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Interpreting News and Research on Contraceptives and STIs

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AHC Media

Long-acting methods safe for teens — Include options in your counseling

Implants & IUDs should be offered as first-line contraceptive choices

When it comes to contraception, most teens choose contraceptive methods with relatively high typical use failure rates, such as withdrawal, condoms, and oral contraceptives (OCs). Such selections, coupled with inconsistent use or nonuse, play a large role in the high level of adolescent unintended pregnancies in the United States. Eighty-two percent of all teen pregnancies are unplanned, and they account for one-fifth of all unplanned pregnancies in the nation.[1]

It's time to meet the need for acceptable, reliable, and effective methods for adolescent contraception. The American College of Obstetricians and Gynecologists (ACOG) has moved toward that goal, with a committee opinion stating that long-acting reversible contraceptives such as the intrauterine device (IUD) and the contraceptive implant are safe, effective, and appropriate options for adolescents.[2] With perfect and typical use pregnancy rates at less than 1% per year, such methods represent top-tier effectiveness for teens, the opinion states. *[Download a PDF of the committee opinion at http://bit.ly/OJd2j1. Also, did you receive the* Contraceptive Technology Update *ebulletin sent Sept. 21 on this latest ACOG guidance? To receive breaking news as it occurs, provide your e-mail address to AHC Media customer service at (800) 688-2421 or customerservice@ahcmedia.com.]*

The implant and IUD also possess the highest rates of patient satisfaction

Next month: CTU Salary Survey results

Where do you stand when it comes to your professional income? Review the results of the 2012 Contraceptive Technology Update annual salary survey, included in the upcoming January 2013 issue of the newsletter. ■

and continuation of all available reversible contraceptives, the committee opinion notes. With their long-acting effectiveness, both methods eliminate the problem of inconsistent use seen with other forms of reversible birth control.

At long last, long-acting contraception (LARC) is being seen in a clear, evidence-based light, says **Linda Dominguez**, NP, nurse practitioner at Southwest Women's Health in Albuquerque and newly-elected chair of the Association of Reproductive Health Professionals in Washington, DC. "Young women at the highest risk of an unintended pregnancy should not be deliberately confined to the lowest effectiveness methods," notes Dominguez.

"[The] committee opinion will add muscle to the ongoing effort to push past the outdated practice habits and patterns that still permeate the field."

Time to change practice

Healthcare providers' concerns about LARC use in adolescents are a barrier to access, the committee opinion states. Intrauterine devices don't increase an adolescent's risk of infertility.[3] Intrauterine devices also can be inserted without technical difficulty in most adolescents and nulliparous women.[2]

In the 1970s, IUDs were made in nulliparous sizes and routinely offered to adolescents as a contraception option, observes **Susan Wysocki**, WHNP-BC, FAANP, president & chief executive officer of Washington, DC-based iWomansHealth, which focuses on information on women's health issues for clinicians and consumers. However, safety concerns linked to one IUD, the Dalkon Shield, led to decreased use and reluctance by providers to offer the method to young women, she says.

"It is about time we put the past behind us and gathered what we have learned in the meantime to be able to offer a method of contraception to teens," says Wysocki.

Flaws in early research led to exaggerations in estimates of the risk of upper-genital tract infection associated with use of intrauterine contraception.[4] Women ages 15-19 have the second highest rate of chlamydia and the highest rates for gonorrhea, so it is appropri-

EXECUTIVE SUMMARY

The American College of Obstetricians and Gynecologists (ACOG) has issued a committee opinion stating that long-acting reversible contraceptives such as the intrauterine device (IUD) and the contraceptive implant are safe, effective, and appropriate options for adolescents.

- The implant and IUD possess the highest rates of patient satisfaction and continuation of all available reversible contraceptives, the committee opinion notes. With their long-acting effectiveness, both methods eliminate the problem of inconsistent use seen with other forms of reversible birth control.
- As with all nonbarrier forms of contraception, clinicians should counsel on dual use of condoms to protect against acquisition of sexually transmitted infections.

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ate to screen for sexually transmitted infections (STIs) at the time or before IUD insertion, the committee opinion states.[2] It is reasonable to screen for infections and place the IUD on the same day, and administer treatment if the test is positive, the opinion notes.[2]

Regarding the fear of pelvic inflammatory disease in young patients, Dominguez says providers need to educate that sexual infections stem from partners, not from devices. As with all nonbarrier forms of contraception, remember to counsel on dual use of condoms to protect against acquisition of STIs, the opinion notes.

Intrauterine contraception and the contraceptive implants are safe for use by adolescents, including immediately after giving birth or after an abortion, the opinion states. Complications from both methods are rare.

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, says, "Since many teens deliver by cesarean section, we should all learn how to place the IUD with lengthened tail strings through the uterine incision to avoid potential contamination from the vagina."

Plan for successful use

Counseling about LARC methods should occur at all health provider visits for sexually active adolescents, including preventive health, abortion, and prenatal and postpartum visits, the committee opinion states. Mothers of adolescents also need to be educated and reassured regarding the safety and wisdom of LARC methods, says Dominguez.

