CONTRACEPTIVE TECHNOLOGY UPDATE®

Interpreting News and Research on Contraceptives and STIs

April 2011: Vol. 32, No. 4
Pages 37-48

IN THIS ISSUE

Financial Disclosure:
Consulting Editor **Robert A. Hatcher**, MD, MPH, Author **Rebecca Bowers**, Executive Editor **Joy Dickinson**, **Anita Brakman** and **Melanie Gold** (Guest Columnists) report no consultant, stockholder, speaker's bureau, research, or other financial relationships with companies having ties to this field of study. **Sharon Schnare** (Nurse Reviewer) discloses that she is a retained consultant and a speaker for Barr Laboratories, Berlex, and Organon; she is a consultant for 3M Pharmaceuticals; and she is a speaker for FEI Women's Health, Ortho-McNeil Pharmaceuticals, and Wyeth-Ayerst Pharmaceuticals.

STD treatment: Time to get on board with expedited partner therapy

New CDC toolkit assists states in promoting supportive policies

Your next patient is a young woman who was in two months ago for a chlamydia infection. You provided her with a prescription and asked that she have her partner come in for evaluation, testing, and treatment. Today's test results are positive for chlamydia. When you discuss the results, the patient tells you her partner never came in for tests or treatment.

For sexually transmitted disease (STD) clinical management to be effective, treatment of patients' current partners must occur to prevent reinfection and curtail further transmission. The standard approach to care has relied on clinical evaluation in a health care setting, with partner notification accomplished by the index patient, by the provider or an agent of the provider, or a combination of these methods.

It might be time to change that approach to care, say public health officials. Chlamydia and gonorrhea are among the most commonly reported infectious diseases in the United States. In 2009, there were more than 1.2 million cases of chlamydia and more than 300,000 cases of gonorrhea reported to the Centers for Disease Control and Prevention (CDC),

EXECUTIVE SUMMARY

The Centers for Disease Control and Prevention has issued a new toolkit designed to cover the key issues related to expedited partner therapy (EPT) authorization and implementation.

- Expedited partner therapy is treating the sex partners of patients diagnosed with chlamydia or gonorrhea by providing prescriptions or medications to the patient to take to his/her partner without the provider first examining the partner. It is permissible in 27 states. It is potentially allowable in 15 states, the District of Columbia, and Puerto Rico.
- Expedited partner therapy might be an effective resource in lowering rates of chlamydia and gonorrhea, two of the most commonly reported infectious diseases in the U.S.

AHC Media

says **Charlotte Kent**, PhD, acting director of the Division of STD Prevention in the CDC's National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention.

Expedited partner therapy (EPT) is the clinical practice of treating the sex partners of patients diagnosed with chlamydia or gonorrhea by providing prescriptions or medications to the patient to take to his/her partner without the health care provider first examining the partner. It is permissible in 27 states. *(Go to the CDC EPT web site, www.cdc.gov/std/ept. Select "Legal Status of EPT by Jurisdiction" to see a breakdown of state standings on EPT.)* To aid clinicians and policy makers in adding new states to the list, the Centers for Disease Control and Prevention has issued a new toolkit designed to cover the key issues related to EPT authorization and implementation. *(Go to the CDC Expedited Partner Therapy web site, www.cdc.gov/std/ept. Select "Legal/Policy Toolkit for Adoption and Implementation of Expedited Partner Therapy.)*

CDC considers expedited partner therapy an additional strategy to ensure the treatment of sexual partners of persons with chlamydia or gonorrhea, says Kent. This treatment assurance for sexual partners is key to reducing re-infection of the index patient, curtails further transmission, and prevents long-term consequences of untreated chlamydia and gonorrhea infections, she notes.

Untreated gonorrhea and chlamydia are the leading preventable causes of pelvic inflammatory disease in women, which can lead to infertility, ectopic pregnancy, and chronic pelvic pain. Serious outcomes of chlamydia and gonorrhea are uncommon in men. However, at a population level, men generally are more efficient STD transmitters than women, and preventing recurrent infections in men might be important in reducing continued transmission in the community, says Kent.

Expedited partner therapy "does not replace traditional partner management or any other partner treatment strategy," she says. "Personal medical evaluation of partners is always preferred when practical, but EPT can be used to treat partners as an option when other management strategies are impractical or unsuccessful."

Data supports EPT

If a patient diagnosed with chlamydia or gonorrhea indicates her partner or partners are unlikely to seek evaluation and treatment, providers can offer patient-delivered partner therapy (PDPT), a form of expedited partner therapy which partners of infected persons are treated without previous medical evaluation or prevention counseling.

The evidence supporting PDPT is based on three clinical trials that included heterosexual men and women with chlamydia or gonorrhea.[1-4]

Contraceptive Technology Update® (ISSN 0274-726X), including STI Quarterly™, is published monthly by AHC Media, a division of Thompson Media Group LLC, 3525 Piedmont Road, NE, 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 105109, Atlanta, GA 30348.

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), $449. 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.) Photocopying: No part of this newsletter may be reproduced in any form or incorporated into any information retrieval system without the written permission of the copyright owner. For reprint permission, please contact AHC Media. Address: P.O. Box 740056, Atlanta, GA 30374. Telephone: (800) 688-2421. World Wide Web: http://www.ahcmedia.com.

Opinions expressed are not necessarily those of this publication. Mention of products or services does not constitute endorsement. Clinical, legal, tax, and other comments are offered for general guidance only; professional counsel should be sought for specific situations.

AHC Media is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation.

This activity has been approved for 15 nursing contact hours using a 60-minute contact hour.

Provider approved by the California Board of Registered Nursing, Provider #14749, for 15 Contact Hours.

