# CONTRACEPTIVE TECHNOLOGY UPDATE®

A Monthly Newsletter for Health Professionals




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## IN THIS ISSUE



**Inserted in this issue:**
**STD Quarterly:** Youth impacted by rising STD tide; surf the Web for teen STD information; HIV prevention conference

**MAY 2004**
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# As more women choose the patch, keep an eye out for counterfeits

*FDA shuts down four Internet sites for distributing fake contraceptive*

A quick review of your clinic's dispensing habits tells the tale: More women are moving to use of the transdermal contraceptive (Ortho Evra; Ortho-McNeil Pharmaceutical, Raritan, NJ). The contraceptive patch is now the favorite nonoral contraceptive method in the United States, according to IMS Health, a Fairfield, CT-based supplier of pharmaceutical industry market research.[1]

With a rise in popularity comes a risk in counterfeiting. The Food and Drug Administration (FDA) has taken action against four foreign Internet sites found to be selling counterfeit contraceptive patches that contain no active ingredients. While counterfeiting is not yet widespread in the U.S. drug market, and no pregnancies have been reported, the FDA is investigating a growing number of such cases.

The regulatory agency has just released a new report detailing its efforts to keep the U.S. drug supply secure against the introduction of counterfeit drugs. (Review an online version of the publication, *The FDA Counterfeit Drug Task Force Final Report*, at www.fda.gov/oc/initiatives/counterfeit/.)

## EXECUTIVE SUMMARY

The Food and Drug Administration (FDA) is warning providers and consumers about the sale of fake Ortho Evra transdermal contraceptives over the Internet. It has closed down four Internet sites that were distributing bogus products.

- While counterfeiting is not yet widespread in the U.S. drug market, the FDA is investigating more cases of such activity.
- Consumers who want to buy drugs via the Internet only should purchase from sites bearing the Verified Internet Pharmacy Practice Sites seal issued by the National Association of Boards of Pharmacy.

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As more consumers seek the convenience of on-line pharmaceutical ordering, what do you need to know to make sure your patients are getting safe, effective contraception?

A call to the Ortho Customer Care Center telephone hotline was the first tip-off regarding the counterfeit patches, says **Mona Terrell**, Ortho-McNeil spokeswoman. The call came from an anxious woman who had ordered a supply of the patches from the Internet. When she received her order, the woman noticed a distinct difference in the appearance and packaging of the product, says Terrell.

The patches did not look the same as the Ortho product, she explains. Also, they were packaged loosely, without identifying materials, lot numbers, expiration dating, or any other labeling information needed to safely and effectively use the prescription product. **(See pictures of the counterfeit patches; go to the product web site, www.orthoevra.com; click on "Breaking News: Ortho Evra Counterfeit Patch Alert." The site has photographs of pharmacy product packaging so women can see the correct product. The FDA also has photographs of the counterfeit patches at its web site, www.fda.ov/bbs/topics/news/photos/contraceptive/counterfeit.html. If consumers cannot access the Internet to review the information on the Ortho Evra web site, they can call the toll-free Ortho-McNeil Customer Care Center telephone number, (800) 682-6532.)**

Ortho immediately contacted the FDA, says Terrell. Since that time, the FDA has shut down the following four Internet web sites for distributing the counterfeit patches:

- www.rxpharmacy.ws;
- www.usarxstore.com;
- www.europeanrxpharmacy.com;
- www.generic.com.

The sites also were selling other products that purported to be versions of FDA-approved drugs. FDA's Office of Criminal Investigation is working with Johnson & Johnson, Ortho-McNeil's parent company, and the Department of Homeland Security's Bureau of Immigration and Custom Enforcement's Cyber Crimes Center to track any further counterfeiting efforts.

## *On-line orders catch on*

Internet buying of prescription drugs is on the rise as more Americans look to the convenience of on-line ordering or wish to find less

expensive medicines.[2] According to the FDA, consumers who want to buy drugs via the Internet only should purchase from sites bearing the Verified Internet Pharmacy Practice Sites (VIPPS) seal issued by the Park Ridge, IL-based National Association of Boards of Pharmacy (NABP).

Internet-based pharmacy practice sites that wish to display the VIPPS seal must submit a detailed application to the NABP, including the pharmacy's policies and procedures. Licensure information is verified with applicable state boards of pharmacy, then a review is performed of the pharmacy's application, policies, and web site, along with an on-site inspection of the pharmacy's facilities.

According to the NABP, it does not regulate on-line pharmacies. Regulation of pharmacy practice is primarily the jurisdiction of the state boards of pharmacy with some federal oversight, the organization states. The NABP began developing the VIPPS program in 1999 after consumers contacted several state pharmacy boards to complain about illegal Internet prescribing and dispensing sites posing as legitimate pharmacies. The VIPPS program is one way for the public to distinguish between legitimate and illegitimate on-line pharmacy practice sites, according to the organization.

On-line sites located outside the United States pose the greatest challenges for state and federal regulators. Cooperation with other nations and their regulatory agencies is key to regulating on-line international pharmacy sites. The NABP says it is working with a number of international regulatory agencies to establish VIPPS programs for their on-line pharmacies.

The NABP just has issued a list of susceptible products that are particularly prone to adulteration, counterfeiting, or diversion. The list of 31 drugs is seen as a starting point by which state boards of pharmacy can begin to take a closer look at possible suspect drugs. The NABP has formed a drug advisory coalition to maintain and update the list. Family planning clinicians will be familiar with two of the drugs on the list: Diflucan (fluconazole, Pfizer, New York City ) and Rocephin (ceftriaxone, Hoffman-La Roche, Nutley, NJ).