In talking about use of the intrauterine contraceptive or the contraceptive implant, discuss potential bleeding changes associated with either method. Adolescents using the copper T380 IUD or the levonorgestrel IUD can expect changes in their menstrual bleeding, particularly in the first few months of use. The copper T IUD might cause heavier bleeding that can be treated with nonsteriodal anti-inflammatory drugs. Women using the levonorgestrel IUD will have a decrease in bleeding over time that will lead to light bleeding, spotting, or amenorrhea.[2]

Teens who use the contraceptive implant should be counseled to expect changes in menstrual bleeding throughout use of the method. In an analysis of 11 studies, the most common bleeding pattern was infrequent bleeding in 33.3% of 90-day cycles, followed by amenorrhea in 21.4% of cycles.[5]

A change in bleeding pattern is the most common reason for discontinuation of use of the implant, so anticipatory guidance regarding such changes might improve satisfaction and continuation, the opinion advises. Tell patients that the bleeding pattern they experience in the first three months is broadly predictive of future bleeding patterns.[6]

In addition to high efficacy, the implant offers other benefits. High rates of infrequent bleeding or amenorrhea lead to higher hemoglobin levels in implant users.[7] Other noncontraceptive benefits include reductions in dysmenorrhea and pelvic pain.[8,9]

Intrauterine devices and the contraceptive implant are the best reversible methods for preventing unplanned pregnancy, rapid repeat pregnancy, and abortions in adolescents, the opinion states. Complications from use are rare and differ little between teens and older women, it notes.

"It's encouraging that ACOG has taken such a positive action [in] strongly recommending increased access for adolescent women to implants and IUDs," says Nelson. "I think we should go further and say that implants and IUDs should be first-line options for all women at risk for pregnancy."

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Abortion rates fall with free contraception

Just-published data from the Contraceptive CHOICE Project, conducted by researchers at Washington University School of Medicine at St. Louis, confirms that provision of contraception at no cost substantially reduced unplanned pregnancies and cut abortion rates by 62-78% over the national rate.[1]

The CHOICE Project enrolled 9,256 adolescents and women at risk for unintended pregnancy to perform a prospective cohort study of adolescents and women desiring reversible contraceptive methods. Females were recruited from the two abortion facilities in the St. Louis region and through provider referral, advertisements, and word of mouth. Contraceptive counseling included all reversible methods but emphasized the superior effectiveness of intrauterine devices (IUDs) and implants, known collectively as long-acting contraceptive (LARC) methods. All participants received the reversible contraceptive method of their choice at no cost. Three-quarter of the women chose LARC methods: 46% levonorgestrel IUD, 12% copper IUD, and 17% subdermal implant.

From 2008 to 2010, annual abortion rates among study participants ranged from 4.4 to 7.5 per 1,000 women, representing a 62-78% drop over the national rate of 19.6 abortions per 1,000 women in 2008, the latest year for which figures are available, researchers note.[1] The lower abortion rates among study participants also is considerably less than the rates in St. Louis city and county, which ranged from 13.4 to 17 per 1,000 women for the same years.[1]

Among girls ages 15-19 who had access to free birth control provided in the study, the annual birth rate was 6.3 per 1,000, far below the U.S. rate of 34.3 per 1,000 for girls the same age.

"Unintended pregnancy remains a major health problem in the United States, with higher proportions among teen-agers and women with less education and lower economic status," says **Jeffrey Peipert**, MD, MPH, MHA, Robert J. Perry professor of obstetrics and gynecology and vice chair for clinical research at Washington University School of Medicine. "The results of this study demonstrate that we can reduce the rate of unintended pregnancy, and this is key to reducing abortions in this country."

Births to teen-agers and abortions are clearly a concern to society, observes **Robert Hatcher**, MD, MPH, professor of gynecology and obstetrics at Emory University School of Medicine in Atlanta. The "get it and forget it" contraceptives, also known as the LARC methods, have been shown by the research group at Washington University in St. Louis to be popular among women and effective at preventing both abortions and births to teen-agers, he states. "If a community wants to approach the issues of abortion prevention and prevention of teen births, the provision of IUDs and implants at no cost must become high priority," says Hatcher. "The same holds for societies around the world."

What drives use?

Few studies in the United States have asked women directly why they use contraception and what benefits they expect or have achieved from its use. Researchers at the Guttmacher Institute in New York City surveyed 2,094 women receiving services at 22 family planning clinics nationwide to fill in this information gap.[2]

Most women participating in the survey said that contraception has had a significant impact on their lives. They said it allowed them to take better care of themselves or their families (63%), support themselves financially (56%), complete their education (51%), or keep or obtain a job (50%).

When asked why they were currently seeking birth control, women expressed concerns about the consequences of an unintended pregnancy on their families' and their own lives. Sixty-five percent of women said they were using contraception because they could not afford to take care of a baby; nearly one in four women said they or their partners were unemployed. Among women with children, nearly

EXECUTIVE SUMMARY

Just-published data from the Contraceptive CHOICE Project, conducted by researchers at Washington University School of Medicine at St. Louis, confirms that provision of contraception at no cost substantially reduced unplanned pregnancies and cut abortion rates by 62-78% over the national rate.

- All reversible methods were available to women at no cost, but counseling emphasized the superior effectiveness of intrauterine devices (IUDs) and implants, known collectively as long-acting contraceptive (LARC) methods. Three-quarter of the women chose LARC methods.
- Among girls ages 15-19 who had access to free birth control provided in the study, the annual birth rate was 6.3 per 1,000, far below the U.S. rate of 34.3 per 1,000 for girls the same age.

all reported that their desire to care for their current children was a reason for contraceptive use.

Women need continued access to a wide range of contraceptives so they can plan their families and determine when they are ready to have children, observes **Laura Lindberg**, PhD, senior research associate at the Guttmacher Institute and coauthor of the research paper. Many of the most highly effective methods have high up-front costs, which can be a barrier to women seeking to prevent an unintended pregnancy, she notes.

"The findings of our study point to the critical role of contraception in the lives of women and their families, and reinforce the need to ensure that women have access to the contraceptive methods that best meet their needs, at low cost, and without having to jump through bureaucratic hoops," states Lindberg.

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When to resume or begin contraception post ECPs?

