CONTRACEPTIVE TECHNOLOGY UPDATE®

A Monthly Update on Contraception and Sexually Transmitted Diseases

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Science eyes HPV vaccine use in men — Will shot be approved for U.S. males?

Vaccine prevented 90% of external genital lesions caused by 4 HPV types

Family planning clinicians have become familiar with providing Gardasil (Merck & Co.), the quadrivalent vaccine for human papillomavirus (HPV), to young women. Will their practice extend to include young men if the vaccine is approved by the Food and Drug Administration (FDA)?

The FDA has accepted Merck's supplemental Biologics License Application for Gardasil for use in boys and men ages 9 to 26 for the prevention of external genital lesions caused by HPV types 6, 11, 16, and 18, says **Jennifer Allen**, Merck spokeswoman. The company expects to hear back from the FDA this fall, she states. Results from a Phase III study in men ages 16 to 26 indicate that the vaccine prevented 90% of external genital lesions caused by types 6, 11, 16, and 18 of HPV.[1] **(Review the trial's results. See "Update on HPV vaccine: Will males be the next ones to receive immunization?" *Contraceptive Technology Update,* February 2009, p. 13.)**

The Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) is set to review the

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AUGUST 2009
VOL. 30, NO. 8 • (pages 85-96)

EXECUTIVE SUMMARY

The Food and Drug Administration is now reviewing the possible use of Gardasil, the human papillomavirus (HPV) vaccine, for use in boys and men ages 9 to 26 for the prevention of external genital lesions caused by HPV types 6, 11, 16, and 18.

- Results from a Phase III study in men indicate that the vaccine prevented 90% of external genital lesions caused by the four HPV types.
- Gardasil use in males is designed to protect against genital warts and less common HPV-related malignancies, such as penile and anal cancer, as well as cancer of the mouth and throat.

cost-effectiveness of male vaccination with the quadrivalent vaccine. How does cost-effectiveness factor into the equation when examining potential use of such a vaccine? As for all vaccines, ACIP will review a variety of data when considering HPV vaccine recommendations for males, including vaccine efficacy, immunogenicity and safety, epidemiology and burden of disease, and cost-effectiveness, explains **Lauri Markowitz**, MD, a CDC medical epidemiologist.

"Cost-effectiveness analyses provide helpful information for ACIP deliberations and are one of several factors considered," she reports. "There is no absolute level of cost-effectiveness that is required before recommendations can be made."

ACIP's input plays an important factor in the potential use of the vaccine, says **Khalil Ghanem**, MD, PhD, assistant professor of medicine and associate fellowship program director in the Division of Infectious Diseases at Johns Hopkins University School of Medicine. While ACIP will not make recommendations unless the vaccine gets FDA approval, its final consideration plays an important role in vaccine use, he explains.

If the committee does not endorse use of the shot in males, the uptake of the vaccine in that population will be significantly hindered because the federally funded Vaccines for Children (VFC) program might not pick it up, says Ghanem. VFC provides funding for children ages 18 years and younger who cannot afford to pay for vaccines; the program covers funding for almost 50% of children's vaccinations in the United States, Ghanem states. If the ACIP endorses a vaccine, the VFC is obliged to include it in its coverage. If the committee does not endorse the vaccine, many insurance companies will not cover its cost, he explains. The vaccine is given in three injections over six months. The series costs about $360.

"In other words, if FDA approves it, but ACIP does not endorse it, most people who will get the vaccine are those who can pay for it out of pocket," Ghanem notes. "That would mean a very small number of people."

Robert Hatcher, MD, MPH, professor of obstetrics and gynecology at Emory University in Atlanta, makes the following prediction: "If public health agencies fail to actively endorse a vaccine that is proven to be effective against HPV infection, the storm of criticism from feminists, like me, who are fully aware that there are men whose reproductive health activities cause cancer in women, is going to be strident and relentless."

Why immunize men?

There are probably two good reasons to think about HPV vaccination in men, says **Joel Palefsky**, MD, professor of medicine at the University of California San Francisco. Palefsky is one of the principal leaders of the study of Gardasil's use in men.

"The first is that men are the way that the virus

Contraceptive Technology Update® (ISSN 0274-726X), including **STD Quarterly**™, is published monthly by AHC Media LLC, 3525 Piedmont Road, Building Six, Suite 400, Atlanta, GA 30305. Telephone: (404) 262-7436. Periodicals Postage Paid at Atlanta, GA 30304 and at additional mailing offices.