Federal and state regulators and the wholesale drug industry are working together to make sure that the American pharmaceutical delivery system is secure. The NABP has developed model rules for adoption by state boards of pharmacy to help provide national and uniform regulation for the licensure of wholesale drug distributors.

Consumers who buy prescription drugs from unlicensed, uncertified pharmacies put themselves at risk of serious illness, says Terrell. Consumers always should consult a physician first if they are interested in prescription contraceptives; prescriptions only should be filled at a retail

## 5 Signs of a Suspect Internet Pharmacy

An e-pharmacy may be suspect if it:

- Dispenses prescription medications without requiring the consumer to mail in a prescription, and if it dispenses prescription medications and does not contact the patient's prescriber to obtain a valid verbal prescription.
- Dispenses prescription medications solely based upon the consumer completing an online questionnaire, without the consumer having a pre-existing relationship with a prescriber and the benefit of an in-person physical examination. State boards of pharmacy, boards of medicine, the Food and Drug Administration, and the Chicago-based American Medical Association condemn this practice and consider it to be unprofessional.
- Does not have a toll-free phone number as well as a street address posted on its site. If the pharmacy only has an e-mail feature as the sole means of communication between the consumer and the pharmacy, it is a suspect site.
- Does not allow consumers to contact the pharmacist if they have questions about their medications. If a site does not advertise the availability of pharmacists for medication consultation, it should be avoided.
- Only sells a limited number of medications, particularly lifestyle medications that treat such conditions and diseases as impotence, obesity, herpes, pain, and acne. Although pharmacies may not sell every medication available in the United States, on-line pharmacies selling only lifestyle medications may not be operating legitimately.

*Source:* Adapted from the National Association of Boards of Pharmacy's "Verified Internet Pharmacy Practice Sites: Most Frequently Asked Questions." Web site: www.nabp.net/vipps/consumer/faq.asp.

pharmacies, through legitimate mail order programs, or through on-line pharmacies certified by the NABP, she states. **(What are the signs of a suspect e-pharmacy? See box on p. 51.)**

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# Egg regeneration study opens fertility window

Current understanding of female reproductive biology may be revised with publication of new research that indicates that female mice retain the ability to make new egg cells well into adulthood.[1] Scientists long have believed that female mammals are born with a finite supply of cells, known as oocytes, that are lost at a steady rate until the supply is exhausted. Such a process leads to menopause in women.

Researchers at the Boston-based Massachusetts General Hospital report that new oocyte-containing follicles continue to develop in the ovaries of adult mice.[1] The research, supported by the federal National Institute on Aging, suggests that these new oocytes come from stem cells located in the ovary.[1]

"If these findings hold up in humans, all theories about the aging of the female reproductive system will have to be revisited," says **Jonathan Tilly**, PhD, an associate professor of obstetrics, gynecology, and reproductive biology at Harvard Medical School, also in Boston and developmental biologist in the hospital's Vincent Center for Reproductive Biology. "We also may need to revisit the mechanisms underlying such environmental effects on fertility as smoking, chemotherapy, and radiation; eventually this could lead to totally new approaches to combating infertility in cancer patients and others."

The concept of egg regeneration will open a new area of research if the findings are supported by other studies and in other species as well, remarks **Lee Lee Doyle**, PhD, chairman of the board of directors of the Washington, DC-based Association of Reproductive Health Professionals (ARHP) and professor emeritus at the University of Arkansas for Medical Sciences in Little Rock.

The big issue is the "if," agrees **Mitchell Creinin**, MD, professor of obstetrics, gynecology, and reproductive sciences at the University of Pittsburgh School of Medicine and chairman of ARHP's education committee.

"There is still a lot of work to be done to understand if these findings can be replicated by others, what they really mean, [and] is this true for humans," he observes.

### Look at the findings

The mechanisms behind the death of oocytes and follicles has been the focus of the Boston-based research group.[2] Scientists in the group have been seeking better ways to regulate cell death during chemotherapy and thus help protect fertility in cancer patients.[3]

The scientists began by comparing the numbers of healthy and degenerating follicles in the ovaries of a particular strain of mice from birth through young adulthood. They hypothesized that if the number of follicles in the ovary is set at or shortly after birth, then the loss of healthy follicles over time would be accounted for by the total number of follicles undergoing degeneration during the same time period. However, they found that the incidence of degenerating follicles was significantly greater than the loss over time of healthy follicles. With evidence that degenerating follicles

**EXECUTIVE SUMMARY**

Researchers at Massachusetts General Hospital in Boston report that female mice retain the ability to make new egg cells well into adulthood. The finding challenges a long-held belief that most female mammals are born with a finite supply of such cells that are lost at a steady rate until the supply is exhausted.

- The just-published findings suggest that new oocyte-containing follicles continue to develop in the ovaries of adult mice. The research indicates that these new oocytes come from stem cells in the ovary.
- Research now focuses on isolating mice ovarian stem cells to identify characteristic active genes within them. If potential stem cells with similar genetic signatures are found within human ovaries, new infertility treatments may be made possible.

disappeared from the ovaries within three days, scientists then deduced that the mouse ovaries continue to produce new oocyte-containing follicles into adulthood.[4]

The scientists replicated the same results in two other strains of mice, then went on to pinpoint the presence of large cells on the surface layer of cells in the mouse ovaries that they identified as germ cells. They also uncovered signs in adult animals of meiosis, the specialized cell division that only occurs in the formation of sex cells, which according to current thinking, should have been halted before birth.[4]

To further their research, the scientists transplanted ovarian tissue from adult wild-type mice into adult female mice developed to express a particular type of protein in their cells. When they examined the transplanted ovarian tissue under microscope, they found follicles housing the protein, which indicated new follicle production in the adult mice ovaries.[4]

### *Opening the door*

When the 20th century began, some scholars suggested that eggs could be replenished in adult mammals; however, a 1951 study provided a definitive argument that egg numbers are determined at birth.[5] Female reproductive biology has rested on that argument ever since.

