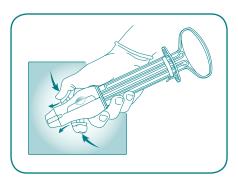


Figure 1

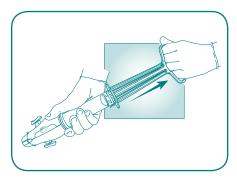


Figure 2

Box 4. Instrument preparation

- Begin with the valve buttons open (not depressed), the plunger
 positioned all the way inside the cylinder, and the collar stop locked in
 place (with the tabs pushed down into the holes in the cylinder).
- Push the buttons down and forward until you feel it/them lock. (See Figure 1.)
- Create a vacuum by pulling the plunger back until the plunger arms snap outward and catch on the wide sides of the cylinder base (See Figure 2.).
 Both plunger arms must be fully extended to the sides and secured over the edges of the cylinder. Incorrect positioning of the arms could allow them to slip back inside the cylinder, possibly injecting the contents of the aspirator back into the uterus. Never grasp the aspirator by the plunger arms.
- Check for vacuum retention before each use by letting the aspirator sit
 for several minutes after establishing a vacuum, then release the buttons.
 A rush of air into the aspirator should be heard, indicating that a vacuum
 was retained.
- If the rush of air is not heard, displace or remove the collar stop, withdraw the plunger and check that the plunger O-ring is free of damage and foreign bodies, properly lubricated and properly positioned in the groove. Also, make sure the cylinder is firmly placed in the valve. Then create a vacuum and test it again. If vacuum is still not retained, discard and use another aspirator.

- b. Preparation of the woman:
 - i. Describe what she will experience and answer all of her remaining questions.
 - ii. Have the woman empty her bladder.
 - iii. Have the woman undress from the waist down and cover with a sheet or equivalent.
 - iv. Help the woman onto the procedure table into dorsal lithotomy position.
- c. Perform a bimanual examination, noting the position and size of the uterus.
- d. Gently insert a speculum (ideally warmed and lubricated), so the cervix is well visualized.
- e. Perform the cervical antiseptic prep.
- f. Perform the paracervical block and apply the tenaculum.
 - i. Use no more than 10-20cc of 0.5-1% lidocaine solution.
 - ii. Inject 1-2cc of anesthetic to the tenaculum site (many clinicians use 12:00; some also use 6:00 when the uterus is retroverted).
 - iii Place the tenaculum at the anesthetized site by opening the tenaculum and closing the "teeth" around a generous amount of cervical tissue.
 - iv. Using the tenaculum, move the cervix to the side to visualize the "reflection," the site at which smooth cervical tissue meets vaginal tissue.
 - v. Inject half of the remaining amount of anesthetic at the "reflection," first at 4:00 and then at 8:00 (or vice versa), burying the needle to a depth of 1-1.5in and taking care to pull back on the plunger first to avoid injecting in a blood vessel.

vi. Clinical pearls:

- Some clinicians state that to reduce the woman's anxiety and pain, it is helpful to ask her to cough just as the needle is inserted into the cervix.
- Inject slowly to decrease pain of injection (Wiebe et al., 1995).
- Mixing bicarbonate with the lidocaine (in approximately a 1:10 ratio by volume of bicarbonate to lidocaine) decreases the acidity of the lidocaine, which speeds the numbing effect and can alleviate stinging caused by the lidocaine injection.

g. Dilate the cervix:*

- Cervical dilatation is required in most but not all cases.
 If the cannula of appropriate size can fit snugly through the os, dilatation is not needed. Table 1 shows suggested dilatation and cannula by uterine size.
- ii. Use gentle operative technique; never use force.
 Mechanical dilators or progressively larger MVA
 Cannula can be used.
- iii. During dilatation, gentle traction should be applied on the tenaculum to straighten the uterine axis as much as possible.
- iv. Gently introduce the first dilator into the cervix just beyond the internal os. A slight "give" may be felt as the dilator slides from the wider external os past the internal os.
- v. Pull the dilator out and turn it over to dilate with the other side (which is the next size up). Progressively dilate to the appropriate size.

