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FDA panel recommends approval of new emergency contraceptive pill

Ulipristal acetate pill already available in 22 European countries

American women might have another option in emergency contraception (EC) if the Food and Drug Administration (FDA) follows the recommendation of its reproductive health panel in approving ulipristal acetate (UPA). Members of the FDA's Advisory Committee for Reproductive Health Drugs voted 11 to 0 during a June 2010 meeting that the material presented by prospective manufacturer HRA Pharma of Paris, France, indicates the drug is effective and safe for use as an emergency contraceptive.

The drug, marketed overseas as ellaOne, was approved in May 2009 by the European Commission for use as an emergency contraceptive within 120 hours of unprotected sexual intercourse or contraceptive failure. Launched overseas in October 2009, the drug is now marketed in 22 European countries. If approved, the drug will be sold in the United States as ella by Watson Pharmaceuticals of Corona, CA. Watson entered into a licensing agreement with HRA Pharma to market the prospective

EXECUTIVE SUMMARY

American women might have another option in emergency contraception (EC). The reproductive health panel of the Food and Drug Administration (FDA) has recommended approval of ulipristal acetate, developed by HRA Pharma. If approved by the federal agency, the drug will be sold in the United States as ella by Watson Pharmaceuticals.

- While the committee's vote might be considered by the federal agency, the FDA is not bound to follow its recommendation.
- If approved, ella would represent the first selective progesterone receptor modulator available in the United States for the indication of EC. It also would be the first EC drug product indicated for use up to 120 hours after unprotected intercourse.

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emergency contraceptive.

If approved, ella would represent the first selective progesterone receptor modulator available in the United States for the indication of EC. It also would be the first EC drug product indicated for use up to 120 hours after unprotected intercourse. Both Plan B One-Step (Teva Women's Health, Woodcliff Lake, NJ) and Next Choice (Watson Pharmaceuticals) are indicated to be taken as soon as possible within 72 hours after unprotected intercourse.

While the committee's vote might be considered by the federal agency, the FDA is not bound to follow its recommendation. Family planning advocates may recall that in December 2003, a similar advisory committee recommended approval to move the emergency contraceptive Plan B to over-the-counter status. Final agency approval did not come forth until August 2006. HRA Pharma is not requesting non-prescription access to ella.

There are about 3 million unintended pregnancies each year in the United States, states **Kirsten Moore**, and chief executive officer of the Reproductive Health Technologies Project, a Washington, DC-based advocacy organization. Despite the many highly effective birth control options women now have to choose from, none are 100% perfect, she notes. "Sometimes, a woman needs a backup birth control method. A condom breaks. A diaphragm slips. A woman forgets to take her pill," states Moore. "There also are cases when sex is unplanned or, unfortunately, unwanted. Every woman's circumstances are different. Ella gives a woman another emergency contraceptive option to prevent unintended pregnancy."

Data indicates efficacy

The 2010 committee's vote followed a review of data from the ulipristal acetate preclinical and clinical development program. The data included the experiences of more than 4,000 women from the United States and Europe, representing the largest development program ever conducted in the emergency contraceptive field, according to HRA Pharma.

In a statement following the committee's vote, **Vanessa Cullins,** MD, vice president for medical affairs at the New York City-based Planned Parenthood Federation of America (PPFA), said, "Ella, or UPA, is safe and effective at preventing ovulation and, therefore, pregnancy in the five days after unprotected intercourse. Given the fact that half of all pregnancies in the U.S. are unintended, it is vital that women have an array of choices available to prevent unplanned pregnancy."[1]

The committee reviewed data from two Phase 3 trials. One investigation was an open-label trial conducted in the United States. Its primary objec-

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tive was to evaluate the efficacy of a single 30 mg dose of ulipristal for EC when used between 48 to 120 hours after unprotected intercourse.[2] The other study was a randomized, single-blind trial conducted in the United States and Europe. Its primary objective evaluated the efficacy of a single 30 mg dose of ulipristal for EC, taken 0-72 hours after unprotected intercourse, compared to that of a single dose of 1.5 mg of levonorgestrel.[3]

Findings from both studies demonstrate that treatment with ulipristal acetate administered within 120 hours after unprotected intercourse is effective. Adverse events reported by at least 5% of women in the two clinical trials were headache, nausea, dysmenorrhea, abdominal pain, fatigue, and dizziness, similar to those experienced by women who use levonorgestrel EC.

How does it work?

According to background documentation filed by HRA Pharma prior to the FDA committee meeting, ulipristal acetate appears to inhibit or delay ovulation, depending on the time of administration in the follicular phase. Administration of ulipristal in the luteal phase also alters the endometrium.[4]

"Based on the findings of the pharmacodynamic studies, ulipristal appears to exert an anti-progesterone contraceptive effect on both the ovary and endometrium, depending on the dose and time of drug administration during the menstrual cycle," the documentation states. "The Summary of Product Characteristics (the basis for European labeling) currently states that 'the primary mechanism of action is thought to be inhibition or delay of ovulation, but alterations to the endometrium may also contribute to the efficacy of the product.'"[4]

It is important to point out that ulipristal acetate suppresses LH (luteinizing hormone) surge after it starts, whereas levonorgestrel emergency contraception works up to point of LH rise, says **Anita Nelson**, MD, professor in the Obstetrics and Gynecology Department at the David Geffen School of Medicine at the University of California in Los Angeles.

Advocates seek approval

The vote by the FDA advisory committee that ella is safe and effective as a form of emergency contraception is a common sense recommendation made by scientific experts, said **Cecile Richards,** PPFA president of Planned Parenthood Federation of America.

"There are many reasons why a woman may face the risk of unintended pregnancy — from failure or improper use of birth control, to sexual assault — and every woman deserves every option available to prevent an unplanned pregnancy," Richards stated.

PPFA, along with 19 other reproductive health groups, have submitted a letter to the committee urging approval of the drug. By having two types of safe and effective emergency contraception, the likelihood would increase that a woman can access a product that works for her situation.

