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IN THIS ISSUE

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Media reports on OC studies raise flags: How to advise patients?

Evidence supports that the Pill is a safe, effective contraceptive

Has the telephone been ringing in your office with questions from patients who are concerned about using oral contraceptives in light of media reports questioning the Pill's safety? If so, you are not alone. What are you doing to help women place such news in proper context?

The first flurry of media activity came with the publication of a study linking oral contraceptive use and increased risk of cervical cancer.[1] More media reports were issued with the presentation of a paper at a recent American Heart Association (AHA) conference which indicated that long-term use of oral contraceptives might increase arterial plaque that can raise the risk of heart disease.[2] News from the AHA conference was widely disseminated, with all three major networks reporting on the paper.

The Association of Reproductive Health Professionals (ARHP) has compiled basic talking points to help clinicians address patient concerns. **[The talking points are available with the online issue of *Contraceptive Technology Update*. If you're accessing your online account for the first time, go to www.ahcmedia.com. Click on the "Activate Your Subscription" tab in the left-hand column. Then follow the easy steps under "Account Activation." If you already have an online subscription, go to www.ahcmedia.com. Select the tab labeled "Subscriber Direct Connect to Online Newsletters. Please select an archive." Choose "Contraceptive Technology Update," and then click "Sign on" from the left-hand column to log in. Once you're signed in, select "2008" and then select the January 2008 issue. For assistance, call Customer Service at (800) 688-2421.]**

"The ARHP community is committed to evidence-based medicine, and misinterpretations of clinical research and sensationalized reporting can have a negative impact on public health," states a letter cosigned by **Beth Jordan**, MD, medical director, and **Wayne Shields**, president and CEO.

The Planned Parenthood Federation of America (PPFA) also has

issued guidance for its affiliates in light of the AHA presentation. The PPFA and ARHP guidance are designed to help clinicians discuss the benefits and risks of oral contraceptive (OC) use with their patients.

"Our message is to communicate to our patients that their health and safety are our top priorities and that the Pill continues to be a safe, effective method of birth control," says the PPFA.

Is Pill use a heart risk?

The paper presented at the AHA conference found that women who use the Pill for 13 years or more had an unexpected increase in the presence of artery-clogging plaque in blood vessels found in the neck and leg. The study also found that women who stopped using the Pill were at increased risk for more plaque.

While in theory, an increase in plaque may mean a higher rate of stroke or heart attack, no existing, scientifically sound studies of oral contraceptive users have shown any excess cases of stroke or heart attack than among low-dose oral contraceptive users, advises the PPFA. Of the myriad oral contraceptive studies done in the past, none has found that the Pill is associated with increased risk of heart disease after pill discontinuation, the PPFA guidance states.

To place the rare risks of heart attack and stroke among OC users in perspective, the PPFA presents the following statistics:

- For nonsmoking women in their 20s who are not on oral contraceptives, the risk of heart attack is 0.01 per 100,000 woman-years of use, and the risk of stroke is 1.9 per 100,000 woman-years of use.
- For nonsmoking women in their 20s who are taking oral contraceptives, the risk of heart attack is 0.02 per 100,000 woman-years of use, and the risk of stroke is 2.2 per 100,000 woman-years of use.
- For smokers in their 30s who are not on oral contraceptives, the risk of heart attack is 1.4 per 100,000 woman-years, and the risk of stroke is 6.8 per 100,000 woman-years.
- For smokers in their 30s who are taking oral contraceptives, the risk of heart attack is 2.04 per 100,000 woman-years, and the risk of stroke is 10.2 per 100,000 woman-years.

The bottom line is that the baseline expected number of events is very small among oral contraceptive users, states the PPFA. Smoking and advancing age are all larger risk factors than oral contraceptive use. No study has shown an increase in these baseline expected numbers of serious cardiovascular events, states PPFA.

Neither providers nor patients should change their behaviors with respect to oral contraceptives in light of this new data, adds PPFA.

"Researchers have told the media that more data is needed and that women and providers should

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Editorial Questions

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not panic," states the guidance. "Instead, women should speak with their health care providers about their risk factors for heart disease and pay close attention to modifying the big risk factors for cardiovascular disease, such as smoking, uncontrolled hypertension, obesity, high cholesterol, and poorly managed diabetes mellitus."

OCs: cervical cancer risk?

Information on a possible link between OC use and cervical cancer risk comes from analysis of data from 24 worldwide studies.[2] Among current users of oral contraceptives, the risk of invasive cervical cancer increased with increasing duration of use, results suggest. The analysis showed relative risk for five or more years' use vs. never use at 1.90 (95% confidence interval 1.69-2.13). The risk declined after use ceased, and by 10 or more years, had returned to that of never users, the analysis indicates. A similar pattern of risk was seen for invasive and in-situ cancer, and in women who tested positive for high-risk human papillomavirus. Relative risk did not vary substantially between women with different characteristics.

Analyses performed in the new publication were routinely stratified by age at first intercourse (younger than 18 years, 18-20 years, and 21 years or older), number of full-term pregnancies (zero, 1-2, 3-4, and five or more), lifetime number of sexual partners (one, 2-5, and six or more), smoking (never, past, and current), and screening status (ever or never likely to have had a previous Pap smear). Those with missing information on any of these adjustment factors were assigned to a separate stratum for the relevant variable; sensitivity analyses were done excluding women or studies with missing adjustment variables, the researchers state.[1]

What should clinicians take away from this research? According to the ARHP, the study shows that long term use of oral contraceptives (more than five years) is associated with an increased risk of cervical cancer. The study also reports that when a woman stops taking oral contraceptives, her risk fades over time and returns to normal after 10 years, notes the ARHP.