Table 1. Suggested Dilatation and Cannula by Uterine Size

	Cannula Size	Dilator Size	
Uterine Size		Denniston (measured in diameter)	Pratt (measured in circumference)
4-6 weeks LMP	4-7mm cannula	5-6mm	19 French
7-9 weeks LMP	5-10mm cannula	7-9mm	19-27 French
9-12 weeks LMP	8-1 mm cannula	9-12mm	27-37 French

Caution: Do not perform uterine aspiration/uterine evacuation until the size and position of the uterus and cervix have been determined. Large fibroids or uterine anomalies may make it difficult to determine the size of the uterus and hard to perform intrauterine procedures, including uterine aspiration/uterine evacuation.

Use a cannula size appropriate to the size of the uterus and amount of cervical dilatation present. Using a cannula that is too small may result in retained tissue or loss of suction. The range of suggested cannula sizes relative to uterine size are shown above.

h. Insert the cannula:

- While gently applying traction to the cervix, insert the cannula through the cervix and into the uterine cavity. Rotating the cannula while applying pressure often helps insertion.
- ii. Do not insert the cannula forcefully through the cervical os into the uterus. Forceful movements may cause uterine perforation or damage to the cervix, pelvic organs or blood vessels. Remain alert to signs that may indicate perforation throughout the procedure and stop suction immediately if they appear.
 - * Throughout the procedure, clinicians should observe the "no-touch" technique, such that no instrument that enters a woman's uterus comes in contact with a contaminated surface before insertion through her cervix. Specifically, the tenaculum, cannula, or dilator tips should not touch the clinician's gloves, the woman's vaginal walls or unsterile parts of the instrument area. This is analogous to IUD insertion technique, which does not require full sterile technique, as long as the loaded IUD and uterine sound do not touch any unsterile surfaces prior to insertion.

i. Suction uterine contents:

- i. Attach the prepared MVA aspirator to the cannula, holding the cannula in one hand and the aspirator in the other hand.
- ii. Start the suction by releasing the buttons of the MVA aspirator; suction will start immediately.
- iii. Gently rotate the aspirator 180 degrees in each direction. Some clinicians use a "round-and-round" approach, twirling the aspirator and cannula around while gently withdrawing, while others use a very gentle in-and-out motion. Blood and tissue should enter the aspirator.
- iv. It is important not to withdraw the opening of the cannula beyond the cervical os, as this will cause the vacuum to be lost. If this happens, or if the aspirator is full, detach cannula from aspirator and re-establish the vacuum.

Signs that the uterus is empty

- No more tissue returns; red or pink foam appears in the cylinder.
- A gritty sensation is felt as the cannula passes over the uterine surface.
- The uterus contracts around (grips) the cannula.
- The woman complains of cramping in response to uterine contractions.
 - v. When the procedure is finished, disconnect the cannula from the aspirator.
 - vi. Empty the aspirator contents by first squeezing the plunger arms and then pushing the plunger into the cylinder.
 - vii. Prepare the aspirator.
 - viii. Repeat steps A-G until the uterus is empty.
 - ix. Keep instruments available in case re-aspiration is necessary.

Solving instrument technical problems

In most MVA procedures, the aspirator vacuum remains constant until the aspirator is approximately 80 percent, or 50mL, full. A decrease in vacuum, however, may occur before the aspiration is complete for the following reasons: the aspirator is full; the cannula is withdrawn past the os prematurely; the cannula is clogged; or there is a loss of vacuum due to incorrect assembly.

If the aspirator fills up so that suction stops:

- Disconnect the aspirator from the cannula, leave the cannula in place inside the uterus.
- Either empty the aspirator into a container by pressing the buttons and pushing the plunger into the cylinder or replace the aspirator.
- Re-establish vacuum in the aspirator, reattach it to the cannula and resume the aspiration.

If the cannula becomes clogged, a lack of tissue or bubbles flowing into the aspirator will be noted. Caution: never try to unclog the cannula by pushing the plunger back in to the cylinder.

- Remove the cannula from the uterus, taking care to prevent contamination.
- Remove the tissue with sterile forceps.
- Reinsert the cannula and continue the procedure, if necessary.