POSTMASTER: Send address changes to *Contraceptive Technology Update*®, P.O. Box 740059, Atlanta, GA 30374.

Subscriber Information

Customer Service: (800) 688-2421 or fax (800) 284-3291. E-mail: (customerservice@ahcmedia.com). Hours of operation: 8:30 a.m.-6 p.m. Monday-Thursday; 8:30 a.m.-4:30 p.m. Friday, EST.

Subscription rates: U.S.A., one year (12 issues), $499. Add $17.95 for shipping & handling. Outside U.S., add $30 per year, total prepaid in U.S. funds. Discounts are available for group subscriptions, multiple copies, site-licenses or electronic distribution. For pricing information, call Tria Kreutzer at 404-262-5482. **Back issues**, when available, are $75 each.(GST registration number R128870672.)

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spreads to women, and if one can improve or reduce the rates of HPV infection in the male population, it has the benefit of protecting unvaccinated women," he explains.

This technique is known as "herd immunity." If large numbers of girls and women do not obtain HPV immunization, then vaccination of men and boys could play a significant role in lowering infection rates among males and females. "If we were dealing with a situation where 100% of eligible women were vaccinated, then it wouldn't be much of a factor," Palefsky observes. "But that's not the reality."

A second reason for immunization in males is that men actually get disease through HPV themselves and would benefit in reduction of such diseases, just as women do, he states. Gardasil use in males is designed to protect against genital warts and less common HPV-related malignancies, such as penile and anal cancer, as well as cancer of the mouth and throat.[2] The virus causes at least 250,000 new cases of genital warts and an estimated 7,500 cancers in males each year, and it causes about 1,000 deaths.[2]

Another consideration for HPV immunization in men is for men who have sex with men and therefore would not benefit from female vaccination, notes Palefsky. Palefsky and research associates recently presented data indicating that the quadrivalent HPV vaccine is effective in reducing the burden of anogenital HPV infection and external genital lesions in young men who have sex with men.[3]

Researchers at Roswell Park Cancer Institute in Buffalo, NY, are strongly advocating a national discussion about the need to vaccinate young men and women against HPV 16 to prevent head and neck cancers. Over the past 10 years, members of the facility's head and neck department have seen a threefold increase in the number of throat cancers. Researchers began testing all head and neck tumors treated at the comprehensive cancer center for the presence of HPV DNA in 2007, says **Saurin Popat**, MD, FRCSC, FACS, attending surgeon in head & neck and plastic & reconstructive surgery at the facility.

The decision to test all tumors was made based on the significant prevalence of HPV 16 in cancers of the oropharynx (tonsil and base of tongue) of 50%-60% of the retrospective studies conducted by the Buffalo facility, and the known presence of HPV-16 in other head and neck sites, explains Popat. Researchers are compiling a database to develop a full picture of the degree of HPV-16 infections associated with head and neck mucosal squamous cell cancers, he states. "If the vaccine in use [Gardasil] and the one[s] in development are able to minimize the long-term persistence of HPV 16 in the bodies of men and women, then perhaps in the decades to come, HPV-16 associated head and neck squamous cell carcinomas, which account for 50%-60% of cancers in the oropharynx, would be reduced by that percentage," says Popat. "This would be a very successful public health outcome for an initiative that recommends vaccinations for young women and men."

Will men line up?

If the vaccine is approved for use in men, what will draw them to receive the shot? Results from a new study indicate that informing men that an HPV shot also would help protect their female partners against developing cervical cancer did not increase their interest in getting the vaccine.[4]

To conduct the study, investigators randomly divided 356 male college students into groups and gave one group a self-protection message that focused on the benefits of HPV vaccination for men and the other a partner-protection message that focused on the benefits of HPV vaccination for men and their female partners. Participants were asked to rate, on a scale of 1 to 6, the likelihood that they would get the vaccine, with 1 equaling "very unlikely" and 6 equaling "very likely."

