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Boost HPV vaccination numbers — next generation is at risk

3-dose coverage declined slightly from 2011 to 2012

According to just-released information, vaccination for human papillomavirus (HPV) rates in U.S. girls ages 13-17 failed to increase between 2011 and 2012; in fact, three-dose coverage actually declined slightly from 2011 to 2012.[1] In 2012, only 53.8% of girls had received one or more doses of HPV vaccine, and only 33.4% had received all three doses of the series.[1]

Drawn from data from the 2012 National Immunization Survey — Teen, among girls unvaccinated for HPV, 84% had a healthcare visit at which they received another vaccine, such as one for meningitis or pertussis, but not the HPV vaccine. If the HPV vaccine had been administered, vaccination coverage for one or more doses could be nearly 93%, rather than 54%, say officials with the Centers for Disease Control and Prevention (CDC).

"Progress increasing HPV vaccination has stalled, risking the health of the next generation," said CDC Director **Tom Frieden**, MD, MPH, in a statement accompanying the report. "Doctors need to step up their efforts by talking to parents about the importance of HPV vaccine just as they do other vaccines and ensure it's given at every opportunity."

Time is of the essence, say public health officials. For each year the three-dose HPV vaccine series coverage remains near the current level of 33% — instead of achieving the Healthy People 2020 goal of 80% coverage — an additional

EXECUTIVE SUMMARY

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- Among girls unvaccinated for HPV, 84% had a healthcare visit at which they received another vaccine, such as one for meningitis or pertussis, but not the HPV vaccine. If the HPV vaccine had been administered, vaccination coverage for one or more doses could be nearly 93%, rather than 54%.
- Be sure to talk with parents about the importance of HPV vaccination. Data indicate that not receiving a healthcare provider's recommendation for HPV vaccine was one of the main reasons parents reported for not vaccinating their daughters.

4,400 women will be diagnosed with cervical cancer, and 1,400 cervical cancer-attributable deaths will occur in the future, says the CDC.

What is the holdup?

Healthcare providers are urged to give a strong recommendation for HPV vaccination for boys and girls ages 11-12. Why? The analysis of the 2012 survey data shows that not receiving a healthcare provider's recommendation for HPV vaccine was one of the five main reasons parents reported for not vaccinating daughters. Other reasons included vaccine not needed (19.1%), vaccine safety concerns (13.1%), lack of knowledge about the vaccine or the disease (12.6%), and daughter not sexually active (10.1%).

Results of a 2011 paper indicate a provider's recommendation is the single most important factor in the decision by adolescents and parents to initiate and complete the HPV vaccination series.[2] *(*Contraceptive Technology Update *offered provider tips in the article "Time to boost numbers for HPV vaccination," May 2013, p. 56.)*

According to the survey analysis, responses provided by some parents indicate gaps in understanding about the vaccine, including why vaccination is recommended at ages 11 or 12. "Parents need reassurance that HPV vaccine is recommended at 11 or 12 because it should be given well in advance of any sexual activity," said Frieden. "We don't wait for exposure to occur before we vaccinate with any other routinely recommended vaccine."

Address safety concerns with parents to alleviate their fear for not vaccinating. Public health officials note that in the seven years of postlicensure vaccine safety monitoring and evaluation conducted independently by federal agencies and vaccine manufacturers, no serious safety concerns have been identified. Reports of adverse events after HPV vaccination to the Vaccine Adverse Event Reporting System (VAERS) have decreased steadily from 2008 to 2012; the numbers of serious adverse events reported also has declined since 2009.[1]

During June 2006 to March 2013, the VAERS received 21,194 adverse event reports occurring in females after receipt of the HPV vaccine; 92.1% were classified as nonserious. Among nonserious adverse events, the most commonly reported generalized symptoms were syncope, dizziness, nausea, headache, fever, and urticaria; the most commonly reported local symptoms were injection-site pain, redness, and swelling. Among the 7.9% of vaccine-related reports classified as serious (requiring hospitalization), the most frequently reported symptoms were headache, nausea, vomiting, fatigue, dizziness, syncope, and generalized weakness.[1]

Make recommendations

CDC is working with healthcare providers in several ways to increase the consistency and strength of recommending the HPV vaccine, says **Anne Schuchat**, MD, the director of CDC's National Center for

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Immunizations and Respiratory Diseases.