If the aperture of the cannula is accidentally withdrawn from the uterus beyond the external os, remove the cannula, taking care not to contaminate it through contact with the vaginal walls or other nonsterile surfaces:

- Detach the aspirator from the cannula, empty the aspirator, then re-establish vacuum.
- Reinsert the cannula if it has not been contaminated.
- If contamination has occurred, insert another sterile or HLD cannula.
- Reconnect the aspirator, release the vacuum and continue aspiration.

Ipas MVA Plus® Troubleshooting Guide

The Ipas MVA Plus aspirator can be processed by many standard methods. When package insert directions are followed, each device can be reused approximately 25-50 times. Although it is easy to use, disassembly, cleaning, processing and reassembly can lead to problems if not handled properly. Below many of these issues are addressed with appropriate solutions.

Buttons won't engage

- Confirm the liner is not twisted.
- Make sure that you push the buttons down and forward toward the tip of the aspirator.
- Use enough force to click the buttons into place.
- Buttons must be pressed at the same time.

Valve body won't close

- Make sure that the liner is in correct position —the internal ridges must be aligned and the liner tabs fit into the notches of the valve body.
- Make sure autoclave temperature does not exceed 121°C/250°F.

Plunger pulls out of cylinder

• Make sure that the collar-stop is in place and the pins are fully engaged and attached.

Fluid path appears blocked

- Open the valve body and check that the valve liner is not twisted.
- · Remove the valve liner and ensure that it is clean and intact.

Vacuum is not established

- Remove the collar stop, withdraw the plunger and check that the o-ring is free of damage or foreign material. Removing the O-ring from the plunger with a sharp object will cause damage.
- Make sure that the O-ring is properly lubricated and properly positioned in the groove on the plunger head.
- Make sure the cylinder is firmly placed in the valve.
- Make sure that the buttons are locked into place before pulling the plunger back.
- Make sure that the liner is not torn or damaged.
- Make sure that the valve closes completely and is not warped.
- Make sure O-ring is not damaged or replaced with one from a source other than Ipas.

Vacuum is not as strong as it should be

- See "Vacuum is not established" above.
- Check liner. The design of the liner has been enhanced to ensure prompt transfer of the vacuum to the uterine cavity. Some users felt there was a delay in the vacuum with the original liner design. Try using a liner with the enhancements.

Mineral deposits appear to be building up in the cylinder or on the valve hinges.

- Soak the instrument briefly in vinegar and brush with a soft brush as needed; rinse with clean water.
- If you cannot remove the deposits, replace the aspirator.

The device becomes misshapen in the autoclave.

- Check that the temperature setting on the steam autoclave is at 121°C/250° F and that the instrument is in the autoclave for only 30 minutes.
- Do not use a "flash" setting (higher temperature settings for shorter periods of time).
- Replace the aspirator if it has become misshapen

Plunger is hard to pull

- Lubricate the O-ring with one drop of silicone or nonpetroleum-based oil, such as vegetable oil: rub the oil around the O-ring and move the plunger back and forth in the barrel.
- Check for mineral deposits.
 - If so, rinse with vinegar or soak in water and wash well to remove the mineral deposits.
 - Brush with a soft brush, if needed.
- Check for buildup of debris on the O-ring and head of plunger from insufficient cleaning.
 - If so, use warm water and a residue free detergent to remove build-up.
 - A non-abrasive brush can be used to aid in build-up removal.
- Check for worn or deteriorated O-ring. If condition is questionable, replace.
- Check for use of a non-lpas replacement O-ring.
- Make sure autoclaving is not performed with plunger inside cylinder. Always disassemble aspirator before processing.
- Make sure autoclave is set at 121°C/250°F. If condition persists, an alternate processing method is recommended.

j. Completing the procedure:

- i. Take the cannula out.
- ii. Take the tenaculum off.
- iii. Use a sponge stick to gently swab any blood from the vaginal vault.
- iv. Observe for any active signs of bleeding. Applying pressure to the tenaculum sites usually stops any oozing.
- v. Remove the speculum.

k. Inspecting the products of conception (POC):

- i. Rinse the POC in a strainer.
- ii. Place the POC in a clear, glass bowl with water to "float" the tissue.
- iii. Inspect the tissue: note gestational sac, villi, decidua, and fetal parts as appropriate.
- iv. Document whether or not POC are consistent with gestational age.
- v. Although pathology review is usually not needed, the tissue specimen may be sent to pathology if clinically indicated (e.g., suspected molar) or required (e.g., by state regulations.