If the latest discovery is confirmed in humans, that argument will be discarded and new therapies may be developed, such as transplanting ovarian stem cells for infertility.[6]

The Boston research group is attempting to isolate the ovarian stem cells from mice and identify characteristic active genes within them. Scientists then will search for potential stem cells with similar genetic signatures in biopsies of human ovaries.

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# Estrogen arm of WHI suspended; what next?

Early summer should see the publication of a detailed analysis from the estrogen-alone arm of the Women's Health Initiative (WHI). The study was suspended in February when scientists determined the therapy did not appear to affect heart disease, the major question being evaluated in the trial.[1] According to initial data from the halted study, estrogen-alone therapy appears to increase the risk of stroke and decrease the risk of hip fracture, and does not increase the risk of breast cancer.[1]

The increased risk of stroke in the estrogen-alone study is similar to what was found in the WHI study of estrogen plus progestin when that trial was stopped in July 2002 after 5.6 years of follow-up.[2] **(See "Hormone replacement therapy: Review choices in light of new data," *Contraceptive Technology Update*, September 2002, p. 97.)** In that study, women taking estrogen plus progestin had eight more strokes per year per 10,000 women than those taking the placebo.[2] The estrogen plus progestin trial was stopped due to an increased risk of breast cancer and because the risk of breast cancer, coronary heart disease, stroke, and blood clots outweighed the beneficial effects on hip fracture and colorectal cancer.

Until the results of the newly suspended trial are analyzed, providers should look to guidance issued by the Food and Drug Administration (FDA) when it comes to use of hormone therapy:

- Discuss the benefits and risks of using estrogen or estrogen with progestin with postmenopausal women who are using or are considering use of hormone therapy.
- Hormone therapy products are approved therapies for relief from moderate to severe hot flashes and symptoms of vulvar and vaginal atrophy. Although hormone therapy is effective for the prevention of postmenopausal osteoporosis, therapy should be considered only for women at significant risk of osteoporosis who cannot take nonestrogen medications.

## EXECUTIVE SUMMARY

The estrogen-only trial of the Women's Health Initiative was suspended in February when scientists determined the therapy did not appear to affect heart disease, the major question being evaluated in the study.

- According to the initial data, estrogen-alone therapy appears to increase the risk of stroke, to decrease the risk of hip fracture, and does not increase the risk of breast cancer.
- Continue to prescribe hormone therapy products for relief from moderate to severe hot flashes and symptoms of vulvar and vaginal atrophy. Although hormone therapy is effective for the prevention of postmenopausal osteoporosis, it should be considered only for women at significant risk of osteoporosis who cannot take non-estrogen medications.

• The FDA recommends that estrogens and progestins should be used at the lowest doses for the shortest duration needed to achieve treatment goals.[1] **(See story on the FDA's revised labeling of estrogen and estrogen plus progestin therapies in "Hormone therapy: Make decisions on a balanced risk-to-benefit basis," *CTU*, April 2003, p. 37.)**

### Treat the symptoms

While professional societies await publication of the detailed analysis of the estrogen-only arm, they advise members to stay the course with previously issued direction on use of hormone therapy.

The Cincinnati-based North American Menopause Society stands by its September 2003 position statement on estrogen and progestin use in peri- and postmenopausal women. **(See resource box on p. 55 to access the document.)** The society will issue further recommendations after the full WHI report is published.[3] The Washington, DC-based American College of Obstetricians and Gynecologists also stands by its previous recommendations; it refers members to information issued on following the WHI announcement of July 2002. **(See resource box on p. 55 to access the information.)**

"It is important to remember that this is one piece of the puzzle, and the fact remains, from my viewpoint, is that the estrogen data actually should be reassuring because they suggest that estrogen alone has fewer side effects and adverse events associated with it than estrogen and progestin," says **Robert Rebar**, MD, executive director of the Birmingham, AL-based American Society for Reproductive Medicine.

Explain to women that the estrogen-only arm of the study was not halted because of unexpected adverse outcomes, says Rebar; rather, it was felt that sufficient information had been gathered.

"These [new] results underscore that the appropriate use of hormone therapy is for the treatment of menopausal symptoms," says **Susan Wysocki**, RNC, NP, president and chief executive officer of the Washington, DC-based National Association of Nurse Practitioners in Women's Health. "Based on the results of this trial, there is no reason to stop therapy if a woman is being treated for symptoms."

### What is next?

According to Rebar, the new WHI findings will cause people to rethink how estrogen should be administered. Questions will arise about the route of administration, whether it should it be used with intermittent progestin, and if so, how frequently and with which progestin, Rebar observes. **(See the resource box on p. 55 for a selection of Internet information on hormone therapy.)**

The new WHI findings strengthen the perspective that the elevated risk of breast cancer associated with combination hormone therapy appears to result from the progestin, not the estrogen component, comments **Andrew Kaunitz**, MD, professor and assistant chair in the obstetrics and gynecology department at the University of Florida Health Science Center/Jacksonville. This represents good news for post-hysterectomy women contemplating use of estrogen due to bothersome vasomotor symptoms, Kaunitz notes.

For postmenopausal women with an intact uterus, the new WHI information suggests that clinicians should look for ways to minimize progestin use in women receiving estrogen, he asserts. One way to accomplish this is with use of the progestin-releasing intrauterine system (IUS) (Mirena IUS, Berlex Laboratories, Montville, NJ). The systemic estrogen is used for symptoms, while local progestin is delivered for endometrial protection.

