# PROVIDING EARLY OPTIONS

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**A Publication of The National Abortion Federation's Medical Abortion Education Initiative**


## Sono as Needed Protocols: Delivering Medical Abortion in Settings without Routine Ultrasound

The availability of mifepristone offers primary care clinicians the opportunity to provide women increased access to early abortion. However, the perceived need to provide routine ultrasound in the delivery of that care creates a barrier to service delivery, as purchasing and finding room for the equipment, and staff training can be insurmountable barriers in many settings. This leads to the practical question, explored during a session entitled "Sono as Needed: Implementing Medical Abortions at Community Health Centers" at NAF's Annual Meeting in April: How can high quality medical abortion services be integrated into settings without on-site ultrasound machines? Dr. Marji Gold of The Access Project, a group dedicated to integrating early abortion into primary medical care, facilitated a lively discussion. This article discusses the questions and concerns that came up during this session, such as:

- Isn't ultrasound mandated for the provision of mifepristone/misoprostol?
- What has the experience been to date with adverse events related to use or non-use of ultrasound?
- What about ectopic pregnancy?
- What are the medico-legal risks?
- How can we manage patients in a "sonography as indicated" practice?

The FDA labeling for Mifeprex does not require ultrasound. Instead, it requires, through the Prescriber's Agreement, that health care providers be able to accurately date a pregnancy and diagnose an ectopic pregnancy. A variety of methods are available to health care providers to confirm and date pregnancy, including patient history, physical examination, and pregnancy testing. Ultrasound is not necessary as a routine matter. Rather it is indicated when other assessments are discordant. This is the standard of care in obstetrics both inside and outside the abortion context not only in the United States but also in other countries where mifepristone has been approved and used safely. (*See, e.g.*, American Academy of Family Physicians, Management of Maternity Care, at 7, 16, available at http://www.aafp.org/x3390.xml ["...diagnosis of pregnancy can be reached based on a combination of subjective symptoms, objective signs, and laboratory results.... Routine use of ultrasound ... is not recommended"]) This is also reflected in NAF's *Clinical Policy Guidelines*.

Additionally, routine ultrasound is not necessary for detection of ectopic pregnancy. As with confirming and dating a pregnancy, other approaches, including physical exam, patient history and symptoms, and hCG testing can serve as a first line of assessment for detecting ectopic pregnancy, and if these suggest an ectopic pregnancy, ultrasound may be indicated to confirm a diagnosis. Approved Mifeprex labeling reflects these standards and assures that a woman will receive or be referred for an ultrasound examination if indicated.

Serious adverse events are rare with medical abortion, and undiagnosed ectopics are extremely rare. A study published in June 2003 outlined a total of 139 adverse events reported to Danco Laboratories that occurred among approximately 80,000 women who had a medical abortion from November 2000 through May 2002 (Hausknecht R. Mifepristone and misoprostol for early medical abortion: 18 months experience in the United States. *Contraception* 2003; 67: 463-465). This is an adverse event rate of 0.17%. Of the adverse events reported in this study, five were undiagnosed ectopic pregnancies. This corresponds to a rate of 0.006% with a 95% confidence interval of 0.002-0.15%. Three of these undetected ectopic pregnancies ruptured, one of which resulted in the patient's death, and two had successful surgical treatment after the misoprostol was administered. According to Danco, in each of these cases, the patient had routine ultrasound.

Adverse event reporting at Planned Parenthood affiliates provides additional data, although there is overlap with the Danco data since adverse events at PPFA affiliates would be included in the adverse events reported to Danco. As of the end of 2003, only seven undiagnosed ectopic pregnancies had occurred among the 81,710 mifepristone/misoprostol abortions provided at Planned Parenthood affiliates, for a rate of 0.0086% (Fjerstad M. Three years in review. *Mife Matters* 2004; 9: 1-3). All Planned Parenthood affiliates are required to perform an ultrasound prior to a medical abortion. *(Continued on page 6)*

### INSIDE THIS ISSUE

# What's in a name?

## *Cytotec vs. Generic Misoprostol in Medical Abortion*

*The following article (Mary Fjerstad, Mife Matters, issue #9, 2004, reprinted with permission) describes an analysis of data from sixteen Planned Parenthood affiliates regarding medical abortion outcomes using brand name Cytotec and generic misoprostol packaged in various ways. We have included additional notes afterward.*

Does using generic or brand-name misoprostol make a difference? Does the climate matter? What's the actual rate of uterine aspiration at affiliates?