l. Immediate post-procedure care:

- i. Immediately process or discard all disposable instruments.
- ii. Remove barriers, such as gloves, and wash hands.
- iii. Reassure the woman that the procedure is finished.
- iv. Help her into a comfortable resting position on the table.
- v. Document all information about the procedure per local protocol.

m. Post-procedure care:

- i. While the woman is recovering, record her vital signs.
- ii. Monitor for pain and bleeding. Prolonged, severe cramping and excessive bleeding are not normal and require prompt evaluation.
- iii. Review the contraceptive plan and initiate the method that day if possible. Discuss whether emergency contraception pills (ECPs) are desired as a back-up method and provide as appropriate.
- iv. Review information concerning HIV/AIDS including risks, benefits of early identification, referral for voluntary HIV counseling and testing, and safer sexual practices. As needed, offer the woman names of local HIV/AIDS support groups that can help.
- v. Women who are Rh negative should receive Rh immunoglobulin (50 micrograms for first-trimester abortions).
- vi. Review after-care instructions (see Box 4).
- vii. Provide the woman with a follow-up appointment.

Box 5. Miscarriage after-care instructions

Prior to discharge, the provider needs to give the woman verbal and written after-care instructions, reviewing the following:

- Instructions for taking any prescribed medications (antibiotics, analgesics).
- Information about routine personal hygiene. For example, bathing and showering are fine.
- Information about resumption of sexual activity and contraception:
 - After an uncomplicated procedure, the woman may have vaginal intercourse and insert tampons as soon as she desires to do so. If she does not want to become pregnant, she should use an effective form of birth control when having intercourse. Conception can occur again within 10 days after uterine evacuation for miscarriage.
- Signs of a normal recovery:
 - Some uterine cramping may occur over the next few days. Discomfort from cramping may be eased by mild analgesics, warm compresses or baths.
 - Some spotting or bleeding is normal. A normal menstrual period should begin within the next four to eight weeks.
- Signs and symptoms that require immediate attention: fever, chills, vomiting, fainting, severe pain, heavy bleeding (more than normal menstrual bleeding).
- Signs and symptoms that should be monitored, and require attention if they worsen rather than diminish over time:
 - prolonged cramping (more than a few days of abdominal pain, cramping or backache)
 - pain in the abdomen or distension of the abdomen
 - foul-smelling vaginal discharge
 - delay in resumption of menstrual periods (more than eight weeks)
- Instructions for seeking emergency care; provide a 24-hour contact number.
- Referrals, as indicated for any identified medical and/or psychosocial
- Date, time and location of follow-up visit.

g. The follow-up visit

- i. Follow-up care may or may not occur at the same facility where the woman received her abortion care (see Box 5).
- ii. Providers should inquire about resolving symptoms of pregnancy, vaginal bleeding, pain, pain medications taken, fever, current contraceptive use, and resumption of normal activities.
- iii. Providers should inquire about lingering concerns or emotions regarding the abortion. The safety and long-term health of a woman after an abortion should be discussed (e.g. provide reassurance that a safe abortion does not affect fertility).
- iv. It is not mandatory to perform a pelvic exam at the followup visit. A pelvic examination and evaluation for STIs should be conducted as clinically indicated.
- v. Contraceptive plans should be reviewed and initiated, if not already started.
- vi. Any diagnostic tests performed before or during miscarriage care, such as STI testing, should be reviewed.
- vii. Preventive care and referrals for other services should be provided, as indicated.

Box 6. Promoting post-procedure continuity of care

If the follow-up visit is not going to occur at the same site where the woman received miscarriage management services, the woman should be given a referral form with information pertinent to her miscarriage care that can be presented to the follow-up provider. Follow-up care providers should be informed to wait a couple of weeks before conducting any routine pregnancy tests, as the results are likely to still be positive during this time. This can create unnecessary anxiety for the woman (and the follow-up provider). A contact number should be provided should the follow-up care provider have questions regarding routine postmiscarriage care.