"I am already using this approach in a small number of patients in my practice," says Kaunitz. "I am hopeful that smaller, menopause size progestin-releasing IUSs will be developed to facilitate use in this clinical setting."

Women with osteoporosis who once looked to

## RESOURCES

- **The Women's Health Initiative web site, operated by the National Heart, Lung, and Blood Institute**, offers a question-and-answer section about the suspension of the estrogen-only arm, as well as a physicians' advisory about the halted study. To review these and other items, visit www.nhlbi.nih.gov/whi.
- **To review the September 2003 position statement on estrogen and progestogen use in peri- and postmenopausal women issued by the North American Menopause Society**, go to the organization's web site, www.menopause.org. Click on "NAMS Position Statement about hormone therapy" to access the document. The web site also offers several resources on menopause treatments.
- **To review recommendations issued by the Washington, DC-based American College of Obstetricians and Gynecologists (ACOG)**, go to the organization's web site, www.acog.org. Click on the news release, "ACOG Statement on the NIH Announcement to Halt Estrogen-Only Arm of the WHI Study," then click on "Questions and Answers" at the end of the press release.
- **The Washington, DC-based Association of Reproductive Health Professionals** has developed a web-based Hormone Therapy Resource Center (www.arhp.org/hormonetherapy/). The site is designed for health care providers and the general public and is updated daily to include the latest news and research on hormone therapy.

estrogen therapy for its bone-strengthening properties will take heart in results from a new study that indicates uses of alendronate (Fosamax, Merck Research Laboratories) enabled postmenopausal women to maintain or increase their bone density through 10 years of treatment with no apparent ill effects. The improved bone density persisted even after the drug was stopped and diminished only gradually.[4]

The new study, the longest clinical trial ever conducted in osteoporosis, found that daily alendronate for 10 years produced increases in bone mineral density at the spine, trochanter, and femoral neck. Safety data, including fractures and stature, did not suggest that prolonged treatment resulted in any loss of benefit.[4]

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# Reach African-Americans with prevention message

*They make up more than half of AIDS cases*

While African-Americans account for just 12% of the U.S. population, the impact of the AIDS epidemic has taken a disproportionate toll on them. More than half of all AIDS cases in 2002 in the United States were among African-Americans, according to the Atlanta-based Centers for Disease Control and Prevention (CDC).

"HIV testing and treatment are particularly challenging for African-Americans, as they are generally less likely to have access to health care in general," says **Hazel Dean**, ScD, MPH, associate director for health disparities in the CDC's National Center for HIV, STD, and TB Prevention. "In addition, they are more likely to test late for HIV, when treatments may not be as effective."

African-American men represented 41% of HIV cases reported among men in 2001.The leading cause of HIV infection among African-American men is sexual contact with other men, according to data reported to the CDC through 2002.[1]

Public health officials are troubled by a recent HIV outbreak among black male college students in North Carolina.[2] In interviewing the men, researchers found that in the year prior to their diagnoses, 4% said they had sex only with women; 58% said that they had sex only with men; and 33% said that they had sex with men and women.[3] Such findings may point to men who "live on the down low," those who describe themselves as heterosexual and have same-sex

## EXECUTIVE SUMMARY

More than half of all AIDS cases in 2002 in the United States were among African-Americans, according to the Centers for Disease Control and Prevention (CDC).

- African-American men represented 41% of HIV cases reported among men in 2001.The leading cause of HIV infection among African-American men is sexual contact with other men, according to data reported to the CDC through 2002.
- Plan now to participate in the 2005 observance of National Black HIV/AIDS Awareness and Information Day. The national mobilization effort is designed to encourage African-Americans across the United States and territorial areas to get educated, get tested, and get involved with HIV/AIDS prevention.

partners, but do not disclose that information to their heterosexual partners.[4]

### Communities reach out

African-Americans are banding together to address the AIDS crisis in the form of National Black HIV/AIDS Awareness and Information Day (NBHAAD). The annual event, which held its fourth observance on Feb. 7, 2004, was co-founded by five national organizations: Concerned Black Men of Philadelphia, Jackson (MS) State University — Mississippi Urban Research Center, the Washington, DC-based National Black Alcoholism and Addictions Council, and the National Black Leadership Commission on AIDS and the Health Watch Information and Promotion Service, both based in New York City. These five groups are collectively referred to as the Community Capacity Building Coalition, The coalition is funded by the CDC through the National Minority AIDS Initiative.

The national mobilization effort is designed to encourage African-Americans across the United States and territorial areas to get educated, get tested, and get involved with HIV/AIDS prevention. While NBHAAD is a nationwide movement, organizers focused 2004's efforts in 16 metropolitan areas with high African-American HIV/AIDS prevalence: Atlanta; Baltimore; Chicago; Cleveland; Dallas; Detroit; Houston; Los Angeles; Miami; New Orleans; New York; Oakland, CA; Philadelphia; Raleigh-Durham, NC; Trenton, NJ; and Washington, DC.

While national organizers still are tallying the results from the 2004 event, more locales came on board to spread the prevention message, says **LaMont Evans**, executive director of Concerned Black Men of Philadelphia. More than 200 locales registered an event or activity in the 2004 observance, he reports.

"More churches and health departments were involved this year as opposed to last year," says Evans. "We had a variety of spokespersons come on board this year who provided public service announcements, which are on the web site, www.blackaidsday.org."

