

CONTRACEPTIVE TECHNOLOGY

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A Monthly Newsletter for Health Professionals



Seek new avenues to raise chlamydia screenings among adolescent women

4% prevalence rate reported among U.S. teens

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With recent findings that 4% of young women between the ages of 14 and 19 in the United States are infected with chlamydia, public health officials are stepping up efforts to screen more adolescent girls for the sexually transmitted disease (STD).¹

Data presented at the 2008 STD Prevention Conference confirm that STDs remain a major health threat for millions of Americans, which underscores the importance of strengthened prevention efforts, says **Raul Romaguera**, DMD, MPH, the newly appointed national chlamydia screening coordinator at the Centers for Disease Control and Prevention's (CDC) Division of STD Prevention. Specifically, missed opportunities for STD screening are identified as significant obstacles to prevention efforts, he notes.

There is a wide cross-section of providers interested in elevating the importance of chlamydia screening and treatment and increasing screening rates among adolescent and young women. They gathered at the first full meeting of the National Chlamydia Coalition in early June. The coalition was established by the Partnership for Prevention, a national membership organization dedicated to building evidence of sound disease

EXECUTIVE SUMMARY

Public health officials are stepping up efforts to screen teen girls for chlamydia in light of recent findings that 4% of U.S. females ages 14-19 are infected.

- Look for ideas to spring from the just-completed first meeting of the National Chlamydia Coalition, which includes a wide cross-section of providers interested in chlamydia screening and treatment.
- The Centers for Disease Control and Prevention continues to implement and expand innovative screening and prevention strategies. One such effort includes chlamydia screening in high school-based health clinics.

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prevention and health promotion policies and practices, in close collaboration with CDC. It is designed to address adherence to recommended clinical practice of annual chlamydia screening for sexually active women younger than age 26, says Romaguera. Steering committee member organizations include Advocates for Youth, American

Academy of Pediatrics, American College of Obstetricians and Gynecologists, American Social Health Association, National Black Women's Health Imperative, National Coalition of STD Directors, National Partnership for Women and Families, and Planned Parenthood Federation of America.

The coalition also will focus on educating health care providers on the importance of chlamydia screening and ways to improve screening rates, advocating for increasing access to and use of chlamydia screening and treatment services, and encouraging research to enhance prevention of the disease and its medical and social consequences, says Romaguera.

Look at new venues

The CDC continues to implement and expand innovative screening and prevention strategies, says Romaguera. One example of such innovation is a confidential chlamydia screening program in high school-based health clinics in California.²

Researchers at the California Family Health Council analyzed data from the CDC-funded Educational Partnerships to Increase Chlamydia Screening (EPICS) program at seven such school-based clinics in rural and urban California. The program provides funding, training, and technical assistance to encourage greater chlamydia screening among at-risk teens.

The purpose of the EPICS program is to expand chlamydia screening to harder-to-reach females ages 25 and younger who would not otherwise present for care at traditional clinic-based screening programs, explains **Rebecca Braun**, MPH, program manager of the Infertility Prevention Project at the Berkeley-based California Family Health Council. Agencies may choose to establish this program in collaboration with educational partners such as high schools and school-based health centers, community colleges, and/or universities where chlamydia screening is not an integral part of reproductive health services, explains Braun. She presented information on the California project at the 2008 National STD Prevention Conference.³

"The populations at risk are those with barriers to accessing health care services," notes Braun. "Such barriers may include lack of affordable health care options, lack of transportation, concerns around confidentiality and cultural competency, or any other factor that limits an individual's ability to receive health care services."

Braun and fellow researchers examined data

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Editor: **Rebecca Bowers**.

Senior Vice President/Group Publisher: **Brenda Mooney** (404) 262-5403 (brenda.mooney@ahcmedia.com).

Associate Publisher: **Coles McKagen** (404) 262-5420 (coles.mckagen@ahcmedia.com).

Senior Managing Editor: **Joy Daughtery Dickinson** (229) 551-9195 (joy.dickinson@ahcmedia.com).

Senior Production Editor: **Nancy McCreary**.

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Editorial Questions

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from 1,321 sexually active adolescent girls who attended the school-based health clinics seeking contraceptive or STD services between July 2006 and June 2007. Overall, almost nine in 10 teens (89.7%) attending the health centers were screened and chlamydia was diagnosed in 6.5% of those screened. This positivity rate is more than double the U.S. Department of Health and Human Services' Healthy People 2010 goal of 3% positivity for adolescents and young adults.³

The 2008 EPICS program in California has expanded to include nine Title X agencies, encompassing a total of 19 school-based health clinics — 16 high schools and three community colleges — throughout California, reports Braun. "Overall, we are optimistic that the data from this study will help health officials focus chlamydia screening and risk-reduction counseling on those most at risk of infection, most notably young black women and older adolescents," she says. "Given the success of this program in reaching at-risk teens and young adults, we recommend that other states consider implementing confidential school-based chlamydia testing and treatment programs as a part of providing comprehensive reproductive health care services."

Internet as a resource?

The American Social Health Association (ASHA) has teamed up with a creative team at Duval Guillaume, a New York City-based advertising agency, to get the word out on the insidious spread of chlamydia. Rather than pass out pamphlets, the health advocacy organization is drawing in young people with the use of an application on a popular Internet social networking site, www.facebook.com.