You have just prescribed the selective progesterone receptor modulator emergency contraceptive pill (ECP), ulipristal acetate (ella, Watson Pharma, Morristown, NJ), to the patient sitting in front of you. What is your counsel on when to initiate hormonal birth control following use of the ECP?

A new review of existing research looks at current guidance on resuming or initiating hormonal contraception after use of ECPs, particularly ulipristal acetate.[1] The drug was approved by the Food and Drug Administration in 2010 for use as an emergency contraceptive. It is unknown how administration of hormonal contraception following use of ulipristal acetate might alter the effectiveness of the emergency or hormonal contraceptive, the review notes.[1]

The review was conducted in preparation for the U.S. adaptation of the World Health Organization's (WHO's) Selected Practice Recommendations for Contraceptive Use. The publication is WHO's companion guidance document to its Medical Eligibility Criteria for Contraceptive Use.[2] The practice recommendations provide evidence-based guidance on contraceptive management questions, such as when can women start specific contraceptive methods, what exams and tests are needed prior to starting a method, what follow-up is needed, and how various side effects can be managed, says **Kathryn Curtis**, PhD, an epidemiologist in the Women's Health and Fertility Branch in the Division of Reproductive Health Centers at the Centers for Disease Control and Prevention (CDC). *(Review the practice recommendations at the WHO web page, http://bit.ly/z3jHlN.)*

In October 2011, the CDC held a meeting to adapt the practice recommendations for use by U.S. healthcare providers, following a process similar to its adaption of the international agency's contraceptive use criteria, says Curtis, a co-author of the current review. Meeting participants examined the scientific evidence and the U.S. context to see whether and how the recommendations might be adapted for best implementation in the United States, she notes.

The U.S. group added a few new recommendations, one which will address how a woman can start regular contraception after emergency contraceptive pills, says Curtis. The current review was conducted in preparation for discussions on the recommendation at the October 2011 meeting.

"The guidance document itself, 'US Selected Practice Recommendations for Contraceptive Use, 2013,' which will contain this recommendation, is expected to be released sometime in early 2013," states Curtis.

EXECUTIVE SUMMARY

A new review of existing research looks at current guidance on resuming or initiating hormonal contraception after use of emergency contraceptive pills (ECPs), particularly ulipristal acetate.

- It is unknown how administration of hormonal contraception following use of ulipristal acetate might alter the effectiveness of the emergency or hormonal contraceptive, the review notes.
- The package insert for the drug advises that due to the medication's high affinity binding to the progesterone receptor, its use might reduce the contraceptive action of regular hormonal methods. The insert advises that a reliable barrier method of contraception be used with subsequent acts of intercourse that occur in the same menstrual cycle.

Reviewers performed a systematic review of the literature to identify articles concerning the resumption or initiation of regular contraception within the same cycle as ECP use. Searches were conducted for articles in any language, published between 1980 and April 2012, and included all methods of ECPs available in the United States. The search strategy identified 184 articles; none met inclusion criteria.[1]

The package insert for ulipristal acetate advises that due to the medication's high affinity binding to the progesterone receptor, its use might reduce the contraceptive action of regular hormonal methods. Therefore, the package insert advises that a reliable barrier method of contraception be used with subsequent acts of intercourse that occur in the same menstrual cycle.[1] However, the precise duration over which the drug might decrease the effectiveness of regular hormonal methods is uncertain, the review notes.[1]

Advice on levonorgestrel-only ECPs

How about levonorgestrel-only ECPs? Package inserts recommend that routine contraception should be continued or initiated as soon as possible following use. "Given levonorgestrel's function as a progesterone agonist, there is no similar theoretical concern for decreased effectiveness of either the levonorgestrel ECP or hormonal contraceptive methods if administered concurrently or in close succession," the reviewers note.

Guidance from the American College of Obstetricians and Gynecologists states that short-term hormonal contraceptives, such as pills, patches, and rings, may be initiated or resumed immediately with a backup barrier method or after the next menstrual period.[3] Its recommendations advise that long-term hormonal methods, such as the levonorgestrel intrauterine system, progestin contraceptive implant, or depot medroxyprogesterone acetate (DMPA), be initiated or resumed after the next menstrual period, when it is clear that the woman is not pregnant.[3]

The current review validates clinicians' current practice of combining levonorgestrel emergency contraception with immediate Quick Start protocols, especially for DMPA and next-day start for combined hormonal methods, 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. It leaves unanswered the new concern that coadministration of ulipristal acetate and any progestin-containing contraceptive might compromise the efficacy of each method, due to the action of the antiprogestin versus the progestin, she notes.

Providers can cope with the decrease in efficacy of the ongoing progestin-containing method by requiring 14 days of back-up method, but you should keep in mind not to do anything that could reduce the efficacy of the emergency contraceptive, says Nelson. This concept is particularly important for overweight and obese patients who might not be able to rely on levonorgestrel emergency contraception, she notes. Results of a 2011 meta-analysis of two randomized controlled trials comparing the efficacy of ulipristal acetate with levonorgestrel suggest obese women who used levonorgestrel EC were at greater risk of pregnancy.[4]

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Ovarian cancer screens not beneficial to women

In new guidance, the U.S. Preventive Services Task Force recommends against screening for ovarian cancer in women.[1] The recommendation applies to asymptomatic women. Women with known genetic mutations that increase their risk for ovarian cancer, such as BRCA mutations, are not included in the guidance.

The task force's recommendation falls in line with screening guidelines by other medical and public health organizations. The American Cancer Society and the American College of Obstetricians and Gynecologists don't recommend screening asymptomatic, average-risk women for ovarian cancer.