In comparison, the benefits of oral contraceptives have been widely documented, states the ARHP. For example, women who use OCs for 10 or more years have a significant decrease in risk of ovarian and endometrial cancer. "While this study shows a slight increased risk of cervical cancer, the risk is still very low," states the ARHP. "An increase in the incidence of a rare event remains a rare event."

Advise women who are concerned about the risks for cervical cancer to use condoms, consider human papillomavirus (HPV) screening and HPV vaccine, obtain regular Pap smears, and avoid smoking, the ARHP guidance states.

Use peer-reviewed curricula on cervical cancer and understanding risk associated with hormonal contraception developed by the ARHP. The association offers two online resources, *Managing HPV: A New Era in Patient Care* and *You Decide: Making Informed Health Choices about Hormonal Contraception*, which are both available at no cost at the ARHP web site, www.arhp.org.

References

1. International Collaboration of Epidemiological Studies of Cervical Cancer. Cervical cancer and hormonal contraceptives: Collaborative reanalysis of individual data for 16,573 women with cervical cancer and 35,509 women without cervical cancer from 24 epidemiological studies. *Lancet* 2007; 370:1,609-1,621.

2. Rietzschel E, De Buyzere M, De Baquer D, et al. Anticonceptive drug use and increased carotid and femoral plaque prevalence: Population data from Asklepios. Presented at the American Heart Association conference. Orlando, FL; November 2007. ■

Progress reported on male contraceptives

While women have several options when it comes to birth control, men are limited to condoms and vasectomies. Researchers around the globe are focusing efforts to expand those choices, including hormonal injections, gels, and implants.

More than 100 investigators took part recently in the second "Future of Male Contraception" conference. The conference was sponsored by the National Institute of Child Health and Human Development (NICHD), CONRAD, the World Health Organization, and the University of Washington.

Since the last conference, there is a resurgence of energy emanating from the new male contraceptive research centers funded by the NICHD, says **Elaine Lissner**, director of the Male Contraception Information Project. Such funding from government and nonprofit sectors is imperative to male contraceptive research, because pharmaceutical

EXECUTIVE SUMMARY

More than 100 investigators took part in the recent "Future of Male Contraception" conference.

- Options now under review are an alternative to vasectomy, the Intra Vas Device, as well as hormonal approaches.
- Results of an online survey indicate men would use a new male contraceptive. Current contraceptive options are not appealing to many men: 43% of male respondents reported they would not be willing to have a vasectomy even if they did not want children.

companies have earmarked little funding for such investigation, she says. "I wouldn't so much say that the field has grown in the past three years; rather, I would say it has been rejuvenated, at a time when science research is being cut left and right, and the foundation has been laid for continued progress in the coming years," says Lissner.

Investigators are looking at several options when it comes to male contraception. Some of the avenues now under research include:

• **The Intra Vas Device (IVD)**, a vasectomy alternative under development by Shepherd Medical Company in Minneapolis. The IVD method relies on soft, hollow silicone plugs that are implanted in each vas deferens. Each plug is anchored to the vas wall with a tiny suture. The device can be inserted by any no-scalpel vasectomy provider and does not require extensive additional training. ***(Contraceptive Technology Update* reported on the device in the article, "Male contraceptive options in the pipeline," August 2006, p. 91.)** Preliminary results from a recent study show that after six months, 92% of the study participants had no sperm or almost no sperm.[1] The next step will be to find funding for long-term studies of effectiveness and fertility return.

• **BMS189453**, a retinoic acid receptor antagonist. Columbia University scientists are looking at an investigative drug that had been abandoned in previous research due to its interference with vitamin A receptors in the testes. Initial tests in mice by the Columbia research team indicate the drug works with no other health effects.[2] Toxicology data in rats and rabbits, which were performed at much higher doses during the drug's initial development, indicate there should be no adverse side effects in humans. Further research will need to be performed to prove this line of inquiry, say the Columbia researchers.

• **Testosterone gel and depot medroxyprogesterone acetate (DMPA)**. Researchers from the University of Washington are examining a hormone regimen based on two products already available on the market: testosterone gel, marketed for men with low testosterone, plus DMPA, a contraceptive injection used in women. To perform the study, men received a DMPA injection once every three months and applied the testosterone gel on a daily basis. While the therapy achieved successful suppression of spermatogenesis, participants in the study had varied responses to the treatment. Six of 44 men dropped out of the study; the remaining were divided in opinion. Half said they were satisfied or very satisfied, one-third were dissatisfied or very dissatisfied, and the rest were undecided or had mixed feelings.[3]

What is the next step in research? The researchers are proposing an all-gel approach by using a testosterone gel along with a nestorone gel, reports **John Amory**, MD, MPH, associate professor of medicine in the Division of General Internal Medicine at the University of Washington.

• **Oral administration of testosterone enanthate (TE)**. University of Washington researchers are looking at coadministration with dutasteride to increase the efficacy of oral TE. Results of one study indicate a significant suppression of follicle stimulating hormone (FSH), but poor luteinizing hormone (LH) suppression.[4] Researchers are considering nano-milled oral testosterone preparations for a male hormonal contraceptive.