2. Expectant management of miscarriage

- a. The reported success rate of expectant management ranges widely, depending on length of follow up, inclusion criteria, comparison intervention and definitions of failed treatment (Chen, 2007; Tang, 2006). Randomized controlled trials comparing expectant management to vacuum aspiration (Nielsen, 1995; Wieringa, 2002) or to medical management (Ngai, 2001; Bagratee, 2004), report success rates ranging from 43-81 percent for expectant management.
- b. Success rates are generally higher for incomplete abortion compared with missed abortion. One large randomized controlled trial found that for incomplete abortion managed expectantly, 25 percent had an unplanned aspiration, whereas 50 percent with missed abortion had unplanned aspiration (Trinder, 2006).
- c. Potential benefits: avoidance of a "procedure" and its associated risks; a perception that it is a more natural and private process.
- d. Potential disadvantages: lower and less consistent success rate compared with medical or surgical management; less predictable duration of time until resolution of miscarriage; potential need for uterine evacuation.

3. Medical management of miscarriage with misoprostol

- a. General considerations:
 - Similar to trials of expectant management, the reported success rates of misoprostol miscarriage management vary depending on length of follow up, dosing schedule, route of administration, and definition of success (Chen, 2007; Tang 2006). Misoprostol for miscarriage management is good option for decentralized care (Gemzell-Danielsson, Rala, 2007)
 - ii. Treatment of incomplete miscarriage with oral misoprostol is associated with a success rate of 87-99 percent (Weeks, 2005; Ngoc, 2005; Phupong, 2004; Dao, 2007; Shwekerela, 2007). Success rates decline to 81-88 percent with missed abortion, both anembryonic pregnancy and early embryonic demise (Zhang, 2005; Ngai, 2001; Bagratee, 2003; Creinin, Moyer, 1997).
 - iii. The use of mifepristone with misoprostol for miscarriage management has not been associated with higher rates of success compared to the use of misoprostol alone (Grønlund, 2002; Wagaarachchi, 2001).
 - iv. The effectiveness of misoprostol largely depends on the length of time allowed for follow up. Care should be taken not to over-diagnose "failed medical management." A decision for completion by vacuum aspiration should be based on the clinical condition of the woman and not on an ultrasound picture, should one be obtained. Clinical follow up is recommended but intervention (by vacuum aspiration) should be avoided until at least seven days following misoprostol administration, unless medically indicated (Blum, 2007). An ultrasound is not required for follow up. If obtained, a 'thickened endometrium' is not a good predictor of the need for vacuum aspiration.
 - v. Potential benefits of medical treatment: avoidance of a "procedure" and its associated risks; a perception that it is a more natural and private process; a higher success rate and more predictable course compared with expectant management.
 - vi. Potential disadvantages of medical treatment: a longer duration of time needed until resolution of miscarriage compared to vacuum aspiration; a potential need for uterine evacuation.

- b. Contraindications to medical management with misoprostol:
 - i. known allergy to misoprostol
 - ii. suspected ectopic pregnancy
- c. Precautions should be taken for women presenting with the following:
 - i. severe anemia
 - ii. coagulation disorder or current anticoagulant therapy
 - iii. intrauterine device in place (remove before treatment)
 - iv. pelvic infection
 - v. any severe medical condition/illness.
- d. Recommended regimens for incomplete abortion for women whose uterine size is less than 12 weeks:
 - i. a single dose of 600µg misoprostol orally (Dao, 2007; Shwekerela, 2007; Bloom 2007)
 - ii. Repeating the dose of misoprostol does not yield a higher success rate for incomplete abortion (Ngoc, 2005; Phupong, 2004).
 - iii. alternative regimen: a single dose of 400μg misoprostol sublingual (Diop, 2009).
- e. Recommended regimens for missed abortion for women whose uterine size is less than 12 weeks:
 - i. a single dose of 800μg misoprostol vaginally (Gemzell-Danielsson 2007)
 - ii. alternative regimen: 600μg misoprostol sublingual (Tang, Lau, 2003; Tang, Ho, 2006) may be repeated every three hours for two additional doses
- f. Reviewing side effects:
 - i. Cramping and bleeding usually starts one to three hours after taking the misoprostol, and peaks in three to five hours. The cramping ranges from mild to intense. The bleeding is often like a heavy period, though it may be heavier. After the miscarriage is complete, vaginal spotting may continue for several weeks.