Ella meets the FDA standards for drug approval, said Moore in comments before the FDA committee.[5] "We ask the FDA not to fall victim once again to political pressure and subject this safe, effective product to unnecessary restrictions that may limit a woman's access to a time-sensitive method of backup birth control," said Moore.

Robert Hatcher, MD, MPH, professor of gynecology and obstetrics at Emory University School of Medicine in Atlanta, says he is not particularly excited about this new emergency contraceptive pill, even though it is somewhat more effective. The reason? Emergency IUD insertions (E-IUDs) are more effective as emergency contraception and might provide long-term pregnancy protection, Hatcher states. In one study, more than 80% of women receiving a copper IUD for EC continued use of the IUD as their ongoing contraceptive.[6]

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Estradiol valerate, dienogest OC gets nod

Add Natazia, an estradiol valerate/dienogest pill, to the list of oral contraceptives approved by the Food and Drug Administration (FDA) and now available to U.S. women. The drug, marketed by Bayer HealthCare Pharmaceuticals of Wayne, NJ, is now available in pharmacies nationwide and is competitively priced with other branded oral contraceptive products, says **Rose Talarico**, company spokesperson. [*Contraceptive Technology Update* checked drug availability/pricing at four Atlanta pharmacies. Two pharmacies (Walgreens and Target) stocked the drug at $86.99 and $89.99 respectively, while two others (Publix and Kroger) had not yet added the formulation.]

The pill contains estradiol valerate and dienogest, formulated in a 4-phasic regimen. Estradiol valerate is a synthetic estrogen that is converted to estradiol in a woman's body. Dienogest is one of several new progestins such as drospirenone, Nestorone, nomegestrol acetate, and trimegestone that have been synthesized in the last two decades. These new progestins are formulated to have no androgenic or estrogenic actions and to be closer in activity to the physiological hormone progesterone.[1]

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Natazia, an estradiol valerate/dienogest pill, is now available to U.S. women. The drug, marketed by Bayer HealthCare Pharmaceuticals, is now available in pharmacies nationwide.

- The pill is formulated in a 4-phasic regimen. Estradiol valerate is a synthetic estrogen that is converted to estradiol in a woman's body. Dienogest is formulated to have no androgenic or estrogenic actions and to be closer in activity to the physiological hormone progesterone.
- The most common side effects noted in clinical trials include headache; metrorrhagia and irregular menstruation; breast pain, discomfort, or tenderness; nausea or vomiting; acne; and increased weight.

The use of natural estradiol (E2) has been studied.[2] The site of metabolism of estradiol valerate to E2 occurs during absorption, so what the liver "sees" and what appears in her circulation is E2, says **Anita Nelson**, MD, medical director of the women's health care programs at Harbor-UCLA Medical Center in Torrance, CA.

Researchers evaluated the safety and efficacy of Natazia in two multicenter Phase 3 clinical trials in North America and Europe. Results of both trials, which involved 1,867 women, indicate the formulation to be effective as a hormonal contraceptive.

The study conducted in the United States and Canada was a multicenter, open-label, single-arm, unintended pregnancy study. It included 490 women ages 18-35 who were treated for up to 28 cycles of 28 days each. Weight range for treated women was 40 to 100 kg (mean weight: 62.5 kg) and the body mass index (BMI) range was 14-30 kg/m2 (mean BMI: 23.3 kg/m2). Of the treated women, 15% discontinued the study treatment due to an adverse event, 13% were lost to follow up, 10% withdrew their consent, 8% discontinued due to other reason, 1% discontinued due to protocol deviation, and 1% discontinued due to pregnancy.

The study conducted in Europe (Germany, Austria, and Spain) was a multicenter, open-label, single-arm contraceptive reliability study, with a total of 1,377 healthy subjects treated for 20 cycles of 28 days each. The weight range for treated women in the European study was 38-98 kg (mean weight: 63.8 kg) and the BMI range was 15-31.8 kg/m2 (mean BMI: 22.8 kg/m2). Of treated women, 10% discontinued the study treatment due to an adverse event, 5% discontinued due to other reason, 2% were lost to follow up, 2% discontinued due to protocol deviation, 2% withdrew their consent, and 1% discontinued due to pregnancy.[3]

The Pearl Index (PI) was the primary measure for assessing contraceptive reliability; the PI calculation was based on criteria established by FDA (pregnancies that occurred in women age 18-35 years during cycles 1 to 13 including pregnancies seven days post-treatment). In the North American study, five pregnancies occurred over 3,969 exposure cycles (PI = 1.64; failure rate at the end of year one was 0.016). A total of nine pregnancies occurred over 11,275 exposure cycles in the European trial (PI = 1.04; failure rate at the end of year 1 was 0.010).[3]

As with any oral contraceptive, women should be

counseled on potential side effects. The most common treatment-emergent adverse reactions (≥2%) in Natazia's clinical trials were: headache (including migraines) (13.2%); metrorrhagia and irregular menstruation (8.0%); breast pain, discomfort, or tenderness (6.6%); nausea or vomiting (6.5%); acne (3.9%); and increased weight (2.8%).[3]

How to take Natazia's tablets

Natazia's tablets must be taken at the same time every day in the order directed on the blister pack. The daily dose should not be skipped or delayed by more than 12 hours. After taking the last white pill (day 28) of the blister pack, women should be instructed to start taking the first dark yellow pill from a new blister pack the very next day whether or not she is having her period. Be sure to counsel for women to have a back-up method such as condoms or spermicides on hand in case pills are missed. Whether or not a woman is switching from another form of hormonal birth control or a non-hormonal method, she should be counseled to use a non-hormonal back-up method such as condoms or spermicide for the first nine days of initial Natazia use.