The event web site allowed individuals to plan events or activities for their locale, as well as to register their events on-line, explains Evans. **[To check out the available support materials, including a CDC-prepared HIV/AIDS fact sheet, go to the web site; click on "NBHAAD Information," then "NBHAAD Toolkit." The CDC fact sheet also is available at the *Contraceptive Technology Update* web site, www.contraceptiveupdate.com. Click on "toolbox." Your user name is your subscriber number from your mailing label. Your password is ctu (lowercase) plus your subscriber number (no spaces).** ]

Event organizers used several innovative ways to reach into communities with the prevention/testing message, says Evans. Orlando organizers collected 1,100 pair of shoes to represent the current HIV infections in their county, while Philadelphia and Los Angeles organizers conducted marches and rallies. Washington, DC, held a health fair in a municipal building on payday for city employees. Other events included free HIV/AIDS testing sites, prayer breakfasts, town hall meetings, and memorial services.

### What can you do?

Testing and prevention are the keys to curtailing the HIV crisis among African-Americans, says Dean. The CDC is partnering with communities to bring new rapid HIV testing to places where African-Americans live, work, and congregate, such as churches and community centers, she notes.

"We have already purchased 250,000 tests with 250,000 more to come, and have conducted 20 regional rapid HIV testing training sessions for health departments and community-based organizations that plan to conduct rapid HIV testing," Dean reports.

How can you participate in HB HAAD 2005?

"The Community Capacity Building Coalition is in the process of developing strategies and ways to providers to be better engaged for National Black HIV/AIDS Awareness and Information Day 2005," Evans offers. "Stay tuned to the web site for more information."

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ASK THE EXPERTS

# Answering questions on emergency contraception

What is your approach when it comes to repeat doses of the levonorgestrel-only emergency contraceptive pill (ECP), Plan B (Women's Capital Corp., Washington, DC)? Comments on this question are offered by the following *Contraceptive Technology Update* Editorial Advisory Board members: **Robert Hatcher**, MD, MPH, professor of gynecology and obstetrics at Emory University School of Medicine in Atlanta and senior author of *Contraceptive Technology*; **Michael Rosenberg**, MD, MPH, clinical professor of obstetrics and gynecology and adjunct professor of epidemiology at the University of North Carolina at Chapel Hill and president of Health Decisions, a private research firm specializing in reproductive health; **James Trussell**, PhD, professor of economics and public affairs and director of the Office of Population Research at Princeton University; and **Susan Wysocki**, RNC, NP, president and chief executive officer of the Washington, DC-based National Association of Nurse Practitioners in Women's Health.

**Question:** A woman received Plan B for unprotected coitus that occurred within the prior 72 hours. She returned the following day requesting it again as she had another act of unprotected coitus. The provider did not give Plan B again, thinking that the woman still had protection. The provider now is asking how long a woman would have protection. Should she have given Plan B a second time within 24 hours?

**Hatcher:** There is no harm in giving her a second dose of Plan B (two tablets at once) on the second day. This case reminds us of two important truths about using Plan B:

1. There is almost no woman wanting treatment with Plan B who should be turned down. If she asks for it, give her Plan B. *(Editor's note: The labeling for Plan B lists only three prescribing precautions: pregnancy, hypersensitivity to any component of the product, and undiagnosed abnormal bleeding.)*[1]

2. As soon as a woman takes Plan B, she must use contraception for the rest of that cycle and thereafter.

**Rosenberg:** This is an emerging area of practice, and this situation has not been studied. However, it seems prudent in this circumstance to go ahead and provide another dose of Plan B. Many physicians now are providing the two pills at the same time, and under that scenario, a second dose of two pills would be given after the second act of unprotected coitus.

**Trussell:** We get asked this question frequently at the Emergency Contraception web site (www.not-2-late.com), but unfortunately, there are no data to provide an answer.

Biologically, it would make sense that ECPs taken five minutes before unprotected intercourse would be just as effective as ECPs taken five minutes after intercourse. But it is not possible to know to pick the time X such that if intercourse occurs more than X hours after ECPs are taken, then the regimen should be repeated. That is the reason why many protocols simply state that ECPs do not protect against pregnancy from intercourse subsequent to treatment.

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# Family planning waivers work, research shows

By **Rachel Benson Gold**
Director for Policy Analysis
The Alan Guttmacher Institute
Washington, DC

Over the past decade, 18 states have obtained federal approval to extend eligibility for Medicaid-covered family planning services to individuals who would otherwise not be eligible. In 2001, these programs served 1.7 million clients, with 1.3 million served in California alone. The first national evaluation of these efforts — commissioned by the Centers for Medicare & Medicaid Services (CMS) in Baltimore — found that every one of the programs studied not only met the requirement that they not result in additional costs to the federal government, but actually saved money.[1]

Although saving public funds while expanding government services is laudable at any time, doing so is particularly significant at a time when states are in financial crisis and resorting to painful cuts to their Medicaid programs.

In general, states have taken one of three approaches to their programs, which technically require a federal waiver of specific provisions of the Medicaid statute. By law, states are required to cover pregnancy-related care, including family planning, for 60 days postpartum for women with incomes up to 133% of the federal poverty level ($15,670 for a family of three in 2004), which is far above states' regular Medicaid eligibility ceilings. Six states — Arizona, Florida, Maryland, Missouri, Rhode Island, and Virginia — extend the postpartum period for family planning services for one to five years. Two additional states, Delaware and Illinois, extend family planning coverage to women who leave Medicaid for any reason.

Ten other states (Alabama, Arkansas, California, Mississippi, New Mexico, New York, Oregon, South Carolina, Washington, and Wisconsin) take a far bolder approach by granting Medicaid coverage for family planning solely on the basis of income to women not previously covered under Medicaid at all. Most of these programs cover women in the state with incomes up to 185% or 200% of the federal poverty line. (Four programs — California, New York, Oregon, and Washington — also cover men.)