Duval Guillaume and a team of computer software developers have devised a Facebook application called MorphMonkey in which users are invited to "make a love child" by morphing pictures of their own faces with that of their friends. Facebook users simply download the MorphMonkey application and click the "Make a Love Child" tab. About 25,000 to 30,000 Facebook users have downloaded this free application, reports **Fred Wyand**, ASHA spokesman.

The humor takes a turn when the user is notified that they have "caught" a chlamydial infection from their friend and are prompted to discover more information on the ASHA web site, www.ashastd.org. Users are allowed to continue making "love children" while having the "disease." However, at the end of eight weeks, they find that

Answer question: 'How to prevent chlamydia?'

What can you tell teens about preventing chlamydia? Check the following information from the Centers for Disease Control and Prevention (CDC):

- The surest way to avoid transmission of chlamydia, or any sexually transmitted disease (STD), is to abstain from sexual contact, or to be in a long-term mutually monogamous relationship with a partner who has been tested and is known to be uninfected.
- Latex male condoms, when used consistently and correctly, can reduce the risk of transmission of chlamydia.
- The CDC recommends yearly chlamydia testing of all sexually active women age 25 or younger, older women with risk factors for chlamydial infections (such as those who have a new sex partner or multiple sex partners), and all pregnant women. Health care providers will perform sexual risk assessments to check if more frequent screening is warranted.
- Any genital symptoms such as an unusual sore, discharge with odor, burning during urination, or bleeding between menstrual cycles could mean an STD infection. If you're an adolescent female and have any of these symptoms, you should stop having sex and consult a health care provider immediately. Treating STDs early can prevent pelvic inflammatory disease.
- If you are diagnosed with chlamydia (or any STD) you should be treated for it, as well notify all recent sex partners (those with whom you have had sex within the preceding 60 days) so they can see a health care provider and be evaluated for STDs. Sexual activity should not resume until all sex partners have been examined and, if necessary, treated.

Source: Centers for Disease Control and Prevention. Chlamydia. Fact sheet. Accessed at www.cdc.gov/std/chlamydia/Chlamydia-Fact-Sheet.pdf.

they are unable to make any more "children" for two days, as their untreated case of chlamydia has made them "infertile." The MorphMonkey application does absolutely no harm to computers and is not a virus, program officials say. Launched in April during STD Awareness Month, the program ran through the end of June, says Wyand.

"We are reaching out to young people in a way that is a little different, with a little bit of a twist

on it," says Wyand. "Not only is Facebook a place that they go, the message is presented in a way that is a little bit fun and interactive." **(How do you talk to teens about preventing the spread of chlamydia? See the article on p. 87.)**

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Keeping OC users on track: What works?

The next patient in your office is a 25-year-old mother of two. She's using oral contraceptives (OCs) for birth control, but when you ask her about her method use, she admits she's having problems remembering to take her daily pill.

According to a just-published study, among a nationally representative sample of women ages 18-44, of the 38% who said they used OCs, almost all of the pill users (98%) said they used a reminder or routine to help them remember to take their pill every day. Yet, 38% of those using the Pill reported

EXECUTIVE SUMMARY

New research indicates many women have trouble remembering their daily oral contraceptive (OC). While 98% of the women said they used a reminder or routine to help them remember to take their pill every day, 38% of those using the Pill reported having missed at least one active pill in the prior three months. Researchers at Columbia University Medical Center are looking to boost success with OCs:

- A cell phone text message reminds women to take their daily pill.
- The "Six Pack" study provides multiple packs at method initiation.

having missed at least one active pill in the prior three months.¹

According to the study, which included telephone interviews with 1,978 women, 8% of pill users reported they had missed one pill in the prior three months, 11% had missed two, and 19% had missed three pills. About 70% of those who missed a pill said they had forgotten to take it; 10% reported access problems (they did not have their pills with them), and 8% said variations in schedule interfered with their pill regimen.¹

Half of all unintended pregnancies occur among contraceptive users²; nine in 10 pregnancies result from inconsistent or incorrect method use, and only one in 10 result from method failure.³ What can family planning providers do to enhance OC use?

R U Taking Yr OC?

Traditional reminders to help women to take their daily pill include placing the pills beside the toothbrush and toothpaste or the multivitamin bottle. How about a fresh approach?

Researchers at Columbia University Medical Center in New York City are using text messages to help today's cell phone-connected young women to remember to take their pills, reports **Katharine O'Connell, MD, MPH**, assistant clinical professor of obstetrics and gynecology at the facility.

The research team has designed a randomized trial of adolescents and young women up to age 24, randomizing the participants to receive/not receive daily text messages to remind them to take their pill. The text message not only serves as a reminder for OCs, but also includes a health message as well, she says.

"We want to see if this generation who seems to have their cell phone surgically implanted into their hand, if this will help increase adherence to the method," notes O'Connell.

Researchers have just begun to enroll women in the study. A total of 1,000 women are scheduled to be included in the trial, says O'Connell. The scientists will look at six-month continuation rates to see how many women continue with method use, she notes.

Will 'Six Pack' help?

What is your clinic's policy when it comes to providing multiple packs of pills? Providing multiple packs of pills reduces patient costs and supports method continuation. Women who receive

three to 12 pill packages in advance require fewer clinic visits, thus decreasing the likelihood of method discontinuation due to failure to obtain more pills on time.³ Research published in 2006 bears this out: Women who were provided an advance 13 cycle-supply of pills had fewer gaps in usage and longer-term contraceptive use.⁴

(Review the research; see “Break down barriers to contraceptive access: provide multiple pill packs,” *Contraceptive Technology Update*, February 2007, p. 13.)