Natazia carries the same contraindications as ethinyl estradiol pills. It should not be used in women with a high risk of arterial or venous thrombotic diseases, undiagnosed abnormal genital bleeding, breast cancer or other estrogen- or progestin-sensitive cancer, liver tumors (benign or malignant) or liver disease, or who are pregnant.

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Organizations advocate for adolescent care

National medical organizations have issued positions on adolescent care will impact your practice. Add the following to the next clinical discussion at your facility:

• The Society for Adolescent Health and Medicine has issued a strong recommendation that 9- to 26-year-olds receive vaccination for human papillomavirus (HPV), regardless of gender.[1]

• The American College of Obstetricians and Gynecologists (ACOG) is calling for two "well-child" visits each year — a general preventive visit and a dedicated reproductive health visit — with both visits to be covered by insurers.[2]

Clinicians have two HPV vaccines for use in young women: Gardasil, Merck and Co.'s quadrivalent vaccine, and Cervarix, GlaxoSmithKline's bivalent vaccine. Gardasil also has been approved for the prevention of genital warts (condyloma acuminata) due to HPV types 6 and 11 in boys and men, ages 9-26. *(*When the Advisory Committee on Immunization Practices (ACIP) issued its October 2009 guidance on use of the quadrivalent vaccine in males, it only indicated that the vaccine be given to males ages 9 through 26 years to reduce their likelihood of acquiring genital warts.[3] It did not recommend the quadrivalent vaccine for routine use among males.

There are several reasons why it is important that clinicians advocate the benefits of routine HPV vaccination for girls as well as boys, says **Jessica Kahn**, MD, MPH, assistant chair of academic affairs and faculty development and associate professor of pediatrics in the Division of Adolescent Medicine at Cincinnati Children's Hospital Medical Center. Kahn serves as chairman of the Society for Adolescent Health and Medicine's Vaccination Committee.

First, HPV infection has clinical consequences in males and therefore vaccination might directly benefit males, says Kahn. HPV infection may cause anogenital warts as well as penile, anal, and oropharyngeal cancers in males. Clinical trials have shown that vaccination prevents diseases caused by the HPV types targeted by the vaccine, as long

EXECUTIVE SUMMARY

National medical organizations have issued positions on adolescent care that will impact clinician practice:
• The Society for Adolescent Health and Medicine has issued a strong recommendation that 9- to 26-year-olds receive vaccination for human papillomavirus, regardless of gender.
• The American College of Obstetricians and Gynecologists is calling for two "well-child" visits each year — a general preventive visit and a dedicated reproductive health visit — with both visits to be covered by insurers.

as males are not infected with those HPV types before they are vaccinated, she states.

Second, the sexual partners of men who are vaccinated also might benefit, because they might have less likelihood of acquiring HPV infection from these vaccinated males, notes Kahn. "Vaccination rates among females are relatively low at this point, and vaccination of males may help to decrease overall rates of HPV and HPV-related disease in the population," she observes.

Third, routine vaccination of males, as well as females, is more egalitarian than gender-based vaccination and might increase vaccine acceptability in certain cultures, says Kahn.

Clinicians also need to advocate for insurance coverage of HPV vaccination for males and females, notes Kahn. While ACIP has designated that vaccination of males should be covered under the Vaccines for Children Program, which provides the vaccine free of cost to those through the age of 18 years who are uninsured, have Medicaid, or are underinsured and attend a federally qualified health center or a rural health center, teens who have private insurance might face hurdles in coverage, says Kahn.

"Unfortunately, since allowing the vaccine to be provided via these government programs doesn't guarantee that the private insurance industry will allow the vaccine to be provided to their subscribers, this sets up the possibility that youth who have private health insurance may be denied coverage for HPV vaccine based on the lack of a more definite recommendation for the routine use of the vaccine in males," she notes.

Teens need two visits

Adolescent girls may need two "well-child" visits each year — a general preventive visit and a dedicated reproductive health visit — and both visits should be covered by insurers, according to an updated ACOG committee opinion.

Current Procedural Terminology (CPT) coding is used to bill office medical procedures. Code 99394 is used for a preventive visit of an established patient ages 12–17. Annual gynecologic visits also may be included in this category.[2]

Preventive medicine services provided to asymptomatic patients may be used only once a year by any health care provider, according to the committee opinion. "This is problematic because some healthcare providers offer the full range of care from general preventive care to reproductive health care, but many times no one clinician provides all the recommended care an adolescent needs," the opinion states. "Therefore, `well-child' care may require two visits, a general preventive visit and a dedicated reproductive health visit."

Both visits are critical to a teen's health, and each of these visits should be covered, says **Diane Merritt**, MD, chair of ACOG's Committee on Adolescent Health Care and professor of obstetrics and gynecology at Washington University in St. Louis.

Merritt notes many adolescents may continue to see their pediatrician or family practitioner for care, which includes vaccinations as well as education and counseling on such issues as growth, development, nutrition, obesity, and substance abuse. When a teen comes to see a reproductive health clinician, a visit might cover such topics as puberty, normal menstruation, sexually transmitted diseases and pregnancy prevention, sexual orientation and gender identity, acquaintance rape prevention, substance abuse, and routine gynecologic procedures. Both types of visits are necessary for optimum adolescent health, says Merritt.

Depending on training and experience, gynecologists pediatricians, family medicine physicians, and adolescent medicine specialists may not provide reproductive care and general preventive care to teens. If they do, it might be difficult to provide the full range of general and reproductive care in one office visit.

"In these instances, a team approach is needed in which one physician offers general preventive care and an OB/GYN provides the necessary reproductive preventive health care," says Merritt. "And both annual visits should be covered by insurance to ensure teens are getting comprehensive preventive care."

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Is contraception part of preventive health?

As of September 2010, federal health reform legislation will require all new private health plans to provide coverage of a slate of preventive health services at no cost to patients. Will contraception be included in that coverage? Reproductive health advocates are calling for such measures.

