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IN THIS ISSUE

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Media report on Ortho Evra patch sets off safety concerns in women

Patch death rate is triple that expected for the Pill, report claims

Has your office telephone been ringing with questions from patients following a recent media report that the death rate for the transdermal contraceptive (Ortho Evra, Ortho-McNeil Pharmaceutical, Raritan, NJ) is three times that expected for oral contraceptives?[1]

Clinicians already have been fielding questions about the patch's safety after media reports were issued following the April 2004 death of an 18-year-old woman who had been using the transdermal contraceptive. **(*Contraceptive Technology Update* reported on the media coverage in its article, "Adverse event reports spark discussions on safety of Evra contraceptive patch," December 2004, p. 133. It also included points from the Association of Reproductive Health Professionals to help clinicians discuss the reports.)**

The latest media alert springs from an article published by the Associated Press (AP), which contained an analysis of adverse event reports provided by the Food and Drug Administration (FDA). The FDA, responding to a Freedom of Information Act request from the news organization, provided the AP with a database that contained about 16,000 reports of

EXECUTIVE SUMMARY

A recent media report analyzed adverse event reports surrounding use of the transdermal contraceptive (Ortho Evra, Ortho-McNeil Pharmaceutical) and claimed that the death rate is three times that expected for oral contraceptives.

- There are limits to the reliability of spontaneous report information upon which the analysis was based, according to Ortho-McNeil. Reports can come from various sources, and there is significant uncertainty regarding their validity, the company states.
- The contraceptive patch, like all combined hormonal contraceptives, carries risks. Ask women to be honest about health risks, including smoking, so they can be appropriately evaluated.

adverse reactions associated with the patch ranging from mild rashes to deaths. According to the AP, 23 deaths associated with the patch were identified; doctors who reviewed the 23 cases found about 17 that appeared to be clot-related, including 12 from 2004, states the news article.[1]

Lawsuits have since been filed against the manufacturer alleging that the Evra birth control patch is "defectively designed" and "unreasonably dangerous."[2]

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Editorial Questions

Questions or comments? Call **Joy Daughtery Dickinson** (229) 551-9195.

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What are the numbers?

The September 2004 media report that sparked initial questions on the patch said it had obtained FDA records, "show[ing] that 17 patch users, ages 17 to 30, suffered fatal heart attacks, blood clots, and possible strokes since August 2002."[3]

CTU contacted Ortho-McNeil for answers to the following questions:

1. If 17 patch-related deaths occurred from August 2002 to September 2004, have similar deaths occurred following that time period? If so, how many?
2. Of the deaths attributed to patch use, how many women had high blood pressure, smoked cigarettes, had a past history of migraine headaches with aura, had a past history of deep vein thrombosis, or were older than age 35?
3. In the patch-related deaths, can the company break down the figures by where the women were in patch use cycle (week 1, 2, 3, or patch-free)?
4. How many of the deceased women were younger than age 20? Between ages 21-34? Older than 35?
5. Can the company provide patch use statistics for 2002, 2003, and 2004?

Michael Beckerich, communications director for Ortho McNeil's consumer pharmaceuticals & nutritionals group declined to directly address the questions regarding adverse event reports. "In terms of the questions regarding Ortho Evra reports, there have been spontaneous reports of adverse events regarding women and Ortho Evra, but we cannot draw any conclusions on the causal relationship with the medication," he states.

Spontaneous reports are used to monitor products once they are on the market; however, there are some limits to the reliability of spontaneous report information, says Beckerich.

"It is often difficult to determine the relationship of the event to use of a particular product," he states. "It is also difficult to confirm reports when contact information needed to follow up is missing from the report."

More than 5 million women have used Ortho Evra since it was introduced three years ago, reports Beckerich. He provided further information on the method in a statement from

Katherine LaGuardia, MD, MPH, director of medical affairs for Ortho Women's Health, which states in part:

"The mortality rate associated with Ortho Evra use cited in the Associated Press story is misleading because it is based on spontaneous reports and inaccurate citation of clinical data. Spontaneous reports can come from various sources, and there is a significant amount of uncertainty regarding the validity of the information. The AP report states a mortality rate of three in 200,000 from Ortho Evra clinical trials. The data show and the product label reflect there were no fatal events associated with Ortho Evra during clinical trials. We know from industry data that more than 2 million women used Ortho Evra in 2004 compared to the 800,000 women cited in the story."

How to discuss safety?

Is there new information to share with patients about Ortho Evra? Scientific evaluation shows the patch has the same risk as pills for thrombosis.[4]

Robert Hatcher, MD, MPH, professor of gynecology and obstetrics at Emory University School of Medicine in Atlanta, offers this observation: There were 17 deaths among women using the patch prior to October 2004. How many have there been since? "We don't know," he says. "We don't know the numerator of this problem."

Approximately 5 million women have used Ortho Evra patches since January 2002, Hatcher reports. "We don't know how many different women in each calendar year used the patch, so we do not know the denominator of this equation," he says. "We simply do not know what 17 deaths mean, nor do we know if the deaths were due to causes possibly related to the patch, such as pulmonary emboli, heart attack, or stroke. I consider it the responsibility of Ortho-McNeil to investigate each death and to come up with answers in the near future to the five questions outlined above."

The patch has been a good method of birth control for many women, and these data do not per se provide any insight as to the relative safety of the patch compared to birth control pills, Hatcher comments.

"One thing these deaths do remind us of is that the same precautions for the prescribing of the patch and the same danger signals for the use of the patch apply as apply to birth control pills," he states. (Teach women to monitor themselves for danger signals by using the "ACHES" mnemonic: **a**bdominal pain, **c**hest pain, **h**eadaches that are severe, **e**ye problems, **s**evere leg pain.[5])

What are you telling patients in light of the media reports? The National Association of Nurse Practitioners in Women's Health (NPWH) offers the following talking points:

- No medication is without risk.
- Ask women to be honest about their health risks, including smoking, so that their personal risks can be appropriately evaluated.