AHC Media is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

AHC Media designates this educational activity for a maximum of 18 AMA PRA Category 1 Credits™. Physicians should only claim credit commensurate with the extent of their participation in the activity.

This activity is intended for OB/GYNs, nurses, nurse practitioners, and other family planners. It is in effect for 24 months from the date of publication.

Editor: **Rebecca Bowers.**
Executive Editor: **Joy Daughtery Dickinson** (229) 551-9195 (joy.dickinson@ahcmedia.com).
Production Editor: **Neill L. Kimball.**

AHC Media

Editorial Questions
Questions or comments?
Call Joy Daughtery Dickinson
(229) 551-9195.

Results of the trials and meta-analyses indicate the magnitude of reduction in reinfection of index case-patients compared with patient referral differed according to the STD and the sex of the index case-patient. Across the trials, reductions in chlamydia prevalence at follow-up were approximately 20%; reductions in gonorrhea at follow-up were about 50%. Rates of notification increased in some trials and were equivalent to patient referral without PDPT in others.[5]

According to the CDC, expedited partner therapy is potentially allowable in 15 states: Alabama, Connecticut, Delaware, Georgia, Hawaii, Idaho, Indiana, Kansas, Maryland, Massachusetts, Montana, Nebraska, New Jersey, South Dakota, and Virginia. It also is potentially allowable in the District of Columbia and Puerto Rico. The EPT toolkit, which was developed by the Arizona State University's Sandra Day O'Connor College of Law, Public Health Law and Policy Program, in collaboration with CDC's Division of STD Prevention, contains four sections:

- sample state legislative language on liability issues related to EPT;
- discussion of selected issues related to practitioners' liability for harms to partners through EPT;
- frequently asked questions on health information privacy for physicians, pharmacists, and other healthcare practitioners concerning EPT;
- considerations for drafting and implementing EPT legislation and regulations.

In addition, the CDC Expedited Partner Therapy web site also provides links to materials from other states that have implemented EPT policies, such as Illinois, Texas, and New Mexico.

The toolkit offers resources to assist states that are interested in adopting laws supportive of expedited partner therapy, as well aids states that have adopted such laws with addressing barriers to their full implementation, says the CDC. It is intended as a resource for voluntary use by government officials at the state and local levels, their public and private sector partners, and others who are interested in adopting or facilitating the implementation of statutes or regulations that permit EPT in clinical practice.

What are the benefits?

How can expedited partner therapy legislation benefit clinicians? There are numerous advantages, says **Jo Ann Woodward**, MH, WHNP-BC, who co-authored a recent journal article on the subject.[6]

"I think EPT legislation in place can help clinicians take better care of their patients, have less risk of pelvic infection because of untreated patients, and have more patient satisfaction, as well as the patients being satisfied because they see the nurse practitioner as a resource for health care," says Woodward.

Woodward believes the sample legal language provided in the CDC EPT Toolkit should address a concern shared by many nurse practitioners regarding the provision of medication to a patient that they have not seen. "If they give medication to a patient they have not seen, indeed does that make them liable if a reaction takes place?" Woodward notes. Referring to the sample state legislative language on liability issues, she says, "I'm not an attorney, but I believe that it relieves a lot of anxiety."

Nurse practitioners should operate within the guidelines of their facilities, says Woodward. However, the resources offered through the CDC Expedited Partner Therapy web site can help clinicians who are interested in spearheading EPT legislation in their states get the ball rolling, she notes.

Robert Hatcher, MD, MPH, professor of gynecology and obstetrics at Emory University School of Medicine in Atlanta, says that for years he provided some women he was treating for sexually transmitted infections with a prescription that provided adequate medication for their partners as well. "I've always believed a little bit of civil disobedience was desirable," says Hatcher. "After all, I was providing services at Grady Memorial Hospital, just a few blocks from Ebenezer Baptist Church, the church of Martin Luther King Jr."

REFERENCES

1. Golden MR, Whittington WL, Handsfield HH, et al. Effect of expedited treatment of sex partners on recurrent or persistent gonorrhea or chlamydial infection. *N Engl J Med* 2005;352:676-685.
2. Schillinger JA, Kissinger P, Calvet H, et al. Patient-delivered partner treatment with azithromycin to prevent repeated Chlamydia trachomatis infection among women: a randomized, controlled trial. *Sex Transm Dis* 2003;30:49-56.
3. Trelle S, Shang A, Nartey L, et al. Improved effectiveness of partner notification for patients with sexually transmitted infections: systematic review. *BMJ* 2007;334:354.
4. Kissinger P, Mohammed H, Richardson-Alston G, et al.

Patient-delivered partner treatment for male urethritis: a randomized, controlled trial. *Clin Infect Dis* 2005;41:623-629.
5. Centers for Disease Control and Prevention. Sexually transmitted diseases treatment guidelines, 2010. *MMWR* 2010; 59(RR-12):7.
6. Wysocki S, Woodward JA. Expedited partner therapy for chlamydia. *Women's Health Care* 2010; 921-926. ■

Check approach to DMPA and irregular bleeding

Many women might choose the contraceptive injection depot medroxyprogesterone acetate (DMPA, Depo-Provera) for its ease of use, but they might discontinue the method due to irregular bleeding. Results of a small study suggest that use of an estradiol vaginal ring for three months at DMPA initiation might decrease bleeding and improve method continuation.[1]

Irregular bleeding is one of the most commonly cited reasons for discontinuation of DMPA, observes **Angela Dempsey**, MD, MPH, assistant professor in the Department of Obstetrics and Gynecology at the Medical University of South Carolina in Charleston. Dempsey served as lead author of the current paper.