**Our conclusions were:**

- The overall uterine aspiration rate among 11,290 mifepristone medication abortion clients was **1.51%.**
- There was no overall difference in the uterine aspiration rates between affiliates using generic and those using brand-name misoprostol.

Background and Study Hypothesis

In late August 2003, three affiliates reported a higher-than-usual number of medication abortion failures. After ruling out many possible factors, we focused on the theory that there might be a difference in the bioavailability of generic misoprostol and Cytotec®, brand-name misoprostol.

When a generic drug receives FDA approval, the manufacturer must show that the generic exhibits the same chemical equivalence and bioequivalence as the brand-name drug. Generic drugs must also demonstrate the same dissolution properties as the brand-name drug. Some misoprostol and mifepristone researchers theorized that buffers, fillers and variations in the manufacturing process of the generic drug could conceivably alter vaginal bioavailability of the active prostaglandin.

If the prostaglandin effect of misoprostol is blunted, theoretically a higher incidence of bleeding events could occur.

Investigation

It was decided that an analysis of the uterine aspiration (UA) rate for a 6-month period at a representative number of affiliates should be undertaken.

In September 2003, when the analysis began, 74 Planned Parenthood affiliates provided Mifeprex at 188 sites.

Sixteen large-volume affiliates were asked to participate in the analysis. These sixteen affiliates collectively provide about 47% of the medication abortions at Planned Parenthood centers nationally. These affiliates were included because they provide a high volume of medication abortions and they had the infrastructure capable of collecting the data being requested. It was decided that the three affiliates reporting the spike in medication abortion failures also should be included in the analysis.

All affiliates participating in the survey provide Mifeprex with the evidence-based alternative treatment plan (200 mg mifepristone followed by 800 mcg of misoprostol administered vaginally) to 63 days LMP, except for one affiliate that provides the EBA regimen up to 56 days LMP.

Each affiliate was asked to report the number of medication abortions for each month during a 6-month period from March through August, 2003. This data would capture the baseline prior to the reported spikes in uterine aspiration (UA) rates and the period during which the spikes were observed. Affiliates were asked to report how many UAs were performed among the number of patients receiving the abortion pill that month. They were also asked to report whether generic misoprostol or Cytotec was used during each month and whether it was distributed from bottles of 100, bottles of 4, or blister packs.

The affiliates were asked to report UAs done for any reason: continuing pregnancy, severe bleeding, prolonged bleeding, or patient request. Affiliates were asked to report UAs whether the procedure was performed by affiliate providers, ER physicians, or the patient's physician in private practice. It's possible that some UAs were not reported by patients if they were performed in the ER or with a private physician. However, affiliates are required to make three attempts to contact patients if they fail to return for their follow-up exam. Even if a patient does not return to the clinic, the affiliate is likely to have communication with the patient and be informed by a UA performed outside Planned Parenthood.

Answers being sought

The information we wanted to know was: *(Cont'd next page)*

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NAF is the professional association of abortion providers in the US and Canada. We serve those who make choice a reality: physicians, nurses, counselors, administrators, advanced practice clinicians and other health care professionals at medical facilities and offices in 48 states, the District of Columbia, Puerto Rico and 8 Canadian provinces. NAF is unique among reproductive health care organizations in that our mission is focused specifically on keeping abortion safe, legal and accessible.

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*The National Abortion Federation (NAF) is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to sponsor continuing medical education for physicians.*

*(Continued from previous page )*

1. the overall crude incidence rate of UAs among medication abortions performed at selected affiliates;
2. whether UA rates were different among the affiliates that used generic misoprostol versus affiliates that used non-generic misoprostol;
3. whether there was a temporal increase in the UA rates in the summer of 2003; and,
4. whether there was evidence of heterogeneity or variability in the UA rates among the affiliates.

What we found

There were 11,290 patients in the data set who received medication abortion at the 16 Planned Parenthoods which participated in the survey.

**1) The overall aspiration rate at all the affiliates was very low.** Among the 11,290 patients, 1.51% received uterine aspiration. This is a low rate of UA, and indicates that at these affiliates, medication abortion was 98.5% successful in ending the pregnancy without the need for uterine aspiration.