"First, we are helping providers enhance their interactions with parents about HPV vaccine," says Schuchat. "We are pointing providers to research study findings to arm them with sound, scientific information they use to help them better address the questions and concerns raised by parents." *(Download a free CDC handout, "Diseases That Vaccines Prevent — Human Papillomavirus," to educate parents. Go to http://1.usa.gov/1155KvD.)*

The CDC also is doing health communication research with providers on the most effective ways to talk with parents about vaccination, says Schuchat. One of the resulting products from that research is a free tip sheet, "Tips and Time-savers for Talking with Parents about HPV Vaccine" at http://1.usa.gov/15JhxO5.

Schuchat also notes that the CDC is engaging provider partners, such as the American Academy of Pediatrics and the American Academy of Family Physicians, to help reach clinicians to ensure they have the information and resources they need to make strong recommendations for the vaccine.

Remind parents that for many families, it's easier than ever to get the HPV vaccine. Because of the Affordable Care Act, most private health insurance plans must cover the HPV vaccine at no out-of-pocket cost, meaning no copay or deductible. *(To see what preventive health services are covered for children, go to http://1.usa.gov/13BAhDo.)*

Minorities at risk

Recent research indicates that women of color are at particular risk for cervical cancer. In 2009, Hispanic women had the highest rate of getting cervical cancer, followed by black, American Indian/Alaska Native, white, and Asian/Pacific Islander women.[3]

To determine HPV and vaccine awareness, knowledge, beliefs, and barriers, researchers at the University of California, Los Angeles (UCLA) conducted telephone interviews in six languages among mothers of vaccine-eligible girls using the Los Angeles County Department of Public Health, Office of Women's Health service referral hotline. The sample consisted of low-income, uninsured, ethnic minority, and immigrant women. Only 29% of daughters initiated the vaccine, and only 11% received all three doses, data indicate. National data for the same time period found that 44% of adolescents had initiated the HPV vaccine and 27% had completed the series.[4]

In a separate study of the population designed to examine geographic access to HPV vaccines for underserved girls, researchers found that while most girls live in close proximity to safety-net vaccination services, rates of initiation were low.[5]

The UCLA School of Public Health & the Jonsson Comprehensive Cancer Center is working with the Los Angeles County Department of Public Health, Office of Women's Health, to evaluate via a randomized trial a theoretically driven, culturally sensitive and individually tailored intervention to increase HPV vaccine receipt among underserved, high-risk girls in Los Angeles. The goal is to increase vaccination rates among low-income, ethnic minority, vaccine-eligible girls.

The program plans to speak directly to mothers of the target population: girls ages 11-18. When the mothers call the health department for information or services, the intervention will educate them about the vaccine and refer them to a conveniently located clinic offering free or low-cost vaccines. The intervention has not yet been launched, says **Roshan Bastani**, PhD, professor of health policy and management in the UCLA Fielding School of Public Health and director of the UCLA Kaiser Permanente Center for Health Equity.

Researchers with the project have translated the materials into six languages: English, Spanish, Mandarin, Cantonese, Vietnamese, and Korean, says Bastani.

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High demand, production delay limit Skyla IUD

Providers might need to seek other long-acting reversible contraceptive methods other than the new smaller levonorgestrel intrauterine device

(IUD), Skyla. Its manufacturer, Bayer HealthCare Pharmaceuticals of Wayne, NJ, has informed providers that it is experiencing limited inventory levels. According to a July 15, 2013, letter issued to providers, the company said it anticipated to be out of stock by the end of that month.[1]

"We are working to resolve this supply issue, and new stock is targeted to be available by year end," the letter states.

Since the successful introduction of Skyla earlier this year, Bayer has experienced a high level of demand for Skyla and a delay in production, says company spokesperson Rosemarie Yancosek. *(Read the* Contraceptive Technology Update *article about the product's approval; see "FDA approves smaller intrauterine system — a 'mini-Mirena,'" March 2013, p. 25.)* The company is currently reviewing the situation and working to ensure there is appropriate product moving forward, she states.

"For additional information, [providers] can contact Bayer's Medical Information Services at (888) 842-2937," says Yancosek. "Bayer will proactively notify customers when product is available."