## *Programs meet the mark*

The CMS study was conducted by the CNA Corp. in Alexandria, VA, along with researchers from the Atlanta-based Emory University and the University of Alabama at Birmingham. It first looked at six state waiver programs (in Alabama, Arkansas, California, New Mexico, Oregon, and South Carolina) to determine whether they met the federal requirement for budget neutrality — that is, that federal spending under the waiver not exceed what federal spending would have been without the waiver.

Using what they deemed to be the most appropriate method for calculating budget neutrality, the researchers found that all six programs resulted in often substantial net savings. For example, the South Carolina program realized total savings of $56 million over a three-year period starting in 1994, while Oregon's program saw savings of nearly $20 million in a single year. These savings were split between the federal and state governments, based on a formula established by CMS for calculating the federal share of Medicaid costs.

In addition, the CMS study found that even as they saved money, the waivers increased access to services. In four of the six states (Alabama, Arkansas, California, and Oregon), the number of clients served in clinics receiving funds through

## *COMING IN FUTURE MONTHS*

- Does abstinence education lower pregnancy risk?
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the Title X program who met the eligibility requirements for the waiver grew after the program was implemented. Geographic availability of services increased in all states, and two states (California and Oregon) demonstrated significant use of private-sector as well as family planning clinic–based services. Finally, the study found evidence in two states (Florida and South Carolina) of a measurable reduction in unintended pregnancy among the total population of women eligible for the waiver — a very high bar for the program to clear, according to the researchers.

### *Lessons to be learned*

The study findings have important implications for federal and state policy-makers and for reproductive health advocates. At the federal level, the study shows that the family planning waivers may well have demonstrated what they were designed to test. Also, it shows that it may be time to give states the authority to expand Medicaid family planning eligibility on their own, without having to go through the process of obtaining a federal waiver — widely acknowledged to be cumbersome at best and prohibitive at worst. Three measures to do just that are pending in the Senate.

The findings have significant relevance for policy-makers at the state level as well. At a time when the states are feeling compelled to make difficult choices about their Medicaid programs, an effort that can reduce costs while actually improving access to care for enrollees may be particularly attractive.

Finally, the study provides important corroborative evidence for a long-standing assertion of reproductive health advocates: that providing additional resources for high-quality family planning services is a wise policy choice, especially in difficult economic times, because it expands access to a service people want and need to improve their own health and well-being *and* saves taxpayers money. In that way, the study could provide important new impetus for advocates and policy-makers at the federal and state levels to find some much-needed common ground.

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## August is date for minority women's summit

Circle Aug. 12-15, 2004, on the calendar for the Minority Women's Health Summit sponsored by the Office of Public Health and Science, Office on Women's Health. The summit, "Women of Color, Taking Action for a Healthier Life: Progress, Partnerships and Possibilities," will build upon the first national conference, "Bridging the Gap: Enhancing Partnerships to Improve Minority Women's Health," held in 1997.

The summit in Washington, DC, will highlight key women's health issues, including cardiovascular disease, cancer, diabetes, and HIV/AIDS. Summit objectives include promoting strategies to diversify leadership in health sciences, education, research, and policy; fostering community partnerships to identify and implement best practices that target prevention, diagnosis, and treatment of diseases that disproportionately affect women of color; and recommending action-oriented strategies to increase positive health outcomes for women of color across the lifespan.

At press time, registration information and packages were scheduled to be available in April 2004. For more information, visit the conference web site at www.4woman.gov/mwhs, telephone summit organizers at (800) 994-9662, fax your request to (202) 690-7172, or correspond via Office on Women's Health, U.S. Department of Health and Human Services, 200 Independence Ave. S.W., Room 718F, Washington, DC 20201. ■

### 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 June 2004 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. ■

# CE/CME Questions

[For details on *Contraceptive Technology Update*'s continuing education program, contact: Customer Service, Thomson American Health Consultants, P.O. Box 740056, Atlanta, GA 30374. Telephone: (800) 688-2421. Fax: (800) 284-3291. E-mail: customerservice@ahcpub.com. Web: www.ahcpub.com.]

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** "**Egg regeneration study opens fertility window" and "Reach African-Americans with prevention message."**)
- Describe how those issues affect service delivery and note the benefits or problems created in patient care in the participant's practice area.
- Cite practical solutions to problems and integrate information into daily practices, according to advice from nationally recognized family planning experts. (**See** "**As more women choose the patch, keep an eye out for counterfeits" and "Estrogen arm of WHI suspended; what next?")**

17. According to the Food and Drug Administration (FDA), what should consumers look for when ordering prescription drugs from an Internet pharmacy site?

A. Verified Internet Pharmacy Practice Sites (VIPPS) seal
B. Good Housekeeping Seal
C. VeriSignSecure Site Seal
D. Hallmark of Authenticity

18. If just-published research (Johnson J, et al. *Nature* 2004) is proven true, what new therapies might potentially be developed?

A. Cloning of human cells
B. Regeneration of human organs
C. Triggering of multiple births
D. Transplantation of ovarian stem cells for infertility

19. According to the FDA, hormone therapy products are approved therapies for relief from moderate to severe hot flashes and (choose one of the following answers):

A. Prevention of coronary heart disease
B. Symptoms of vulvar and vaginal atrophy
C. Early signs of dementia
D. Prevention of colorectal cancer

20. According to the Centers for Disease Control and Prevention, what is the leading cause of HIV infection among African-American men?

A. Sexual contact with women
B. Intravenous drug use
C. Sexual contact with other men
D. Blood transfusion

**Answers:** 17. A 18. D 19. B 20. 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™

# Youth are at risk for sexually transmitted diseases: What can providers do to stem the tide?

*Almost 50% of new cases are under 25 years old*

Your next patient is 19, sexually active, and says her boyfriend infrequently uses condoms because she takes an oral contraceptive and is protected against pregnancy. What information should you share with her about protection against sexually transmitted diseases (STDs)?