**2) There was no overall difference in the uterine aspiration rate among affiliates that used generic misoprostol vs. brand-name Cytotec.**

**3) There were some scattered unexplained rises in uterine aspirations at several affiliates using both generic misoprostol and brand-name Cytotec in May, June, and July. By August, all affiliates returned to their baseline low rates.**

**4) There was some heterogeneity between affiliates in the uterine aspiration rates. One affiliate had an average uterine aspiration rate of 4.59 per 100 over the six-month period. Four affiliates reported zero uterine aspirations over the six-month period. These four affiliates together provided 1,061 medication abortions.**

Discussion of results and recommendations

Misoprostol is hygroscopic, meaning it attracts moisture. It is possible, but unlikely, that hot or humid conditions affected misoprostol in the hot or humid months and caused a transient increase in uterine aspiration rates. Since UA rates returned to normal in August, which is also hot and humid, this explanation seems unlikely.

Nonetheless, providers should be conscientious about storing misoprostol at the recommended temperature, and not exposing it to hot or humid conditions. PPFA Medical Standards and Guidelines recommend that once a bottle of misoprostol is opened (if dispensing from bottles of 100), the bottle should be discarded after 30 days.

In addition, it's important and useful for affiliates to track rates of uterine aspiration to identify trends.

Additional note from *Providing Early Options:* This analysis provides some data for clinicians about a long wondered-about question. According to PPFA's Medical Division, the Medical Standards and Guidelines recommendation about discarding 100-count misoprostol bottles 30 days after opening is based on observations by medical abortion researchers and recommendations by experts. It is not strictly evidence-based practice. As such, NAF's medical abortion protocols and *Clinical Policy Guidelines* do not make recommendations one way or the other about this issue.

As described in the article above, generic drug manufacturers are required to demonstrate the chemical equivalence, bioequivalence, and dissolution properties of the brand-name drugs they are copying. The FDA orange book code specifies whether a generic manufacturer's product is rated therapeutically equivalent to the brand-name drug. Some generics are not therapeutically equivalent to the patent drug they copy. However, Ivax's generic misoprostol is rated "AB" which is the highest rating, essentially therapeutically equivalent to the brand name product.

Manufacturers perform stability testing on their products in order to determine the expiration dating that is printed on the package. Manufacturers test the product in all dosage forms and in both "open dish" and unopened market packaging for a long period of time. In the case of Cytotec, the product label says, "store at or below 77 degrees Fahrenheit, in a dry area." We contacted Pfizer, the company that now owns Cytotec, and they indicated there are no stability issues with misoprostol. The package insert for Ivax's generic misoprostol says, "store at controlled room temperature (59-86 degrees Fahrenheit) in a dry area."

Perhaps of greater relevance than generic vs. brand name is the issue of exposure to air, moisture, temperature, and light. Vendors that distribute medications sometimes repackage drugs that they receive from the manufacturer into smaller packages for patient use. Opening the manufacturer's bottle and repackaging pills, even if it only takes a few minutes, starts the process of any stability breakdown that may occur because the pills have now been exposed to new air, moisture, and light. Bottles of 4 tablets of misoprostol, whether Cytotec or generic, have been repackaged from their original manufacturer's packaging. Bottles of 100 tablets (200 mcg) are likely to be in the manufacturer's original packaging, since the manufacturers of Cytotec and generic misoprostol both produce bottles of 100.

In addition, clinics should be aware that the product may have been exposed to hot or cold temperatures in transit from the vendor. It's important to know how the product is being shipped and, as a result, the duration of the product's exposure to variations in temperature during transit. The Planned Parenthood study is an important retrospective analysis of the effectiveness of Cytotec vs. generic misoprostol. A randomized, controlled trial, with strict controls on the storage conditions of the medication, both in the clinic and in transport from the distributor(s) to the clinics, and any environmental exposure due to repackaging, would further clarify any potency and efficacy trends. We will continue to keep readers updated on new information or data that emerges regarding this issue.