Check the "mini-Mirena"

The Skyla IUD and its inserter are smaller in size than its sister product, the Mirena IUD, also manufactured by Bayer. Skyla's small, flexible plastic T-shaped device measures 28 mm by 30 mm, as compared to Mirena's 32 mm by 32 mm dimensions. Skyla has a smaller inserter diameter; it is 3.8 mm in diameter, compared to Mirena's 4.75 mm diameter inserter.

Skyla contains 13.5 mg levonorgestrel. The drug is released at an average in vivo rate of approximately 6 mcg/day over three years. In comparison, Mirena contains 52 mg of levonorgestrel. Its drug is released at a rate of approximately 20 mcg per day, which decreases progressively to half that value after five years. Skyla is labeled for up to three years of effective use; Mirena carries labeling for up to five years of effective use.

One perceived advantage of Skyla lies in its specific labeling regarding use in nulliparous women. The product labeling for Skyla specifically states that it can be used whether or not a woman has had a child, whereas the labeling for Mirena states it is recommended for women who have had at least one child. Mirena has not revised its labeling regarding use in nulliparous women, even though it is generally seen as safe. The US MEC classes such use as a 2, where benefits generally outweigh any risks.

Donna Gray, CNM, WHNP, a clinician at the Wyoming County Health Department's Men's and Women's Reproductive Health Center in Silver Springs, NY, has performed just one Skyla insertion in a nulliparous teen. There were no problems with device insertion, and the patient is doing well with the method, she states. She sees the device as a good option for nulliparous women or those who only want to wait three years between childbirth.

More providers might be looking at IUDs as appropriate birth control in adolescents following a 2012 committee opinion from the American College of Obstetricians and Gynecologists (ACOG). The ACOG opinion states that long-acting reversible contraceptives such as the intrauterine device and the contraceptive implant are safe, effective, and appropriate options for adolescents.[2] *(*CTU *reported on the opinion. See "Long-acting methods safe for teens — include options in your counseling," December 2012, p. 133.)*

What are your options?

If Skyla supply is unavailable, what options are open to clinicians? Clinicians should be reminded that often the women who would benefit from Skyla would be excellent candidates for the contraceptive implant, says **Anita Nelson**, MD, professor in the Obstetrics and Gynecology Department at the David Geffen School of Medicine at the University of California in Los Angeles.

The implant and IUD possess the highest rates of patient satisfaction and continuation of all available reversible contraceptives, according to the ACOG committee opinion.[2] With their long-acting effectiveness, both methods eliminate the problem of inconsistent use seen with other forms of reversible birth control.

"We need to always to remember all the alternatives and not get trapped inside the endometrium," says Nelson.

In talking about use of the intrauterine contraceptive or the contraceptive implant, remember to discuss potential bleeding changes associated with those meth-

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ods. Women who use the contraceptive implant should be counseled to expect changes in menstrual bleeding throughout use of the method. In an analysis of 11 studies, the most common bleeding pattern was infrequent bleeding in 33.3% of 90-day cycles, followed by amenorrhea in 21.4% of cycles.[3]

A change in bleeding pattern is the most common reason for discontinuation of use of the implant, so anticipatory guidance regarding such changes might improve satisfaction and continuation. Tell patients that the bleeding pattern they experience in the first three months is broadly predictive of future bleeding patterns.[4]

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Help college-age women plan forward with LARCs

Results of a recent national survey indicate about half of women ages 18-25 identified personal goals they want to achieve before having children.[1] Long-acting reversible contraceptives (LARCs), such as intrauterine devices (IUDs) and the contraceptive implant, can help young women achieve their goals.

Case in point: In a national survey of 700 women sponsored by the manufacturer of the contraceptive implant, Nexplanon [Merck & Co., Whitehouse Station, NJ], about half of women ages 18-25 (228 out of 466 women who said they are not planning to have children in the next year, or at all) want to achieve their personal goals before having children.

Contraceptive methods are tools to help meet life goals and are not a goal in and of themselves, says **Linda Dominguez**, NP, a nurse practitioner at Southwest Women's Health in Albuquerque and chairperson of the Association of Reproductive Health Professionals. When clinicians are solely focused on a "prescriptive approach," they overlook the opportunity to engage the woman and her partner in exploring present and future life planning, she notes. A patient's personal, educational, financial, and relationship goals are fundamental motivators and milestones; ideally, her contraceptive method should support those goals, states Dominguez.