Irregular bleeding is most frequent in the first three months of DMPA use, and then it decreases steadily throughout the remainder of time a woman is using the method, Dempsey notes. There is evidence to suggest that treatment with estrogen supplementation is beneficial in decreasing the amount and duration of bleeding in women using progestin-only contraceptive methods.[2,3]

EXECUTIVE SUMMARY

Results of a small study suggest that use of an estradiol vaginal ring for three months at depot medroxyprogesterone acetate (DMPA) initiation might decrease bleeding and improve method continuation.

- Irregular bleeding is one of the most commonly cited reasons for discontinuation of DMPA. Irregular bleeding is most frequent in the first three months of DMPA use, and then it decreases steadily throughout the remainder of time a woman is using the method.
- Structured counseling for DMPA patients is effective. Communicate the message that DMPA will change a woman's period. Women who are unwilling to accept a change in their menstrual periods should be offered other forms of contraception.

Investigators in the current study wanted to identify a possible intervention for the first three months of DMPA use that might decrease the amount of irregular bleeding and improve continuation and acceptability, says Dempsey. "We specifically chose to investigate the estradiol ring, as opposed to oral estrogen or estrogen patches, because it is designed to be used vaginally for three consecutive months, which would conveniently allow placement at the time of the initial DMPA injection and then require no further action on the part of the patient until it was time for the second injection," says Dempsey.

How did it work?

To conduct the prospective, randomized, controlled trial, women initiating DMPA were randomized to receive an estradiol vaginal ring for three months versus DMPA alone. Bleeding diaries and questionnaires at three and six months assessed bleeding, continuation, and ring acceptability.

Seventy-one participants enrolled; 49 completed the first follow-up period. The median number of bleeding or spotting days was 16 in the estrogen ring group (n = 26) versus 28 in the DMPA alone group (n = 23) (p = .19). Seventy-seven percent of the intervention group received a second injection compared with 70% in the DMPA alone group (p = .56). For each additional day of bleeding and/or spotting reported, women were 3% less likely to receive a second injection (odds ratio 0.97, 95% confidence interval 0.94-0.99). Acceptability of the vaginal ring was high among those in the intervention group, researchers report. Vaginal estrogen supplementation during DMPA initiation is acceptable to women and might decrease total bleeding, researchers conclude.[1]

Research shows that providers play an important role in ensuring the highest possible continuation rates for DMPA.[4]

Structured counseling for DMPA patients is effective, according to *A Pocket Guide to Managing Contraception*. Results of a Mexican study indicate discontinuation from bleeding problems (amenorrhea, irregular bleeding, and heavy bleeding) fell from 32% to 8%.[5]

Use the following structured counseling approach from the *Pocket Guide* for women who are considering DMPA use:

- Communicate the message that DMPA will change a woman's period. Say that no woman's

periods stay the same as they were before starting DMPA.

• Ask, "Will you find it acceptable if there are major changes in your period?" If no, steer clear of DMPA use, as well as other progestin-only methods, including progestin-only pills, the contraceptive implant Implanon, and the levonorgestrel intrauterine device Mirena.

• Have the patient repeat back her understanding of the message, particularly that over time, women using DMPA stop having periods most months. Counsel that women tend to have very irregular periods almost immediately after DMPA use.

• Provide written instructions that clearly highlight key messages about the method. *[A free patient handout on DMPA from the Association of Reproductive Health Professionals is available with the online issue. For assistance, contact customer service at customerservice@ahcmedia.com or (800) 688-2421.]*

• Remember to ask at each three-month injection visit what has happened to a patient's pattern of bleeding, check whether amenorrhea has begun, and question the patient's feelings about her current bleeding patterns.[6]

REFERENCES

1. Dempsey A, Roca C, Westhoff C. Vaginal estrogen supplementation during Depo-Provera initiation: a randomized controlled trial. *Contraception* 2010;82:250-255.
2. Alvarez-Sanchez F, Brache V, Thevenin F, et al. Hormonal treatment for bleeding irregularities in Norplant implant users. *Am J Obstet Gynecol* 1996;174:919-922.
3. Said S, Sadek W, Rocca M, et al. Clinical evaluation of the therapeutic effectiveness of ethinyl oestradiol and oestrone sulphate on prolonged bleeding in women using depot medroxyprogesterone acetate for contraception. World Health Organization, Special Programme of Research, Development and Research Training in Human Reproduction, Task Force on Long-acting Systemic Agents for Fertility Regulation. Hum Reprod 1996;11(Suppl 2):1-13.
4. Hubacher D, Goco N, Gonzalez B, et al. Factors affecting continuation rates of DMPA. *Contraception* 1999;60:345-351.
5. Canto De Cetina TE, Canto P, Ordoñez Luna M. Effect of counseling to improve compliance in Mexican women receiving depot-medroxyprogesterone acetate. *Contraception* 2001;63:143-146.
6. Zieman M, Hatcher RA, Cwiak C, et al. *A Pocket Guide to Managing Contraception*. Tiger, GA: Bridging the Gap Foundation; 2010. ■

Pay attention to age in chlamydia screening

What is your practice when it comes to screening women for chlamydia? The Centers for Disease Control and Prevention (CDC) recommends annual chlamydia screening for all sexually active young women age 25 and younger.[1]

However, when it comes to screening women above age 25, the CDC recommends against routine screening unless the individuals are at increased risk of infection from the sexually transmitted disease (STD). What constitutes an increased risk? Look for a history of sexually transmitted infections, new or multiple sex partners, inconsistent condom use, or the practice of exchanging sex for money or drugs.[1]

Many clinicians might not be following national guidance on age-based screening when it comes to chlamydia. In 2008, 2,325,980 women were screened for chlamydia in Title X clinics; of that number, 890,550 were age 25 and above.[2] It is highly unlikely that all of these women were tested due to a risk factor, according to a recent editorial on the subject.[3]

Because younger women are at increased risk for chlamydia compared to older women, screening them is more likely to result in finding disease, says **Susan Philip**, MD, MPH, director of the San Francisco STD Prevention and Control Services for the San Francisco Department of Public Health. Officials with that department have implemented a structural intervention aimed at reducing chlamydia screening among females over age 25 at sites

EXECUTIVE SUMMARY

The Centers for Disease Control and Prevention recommends annual chlamydia screening for all sexually active young women age 25 and younger.