"For many women, Evra and other hormonal methods of contraception remain safe and are among the most effective ways to prevent unintended pregnancy," states the NPWH.[6]

References

1. Mendoza M. Birth-control patch may pose health risk. *Washington Post*, July 17, 2005. Accessed at: www.washingtonpost.com/wpdyn/content/article/2005/07/16/AR2005071600798.html.
2. Cable News Network. Women sue birth control patch maker. July 25, 2005. Accessed at: money.cnn.com/2005/07/25/news/fortune500/birth_control_patch.
3. Edelman S. 'Sex patch' tied to 17 deaths: FDA. *New York Post*, Sept. 19, 2004. Accessed at: www.nypost.com/seven/09192004/news/nationalnews/30487.htm.
4. Audet MC, Moreau M, Koltun WD, et al. Evaluation of contraceptive efficacy and cycle control of a transdermal contraceptive patch vs. an oral contraceptive. *JAMA* 2001; 285:2,347-2,354.
5. Hatcher RA, Trussell J, Stewart F, et al. *Contraceptive Technology*. 18th revised ed. New York City: Ardent Media; 2004.
6. National Association of Nurse Practitioners in Women's Health. Ortho Evra media reports sends women looking for answers. *Monthly Cycle*, August 2005. Accessed at: www.npwh.org/newletter/newsletteraugust05.htm. ■

Mifepristone label gets new safety information

The manufacturer of the abortion pill mifepristone (Mifeprex, Danco Laboratories; New York City) has revised the safety information for the drug's label and issued a letter to health care providers in light of five deaths from serious bacterial infection and sepsis following use of the medication abortion regimen.

According to Danco, there have been more than 460,000 estimated uses of Mifeprex from September 2000 through June 2005. During that time, the company says it has received reports of

EXECUTIVE SUMMARY

The U.S. manufacturer of mifepristone has revised the safety information for the drug's label and issued a letter to providers in light of five deaths from serious bacterial infection and sepsis following use of the medication abortion regimen.

- The company received the reports of the deaths following treatment with mifepristone and misoprostol.
- Patients should seek immediate care if they develop weakness, nausea, vomiting or diarrhea, with or without abdominal pain and fever, more than 24 hours after taking misoprostol. These symptoms, even in the absence of fever, may indicate sepsis.

five deaths following treatment with Mifeprex and misoprostol. One case occurred in 2001 during a Canadian clinical trial; the other four cases of septic deaths came from California during September 2003 to June 2005. Scientists have identified the bacteria in two of the cases as *Clostridium sordellii,* an anaerobic, gram-positive bacteria; the others cases are under investigation by the Food and Drug Administration (FDA), along with the Centers for Disease Control and Prevention (CDC), state and local health departments, and Danco Laboratories.

The company is working closely with FDA to alert health care providers. It has issued a "Dear Doctor Letter" to all Mifeprex providers and emergency department directors, reports **Cynthia Summers**, DrPH, Danco's director of marketing and public affairs. **(To read the letter, see the resource listing on p. 117.)**

The FDA is working with the manufacturers of Mifeprex and misoprostol tablets to conduct special tests to ensure there was no contamination of either product with *Clostridium sordellii.* The investigations are ongoing, according to the agency.

In its alert to health care professionals, the FDA advises clinicians to tell patients to contact it if they develop weakness, nausea, vomiting or diarrhea, with or without abdominal pain and fever, more than 24 hours after taking misoprostol. These symptoms, even in the absence of fever, may indicate sepsis, the agency notes. Patients also should contact health care providers immediately if they have heavy bleeding (defined as soaking through two thick full-size sanitary pads per hour for two consecutive hours), or a fever of 100.4°F or higher that lasts for more than four hours.

In November 2004, the FDA announced the addition of information concerning rare cases of serious and sometimes fatal infections to the warnings section of the Mifeprex label. ***(Contraceptive Technology Update* reported on the revision of the label's safety information in the article, "Update: FDA strengthens mifepristone labeling," March 2005, p. 33.)**

Although the oral provision of misoprostol is the FDA-approved regimen, all four deaths in California involved intravaginal administration of misoprostol. A causal relationship between intravaginal administration of misoprostol and an increased risk of infection or death has not been established, states Summers. The company is closely working with the FDA, health care providers, and other medical experts to understand the circumstances surrounding these events, she adds.

Physicians are free to prescribe FDA-approved drugs as they wish. Summers points out. There are many studies published in the peer-reviewed medical literature that discuss various regimens of Mifeprex and misoprostol, and many physicians may be basing their regimens on that literature, she notes.

The FDA-approved regimen for medication abortion using mifepristone and misoprostol is:

- Day One: Three tablets of 200 mg Mifeprex orally at once.
- Day Two: Two tablets of 200 mcg misoprostol orally at once.
- Day 14: The patient must return to confirm that a complete termination has occurred. "Danco uses only the FDA-approved regimen in its labeling and promotional materials and does not promote any other regimens," Summers explains.

Should women undergoing medication abortion receive antibiotics to prevent fatal infections? The FDA says it does not have sufficient information to recommend such use of preventive antibiotics.[1]

Fatal sepsis very rare

Reports of fatal sepsis in women undergoing medical abortion are very rare: 1 in 100,000, the agency reports.[1]

"Preventive antibiotic use carries its own risk of serious adverse events such as severe or fatal allergic reactions," the agency notes. "Also, preventive use of antibiotics can stimulate the growth of 'superbugs,' bacteria resistant to everyday antibiotics."

Planned Parenthood Federation of America

RESOURCE

Visit the Mifeprex web site, www.earlyoption pill.com, to download files of the health care provider letter, as well as the revised prescribing information, medication guide, and patient agreement. Information also is available in Spanish. At the opening page, scroll down to "Information for Providers." Click on the prescribing information, medication guide and patient agreement listed under it. The Spanish information is listed under the "En Español — Informacion Para Los Pacientes" section.

(PPFA), based in New York City, is revising its patient information to reflect the new information, reports **Scott Spear**, MD, chairman of PPFA's National Medical Committee.

Remind patients that medication abortion (also known as medical abortion) is an evidence-based regimen, it appears to be safe, and that the infections that have been found do not appear causally related to mifepristone or misoprostol, he says.

Anita Nelson, MD, professor in the obstetrics and gynecology department at the University of California in Los Angeles (UCLA) and medical director of the women's health care programs at Harbor-UCLA Medical Center in Torrance, says, "The change in the warning for mifepristone to mention that generalized malaise even in the absence of fever should prompt the patient to seek evaluation seems prudent, as long as it is understood that medical abortions is a safe and effective procedure, with fewer risks than pregnancy."