"Often clinicians avoid asking 'personal' questions that are not of a purely clinical nature," observes Dominguez. "But in sexual and reproductive health, it is imperative to discuss and explore life goals and the contraceptive choices that can help to meet those landmarks."

Finding a safe, effective contraceptive method for young women is key; about half of all pregnancies are unintended;[2] women ages 18-19 and 20-24 have the highest rates of unintended pregnancies.[3]

With 43% of unintended pregnancies stemming from incorrect or inconsistent contraceptive use,[4] long-acting reversible methods could help women achieve their contraceptive and personal goals. While use of LARC methods is growing, overall use remains low: about 9%.[5]

Young women need accurate information on LARC methods. Data indicates between 50% and 60% of young women have never heard of the IUD,[6-9] while more than 90% have no knowledge about implants.[7]

Incorporating young women's perspectives on LARC methods into family planning facilities' efforts to provide these methods to a younger population might increase their use among young women, notes a recent study of provider and patient perspectives on long-acting methods.[10]

Get ready to see data on LARC methods from a large cluster randomized trial conducted by the

EXECUTIVE SUMMARY

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University of California, San Francisco (UCSF) Bixby Center for Global Reproductive Health.

Trial looks at impact of LARC training

To explore ways to improve LARC access, the center recently concluded the UCSF and Planned Parenthood National Trial of Contraceptive Acceptability. Working in partnership with 40 Planned Parenthood health centers, the trial tested the impact of a clinic-wide training about LARC. The training included information geared for health educators, clinicians, front-desk staff, clinic managers, and billing experts, says lead investigator **Cynthia Harper**, PhD, associate professor in the Department of Obstetrics, Gynecology and Reproductive Sciences at the UCSF School of Medicine and faculty member of the Bixby Center. Twenty Planned Parenthood health centers received the training intervention, and twenty control Planned Parenthood health centers offered standard care, she states.

The Planned Parenthood health centers enrolled clients ages 18-25 who received contraceptive counseling for one year of follow-up. The study had 500 participating staff and 1,500 participating patients; its 12-month follow-up rate for clients was 84%. Planned Parenthood health centers also collected service statistics for more than 200,000 annual female contraceptive clients.

Scientists are analyzing the data, and research will be presented later this year, says Harper. The research questions will compare outcomes in intervention versus control health centers, and they will focus on such questions as:

- What proportion of clients selected LARC versus other contraceptive methods?
- What proportion of clients continued to use their selected contraceptive after one year?
- What was the client rate of unintended pregnancy at one year?
- Are there differences in provider LARC knowledge, attitudes, or practices?

The trial's objective is aimed at helping women have increased access to LARC methods in the United States, especially women who are at the highest risk of unintended pregnancy, says Harper. College-age women are an important age group, because they have many years during which they don't want to get pregnant. Providers traditionally have not been talking to these women about LARC methods, she notes.

"We are trying to teach [providers] that a much wider set of women can use IUDs and implants," says Harper.

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For gestational diabetes, check prior status

Address contraception at each visit

Your new patient is a young mother of three. When you quiz her on complications incurred in her prior pregnancies, she discloses she was diagnosed with gestational diabetes mellitus (GDM) in the last pregnancy. What is your approach when it comes to family planning counseling for her?

GDM is a condition in which hyperglycemia occurs or is first recognized during pregnancy. It is associated with complications for the mother and baby during and after pregnancy. During pregnancy, women with GDM are at an increased risk of developing pre-eclampsia,

having a caesarean birth, and developing type 2 diabetes in the future. Babies born to women with GDM are at an increased risk of macrosomia (birthweight greater than 4,000 g), birth trauma due to their size, respiratory distress syndrome, and other health complications.[1] Research indicates in utero exposure to hyperglycemia has long-lasting effects on the infant, increasing the risk of future obesity and type 2 diabetes mellitus.[2]