• Women 26 and older should not be screened unless they are at increased risk of infection. Risk factors include history of sexually transmitted infections, new or multiple sex partners, inconsistent condom use, or the practice of exchanging sex for money or drugs.

• The San Francisco Department of Public Health developed a structural intervention to reduce chlamydia screening in women over age 25 at its screening sites. An analysis indicates it resulted in a 24.4% reduction in test volume and an associated cost savings of nearly $40,000 in its first year of implementation.

in the San Francisco STD Screening Program. An analysis of the intervention indicates it resulted in a 24.4% reduction in test volume and an associated cost savings of nearly $40,000 in its first year of implementation.[4]

"We really want to make sure we are focusing our resources on testing this very high risk population of young women," says Philip.

Putting emphasis on screening young women for chlamydia is effort well spent. Chlamydia screening among young women has been recognized by the National Commission on Prevention Priorities as one of the most beneficial and cost-effective preventive services among all evidence-based clinical preventive services recommended by the United States Preventive Services Task Force.[5]

How did they do it?

Prior to its intervention, officials in the San Francisco STD Prevention and Control Services office had worked with the test sites to educate clinicians on the importance of screening women ages 25 and under for chlamydia, says **Kyle Bernstein**, PhD, ScM, chief of epidemiology, research, and surveillance within the STD Prevention and Control Services office. However, the message was not being received: 64% of tests submitted to the San Francisco Public Health Laboratory in 2008 were among women age 26 and above.

To implement the intervention, the STD Prevention and Control Services office began working with the San Francisco Department of Public Health Lab to further examine screening practices. Two changes were made in testing procedures: an "other" box was omitted from the lab requisition form (since no other reason for testing would fall under the department's guidance for screening), and lab personnel began electronically capturing the reason for each test.

STD Prevention and Control Services personnel then met with different test sites to review the new lab procedures. Prior to the program kickoff, a grace period was held, Bernstein explains. If specimens came in without a stated reason for testing, the lab would contact clinicians to let them know that while in the future specimens could not be submitted without a reason for testing, the specimen would be processed. However, as of Jan. 1, 2009, any specimen submitted to the San Francisco laboratory without a reason for testing listed on the requisition form would not be tested.

Did it work?

To see if the changes were effective, STD Prevention and Control Services compared testing volume and positivity from eight screening program sites during 2008 and 2009.

To see if the changes were effective, STD Prevention and Control Services compared testing volume and positivity from eight screening program sites during 2008 and 2009. During 2008, 893 chlamydia tests were run on females over age 25; 52 new infections were identified (5.8% positivity). During the same period in 2009, 922 chlamydia tests were run on women over age 25, with 60 infections identified (6.5% positivity). Compared to 2008, in 2009, the number of chlamydia tests submitted to the public health laboratory in women over 25 declined 24.4% while increasing 3.2% in females age 25 and younger. Seven fewer chlamydia infections was identified in the older population in 2009 compared to 2008, public officials note. The result? Unnecessary chlamydia testing among older females was reduced by 24% without largely appearing to impact case finding.[4]

The intervention has drawn interest from other programs, says Bernstein.

"While the intervention may not be necessarily appropriate everywhere, the approach and evaluation we took is applicable," he notes.

REFERENCES

1. Centers for Disease Control and Prevention. Sexually transmitted diseases treatment guidelines, 2010. *MMWR* 2010; 59(RR12);1-110.

2. Office of Population Affairs. Family planning annual report: 2008 national summary. Rockville, MD: Department of Health and Human Services, 2009.

3. Berman SM, Satterwhite CL. A paradox: overscreening of older women for chlamydia while too few younger women are being tested. *Sex Transm Dis* 2011;38:130-132.

4. Bernstein KT, Marcus JL, Snell A, et al. Reduction in unnecessary Chlamydia screening among older women at title X-funded family planning sites following a structural intervention — San Francisco, 2009. *Sex Transm Dis* 2011;38:127-129.

5. Maciosek M, Coffield AB, Edwards NM, et al. Priorities among effective clinical preventive services: Results of a systematic review and analysis. *Am J Prev Med* 2006;31:52-61. ■

Medication abortions: Upswing reported

Findings from a new national report reflect an increase in the use of early medication abortion. The number of such procedures performed in nonhospital facilities rose from 161,000 to 199,000 between 2005 and 2008, and the proportion of all nonhospital abortions that were early medication procedures increased from 14% to 17%.[1]

Early medication abortion has become an integral part of abortion care; 59% of all known abortion providers now offer this service. That early medication abortion is becoming more widely available is good news, says **Rachel Jones**, PhD, senior research associate at the Guttmacher Institute in New York City and lead author of the new study.

"U.S. government reports have shown that abortions are increasingly occurring earlier in pregnancy, when the procedure is safest," said Jones in a statement accompanying the new publication. "Increased access to medication abortion is helping to accelerate that trend."

The Food and Drug Administration (FDA) approved mifepristone (Mifeprex, Danco Laboratories, New York City) for use in early medication abortion in 2000. Mifepristone acts as an antiprogesterone to block continued support of the pregnancy. A second drug, misoprostol, is administered following mifepristone to induce expulsion of the products of conception.[2]

"U.S. government reports have shown that abortions are increasingly occurring earlier in pregnancy, when the procedure is safest. Increased access to medication abortion is helping to accelerate that trend."