While many health plans already cover prescription contraceptives, women face challenges when it comes to insurance co-payments. Co-payments may be set at up to $50 per month for birth control pills to several hundred dollars for a longer-acting method such as an intrauterine device.[1] Twenty-seven states have laws that require insurers include some level of contraceptive coverage in their plans.[2]

By including contraceptive services under preventive care, the United States could move forward in reaching its goal of decreasing unintended pregnancies to 30% by 2010. Such efforts are needed. Statistics indicate approximately one-half of all pregnancies in the United States were unintended in 2001, the last year for which data is available.[3] Unintended pregnancy is associated with an increased risk of morbidity for women, as well as with health behaviors during pregnancy that are associated with adverse effects. Unintended pregnancies carry a high economic cost as well: The direct medical costs of unintended pregnancies in the United States were estimated at $5 billion in 2002.[4]

For contraception to be included under the new legislation, the Department of Health and Human Services (HHS) requires an official interpretation of the legislation's requirement and of the specific preventive services it requires. The Health Resources and Services Administration (HRSA), which falls under HHS, is contracting with the Institute of Medicine to review supporting data regarding contraceptive services, says **Judy Waxman**, vice president for health and reproductive rights at the National Women's Law Center in Washington, DC.

The institute will take a comprehensive look at the subject, weigh the evidence, and will issue its findings to HRSA, says Waxman. While similar data reviews have taken up to three years, findings may be released to HRSA more rapidly, perhaps in nine months to a year, Waxman states. The accelerated timeline is projected given that the health care reform legislation goes into effect September 2010, says Waxman.

In 2007, the Washington, DC-based National Business Group on Health, a membership group for large private- and public-sector employers, recommended that all employer-sponsored health plans include comprehensive coverage of unintended pregnancy prevention services, free of any cost-sharing, as part of a recommended minimum set of benefits for preventive care.[5] By including the full range of prescription contraceptive methods, sterilization services, lab tests, counseling services, and patient education to a plan that currently includes no coverage at all, estimates indicate costs at about $40 per member per year.

Even putting aside the fact that the $40 annual figure does not account for the likely cost-savings from contraceptive coverage, such a figure is "miniscule" when compared with overall insurance premiums, says Adam Sonfield, Guttmacher Institute senior public policy associate. Annual average premiums are more than $4,800 for an individual employee and nearly $13,400 for a family, according a 2009 study from the Kaiser Family Foundation.[6]

If plans could offer coverage of contraceptive services, counseling, and supplies without cost sharing, several benefits could be achieved, according to a 2010 Guttmacher Institute analysis.[7] These include closing gaps in insurance coverage, reducing the disincentive to seeking care that even modest cost sharing can pose, and enhancing effectiveness of contraceptive use.

"It simply makes eminent sense to ensure that family planning services are comprehensively integrated into preventive care," says Sonfield. "This must include coverage for the full range of contraceptive drugs and devices, related services such as insertion and removal of devices, and counseling and patient education."

EXECUTIVE SUMMARY

As of September 2010, the health reform law will require all new private health plans to provide coverage of a slate of preventive health services at no cost to patients. Will contraception be included?

- While many health plans already cover prescription contraceptives, women face challenges when it comes to insurance co-payments. Co-payments may be set at up to $50 per month for birth control pills to several hundred dollars for a longer-acting method such as an intrauterine device.
- The Institute of Medicine has been contracted to review supporting data regarding contraceptive services so federal officials may make an official interpretation of the law's requirement.

Contraceptive provision qualifies as a preventive service under the current legislation, says Waxman, as it represents a public health issue in terms of women being able to prevent unintended pregnancies for their health and for the health of future children.

"It fits," states Waxman. "It's going through the process it needs to, and we're hopeful" it will be included in preventive coverage.

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Multipurpose methods: New prevention option?

When it comes to unplanned pregnancy and sexually transmitted diseases (STDs), young women, adolescents, and the poor often are the most at risk. However, women from all socioeconomic groups face challenges to their sexual and reproductive health.

Consider the global statistics. Each year:

- more than 120 million couples have an unmet need for contraception;
- an estimated 80 million women experience an unplanned pregnancy, of which 45 million end in abortion;
- about 340 million people acquire new gonorrhea, syphilis, chlamydia, or trichomonas infections;[1]
- nearly 2.7 million people are infected with HIV, and there are two million AIDS-related deaths.[2]

A new initiative has been formed to promote the development and use of multipurpose prevention technologies (MPTs), tools that prevent unintended pregnancy, STDs (including HIV), and/or other reproductive tract infections. Clinicians may recognize these as "combination" or "dual" technologies, No matter the nomenclature, these types of products represent an integrated reproductive health solution for women around the world.

The good news? Such MPTs as male condoms, female condoms, and diaphragms are now in existence, says **Bethany Young Holt**, PhD, MPH, director of the Northern California-based Coalition Advancing Multipurpose Innovations (CAMI), part of the Public Health Institute. CAMI serves as the non-aligned convener and facilitator for the new Initiative for Multipurpose Prevention Technologies (IMPT), a global health initiative that is aimed at raising awareness about and support for new and existing technologies that can be used in various combinations to address multiple reproductive and sexual health needs.

"One of the goals of this initiative is to think in new ways about prevention and health, and to help improve cross-communication, collaboration, and efficiencies between the various clinical areas: contraception, HIV/AIDS, STIs, sexuality, etc.," says **Wayne Shields**, president and chief executive officer of the Washington, DC-based Association of Reproductive Health Professionals, a member organization of the initiative. "The idea also is to combine currently available, soon-to-be available, and longer-term methods in unique ways that provide the best possible protection."

What's in exploration?

About 150 invited delegates from 11 countries gathered in March 2009 to discuss advancing prevention technologies. Attendees represented a wide range of disciplines: basic sciences, family planning, sociology, public health, and international development, says Holt. The initiative sprung from that effort. The United States Agency for International Development (USAID) provided seed money to track the pipeline of available and emerging MPTs as well as for an initial advocacy brief to help initiative members to articulate what

EXECUTIVE SUMMARY

A new initiative will promote the development and use of multipurpose prevention technologies, tools that prevent unintended pregnancy, sexually transmitted diseases, and/or other reproductive tract infections.