Reference

1. Food and Drug Administration (FDA). Questions and Answers on Mifeprex (mifepristone). Accessed at: www.fda.gov/cder/drug/infopage/mifepristone/mifepristone-qa20050719.htm. ■

Study shows OTC access doesn't increase EC use

If emergency contraception (EC) is made available over the counter (OTC) in the United States, will it lead to more unprotected sex and increased use? Results from a just-published analysis of British use of the drug indicates that it will not.[1]

EC has been available without prescription across Britain to women age 16 and older since January 2001. ***(Contraceptive Technology Update* reported on the move in its article, "Emergency contraception: Going over the counter?" February 2001, p. 17.)** The new study, an analysis of data of contraceptive use in women ages 16-49 from 2000 to 2002, shows that making EC available OTC has had no discernible effect on use, either in terms of number of uses per year for individual women, or in terms of overall numbers of women using the method, reports **Cicely Marston**, PhD, lecturer in social science and public health at Imperial College London and lead author of the analysis.

"The drug has an excellent safety profile, and timing is crucial for its effectiveness: The longer it takes to obtain it, the less likely it is to work," she observes. "Because over-the-counter provision has not had negative effects, and because of the potential gains in terms of convenience and rapid access, EC should be made available over the counter as soon as possible in other countries, including the USA."

To conduct the study, researchers analyzed contraceptive use data collected by the Omnibus Survey, a multipurpose survey performed by the United Kingdom's Office for National Statistics in London. There was no significant change in the proportion of women using EC, researchers found. In 2000, 8.4% of women surveyed used the method, compared to 7.9% in 2001 and 7.2% in 2002. The researchers also saw no significant change in contraceptive use among the women over the course of the study, and they recorded no significant uptick in the proportions of women having unprotected sex or using EC more than once during a year.

Scientists did note one change: When access was broadened, fewer women obtained EC from physicians, while a greater proportion bought it over the

EXECUTIVE SUMMARY

Results from an analysis of British use of emergency contraception (EC) indicates over-the-counter access does not lead to more unprotected sex and increased use.

- EC has been available without prescription to British women age 16 and older since January 2001.
- An application to take the EC pill Plan B over the counter in the United States still is pending at the Food and Drug Administration. If the request is approved, Plan B will be sold without a prescription for women age 16 and older, while prescription status will be maintained for women age 15 and younger.

States move on EC access issue

New Hampshire now is the seventh state to increase access to emergency contraception (EC). Legislation has been signed into law to allow pharmacists to dispense emergency contraception to customers without a doctor's prescription. Other states with similar laws include Alaska, California, Hawaii, Maine, New Mexico, and Washington.

The bill was signed by Gov. John Lynch in June 2005, with the law becoming effective in August. Only pharmacists who voluntarily participate in a training session sponsored by the state will be able to dispense EC without prescription. Pharmacists will not be required to undergo the training if they do not plan to participate in the program.[1]

While a similar EC access bill cleared the New York legislature in June, the measure was vetoed in August by Gov. George Pataki. The bill would have allowed pharmacists and nurses to dispense EC to women without a doctor's prescription with no age restrictions using blanket prescriptions issued by physicians, certified nurse midwives, or certified nurse practitioners.[2] While Pataki rejected the bill since it did not include age restrictions or require parental consent for minors seeking EC, he has indicated he will work with the state legislature to enact revised legislation.[3]

References

1. New Hampshire governor signs bill allowing emergency contraception to be sold without doctor's prescription. *Kaiser Daily Reproductive Health Report*, June 17, 2005. Accessed at: www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=30814.
2. N.Y. governor outlines changes needed to avoid veto of legislation making EC available without doctor's prescription. *Kaiser Daily Reproductive Health Report*, Aug. 4, 2005. Accessed at: www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=2&DR_ID=31820.
3. N.Y. governor vetoes legislation that would have made EC available without doctor's prescription. *Kaiser Daily Reproductive Health Report*, Aug. 5, 2005. Accessed at: www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=2&DR_ID=31838. ■

counter.[1] EC sells OTC in Britain for approximately $36 to $46.[2]

United States awaits FDA ruling

Barr Pharmaceuticals of Woodcliff Lake, NJ, is awaiting a decision from the Food and Drug Administration (FDA) on its request to take its levonorgestrel-only EC, Plan B, over the counter, says **Carol Cox**, company spokeswoman. If the request is approved, Plan B will be sold without a prescription for women ages 16 and older, while prescription status will be maintained for women ages 15 and younger. **(Editor's note: On Aug. 26, 2005, the FDA again postponed its decision on OTC sale of Plan B. The agency called for 60 days of public comment on whether and how drug stores can enforce an age limit on OTC sales of the drug. To check what states are doing to increase EC access, see the update box, at left.)**

A new analysis of use of the EC Hotline web site, (www.NOT-2-LATE.com), jointly operated by the Office of Population Research at Princeton (NJ) University and the Association of Reproductive Health Professionals, shows that women are in need of information when it comes to EC and other reproductive health matters.[3] Women often are reluctant to ask for advance prescriptions for EC pills, and providers rarely offer them without being asked, according to the findings.

When women have a condom failure or fail to use contraception, they may not know about EC and, even if they do, they may face hurdles in finding a provider who can prescribe EC pills and then locating a pharmacy to get the prescription filled, researchers note. Unprotected intercourse often occurs on weekends or holidays when access to medical providers is limited, they state.[3]

References

1. Marston C, Meltzer H, Majeed A. Impact on contraceptive practice of making emergency hormonal contraception available over the counter in Great Britain: Repeated cross-sectional surveys. *BMJ* 2005; 331:271.
2. Bissell P, Anderson C. Supplying emergency contraception via community pharmacies in the UK: Reflections on the experiences of users and providers. *Soc Sci Med* 2003; 57:2,367-2,378.
3. Wynn L, Trussell J. The morning after on the internet: Usage of and questions to the emergency contraception web site. *Contraception* 2005; 72:5-13. ■

Certain types of breast disease may signal risk

New evidence indicates that women with benign breast disease have a higher risk for breast cancer, and that certain types of breast disease may predict the near-term development of breast cancer.[1] The new findings may provide a first step in stratifying women with a benign lesion into high- and low-risk groups, states an accompanying editorial to the new research.[2]

Benign breast disease refers to any lumps or mammographically detected abnormalities that have been biopsied and found to not contain cancerous cells. According to the American Cancer Society, about seven in 10 biopsies done for benign breast conditions do not contain any hyperplasia.[3]

To conduct the new study, a scientific team examined medical records of 9,087 women diagnosed with benign breast disease in the Mayo Clinic Surgical and Pathology Indices at Rochester, MN, then noted the incidence of breast cancer for a median of 15 years after the initial diagnosis. All benign breast samples were evaluated by a breast pathologist unaware of initial diagnoses or patient outcomes and assigned to one of three categories of benign breast lesions: nonproliferative (no cell overgrowth), proliferative (overgrowth of normal cells), and atypical (overgrowth of abnormal cells). Researchers also asked the women about their family history of breast cancer.