Columbia University Medical Center researchers have initiated the “Six-Pack” study to see if provision of multiple packs aids in method success. The genesis for the current study springs from earlier research that indicated that the more packs of pills a woman received upon method initiation, the longer she stayed on the Pill, says O’Connell.

The research team is enrolling 750 women who are being randomized to receive three packs of pills or seven, with researchers looking at six-month continuation rates. It’s important to look at six-month continuation rates, notes O’Connell. Reported six-month OC discontinuation rates vary from 18% to 50%.⁵⁻⁷

Providing six packs of pills is a step in the right direction, says **Robert Hatcher**, MD, MPH, professor of gynecology and obstetrics at Emory University School of Medicine in Atlanta. “When will we permit pills to play the role they could be by providing a full year’s supply at time?” he asks.

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Pill with dienogest progestin under review

Research is eyeing an oral contraceptive (OC) formulation with a new progestin: dienogest. Results of an efficacy trial, presented at the 2008 Clinical Meeting of the American College of Obstetricians and Gynecologists (ACOG), indicate the formulation is effective, safe, and well tolerated.¹

The new pill, under development by Bayer HealthCare Pharmaceuticals in Wayne, NJ, is a four-phasic OC composed of estradiol (E2) valerate and dienogest. Bayer’s parent company, Bayer Schering Pharma AG in Berlin, filed for registration of the OC with European regulatory authorities in December 2007. Phase III studies are being conducted for U.S. regulatory authorities, reports **Gerard Nahum**, MD, senior director of medical affairs — women’s healthcare, at Bayer HealthCare Pharmaceuticals.

No pills in the United States contain dienogest, one of several new progestins that have been synthesized in the last two decades. Bayer introduced an OC containing dienogest, trademarked as Valette, in Australia in 2007. Valette contains 2 mg dienogest and 30 mcg ethinyl estradiol.

Organon is conducting two pivotal Phase IIIa trials in the United States for a monophasic oral contraceptive containing E2 and another new progestin, norgestrel acetate (NOMAC). (*Contraceptive Technology Update* reported on the research. See “Advanced trial under way for oral contraceptive,” February 2008, p. 22.)

Dienogest and NOMAC have been designed to

EXECUTIVE SUMMARY

Results of an efficacy trial of a four-phasic oral contraceptive composed of estradiol (E2) valerate and dienogest indicate the formulation is effective, safe, and well tolerated.

- No pills in the United States contain dienogest, one of several new progestins that have been synthesized in the last two decades. U.S. trials are under way for a monophasic oral contraceptive containing E2 and another new progestin: norgestrel acetate (NOMAC).
- Dienogest and NOMAC have been designed to bind very specifically to the progesterone receptor and not to other steroid receptors to avoid androgenic, estrogenic, or glucocorticoid side effects.

bind specifically to the progesterone receptor and not to other steroid receptors in an effort to avoid androgenic, estrogenic, or glucocorticoid side effects.

Check the results

To conduct the analysis of the E2/dienogest pill, scientists developed a multicenter, open-label study of women ages 18-50 years, using 20 28-day cycles. The four-phase formulation included two days of 3 mg E2 valerate, five days of 2 mg E2 valerate and 2 mg dienogest, 17 days of 2 mg E2 valerate and 3 mg dienogest, two days of 1 mg E2 valerate, and two days of placebo pills. A total of 1,377 women received the study medication.

In women ages 18-35 (998), 12 pregnancies occurred over an exposure of 16,608 cycles, yielding a Pearl Index of 0.94 [upper limit of two-sided 95% confidence interval (CI) 1.65]. Five of the pregnancies were attributed to method failure, yielding an adjusted Pearl Index of 0.40 (upper limit of the 95% CI 0.92). In the entire study population, 13 pregnancies occurred over an exposure time of 23,368 cycles for a Pearl Index of 0.73 (upper limit of 95% CI 1.24). Six of those pregnancies were attributed to method failure for an adjusted Pearl Index of 0.34 (upper limit of 95% CI 0.73).

The discontinuation rate due to adverse effects was 10.2%, report researchers. Nearly 80% of women were satisfied or very satisfied with treatment; emotional and physical well-being remained the same or improved in 89.7% and 86.4% of women, respectively.¹

What is its impact?

Researchers also presented information on the pill's metabolic effects at ACOG's 2008 Clinical Meeting. To analyze the drug, researchers designed an open-label randomized study in which women ages 18-50 received a four-phasic regimen containing E2 valerate and dienogest or a sequential regimen of ethinyl E2 and levonorgestrel for seven cycles. The regimen was six days of 0.03 mg ethinyl E2/0.05 mg levonorgestrel, five days of 0.04 mg ethinyl E2/0.075 mg levonorgestrel, 10 days of 0.03 mg ethinyl E2/0.125 mg levonorgestrel, and seven days placebo pills. Scientists recorded individual-specific relative change in high-density lipoprotein and low-density lipoprotein cholesterol from baseline to Cycle 7. Hemostatic characteristics, carbohydrate metabolism characteristics, and hormone

levels also were assessed.