While gestational diabetes mellitus typically resolves after birth, women with the condition are at risk of developing it again in future pregnancies. It is critical to address contraception at each interconception visit with women with prior gestational diabetes, according to a new review on the subject.[3] Women with prior gestational diabetes mellitus must be counseled that GDM in one pregnancy not only increases the risk for the condition in further pregnancies, particularly in nonwhite women, but also that pregnancy might accelerate the rate of beta cell exhaustion and subsequent development of diabetes mellitus.[4-6]

Women who become diabetic during an interconception interval are at risk for unplanned pregnancy during periods of maternal hyperglycemia, the review article states. Women with a history of GDM must be monitored for manifestations of increasing insulin resistance, hyperglycemia, dyslipidemia, hypertension, and increased adiposity.[3]

Clinicians need to be strategic in thinking with patients with a prior history of GDM, says **Ruth Mielke**, PhD, RN, CNM, assistant professor in the School of Nursing at California State University, Fullerton and staff nurse midwife at Eisner Pediatric and Family Medical Center in Los Angeles. Use every visit — whether it's for a weight check, a blood pressure check, or another reason — to review the patient's contraceptive choices and ensure it is correctly and consistently used, says Mielke, who served as lead author of the current review article.

Program your electronic medical records to highlight history of GDM in the chronic diseases listing so it appears when the chart is reviewed, she suggests. If using traditional paper charting, use color coding to denote charts of patients with a GDM history, Mielke advises.

Postpartum care is key

Although the carbohydrate intolerance of women with GDM frequently resolves after delivery, it is estimated that up to one-third of affected women will have diabetes or impaired glucose metabolism at postpartum screening, and 15-50% will develop type 2 diabetes later in life.[7-12] According to a new GDM practice bulletin issued by the American College of Obstetricians and Gynecologists, either a fasting plasma glucose test or the 75-g, two-hour oral glucose tolerance test are appropriate for diagnosing overt diabetes in the postpartum period.[13] Although the fasting plasma glucose test is easier to perform, it is not as sensitive in teasing out other forms of abnormal glucose metabolism. Results of an oral glucose tolerance test can better detect impaired fasting glucose level and impaired glucose tolerance.[13]

Women in the postpartum period with impaired fasting glucose, impaired glucose tolerance, or diabetes should be referred for therapy. Women with impaired conditions might respond to lifestyle modification and pharmacologic interventions to decrease development of diabetes later in life. Repeat testing should be done at least every three years for women who had a pregnancy affected by GDM and who register normal results in postpartum screening.[13] Women with prior GDM who possess additional risk factors, such as obesity or family history of diabetes, should be tested annually. Lifestyle modifications that are effective in preventing and delaying development of diabetes should be encouraged.

Look at LARC methods

A general principle to remember when discussing birth control options with women following a pregnancy complicated by GDM is that another pregnancy would be significantly more hazardous for the woman than any contraceptive method, says **Anita Nelson**, MD, professor in the Obstetrics and Gynecology Department at the David Geffen School of Medicine at the University of California in Los Angeles.

Long-acting reversible contraceptive (LARC) methods, such as intrauterine contraception and the contraceptive implant, are good options for women with prior GDM, notes Mielke. They offer top-tier effectiveness and allow women to return to fertility when

EXECUTIVE SUMMARY

It is critical to address contraception at each interconception visit with women with prior gestational diabetes mellitus (GDM), according to a new review. While the condition typically resolves after birth, women with the condition are at risk of developing it again in future pregnancies.

- GDM is a condition in which hyperglycemia occurs or is first recognized during pregnancy. It is associated with complications for the mother and baby during and after pregnancy.
- For women with prior GDM, the U.S. Medical Eligibility Criteria for Contraceptive Use lists all contraceptive methods — combined and progestin-only pills, intrauterine devices, as well as the contraceptive ring, patch, injection and implant— as "no restriction" on use.

they are ready to have more children, she notes. With their 'set-it-and-forget-it' convenience, LARC methods are a good fit for active young mothers.

For women with prior GDM, the U.S. Medical Eligibility Criteria for Contraceptive Use lists all contraceptive methods — combined and progestin-only pills, intrauterine devices, as well as the contraceptive ring, patch, injection, and implant— as "no restriction" or Category One.[14]

"With this as a foundation, contraception for women with prior GDM must be further tailored with each woman's risk profile in mind (e.g. age, body mass index, cardiovascular risk)," states the review article.