- The Initiative for Multipurpose Prevention Technologies is a global effort aimed at technologies that can be used in various combinations to address multiple reproductive and sexual health needs.
- Some technologies already are on the market. Other methods in the research pipeline include a one-size cervical barrier that delivers an HIV-preventing microbicide and a vaginal ring technology that prevents HIV and herpes simplex virus.

is available and forthcoming in the field of multipurpose technologies. The San Francisco-based Mary Wohlford Foundation, a long time supporter of CAMI, also is providing core support.

What MPTs that are being explored? These approaches include combinations of devices and drugs, combinations of drugs or vaccines, and other novel approaches, such as:

• A one-size cervical barrier that delivers an HIV-preventing microbicide.

The device potentially could prevent pregnancy, HIV, and other pathogens. The SILCS Diaphragm, a single-size reusable device, was patented by Seattle-based PATH (Program for Appropriate Technology) in 1998. PATH has partnered with Arlington, VA-based CONRAD (Contraceptive Research and Development Program) to explore development of the device. Science also is eyeing the use of BufferGel, a novel microbicide developed by ReProtect of Baltimore, used with a emerging single-size barrier, called the Duet.

• A vaginal ring technology that simultaneously prevents HIV and herpes simplex virus.

This technology could be especially appealing to women at risk of either infection who want to have children. CONRAD is exploring such technology by combining tenofovir and acyclovir in a vaginal ring.[3]

• Combined vaccines that provide protection against human papillomavirus and hepatitis B virus.

Vaccines that protect against each of these infections are manufactured through similar processes, delivered on similar immunization schedules, and approved for co-administration, according to the initiative.[4]

• New delivery systems for microbicides, such as nanoparticles and bioresponsive gels.

Such systems eventually could be combined with antimicrobial agents to provide a dual defense against pathogens, according to the initiative.[4]

• Bacterial therapeutics.

Oral and vaginal administration of probiotics might be useful in preventing and treating bacterial vaginosis, urinary tract infections, HIV, and other infections.[5]

Look for more research to emerge on multipurpose technologies. USAID has earmarked funding to advance such investigations, says Holt.

Progress also is being made in products in the development pipeline. For example, the Woman's Condom, under development by PATH, is being evaluated in a Phase III contraceptive efficacy trial. The Woman's Condom is a 9-inch thin, pliable plastic pouch that conforms to the shape of the vagina. It has a flexible soft outer ring designed to protect the external genitalia, with four oblong foam pieces on the outside of the pouch which are engineered to cling lightly to vaginal walls, ensuring device stability. The distal end of the pouch and foam pieces are packaged into a capsule that serves as an insertion aid. It dissolves quickly when inserted into the vagina.[6]

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Teen TOPICS

New data emerge on teen sexual health

By **Anita Brakman**, MS, Education & Research Manager and **Kaiyti Duffy**, MPH, Director of Education and Research Physicians for Reproductive Choice and Health New York City **Melanie Gold**, DO, FAAP, FACOP Clinical Associate Professor of Pediatrics University of Pittsburgh School of Medicine Staff Physician University of Pittsburgh Student Health Service

Morbidities and mortalities among adolescents often are the result of risk-taking behaviors. By tracking behavioral trends, clinicians can provide more tailored education, counseling, and screenings to adolescents. To enhance sexual health services for young people, the National Survey of Family Growth (NSFG) and Youth Risk Behavior Survey (YRBS) recently released new data on a wide range of behaviors including sexual activity, contraception, and condom use.[1, 2]

Both surveys use nationally representative samples. YRBS surveys high school students on a variety of behaviors and relies on a written questionnaire given in classrooms. In 2009, 16,460 questionnaires were completed in 158 schools. NSFG focuses solely on reproductive and sexual topics, targets individuals ages 15-44, and gathers data through face-to-face interviews conducted in households nationwide. The data just released is based on 13,495 interviews conducted between 2006 and 2008, including 2,767 teens.

Adolescents' overall rates of sexual activity are stable, remaining similar to rates found in the 2002 NSFG and 2007 YRBS. In the 2009 YRBS, 46% of female and male students report having ever had sex, and 26% of females and 33% of males report having sexual intercourse within the last three months. NSFG 2006-2008 data from never-married participants ages 15-19 years report a slightly smaller percentage of adolescents having ever had sex (42% females, 43% males). A slightly larger percentage of female participants (30%) and smaller percentage of males (28%) reported sexual activity within three months. Results from both surveys reflect an overall trend of declining adolescent sexual activity since the surveys began, in 1991 for YRBS and 1988 for NSFG.

Many sexually active teens are taking steps to protect themselves against pregnancy and sexually transmitted infections (STIs). According to NSFG, 99% of sexually experienced females ages 15-19 years reported ever using contraception. At first sex, 79% of females used contraception, with 68% using a condom and 15% using birth control pills. This does not reflect a significant change since 2002.

Among males, 87% report they had used some method at first intercourse, with condoms being most common at 82%. This is a significant increase over the 71% reported in the 2002 NSFG. Males also reported a significant change in using dual contraceptive methods at first intercourse, increasing from 11% in 2002 to 19% in 2009. Examining contraceptive use at first sex might be especially important because of NSFG findings that females who report using contraceptives at first intercourse are less likely to report experiencing births before age 20.

The YRBS does not measure reported condom or contraceptive use at first intercourse, but does measure these behaviors at most recent or last intercourse. YRBS found no change in reported condom use at last intercourse in 2009 (61%) compared to 2007 (62%) or over time since 2003 (63%). Until 2003, data showed a positive trend of increasing condom use ever since the 1991 low of 46%. YRBS reports 23% of sexually active students used birth control pills or Depo-Provera at last intercourse in 2009, a significant increase over 19% in 2007.