*Additional resource: The United States Pharmacopoeia performs independent chemical analysis and stability testing post-FDA-approval and publishes the results in the USP-DI.*

# Assessing Medical Abortion Outcomes: Ultrasound vs. hCG Testing

Although it is not a part of the FDA-approved regimen, the use of ultrasound to confirm the outcome of mifepristone/misoprostol abortion is quite typical in U.S. practice. This is not the case in other countries, and there is interest in the U.S. in providing mifepristone/misoprostol without routine ultrasound, as a means of expanding access to this method in practices where ultrasound is not readily available (see "Sono As Needed Protocols" on p. 1). A European study (Fiala C, Safar P, Bygdeman M, Gemzell-Danielsson K. Verifying the effectiveness of medical abortion; ultrasound versus hCG testing. *European Journal of Obstetrics & Gynecology and Reproductive Biology* 2003; 109: 190-195) provides some data about the relative usefulness of ultrasound and hCG monitoring as a means of assessing medical abortion outcomes.

The study involved 217 women at 49 days LMP or less (confirmed by ultrasound) who received 600 mg mifepristone, followed 2 days later by 400µg oral misoprostol administered in the health center. Patients received an additional 400µg of oral misoprostol 3 hours after the first dose if bleeding was lighter than the first day of menstruation or had not started. All women had a transvaginal ultrasound and serum hCG drawn at their first visit. Follow-up evaluation, which included another ultrasound and serum hCG, occurred sometime between day 6 and 18, depending on patient preference. All but 4 women had a complete abortion without the need for vacuum aspiration, for a success rate of 98.2%.

Researchers found that hCG levels dropped to a mean of 3% of the pre-treatment hCG level in cases of successful medical abortion (S.D. 3, range 1-44% of the initial value, with only 3 cases above 27%). In the two cases of continuing pregnancy, the hCG levels increased to 159% and 7900% of the pre-treatment value on day 10 and day 8, respectively. Further analysis revealed that there is a positive predictive value of 0.995 for successful medical abortion if 20% of the pretreatment value is used as a cut-off criterion. Additionally, when the drop in hCG is less than 80% of pre-treatment value, "the negative predictive value is 0.5 and further evaluation using ultrasound examination and repeated hCG measurements are needed to confirm the outcome of the treatment."

Only a subset of 167 women (77% of subjects), those whose pre-treatment ultrasound documented an intrauterine pregnancy as defined by the presence a yolk sac or CRL, could be assessed for complete abortion using ultrasound. Because of "inhomogeneous" uterine content, researchers found ultrasound assessment of completion difficult in some cases and in fact could not verify completion in 17 (10.2%) of the cases at the first follow-up visit. The reliability of ultrasound in diagnosing successful expulsion, in cases where an intrauterine pregnancy was confirmed at the pre-treatment visit, was 89.9%. The authors suggested that inexperience with or inadequate training in reading post-medical abortion ultrasounds may lead to unnecessary vacuum aspirations because of the pattern of a thickened endometrium after medical abortion.

Discussion: This study provides some useful information particularly regarding the predictive value of a drop at follow-up in hCG levels to 20% of the pretreatment levels. Most mifepristone/misoprostol providers in the U.S. are using a protocol of 200 mg mifepristone followed by 800µg vaginal misoprostol. Since the current study used a different regimen, it's not known if findings would be similar with the most common U.S. protocols. This study reaffirms the normal ultrasound finding of a thickened endometrium (mean 10mm, S.D. 4, range 1-24mm in this study) following successful medical abortion and the need for providers to be aware of this when interpreting ultrasound scans. As we've discussed in previous issues of *Providing Early Options*, the absence of a gestational sac, when one was observed on a pre-treatment ultrasound, is an indication of a complete medical abortion. To avoid unnecessary interventions, treatment of the patient should be based on her clinical signs and symptoms rather than ultrasound findings of a thickened endometrium.

## NAF Educational Program Update

Since 2000, 12,750 health care professionals have participated in NAF-sponsored or supported medical abortion and ultrasound seminars, lectures, and workshops. Here's a quick summary of where we've been in the past year.

Ultrasound Trainings: NAF member clinics have graciously hosted trainings in Ann Arbor, MI; Austin, TX; Dayton, OH; and San Francisco, CA.

National & Regional Conferences: We continue to focus on advanced practice clinicians and primary care providers. For example, NAF presented at the Nurse Practitioners in Women's Health Care 27th Post-Graduate Seminar. We are collaborating with other organizations to provide medical-abortion related training to these audiences. We have conducted two ultrasound trainings for Family Practice Residency Faculty with the UCSF Teach Project, and three Medical Abortion Seminars for Advanced Practice Clinicians and Primary Care Physicians with the Abortion Access Project, one each in Eugene, OR; Portland, OR; and with TARAL in Austin, Texas.