The team identified two risk factors for breast cancer after the diagnosis of benign breast disease: the histologic classification of a benign breast lesion and a family history of breast cancer. Investigators found that women with the most common, nonproliferative forms of benign disease had no increased risk of developing breast cancer, as long as they did not have a strong family history of breast cancer. However, proliferative and atypical lesions pointed to an increased risk of a future breast cancer, even when the family history of breast cancer was negative.[1]

About two-thirds of the women were found to have nonproliferative growths, which in and of themselves, are not associated with an increased risk of a later breast cancer, explains **Lynn Hartmann**, MD, an oncologist at the Mayo Clinic School of Medicine in Rochester and lead author of the new research. Another 30% contained excess numbers of normal-appearing cells. These so-called proliferative cells are associated with an approximate two times increased risk of a later breast cancer, she states. The remaining 3%-4% of findings contained excess number of cells that appeared abnormal. Women with these atypia findings have a quadruple increased risk of a later breast cancer, according to Hartmann.

EXECUTIVE SUMMARY

Women with benign breast disease have a higher risk for breast cancer, and certain types of breast disease may predict the near-term development of breast cancer, results from a new study indicate.

- The research identified two risk factors for breast cancer after the diagnosis of benign breast disease: histologic classification of a benign breast lesion and a family history of breast cancer.
- Women with the most common, nonproliferative forms of benign disease had no increased risk of developing breast cancer, as long as they did not have a strong family history of breast cancer. However, proliferative and atypical lesions pointed to an increased risk of a future breast cancer, even when the family history was negative.

How to explain risks?

When women hear that they are at "increased risk for breast cancer," they can become anxious, says **Joann Elmore**, MD, MPH, University of Washington School of Medicine in Seattle and co-author of the editorial accompanying the new research.

Even without hearing that "you are at increased risk of breast cancer," most women in the United States overestimate their individual risk of breast cancer, she reports. In addition, many women in the United States have had breast biopsies, and most of these women will have benign breast disease. These are the women who will be told that they are at "increased risk" of breast cancer, Elmore adds.

So how can you talk to women about the new findings? Absolute risk statistics may be more helpful to explaining the results, according to the editorial:

- Among 100 women with nonproliferative histologic findings, about six women will develop breast cancer.
- Among 100 women with proliferative disease, the number in whom breast cancer will develop increases from five to about 10.
- Among 100 women with atypical hyperplasia,

Use resource for breast cancer awareness month

Boost your clinic's participation in the October observance of National Breast Cancer Awareness Month. Review the tips offered in an on-line promotion guide published by the board of sponsors for the national event.

Go to **www.nbcam.org**, the official web site for the event, and click on "Promotion Guide." The link will allow you to download the entire publication, or you may browse individual sections on-line. One section offers individual breast cancer statistics for each state, while another section offers examples of what others have done in the past to remind women to obtain their annual mammogram. Logos, including the pink ribbon awareness symbol, also are available for use. Click on "Download Center."

The site also offers a number of other resources, Click on "NBCAM Resources," then "Posters and Brochures" to view the selections. An "Early Detection Brochure" is available in English and Spanish, as well as African-American, Asian, and Hispanic women posters. Reproduction and distribution of these material is permitted and encouraged, according to the web site. ■

about 19 women will develop breast cancer.[2]

Pay attention to how you "frame" the risks, the editorial suggests. Negative framing, as stated in the absolute risk examples above, may aid in willingness to participate in a treatment or a screening, whereas positive framing may not, the editorial states.[2]

"Expressing the absolute risk in a positive frame would lead us to say that among 100 women in the general population, breast cancer will not develop in 95 of them within the next 15 years; among 100 women with a biopsy revealing nonproliferative disease, 94 will not receive a diagnosis of breast cancer," the editorial explains.[2]

(October is National Breast Cancer Awareness Month. Use the resource, above, to prepare your clinic's observance of the event.)

References

1. Hartmann LC, Sellers TA, Frost MH, et al. Benign breast disease and the risk of breast cancer. *N Engl J Med* 2005; 353:229-237.

2. Elmore JG, Gigerenzer G. Benign breast disease — the risks of communicating risk. *N Engl J Med* 2005; 353:297-299.

3. American Cancer Society. *Benign Breast Conditions*. Accessed at: www.cancer.org/docroot/CRI/content/CRI_2_6X_Benign_Breast_Conditions_59.asp. ■

Check choices for women with epilepsy

In reviewing the chart for your next patient, you note that she is a 28-year-old woman with epilepsy. What information do you need to provide her when it comes to contraceptive choices? Many family planning clinicians encounter this scenario. Epilepsy is one of the most common chronic health conditions affecting reproductive-age women.[1]

Many antiepileptic drugs (AEDs) are teratogenic; women using them require excellent contraception, says **Anita Nelson**, MD, professor in the obstetrics and gynecology department at the University of California in Los Angeles (UCLA) and medical director of the women's health care programs at Harbor-UCLA Medical Center in Torrance. In addition, many AEDs interfere with vitamin K synthesis and cause heavier menstrual blood loss, she reports.

"One final caveat is that many of the AEDs increase hepatic cytochrome P450 activity and cause women to metabolize sex steroids more rapidly," Nelson points out. "For that reason, women using oral contraceptives (OCs) should avoid low-dose formulations."

Cytochrome P450-inducing antiepileptic drugs enhance hepatic metabolism of contraceptive steroids and increase binding of steroids to serum proteins, which results in a reduction of the concentration of biologically active steroid hormone.[1] Women receiving a liver enzyme-inducing antiepileptic medication have at least a 6% failure rate per year for OCs.[2]

Agents that induce liver enzymes and may compromise OC efficacy include carbamazepine (Tegretol), felbamate (Felbatol), oxcarbazepine (Trileptal), phenobarbital (Luminal), phenytoin (Dilantin), primidone (Mysoline), and topiramate (Topamax). In the case of topiramate, check the dosage of the drug, says **Susan Wysocki**, RNC, NP, president and chief executive officer of the National Association of Nurse Practitioners in Women's Health.

Labeling for oral contraceptives states that topiramate will decrease the efficacy of OCs; however, in the topiramate label, it says that the dose that decreases the efficacy is 200 mg, she says. This finding is borne out in a 2004 study, which notes that the drug only increases the oral clearance of ethinyl estradiol in an oral contraceptive at high dosages (more than 200 mg/day).[3]

EXECUTIVE SUMMARY

Epilepsy is one of the most common chronic health conditions affecting reproductive-age women. Since many antiepileptic drug (AEDs) are teratogenic, women using them require effective contraception.