Sexual activity eyed

NSFG also assesses the context within which teens engage in sexual activity. For example, among 18-24 year olds whose first intercourse

COMING IN FUTURE MONTHS

- Contraception tips for women in perimenopause
- Review results of tenofovir vaginal gel trial
- Focus on new national HIV prevention strategy
- Antibodies might boost AIDS vaccine research

occurred before age 20, 14% of females' and 25% of males' first intercourse was with someone as "just friends." A larger group reported "going steady" (72% females, 56% males).

In regard to how much first intercourse was wanted, 47% of females in this category reported mixed feelings, 43% really wanted it at the time, and 10% really didn't want it to happen. Women whose first intercourse was at age 14 years or younger, or whose partner was at least three years older than they were at the time, were more likely to report not really wanting first intercourse. Women whose first male partners were older by three years or more also were more likely than peers to report experiencing nonvoluntary first intercourse (12.8%). Males were more likely to report wanting first intercourse at the time it occurred, and there were no correlations between age of first intercourse or age of partner and how much sex was wanted by males.

NSFG also explores why some teens delay sex. In 2006-2008, NSFG found the most common reason reported by sexually inexperienced teens ages 15-19 to delay sex is that such behavior is "against religion or morals," with 41% of females and 35% of males giving this response. This is consistent with 2002 findings. The only significant change since 2002 in sexually inexperienced teens' reasons for delaying sex was a decrease in young males reporting they "do not want to get a female pregnant right now" from 25% to 12%. Eighteen percent of females reported avoiding pregnancy as their main reason for delay. The least popular reason for delay was preventing STIs, cited by just

CNE/CME INSTRUCTIONS

Physicians and nurses participate in this continuing nursing 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. ■

CNE/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;
- describe how those issues affect services and patient care;
- integrate practical solutions to problems and information into daily practices, according to advice from nationally recognized family planning experts;
- provide practical information that is evidence-based to help clinicians deliver contraceptives sensitively and effectively.

9. What were the most common side effects noted in clinical trials of ulipristal acetate as an emergency contraceptive?
   A. Headache, nausea, dysmenorrhea, abdominal pain, fatigue, and dizziness.
   B. Headache, nausea, dysmenorrhea, diarrhea, fatigue, and dizziness.
   C. Headache, joint pain, dysmenorrhea, abdominal pain, fatigue, and dizziness.
   D. Headache, nausea, pelvic pain, abdominal pain, fatigue, and dizziness.

10. What is the progestin in the oral contraceptive Natazia?
    A. Nomegestrol acetate
    B. Dienogest
    C. Drospirenone
    D. Trimegestone

11. Which vaccine has been approved for the prevention of genital warts (condyloma acuminata) due to HPV types 6 and 11 in boys and men, ages 9-26?
    A. Menomune
    B. Menactra
    C. Gardasil
    D. Cervarix

12. What is the name of the one-size cervical barrier patented by the Program for Appropriate Technology?
    A. Duet
    B. Lea's Shield
    C. Instead Cup
    D. SILCS Diaphragm

Answers: 9. A 10. B 11. C 12. D.

6% of females and 7% of males.

The low priority of STI prevention found in NSFG data is concerning when compared to the data on HIV/AIDS education from YRBS. In 2009, 13% of students reported never being taught about AIDS or HIV infection in school, a significant increase over 10% in 2007. While such education was on the rise from 1991-1997, it has been declining ever since then.

The data highlight which risk and protective behaviors teens are engaged in, and underscore the importance of taking a comprehensive sexual health history and providing medically accurate counseling on sexually transmitted infections, condom use, and contraception.[1-2]

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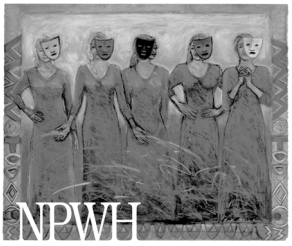
Contraceptive Technology Update is endorsed by the National Association of Nurse Practitioners in Women's Health and the Association of Reproductive Health Professionals as a vital information source for health care professionals.



S·T·D
QUARTERLY™

Check out new HIV testing approaches — Could they impact epidemic in United States?

Approaches allow patients to be diagnosed earlier than ever

What will it take to stem the incidence of HIV in the United States? According to the Centers for Disease Control and Prevention (CDC), about 56,300 people were newly infected with HIV in 2006, the most recent year for which data are available.[1] More than half (53%) of these infections occurred in men who have sex with men (MSM). Black/African American men and women also were found to be at risk. Their estimated incidence rates were seven times as high as the incidence rate among whites. *(*Contraceptive Technology Update *reported on the rates in "Time to step up HIV testing in women," November 2008, p. 125.)*

U.S. public health officials have stepped up testing efforts since 2006 when the CDC called for voluntary HIV screening to become a routine part of medical care for all patients ages 13 to 64.[2] *(To read more about the recommendations, see "New HIV screening guidelines issued — How will they impact your practice?" December 2006, p. 133.)* While increased testing is an important strategy in the fight against HIV, results for standard HIV tests usually are not positive until several weeks after infection occurs. This gap in detection is problematic, as those with recent HIV infection generally have very high amounts of virus in their body fluids and might be more likely to transmit HIV infection to others.[3]

Research is looking at new diagnostic tools that will allow patients to be diagnosed earlier than ever. The Food and Drug Administration (FDA) recently approved Abbott's ARCHITECT HIV Ag/Ab Combo assay, which can simultaneously detect HIV antigen and antibodies. Science also is eyeing adding nucleic acid testing (NAT) to rapid testing to boost HIV detection yield. Results of a just-published paper indicate that adding NAT testing to a community-based HIV testing program increased the HIV detection yield by 23%.[3]

How might such diagnostic tools impact the incidence of HIV in the United States? Early and accurate diagnosis of HIV is critical in controlling the

EXECUTIVE SUMMARY

New HIV diagnostic tools now allow patients to be diagnosed earlier than ever before. Just approved: Abbott's ARCHITECT HIV Ag/Ab Combo assay, which simultaneously can detect HIV antigen and antibodies.