4th Year Launch of Medical Abortion Education Project (MAEP): NAF-trained MAEP faculty have presented medical abortion education programs to more than 6,400 participants at grand rounds, medical schools, conferences, medical meetings, and other settings. A new goal for this year's MAEP program is to facilitate the integration of medical abortion content in medical school curricula. MAEP is a collaboration with the American Medical Women's Association's Reproductive Health Initiative, the Association of Reproductive Health Professionals, National Abortion Federation, and Physicians for Reproductive Choice and Health.

# Expert Consensus: Abortion Is Not Linked to an Increase in Breast Cancer Risk

For several years, the National Abortion Federation has worked to refute the false and misleading claim of anti-choice activists that abortion causes breast cancer. The National Cancer Institute (NCI) convened the *Early Reproductive Events and Breast Cancer Workshop* in February 2003, to study the link between breast cancer risk and reproductive events. The workshop included more than 100 of the world-renowned experts who study pregnancy and breast cancer risk. These leading experts analyzed recent clinical, epidemiological, and animal studies on the link between pregnancy, breast cancer risk, and abortion. They found that recent studies conclusively established that abortion does not cause an increase in breast cancer risk.

Furthermore, a recent study published by the Collaborative Group on Hormonal Factors in Breast Cancer in the medical journal *Lancet* investigated whether there was any correlation between abortion and breast cancer. Data from 53 studies undertaken in 16 countries with liberal abortion laws were included in the analysis of this study. According to the *Lancet* press release, "Authors of the study conclude that the totality of the worldwide evidence does not suggest any increase in the risk of developing breast cancer for women who have had a pregnancy that ended in miscarriage or induced abortion."

The findings of the NCI workshop and the *Lancet* study render the anti-choice activists' claim that abortion increases a woman's risk of breast cancer wholly inaccurate. The NCI's findings are now posted on its website and contained in its updated fact sheet.

In spite of the scientific evidence to the contrary anti-choice forces have lobbied state legislators to enact laws mandating the discussion of breast cancer as a recognized risk of abortion in informed consent materials. Several states have enacted such laws, and numerous other states have seen the introduction of similar legislation.

Anti-choice groups, including the Coalition on Abortion/Breast Cancer, Life Dynamics, and the Justice Foundation, have threatened litigation to require abortion providers to disclose a link between abortion and an increased risk of breast cancer. In decisions in the first of such lawsuits, one in North Dakota and one in California, the judges ruled in favor of the clinics. The judges held that because no convincing scientific evidence linking a risk of breast cancer to abortion exists, there is no obligation to inform patients of any such link. Because similar suits may follow, it is vital that the conclusive findings of the NCI become well-known public knowledge.

NAF has developed a Breast Cancer Action Kit and a Fact Sheet to ensure that you have some of the more pertinent and helpful materials at hand should you confront this issue in your state.

If you have any questions about these materials or need additional assistance, please contact NAF at (202) 667-5881. If you would like media-specific input on writing letters to the editor, op-ed, or would like to see editorials or letters written by other NAF members and pro-choice allies, you may also wish to contact Alyssa Barnum, NAF's Communications Director.

### NAF's Fact Sheet Series: Updated and Now Accessible Online!

The Truth About Abortion, NAF's fact sheet series, has been revised. For the latest research-based facts on a broad range of topics related to abortion, including medical abortion, abortion and breast cancer, and the safety of abortion, go to www.prochoice.org, and click on 'Abortion Facts.' Myths about abortion abound, and NAF's scientifically accurate fact sheets help women considering abortion, policy makers, and reporters distinguish between fact and fiction.

## NAF & PPFA Respond to FDA Petition

On May 24, NAF and Planned Parenthood Federation of American (PPFA) submitted to the FDA a joint response to a citizen's petition to the FDA filed in August 2002 by Concerned Women for America, the Christian Medical Association, and the American Association of Pro-Life Ob/Gyns calling for a stay and repeal of the approval of Mifeprex. The NAF and PPFA comments also incorporate information related to the petitioners' October 2003 follow-up response to comments filed by Danco Laboratories and the Population Council.