Findings indicate the formulation with E2 valerate and dienogest showed a more favorable effect on lipid profiles and had a lesser effect on hemostatic characteristics than ethinyl E2 and levonorgestrel. No clinically relevant changes in metabolic characteristics were observed in either treatment group, researchers report.²

Bayer also is eyeing use of the E2 valerate/dienogest formulation for the treatment of the prolonged, frequent, and excessive bleeding noted in dysfunctional uterine bleeding; however, the company says it is only seeking approval for the oral contraception indication at this time.³

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New review focuses on emergency contraception

When it comes to emergency contraception (EC), what does your clinic offer? A new review has found that mifepristone is the most effective EC method to prevent unwanted pregnancy; however, the drug has not gained U.S. regulatory approval for that use.¹

To perform the analysis, researchers evaluated the results of 81 clinical trials that encompass the experience of 45,842 women who sought EC after one act of unprotected intercourse. The trials included in the review compared the effectiveness of mifepristone and levonorgestrel hormonal pills, the Yuzpe regimen (a method of combined hormone pills, repeated once 12 hours apart), and the copper intrauterine device (IUD).

Most of the clinical trials studied mifepristone in two levels: low dose (less than 25 mg) and middle dose (25 mg to 50 mg). Levonorgestrel trials included a single dose of 1.5 mg or two doses

EXECUTIVE SUMMARY

A new review of clinical trial results indicates mifepristone is the most effective emergency contraceptive (EC); however, the drug isn't approved in the United States for this use.

- Most of the trials studied mifepristone in two levels: low dose and middle dose. Levonorgestrel trials included a single dose of 1.5 mg or two doses of 0.75 mg given 12 hours apart. Mifepristone, given in the middle dose, was the most effective hormonal regimen in preventing pregnancy.
- More pregnancies occurred with levonorgestrel EC than with mid-dose mifepristone or low-dose mifepristone. Single-dose levonorgestrel EC had the same effectiveness as the split dose; levonorgestrel, however, was more effective than the Yuzpe regimen in preventing pregnancy.

of 0.75 mg given 12 hours apart. The reviewers found mifepristone, given in the middle dose, was the most effective hormonal regimen in preventing pregnancy.

Reviewers found that more pregnancies occurred with levonorgestrel EC than with mid-dose mifepristone or low-dose mifepristone. Single-dose levonorgestrel EC had the same effectiveness as the split dose, report researchers; levonorgestrel, however, was more effective than the Yuzpe regimen in preventing pregnancy.¹

Based on the review of current evidence, mifepristone should be the first choice of hormonal EC where available, reviewers concluded. If it is not available, single-dose levonorgestrel (1.5 mg) should be offered, the reviewers state. Copper IUD insertion can be offered to women presenting too late for EC pills, who are not at risk of sexually transmitted diseases, and who prefer long-term contraception, researchers conclude.

What do you use?

Family planning providers are most familiar with Plan B (Barr Pharmaceuticals; Pomona, NY), the only dedicated EC drug on the U.S. market. Since the company began distributing the over-the-counter version of the drug in November 2006, sales of the drug have soared. All national pharmacy chains now stock it, and 2007 estimates for Plan B sales were pegged at \$80 million, almost double its 2006 figures.²

Plan B consists of two doses of 0.75 mg

levonorgestrel, taken 12 hours apart. Studies have shown that a single 1.5 mg dose is as effective as two 0.75 mg doses 12 hours apart.^{3,4}

When Plan B is not available, certain types of combination oral contraceptives can be used as EC. A total of 23 brands of combined oral contraceptives are approved in the United States for use as EC.⁵

Emergency insertion of a copper IUD is more effective than use of EC pills.⁵ Research results indicates use of the IUD method reduces the risk of pregnancy following unprotected intercourse by more than 99%.⁶ Guidelines issued by the World Health Organization allow IUDs to be inserted up to Day 12 of the menstrual cycle with no restrictions and at any other time in the cycle if it is reasonably certain that the patient is not pregnant.⁷

Mifepristone in the United States?

Providers are familiar with mifepristone in its use in medication abortion. The drug is marketed in the United States as Mifeprex (Danco Laboratories, New York City). Is the company planning to seek federal regulatory approval of the drug for use in emergency contraception?

"Danco does not at this time have plans to pursue use of Mifeprex as an emergency contraceptive," says **Abigail Long**, company spokeswoman.

What are some of the factors that may keep mifepristone from gaining acceptance as a method of emergency contraception in the United States? **Beth Jordan**, MD, medical director of the Association of Reproductive Health Professionals, observes, "I think some of the biggest factors are related to the fact that so many people continue to be confused by the fact that one drug can be used for many indications."

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Use new screening tool for menstrual migraine

The woman in your exam room says she has severe headaches that usually begin about two days before her menstrual cycle. When they occur, they get more severe in intensity. She does not report any signs of neurological aura, such as flashing lights or tingling sensations, with the headaches. What's your diagnosis?

All signs point to menstrual migraine. To help women's health care providers identify menstrual migraine and track their prevalence, researchers have developed a three-question questionnaire. According to results presented at the May 2008 American College of Obstetricians and Gynecologists (OB/GYN) annual meeting, the questionnaire has a sensitivity of 94% and a specificity of 74%.¹

It is important that providers accurately assess the presence of menstrual migraine. More than 50% of women with migraine report an association between migraine and menstruation; 12 million women experience worsening of migraines in association with the menstrual cycle.^{2,3} Further research indicates an association with menses is observed by 60% of women with migraine headaches. In 7%-14% of women with migraines, headaches occur exclusively with menses.⁴ Headache pain associated with menstrual migraine has been shown to

EXECUTIVE SUMMARY

To help providers identify menstrual migraines and track their prevalence, researchers have developed a three-question questionnaire. The questionnaire has a sensitivity of 94% and a specificity of 74%.