- Cytochrome P450-inducing antiepileptic drugs enhance hepatic metabolism of contraceptive steroids and increase binding of steroids to serum proteins, which results in a reduction of the concentration of biologically active steroid hormone. Women may wish to back up their oral contraceptive choice with a second form of birth control if they are taking one of these drugs.
- Other hormonal choices include the levonorgestrel intrauterine system and depot medroxyprogesterone acetate injections.

Women may wish to back up their OC choice with a second form of birth control, such as a diaphragm, spermicidal cream, or condoms, if they are taking one of the cytochrome P450-inducing AEDs.

Agents that do not compromise OC efficacy include gabapentin (Neurontin), levetiracetam (Keppra), tiagabine (Gabitril), valproate (Depakote), and zonisamide (Zonegran).[1] One AED, Lamictal, was originally included in this group; however, its manufacturer, GlaxoSmithKline of Research Triangle Park, NC, revised the drug's label and issued an August 2004 letter to health care providers to add results from an interaction study of an oral contraceptive preparation (30 mcg ethinyl estradiol and 150 mcg levonorgestrel) administered in combination with Lamictal at 300 mg per day.

The study found that Lamictal had a modest effect on levonorgestrel plasma concentrations; the effect on ethinyl estradiol concentrations was minimal.[4] An increase in serum FSH (follicle stimulating hormone) and LH (luteinizing hormone) concentrations and a marginal increase in serum estradiol concentrations were observed during the period of coadministration of the oral contraceptive and Lamictal.[4] There was no hormonal evidence of ovulation as evidenced by progesterone serum concentrations.[4]

"The clinical significance of the observed hormonal changes on ovulatory activity is unknown," states the revised label. "However, the possibility of decreased contraceptive efficacy in some patients cannot be excluded; therefore, patients should be instructed to promptly report changes in their menstrual pattern [e.g., breakthrough bleeding]."[5]

The effect of other hormonal contraceptive preparations or hormone replacement therapy on the pharmacokinetics of lamotrigine has not been evaluated, although the effect may be similar, the company notes.

What contraceptive choices may work best for women with epilepsy? The most effective methods are the levonorgestrel intrauterine system (Mirena, Berlex Laboratories, Montville, NJ) and injectable depot medroxyprogesterone acetate (DMPA, Depo-Provera, Pfizer, New York City), recommends Nelson.

If OCs are used, at least a 35 mcg formulation is generally needed, she advises. Extended-cycle OC use with shortened pill-free intervals are particularly attractive for these women, she notes.

Advise women to check for breakthrough bleeding while on hormonal contraception; such bleeding midcycle may be a sign of ovulation.[6] Provide women with condoms or spermicide as backup contraception.[6]

References

1. Morrell MJ. Epilepsy in women. *Am Fam Physician* 2002; 66:1,489-1,494.
2. Mattson RH, Cramer JA, Darney PD, et al. Use of oral contraceptives by women with epilepsy. *JAMA* 1986; 256:238-240.
3. Bialer M, Doose DR, Murthy B, et al. Pharmacokinetic interactions of topiramate. *Clin Pharmacokinet* 2004; 43:763-780.
4. GlaxoSmithKline. Dear Healthcare Professional [Letter]. Research Triangle Park, NC; August 2004.
5. GlaxoSmithKline. Lamictal (lamotrigine) prescribing information. Research Triangle Park, NC; August 2004.
6. Epilepsy Foundation. *Birth Control for Women with Epilepsy*. Accessed at: www.epilepsyfoundation.org/answerplace/Life/adults/women/weibirthcontrol.cfm. ■

ASK THE EXPERTS

How to start mini-pills in a breast-feeding mom

How do you initiate mini-pills in a lactating woman who specifies such pill use for contraception? The following experts weigh in on the subject: **Robert Hatcher**, MD, MPH, professor of gynecology and obstetrics at Emory University School of Medicine in Atlanta, and **Sharon Schnare**, RN, FNP, CNM, MSN, clinician at South Kitsap Family Care Clinic, Port Orchard, WA.

Question: If a breast-feeding mother wants to start oral contraception six months postpartum rather than the initial three to six weeks, can you start mini-pills at any time? If she has not had a period yet, we don't know where she may be in her cycle. Do you just pick a random Sunday start date, or have to do any labs, etc.?

Hatcher: Your breast-feeding mom has not had a period yet. But she is in a period of time when it is quite likely that she will ovulate before her first period. The probability that ovulation will precede the first menstrual period in a lactating woman increases from 33%-45% during the first three months to 64%-71% during months four to 12 and 87% after 12 months.[1-3] She may have ovulated already.

You may start her on mini-pills immediately if she have been using condoms for the past two weeks and has a negative pregnancy test. If she has not had intercourse for the past two weeks and has a negative pregnancy test, she also may start mini-pills. If she has a period, then start mini-pills immediately (on the first day of bleeding).

Schnare: This postpartum woman may start mini-pills at any time, irrespective of her cycle. I would assess whether she has had unprotected intercourse. I would do a pregnancy test and offer her Plan B and condoms. If she is not pregnant, I would start progestin-only pills immediately with a seven-day backup. Have her keep a menstrual calendar, and encourage her to return for more effective contraception if she is interested. It is important that she know to take the mini-pill every day within a two-hour window. This may be most challenging for a mother with a 6-month-old baby.

Starting combination hormonal contraception

When do you start combination hormonal contraceptives in women who are not regularly menstruating? **Andrew Kaunitz**, MD, professor and assistant chair in the obstetrics and gynecology department at the University of Florida Health Science Center/Jacksonville, offers this approach:

Kaunitz: This question comes up frequently. The question refers to a woman with lactational amenorrhea. Another example when this question arises is in the patient with amenorrhea/oligomenorrhea associated with polycystic ovarian syndrome: She will benefit from starting combination hormonal contraception but because she does not regularly menstruate, clinicians query when to initiate birth control.

The answer is straightforward. Combination methods can be initiated any time the clinician can be sure the patient is not pregnant.

Sometimes the history is sufficient (the patient indicates she has never been sexually active or has not been active for an extended period of time); other times it is important to perform a sensitive urine pregnancy test to rule out pregnancy.

If the patient would benefit from a Sunday start (or a start day any other day of the week), the method can be started on that particular day. Otherwise, the contraceptive should be started as soon as pregnancy can be excluded.