Researchers report there was little difference between the groups, with both expressing only moderate interest in getting the vaccine. Those who received the self-protection message had a mean response of 3.9 on the 6-point scale, while the mean response from the group who got the partner-protection message was 3.8. Men who identified themselves as being in a committed relationship also did not indicate a higher degree of interest in the vaccination, researchers note.[4]

What might propel men to get vaccinated? In a study of some 500 men, the main reasons for wanting the vaccine included a desire to stay healthy (67.4%); prevention of cancer in sexual partner(s) (52.9%); prevention of anal, penile, and head and neck cancer (41%); fear of cancer (33.4%); and prevention of genital warts (32.8%).[5] "Although many men want to receive the HPV vaccine, more remain undecided," state the researchers. "Pending favorable safety and efficacy results from a clinical trial for men, substantial factual education will likely convince many ambivalent men to receive the HPV vaccine."

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Science circles in on vaginal ring technology

What if a vaginal ring could deliver protection against unplanned pregnancy and HIV infection? Scientists are testing a ring loaded with multiple antiviral drugs to prevent HIV infection, and they also are weighing its use in pregnancy prevention.[1]

Researchers at Weill Cornell Medical College in New York City have looked at rings made of biosoluble acacia gum or nonbiodegradable hydrogel of 2-hydroxyethyl methacrylate and sodium methacrylate.[2] For pregnancy prevention purposes, they are testing a three-pronged approach, using nonhormonal compounds such as ferrous gluconate to cause spermiostasis, l-ascorbic acid to increase the viscosity of the cervical mucus, and mixtures of polyamino and polycarboxylic acids to sustain vaginal pH close to 4.5, which is healthy for the vagina but inhospitable for sperm. Inventors of the ring technology include **Brij Saxena**, PhD, professor of reproductive biology and endocrinology, and **Mukul Singh**, MD, PhD, associate research professor of obstetrics and gynecology, both at Weill Cornell Medical College, and Sidney Lerner of BioRings in New York City.

Early tests of the nonhormonal compounds in the hydrogel formulation in rabbits indicated the potential for the development of a biocompatible, nonhormonal, intravaginal contraceptive device.[3] To test the ring's effectiveness in preventing HIV infection, researchers looked at incorporating the reverse transcriptase inhibitors TMC120, PMPA, 3'-azido-3'-deoxythymidine, and a new anti-HIV agent, Boc-lysinated betulinic acid, into vaginal rings with different combinations. Scientists used high-performance liquid chromatography, gas chromatography, or immunoassay to determine daily and cumulative release rates of the inhibitors. Anti-HIV effects were measured by assessment of p24 Gag antigen in T-cell cultures exposed to HIV-1 isolates. These anti-HIV agents, when combined, were found to block infection in human cells exposed to the virus in a laboratory setting.[1]

"We realize if we use more than one anti-HIV agent, we are able to act at different steps of the life cycle of the virus and become much more potent than if we only use one," says Saxena.

Researchers are now working toward approval and funding of a comprehensive trial of the ring formulation for pregnancy and HIV protection. Use of the ring will empower women to protect themselves on two fronts, state Saxena and Singh.

EXECUTIVE SUMMARY

Science is now eyeing two approaches to vaginal ring technology. Researchers at Weill Cornell Medical College are testing rings using nonhormonal compounds such as ferrous gluconate, l-ascorbic acid, and mixtures of polyamino and polycarboxylic acids for pregnancy prevention, as well as eyeing combinations of anti-HIV agents for infection protection.

- Analysis is being conducted on data from a Phase III trial of a vaginal ring developed by the Population Council using the progestin Nestorone and ethinyl estradiol.
- The ring is designed to be used for one year, with a regimen of 21 days in and seven days out.

Nestorone ring moves up

Scientists at the Population Council, a New York City-based research organization, have closed data collection on a Phase III trial of a vaginal ring using a combination of the progestin Nestorone with ethinyl estradiol. The trial closed in December 2008, while a six-month follow-up looked at return to fertility in women who were desiring to become pregnant after the trial or who were planning to use a nonhormonal contraceptive, says **Ruth Merkatz**, RN, PhD, the Population Council's director of clinical development.

The council's vaginal ring is a thin, flexible

product made of silicone rubber that delivers Nestorone, a synthetic progestin similar to the natural hormone progesterone, and a low dose of ethinyl estradiol. The ring inhibits ovulation by continuously releasing a low dose of hormones through the vaginal walls and then the bloodstream. Earlier research indicates the ring, used on a regimen of 21 days in and seven days out, provided women safe and effective contraception.[4] "The ring permits the diffusion of the drug out into the bloodstream, and you can get very rapid blood levels through that system for a very rapid effect," observes Merkatz.