- More than 50% of women with migraine report an association between migraine and menstruation; 12 million women experience worsening of migraines with their menstrual cycles.
- Triptans are effective in the treatment of menstrual migraine. Such drugs generally are well tolerated and their long-term safety is being evaluated.

be more severe, less likely to respond to treatment, and more likely to be associated with nausea and vomiting than that associated with nonmenstrual migraine headaches.⁵

"We think these are very simple questions that could be put in a waiting room in an OB/GYN office in order to identify patients who are likely to have migraine and who therefore are likely to have impact in their lives from migraine," says **Stewart Tepper**, MD, director of research for the Center for Headache and Pain at the Neurological Institute of the Cleveland Clinic Foundation. "The purpose of the questionnaire is to simplify things for the gynecologist and to increase the likelihood that a significant disabling illness could be addressed by the gynecologist, because they serve as primary care physicians."

Ask the questions

To develop the questionnaire, Tepper and research colleagues administered a nine-item questionnaire to patients from a headache clinic with unknown menstrual migraine status. The attributes of each question were compared to a validated headache calendar to develop a three-item menstrual migraine questionnaire. The headache calendar and questionnaire then were administered to nonpregnant/nonmenopausal OB/GYN patients. A diagnosis was assigned by a blinded specialist using the headache calendar.¹

The three items on the menstrual migraine questionnaire include:

- Do you have headaches that are related to your period most months?
- When your headaches are related to your period, do they eventually become severe?
- When your headaches are related to your period, does light bother you more than when you don't have a headache?

Researchers found that if women responded positively to the first question and to one or both of the other two questions, the screening tool had a sensitivity of 0.94 and a specificity of 0.74 for detecting pure menstrual migraines.¹

Check treatment options

While most women's health providers assume that most of their patients have headaches, providers need to dig deeper to find out whether a woman's menstruation is associated with the headache, says **Lee Shulman**, MD, professor in obstetrics and gynecology and chief of the Division

of Reproductive Genetics in the Department of Obstetrics and Gynecology at the Feinberg School of Medicine of Northwestern University in Chicago. If headaches are delineated, even if they are menstrual-related, consideration of referral to a headache center or headache expert is warranted to ensure that there is not a serious cause for the headache, Shulman contends.

Triptans, which include almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan, and zolmitriptan, are effective in the acute treatment of menstrual migraine.⁶ Triptans generally are well tolerated, and the long-term safety of these drugs is being evaluated.⁷

The consistent ebb and flow of hormones during the reproductive cycle functions as a trigger in preventing or provoking migraine. Providers may look at using perimenstrual estrogen supplements to blunt the drop in estrogen or prescribe a continuous regimen of combined oral contraceptives to avoid hormonal fluctuations. There are risk factors associated with estrogen use; the use of oral contraceptives in women with migraine is an independent risk factor for stroke.⁸

“What we don’t really have are good randomized controlled trials that either strategy is particularly effective,” says Tepper. “There may be a misperception that we actually have evidence-based results.”

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Universal coverage looms large in U.S.

By **Adam Sonfield**
Senior Public Policy Associate
Guttmacher Institute
Washington, DC

With high and rising levels of uninsurance and health care costs, federal and state policymakers have taken note. Three northeastern states — Maine, Massachusetts, and Vermont — have enacted legislation over the past few years, with the goal of achieving near-universal coverage. National leaders, including the presidential candidates, have presented plans to reform the U.S. health insurance system. Democratic and Republican leaders have promoted very different models to that end, with differing implications for coverage and accessibility of reproductive health services.¹

For Americans too young to qualify for Medicare, here are the major avenues for coverage:

- Employer-sponsored health insurance, which covers 61% of Americans younger than 65,² is generally high-quality, yet premiums are most affordable for those working at large employers. Also, coverage has declined steadily for decades.
- Many low-income Americans (13% of Americans younger than 65, including 40% of those who are poor) rely on Medicaid or related public programs. The programs’ benefit packages are broad, but eligibility varies widely across states. Large groups, including childless adults and most recent immigrants, typically are excluded.
- Insurance coverage through small employers or the individual market essentially is a last resort. Even when coverage is available, it typically is at a higher cost and with more restrictive terms and benefits than in other sectors.

Publicly funded health clinics are relied upon heavily by Medicaid recipients, by those whose private insurance is limited, and by the 18% of nonelderly Americans who are uninsured.

Most Democratic leaders, as well as bipartisan coalitions in some states, including Massachusetts, have endorsed an approach that seeks to minimize

change. This public-private partnership approach would seek to shore up employer-sponsored coverage through subsidies and requirements and to expand the scope of who is covered under Medicaid and State Children's Health Insurance Program (SCHIP). A third component would create an alternative or replacement for the individual and small employer insurance markets by establishing a "connector" or "exchange" that would gather individuals into a large insurance pool and provide them a choice of plans.

Policy-makers have envisioned a range of provisions to make these three components function smoothly as a system and ensure meaningful access to care. These potential reforms include limits on insurers' ability to manipulate premiums and benefits; mechanisms to allow for comparison of competing plans; and subsidies (and perhaps requirements) to ensure that all Americans obtain coverage. Although many experts believe this approach will ultimately save money and most proposals include a series of cost-control provisions, others predict a need for substantial new government investment.