Will men use it?

Robert Hatcher, MD, MPH, professor of gynecology and obstetrics at Emory University School of Medicine in Atlanta, is not overly excited about the news in the area of male contraception. His opinion? The two best — or close to best — contraceptives ever developed have been available since 1900: vasectomy and condoms. Vasectomy, after several negative semen analyses, approaches 100% effectiveness, but in only four nations in the world (New Zealand, the United Kingdom, the Netherlands, and Bhutan) do more men have vasectomies than there are women who obtain tubal sterilizations, says Hatcher.

"Condoms, a method that is 90% effective against HIV transmission, are used by well under 20% of couples at risk for transmitting HIV," Hatcher points out. "We've had excellent methods of birth control for men, and men simply do not step up to

the plate and use them."

Results from an online survey of 1,930 men and women show that some men may be ready to change their ways if a new method is presented.[4] The survey included responses gathered September 2006 to September 2007 during visits to the web site www.MaleContraceptives.org. Three-quarters of the respondents identified themselves as male, with 25% as female. Most respondents were of reproductive age (97%) and lived in the United States, Canada, or the United Kingdom.

Most male respondents said they would use a new male contraceptive. Two-thirds of men indicated enthusiasm about using any new male contraceptive, while one-third were interested in a particular contraceptive. More than half (61%) of the men said they would like to see a systemic nonhormonal drug as their first or second choice of mechanism.

Current contraceptive options are not appealing to many of the men: 43% of male respondents reported they would not be willing to have a vasectomy even if they did not want children. One-third of the men said their motivation for wanting new contraceptive options comes from a desire to share the burden of family planning with their partner.[4]

"We've seen today that the pipeline is full — everything from new targets to actual human trials," says **Kirsten Thompson**, director of the International Male Contraception Coalition. The demand is there, she maintains. "Hundreds of men have voiced their opinion on our web site and in surveys, so it's just a question of whether policymakers act on that demand," Thompson says.

References

1. Boelter C, Cline K, Stein DG, et al. Preliminary results of a clinical evaluation of the Intra Vas Device. Presented at the Future of Male Contraception conference. Seattle; September 2007.

2. Chung SSW, Reczek PR, Wolgemuth DJ. Retinoic receptor alpha inhibitor as a contraceptive: RAR antagonists testicular toxins or new and novel male contraceptives? Presented at the Future of Male Contraception conference. Seattle; September 2007.

3. Page ST, Amory JK, Kalhorn TF, et al. Testosterone gel plus depot medroxyprogesterone acetate is effective for male contraception but residual intratesticular androgens do not explain treatment failure. Presented at the Future of Male Contraception conference. Seattle; September 2007.

4. Amory JK, Kalhorn TF, Page ST. Pharmacokinetics and pharmacodynamics of oral testosterone enanthate in oil plus dutasteride for four weeks in normal men: Implications for male hormonal contraception. Presented at the Future of Male Contraception conference. Seattle; September 2007. ■

Drug interactions and OCs — Base decisions on facts

Do you still recommend that women use backup contraception when prescribed antibiotics during oral contraceptive use? If you do, it's time to check your approach, according to information presented at the *Contraceptive Technology* conference.[1]

There is no evidence that shows that antibiotics will reduce estrogen and progestin in a clinically significant way or increase pregnancy rates, says **Michael Policar**, MD, MPH, associate clinical professor in the department of obstetrics, gynecology and reproductive sciences at the University of California San Francisco. Policar presented information at the 2007 *Contraceptive Technology* Quest for Excellence conference in Atlanta.

"In the absence of pharmacokinetic, observational or epidemiological data, it is no longer accepted that an interaction between antibiotics and OCs exists," he notes.

In hormonal contraceptive users taking a short or long course of antibiotics, there is no evidence-based reason to routinely recommend backup contraception or a change to a more effective method, says Policar. If a woman is informed of a potential interaction, the extremely low magnitude of risk must be stressed. Pregnancies that occur in women using both hormonal contraceptives and antibiotics are due to other factors, he adds.

Robert Hatcher, MD, MPH, professor of

EXECUTIVE SUMMARY

Clinicians need to check for "red-flag" medical conditions to determine potential drug interactions with oral contraceptives (OCs), including seizure disorder/epilepsy, tuberculosis, skin and nail fungal infections, depression (use of St. Johns wort), and HIV infection.

- There is no evidence that antibiotics will reduce estrogen and progestin levels in a clinically significant way or increase pregnancy rates in women who use OCs.
- With anti-epileptic drugs (AEDs), certain enzyme-inducing drugs can reduce hormonal contraceptive efficacy by increasing the secondary metabolism of estrogen and progestin by induction of CYP450 enzymes and increasing sex hormone binding globulin. The risk of ovulation is more dependent on reduction in the progestin level than the estrogen level.

gynecology and obstetrics at Emory University School of Medicine in Atlanta, offers the following case study when it comes to OC use and drug interactions:

A 23-year-old woman has had a history of seizures and depression. She has a serious problem with drugs and alcohol. She is on carbamazepine and topiramate (Topamax, Ortho-McNeil Neurologics; Titusville, NJ), as well as oral contraceptives. She became pregnant during the last cycle of a stormy relationship. She is in her first trimester.