The studies simply do not support any benefit in testing such women, and there is clear harm, such as unnecessary major surgery, says **Virginia Moyer**, MD, MPH, professor of pediatrics at Baylor College

of Medicine in Houston and chair of the task force. Despite no data to indicate screening benefit, some doctors continue to recommend screening. A 2012 report, based on a survey of 1,088 doctors, indicated about one-third of those surveyed believed the screening was effective and that many routinely offered it to patients.[2]

"It is important that people follow this [guidance]," says Moyer. "This is expending resources to do a test which is almost certain to cause more harm than good, and is a very poor way to practice medicine."

No benefits confirmed

Women are rightly concerned about ovarian cancer. It has the highest mortality rate of all types of gynecologic cancer and is the fifth-leading cause of cancer death among women. In 2012, the American Cancer Society estimates about 22,280 new diagnoses and about 15,500 deaths from the disease.[3] Most women with ovarian cancer are diagnosed in advanced stages of the disease and have a five-year survival rate of about 44%.[4]

The hope that early detection might improve prognosis prompted the National Cancer Institute's Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial. The trial enrolled nearly 80,000 women, ages 55-74, between November 1993 and July 2001 at 10 screening centers across the United States. The study was designed to evaluate the efficacy of the common screening routines of transvaginal ultrasound and testing with CA-125, a blood test used to measure the level of a tumor marker produced in higher amounts in women with ovarian or other cancers.

Half the women were screened annually with CA-125 for six years and transvaginal ultrasound for four years, and the other half had routine medical care without a screening. Both study groups were followed for a maximum 13 years until February 2010. The researchers then examined the ovarian cancer-specific mortality results from the two groups.

The data revealed that the difference in survival between the two groups was not statistically significant, suggesting simultaneous CA-125 and transvaginal ultrasound does not reduce disease specific mortality in women at average risk for ovarian cancer.[5]

The screenings were associated with bleeding, fainting, nausea, and bruising, investigators report. False positives often resulted in unnecessary diagnostic tests that were associated with infection, heart problems, and bowel injury. Of the women who received false-positive results, more than 1,080 had their ovaries removed; of those, more than 222 experienced a major surgical complication.[5]

More insight needed

Edward Partridge, MD, a gynecologic oncologist and director of the University of Alabama at Birmingham Comprehensive Center and a coauthor of the study, says, "This study shows that we need better markers that are more sensitive and specific for the disease, along with improved imaging technologies. We have scientists who are working in those areas, but more research and research funding is needed to help us better understand the beginnings of the disease, how it progresses, and how we can prevent it."

Science's real dilemma with ovarian cancer is that researchers are unsure if ovarian cancer truly starts out at stage 1, progressing through stages 2, 3, and 4, says Partridge. He suggests there is a "distinct" possibility that there are two types of ovarian cancer: one that starts out as Stage 1 and remains so for a long time, and another that might start out as stage 3, with a field effect. With such an effect, the mechanism for the development of the cancer on the surface of the ovary — its epithelial lining — also simultaneously affects the peritoneal cavity, says Partridge. If this premise is proven to be true, early detection will never make a difference — only an effective treatment, he states.

Even if testing could be improved to reduce false-positive results, it still would not save women's lives, says Partridge. The death rate would be the same whether women were screened or not, which sug-

EXECUTIVE SUMMARY

In new guidance, the U.S. Preventive Services Task Force recommends against screening for ovarian cancer in women. The recommendation applies to asymptomatic women. Women with known genetic mutations that increase their risk for ovarian cancer, such as BRCA mutations, are not included in the guidance.

- The task force's recommendation falls in line with screening guidelines by other medical and public health organizations. The American Cancer Society and the American College of Obstetricians and Gynecologists don't recommend screening asymptomatic, average-risk women for ovarian cancer.
- Some doctors continue to recommend screening, despite no data to indicate benefit. About one-third of providers surveyed in a 2012 report said they believed such screening is effective.

gests that the test simply cannot find the cancer early enough to make a difference.

"We need a lot of research," says Partridge. "Taking the current test and making it a little more sensitive, it is clear that it is not going to make any difference."

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Teen TOPICS

What about boys and emergency contraception?

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When the Food and Drug Administration (FDA) approved Plan B Emergency Contraception (EC) for over-the-counter use in 2006, it opened up a new way for young men to be involved in preventing unintended pregnancy. For the first time, a dedicated EC product became available directly from pharmacies to any individual age 18 or older without a prescription.

In 2009, the age limit was lowered to include access for 17-year-olds. The same age-restricted structure is in place for generic levonorgestrel EC products as well. Individuals 16 and younger still require a prescription for EC, which can be written only for female patients. Ulipristal acetate, a newer type of EC product, is only available by prescription regardless of age, and again it is available only to females.

The American Academy of Pediatrics and Society for Adolescent Health and Medicine support over-the-counter access to EC without age restrictions, and they encourage physicians to counsel all adolescents, males and females, about this method of preventing pregnancy.[1,2]

Timeliness is crucial

Educating young men about this option and dispensing EC if possible is one more way to increase the likelihood of that EC will be used in a timely manner after unprotected sexual intercourse or contraceptive failure. Timeliness is essential with levonorgestrel EC, as efficacy drops over the 120-hour window for use.