National Republican leaders, in contrast, tout a free-market approach that would emphasize the individual market, on the theory that individual consumers will make better and cheaper decisions than employers or the government. Potential reforms include:

- the expansion of "consumer-directed" plans, combining tax-sheltered health savings accounts with coverage that kicks in only after substantial out-of-pocket payments;
- a revamping of incentives in the tax system to make the individual market more attractive;
- various mechanisms, such as allowing Americans to purchase insurance across state lines, for bypassing or eliminating state and federal regulations such as benefit mandates, that conservatives blame for rising costs.

Opponents of this approach argue that the individual market has inherently high administrative costs that make it prohibitively expensive for many Americans, despite the tax credits included in some proposals. Even if premiums were affordable, high

deductibles and cost-sharing may dissuade people from seeking needed care — if they can even figure out what care is truly needed. Consumers in the individual market will struggle to determine what to purchase and how. Without significant government regulation, Americans who are sick may not be able to purchase an insurance plan that includes the services they need, or they may not be able to buy any plan at all.

In part because of government requirements, employer-sponsored insurance and Medicaid typically cover a broad range of reproductive health services, including pregnancy-related care, gynecologic exams, contraception, and testing and treatment for breast and cervical cancer and sexually transmitted infections (STIs). (Coverage of abortion and infertility treatment tends to be more limited.) The public-private partnership approach is not likely to change this coverage, except by drawing more people into the system and, perhaps, by expanding coverage of preventive services.

In contrast, free-market proposals, by undermining benefit mandates, might affect coverage of many reproductive health services. High premiums, deductibles, and copayments might discourage Americans from seeking this care.

With Democratic and Republican leaders touting competing health care philosophies, the 2008 elections may have a substantial impact on the future of reproductive health coverage. Most likely, the political battle will be over broad questions about the shape of the system, the role of government, and how society can afford to expand coverage and contain costs. It is not currently thought likely that Congress will debate the finer points of a benefit package, points that may instead subsequently be left to the quieter, but equally critical, work of regulators.

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COMING IN FUTURE MONTHS

■ Review options for permanent birth control

■ New guidelines issued on osteoporosis prevention

■ Nonhormonal vaginal ring eyed for contraception

■ Check long-term reversible methods for high-risk women

■ Research eyes vulvodynia protocol

Sign up now for annual conference

Circle the dates on your calendar for Reproductive Health 2008, the annual meeting for the Association of Reproductive Health Professionals (ARHP), Planned Parenthood Federation of America, and the Society of Family Planning. The meeting is scheduled for Sept. 17-20 in Washington, DC.

The conference is designed to help providers apply new knowledge and understanding to the diagnosis and treatment of men and women for a variety of reproductive health conditions, as well as to provide improved guidance to patients on family planning, including lessons learned from international research. Topics to be discussed include the human papillomavirus vaccine, medication abortion, and intrauterine contraception.

Rates vary for members and nonmembers. Lower registration rates are available prior to July 31. To register online, visit the ARHP web site, www.arhp.org, and click on "Reproductive Health 2008," and "Online Registration." Registration also may be made by mail or fax by downloading the registration form. Click on "Register by mail or fax" on the Reproductive Health 2008 opening page. ▼

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 **December** issue, you must complete the evaluation form provided and return it in the reply envelope provided in that issue to receive a certificate of completion. When your evaluation is received, a certificate will be mailed to you. ■

Women with disabilities focus of web resource

Does your practice include reproductive health care of women with physical, developmental, or sensory disabilities? The American College of Obstetricians and Gynecologists

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.
5. According to the National Health and Nutritional Examination Survey (NHANES) 2003-2004, what percentage of young women between ages 14 and 19 in the United States are infected with chlamydia?
 - A. 4%
 - B. 5%
 - C. 8%
 - D. 10%
 6. What is the progestin contained in the four-phasic pill under development by Bayer HealthCare Pharmaceuticals?
 - A. Drospirenone
 - B. Dienogest
 - C. Nestorone
 - D. Trimegestone
 7. According to *Cochrane Database of Systematic Reviews* (2008; CD001324. DOI:10.1002/14651858.CD001324.pub3), what is the most effective EC?
 - A. Single-dose levonorgestrel
 - B. Yuzpe regimen
 - C. Mifepristone
 - D. Split-dose levonorgestrel
 8. What class of drugs has been shown to be effective in the acute treatment of menstrual migraine?
 - A. Opiates
 - B. Integrase inhibitors
 - C. Gamma-secretase modulators
 - D. Triptans

Answers: 5. A; 6. B; 7. C; 8. D.

(ACOG) offers a freely downloadable slide program, "Reproductive Health Care for Women with Disabilities," to assist women's health care clinicians in this arena.

Now available are the first two parts of the six-part series, which cover the scope of disability in women, sexuality, psychosocial issues, the gynecologic examination, and the gynecologic health screening. The program was recorded by Raymond Cox Jr., MD, MBA, chairman of the Department of Obstetrics and Gynecology at St. Agnes Hospital in Baltimore, and Caroline Signore, MD, MPH, postdoctoral fellow in the Division of Epidemiology, Statistics, and Prevention Research at the National Institute of Child Health and Human Development of the National Institutes of Health in Bethesda, MD. Elisabeth Quint, MD, clinical associate professor in the Department of Obstetrics and Gynecology at University of Michigan in Ann Arbor served as faculty chair.