The facts contained in just-published research may give her pause.[1] The new findings indicate that of approximately 18.9 million new cases of STD that occurred in 2000, 9.1 million (48%) were among persons ages 15-24.[1] Three STDs [human papillomavirus (HPV), trichomoniasis, and chlamydia] accounted for 88% of all new cases of STD among 15- to 24-year-olds.


## EXECUTIVE SUMMARY

New data underscore the prevalence of sexually transmitted diseases (STDs) in American teens: Approximately 18.9 million new cases of STD occurred in 2000, of which 9.1 million (48%) were among persons ages 15-24.

- Three STDs (human papillomavirus, trichomoniasis, and chlamydia) accounted for 88% of all new cases of STD among 15- to 24-year-olds.
- Better tests, routine screening programs, and new therapies have allowed more STDs to be detected and treated. However, the total estimated burden of the new cases among 15- to 24-year-olds in 2000 adds up to $6.5 billion.


"While 15- to 24-year-olds represent 25% of the sexually experienced population, in 2000 they accounted for almost half of the estimated new cases of STDs," says **Hillard Weinstock**, MD, an epidemiologist with the Atlanta-based Centers for Disease Control and Prevention (CDC) and lead author of the new research. "These data confirm what we've known for some time: that the burden of STDs is on younger people."

Better tests, routine screening programs, and new therapies have allowed more STDs to be detected and treated. However, STDs are taking a heavy toll on young adults; according to a second report, the total estimated burden of the 9.1 million new cases of STDs that occurred among 15- to 24-year-olds in 2000 add up to $6.5 billion.[2]

Providers need to be concerned when it comes to care of young adults: Those who are sexually active may have multiple sex partners, may be more likely to engage in unprotected intercourse; and younger individuals may be more vulnerable biologically to some STDs, says Weinstock.

"This study highlights the vulnerability of America's youth to STDs and the need for greater emphasis on STD prevention efforts," states Weinstock.

### Young adults need info

One reason the rates of STDs are so high in youth is that society does not do a very good job

of communicating about the risks and where to get help, says **Joan Cates**, MPH, a doctoral student in the School of Journalism and Mass Communication at the University of North Carolina at Chapel Hill. Shame and fear make the situation worse, she maintains.

Cates is principal investigator for the "Our Voices, Our Lives, Our Futures: Youth and STDs," a project aimed at providing clarity and consensus about the scope and impact of STDs in U.S. adolescents and young adults. Funded by the William T. Grant Foundation in New York City, the project is using qualitative and quantitative research methods to raise public awareness about the problem.

To assess the magnitude, economic impact, and psychosocial burden of STDs in youth, the project convened two panels: one comprised of experts in public health, behavioral science, medicine, economics, and communication; and another formed of young people, all recruited through Advocates for Youth, a nonprofit public health organization based in Washington, DC. The two panels worked together to define challenges and recommend solutions for preventing STDs among young Americans. Their findings have just been published in report form.[3] (Review the publication on-line. Go to www. jomc.unc. edu/youthandSTDs/ourvoices.html and click on the publication's title, Our Voices, Our Lives, Our Futures: Youth and Sexually Transmitted Diseases.)

> ***"These data confirm what we've known for some time: that the burden of STDs is on younger people."***

"Our research showed that parents need to be more open about sexual health with their children as they grow up, potentially romantic partners need to discuss risk and protection, and health care providers need to include routine and confidential sexual health assessments with their young patients," says Cates.

Several national prevention organizations support educating youth to reduce the risk of STDs by delaying sexual intercourse, using condoms if sexually active, and seeking diagnosis and treatment for infection. Education programs need to include messages about sexual health in addition to warnings about disease, the *Our Voices* report states).[3]

If young adults do decide to delay sexual intercourse, they still are in need of information when it comes to STD protection, according to new research.[4]

Teens who pledge to remain virgins until marriage have the same rates of sexually transmitted diseases as those who don't pledge abstinence, according to a study that examined the sex lives of 12,000 adolescents.[5] Pledgers are less likely to know that they have an STD than nonpledgers, even though they are not less likely to have one, researchers found. Just saying "no" without understanding STD risk or how to protect oneself from risk turned out to create greater risk and higher STD acquisition than should be the case, the researchers state.[5]

## Check your approach

What can you do to help stem the rising STD tide in young adults? The *Our Voices* report offers the following suggestions for health care providers:

- Make sure each patient understands that all conversations ideally are private. Explain under what conditions you cannot maintain confidentiality.
- Screen youth for STDs regularly and consistently.
- Screen men and women.
- Don't assume that youth are comfortable telling you the whole story immediately. Work to gain their trust.
- Speak privately with youth. Explain to parents why this is important.
- Work with parents to reinforce health education and strengthen your relationship with the patient.[3] **(Also see "Key Messages on STD and Reproduction" on p. 2.)**

What is your advice when it comes to condom use? For people whose sexual behaviors place them at risk for STDs, correct and consistent use of a male latex condom can reduce the risk. When used correctly and consistently, latex condoms can aid in preventing sexual transmission of HIV and can reduce the risk of chlamydia, gonorrhea, genital herpes, syphilis, and trichomoniasis.

While the effectiveness of condoms in preventing HPV is unknown, condom use has been associated with a lower rate of cervical cancer, an

## Key Messages on STDs and Reproduction

- ❑ Sexually transmitted diseases (STDs) can affect the full cycle of reproductive health.
- ❑ Birth control pills do not prevent STDs. To prevent infection, use condoms in addition to another method of contraception.
- ❑ If left untreated, some STDs can lead to permanent infertility.
- ❑ Some STDs can be passed from a pregnant woman to her fetus or baby.
- ❑ If detected, STDs can be treated during pregnancy to help protect the baby.