- ii. Prolonged or serious side effects are rare (Blum, 2007; Gemzell-Danielsson, 2007). Nausea, diarrhea, vomiting, headache, rash, fever and chills sometimes occur following misoprostol, but are usually transient, lasting less than one day if these symptoms occur at all.
- g. Review warning signs and reasons to call:
 - i. Bleeding is heavy enough to completely soak two pads per hour for two consecutive hours or more.
 - ii. A sustained fever higher than 100.4 degrees Fahrenheit or onset of fever beginning more than one day after misoprostol.

h. Follow-up visit:

- i. A history (bleeding diary), clinical examination and bimanual exam should be performed seven to 14 days following misoprostol administration. Miscarriage completion can usually be confirmed by these steps alone.
- ii. Ultrasound confirmation of miscarriage completion is not mandatory. In cases of uncertainty, however, ultrasound may be useful.
- iii. The endometrial thickness following a misoprostoltreated miscarriage has not been proven to be predictive of success (Creinin, Harwood, 2004).
- iv. Clinicians need to consider the woman's clinical history when deciding whether to intervene. Usually vacuum aspiration is not undertaken solely based upon ultrasound findings. If the woman's clinical status is stable, her expectations and personal preferences should also be factored into the decision.

VI. Resources

This list of resources consists of sources we recommend to assist you with the integration of MVA for miscarriage management into women's reproductive health-care services. This list is not exhaustive, nor is it an endorsement of any specific vendors or products.

Adolescents

- Clinic Assessment of Youth Friendly Services: A Tool for Assessing and Improving Reproductive Health Services for Youth - this manual is designed to help assess the quality of services provided to adolescents at a facility or within a program in order to make services more youth friendly. www.pathfind.org/site/DocServer/mergedYFStool.pdf/ docID=521
- **Youth-friendly services:** a manual for service providers this manual from EndgenderHealth contains a useful handout listing characteristics of a youth-friendly reproductive health service. www.engenderhealth.org/res/offc/qi/yfs/index.html

Bibliographies

• Reproductive Health Access Project – bibliographies on contraception, miscarriage management and adolescent sexuality. Also has recommended books on reproductive health. www.reproductiveaccess.org/resources.htm

Billing Codes and Title X

- Centers for Medicare and Medicaid Services Healthcare Common Procedure Coding System, or HCPCS codes, www.cms.hhs.gov/MedHCPCSGenInfo/
- U.S. Department of Health and Human Services. ICD-9 provider and diagnostic codes, www.cms.hhs.gov/ICD9ProviderDiagnosticCodes/

Embryo-fetal development

• A Guide to Fetal Development: The First Trimester – Center for Choice (Toledo, Ohio). Fax a request to 419.259.2644 or call for an order form at 419.225.7769. Book is \$75, including shipping. 1.800.589.6005

www.centerforchoice.com

Equipment recommendations

- Armstrong Medical "Smart Carts" or "Narrow Carts" 1.800.323.4220 www.armstrongmedical.com
- Biz Chair 1.800.924.2472 www.BizChair.com
- Future Health Concepts 1.888.282.8644 www.futurehealthconcepts.com
- Metro Metro Basic 36.20 and carts, procedural 1.800.323.4220 www.metrocarts.com
- Midmark/Ritter exam tables with knee crutches www.midmark.com

Licensing organizations

- National Council of State Boards of Nursing www.ncsbn.org
- State licensing agencies for nursing and/or board of medicine or state department of professional regulation and/or licensing services

Manual vacuum aspiration (MVA)

- Clinical Laboratory Improvement Amendments (CLIA) Regulations, U.S. Department of Health and Human Services, Centers for **Medicare and Medicaid Services** www.cms.hhs.gov/CLIA
- HPSRx Enterprises distributor for Ipas manual vacuum aspirators and general medical supplies. 1.800.850.1657
- **Ipas** tips for using the Ipas MVA Plus. www.ipas.org/Library/Other/Tips_for_Using_the_Ipas_MVA_ Plus.pdf
- Occupational Safety and Health Administration (OSHA)
 - recommendations on use of glutaraldehyde for high-level disinfection.
 - www.osha.gov/SLTC/etools/hospital/hazards/glutaraldehyde/ glut.html
- **Sterrad** recommendations on use of Sterrad for processing aspirators.
 - www.sterrad.com

Medication and supply vendors

• American Pharmaceutical Partners – vasopressin, oxytocin and cefoxitin.