References

1. Campbell OMR, Gray RH. Characteristics and determinants of postpartum ovarian function in women in the United States. *Am J Obstet Gynecol* 1993; 169:55-60.

2. Lewis PR, Brown JB, Renfree MB, et al. The resumption of ovulation and menstruation in a well-nourished population of women breast-feeding for an extended period of time. *Fertil Steril* 1991; 55:529-536.

3. Kennedy KI, Trussell J. "Postpartum contraception and lactation." In: Hatcher RA, Trussell J, Stewart F, et al. *Contraceptive Technology*: 18th revised edition. New York City: Ardent Media; 2004. ■

CTUPDATES
News ■ Resources ■ Events

Trichomoniasis is focus of new Internet site

Take a look at www.trichomoniasis.net, the first comprehensive web site to focus on the sexually transmitted disease (STD) trichomoniasis.

The new site provides an overview of the STD, discussion of its prevalence and increased health risks, a detailed description of its signs and symptoms, and current methods of diagnosis and treatment.

Caused by the single-celled trichomonad parasite, signs of trichomoniasis in women can include a yellow, gray, or green frothy vaginal discharge. In many cases, it is accompanied by a foul odor. Burning, itching, soreness, and redness also are often present. Urination and intercourse may be painful, and the signs and symptoms may worsen during menstruation. Trichomoniasis is frequently

asymptomatic in men, who may unknowingly transmit the infection to their sexual partners. When symptoms are present in men, they may consist of urethral discharge and irritation.

The site is sponsored by Presutti Laboratories of Palatine, IL, manufacturers of Tindamax (tinidazole), which is approved for treatment of the bacterial STD. Full prescribing information for Tindamax can be found at www.Tindamax.com. ▼

NIH panel wants menopause 'demedicalized'

An independent panel convened by the National Institutes of Health (NIH) would not recommend the use of any bioidentical or natural hormones for treating menopausal symptoms. The panel says there are scant data on the benefits and adverse effects of these compounds.

"The panel could not endorse alternatives because of scant data, but we should not accept this statement," says **Joseph L. DeStefano**, head of women's health care at the AtlantiCare Regional Medical Center in New Jersey. "Women and physicians should be writing to NIH and our political leaders for NIH to begin studies to provide us with this data. After all, it took more than 50 years to obtain the accurate and meaningful data on hormone therapy."

In its report, the NIH State-of-the-Science Conference on Management of Menopause-Related Symptoms says that many women go through menopause without being disabled by symptoms. Therefore, they say that period of life should not be considered a disease. Women and their health care providers have a tendency to "medicalize" menopause, the panel says. This can lead to overuse of treatment approaches that are known to carry serious risks or whose safety is as yet unclear.

"There is great need to develop and disseminate information that emphasizes menopause as a normal, healthy phase of women's lives and promotes its demedicalization," the panel says in the conclusion of its report.

For more information about the panel's conclusions, go to www.consensus.nih.gov/ta/025/025MenopauseINTROpostconf.htm. ▼

Need STD information? Check ASHA web site

Looking for current information on sexually transmitted diseases (STDs)? Check out www.ashastd.org, the newly redesigned web site for the American Social Health Association (ASHA).

ASHA, a Research Triangle Park-based nonprofit organization, offers information on all STDs, as well as patient information resources. By clicking on "Publications," "Organizations," then "Easy-Read Series Brochures," providers can review a list of titles available for order, including "Herpes — What You Should Know" and "Playing It Safe: The Right Way to Use A Condom," both written at a sixth-grade reading level.

The site also offers ordering information for Spanish STD brochures. ■

CE/CME Instructions

Physicians and nurses participate in this continuing medical education/continuing education program by reading the articles, using the provided references for further research, and studying the questions at the end of the issue. Participants should select what they believe to be the correct answers and refer to the list of correct answers to test their knowledge. To clarify confusion surrounding any questions answered incorrectly, please consult the source material. After completing this activity with the **December** issue, you must complete the evaluation form provided and return it in the reply envelope provided in that issue to receive a certificate of completion. When your evaluation is received, a certificate will be mailed to you. ■

COMING IN FUTURE MONTHS

- Research eyes triphasic pills in continuous-use regimen
- Vaginal contraceptives: New options in research pipeline
- Are costs keeping women from getting reproductive care?
- Is same-day administration of DMPA effective?
- Will vaginal administration work for emergency contraception?

CE/CME Questions

After reading *Contraceptive Technology Update*, the participant will be able to:

- **Identify** clinical, legal, or scientific issues related to development and provisions of contraceptive technology or other reproductive services. (See **"Certain types of breast disease may signal risk"** in this issue.)
- **Describe** how those issues affect service delivery and note the benefits or problems created in patient care in the participant's practice area. (See **"Mifepristone label gets new safety information."**)
- **Cite** practical solutions to problems and integrate information into daily practices, according to advice from nationally recognized family planning experts. (See **"Media report on Ortho Evra patch sets off safety concerns in women"** and **"Check choices for women with epilepsy."**)

13. In the "ACHES" mnemonic used to teach women potential danger signals of combined hormonal contraceptives, the "A" stands for:

A. Anxiety
B. Amenorrhea
C. Asthma
D. Abdominal pain

14. The bacteria that may be linked to two deaths involving medication abortion is

A. *Clostridium sordellii*
B. *Mycoplasma hominis*
C. *Streptococcus agalactiae*
D. *Calymmatobacterium granulomatis*

15. What two risk factors for breast cancer did researchers identify after the diagnosis of benign breast disease in the *New England Journal of Medicine* (2005; 353:229-237)?

A. Histologic classification of a benign breast lesion and two alcoholic drinks per day
B. Histologic classification of a benign breast lesion and a family history of breast cancer
C. Use of tobacco products and a family history of breast cancer
D. Histologic classification of a benign breast lesion and use of hormonal contraception

16. Which drug listed below is NOT an agent that induces liver enzymes and may compromise oral contraceptive efficacy?

A. Carbamazepine
B. Phenobarbital
C. Gabapentin
D. Phenytoin

Answers: 13. D; 14. A; 15. B; 16. C.

Contraceptive Technology Update *is endorsed by the National Association of Nurse Practitioners in Women's Health and the Association of Reproductive Health Professionals as a vital information source for health care professionals.*

S·T·D QUARTERLY™

Male circumcision and HIV prevention: Method can dramatically reduce risk, study says

More research to assess method as risk prevention tool will be completed in '07

No doubt you have scanned news reports of a recent study of male circumcision, used as an HIV prevention intervention, which resulted in dramatic reduction in HIV incidence among circumcised men.[1] But does the news translate into an immediate change in public health policy?