The Population Council ring under development is designed to be used for one year. This timing differs from the Ortho Evra (Ortho Women's Health & Urology; Raritan, NJ), which calls for a new ring after three weeks of use. A product that is purchased only once a year might result in lower costs and fewer trips to a medical provider or pharmacy, say Population Council officials. With fewer to manufacture and fewer to discard, a product that is replaced annually also could have a reduced impact on the environment, they note.[5]

Researchers must analyze the collected data and prepare them for submission to the Food and Drug Administration (FDA) in the form of a New Drug Application. Using the safety and efficacy data collected and other information, the FDA will decide whether the product can be approved for use in the United States.

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New progestins eyed for contraception in U.S.

While not yet available in the United States, international researchers are examining use of contraceptive progestins in two birth control methods: a transdermal patch using gestodene and an oral contraceptive formulation using dienogest.

Bayer Schering Pharma AG, Germany, has initiated two Phase III trials to examine a transdermal patch using ethinyl estradiol and gestodene. The first one is in the United States, and another one is in Germany, Italy, Spain, France, Australia, Argentina, Chile, and Mexico. About 3,300 women will be enrolled in the two studies, which began in May, says **Friederike Lorenzen**, a company spokeswoman. Gestodene is a synthetic progestogen that belongs to the 19-nortestosterone derivative chemical family, which includes norethisterone, levonorgestrel, desogestrel, and norgestimate.[1]

The patch under review contains a formulation comparable to an oral dose of 20 mcg ethinyl estradiol and 50 mcg gestodene, she reports. The patch, transparent in color, will be applied once per week, which will result in three patches per cycle (21 days) and one week off. Early research indicates the patch is effective in reversibly inhibiting ovulation, is well tolerated, and is regarded as "very convenient" by most users.[2]

Company officials plan to submit the new patch for registration worldwide, with first filing expected in 2012. Lorenzen confirms that Food and Drug Administration (FDA) approval will be sought for U.S. use.

Women in the United States are familiar with

EXECUTIVE SUMMARY

While not yet available in the United States, international researchers are examining use of contraceptive progestins in two birth control methods: a transdermal patch using gestodene and an oral contraceptive formulation using dienogest.

- Two Phase III trials began in May 2009 to test the efficacy of a transdermal patch using ethinyl estradiol and gestodene. About 3,300 women are scheduled to be enrolled in the two studies.
- Women in several European countries have access to a new estradiol valerate/dienogest oral contraceptive, Qlaira. Research indicates the 4-phasic oral contraceptive is effective, safe, and well tolerated.

transdermal contraception; the FDA approved Ortho Evra (Ortho Women's Health & Urology; Raritan, NJ) in 2002. The patch delivers 150 mcg of the progestin norelgestromin and 20 mcg ethinyl estradiol per day.

When the Ortho Evra patch first became available, many women were enthusiastic regarding use of transdermal contraception, observes **Andrew Kaunitz**, MD, professor and associate chair in the Obstetrics and Gynecology Department at the University of Florida College of Medicine — Jacksonville. However, pharmacokinetic data indicated that the release of ethinyl estradiol (EE) from this first-generation patch was associated with substantially higher area under the curve for EE than low-dose oral contraceptives.[3-6] The FDA added this information to the package insert for Evra; reports then emerged that Evra might be associated with a higher risk of thromboembolic disease than oral contraceptives, says Kaunitz. ***(Contraceptive Technology Update* reported on the revised labeling in the articles, "FDA updates study data information on Ortho Evra contraceptive patch labeling," April 2008, p. 37; and "FDA revises Evra safety labeling due to increased estrogen levels," January 2006, p. 1.)**

"The result of this history is that clinicians and women became wary regarding the patch's safety, and prescriptions and use declined," he says. "Provided that efficacy and adequate cycle control can be achieved, I believe U.S. clinicians and women would be receptive to a second-generation, lower-estrogen contraceptive patch."

Dienogest pill released

Women in several European countries now have access to a new estradiol valerate/dienogest oral contraceptive, Qlaira. The pill, developed by Bayer Schering Pharma AG, is available in Germany and other European countries, with more countries to be added in fall 2009. Bayer also plans to seek FDA approval for the pill, Lorenzen confirms.