While no studies have been published on advance provision of emergency contraception to men, similar studies of female adolescents show advance access to EC increases likelihood of use and decreases time between having unprotected intercourse and taking EC. Additionally, these studies have found no increase in the rates at which young people engage in unprotected intercourse based on increased availability of EC.[3]

A recent article in "Perspectives on Sexual and Reproductive Health" examined the literature on males and emergency contraception, and it found that many young men still are not even aware of this method.[4] One of the first studies to report on male adolescents' knowledge of EC found that less than a quarter (24%) had ever heard of EC.[5]

More recent studies show increasing awareness of emergency contraception among males of various ages, but younger men still are much less aware than their older counterparts. In one study of high school students, 38% of males reported knowledge of EC.[6] In comparison, studies of college-age men show that as many as 65% report

being aware of emergency contraception.[7,8]

Check pharmacy access

Since clinicians cannot prescribe emergency contraception to young men, access for young men remains primarily at the pharmacy. Marcell's review above found few studies focused specifically on pharmacies' provision of EC to males. Examining pharmacist practices in Rhode Island, one study found 63% of pharmacists reported selling EC to males in the last year. Seventy-one percent of pharmacists in this study reported believing males should be allowed to purchase EC. However, fewer pharmacists approved of males purchasing emergency contraception in advance to have on hand (46%). Very few (4%) reported refusing to sell EC to males.[9] Unfortunately this study did not report customer age.

A study in New York identified five out of 36 pharmacies visited asked male purchasers for detailed information about the intended user of the medication before allowing sale. Two pharmacists asked that the woman planning to use the medication must be present along with identification.[10] Such restricted access is not in line with the FDA guidelines for over-the-counter emergency contraception provision and impedes timely access to effective EC use.

Over the past two years, the American Civil Liberties Union has documented several cases of men being refused EC at pharmacies based on their gender.[11] An in-person mystery shopper effort by teens participating in the Teen Outreach Reproductive Challenge project of the National Institute for Reproductive Health earlier this year also found refusals based on gender in a small pilot study of New York City independent pharmacies in three neighborhoods. While this study was not solely focused on EC access for males, they did find that male mystery shoppers were more likely to be refused than female shoppers.[12]

While prescription to males might be possible in the future using a structure similar to expedited partner therapy for sexually transmitted infections (STIs), for now, clinicians can only provide adolescent males under 17 with counseling and information. Educating young men about emergency contraception as well as ongoing contraceptive methods allows them to be active participants in efforts to prevent unintended pregnancy.

Additionally, encouraging dual use of hormonal contraception and condoms provides both partners with the best protection against pregnancy and STIs.

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Concern is growing for UTI antibiotic resistance

Check your last 10 patient charts. Chances are at least one patient reported a urinary tract infection (UTI). What was your chosen method of treatment?

Such infections are among the most common problems encountered by women's health clinicians. The estimated lifetime risk for experiencing a UTI is above 60% in women, and

uncomplicated UTIs are one of the most common reasons for antibiotic use among otherwise healthy women.[1,2]

Just-presented research from Oregon State University in Corvallis suggests that more powerful antibiotics are used more frequently than necessary for treatment of such infections.[3] The Oregon scientists recommend that healthcare providers and patients discuss the issues involved with antibiotic therapy and look to use of stronger drugs only if necessary.

To analyze national trends of antibiotic prescribing for cystitis, Oregon researchers looked at 1998-2009 data from the National Ambulatory Medical Care Survey and the National Hospital Ambulatory Medical Care Survey, both nationally representative surveys of ambulatory and emergency department visits. Focusing on women above age 17, investigators examined trends in rates of cystitis visits and related antibiotic prescribing, and they used tests for trends.

Their analysis shows that annual rates for cystitis visits were stable ($p = 0.45$) between 1998 and 2009, with an average of 195 visits per 1,000 women. During this period, however, researchers report the proportion of visits with receipt of an antibiotic significantly increased.

Prescribing of first-line urinary anti-infectives such as trimethoprim/sulfamethoxazole, trimethoprim, fosfomycin, and nitrofurantoin remained constant ($p = 0.10$), yet quinolone use grew significantly ($p < 0.01$).

Overuse of the most powerful drugs, especially quinolone antibiotics, speeds the development of bacterial resistance to these drugs, say experts. Antibiotic resistance has gained global prominence with methicillin-resistant Staphylococcus aureus (MRSA), but resistance is a similar concern in many other bacteria as well.

"Because of higher levels of antibiotic resistance to older drugs in some regions, some doctors are now starting with what should be their second choice of antibiotic, not the first," said **Jessina McGregor**, PhD, assistant professor of pharmacy at the university in a statement accompanying the research findings. "We need to conserve the effectiveness of all these anti-infective medications as best we can."

Check guidance for use

The American College of Obstetricians and Gynecologists (ACOG) and the Infectious Diseases Society of America (IDSA) have issued guidance on antibiotic use for uncomplicated UTI treatment. ACOG released its guidance in 2008, with the IDSA recommendations published in 2011.[2,4]

Appropriate treatments listed by ACOG and IDSA include: trimethoprim/sulfamethoxazole (160/800 mg tablet twice daily for three days; not recommended in areas where local resistance rates exceed 20%); nitrofurantoin monohydrate/macrocrystals (100 mg twice daily for five days); and fosfomycin trometamol (3 g powder single dose). ACOG also recommends trimethoprim alone (100 mg, twice daily for three days).[5]

According to the ACOG guidance, trimethoprim/sulfamethoxazole for three days is the preferred therapy. The IDSA guidance does not designate any of the four antimicrobials it recommends as preferred; however, it does note that fosfomycin has lower efficacy than other recommended agents.

While fluoroquinolones are highly effective in three-day regimens, drug resistance is increasing, and overuse will hinder fluoroquinolones' effectiveness against more important infections. The ACOG guidance advises against prescribing fluoroquinolones as first-line agents in areas where resistance prevalence to trimethoprim/sulfamethoxazole is low. *(Look at ResistanceMap [www.cddep.org/resistancemap], a web-based collection of tools developed by the Washington, DC-based Center for Disease Dynamics, Economics & Policy, that allow exploration of more than 50 antimicrobial surveillance indicators from North America and Europe.)* The IDSA recommendations call for fluoroquinolone use for acute cystitis only if a recommended antimicrobial cannot be used due to factors such as availability, allergy history, or tolerance.[5]

EXECUTIVE SUMMARY

Just-presented research from Oregon State University in Corvallis suggests that more powerful antibiotics are used more frequently than necessary for treatment of uncomplicated urinary tract infections.