Look for these types of "red-flag" medical conditions when it comes to potential drug interactions, says Policar. Such conditions include seizure disorder/epilepsy, tuberculosis, skin and nail fungal infections, depression (use of St. John's Wort) and HIV infection.

With anti-epileptic drugs (AEDs), certain enzyme-inducing drugs can reduce hormonal contraceptive efficacy by increasing the secondary metabolism of estrogen and progestin by induction of CYP450 enzymes and increasing sex hormone-binding globulin (SHBG), which decreases free progestin. The risk of ovulation is more dependent on reduction in the progestin level than the estrogen level. Enzyme-inducing AEDs include: carbamazepine (Tegretol), felbamate (Felbatol, MedPointe Pharmaceuticals; Somerset, NJ), lamotrigine (Lamictal, GlaxoSmithKline), oxcarbazine (Trileptal, Novartis), phenobarbital (generic), phenytoin (Dilantin, Pfizer; New York City), and topiramate (Topamax, Ortho-McNeil).[2]

Look for use of AED drugs beyond treatment of seizures, says Policar. For example, carbamazepine is now used for treatment of trigeminal neuralgia, schizophrenia, and bipolar disorder, while topiramate is being used in treatment of migraines, bipolar disorder, and obesity.

Pills are so complex, notes Hatcher. While the patient in the case study above may have understood that the AED drugs she was taking might cause birth defects, she did not understand that they may also make her oral contraceptive less effective. The woman opted to have an abortion and chose a more effective birth control method. Such options would include intrauterine contraception (Mirena, Bayer HealthCare Pharmaceuticals; Wayne, NJ, and ParaGard, Barr Pharmaceuticals, Pomona, NY) and the contraceptive injection depot medroxyprogesterone acetate (DMPA; Depo Provera, Pfizer.)

Look for use of rifampin (generic) and rifampin-containing drugs [Rifadin (Sanofi-Aventis; Bridgewater, NJ); Rimactane (Novartis); Rifamate (Sanofi-Aventis), Rifater (Sanofi-Aventis)], as well as rifapentine (Priftin, Sanofi-Aventis), commonly used in tuberculosis treatment, says Policar. These drugs are enzyme inducers. Rifampin also is being used as a treatment for methicillin-resistant *Staph aureus* (MRSA) skin infections.

Clinical recommendations for birth control for patients on rifampin for tuberculosis treatment include intrauterine contraception and DMPA. Patients on a short-term course of the drug for MRSA should use backup contraception, advises Policar.

What about women with skin and nail fungal infections? Griseofulvin (generic), once used for treatment of ringworm and nail infections, has been linked to induction of hepatic enzymes, but only insufficient, outdated data are available, says Policar. Newer antifungal drugs such as fluconazole (generic), itraconazole (generic), and ketoconazole (generic) have no hormonal drug interaction, he states.

Caution: St. John's Wort

When asking patients about drug use, don't forget to check over-the-counter drugs, says Policar. One such drug is St. John's Wort, now widely used for depression. Research shows induction of the CYP450 enzyme, comparable to rifampin and carbamazepine when given for 10 or more days.[3] Caution patients that oral contraceptive effectiveness may be reduced if St. John's Wort is used, says Policar.

How about drugs used for treatment of HIV infection? Data from a few small unpublished studies show that OC metabolism may be altered when using antiretroviral drugs; however, there are no studies of clinical effect, he notes. The World Health Organization eligibility criteria classes use of oral contraceptives in women using antiretroviral drugs, as a "2," in which the advantages of using the method generally outweigh the theoretical or proven risks.[4] Clinicians need to stay tuned for more research in this area, says Policar.

References

1. Policar MS. Drug interactions with contraceptives: EBM or urban legend? Presented at the 2007 *Contraceptive Technology* Quest for Excellence conference. Atlanta; November 2007.

2. Thorneycroft I, Klein P, Simon J. The impact of antiepileptic drug therapy on steroidal contraceptive efficacy. *Epilepsy Behav* 2006; 9:31-39.

3. Markowitz JS, Donovan JL, DeVane CL, et al. Effect of St.

John's Wort on drug metabolism by induction of cytochrome P450 3A4 enzyme. *JAMA* 2003; 290:1,500-1,504.

4. World Health Organization. *Medical Eligibility Criteria for Contraceptive Use*. Geneva: World Health Organization; 2004. ■

New information shows chlamydia's spread

It's time to increase chlamydia screening in your clinic. Results of a new study show that, despite current screening recommendations, more than 2 million people are infected with chlamydia in the United States.[1]

To perform the study, researchers affiliated with the Centers for Disease Control and Prevention (CDC) looked at the frequency of gonorrhea and chlamydia infection among 6,632 people ages 14-39 who completed a national survey. They analyzed the information to estimate the frequency of these sexually transmitted disease (STD) infections in the entire U.S. population. They examined the frequency of infection according to patient factors, such as age, sex, race, or ethnic background, and history of previous sexually transmitted infection.

The researchers estimated about two out of every 100 people have chlamydia infection, while fewer than one out of every 400 people have gonorrhea infection. Adolescents had the highest disease burden for gonorrhea and chlamydia compared with other age groups, researchers report.[1]

"The prevalence data from this study serve as a reminder that chlamydia and gonorrhea pose a serious concern to the health of Americans," says **Deblina Datta**, MD, medical epidemiologist in CDC's Division of STD Prevention. "STDs often have no symptoms and, therefore, frequently go unrecognized and undiagnosed."