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Gonorrhea treatments offer 2 new options

Results of a trial conducted by the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) indicate two new antibiotic regimens using existing drugs successfully treated gonorrhea infections in a clinical trial.[1] The regiments are injectable gentamicin in combination with oral azithromycin, and oral gemifloxacin in combination with oral azithromycin.

What does this mean for new treatment options in the face of growing antibiotic resistance to the sexually transmitted infection (STI)?

"These new treatment options identified in the trial provide hope in the fight against drug-resistant gonorrhea," states **Robert Kirkcaldy**, MD, MPH, a CDC medical epidemiologist who led the trial. "They also offer fallback regimens for certain patients, but they do not address the urgent need for additional first-line treatments."

What led researchers to pick these two particular drug combinations for the study? According to Kirkcaldy, previous lab data suggested the drugs held promise; however, they had not been fully evaluated for gonorrhea treatment in a clinical trial. With cases of drug-resistant gonorrhea rising, the number of effective and well-studied gonorrhea treatment options dwindling, and few new treatments in the pipeline emerging, the trial became a public health priority, Kirkcaldy states.

The trial results represent an encouraging development in a discouraging field, says Kirkcaldy. While they move science in the right direction, patients urgently need more oral options with fewer side effects, he states.

What is the next step in research in determining drug options for gonorrhea treatment? According to Kirkcaldy, the CDC is working closely with the National Institutes for Allergy and Infectious Disease at NIH and other research laboratories to identify drugs that look promising in the laboratory and could be potential treatment options for gonorrhea. However, broader action is needed to prevent untreatable gonorrhea from becoming a reality in the United States, he says. Researchers and pharmaceutical companies must jumpstart research to identify or develop new, effective drugs and drug combinations.

"In addition to looking for new treatment options,

we must also continue to monitor how existing treatment options are performing," states Kirkcaldy. "Health departments and labs must help the CDC keep a watchful eye on emerging drug resistance, especially through culture testing."

In other efforts, the CDC is also calling on public and private partners to help develop other urgently-needed tools – such as improved diagnostics and a gonorrhea vaccine, says Kirkcaldy.

Why the push?

Gonorrhea is one of the most common STIs in the United States. The most recent CDC report estimates about 820,000 new infections each year.[2] While some men and women might have symptoms such as discharge or burning when urinating, most people infected with gonorrhea do not exhibit symptoms.

Left untreated, gonorrhea can result in serious health problems, particularly for women. They might develop chronic pelvic pain, ectopic pregnancy, and infertility. Gonorrhea infection also increases a person's risk of contracting and transmitting HIV, states the CDC.

The drugs included in the clinical trial are approved by the Food and Drug Administration and are available in the United States. The study represents the first effort to evaluate them as combination therapy for gonorrhea.

Scientists conducted a non-comparative trial, randomizing patients with urogenital gonorrhea to one of two regimens: 240 mg of gentamicin intramuscularly plus 2 g of azithromycin orally, or 320 mg of gemifloxacin orally plus 2 g of azithromycin orally. The primary outcome was defined as microbiologic cure of urogenital infections (a negative follow-up culture) at 10-17 days post-treatment. All study participants who returned for follow-up and had evaluable follow-up cultures were included in the protocol analysis.

The study, which began in 2010, enrolled 401 men and women ages 15-60 with untreated gonorrhea infection at clinical trial sites in Baltimore, Birmingham, AL, Los Angeles, Pittsburgh, and San Francisco. Researchers report 100% effectiveness of the injectable gentamicin/oral azithromycin combination in curing genital gonorrhea infections and 99.5% effectiveness of the oral gemifloxacin/oral azithromycin combination. Both combinations cured 100% of infections of the throat and rectum, data indicate.

The downside? Many trial participants reported adverse effects, mostly gastrointestinal issues, from the drugs. The most common adverse events in the injectable gentamicin/oral azithromycin arm were mild to moderate nausea (27% of participants), diarrhea (19%), abdominal discomfort/pain, and vomiting (both 7%). In the oral gemifloxacin/oral azithromycin arm, the most common adverse events were nausea (37% [with 8% recorded as moderate-severe]), diarrhea (23%), and abdominal discomfort/pain (11%).[1] Results of the study were presented in July 2013 at the annual meeting of the International Society for Sexually Transmitted Diseases Research in Vienna, Austria.