The trial, which looked at men ages 18-24 in the Gauteng province in South Africa, is the first randomized control trial to demonstrate a strong protective effect of safe male circumcision on HIV acquisition by males, says **Bertran Auvert**, MD, PhD, professor of public health at the University Versailles Saint-Quentin in Paris.

Auvert and his research team presented the findings at the recent International AIDS Society conference in Rio de Janeiro, Brazil.

Researchers randomly assigned the men, all heterosexual males living in a high HIV prevalence area, to undergo circumcision or wait 20 months for the procedure. Previous acceptability studies had shown that men in the area would consider circumcision if it would reduce the risk of HIV. The randomized trial, which began in 2002, was halted early after initial results indicated that the intervention prevented six to seven out of 10 potential HIV infections.[1]

While the results of the study are being met with interest, more work will be needed to confirm its results, say officials with the Joint United Nations Programme on HIV/AIDS (UNAIDS).

"Although the trial shows promising protective effects of adult male circumcision in reducing HIV acquisition, UNAIDS emphasizes that more research is needed to confirm the reproducibility of the findings of this trial and whether or not the results have more general application," noted the organization in a statement issued after the conference presentation. "In particular, the findings from two ongoing trials in Uganda and Kenya, funded by the U.S. National Institutes of Health, will be important to clarify the relationship between male circumcision and HIV in differing social and cultural contexts."[2]

What role might circumcision play in the prevention of HIV acquisition? Scientists propose that the inner surface of the foreskin, which contains Langerhans cells, may provide a potential

EXECUTIVE SUMMARY

The first randomized control trial of male circumcision used as an HIV prevention intervention in South African men resulted in a dramatic reduction in HIV incidence among circumcised men. The trial, which began in 2002, was halted early after initial results indicated that the intervention prevented six to seven out of 10 potential HIV infections.

- Two similar trials are under way in Kenya and Uganda and are expected to be completed in 2007.
- If male circumcision is found to be an effective HIV prevention tool, it will need to be presented as part of a comprehensive prevention package, public health officials say.

source of initial cell contact for HIV infection.[3] The foreskin also may offer an environment for survival of bacterial and viral matter, since it is susceptible to tears, scratches, and abrasions.[4]

The idea that male circumcision may lower the risk of HIV acquisition is not new; such a hypothesis was raised early in the AIDS crisis.[5] Scientists have noted the highest rates of HIV infection in Africa have occurred in regions of the continent where the predominant tribal or religious cultures do not practice circumcision. Adult HIV infection rates above 30% are found in Zimbabwe, Botswana, Swaziland, and eastern South Africa, where circumcision is not practiced, while HIV infection rates remain below 5% in West Africa and other parts of the continent where circumcision is commonplace.[6]

Scientists have continued to examine circumcision's role in a number of observational studies. A meta-analysis published in 2000 of 27 such studies concludes that the practice is associated with a significantly reduced risk of HIV infection among men in sub-Saharan Africa, particularly those at high risk of HIV.[7]

International researchers projected new directions for further research at a February 2000 meeting organized by the Horizons Project of the New York City-based Population Council. They called for not only research on the mechanisms and expected effect of male circumcision on HIV infection and the possible existence of serious confounders, but they also called for studies on the practicality, feasibility, acceptability, and cost-effectiveness of male circumcision as an HIV intervention.[8]

Look for more results

Scientists are moving forward with two other randomized control trials, both designed to assess whether circumcision of adult males protects against HIV. One such study is under way in Kisumu, Kenya, led by Robert Bailey, PhD, MPH, professor of epidemiology and biostatistics at the University of Illinois at Chicago; the other, centered in Rakai, Uganda, is headed by **Ronald Gray**, MD, MSc, professor of reproductive epidemiology at Johns Hopkins University in Baltimore. The National Institute of Allergy and Infectious Diseases is providing funding for both trials.

The Kenya research, conducted in an area where less than 10% of adult men are circumcised, is being designed to assess the effectiveness of male circumcision in reducing HIV incidence. Uncircumcised men ages 18-24 years old will be offered voluntary HIV counseling and testing. HIV-negative men will be asked to enroll in the study. Consenting men will be assigned randomly to the treatment (circumcised) arm or the control (uncircumcised) arm of the study. Follow-up visits will be scheduled every six months for two years. Uncircumcised men will be offered circumcision at the end of follow-up. Enrollment of the 2,700 men is under way, and the trial is expected to be completed in 2007.

In the Uganda trial, enrollment of 5,000 HIV-negative men has been completed, Gray reports. The study's review board will decide on when an interim analysis might be done. One was planned for mid-2006, Gray states. The final study will be completed in mid-2007.

What is the next step?

If research confirms that male circumcision is an effective intervention in reducing HIV risk, men should not assume that they will be protected from acquiring the virus through circumcision alone, UNAIDS officials state. If effective, the method should be presented as part of a comprehensive prevention package, which includes correct and consistent condom use, behavior change, and voluntary counseling and testing, according to UNAIDS.

Africa has the highest HIV/AIDS infection rates in the world, with more than 25 million people infected. News of the South African trial may increase demand for male circumcision services, note UNAIDS officials.

"Although UNAIDS believes that it is premature to recommend male circumcision services as part of HIV prevention programs, there is heightened interest from governments and the general public in male circumcision in a number of African countries," state UNAIDS officials. "Governments should take steps now to ensure that male circumcision is conducted by trained practitioners in safe and equipped settings in order to reduce the rate of postoperative complications."

References

1. Auvert B, Puren A, Taljaard D, et al. Impact of male

circumcision on the female-to-male transmission of HIV. Abstract TuOa0402. Presented at the International AIDS Society Conference on HIV Pathogenesis and Treatment. Rio de Janeiro; July 2005.

2. Joint United Nations Programme on HIV/AIDS. UNAIDS statement on South African trial findings regarding male circumcision and HIV. July 26, 2005. Accessed at: www.who.int/mediacentre/news/releases/2005/pr32/en/print.html.

3. Soto-Ramirez LE, Renjifo B, McLane MF, et al. HIV-1 Langerhans' cell tropism associated with heterosexual transmission of HIV. *Science* 1996; 271:1,291-1,293.

4. Cameron DW, Simonsen JN, D'Costa LJ, et al. Female to male transmission of human immunodeficiency virus Type 1: Risk factors for seroconversion in men. *Lancet* 1989; 2:403-407.