Research presented during the 2008 annual clinical meeting of the American College of Obstetricians and Gynecologists indicates the 4-phasic oral contraceptive is effective, safe, and well tolerated.[7] ***(CTU* reported on the data; see "Pill with dienogest progestin under review," August 2008, p. 89.)** Dienogest is one of several new progestins such as drospirenone, Nestorone, nomegestrol acetate, and trimegestone that have been synthesized in the last two decades. These new progestins are formulated to have no androgenic or estrogenic actions and to be closer in activity to the physiological hormone progesterone.[8]

Bayer also is developing Qlaira for the treatment of heavy and/or prolonged menstrual bleeding in women without organic pathology who desire oral contraception. Why is the company pursuing this line of research? "It's an unmet medical need, and no other contraceptive has yet been approved for treating this disease," says Lorenzen.

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Express STI testing: Can it work in your clinic?

Look out in the waiting room of your clinic. How many patients are waiting to be seen by a provider to be tested for a sexually transmitted infection (STI)?

EXECUTIVE SUMMARY

The Denver Metro Health Clinic uses a triage system to identify low-risk individuals who qualify for an express, testing-only visit to screen for major communicable diseases without a physical examination.

- A 2008 evaluation of the service indicates the triage system safely and effectively identifies those appropriate for express visits, reduces waiting times for patients, and increases clinic throughput.
- The system identifies low-risk individuals who qualify for an express, testing-only visit to screen for major communicable diseases without a physical examination. The agency also has modified its entry system from its original walk-in visit protocol, with appointments now made over the telephone through a computerized scheduling system.

The Denver Metro Health Clinic, the largest STI clinic and HIV testing facility in the Rocky Mountain region, has found an effective way to enhance clinic efficiency. It uses a triage system to identify low-risk individuals who qualify for an express, testing-only visit to screen for major communicable diseases without a physical examination. A 2008 evaluation of the service indicates the triage system safely and effectively identifies those appropriate for express visits, reduces waiting times for patients, and increases clinic throughput.[1]

Clinic officials developed the express visit option in 2003 as a no-cost alternative to a full clinic visit, says **Cornelis Rietmeijer**, MD, PhD, director of the STD Control Program at the Denver Public Health Department. At the time, the clinic was required to charge a copay for such visits, which led to a significant reduction in clinic volume, as well as the number of cases of diagnosed gonorrhea and chlamydia[2], notes Rietmeijer. The express visit system was expanded after the clinic switched to its current electronic medical record system in March 2005, he states.

Where to begin?

The Denver clinic handles about 16,000 visits each year. As a part of Denver Health, which includes a public hospital and 10 community health clinics, and the Denver Public Health Department, the clinic offers free confidential testing, counseling, and treatment for a comprehensive array of STIs for Denver residents.

Before the express visit system, the clinic routinely faced long lines of patients waiting for services at the beginning of the day. Some individuals mistakenly came to the clinic for primary care services and often waited for hours before being seen by clinic staff and told that such services were not available. While clinicians realized that many low-risk patients could be tested without a physical examination, the clinic lacked an effective system for identifying such individuals.

The clinic developed a triage system to identify low-risk individuals who could qualify for an express, testing-only visit that could screen for major communicable diseases but not include a physical examination. It also has modified its entry system from its original walk-in visit protocol. Appointments now are made over the telephone through a computerized scheduling system used by all Denver Health facilities. Separate queues are maintained for those with appointments and walk-ins.

Train staff for triage

Trained medical assistants, called health care partners, triage patients by asking specific questions and gathering information about prior clinic visits, reasons for the visit (such as symptoms, checkup, contact with someone who has an STI), and sexual preferences and behaviors. Walk-ins are triaged on a first-come, first-served basis, while those who make appointments are triaged over the telephone. Those with telephone appointments are told to arrive early for a second brief triage prior to their visit.

To qualify for an express visit, a patient must not have any symptoms of an STI or have engaged in risky behaviors, such as men having sex with men, contact with someone with an STI, injection of drugs, or exchange of sex for money or drugs. Once qualified as an express visit patient, a patient receive stickers that designate what tests should be performed. If needed, patients have blood drawn by the medical assistant for rapid syphilis and/or HIV testing, and then they provide a urine sample and/or vaginal swab to test for chlamydia and gonorrhea. If the initial syphilis or HIV test is positive, staff conduct standard follow-up confirmatory tests.