EXECUTIVE SUMMARY

Results from a new study show that, despite current screening recommendations, more than 2 million people are infected with chlamydia in the United States.

- The study, which looked at gonorrhea and chlamydia rates, estimates that about two out of every 100 people have chlamydia infection, while fewer than one out of every 400 people have gonorrhea infection. Adolescents had the highest disease burden for gonorrhea and chlamydia compared with other age groups.
- All sexually active, nonpregnant women age 24 years or younger should be screened for chlamydia, according to updated guidance from the U.S. Preventive Services Task Force.

New guidance issued

A new update has been issued for the original 2001 U.S. Preventive Services Task Force (USPSTF) recommendations for screening sexually active adolescents and adults for chlamydial infection.[2,3]

What are the risks for chlamydia in women? According to the guidance, women are at risk if they have one or more of the following factors:

- They are 24 years of age or younger and are sexually active.
- They have previously had chlamydia or another sexually transmitted infection.
- They have new or multiple sexual partners.
- They do not use condoms regularly.
- They exchange sex for money or drugs.[2]

All sexually active, nonpregnant women age 24 years or younger should be screened for chlamydia, advises the current guidance. This represents a change in age from the previous USPSTF recommendation on chlamydia screening and was done to align the recommendation with the evidence in support of screening, including national surveillance data assembled by the CDC. Nonpregnant women who are age 25 years or older should be screened only if they are at increased risk for infection.[2]

All pregnant women age 24 years or younger and older pregnant women who are at increased risk for chlamydial infection should be screened, according to the new guidance. There is not enough available information to know whether men should be screened routinely for chlamydia, the guidance concludes.[2]

Better implementation of current screening and prevention efforts are critical to ensuring that young people — especially women — do not suffer the long-term effects of untreated chlamydia, says Datta.

Chlamydia screening for women is critical, she states. When left untreated in women, chlamydia can cause pelvic inflammatory disease, ectopic pregnancy, chronic pelvic pain, and infertility as long term outcomes, Datta says. In the short term, infection can cause cervicitis and urethritis, she notes. STDs such as chlamydia and gonorrhea also may increase the risk for HIV transmission, she adds.

What puts teens at risk for STDs such as chlamydia and gonorrhea? Datta points to such

likely factors as more unprotected intercourse, increased substance use, and less frequent health care-seeking behavior. Adolescent females may be more susceptible to infection due to increased ectopy of the adolescent cervix, she notes.

What are your options when it comes to boosting screening rates in your clinic? Results from a randomized trial provide evidence that use of exam room screening reminders, physician opinion leaders, and screening measurement and feedback to physicians can improve chlamydia testing rates in women making preventive care visits.[4]

Researchers randomized 23 primary care clinics, all part of the Group Health Cooperative managed care plan in Washington state, to receive standard care or intervention care. Clinic-level intervention strategies included use of clinic-based opinion leaders, who educated clinicians on screening and counseling of young women; computerized reports that provided physicians with feedback on the proportion of eligible women screened by them; and exam room reminders to screen young women ages 14-25 for chlamydia infection.

While the clinic-level intervention did not significantly affect overall chlamydia testing, testing rates increased significantly for women making preventive care visits. Screenings were increased by 23% for visits for Pap tests and by 22% for physical exam visits. Using a chart prompt to screen for chlamydia (which was delivered to a random subsample of women) had no significant effect, researchers report.[4]

A combination of clinic-level change and patient activation strategies may improve health plan-wide testing, particularly among asymptomatic women, researchers conclude.[4] **(To obtain more ideas on increasing screening rates, see *Contraceptive Technology Update*'s "Spotlight on chlamydia: Boost your screening rate in young women," August 2007, p. 85.)**

References

1. Datta SD, Sternberg M, Johnson RE, et al. Gonorrhea and chlamydia in the United States among persons 14 to 39 years of age, 1999 to 2002. *Ann Intern Med* 2007; 147:89-96.
2. U.S. Preventive Services Task Force. Screening for chlamydial infection: U.S. Preventive Services Task Force recommendation statement. *Ann Intern Med* 2007; 147:128-134.
3. Meyers DS, Halvorson H, Luckhaupt S, et al. Screening for chlamydial infection: An evidence update for the U.S. Preventive Services Task Force. *Ann Intern Med* 2007; 147:135-142.
4. Scholes D, Grothaus L, McClure J, et al. A randomized trial of strategies to increase chlamydia screening in young women. *Prev Med* 2006; 43:343-350. ■

Help women cut cancer risks with ACOG guide

The next patient in your exam room is a 35-year-old mother of three. When you talk with her about her risks for cancer, she tells you they are low, because no one in her family has had the disease. What is your next step?

This scene is familiar. Nearly two-thirds of women believe that if there is no family history of cancer, then a woman is at low risk for developing the disease, according to results of a new national survey.[1] The American College of Obstetricians and Gynecologists (ACOG) has just released a new web-based patient guide, *Protect & Detect: What Women Should Know about Cancer,* to help improve women's understanding of their risk of developing cancer and the lifestyle changes they can make to reduce their risks. *(Editor's note: To access the free web guide, go to the ACOG web site, www.acog.org. Under "Women & Cancer," click on the Protect & Detect image.)*

The guide discusses the primary cancers occurring in women — breast, cervical, colorectal, lung, ovarian, and uterine cancer — and provides information about who is most at risk, how cancer can be prevented, what available screenings are and their recommended frequency, and how cancer is treated. A key message in the guide is that cancer can occur without symptoms. Even if the symptoms are present, they might be mistaken for a harmless

EXECUTIVE SUMMARY

The American College of Obstetricians and Gynecologists (ACOG) has just released a web-based patient guide, *Protect & Detect: What Women Should Know about Cancer*, to help women understand their risks and the lifestyle changes they can make to reduce their risks.