EXECUTIVE SUMMARY

Findings from a new national report reflect an increase in the use of early medication abortion. The number of such procedures performed in nonhospital facilities rose from 161,000 to 199,000 between 2005 and 2008, and the proportion of all nonhospital abortions that were early medication procedures increased from 14% to 17%.

- Early medication abortion has become an integral part of abortion care; 59% of all known abortion providers offer this service.
- While overall abortion rates in the United States have steadily declined since 1981, the new report indicates the trend has stalled.

Research of medication abortion has looked at alternative regimens using methotrexate and misoprostol, or a misoprostol-only approach. Neither alternative approach carries FDA approval.

More abortion providers are looking at use of mifepristone. Guttmacher Institute analysts report an increase in the number of mifepristone-induced abortions, from 158,000 in 2007 to 187,000 in 2008. This increase over one year corresponds with recent usage estimates from the drug's manufacturer and might suggest an increased reliance on the procedure, say analysts.[1] The median charge for early medication abortions was $490, report analysts. This compares to a $470 median charge for a surgical abortion at 10 weeks gestation.[1]

To perform the current analysis, Guttmacher researchers classified providers as operating in abortion clinics, other clinics, hospitals, or physicians' offices. In 2008, 1,066 facilities (59%) provided one or more early medication abortions, slightly higher (4%) than in 2005, they report. While the number of nonspecialized clinics that provided early medication abortion services increased by 23%, the numbers of hospitals and physicians' offices declined by 13% and 9% respectively.

Eighty-three percent of abortion clinics and 88% of other clinics performed at least one early medication abortion in 2008, compared to 25% of hospitals and 55% of physicians' offices. The likelihood of providing early medication abortion services increased with caseload; 30% of the smallest providers said they offered such services, compared to 94% of the largest providers. At least 9% of abortion providers said they offer only early medication abortion services. Eleven percent of physicians' offices were in this group, as were 27% of nonspecialized clinics.[1]

Rate decline stalls

While abortion rates in the United States have steadily declined since 1981, the new report indicates the trend has stalled. In 2008, there were 19.6 abortions per 1,000 women ages 15-44, well below the 1981 peak of 29.3 abortions for every 1,000 women. The 2008 abortion rate showed no change from the 2005 rate of 9.4 abortions; like-

wise, the total number of abortions in 2008 (1.21 million) essentially was unchanged from 2005, Guttmacher analysts report.[1]

Sharon Camp, PhD, Guttmacher president and chief executive officer, in a statement accompanying the report, said, "In this time of heightened politicization around abortion, our stalled progress should be an urgent message to policymakers that we need to do more to increase access to contraceptive services to prevent unintended pregnancy, while ensuring access to abortion services for the many women who still need them."

The report also indicated little change in the number of abortion providers; 1,787 providers were represented in the 2005 survey, compared to 1,793 in 2008. Most counties (87%) in the United States have no abortion provider; 35% of women of reproductive age lived in those counties, the 2008 survey shows.

Delaware had the highest abortion rate in 2008 (40 per 1,000 women), partly due to a 37% increase in the number of abortions. Much of the increase was attributed to one provider who acknowledged underreporting abortions in the 2005 survey. New York and New Jersey had the second and third highest abortion rates: 38 and 31 abortions per 1,000 women respectively. The abortion rate in the District of Columbia dropped 45% between 2005 and 2008, from 54 to 30 per 1,000, which made it the fourth highest in the country. High rates were also seen in Maryland, California, Florida, Nevada, and Connecticut (25–29 per 1,000).[1]

Harassment of abortion providers is on the upswing. The number of large nonhospital providers (those offering 400 abortions or more) reporting antiabortion harassment rose from 82% in 2000 to 89% in 2008. Harassment was particularly common among providers of all sizes in the Midwest and South. Picketing was the most common form of harassment (reported by 55% of providers), followed by picketing combined with blocking patient access to facilities (21%), the report notes.

REFERENCES

1. Jones RK, Kooistra K. Abortion incidence and services in the United States, 2008. *Perspect Sex Reprod Health* 2011; 43:41-50.
2. Zieman M, Hatcher RA, Cwiak C, et al. *A Pocket Guide to Managing Contraception*. Tiger, GA: Bridging the Gap Foundation; 2010. ■

HPV vaccination in men — How to boost uptake

While the human papillomavirus (HPV) vaccine has been approved for use in men, how many are open to receiving it? New research indicates men might be more willing to receive vaccination when they learn the vaccine can prevent cancer.[1]

The Food and Drug Administration (FDA) in December 2010 approved Gardasil, the Merck & Co. quadrivalent vaccine, for prevention of anal cancer and associated precancerous lesions (anal intraepithelial neoplasia grades 1, 2, and 3, related to HPV types 6, 11, 16, and 18 in males and females ages 9-26. (*See "New indication OK'd for HPV vaccine," in the* STI Quarterly *inserted in the March 2011 issue of* Contraceptive Technology Update*, p. 3.)* The vaccine also is approved for the prevention of genital warts caused by types 6 and 11 in males and females.

Researchers at the University of North Carolina at Chapel Hill (UNC-CH) Gillings School of Global Public Health and the Lineberger Comprehensive Cancer Center have found that men are more open to getting the HPV vaccine when it is described as also preventing HPV-related cancers, including anal cancer, as opposed to preventing genital warts alone.

What led the research team to look at this issue? The researchers were seeking how to get more boys and men to get their recommended doses of HPV vaccine, says **Annie-Laurie McRee**, a UNC-CH doctoral student and lead author of the study. "In a previous study, we found that how you 'frame' HPV vaccination messages can make the vaccine more acceptable to women,"[2] says

EXECUTIVE SUMMARY

New research indicates men might be more willing to receive human papillomavirus (HPV) vaccination when they learn the vaccine can prevent cancer.