- An analysis of nationally representative surveys of ambulatory and emergency department visits shows that annual rates for cystitis visits were stable between 1998 and 2009; however, visits with receipt of an antibiotic significantly increased. Prescribing of first-line urinary anti-infectives remained constant, yet quinolone use grew significantly.
- Overuse of the most powerful drugs, especially quinolone antibiotics, speeds the development of bacterial resistance to these drugs, say experts.

Tools in development

Oregon State University researchers are developing tools to help clinicians select the most appropriate antibiotic for individuals. Until they are available, providers can help select appropriate treatments for their patients by obtaining a detailed history of past medication use, becoming informed of local community levels of resistance, and improving levels of patient communication.

Cystitis is one of the most common reasons that many women see a doctor and are prescribed an antibiotic, noted McGregor. That is the reason that researchers are sounding the alarm on antibiotic resistance.

"Any infection can be serious if we don't have medications that can help stop it, which is why we need to preserve the effectiveness of all our antibiotics as long as we can," she stated.

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COMING IN FUTURE MONTHS

- ■ Prevention strategies for chlamydia re-infection
- ■ Check drug interactions with contraceptives
- ■ Contraception screening: What's needed, and what's not
- ■ How to diagnose & manage vaginitis

CNE/CME Objectives & Instructions

To earn credit for this activity, please follow these instructions.

1. Read and study the activity, using the provided references for further research.
2. Log on to www.cmecity.com to take a post-test; tests can be taken after each issue or collectively at the end of the semester. First-time users will have to register on the site using the 8-digit subscriber number printed on their mailing label, invoice or renewal notice.
3. Pass the online tests with a score of 100%; you will be allowed to answer the questions as many times as needed to achieve a score of 100%.
4. After successfully completing the last test of the semester, your browser will be automatically directed to the activity evaluation form, which you will submit online.
5. Once the completed evaluation is received, a credit letter will be e-mailed to you instantly.

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.

CNE/CME QUESTIONS

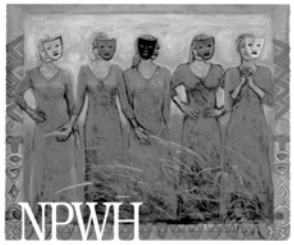
1. What two methods possess the highest rates of patient satisfaction and continuation of all available reversible contraceptives?
   A. Intrauterine device and implant
   B. Oral contraceptives and contraceptive injection
   C. Progestin-only pills and contraceptive vaginal ring
   D. Male condoms and contraceptive patch

2. What class of drug is ulipristal acetate?
   A. Receptor full agonist
   B. Selective progesterone receptor modulator
   C. Full antagonist
   D. Inverse agonist

3. What are two common screenings for ovarian cancer?
   A. Pap test and testing with CA-125
   B. Transvaginal ultrasound and endometrial sampling
   C. Transvaginal ultrasound and testing with CA-125
   D. Pap test and endometrial sampling

4. What is NOT a first-line recommended drug for treatment of uncomplicated urinary tract infection?
   A. Trimethoprim/sulfamethoxazole
   B. Nitrofurantoin monohydrate/macrocrystals
   C. Fosfomycin trometamol
   D. Fluoroquinolones

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 healthcare professionals.



S·T·I
QUARTERLY

Initiative for HIV vaccine research funded — Quest for a shot persists

Federal monies designed to accelerate vaccine development

Is development of a HIV vaccine still important with such established HIV prevention approaches as male and female condom use, voluntary medical male circumcision, and pre-exposure prophylaxis (PrEP) now in place to limit exposure to HIV and reduce infectiousness?

Federal public health officials say "yes." The National Institute of Allergy and Infectious Diseases (NIAID) has awarded $31 million in first-year funding to Duke University in Durham, NC, and the Scripps Research Institute in La Jolla, CA, as leaders of the new Centers for HIV/AIDS Vaccine Immunology & Immunogen Discovery (CHAVI-ID). The initiative is designed to accelerate HIV vaccine development.

"In recent years, considerable progress has been made in identifying antibodies that can prevent a broad range of HIV strains from infecting human cells," said **Anthony Fauci**, MD, NIAID director, in a release accompanying the announcement. The initiative is aimed at understanding how such antibodies and other immune responses work to protect against HIV infection, thereby aiding scientists to design an effective HIV vaccine, he noted.

The initiative is projected to receive up to $186 million or more over the next six years. By supporting multidisciplinary research into immune responses that prevent or contain HIV infection and generating model vaccine components that can induce these protective immune responses, scientists hope to accelerate HIV vaccine development.

Vaccine discovery and development takes time and money. An estimated $845 million was expended globally in 2011 alone.[1] However, leaders from across the spectrum of HIV research who attended the September 2012 AIDS Vaccine 2012 Conference unanimously agreed on the need to continue the quest for an HIV vaccine. **Myron Cohen**, MD, director of the Institute for Global Health & Infectious Diseases at the University of North Carolina at Chapel Hill, said, "We recognize that suppressive treatment of HIV infection drastically reduces the probability of onward HIV

EXECUTIVE SUMMARY

The National Institute of Allergy and Infectious Diseases has awarded $31 million in first-year funding to Duke University in Durham, NC, and the Scripps Research Institute in La Jolla, CA, as leaders of the new Centers for HIV/AIDS Vaccine Immunology & Immunogen Discovery.