Comprehensive adds full physical

Comprehensive visits include everything offered in the express visit, along with a full physical examination oriented at identifying other STIs.

Additional testing may be performed as needed.

All patients are offered treatment for and appropriate education about any STIs identified immediately through laboratory results or physical examination. For those tests where results are not available immediately (such as confirmatory HIV or syphilis testing), clients are asked to call the clinic results line one week after their visit. Those who test positive and do not call receive a text message. The clinic obtains consent to contact the patient in this manner during the registration process. Patients with a positive diagnosis are offered free treatment and follow-up.

Is express best?

During the first year after introduction of the express-visit option, the clinic handled 8% more visits without increased staffing, including 18% more women and 32% more individuals under age 20.[1] The program required no new staff. Incremental costs of the program were minimal, consisting primarily of upfront training for medical assistants.

The process offers time savings for patients as well. A post-implementation time-motion study found that the express visit was much shorter than a comprehensive visit, saving women nearly an hour (46 minutes vs. 105 minutes) and men more than half an hour (52 minutes vs. 85 minutes). These figures do not include time in the waiting room before the triage (which averaged roughly a half-hour for both groups) or triage time, which averaged two minutes.[1]

The triage system effectively identified those at low risk of common STIs, analysis shows.[1] Rates of chlamydia, gonorrhea, syphilis, and HIV were much lower in express visit patients (9.8%) than in those receiving a comprehensive visit (26%). Separate analyses of specific patient subgroups indicated that the potential for underdiagnosis of other STIs (for which diagnosis usually requires a physical examination) appeared to be quite low in express visit patients, researchers found.[1]

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Talking new technology: Reach teens via new media

Wondering how to get prevention messages to adolescents? Public health officials are looking at new approaches such as text messaging on cell phones and Internet social networking sites to reach, educate, and engage teens regarding their sexual and reproductive health.

Mastering new technology to reach adolescents is key for disseminating information. A recent report from the MacArthur Foundation shows that youth use social networking sites, online games, and video-sharing sites to connect with peers, to learn, and to engage in self-expression.[1] A new presentation from the Pew Internet & American Life Project reports that 28% of adolescents look online for health and fitness information.[2]

How youth interact with virtual media in their daily lives is a topic of considerable importance. The Section of Family Planning and Contraceptive Research and the Center for the Study of Race, Politics, and Culture at The University of Chicago hosted a June 2009 symposium, "Virtual Sex Ed: Youth, Race, Sex, and New Media" to focus on the subject.

How to hook teens

When it comes to reaching large numbers of teens, the cell phone offers an attractive platform. Research indicates 45% of adolescents ages 12-17 owned cell phones in 2004; by early 2008, that

EXECUTIVE SUMMARY

Public health officials are looking at new approaches such as text messaging on cell phones and Internet social networking sites to reach, educate, and engage teens regarding their sexual and reproductive health. The cell phone offers an attractive platform. Research indicates 71% of adolescents ages 12-17 owned cell phones in 2008.

- Hookup, a new youth-focused text messaging program, has been launched by the California Family Health Council in partnership with Internet Sexuality Information Services and the California Department of Health Sexually Transmitted Diseases (STD) Control Branch.
- The program delivers health information to teens via their cell phones.

number had climbed to 71%.[2]

Hookup, a new youth-focused text messaging program, has been launched by the California Family Health Council in partnership with Internet Sexuality Information Services (ISIS) and the California Department of Health Sexually Transmitted Diseases (STD) Control Branch, to deliver health information.

The Hookup project is a way to provide youth with relevant sexual health information and an easy resource for finding youth-friendly local clinics that offer free or low-cost birth control, STD/HIV testing and other reproductive health services, says **Rebecca Braun**, MPH, a program manager at the council. "This program is the first statewide text-messaging service of its kind, reaching youth with critical sexual health information in a unique and resourceful way and connecting them to the services they need to stay healthy," she states.

How does it work?

Launched in April 2009 during STD Awareness Month, the Hookup program builds on the success of ISIS' existing SexINFO program in San Francisco to reach larger numbers of California youth, explains Braun. To use the Hookup service, youth text the word "hookup" to the phone number 365247 and are "hooked up" for weekly sexual health tips. The number is a reminder that the service is available 365 days a year, 24 hours a day, and seven days a week. Each tip contains a prompt to text the word "clinic" plus a zip code to get contact information for two local clinics.