- The Food and Drug Administration in December 2010 approved Gardasil, for prevention of anal cancer and associated precancerous lesions related to HPV types 6, 11, 16, and 18 in males and females ages 9-26. The vaccine also is approved for the prevention of genital warts caused by types 6 and 11 in males and females.
- It is estimated that fewer than 1% of boys ages 11 to 17 have been immunized against HPV. On college campuses, the share of vaccinated might be closer to 15%.

McRee. "So we wanted to explore how the added benefit of preventing cancer in men would affect men's interest in HPV vaccine."

Researchers surveyed a national sample of more than 600 men ages 18-59 and asked about their willingness to get vaccinated. Sixty percent wanted the cancer-preventing vaccine, compared to 42% when the vaccine was depicted as only protecting against warts. The effect of outcome framing was the same for heterosexual and gay/bisexual men and for the cancer types examined.

Why is it so important that men be reached with the correct message about HPV vaccination? The very low use of HPV vaccine by men and boys indicates clinicians are missing an important public health opportunity, says **Noel Brewer**, PhD, senior investigator on the study, UNC-CH Lineberger member and associate professor of health behavior and health education in the public health school. It is estimated that fewer than 1% of boys ages 11 to 17 have been immunized against HPV; on college campuses, the share of vaccinated men might be closer to 15%.[3]

"Some men mistakenly believe that the vaccine is just for women; now they can know that it is for men, too," Brewer says. "Our findings show that it is critical for men to get the message that HPV vaccine can prevent cancer in men in addition to genital warts, because that increases their willingness to get vaccinated."

Data upholds efficacy

In talking about the Gardasil HPV vaccine, be sure to include results from a just-published study which shows it prevents 90% of genital warts in men when it is offered before exposure to the four HPV strains covered by the vaccine.[4] The study also found a nearly 66% effectiveness in the general population of young men regardless of prior exposure to these strains.

The four-year international clinical trial study, led by researchers at the H. Lee Moffitt Cancer Center in Tampa, FL, and the University of California San Francisco (UCSF) provides the first reported results of using the HPV vaccine as a prophylactic in men. Initial data from the study was reviewed by the FDA in its initial approval for use of the vaccine in men to prevent warts, while results from a substudy led the agency last year to expand approval to prevent anal cancer.

The double-blind study included 4,065 healthy men ages 16-26, enrolled at 71 sites in 18 countries. Of those patients, 85% reported having exclusively female sexual partners, with the remainder self-identified as having sex with men.

The men were tested at the onset of the trial for previous exposure to HPV strains 6, 11, 16, and 18, and were randomly selected to receive a placebo or a vaccine that targeted the four strains. Men with a history of anal or genital warts or lesions were excluded from the study. Participants received six follow-up examinations over the following three years to assess the vaccine's effectiveness. Researchers report that in addition to preventing warts, the vaccine also effectively prevented HPV-persistent infection in 86% of the participants without previous exposure.

The study results represent an "exciting development" in the world of sexually transmitted diseases, said **Joel Palefsky**, MD, a UCSF professor of medicine who co-led the research along with epidemiologist Anna Giuliano, PhD, from the H. Lee Moffitt Cancer Center and Research Institute. "It shows that if we vaccinate males early enough, we should be able to prevent most cases of external genital warts in this population," said Palefsky in a release accompanying the study's publication.

REFERENCES

1. McRee AL, Reiter PL, Chantala K, et al. Does framing human papillomavirus vaccine as preventing cancer in men increase vaccine acceptability? *Cancer Epidemiol Biomarkers Prev* 2010;19:1937-1944.
2. Sperber NR, Brewer NT, Smith JS. Influence of parent characteristics and disease outcome framing on HPV vaccine acceptability among rural, Southern women. *Cancer Causes Control* 2008;19:115-118.
3. Harris G. US panel debates value of HPV vaccine for boys. *New York Times*, October 28, 2010. Accessed at http://www.nytimes.com/2010/10/29/us/29vaccine.html.
4. Giuliano AR, Palefsky JM, Goldstone S, et al. Efficacy of quadrivalent HPV vaccine against HPV infection and disease in males. *N Engl J Med* 2011; 364:401-411. ■

Diaphragms: Update your clinical knowledge

While it is not in the top tier of contraceptive effectiveness, the diaphragm remains an option as a female-controlled method of birth control. What do you know about this form of family planning?

Use of the diaphragm has changed dramatically in the last two and a half decades, according to data from the 1982, 1995, 2002, and 2006–2008 National Survey of Family Growth (NSFG).[1] In 1982, 8% of U.S. women who were using contraception chose the diaphragm. As new methods emerged, use of method declined, By 2006–2008, use of the diaphragm had virtually disappeared from NSFG survey reports; the number was so low analysts termed the figure "does not meet the standard of reliability or precision."[1]

The diaphragm is used with a spermicide. When it is used in conjunction with spermicidal cream or gel, 16% of women will experience an unintended pregnancy in the first year of typical use; 6% will experience an unintended pregnancy in the first year of perfect use.[2]

The diaphragm offers several benefits:

- The woman controls the method.
- Its use does not involve taking a drug.
- Contraception can be reversed immediately; there is no delay in returning to baseline fertility.[3]

However, the method provides no protection against HIV and some sexually transmitted diseases (STDs). A clinician must fit the device. A speculum and bimanual exam is recommended before initiating use. The diaphragm has a higher failure rate than hormonal methods. *A Pocket Guide to Managing Contraception* recommends that advance emergency contraceptive pills be provided when device use is initiated.[4] *[To talk with patients about the diaphragm, use a free patient handout from the Association of Reproductive Health Professionals, available with the online issue. For assistance, contact customer service at customerservice@ahcmedia.com or (800) 688-2421.]*

Silicone now norm

Two manufacturers provide diaphragms in the United States: CooperSurgical of Trumbull, CT, which manufactures the Milex Arcing Style Diaphragm and the Milex Omniflex Style Diaphragm, and Ortho-McNeil-Janssen Pharmaceuticals of Titusville, NJ, which manufactures the Ortho All-Flex Diaphragm.