- Science also is eyeing adding nucleic acid testing (NAT) to rapid testing to boost HIV detection yield. By adding NAT testing to a community-based HIV testing program, HIV detection yield was increased by 23%.
- Results for standard HIV tests are not usually positive until several weeks after infection. Those with recent HIV infection generally have high amounts of virus in their body fluids and might be more likely to transmit HIV infection.

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HIV epidemic, says **Sheldon Morris**, MD, MPH, assistant clinical professor at the University of California, San Diego's (UCSD) Antiviral Research Center. "To those of us in the HIV prevention and testing field there is a need to have a strategy for detection of early HIV infection which could be the ARCHITECT [assay] or a nucleic acid strategy," states Morris, lead author of the current research. "Areas of high prevalence should be using these tests, and there should be an expected reduction in HIV transmission."

Test arrives by year end

The ARCHITECT HIV Ag/Ab Combo assay is the first test approved in the United States that can simultaneously detect HIV antigen (a protein produced by the virus immediately after infection) and antibodies, which are developed days later as the body works to fight off the infection. Abbott's new assay detects the HIV p24 antigen. The test will be available before the end of the year, says **Darcy Ross**, senior manager for Abbott Diagnostics' Division of Public Affairs.

The early phase of HIV infection (when symptoms begin to emerge) cannot be detected by most routinely used serological HIV tests. Conventional HIV tests detect HIV-specific antibodies in blood or oral fluids that are produced by the immune system during seroconversion or the development of detectable antibodies, which occurs approximately 22-25 days after initial infection. Testing for the antigen reduces the "window period" in which an individual might have been exposed to HIV and might have a reactive test result.

In a study conducted in a high-risk population, the Abbott assay detected nearly two-thirds of early, acute HIV infections.[4] In the study, blood samples were collected every six months from men who have sex with men, all who were HIV antibody negative at enrollment. The previous seronegative specimens from patients who subsequently tested HIV antibody positive were tested individually with two HIV RNA assays. Those determined positive by both methods were classified as acute infections. The specimens then were tested with the Abbott assay and two third-generation HIV antibody tests. The Abbott combination assay detected 61.9% (13) of the acute infections. Only 14.3% (3) of the acute samples were identified as positive by one of the third-generation antibody tests. There were a total of 21 acute infections among 217 samples from seronegative individuals.[4]

The new test will run on Abbott's existing ARCHITECT line of diagnostic testing instruments. It already has been approved for use outside the United States; in Europe, HIV antigen-antibody combination testing is routine in public health settings. In fact, United Kingdom HIV testing guidelines specify the HIV combination test as the first-line test.

The new Abbott assay represents the first in what are known as fourth-generation HIV detection tests, says **Peter Leone**, MD, professor of medicine at the University of North Carolina at Chapel Hill and medical director of the North Carolina HIV/STD Prevention and Control Branch.

"We think that this test, and there may be other fourth-generation assays that will be available in the next year or so, really has a way of changing the landscape of HIV testing in the U.S., allowing us to close the gap," says Leone.

Can NAT testing work?

How can adding NAT testing to standard tests for HIV identify more patients with HIV infection? To perform the current study, researchers looked at more than 3,000 patients who sought HIV testing in clinics and other testing sites in and near San Diego. Many of the sites serve populations at high risk for HIV infection. The research was designed as a prospective study of the Early Test, a testing program developed by UCSD to identify and stage HIV infection.

Patients first were tested for HIV infection with a rapid saliva test. If test results were positive for HIV, a counselor gave patients their test results, and a blood sample was obtained for standard HIV tests. If the results were negative, a blood sample was obtained for the nucleic acid test. Patients who took the nucleic acid test were told that if the results were positive, they would be contacted by a staff member within two weeks. If patients had not been contacted in two weeks, they were instructed to call a voicemail number or log in to a web site to retrieve their results by using an anonymous personal identification number to protect their privacy.

Of 3,151 persons tested, 79 had newly diagnosed cases of HIV, researchers report. A total of 64 had positive results from the rapid HIV test, and 15 had positive results only by NAT testing. Of all HIV infections, 44% (in 35 persons) were in the acute and early stages. Most participants (56%) and persons with HIV (91%) were men who have sex with men.[3]

The Early Test program is ongoing, says Morris. The next steps in researchers for UCSD investigators might yield a comparative effectiveness study with fourth generation testing.

Cost analyses are yet to be published for either test, notes Morris. Researchers also will be looking at the "cut-off" for prevalence where test strategies similar to the Early Test remain effective, he states.

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Erectile dysfunction drug use, STD rate eyed

Check for use of erectile dysfunction (ED) drugs among older male patients; a new analysis of insurance records of more than 1.4 million U.S. men over 40 found that those who used ED drugs were more likely to have sexually transmitted diseases (STDs) than were non-users.[1]

To perform the study, researchers used a database of insurance claims from 1997 to 2006 to look at 33,968 men with at least one prescription for an ED drug and more than 1 million men without a prescription. They analyzed information from the database to determine the frequency of STDs in men with and without a prescription for an ED drug, looking at billing codes for STDs in the year before and after a patient received the first prescription for an ED drug.