The full text of the document submitted to the FDA is available on the NAF website at www.prochoice.org/fda_comments.pdf. An executive summary may be accessed at www.prochoice.org/mife_executive_summary.pdf.

The NAF/PPFA response is a comprehensive, up-to-date, and extensively referenced discussion of the rationale for the existing Mifeprex provider qualifications and ultrasound-as-needed protocol, and the safety and efficacy of mifepristone/misoprostol including evidence-based alternative regimens. We hope that it will be a useful resource for others.

## Developing Cultural Competency in Reproductive Healthcare

We are excited to announce a new NAF publication: "Developing Cultural Competency in Reproductive Healthcare." The proceedings from a full-day cultural competency seminar held at the 2003 NAF Annual Meeting are the foundation of the report. Additionally, the publication includes three NAF member model outreach programs and a vast list of cultural competency and diversity building resources. It is available on the NAF website.

NAF's Outreach Director, Lea Gilmore, will present a seminar called "Cultural and Linguistic Competency in Reproductive Healthcare: Understanding Every Woman" at the Society of Teachers of Family Medicine/American Academy of Family Physicians (STFM/AAFP) Annual Conference on Patient Education in San Francisco in November.

If this is a topic that interests you, NAF also disseminates a monthly e-newsletter on cultural competency and diversity issues. To subscribe, send an e-mail to lgilmore@prochoice.org.

# Sono As Needed Protocols *(Continued from front cover)*

From a risk management perspective, in these cases at least, routine ultrasound did not appear to have been useful in terms of diagnosing ectopic pregnancy. However, it can be argued that had these women had a surgical abortion instead of a medical abortion, the absence of a gestational sac or pregnancy tissue in the aspirate could have provided immediate evidence of ectopic pregnancy. It is also not known how many ectopic pregnancies that were detected through a pre-medical abortion ultrasound might not have been detected at this early stage in the medical abortion process through other assessment methods. Clearly, however, the cases reported to Danco of undetected ectopics that were subsequently treated successfully through surgery after the administration of misoprostol point to factors (such as scant bleeding after misoprostol) that can alert providers to the possible presence of an ectopic pregnancy. Importantly, medical abortion does not increase the risk of an ectopic pregnancy. In fact, women who seek early abortion care have a lower rate of ectopic pregnancy than the general population (Edwards J, Creinin M. Surgical abortion for gestations of less than 6 weeks. *Curr Probl Obstet Gynecol Fertil* 1997; 20: 11-19).

How, then, do you manage patients without the routine use of ultrasound? In order to challenge the assumption that routine sonography is necessary, family physicians have been modeling and evaluating a "sono as indicted" regimen in their practices, and teaching it as part of the "how to" of medical abortion. One such regimen (available at www.theaccessproject.org/IndicationsForSonography.html) states "It is acceptable to confirm gestational age prior to the abortion as we do for routine pregnancy - with a uterine size on pelvic exam that is consistent with gestational age. Also, after the procedure, if a women reports cramping and bleeding after inserting misoprostol, and also notes the disappearance of pregnancy-related symptoms (nausea, urinary frequency, constipation, etc), it is acceptable to use declining serum hCG levels as evidence of a complete procedure." The following indications for sonography are based on the indications included in The Access Project protocol:

**Prior to** a medical abortion:

1. Gestational age > 8 weeks LMP
2. On exam, size/dates discrepancy
3. Uncertain LMP (or no menses - after delivery, abortion, stopping Depo Provera, etc)
4. Adnexal mass or pain
5. Pregnancy occurred while on oral contraceptives or at the end of a course of other hormonal contraception.
6. History of previous ectopic
7. Provider uncertainty with exam

**Following** a medical abortion:

1. History not consistent with successful medical abortion (no bleeding, no cramping or only light bleeding)
2. Woman still feels pregnant (breast tenderness, nausea)
3. Serum hCG not declining
4. Provider uncertainty with history

Additional information about the monitoring of serum hCG levels is included in the article "Assessing Medical Abortion Outcomes: Ultrasound vs. hCG Testing" on page 4.