To access the PowerPoint presentation with scripted notes, go to the ACOG web site, www.acog.org. Under "Announcements," click on "Reproductive Health Care for Women with Disabilities." ■

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More education is needed to boost HPV vaccination rates in preteen girls, CDC says

When it comes to administering the vaccine for human papillomavirus (HPV), providers are following the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices' recommendation to target all girls ages 11-12 for routine vaccination.

But how do parents figure into the vaccination picture? Results from a new national study indicate that U.S. mothers report they are less likely to vaccinate daughters under age 13 against the disease, even though the vaccine is recommended for preteen girls.¹

Parental attitudes about HPV vaccines will be key determinants of adolescent vaccination, says **Jessica Kahn**, MD, MPH, associate professor of pediatrics and director of research training in the

Division of Adolescent Medicine at Cincinnati Children's Hospital Medical Center and the University of Cincinnati College of Medicine. Previous studies have shown that parents generally support vaccination of their children, but some parents have specific concerns about their child receiving an STD vaccine,^{2,3} and some are reluctant to immunize daughters in the age range targeted for vaccination, says Kahn, lead author of the research paper.

Most published studies on parental attitudes on HPV vaccines enrolled parents from a limited geographic area and were conducted prior to vaccine licensing, says Kahn. For those reasons, co-authors of the current paper decided to conduct a national, post-licensing study involving mothers of adolescent and young adult women, she explains.

"Our aims were to characterize mothers' attitudes about HPV vaccines and intention to make sure that daughters in different age groups were vaccinated; to explore mothers' intention to be vaccinated themselves, if the vaccine were recommended for women their age; and to identify factors (demographic, attitudinal, and behavioral)

EXECUTIVE SUMMARY

Results from a new national study indicate that mothers in the United States report they are less likely to vaccinate daughters younger than age 13 for human papillomavirus (HPV), even though the vaccine is recommended for preteen girls.

- Previous studies have shown that parents generally support vaccination, but some have specific concerns about their child receiving a vaccine for a sexually transmitted disease, and some are reluctant to immunize daughters in the age range targeted for vaccination.
- Use information developed by the Centers for Disease Control and Prevention to educate parents and young girls about the importance of early vaccination.

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linked to intention to vaccinate a daughter in different age groups," Kahn states.

Researchers surveyed 10,521 mothers of adolescents enrolled in the Growing Up Today Study, a longitudinal study of the children of mothers participating in the Nurses Health Study II between June 2006 and February 2007. In the study, while 86% of mothers registered intention to vaccinate a 16- to 18-year-old daughter, and 68% said they intended to vaccinate a 13- to 15-year-old daughter, fewer than half (48%) registered intention to vaccinate a 9- to 12-year-old daughter.¹

The most powerful individual predictors that were most associated with mothers' likelihood to vaccinate their younger daughters were belief that HPV vaccination would provide protection against cervical cancer, belief that vaccinated girls would not practice riskier sex, belief that a daughter's clinician would recommend HPV vaccines for her, and belief that a daughter is at risk for HPV infection.¹

Researchers from Indiana University, the University of Texas Medical Branch Galveston and Harvard University Medical School participated in the analysis, which was funded by the American Cancer Society.

What's the next step?

Since mothers' personal beliefs play such an important role in their decisions to have younger daughters immunized against HPV, the development of evidence-based messages that emphasize adolescent girls' risk for HPV infection, the effectiveness of the vaccine in preventing cervical cancer, and clinician endorsement of vaccination may increase the acceptability of the HPV vaccine among parents and help to maximize HPV vaccine uptake, says Kahn. The research team intends to study interventions to increase mothers' willingness to vaccinate their daughters.

"Identification of factors linked to intention can help us to design evidence-based interventions to improve vaccine acceptability among mothers and thus improve vaccine uptake among their daughters," says Kahn. "Our findings can help to create key messages for these interventions."

The American Cancer Society estimates that in 2008, 11,070 women will be diagnosed with cervical cancer in the United States.⁴ Gardasil is

HPV Vaccine Questions and Answers

- **Will girls and women who have been vaccinated still need cervical cancer screening?**

Yes, for three reasons. Number one, the vaccine will not protect against all types of HPV that cause cervical cancer, so vaccinated women will still be at risk for some cancers. Second, some women may not get all required doses of the vaccine, or they may not get them at the right times, so they may not get the vaccine's full benefits. And last, women may not get the full benefit of the vaccine if they receive it after they have already acquired one of the four HPV types.

- **Should girls and women be screened before getting vaccinated?**

No. Girls and women do not need to get an HPV test or Pap test to find out if they should get the vaccine. An HPV test or a Pap test can tell that a woman may have HPV, but these tests cannot tell the specific HPV type or types that a woman has. Even those with one HPV type could get protection from the other vaccine HPV types they have not yet acquired.

- **Will girls be required to get vaccinated before they enter school?**

There are no federal laws that require children or adolescents to get vaccinated. All school and day care entry laws are state laws, so they can vary from state to state. Check with your state health department or board of education to find out what vaccines are needed for children or teens to enter school or day care in your state.

Source: Centers for Disease Control and Prevention. HPV Vaccine Questions and Answers. Accessed at www.cdc.gov/std/hpv/STDFact-HPV-vaccine.htm#hpvvac5.

designed to protect against infection from four HPV types, including two types (HPV 16 and 18) that cause about 70% of cervical cancers.