Guidance remains same

While the study's results appear promising, they do not change current gonorrhea treatment guidelines, states the CDC. The agency still recommends only one first-line treatment regimen. That regimen is injectable ceftriaxone, in combination with one of two other oral antibiotics: azithromycin or doxycycline.[3] *(To be sure you have the most current recommendations, use the free CDC fact sheet at http://1.usa.gov/Xdyz5k.)*The CDC says it is taking the findings of the current trial into consideration for inclusion in future treatment guidelines.

"This regimen remains highly effective in treating gonorrhea and causes limited side effects," the agency reported in a released statement. "However, providers may consider using the regimens studied in this trial as alternative options when ceftriaxone cannot be used, such as in the case of a severe allergy."

Having an injectable option, as opposed to one that requires intravenous administration, will make it so much easier for clinics to offer more effective therapies, says **Anita Nelson**, MD, professor in the Obstetrics and Gynecology Department at the David Geffen School of Medicine at the University of California in Los Angeles. Oral combination therapy is even easier for the patient to take, but requires patient compliance to achieve optimal benefit, she notes.

EXECUTIVE SUMMARY

Results of a trial conducted by the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health indicate two new antibiotic regimens using existing drugs successfully treated gonorrhea infections in a clinical trial. The regimens are injectable gentamicin in combination with oral azithromycin, and oral gemifloxacin in combination with oral azithromycin.

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Nonhormonal options eyed for contraception

The next patient in your exam room is looking for a contraceptive method that is non-hormonal and can be used on a on-demand basis. What is your next move?

Spermicidal products, while offering less contraceptive protection than other methods, give women an option that is female-controlled, nonhormonal, and noninvasive. While commonly marketed for use with a diaphragm, they can be used alone for birth control. They rank in the lowest tier of contraceptive effectiveness, with 18 or more pregnancies per 100 women in one year with typical use.[1] According to *Contraceptive Technology,* 28% of women will experience an unintended pregnancy during the first year of typical use of spermicides; with perfect use, the number decreases to 18%.[1]

The active chemical agent in current products is nonoxynol-9 (N-9), a surfactant that destroys the sperm cell membrane. Spermicide concentration in U.S. products ranges from 8-12.5% in foam and from 2% to 4% in gels and creams.[2] Frequent use of spermicides containing N-9 has been associated with disruption of the genital epithelium, which might be associated with an increased risk for HIV transmission.[3]

Women in the United States might have another option in spermicides. Enrollment for a 3,200-subject Phase III registration study has been completed for Amphora, a non-hormonal contraceptive gel. The three-year trial compares Amphora to Conceptrol, the only N-9 spermicidal gel approved by the Food and Drug Administration (FDA). The Amphora trial began in April 2011 and will be completed in 2014, says Sean Edwards, president of Evofem, a San Diego-based biotechnology firm in charge of developing the potential product. Thirty-eight clinical sites participated in the trial.

Take a closer look

Amphora is an acid-buffering product that inactivates sperm, preventing conception. In early testing, Amphora showed promise as a contraceptive gel through its ability to immobilize sperm and to prevent certain sexually transmitted infections (STIs), including gonococci, herpes, chlamydia, HPV, and HIV.[4-7] However, it has not been tested for efficacy in preventing STIs. *(*Contraceptive Technology Update *reported on Amphora. See "Potential spermicide enters advanced trial," June 2011, p. 63.)*

Originally developed by the Topical Prevention of Conception and Disease Program at Rush–Presbyterian-St. Luke's Medical Center, Chicago, Amphora was licensed to Evofem's former company, Instead, in 2002, with patent protection granted in March 2004. Shortly thereafter, Amphora was granted FDA clearance for use as a personal lubricant; however, it has not been commercially marketed as such in the United States, states Edwards.

Clinicians will need to analyze the data for Amphora to finally quantify failure rates and discontinuation rates, observes **Anita Nelson**, MD, professor in the Obstetrics and Gynecology Department at the David Geffen School of Medicine at the University of California in Los Angeles. "Interestingly, spermicides may be used to bridge patients to more effective methods, so high, long-term discontinuation rates may not be as critical as they might be for longer-acting methods," she observes.