The two styles of Milex diaphragms have been manufactured in silicone for several years. The Ortho All-Flex was previously manufactured in latex; the silicone version replaced it in 2009, says **Jeff Christensen**, an Ortho spokesperson.

The Milex diaphragms always should be used with a spermicidal gel, according to product literature. The Ortho All-Flex diaphragm always should be used in combination with a spermicidal jelly or cream, its product literature notes.

A Cochrane Review of evidence regarding use of the diaphragm with or without spermicide identified only one randomized controlled trial that met review parameters.[3] In that trial, no significant difference was found in the pregnancy rates (with typical use or consistent use) or discontinuation rates between the diaphragm-with-spermicide and diaphragm-without-spermicide groups. A trend toward higher pregnancy rates was noted in the diaphragm-without-spermicide group; however, the study failed to recruit the planned number of participants and consequently was underpowered. Therefore, the study provided insufficient evidence to change the commonly recommended practice of using the diaphragm with spermicide, the Cochrane Review team concludes.[5]

Spermicide is available

Once a woman receives her diaphragm, what spermicides are available for use with it?

In the United States, Gynol Regular Strength Vaginal Contraceptive Jelly, Gynol II Extra Strength

EXECUTIVE SUMMARY

Use of the diaphragm has changed dramatically in the last two and a half decades, according to data from the National Survey of Family Growth (NSFG). In 1982, 8% of U.S. women who were using contraception chose the diaphragm.

- As new methods emerged, use of method declined. By 2006–2008, use of the diaphragm had virtually disappeared from NSFG survey reports.
- While not in the top tier of contraceptive effectiveness, the diaphragm offers the advantages of a female-controlled form of birth control that does not involve taking a drug, with an immediate return to baseline fertility.

COMING IN FUTURE MONTHS

- Research explains link between chlamydia, ectopic pregnancies
- Review contraceptive options for women with medical problems
- Progestin-only contraceptive patch in research
- New insights into polycystic ovary syndrome

Vaginal Contraceptive Jelly, and Options Conceptrol Vaginal Contraceptive Gel are offered over the counter in several retail outlets, including Walgreens, Wal-Mart, Kmart, CVS, and Rite Aid. The brands were acquired in 2008 by Revive Personal Products Co. of Madison, NJ, from Johnson & Johnson, says **Mike Lesser**, chief executive officer.

All three products rely on the spermicide nonoxynol-9 (N-9) for efficacy. Gynol Regular Strength contains 2% N-9, while Gynol II Extra Strength contains 3% N-9. Options Conceptrol contains 4% N-9.

In 2007, the Food and Drug Administration (FDA) issued a final rule requiring all manufacturers of over-the-counter stand-alone vaginal contraceptive and spermicidal N-9 products to include a warning that N-9 does not provide protection against infection from HIV or other STDs. in January 2003, the FDA proposed new warning statements and other labeling information for such products after results from a major clinical study in Africa and Thailand showed that women using a contraceptive gel product containing N-9 were not protected against HIV and other STDs and were at higher risk for HIV infection than women using a placebo gel.[6]

According to guidance from the World Health Organization, N-9 can be used as a contraceptive, alone or in combination with a cervical barrier method, among women at low risk of HIV/STI infection who use the product no more than once daily.[7]

The two Gynol jellies and Options Conceptrol gel are not available in Canada. Johnson & Johnson had ceased distribution prior to Revive's acquisition of the products, says Lesser. The com-

continued on page 48

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

CNE 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;
- provide practical information that is evidence-based to help clinicians deliver contraceptives sensitively and effectively.

13. What two sexually transmitted diseases are among the most commonly **reported** infectious diseases in the United States?
A. Chlamydia and gonorrhea
B. Chlamydia and syphilis
C. Gonorrhea and chancroid
D. Chlamydia and trichomoniasis

14. What was the hormone used in the vaginal ring in the study of irregular bleeding in women using depot medroxyprogesterone injections (Dempsey A, et al)?
A. Estrone
B. Estradiol
C. Estriol
D. Equilin

15. Which medication abortion regimen has received approval from the Food and Drug Administration?
A. Methotrexate and misoprostol
B. Misoprostol alone
C. Mifepristone and misoprostol
D. Mifepristone alone

16. Which vaccine has been approved for prevention of anal cancer and associated precancerous lesions related to HPV types 6, 11, 16, and 18 in males and females ages 9-26?
A. Cervarix
B. Kinrix
C. Twinrix
D. Gardasil

Answers: 13. A; 14. B; 15. C; 16. D

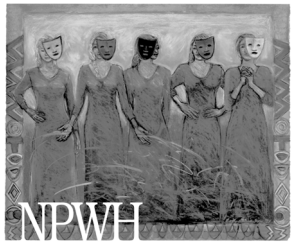
continued from page 47

pany is contemplating re-entering the Canadian market due to interest in the products, he notes.