*As an outgrowth of the discussion at this NAF Annual Meeting session, a group of clinicians and researchers have initiated a research project to help define ways to limit the need for ultrasound in the provision of medical abortion services, thereby reducing routine use of ultrasound. We will continue to share new information as it becomes available.*

**So what do the data say about the need for ultrasound?**
No studies have evaluated if the routine use of ultrasound for evaluation of gestational age or status at the follow-up exam improves clinical outcomes. However, a study by Fielding and colleagues (Fielding SL, Schaff EA, Nam N-y. Clinicians' perception of sonogram indication for mifepristone abortion up to 63 days. *Contraception* 2002; 66: 27-31) attempted to evaluate if clinicians were able to accurately assess when ultrasound was necessary for estimating gestational age and medical abortion outcome. In this study, that included a subset of 1,016 women enrolled in a medical abortion trial, gestational age was initially assessed by history and physical examination. Immediately after this assessment, clinicians filled out a form indicating whether they perceived that a sonogram was 1) not indicated; 2) desired but not indicated; or 3) indicated. Then transvaginal ultrasonography was performed. Clinicians judged that an ultrasound was not indicated to confirm gestational age in 60%, 66% and 46% of women they assessed to be $\leq$ 42 days', 43-49 days', and $\geq$ 50 days' gestation respectively. In an additional 16%, 19%, and 23% of cases assessed to be $\leq$ 42 days', 43-49 days', and $\geq$ 50 days' gestation respectively, ultrasound was rated as desired but not indicated. Only 1.4% of women were assessed to be $\leq$ 63 days' gestation and ultrasonography confirmed a gestation > 63 days. 9.1% of women were clinically assessed to be > 63 days' gestation and ultrasonography confirmed a gestation $\leq$ 63 days. These women would have been denied a medical abortion without ultrasonography.

Follow-up evaluation of 877 women (who were confirmed to be $\leq$ 63 days' gestation before treatment) was performed by history and physical examination 1-5 days after misoprostol administration. Clinicians felt certain that an ultrasound would not have been needed to determine outcome in 59.5% of women. Among the 522 women for whom clinicians felt confident that complete abortion had occurred and an ultrasound was unnecessary, 7 (1.3%) did not have a complete abortion. Among the 355 women for whom clinicians felt an ultrasound examination was desired or indicated to confirm expulsion, 95.2% had expelled the pregnancy. For the 24 women whose abortions were not complete on ultrasound, clinicians correctly detected the need for an ultrasound in 17 or 71% of cases. *(Continued on next page)*

# Ask An Expert!

*Here are the perspectives of two experts on a common question about medical abortion. Keep in mind, there are many different approaches to setting up medical abortion protocols and managing medical abortion patients, depending on your practice size and setting, your staffing, your clientele, your experience level, and many other factors. Variations in the needs of individual patients and differences in the resources available to clinical providers may justify alternative approaches to those discussed below.* We welcome your suggestions for an "Ask An Expert" question for our next issue.*

**E. Steve Lichtenberg, MD, MPH** is medical director of Family Planning Associates Medical Group in Chicago, IL, editor of *A Clinician's Guide to Medical and Surgical Abortion*, serves on several committees of the Board of Directors of the National Abortion Federation, including the Clinical Policies Committee, and is a member of Planned Parenthood Federation of America's National Medical Committee.

**Beverly Winikoff, MD, MPH** is President and Founder of Gynuity Health Projects in New York, NY. She has led numerous studies on medical abortion, particularly in international settings, and has published extensively on this subject.

**Question:** ***We give women in our practice prophylactic antibiotics for 1st trimester aspiration abortions. Should we do the same for women who have medical abortions?***

**E. Steve Lichtenberg, MD, MPH:** At first thought, one would intuitively think the answer should be "yes." After all, the meta-analysis by Sawaya et al. (Sawaya GF, Grady D, Kerlikowske K, Grimes DA. Antibiotics at the time of induced abortion: the case for universal prophylaxis based on a meta-analysis. *Obstet Gynecol* 1996; 87: 884-190) that examined the 12 best randomized trials of routine periabortal prophylaxis after elective vacuum abortion up to 15 weeks from LMP found a 42% advantage in preventing postabortal infection. This protective effect included many women who were cervical-screen negative for gonorrhea and chlamydia.

Moreover, medical abortion can be a process that takes a number of days to progress to completion even when the gestational sac is expelled in the first 24 hours; the ensuing 7 to 10 days may be spent in the gradual expulsion of decidua and clot--a potentially rich medium for the incubation of pathogens residing in the vagina a few millimeters downstream from open cervical passage into the endometrium.