The first few tips from the Hookup program were centered on STD prevention, screening, and treatment information, in observance of STD Awareness Month, says Braun. Messages have since branched out to include such topics as correct condom use, birth control methods, emergency contraception, sexual communication, domestic violence, substance abuse, and cervical cancer. In the coming months, program officials intend to give youth the opportunity to send their own sexual health tips, the best of which will be featured as future weekly texts from the program.

Braun estimates initial design and implementation of the program at about $40,000, which included conducting focus groups with youth statewide, developing a marketing campaign and associated materials, creating weekly sexual health tips, constructing web content to provide in-depth information on each tip, producing a database of clinics compatible with Short Message Service text messaging services, and designing an evaluation plan for measuring impact of text messaging service on youth. Annual program maintenance is estimated at $6,000, which includes maintaining network services and providing regular updates to the Hookup clinic database. The responsibility for these projects has been spread across the partnership, she reports.

Since the program's launch, more than 800 people have signed up for the service, with about 30% requesting clinic referrals, and the numbers continue to grow, says Braun.

"We have heard very positive feedback from clinic and community outreach staff who have been spreading the word about the project throughout the state," she states. "We are planning to implement an evaluation project that will allow us to receive direct feedback from Hookup users and then make adjustments as necessary to ensure we are meeting the needs of youth."

References

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Continue screening for syphilis in pregnancy

What is included in your practice during a first prenatal visit? If syphilis screening is not on the list, be sure to add it. Following a systematic review of current evidence, the U.S. Preventive Services Task Force has just reaffirmed its 2004 recommendation that clinicians screen all pregnant women for syphilis infection.[1] ***(Contraceptive Technology Update* reported on the 2004 advisory in the October 2004 article, "New syphilis guidelines will change your practice," *STD Quarterly*, supplement, p. 3.)**

"The fact that we have good evidence showing that universal screening really decreases infants with congenital syphilis is what pushed the task force to put this in an "A" recommendation,

EXECUTIVE SUMMARY

The U.S. Preventive Services Task Force has just reaffirmed its 2004 recommendation that clinicians screen all pregnant women for syphilis infection.

- Nontreponemal tests commonly used for initial screening include venereal disease research laboratory and rapid plasma reagin tests. Confirmatory tests include: fluorescent treponemal antibody absorbed and *treponema pallidum* particle agglutination tests.
- Parenteral benzathine penicillin G is advised for treatment of syphilis in pregnancy. Since evidence on the efficacy or safety of alternative antibiotics in pregnancy is limited, women who report penicillin allergies should be evaluated for penicillin allergies and, if present, desensitized and treated with penicillin, the new guidance advises.

which is our strongest recommendation," says **Ned Calonge**, MD, MPH, task force chairman and chief medical officer for the Colorado Department of Public Health and Environment in Denver.

How important is early prenatal care when it comes to screening pregnant women for syphilis? According to **Tracy Wolff**, MD, MPH, medical officer for the task force program, evidence shows that universal screening of pregnant women for syphilis is effective in decreasing the likelihood that infants will develop syphilis infection. Analysts found evidence that such effectiveness is related to the receipt of early prenatal care that allows for adequate treatment and follow-up prior to delivery, says Wolff, who served as lead author for the literature compilation that lead to the task force's recommendation.[2]

In 2002, the Centers for Disease Control and Prevention (CDC) reported that while most women who had a fetus with congenital syphilis had received prenatal care, nearly two-thirds received care later in the pregnancy, after the first trimester[3], Wolff notes. For this reason, the task force and many other organizations advise that screening occur at the first prenatal visit, and many organizations recommend repeat serologic testing in the third trimester and at delivery for women at high-risk for syphilis, she states.

Who and how to screen?

What clinical considerations come into play when screening pregnant women for syphilis? Most organizations, such as the American College of Obstetricians and Gynecologists and the American Academy of Pediatrics, recommend testing high-risk women again during the third trimester and at delivery.[1] Women who may be considered at increased risk for syphilis infection include:

- uninsured women;
- women living in poverty;
- sex workers;
- illicit drug users;
- those diagnosed with other sexually transmitted diseases;
- women living in communities with high syphilis morbidity.