5. Fink AJ. A possible explanation for heterosexual male infection with AIDS. *N Engl J Med* 1986; 315:1,167.

6. Russell S. Circumcision may offer Africa AIDS hope. *San Francisco Chronicle*, July 6, 2005: A2.

7. Weiss HA, Quigley MA, Hayes RJ. Male circumcision and risk of HIV infection in sub-Saharan Africa: A systematic review and meta-analysis. *AIDS* 2000; 14:2,361-2,370.

8. Van Dam J, Anastasi M. *Male Circumcision and HIV Prevention: Directions For Future Research*. Washington, DC: Horizons Project, Population Council; 2000. ■

Task force: Screen all pregnant women for HIV

Consider these facts: Women are the fastest-growing group in the United States with newly diagnosed HIV, and last year, an estimated 6,000-7,000 women with HIV gave birth.[1,2] Almost half of those women did not consider themselves to be in a risk group.[3]

The U.S. Preventive Services Task Force (USPSTF) has just released new recommendations calling for all pregnant women, not just those considered at high risk, to be screened for HIV.[4] **(Access the recommendations; see the resource box on p. 4.)**

"HIV screening thus has the potential to save much suffering and many lives," says **Diana Petitti**, MD, task force vice-chair and senior scientific advisor for health policy and medicine for Kaiser Permanente Southern California in Pasadena. "The test should be viewed as just like any other test during pregnancy: As one more thing that a woman can do to try to improve the health of her baby."

The evidence review performed prior to the issuance of the new recommendations confirms that perinatal HIV infection is an increasingly preventable disease,[5] says **Roger Chou**, lead author of the evaluation and assistant professor of medicine and medical informatics and clinical epidemiology at Oregon Health & Science University in Portland. Perinatal transmission rates of up to 25% without treatment have been reduced to 1%-2% with the use of currently recommended interventions, he notes.

Studies indicate that screening only pregnant women who report risk factors for HIV infection could miss more than half of infected women,[6] Chou points out. Many women are not aware that they have been exposed to HIV (for example, through unprotected vaginal intercourse with a male partner) or are unwilling to disclose socially undesirable high-risk behaviors, he states.

"Clearly, more complete uptake of universal prenatal HIV testing and use of recommended interventions would further reduce the incidence of perinatal HIV infection in the U.S.," states Chou. "Routine prenatal HIV screening and 'opt-out' testing policies could help improve uptake of HIV testing."

Why the move?

The task force issued a recommendation in 1996 calling for a targeted strategy of routine counseling and screening of high-risk pregnant women and those who live in communities with a higher rate of HIV-positive newborns.[7] The task force updated its recommendation with the

EXECUTIVE SUMMARY

The U.S. Preventive Services Task Force has just released new recommendations calling for all pregnant women to be screened for HIV.

- Women are the fastest-growing group in the United States with newly diagnosed HIV. An estimated 6,000-7,000 women with HIV gave birth in 2004. About half of the HIV-positive women did not consider themselves to be in a risk group.
- Screening only pregnant women who report risk factors for HIV infection could miss more than half of infected women.
- Elective cesarean section and avoidance of breast-feeding can further reduce the chances of a woman's passing HIV infection to her infant.

RESOURCE

Review the U.S. Preventive Services Task Force new recommendations by visiting the Rockville, MD-based Agency for Healthcare Research and Quality web site at www.ahrq.gov. Under "Clinical Information," click on "Preventive Services." Under the heading "U.S. Preventive Services Task Force (USPSTF)," click on "Clinical Categories." Under "Infectious Diseases," click on "Human Immunodeficiency Virus (HIV) Infection: Screening." By then clicking on "Supporting Documents," readers can download documents of the statement, review of the evidence, and evidence synthesis.

advent of more recent evidence indicating wider acceptance of HIV testing among pregnant women and reports of more women diagnosed and treated for HIV prior to delivery due to universal testing.

The recommendation follows similar guidelines issued by the Centers for Disease Control and Prevention (CDC), the American College of Obstetricians and Gynecologists (ACOG) and the American Academy of Pediatrics (AAP). **(*Contraceptive Technology Update* reported on the initial call for universal screening in its article, "Universal HIV tests eyed for prenatal care," August 2000, p. 96.)**

The USPSTF notes that ACOG, AAP, and the CDC go further in recommending that HIV testing be part of a routine battery of prenatal blood tests unless declined. The CDC and ACOG also recommend retesting women in their third trimester of pregnancy who are known to be at high risk for acquiring HIV, as well as rapid HIV testing in labor for women with undocumented HIV status, the task force notes.[4]

In analyzing available evidence, the task force also found evidence that elective cesarean section and avoidance of breast-feeding can further reduce the chances of a woman's passing HIV infection to her infant.[5] Since 1995, advancements in treating HIV-positive patients with highly active antiretroviral therapy (HAART), a treatment regimen that combines three or more medications, have been shown to slow the progression of the disease as well as to reduce HIV-related death rates.

"Treatment during pregnancy, planned delivery, and use of formula can reduce the risk of mother-to-infant transmission to less than 1%," says Petitti.

References

1. Lee LM, Fleming PL. Trends in human immunodeficiency virus diagnoses among women in the United States, 1994-1998. *J Am Med Womens Assoc* 2001; 56:94-99.
2. Bulterys M, Nolan ML, Jamieson DJ, et al. Advances in the prevention of mother-to-child HIV-1 transmission: Current issues, future challenges. *AIDScience* 2002; 2(4). Available at www.aidscience.org/Articles/aidscience017.asp.
3. Office of Inspector General, Health and Human Services. Reducing obstetrician barriers to offering HIV testing. OEI-05-01-00260. Washington, DC: Department of Health and Human Services; March 2002.
4. US Preventive Services Task Force. Screening for HIV: recommendation statement. *Ann Intern Med* 2005; 143:32-37.
5. Chou R, Smits AK, Huffman LH, et al. Prenatal screening for HIV: A review of the evidence for the U.S. Preventive Services Task Force. *Ann Intern Med* 2005; 143:38-54.
6. Barbacci MB, Dalabetta GA, Repke JT, et al. Human immunodeficiency virus infection in women attending an inner-city prenatal clinic: Ineffectiveness of targeted screening. *Sex Transm Dis* 1990; 17:122-126.
7. U.S. Preventive Services Task Force. *Guide to Clinical Preventive Services*. Second ed. Washington, DC: Office of Disease Prevention and Health Promotion; 1996. ■