On further reflection, however, an instrumental (vacuum) abortion involving mechanical entry into the uterine cavity is fundamentally different from a purely expulsive process. The only randomized trial exploring this distinction in women undergoing a curettage for spontaneous abortion was by Prieto et al. (Prieto JA, Eriksen NL, Blanco JD. A randomized trial of prophylactic doxycycline for curettage in incomplete abortion. *Obstet Gynecol* 1995; 85: 692-696) who found no statistically significant advantage in routinely treating prophylactically with doxycycline. In terms of prevalence, infection after medical abortion has been very infrequent, buttressing the argument against routine prophylaxis.

So, at present, the recently evaluated answer from expert consensus panels at NAF and the National Medical Committee of the Planned Parenthood Federation of America is "no" to routine prophylaxis after uneventful medical abortion in the first trimester.

**Beverly Winikoff, MD, MPH:** I'd start right out with thinking that "no," it was NOT necessary. Medical abortion differs fundamentally as a procedure from intervention with instruments into the uterus. As such, it is more comparable to a spontaneous uninstrumented abortion, which does not have the same risk of infection, even if bleeding lasts for a number of days.

As additional information, we have just completed a review of documentation of infection after medical abortions performed with no antibiotic prophylaxis. (Shannon C, Brothers LP, Philip NM, Winikoff B. Infection after medical abortion: A review of the literature. *Contraception* 2004; 70: 183-190) We find that true, validated infection is exceedingly rare -- rarer than infection AFTER antibiotic prophylaxis in first trimester surgical procedures. This conclusion holds true for all regimens of medical abortion and all routes and doses of misoprostol.

The bottom line seems to be that there is no clinical or theoretical justification for providing routine prophylactic antibiotics to women undergoing early first trimester medical abortion using mifepristone and misoprostol.

* Neither the National Abortion Federation, its officers, employees, or members are responsible for adverse clinical outcomes that might occur in the course of delivery of abortion services in which they are not expressly and directly involved in the role of primary caregiver.

*(Continued from page 6, sidebar)* Clinicians involved in this study were accustomed to participating in clinical trials in which ultrasound was used routinely for assessing gestational age and abortion outcome. Nonetheless in only 1% (14/1013) of their assessments did clinicians underestimate gestational age, that is, assess women as under 63 days when they were actually greater than 63 days. Their confidence and accuracy in assessing abortion outcomes was somewhat lower. The researchers concluded that sonograms may be more important at follow-up to confirm a complete abortion, unless a serial hCG is performed.

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*Keeping Abortion Safe, Legal, and Accessible*

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# Medical Abortion in South Africa

With significant expertise in training medical abortion providers, NAF began working with Gynuity Health Projects to develop and provide training on mifepristone in South Africa's public health sector. In November 2003, we conducted our first training in Johannesburg, South Africa, in conjunction with the launch of an operations study to demonstrate the feasibility of integrating medical abortion into public health sector termination of pregnancy services.

In 1997, South Africa moved far beyond the United States by not only affirming, with legislation, the right of women to terminate their pregnancies, but also encouraging the development and integration of abortion services as part of reproductive health services at the primary health care level. Mifepristone was approved for use by the South African Medicines Control Council in August 2001. However, the National Department of Health (DOH) additionally needs to approve its use in the public health sector, through which the majority of women receive their health care. Our project is one step toward making medical abortion an early option for South African women.

NAF, in collaboration with our South African partners, conducted a medical abortion training in November 2003 for 15 nurse-midwives, physicians, and researchers from Guatang and Western Cape provinces. Held at Baragwanath Hospital in Johannesburg, this training prepared each operations research study team to begin offering medical abortion using mifepristone and misoprostol under the study protocol outlined by Gynuity and Ibis Reproductive Health. The participants were selected because of their capacity to participate in the research project, continue medical abortion services after the study was completed, and train others.

Several South African colleague organizations have expressed interest in the medical abortion project and have joined as advocates and research partners. Our South African colleagues include the Women's Health Project, the Reproductive Health Research Unit (Johannesburg) and the Women's Health Research Unit (Capetown). Ipas South Africa staff were also invited to the training in South Africa. These groups are the driving force and leaders in moving any new policies forward. Once the study's final report is provided to the National Department of Health, NAF will work with their colleagues to determine the next steps for medical abortion training rollout.