- The guide discusses the primary cancers occurring in women — breast, cervical, colorectal, lung, ovarian, and uterine cancer — and provides information about those who are most at risk, prevention, available screenings and recommended frequency, and treatments.
- ACOG also has released new guidelines for colorectal cancer screening that recommend that women, beginning at age 50, be screened for the disease by colonoscopy every 10 years.

health condition or might not appear until the disease is advanced.

When, how to screen?

ACOG also has released new guidelines for colorectal cancer screening that recommend that women, beginning at age 50, be screened for the disease by colonoscopy every 10 years.[2] The new guidance comes after the organization's partnership in a campaign with the American Society for Gastrointestinal Endoscopy (ASGE) to reduce deaths from colorectal cancer among women.

Colorectal cancer is the second-leading cause of cancer death in adults in the United States and the third-leading cause of cancer death among women, following lung and breast cancers.[3] Each year, colorectal cancer causes death in more than 26,000 women, which is nearly twice as many as ovarian, cervical, and uterine cancers combined. It is estimated that one in 18 women will develop colorectal cancer in her lifetime.[3]

"Colorectal cancer kills over 26,000 women each year, but it doesn't have to," says **Grace Elta**, MD, FASGE, ASGE president. "Starting at age 50, everyone should have a colonoscopy to screen for colorectal cancer because colonoscopy allows for the detection and removal of benign polyps or growths in the colon before cancer develops."

ACOG changed its colorectal cancer screening recommendations because colonoscopy allows for direct visualization of the entire colon surface, with the concurrent ability to remove precancerous polyps. The procedure also allows access to right-sided lesions (the main type of advanced colorectal cancer occurring in women), which are more likely to be missed by other screening methods. Previously, ACOG recommended that all women age 50 and older be screened for colorectal cancer by one of several methods, with no single method being preferred over another.

According to the new ACOG guidelines, the organization does not recommend fecal DNA testing or CT colonography — also known as "virtual colonoscopy" — for screening outside the research setting, pending further data on their effectiveness.[2]

Results of the new survey show that women may be fearful of learning about their cancer risks. One in five (20%) women surveyed say they do not want to know if they have cancer. While 77% of women believe that seeing a health care provider regularly can help reduce their risk of cancer, only 56% saw their health care provider on a regular basis in the past year. About one-third of women surveyed (29%) had neither seen a health care provider on a regular basis nor had a Pap test or a mammogram in the past year.

When questioned further about their lack of care, about one-fifth (18%) said they didn't think it was necessary and another 14% said either they didn't know how to get screened (7%) or thought it was a waste of time (7%). However, the greatest majority of women (37%) said they could not afford care. This finding is very disheartening, says **Douglas Laube**, MD, MEd, ACOG immediate past president of ACOG.

Many women know what to do to help prevent cancer, but issues related to access to care remain problematic for many women today, says Laube. The greatest potential to further reduce cancer deaths in women will come from efforts to improve screening and access to preventive health care, particularly for women without insurance, he states.

"Ensuring health care coverage for uninsured women is among ACOG's top legislative priorities," says Laube. "ACOG will advocate for policies that expand access to comprehensive health coverage and highlight the special needs of uninsured women in our support for universal coverage."

References

1. Harris Interactive for The American College of Obstetricians and Gynecologists. *A Study about Women and Cancer Prevention*. Washington, DC; October 2007.
2. American College of Obstetricians and Gynecologists. Colonoscopy and colorectal cancer screening and prevention. ACOG Committee Opinion No. 384. *Obstet Gynecol* 2007; 110:1,199-1,202.
3. American College of Obstetricians and Gynecologists. *Protect & Detect: What Women Should Know About Cancer*. Washington, DC; 2007. Accessed at: www.acog.org/from_home/misc/protectAndDetect.pdf. ■

COMING IN FUTURE MONTHS

- Counter media reports with evidence-based medicine
- Female condoms — Where are they in your clinic?
- Abstinence-based education — Does it work?
- Talk with women on herpes risk
- Low literacy — Make it a nonfactor in patient education

Boost Hispanic women's HPV prevention awareness

Despite intense screening in the past decade, higher rates of cervical cancer persist in Hispanic women.[1] How can you reach these women with the information they need for prevention and detection?

According to the American Cancer Society, the incidence of cervical cancer for Hispanic women in the United States is almost twice as high as non-Hispanic white women. Hispanic women have the second highest mortality rate from cervical cancer (after African-American women), with mortality for Hispanic women higher in communities along the Texas-Mexico border.[2]

Despite the high prevalence of disease, findings from a recent survey conducted by Lake Research Partners for the American Social Health Association (ASHA) indicate that Hispanic women are less aware than other women that HPV is sexually transmitted. What are some of the steps ASHA is taking to improve awareness among Hispanic women? Two key components of reducing the cervical cancer burden among Hispanic women is promoting awareness and addressing issues of access to care, says **Fred Wyand**, ASHA spokesman. ASHA's publications and posters on HPV and cervical cancer are available in Spanish and are culturally sensitive, he says. **(See the resource box, above right, for ordering information.)**

"We are also assessing our web sites, including our Spanish-language portal quierosaber.org, in order to make the content as up-to-date and comprehensive as possible, and of course this will include HPV and cervical cancer screening/vaccines," he states.