REFERENCES

1. Mosher WD, Jones J. Use of contraception in the United States: 1982–2008. National Center for Health Statistics. *Vital Health Stat* 2010;23:9.
2. Trussell J. Contraceptive efficacy. In: Hatcher RA, Trussell J, Nelson AL, et al. *Contraceptive Technology*. 19th ed. New York: Ardent Media; 2007.
3. Cook LA, Nanda K, Grimes DA, et al. Diaphragm versus diaphragm with spermicides for contraception. *Cochrane Database Syst Rev* 2003; Doi: 10.1002/14651858.CD002031.
4. Zieman M, Hatcher RA, Cwiak C, et al. *A Pocket Guide to Managing Contraception*. Tiger, GA: Bridging the Gap Foundation; 2010.
5. Bounds W, Guillebaud J, Dominik R, et al. The diaphragm with and without spermicide. A randomized, comparative efficacy trial. *J Reprod Med* 1995;40:764-774.
6. Van Damme L, Ramje G, Alary M, et al. Effectiveness of COL-1492, a nonoxynol-9 vaginal gel, on HIV-1 transmission in female sex workers: a randomised controlled trial. *Lancet* 2002;360:971-977.
7. World Health Organization, Department of Reproductive Health and Research. WHO/CONRAD technical consultation on nonoxynol-9. WHO, Geneva, Oct. 9-10, 2001. Summary Report. World Health Organization, 2003. ■

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



Association of Reproductive Health Professionals

HEALTH MATTERS
Diaphragm

www.arhp.org/healthmatters

What is the diaphragm?

The diaphragm is a flexible rubber cup that is inserted into the vagina and fits over the cervix. It is used with a spermicide.

How effective is the diaphragm?

If always used correctly, 6 out of 100 women who use the diaphragm will get pregnant each year. If not always used correctly, 16 out of 100 women who use the diaphragm will get pregnant per year.

Using spermicide with the diaphragm makes it much more effective at preventing pregnancy.

How does it work?

The diaphragm covers the cervix to block sperm from entering the uterus. The spermicide also kills sperm so it cannot reach the uterus.

Diaphragms come in different sizes. A health care provider will fit you for the right size and show you how to use it. If your body changes in certain ways, you might need a different size diaphragm. Get your provider to check the fit if your weight changes by 10 or more pounds or if you get pregnant.

- To use the diaphragm, first cover the inside of it with spermicide. Then insert it into your vagina so that it covers your cervix.
- You can insert the diaphragm up to 6 hours before sex. You should leave it in for at least 6 hours after the last time you have sex. Don't leave it in for more than 24 hours.
- If you want to have sex again before 6 hours have passed, add more spermicide into the vagina. You do not need to remove the diaphragm when you do this.
- Do not use the diaphragm when you have your period.

What are the benefits of using the diaphragm?

- The diaphragm is safe, simple, and convenient.
- You can insert the diaphragm ahead of time so that it doesn't interrupt sexual activity.
- With proper care, your diaphragm should last about two years.

What are the downsides of using the diaphragm?

- The diaphragm does not protect against sexually transmitted infections (STIs).
- You must use the diaphragm each time you have sex.
- Getting a diaphragm requires a visit to a health care provider and a prescription.
- The diaphragm is less effective at preventing pregnancy than some other birth control methods.
- The diaphragm cannot be used when you have your period.
- The diaphragm can cause vaginal irritation. This may put you at risk for infection.

Health Matters is a publication of ARHP for the general public that provides a brief overview of existing facts and data on various topics related to reproductive health.

Where can I get the diaphragm?

A trained health care provider can determine the right size diaphragm for you and give you a prescription. You can purchase it at a drugstore or clinic.

Where can I get more information?

For more information on the diaphragm, talk to your health care provider.

Compare the diaphragm to other birth control options using ARHP's Method Match at www.arhp.org/MethodMatch.

Association of Reproductive Health Professionals

HEALTH MATTERS
Birth Control Shot

www.arhp.org/healthmatters

What is the shot?

The birth control shot is an injection of a hormone called progestin. Each shot prevents pregnancy for about three months.

How effective is the shot?

The birth control shot is very effective. If always used correctly, less than 1 out of 100 women will get pregnant each year using the shot. If not always used correctly, 3 out of 100 women will get pregnant each year using the shot.

When you first start on the shot, it takes several days to begin working. Use a backup form of birth control for 7 days after you get the first shot.

How does it work?

A health care provider will give you the shot in your arm every 12 weeks. The hormone in the shot keeps your ovaries from releasing eggs and thickens your cervical mucus to block sperm from getting into the uterus.

What are the benefits of using the shot?

- The shot is safe, convenient, and very effective.
- If you use the shot, you don't have to think about birth control every day or each time you have sex.
- The progestin in the shot offers several health benefits, including fewer menstrual cramps, lighter or no periods. It also reduces the risk of pelvic inflammatory disease and endometrial cancer.
- The shot can be a good birth control method for women who cannot use estrogen.

What are the downsides of using the shot?

- The shot does not protect against sexually transmitted infections (STIs).
- You must visit your health care provider every 12 weeks.
- Some women may have side effects while using the shot. Irregular bleeding is the most common side effect, especially in the first 6 to 12 months. Other, less common, side effects include changes in appetite or weight gain, breast tenderness, and nausea and vomiting.
- Women who use the birth control shot may have temporary bone thinning. Bone growth begins again when you stop using the shot. You can help protect your bones by exercising regularly and getting extra calcium and vitamin D.
- Women can get pregnant after they stop using the shot, but it may take about a year after the last shot.
- Women with certain conditions (history of or current breast cancer, anorexia, and steroid use) should not use the shot.

Health Matters is a publication of ARHP for the general public that provides a brief overview of existing facts and data on various topics related to reproductive health.

Where can I get the shot?

A health care professional can give you the shot in a medical office or clinic.

Where can I get more information?

For more information on the birth control shot, talk to your health care provider.

Compare the shot to other birth control options using ARHP's Method Match at www.arhp.org/MethodMatch.