Prevalence of the disease is higher in the southern United States, in metropolitan areas, and in Hispanic and African-American populations.

What tests may be used for screening? Nontreponemal tests commonly used for initial screening include venereal disease research laboratory (VDRL) and rapid plasma reagin (RPR) tests. Confirmatory tests include: fluorescent treponemal antibody absorbed (FTA-ABS) and *Treponema pallidum* particle agglutination (TPPA) tests.

How to treat?

What treatment should be used if syphilis is detected? In its most recent recommendation, the CDC calls for the use of parenteral benzathine penicillin G for the treatment of syphilis in pregnancy.[4] Because evidence on the efficacy or safety of alternative antibiotics in pregnancy is limited, women who report penicillin allergies should be evaluated for penicillin allergies and, if present, desensitized and treated with penicillin, the task force advises.[1]

COMING IN FUTURE MONTHS

- Bleeding disorders: New guidance issued
- Begin postpartum contraception early
- How to manage difficult vulvovaginal discomfort
- Managing contraceptive side effects: Providers share tips
- Abnormal breast findings: When to treat, refer

Follow-up serologic tests should be performed after treatment to document decline in titers, according to the task force. To make sure that results are comparable, follow-up tests should be performed by using the same nontreponemal test that initially was used to document the infection.

Study examines birth defect

What is the potential for harm to the fetus during treatment with penicillin? Analysts found one Hungarian study that used multiyear data from a national congenital abnormality registry. Investigators in the Hungarian study identified 1,374 cases of isolated orofacial clefts and reviewed medical records and questionnaire results for medication use. They then compared the prevalence of isolated orofacial clefts in children born to women who received penamecillin (an oral form of penicillin not available in the United States) with a control population and a control group with noncleft malformations. Investigators found no association between penamecillin and isolated orofacial clefts.[5]

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1. U.S. Preventive Services Task Force. Screening for syphilis infection in pregnancy: U.S. Preventive Services Task Force reaffirmation recommendation statement. *Ann Intern Med* 2009; 150:705-709.

2. Wolff T, Shelton E, Sessions C, et al. Screening for syphilis infection in pregnant women: Evidence for the U.S. Preventive Services Task Force reaffirmation recommendation

CNE/CME Instructions

Physicians and nurses participate in this continuing nursing medical education/continuing education program by reading the articles, using the provided references for further research, and studying the questions at the end of the issue. Participants should select what they believe to be the correct answers and refer to the list of correct answers to test their knowledge. To clarify confusion surrounding any questions answered incorrectly, please consult the source material. After completing this activity with the **December** issue, you must complete the evaluation form provided and return it in the reply envelope provided in that issue to receive a certificate of completion. When your evaluation is received, a certificate will be mailed to you. ■

CNE/CME Questions

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

- **identify** clinical, legal, or scientific issues related to development and provisions of contraceptive technology or other reproductive services.
- **describe** how those issues affect services and patient care.
- **integrate** practical solutions to problems and information into daily practices, according to advice from nationally recognized family planning experts.

5. The HPV vaccine Gardasil has been tested in males to prevent which types of HPV?
A. HPV types 6, 11, 16, and 18
B. HPV types 1, 16, 18, and 26
C. HPV types 6, 11, 18, and 27
D. HPV types 6, 11, 16, and 28

6. What nonhormonal compound causes spermiostasis in the vaginal ring under development by researchers at Weill Cornell Medical College?
A. Boc-lysinated betulinic acid
B. Ferrous gluconate
C. L-ascorbic acid
D. TMC120

7. The transdermal patch now in Phase III trials by Bayer Schering Pharma AG contains the progestin:
A. levonorgestrel.
B. norelgestromin.
C. gestodene.
D. dienogest.

8. What tests may be used for screening pregnant women for syphilis?
A. KOH wet mounts and rapid plasma reagin tests
B. Venereal disease research laboratory and darkfield microscopy
C. Rapid plasma reagin tests and molecular testing
D. Venereal disease research laboratory and rapid plasma reagin tests

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

statement. *Ann Intern Med* 2009; 150:710-716.

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5. Puho´ EH, Szunyogh M, Me´tneki J, et al. Drug treatment during pregnancy and isolated orofacial clefts in Hungary. *Cleft Palate Craniofac J* 2007; 44:194-202. ■

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