Access to care is an important aspect when it comes to prevention. ASHA's policy office in Washington, DC, regularly works with Capitol Hill staff to promote the issue of screening for at-risk populations, including Hispanic and African-American women, says Wyand. ASHA has organized briefings on this issue for media and legislators, as well as convened meetings of stakeholders representing government, women's and minority health organizations, and the pharmaceutical industry to develop plans of action around access to HPV vaccines in at-risk women, he states.

ASHA also has developed a model curriculum for its Cervical Cancer Prevention Project that organizations and public health agencies may adapt to increase Pap testing and follow-up among low-income African American and Hispanic women in any community. *(Editor's note: Visit the ASHA web site, www.ashastd.org, for a free download of the program. Click on "About ASHA," "Research and Evaluation," "To view a sample of ASHA's successful projects, click here," and "The Cervical Cancer Prevention Project.")*

To help raise awareness in Hispanic women, the National Latina Institute for Reproductive Health (NLIRH), an advocacy group, has developed tools for organizing house parties, community forums, and legislative advocacy days for its "Latinas for Cervical Cancer Prevention" campaign. The organization recently hosted a virtual *cafecito* (informal discussion over coffee) to discuss women of color,

EXECUTIVE SUMMARY

Despite intense screening in the past decade, higher rates of cervical cancer persist in Hispanic women. The incidence of cervical cancer for Hispanic women in the United States is almost twice as high as non-Hispanic white women.

- Hispanic women have the second-highest mortality rate from cervical cancer (after African American women), with mortality for Hispanic women higher in communities along the Texas-Mexico border.
- The National Latina Institute for Reproductive Health has developed tools for organizing house parties, community forums, and legislative advocacy days for its cervical cancer prevention campaign.

RESOURCE

The American Social Health Association (ASHA) offers HPV/cervical cancer prevention patient education material in Spanish. Look at two brochures, *El Papanicolaou — Lo Que Toda Mujer Deberia Saber (Pap Tests: What Every Woman Should Know)* and *Preguntas y Respuestas Acerca del PVH (Questions and Answers about HPV).* ASHA also offers a *Prevent Cervical Cancer* poster in Spanish. Both brochures are $17.50 per pack of 50; the poster is $2.95. Shipping and handling charges are as follows: up to $25, $5.95; $25.01-$74.99, $7.95; $75-$499.99, 10%; $500-$1,999, 8%; $ 2,000 and above; 7%. Discounts are available for large orders; contact customer service at (800) 783-9877 for more information. Questions also can be answered by e-mailing customerservice@ashastd.org. To order online, visit the ASHA web site, www.ashastd.org, and click on "Product Catalog."

cervical cancer prevention and the HPV vaccine, says **Miriam Zoila Pérez**, senior advocacy associate.

"The purpose of this campaign is to foster dialogue and create spaces for people to have open and honest discussions about their uncertainties, fears, and questions about cervical cancer prevention," she says. "The goal is to educate one another, but to also educate important decision makers in our lives and communities: legislators, but also school board officials, principals, PTA members, community health center staff, parents, teachers, and local politicians."

The organization has developed a "frequently asked questions (FAQ)" sheet, as well as a postcard, to help spread the word about cervical cancer prevention awareness. It also has developed a guide to help advocates organize their own *cafecito*s. *(Editor's note: To access these tools, visit the web site, www.latinainstitute.org, and click on "Take Action," and "Cervical Cancer Prevention.")*

While the HPV vaccine may prove to be an important tool in the fight against cervical cancer, it may be out of reach for many women due to costs. Barriers to accessing the HPV vaccine are compounded for Hispanic and immigrant women, who may have limited English proficiency, may be without health insurance and/or may be undocumented, says NLIRH. The advocacy group is working toward a standard of care that will provide these women with all the possible options for preventing cervical cancer.

NLIRH supports full access to new reproductive technologies "when they are coupled with unbiased information and implementation that is free from coercive policies and practices," according to its fact sheet.[2]

CNE/CME Instructions

Physicians and nurses participate in this continuing medical education/continuing education program by reading the articles, using the provided references for further research, and studying the questions at the end of the issue. Participants should select what they believe to be the correct answers and refer to the list of correct answers to test their knowledge. To clarify confusion surrounding any questions answered incorrectly, please consult the source material. After completing this activity with the **June** 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. ■

References

1. Saraiya M, Ahmed F, Krishnan S, et al. Cervical cancer incidence in a prevaccine era in the United States, 1998-2002. *Obstet Gynecol* 2007; 109(2 Pt 1):360-370.

2. National Latina Institute for Reproductive Health. *The Human Papillomavirus (HPV), Cervical cancer and the HPV*

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.

1. The Intra Vas Device, a vasectomy alternative now under development, relies on soft, hollow silicone plugs inserted in:

A. each of the vas deferens.
B. the scrotum.
C. the penis.
D. the testicles.

2. Which "red-flag" medical conditions should clinicians look for when it comes to potential drug interactions with oral contraceptives?