The research indicates that both in the year before and after drug initiation, men

with a prescription had higher rates of STDs than those with no prescription. What were the STDs that accounted for these differences? Predominantly HIV and chlamydia, the scientists report.[1]

Since the first ED drug sildenafil (Viagra, Pfizer, New York City) was introduced in the United States in 1998, use of such drugs has increased. Why? Statistics indicate nearly 40% of men ages 57 to 85 years have some degree of ED.[2] *(*Contraceptive Technology Update *reported on the increase of EDs in seniors. See "Increase the radar for STDs in seniors," September 2008, p. 106.)* Viagra has been followed by similar drugs such as tadalafil (Eli Lilly, Indianapolis) and vardenafil (Levitra, Bayer Health Care, Berlin, Germany). Another drug soon will join the list. The Food and Drug Administration gave approval in June 2010 to Bayer's Staxyn, a 10 mg vardenafil tablet. The drug, to be marketed later this year by Bayer's U.S. marketing partners, GlaxoSmithKline and Merck & Co., is offered in an orodispersible formulation, meaning that it disintegrates on the tongue without liquid.

Researchers in the current paper note that selection bias precludes conclusions about whether use of ED treatments directly leads to increases in STDs. The researchers plan to further examine the issue, says **Anupam Jena**, MD, PhD, a resident physician at Massachusetts General Hospital Department of Medicine in Boston. The team is looking at changes around the time that sildenafil was introduced, says Jena, who served as lead author for the current study. Analysis is focusing on those at highest risk of having ED (such as those with diabetes) and comparing them with others with chronic diseases that are not predisposed to the condition, he says.

The scientists also are searching for changes within health plans over time, tracking changes following coverage of ED drugs. By looking for increases in STD rates following drug coverage, the researchers hope to remove selection bias, Jena notes.

When prescriptions for ED drugs are being considered, clinicians and patients should discuss the risk for STDs and ways to prevent getting them and transmitting them to others, says researchers.

Health care providers need to recognize that their older adult patients who are on ED drugs already are at a higher risk of having or acquiring an STD, says **Dana Goldman**, PhD, director of the Schaeffer Center for Health Policy and Economics at the University of Southern California in Los Angeles, the current study's senior author. Both the physicians who prescribe these drugs and the pharmacists who fill those prescriptions should counsel all patients on the importance of safer sexual practices, he states.

Such counseling is important. Research indicates people over age 50 are one-sixth as likely to use condoms during sex and one-fifth as likely to have been tested for HIV compared with persons in their 20s.[3]

"Clinicians should counsel all of their adult patients about sexual health and safety and remember that no sexually active population group is immune to STDs," states an accompanying editorial by **Thomas Fekete**, MD, professor of medicine and section chief

EXECUTIVE SUMMARY

A new analysis of insurance records of more than 1.4 million U.S. men over age 40 found that those who used erectile dysfunction (ED) drugs were more likely to have sexually transmitted diseases (STDs) than were non-users.

- Researchers analyzed information from a database of insurance claims to determine the frequency of STDs in men with and without a prescription for an ED drug. They examined billing codes for STDs in the year before and after a patient received the first prescription for an ED drug.
- Data indicate that both in the year before and after drug initiation, men with a prescription had higher rates of STDs than those with no prescription.

of infectious diseases at the Temple University School of Medicine in Philadelphia. "Although counseling about safer sex practices should not wait until a patient requests ED medications and is already in a higher-risk group, the presence of higher rates of serious STDs, such as HIV infection, in men who use ED drugs compared with those who do not make it critical that all ED drug prescriptions be accompanied by assessment of STD risk and counseling about safe sex."[4]

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Sexual, social factors put women at greater HIV risk

Adaora Adimora, MD, MPH, professor of medicine in the Division of Infectious Disease at the University of North Carolina School of Medicine in Chapel Hill, recently discussed her research on the nuances of HIV risk behavior among women with AHC Media, publisher of *Contraceptive Technology Update*. Our first question was: Would you please explain your findings that there is an association between women having concurrent relationships and having non-monogamous partners?

Adimora: We found that women who have multiple partnerships often have relationships with men who also have multiple partners at the same time. This finding in and of itself is not especially surprising. If you know your partner is not exclusively committed to you, you'll probably have less motivation to be exclusively committed to him. The finding is important from an epidemiologic standpoint, though, because it suggests that the sexual networks are densely connected, affording more opportunities for HIV spread.

AHC Media: How important a factor is this when compared with other HIV risk factors, including substance use?

Adimora: From a network perspective, concurrency and sexual mixing between different risk subpopulations are important. These are links between substance users and non-substance users that can bridge spreading of infection from drug using networks to the general population of people who don't use drugs. What's notable from an epidemiological standpoint is the presence of sexual mixing between different subpopulations and concurrency. For an infection to spread within a population, you need both links to other people and a source of infection. This mixing between drug users and the general population and concurrency can be especially powerful in spreading infection.

AHC Media: Your research underscores the importance of reducing the economic and contextual barriers to long-term stable monogamy. Would you please explain some more about these barriers, particularly within the African American community?

Adimora: Probably the biggest barriers for African Americans are poverty, discrimination, and the low sex ratio — the ratio of men to women. Here are some examples: the shortage of black men (low sex ratio) places women at a disadvantage in negotiating and maintaining mutually monogamous relationships. Poverty stresses relationships. It decreases the likelihood that people will marry and increases their risk of divorce. Incarceration is destructive to long-term relationships and is associated with concurrency, and it also increases risk of poverty and the number of available men.

I also refer you to a piece in The New York Times [May 30, 2010 — "Blacks in Memphis Lose Decades of Economic Gains"] that graphically describes the marked differences in wealth between U.S. whites and blacks and Hispanics and the disproportionately devastating effects the recent recession has had on blacks in the U.S. These differences in wealth result in marked differences not only in life opportunities — but also in risk environments for African Americans.

AHC Media: What is your 'take-home' message with regard to public HIV prevention strategies and also with how clinicians should address HIV prevention with patients who are newly infected?

Adimora: We need to gain more understanding of what personal and contextual factors influence concurrency, increase public awareness of the HIV transmission risk it poses, and develop effective, culturally appropriate interventions to reduce concurrency or increase condom use in such situations. To successfully control the HIV epidemic, we'll need to address the economic forces, social influences, and other contextual factors that [undermine] stable monogamy, thereby increasing concurrency in the overall population and in different population subgroups.

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