- By supporting multidisciplinary research into immune responses that prevent or contain HIV infection and generating model vaccine components that can induce these protective immune responses, scientists hope to accelerate HIV vaccine development.
- While suppressive treatment of HIV infection reduces the probability of onward HIV transmission, the need remains for an effective HIV vaccine, public health officials state.

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transmission, which should eventually slow the spread of HIV, but the urgent and widespread treatment of HIV is not a substitute for a preventive vaccine. We need an HIV vaccine."

According to the Joint United Nations Program on HIV/AIDS, about 34.2 million people were living with HIV/AIDS in 2011, and the rate of new HIV infections continues to exceed 7,100 per day.[2] In the United States, approximately 50,000 Americans become infected with HIV each year.[3]

Focus on immune factors

Duke University will receive $19.9 million in the first year for its role in the new program. Led by **Barton Haynes**, MD, director of the Human Vaccine Institute in the Department of Medicine at the university, the Duke team's work will focus on inducing broadly neutralizing antibodies that can prevent HIV-1 infection, as well as on generating protective T cell and innate immune system responses.

One strategy researchers will deploy is the evaluation of maturation pathways of broad neutralizing antibodies as they arise. The scientists will use these pathways as roadmaps for candidate vaccines to stimulate protective antibody responses. The program will encompass nine components: operations and management, genomics, lineage-based structural design, B-cell biology, neutralizing antibody development and sequencing, mucosal biology, virus biology, computational biology, and nonhuman primate testing.

The work will extend the work of Duke University's original Center for HIV/AIDS Vaccine Immunology consortium, whose federal funding grant ended in June 2012. Haynes led the initial group. "We were privileged to have the grant over the past seven years, and the work in this consortium helped us understand what needed to be done to make a successful AIDS vaccine," said Haynes, who also serves as director of the Duke Human Vaccine Institute and is a Frederic M. Hanes professor of medicine and immunology. "The CHAVI-Immunogen Discovery grant will be used to learn how to do what we need to do."

Antibodies, B cells eyed

The team based at Scripps Research Institute will conduct research on antibodies and B cells, the cells that make antibodies. This work will guide the development of immunogens (substances that evoke an immune response) that are capable of eliciting protective antibodies to HIV. Researchers also will focus on studying CD4+ T cells in an attempt to harness the cells' direct antiviral activity, as well as their ability to help B cells produce antibodies.

Researchers at Emory University in Atlanta also are working with the Scripps team. They are looking to understand the mechanisms of Tfh cell generation after immunization with HIV envelope (ENV) proteins and are identifying adjuvants that can enhance these T helper cells and also induce potent responses by B cells.

Five components are included in the Scripps program: operations and management, glycobiology (the study of the structure, biosynthesis, and biology of carbohydrates), nonhuman primate testing, concept-to-clinic discovery, and data management. The award provides an initial $11.1 million to the institute for the first year of work.

"We will work toward an HIV vaccine based on a deep understanding of the critical attributes of immune responses that provide protection against AIDS viruses, through these two focused and highly integrated efforts," said Scripps Research Professor **Dennis Burton**, PhD, who will head the La Jolla, CA, initiative. Burton also serves as scientific director of the International AIDS Vaccine Initiative's Neutralizing Antibody Center, at the Scripps Research Institute campus, and program leader at The Ragon Institute of Massachusetts General Hospital, Massachusetts Institute of Technology, and Harvard University, located in Charlestown, MA.

More research to do

Just one vaccine trial is under way. The HVTN 505 study began in 12 U.S. cities in June 2009 with NIAID sponsorship and funding. It is being conducted by the HIV Vaccine Trials Network (HVTN). The trial is testing a combination of experimental vaccines in men who have sex with men and transgender women in the United States. The trial is testing the safety and efficacy of a two-part HIV vaccine regimen consisting of one vaccine designed to prime the immune system, followed by another vaccine designed to boost the immune response. *(*Contraceptive Technology Update *reported on the trial. See "New research may boost AIDS vaccine research," October 2010, p. 118.)*

Additional studies are in the planning stages, including three studies to pursue improvement on the RV144 results in South Africa and Thailand; however, these are not likely to begin before 2014. The RV144 study, a six-year clinical trial, was the first to produce evidence of an HIV vaccine that showed some protective effect against HIV infection.[4] The trial was sponsored by the Surgeon General of the United States Army and conducted by the Thailand Ministry of Public

Health, with support from the United States Army Medical Research and Materiel Command and NIAID. *(*CTU *reported on the results in its* STI Quarterly *supplement. See "HIV vaccine update: Progress made, but more work is left to do in research," December 2009, supplement 1.)*

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HPV shot safety affirmed in teens, young women

New data confirms the safety of the quadrivalent human papilloma virus (HPV4) vaccine.[1] Results of the large study indicate that immunization was associated only with same-day syncope and skin infections in the two weeks after vaccination, similar to previous findings.[2]

"I think there are two important findings in this study," says **Kevin Ault**, MD, professor of gynecology and obstetrics at Emory University in Atlanta. "It is a post marketing study, so it is a 'real world' report of vaccine safety after widespread use of the HPV4 vaccine, [and] it is reassuring, as other HPV4 vaccine safety reports have been."

EXECUTIVE SUMMARY

New data confirms the safety of the quadrivalent human papilloma virus (HPV4) vaccine. Results of the large study indicate that immunization was associated only with same-day syncope and skin infections in the two weeks after vaccination, similar to previous findings.

- Immunization and injections in general have a known association with syncope, particularly in young women.
- Prior data suggests that increased fainting occurs among females 13 years and older after receiving any vaccine.
- To avoid serious injury related to a syncopal episode, vaccine providers should consider observing patients for 15 minutes after they receive the HPV shot.