A. Current antibiotic use, tuberculosis, skin and nail fungal infections, depression (use of St. John's Wort), and HIV
B. Seizure disorder/epilepsy, tuberculosis, skin and nail fungal infections, depression (use of St. John's Wort), and HIV
C. Sexually transmitted diseases, tuberculosis, skin and nail fungal infections, and depression (use of St. John's Wort)
D. Seizure disorder/epilepsy, tuberculosis, skin and nail fungal infections, depression (use of St. John's Wort), and use of contact lens

3. Which of these is NOT a risk factor for chlamydia in women?

A. Age 24 years or younger and sexually active
B. Previous history of chlamydia or another sexually transmitted infection
C. Previous pregnancy
D. New or multiple sexual partners

4. The American College of Obstetricians and Gynecologists has issued new guidelines for colorectal cancer screening that recommend that women, beginning at age 50, be screened for the disease by colonoscopy:

A. every two years.
B. every three years.
C. every five years.
D. every 10 years.

Answers: 1. A; 2. B; 3. C; 4. D.

Vaccine. Frequently Asked Questions. Fact sheet. September 2007. Accessed at: www.latinainstitute.org/takeaction/documents/HPV_FAQ-24Sept07-FINAL.pdf. ■

Help women discuss HPV with new brochure

Help women discuss HPV, cervical cancer, and Pap tests with health care providers, with a new brochure, *"Ask How You Can Prevent Cervical Cancer."*

Developed by the American Social Health Association and the Society of Gynecologic Oncologists, the brochure includes information and questions women should ask. Copies of the brochure can be ordered by e-mailing requests to info@ashastd.org. The brochures are free upon request. ASHA reserves the right to limit quantities. ■

Correction

The article "What pills do you offer? Readers share options" in the November 2007 *Contraceptive Technology Update* should have said that Lybrel, from Wyeth Pharmaceuticals, is the first low-dose combination contraceptive pill taken 365 days a year, without a placebo phase or pill-free intervals. ■

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.*

Dear ARHP Member:

The media has been abuzz with two new studies on oral contraceptives. The ARHP community is committed to evidence-based medicine, and misinterpretations of clinical research and sensationalized reporting can have a negative impact on public health.

ARHP has compiled a few basic talking points to help health care providers address any patient concerns or media inquiries. This information is not an analysis of either study, but it is intended to help providers convey the scientific meaning of these studies in a simple, fact-based framework to patients.

Study No. 1 — Oral Contraceptive Pill (OCP)/Arterial Plaque

These talking points are to assist you in alleviating patient concerns about recent media coverage of a study on oral contraceptives and risk of heart attacks and stroke.

1. There is no need for women to immediately stop taking oral contraceptives based on this study.
2. The results of the study are from a single, small, unpublished paper and they show ***no increased risk of actual heart attacks or strokes*** among women using oral contraceptive pills.
3. Instead, the results do show slight increase in arterial plaque buildup among OCP users aged 35-55, a population already at low risk for heart disease.
4. There is a large body of published, peer-reviewed evidence that shows the risk of heart attack and stroke for women who use oral contraceptives is very small.
5. With regard to actual events, the one-year risk of dying for nonsmokers using oral contraceptives is very low: two women out of 100,000. This means that in a typical sized football stadium packed with 100,000 women, only two would be at risk of dying.
6. For comparison purposes, consider the following:
   a. In a one-year period, 12 out of 100,000 women are at risk of dying from pregnancy.
   b. In a one-year period, 20 out of 100,000 people are at risk of death due to an automobile accident.
7. For women who are concerned about heart disease, there are several steps they can take:
   a. Don't smoke
   b. Eat a healthy diet
   c. Get regular exercise
   d. Maintain a healthy weight
   e. Control blood pressure, cholesterol, and diabetes

Study No. 2 — Oral Contraceptive Pill/Cervical Cancer

These talking points are to assist you in alleviating patient concerns about recent media coverage of a study, published in *The Lancet* (Nov. 10, 2007), on oral contraceptives and increased risk of cervical cancer.

1. This study shows that long-term use of oral contraceptives (more than five years) is associated with an increased risk of cervical cancer. The study also reports that when a woman stops taking oral contraceptives, her risk fades over time and returns to normal after 10 years.
2. In comparison, the benefits of oral contraceptives have been widely documented. For instance, women who use OCPs for 10 or more years have a significant decrease in risk of ovarian and endometrial cancer.
3. While this study shows a slight increased risk of cervical cancer, the risk is still very low. An increase in the incidence of a rare event remains a rare event.
4. For women who are concerned about cervical cancer there are some steps she can take:

a. Use condoms
b. Don't smoke
c. Consider HPV screening and vaccine
d. Get regular pap smears

ARHP has intensive, peer-reviewed curricula on both cervical cancer and understanding risk associated with hormonal contraception. For more information on these topics, please access these two resources:

• ***Managing HPV: A New Era in Patient Care*** www.arhp.org/healthcareproviders/visitingfacultyprograms/hpv/index.cfm

• ***You Decide: Making Informed Health Choices about Hormonal Contraception*** http://www.arhp.org/healthcareproviders/visitingfacultyprograms/riskperspective/index.cfm

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Source: Association of Reproductive Health Professionals, Washington, DC.