New condom designs eyed

EXECUTIVE SUMMARY

Enrollment for a 3,200-subject Phase III registration study has been completed for Amphora, a non-hormonal contraceptive gel. The three-year trial compares Amphora to Conceptrol, a nonoxynol-9 gel.

- Amphora is an acid-buffering gel that inactivates sperm, preventing conception.
- The Bill & Melinda Gates Foundation will announce winners later this fall for its challenge, "Develop the Next Generation of Condom." More than 500 applications have been submitted. The Foundation is looking for a next-generation condom that "significantly preserves or enhances pleasure, in order to improve uptake and regular use."

Could clinicians see a new condom come their way? The Bill & Melinda Gates Foundation will announce winners later this fall for the 11th round of its Grand Challenges Explorations, which includes "Develop the Next Generation of Condom." More than 500 applications have been submitted, say foundation officials.

According to the foundation, it is looking for a next-generation condom that "significantly preserves or enhances pleasure, in order to improve uptake and regular use." Attributes that increase ease-of-use for male and female condoms, such as better packaging or designs that are easier to properly apply, will be considered. In addition, attributes that address and overcome cultural barriers also are desired.

To be considered for the challenge, the foundation states proposals must have a testable hypothesis, include an associated plan for how the idea would be tested or validated, and yield interpretable and unambiguous data in Phase I testing, in order to be considered for Phase II funding.

Male latex condoms, when used consistently and correctly, can reduce the risk of pregnancy and many STIs, including HIV.[8] They are inexpensive, available without a prescription, and easy to use.

The one major drawback to more universal use of male condoms is the lack of perceived incentive for consistent use, states foundation material for the condom challenge. Males might perceive condoms as decreasing pleasure as compared to no condom, creating a trade-off that many men find unacceptable, the foundation notes. Officials look to the challenge to see if it is feasible to develop a product without this stigma, or even better, is perceived to enhance pleasure.

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COMING IN FUTURE MONTHS

- ■ Contraceptive coverage: where does the U.S. stand?
- ■ What do teens know about contraception?
- ■ Check out rapid HIV tests
- ■ Review apps for the family planning clinician

CNE/CME OBJECTIVES & INSTRUCTIONS

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

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

After reading *Contraceptive Technology Update*, the participant will be able to:

- identify clinical, legal, or scientific issues related to development and provisions of contraceptive technology or other reproductive services;
- describe how those issues affect services and patient care;
- integrate practical solutions to problems and information into daily practices, according to advice from nationally recognized family planning experts;
- provide practical information that is evidence-based to help clinicians deliver contraceptives sensitively and effectively.

CNE/CME QUESTIONS

1. According to Centers for Disease Control and Prevention (CDC), (MMWR 2013; 62(29):591-595), what is NOT one of the main reasons parents reported for not vaccinating daughters against human papillomavirus?
   A. Cost
   B. Vaccine not needed
   C. Vaccine safety concerns
   D. Lack of knowledge about the vaccine or the disease

2. What is the size of the Skyla intrauterine device?
   A. 20 mm by 25 mm
   B. 28 mm by 30 mm
   C. 32 mm by 32 mm
   D. 35 mm by 37 mm

3. According to Frost JJ, Darroch JE, Remez L. (New York: Guttmacher Institute; 2008), what percentage of unintended pregnancies stem from incorrect or inconsistent contraceptive use?
   A. 10%
   B. 27%
   C. 43%
   D. 70%

4. Results of a trial conducted by the Centers for Disease Control and Prevention and the National Institutes of Health indicate which two antibiotic regimens using existing drugs, successfully treated gonorrhea infections in a clinical trial?
   A. Injectable gemifloxacin in combination with oral azithromycin, and oral gentamicin in combination with oral azithromycin
   B. Injectable azithromycin in combination with oral gentamicin, and oral gemifloxacin in combination with oral azithromycin
   C. Injectable ceftriaxone in combination with oral azithromycin, and oral gemifloxacin in combination with oral azithromycin
   D. Injectable gentamicin in combination with oral azithromycin, and oral gemifloxacin in combination with oral azithromycin

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

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