The study was conducted within the Northern and Southern California Kaiser Permanente integrated healthcare delivery systems. It included 189,629 females who received one or more doses of the vaccine between August 2006 and March 2008. More than 99% of the females were between ages 9-26 when they received the first shot, with approximately half between the ages of 9-15 at first dose.[1] Investigators designed the study to compare the risk of emergency department visits and hospitalizations during post-vaccination intervals of 1-60 days, 1-14 days, and day 0 (day of vaccination), with control intervals ranging from 60 days for those who received one dose of the quadrivalent vaccine to 180 days for those who received three doses.

What were the outcomes?

"Taking into account all the analyses, sub-analyses and relevant medical record reviews, an independent safety committee noted that there may be an association between HPV4 vaccination and same-day syncope, as well as skin infections during the two weeks after immunization," says lead author **Nicola Klein**, MD, PhD, co-director and research scientist at the Kaiser Permanente Vaccine Study Center in Oakland, CA.

The association between the quadrivalent vaccine (Gardasil, Merck & Co., West Point, PA) and syncope was not unexpected, investigators state. Immunization and injections in general have a known association with syncope, particularly in young women. *(*Contraceptive Technology Update *reported on this finding; see "Updated guidance issued on use of HPV vaccines," August 2010, p. 93.)*

The study also detected an association between the vaccine and skin infections in the two weeks following shot administration. "Medical record review suggested that some cases may have been local injection site reactions; however, females who received HPV4 sought increased clinical care for skin conditions following vaccination," the investigators note.

That the study detected two potentially expected outcomes provides reasonable reassurance that it was a valid approach to uncovering HPV4-associated safety signals, Klein notes. The findings substantiate the overall safety of the HPV4 vaccine in women and girls following routine administration, she states.

As noted in the current research, prior data suggests that increased fainting occurs among females 13 years and older after receiving any vaccine.[3] To avoid serious injury related to a syncopal episode, vaccine providers should con-

sider observing patients for 15 minutes after they are vaccinated.[4] *(*CTU *reported on fainting episodes associated with vaccine administration; see "Research supports safety of HPV vaccine," May 2009, p. 56.)*

The 15-minute time period is suggested by the Centers for Disease Control and Prevention (CDC) for all vaccines, notes Ault. Clinicians should make patients wait 15 minutes after they have received any vaccine to leave the office, Ault states.

Who gets the shot?

Be sure your office is identifying potential candidates for HPV vaccination. The Food and Drug Administration approved the quadrivalent HPV vaccine in 2006 for females between ages 9-26 for prevention of a range of diseases attributed to HPV. The vaccine later was approved to protect boys and men against the HPV types that cause most genital warts and anal cancers.

The CDC recommends the HPV vaccine for all boys ages 11 or 12 and for males through age 21 who have not already received all three doses. It also is recommended for gay and bisexual men (or any man who has sex with men) and men with compromised immune systems (including HIV) through age 26, if they did not receive full vaccination at a younger age. The vaccine is safe for all men through age 26, but it is most effective when given at younger ages, according to the CDC.

The Advisory Committee on Immunization Practices voted in 2011 to recommend that males be routinely vaccinated against HPV, a move many public health officials hailed as a potential boost for use of the shot. *(To read about the recommendation, see "Finally! HPV male shot routinely recommended," January 2012, p. 6.)*

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Make plans to attend workshop on HIV & women

Toronto, Canada is the site for the third International Workshop on HIV & Women. The conference will be held Jan. 14-15 at the Fairmont Royal York Hotel.

The January event will provide a platform for international scientific exchange on the increasingly recognized problems of HIV and women. The workshop will gather a cross-disciplinary team of research experts and trainees to present and discuss the latest developments and strategies for the future in an interactive and science-focused setting.

Program presentations of interest to family planners will include contraception and risk of HIV acquisition, contraception and risk of HIV transmission, contraception and risk of HIV progression, and drug interactions with contraceptives. Abstracts will cover such topics as designing and implementing treatment programs for HIV-infected women; HPV screening, treatment, and vaccines; and the impact of HIV drug resistance on optimal management of women.

Online registration for the event will be open until Dec. 31. Individuals wishing to register after that date will need to do so at the workshop. To register for the event, go to http://bit.ly/S1xWtf. ■

Register now: ARHP to hold contraception webinars

The Association of Reproductive Health Professionals (ARHP) is hosting a series of free continuing medical education webinars on the latest contraceptive technologies in development and soon-to-be-released birth control methods.

The first webinar will be presented Dec. 13 by Laneta Dorflinger, PhD, distinguished scientist and vice president at FHI 360, a Durham, NC-based nonprofit human development organization. The second webinar will be presented Jan. 16 by Grace Shih, MD, MAS, health sciences assistant clinical professor at the University of California, San Francisco School of Medicine.

Registration is free, but space is limited. Each webinar will be recorded for on demand access and will be available in the ARHP archive library 10 days post presentation. To register for a webinar, visit www.arhp.org/new. ■

CONTRACEPTIVE TECHNOLOGY UPDATE®

A Monthly Update on Contraception and Sexually Transmitted Diseases

2012 Index

When looking for information on a specific topic, back issues of Physician Risk Management *might be useful. If you haven't already activated your online subscription so that you can access the newsletter archives through the company web site, go to www.ahcmedia.com and click on "Activate Your Subscription" on the right side of the page. Or contact our customer service department at P.O. Box 105109, Atlanta, GA 30348. Phone: (800) 688-2421 or (404) 262-5476. Fax: (800) 284-3291 or (404) 262-5560. E-mail: customerservice@ahcmedia.com.*

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