*Source:* Cates JR, Herndon NL, Schulz SL, et al. *Our Voices, Our Lives, Our Futures: Youth and Sexually Transmitted Diseases*. Chapel Hill, NC: School of Journalism and Mass Communication, University of North Carolina at Chapel Hill; 2004.

HPV-associated disease.[6]

For tips on correct condom use, a free handout, "The Do's and Don'ts of Condom Use," is available from the Research Triangle Park, NC-based American Social Health Association (ASHA). **[To access the handout, go to at the *Contraceptive Technology Update* web site, www.contraceptiveupdate.com. Click on "toolbox." Your user name is your subscriber number from your mailing label. Your password is ctu (lowercase) plus your subscriber number (no spaces).]**

Explain to patients that the condom should be placed on an erect (hard) penis before there is any contact with a partner's genitals, according to the ASHA information. Use plenty of water-based lubricant with latex condoms to reduce friction and help prevent the condom from tearing. Squeeze the air out of the tip of the condom when rolling it over the erect penis to provide room for the semen. When preparing to remove the penis after sex, hold the condom in place at the base of the penis.

Most youth do not use condoms every time they have sex, and most have not been taught the correct way to use a condom, according to the *Our Voices* report. Take time in demonstrating correct condom use when discussing condoms with young adult patients.

### *References*


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# Teen STD information is available on the web

Check the following web sites to get teen-friendly information to share with your adolescent patients:

**1. American Social Health Organization's I Wanna Know. Web: www.iwannaknow.org.**

This comprehensive teen sexual health web site, operated by the Research Triangle Park, NC-based American Social Health Organization, offers fingertip access to dynamic and reliable sexual health information for teens and their parents. Teens can search for answers by looking through a list of frequently asked questions, drawn from

queries repeatedly asked during chat sessions held on the site Mondays, Thursdays, and Fridays from 5-7 p.m. Eastern Time or from web site e-mail. Of current interest is a list of questions for teens to ask tattoo artists and body piercers, whose potential use of unsterilized, unclean needles may lead to spread of hepatitis B or C.

**2. Kaiser Family Foundation's Youth and HIV/STDs. Web: www.kff.org.**

The Menlo Park, CA-based Henry J. Kaiser Family Foundation web site offers a number of resources on adolescents and STDs. Click on "Youth & HIV/STDs" under "Topics" on the site's main page. The site offers results from the Foundation's *National Survey of Teens on HIV/AIDS 2000*, a nationally representative survey of ages 12-17, designed to assess attitudes and knowledge about the epidemic among a generation at risk.

Of interest is *Get Informed… Get the Facts*, a publication aimed at those at risk for HIV/STDs. The publication offers a section on "Should I Get Tested?" which answers questions on testing intervals.

**3. Planned Parenthood Federation of America's Teenwire. Web: www.teenwire.com.**

Current information on STD and pregnancy prevention is presented in a teen-friendly manner on this web site, operated by the New York City-based Planned Parenthood Federation of America. It offers an archive of answers to such questions as "Can you get STIs (sexually transmitted infections) from kissing?" and "Can you get crabs by having sex?"

**4. MEDLINEplus Health Information. Web: www.nlm.nih.gov/medlineplus/teenhealth.html.**

Choose from a number of resources listed in the Teen Sexual Health section of MEDLINEplus, which offers free health information from the world's largest medical library, the Bethesda-based National Library of Medicine. This site offers links to the latest adolescent health news, as well as information on nutrition, prevention and screening, research, specific conditions, and teen health organizations.

**5. Scarleteen. Web: www.scarleteen.com.**

Scarleteen, owned by Heather Corinna, a Minneapolis-based writer and educator, provides up-to-date information on sexuality and reproductive health for teens, young adults, parents, and educators. Billed as "sex education for the real world," the site's "Infection Section" covers common STDs and offers a quick risk assessment for such infections.

**6. Coalition for Positive Sexuality. Web: www.positive.org.**

The Washington, DC-based Coalition for Positive Sexuality, a grass-roots organization formed to provide candid sex education materials, maintains this site with information that it terms is "pro-safe sex, pro-teen, pro-choice, pro-queer, and pro-woman." It features "Just Say Yes," a guide that offers answers to many sexual health questions, such as "What if I get a disease?" ▼

# Set the date for HIV prevention conference

Plan now to attend the HIV Prevention Leadership Summit, scheduled for June 16-19, 2004, at the Georgia World Congress Center in Atlanta.

Formerly known as the Community Planning Leadership Summit for HIV Prevention, the annual event brings together health department staff, community co-chairs, and community planning leaders to discuss HIV prevention strategies. The 2004 summit, "Retooling to Maximize the Power of Prevention," will offer 70 workshops, as well as roundtables and other sessions, all designed for staff of health department HIV prevention programs, capacity building assistance providers, and community-based organizations providing HIV prevention services funded by the Centers for Disease Control and Prevention (CDC), community co-chairs and community planning leaders, and other federal and national partner agencies involved in HIV prevention and care.

Sponsors of the event include the CDC, the Academy for Educational Development, the National Alliance of State and Territorial AIDS Directors, the National Association of People with AIDS, and the National Minority AIDS Council, all based in Washington, DC. Registration prior to May 14 is $225; after May 14, the fee is $250. Register on-line at the National Minority AIDS Council web site, www.nmac.org; click on "Conferences," "HPLS 2004," and "Registration." ■