"It is very important that women be vaccinated, and because this vaccine is a preventative, not a cure, it is very important the girls be vaccinated before beginning sexual relations," says **Curtis Allen**, a CDC spokesman. "It is also very important that parents understand the reason for the vaccine and also that they can explain the reason for the vaccine to their young daughters."

In girls and women who have not been

infected with any of the four HPV types contained in the Gardasil vaccine, research indicates that the vaccine is about 100% effective in preventing precancers of the cervix, vulva, and vagina, and genital warts caused by those HPV types.⁵

“Education is a very important part of any vaccine program, but it is important that parents understand why the Advisory Committee on Immunization Practices made the decisions that they did and why it is important for their daughters to be vaccinated against HPV,” says Allen.

The CDC has developed an informational handbook for clinicians, “Human Papillomavirus: HPV Information for Clinicians.” The handbook contains a freely reproducible handout for parents, “*What Parents of Preteens/Adolescents Should Know About the HPV Vaccine.*” The handout is available in both English and Spanish. (To download the clinician handbook, go to the web site www.cdc.gov/std/hpv/hpv-clinicians-brochure.htm.)

Cover important facts about HPV with those who are vaccinated (see box on p. 2), and stress these important messages with parents:

- **The vaccine is given through a series of three shots over a six-month period.** Your daughter will need to come back for the second and third shots two and six months (respectively) after the first shot. It is very important that she receive all three shots, since it is not yet known how much protection she would get from receiving only one or two shots of the vaccine.

- **The vaccine causes no serious side effects.** The most common side effect is soreness at the injection site.

- **The HPV vaccine costs about \$120 per dose, or \$360 for the series.** You may be able to get it for free or at low-cost through your health insurance plan or federal or state programs.

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NEWS BRIEFS

Get HPV vaccine dose replacements via plan

Have you administered the initial dose of Gardasil, the quadrivalent human papillomavirus (HPV) vaccine, to a young woman with private insurance, only to later discover that her policy does not cover vaccine reimbursement?

Vaccine manufacturer Merck & Co. has announced the Dose Replacement Program to help address Gardasil reimbursement concerns for privately insured patients ages 19-26. The company has launched the program to help providers prevent missed opportunities when it comes to vaccinating women in the 19-26 age range.

According to Merck, there are fewer government programs available to help provide access to the HPV vaccine for women ages 19-26 whose private insurance benefits do not include first dollar vaccine coverage. In addition, there is no national program for women ages 19-26 comparable to the Vaccines for Children program that provides vaccines for those ages 9 to 18.

Providers who enroll in the Merck program are eligible to receive one replacement dose for every 10 doses purchased during the quarter. Program participants can receive at least one replacement dose as long as they have purchased a single dose in the quarter.

The new program applies to doses administered on or after May 16, 2008. The program does not cover doses administered to patients who are

eligible for any government-funded health care program or who have no health insurance. Program coverage is not available in Massachusetts, Michigan, Missouri, Minnesota, or Rhode Island.

The company says it expects the program to extend through 2009 while company officials work with appropriate stakeholders to identify long-term solutions to reimbursement challenges.

To enroll in the program, visit its web site, www.drp4gardasil.com. If you do not have internet access, you may request information by calling the program's toll-free number, (800) 668-8414. ▼

Get online resources for STD awareness

Educational tools, materials available

Need to boost awareness about various sexually transmitted diseases (STDs) at your clinic? Check out the wide variety of online resources at the Centers for Disease Control and Prevention's (CDC) STD Awareness Month site, www.cdcnpin.org/stdawareness/sam.htm.

While April 2008 was designated as STD Awareness Month, the CDC is encouraging providers to visit the site throughout the year to download materials, education tools, and information to support STD awareness activities.

Download basic prevention and treatment brochures through *The Facts* series offered at the online site. Available in English and Spanish, the brochures are freely reproducible in Adobe PDF. Each title covers such STDs as chlamydia, herpes, gonorrhea, pelvic inflammatory disease, and trichomoniasis.

The site also offers innovative E-Cards, which allows senders to send colorful prevention messages via e-mail. Messages include such information as "1 in 4 Americans have an STD" and, "It is estimated that over 2 million Americans have chlamydia."

Other resources include links to such sites as the California STD/HIV Prevention Training Center's SWAP Site (www.stdhivtraining.org; click on "Material Swap"), which provide

agencies with free access to locally developed, original health education and promotional materials. Also included is a link to the CDC's STD and HIV Testing Resources site (www.hivtest.org), which allows providers to list their testing services in CDC's searchable database of HIV/AIDS, viral hepatitis, STD, and tuberculosis service providers. Click on the "Get Tested!" icon. ▼

Use online resource to link to STD information

Interested in sharing information on sexually transmitted disease (STD) prevention? Check out www.STDPreventionOnline.org, a service of The Internet & STD Center of Excellence. The center is sponsored by the Centers for Disease Control and Prevention and carried out by the Denver Department of Public Health.

The web site allows providers to explore, identify, implement, and evaluate innovative technologies and applications that show promise in addressing STD prevention. Applications may target patients, clinicians, epidemiologists, public health workers, researchers, or others in the prevention field. The site also offers a free job bank as well as a calendar of upcoming conferences.

To reach the link, click on the "Get Tested!" icon on the opening page of the STD Awareness Month site. ■

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