1.888.386.1300

• Berkeley Medevices – cannulae, vacuum aspirators and accessories. 510.231.4346

- Henry Schein general medical supplies and medications. 1.800.772.4346
- HPSRx Enterprises a distributor for Ipas manual vacuum aspirators and general medical supplies and medications. 1.800.850.1657
- McKesson general medical supplies and medications. 1.800.366.8990
- MedGyn Products, Inc. forceps, curettes, specula and tennacula. 1.800.451.9667
- **Medline** general medical supplies. 1.800.633.5463
- **Pharmpax** will repackage medications into patient-friendly dosage, with instructions. 1.800.547.6315
- Pie Medical ultrasound machines and equipment. 732.245.0091
- Shimadzu Medical Systems ultrasound machines and equipment. 1.800.228.1429

Miscarriage information for women and providers

- American College of Obstetricians and Gynecologists has information for professionals and women on miscarriage. www.acog.org
- **Ipas WomanCare**[™] a medical kit designed for use by health-care provides for MVA; also contains a frequently asked questions (FAOs) information sheet for women. www.ipaswomancare.org
- March of Dimes has resources for both women and professionals on miscarriage. www.marchofdimes.org
- National Institute of Child Health and Human Development has resources for both women and professionals on miscarriage. www.nichd.nih.gov/womenshealth
- National Institute of Health, Office of Women's Health has Frequently Asked Question (FAQs) information sheets on a variety of women's health topics, including miscarriage and a special web page on pregnancy. www.4woman.gov/owh
- National Library of Medicine MedlinePlus and search on miscarriage. www.nlm.nih.gov.libproxy.lib.unc.edu/medlineplus/ medlineplus.html
- **National Women's Health Information Center** has miscarriage information and resources for women, as well as professionals. www.4woman.org

National reproductive health organizations

- Association of Reproductive Health Professionals a nonprofit
 membership association comprised of experts in reproductive
 health. ARHP activities include the development and
 implementation of clinical conferences, visiting faculty
 programs, monographs, an international peer-reviewed journal,
 Contraception, and online education. ARHP-sponsored
 programs and conferences feature the latest research, emerging
 technologies, hands-on training, and useful information for
 health care practice.
 www.arhp.org
- **Guttmacher Institute** a nonprofit organization focused on sexual and reproductive health research, policy analysis and public education. www.guttmacher.org
- Planned Parenthood Federation of America national women's health-care provider, educator, and advocate; serving women, men, teens, and families.
 www.plannedparenthood.org

Special considerations for working with diverse populations

- Abuse and Women with Disabilities provides physician guidelines. www.bcm.edu/crowd/abuse_women/ABUGUIDE.htm
- Americans with Disabilities Act Homepage www.usdoj.gov/crt/ada/adahom1.htm
- ATT Language Line 24-hour access to interpretation of over 140 languages. 1.800.628.8486.
- Harnessing Hispanic Health Training session Emory University Regional Training Center video conference session that provides information on how to better serve Hispanic populations. www.rtc4training.com
- Hormonal Contraception and HIV www.fhi.org/en/RH/Pubs/Network/v24_1/index.htm
- National Center for Cultural Competence a variety of resources and tools to become culturally competent. www11.georgetown.edu/research/gucchd/nccc/
- National Latina Institute for Reproductive Health works to ensure the fundamental human right to reproductive health care for Latinas, their families and their communities through education, policy, advocacy and community mobilization. www.latinainstitute.org
- The Lesbian, Gay, Bisexual, Transgender Community Center - provides groundbreaking social service, public policy, educational and cultural/recreational programs. www.gaycenter.org/program_folders/Program.2004-02-12.2460171468/program_view
- Sexual and Reproductive Health of Women living with HIV/AIDS: Guidelines on Care, treatment and support for women living with HIV/AIDS and their children in resource-constrained settings, 2006 - a World Health Organization publication. www.who.int/reproductive-health/docs/srhwomen hivaids/ text.pdf

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