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New moms choose sterilization over IUDs: What can reverse trend?

Include reversible options when permanent procedures discussed

While intrauterine devices (IUDs) represent a safe, effective, and reversible form of birth control, results of a new study indicate many U.S. women choose sterilization immediately postpartum.[1]

The current study looked at data from 2001-2008 Nationwide Inpatient Sample, the largest all-payer inpatient care database in the United States, to identify women who had tubal sterilization or IUD insertion performed shortly after giving birth. Researchers found that women had an IUD inserted in one in every 37,000 post-deliveries, while tubal sterilizations were performed one in every 13 postpartum circumstances.[1]

Like IUDs, tubal sterilization is highly effective and can be initiated in the postpartum period prior to hospital discharge, notes lead study author **Maura Whiteman**, PhD, an epidemiologist in the Women's Health and Fertility Branch in the Division of Reproductive Health at the Centers for Disease Control and Prevention (CDC). However, IUDs have some potential advantages in that they are easily reversible and IUD insertion does not involve a surgical procedure, she explains.

"We undertook this study to see how often IUD insertion was being performed during delivery hospitalizations in the U.S. compared to tubal sterilization," says Whiteman. "We also wanted to examine characteristics associated with the likelihood of undergoing these procedures to assess whether IUDs may be underutilized in some groups relative to tubal sterilization, such as those who may be more likely to experience post-sterilization regret."

Next Month: Routine HPV Vaccine Recommended for Males

Be sure to see the January 2012 issue for coverage of the Advisory Committee on Immunization Practices' recommendations for routine vaccination of males 11 or 12 years old for protection against human papilloma virus (HPV). The HPV vaccine will afford protection against certain HPV-related conditions and cancers in males and also might provide indirect protection of women by reducing transmission of HPV.

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Providing effective contraception in the postpartum is an important goal in pregnancy prevention. In 2001, 49% of all pregnancies were unintended, and 21% of those women gave birth within 24 months of a previous birth, according to the CDC.[2] Postpartum contraception improves health by lengthening birth intervals: On a global scale, if births are scaled 3-5 years apart, the mother is 2.5 times more likely to survive childbirth, the baby is 1.5 times more likely to survive the first week of life, and 2.5 times more likely to survive to five years of age.[3]

A recent update to the *U.S. Medical Eligibility Criteria for Contraceptive Use* reinforces the safe use of intrauterine contraception in the postpartum.

The levonorgestrel-releasing IUD (Mirena, Bayer HealthCare Pharmaceuticals, Wayne, NJ) and the copper-bearing IUD (ParaGard, Teva Women's Health, North Wales, PA), can be inserted postpartum, including immediately after delivery. The Mirena is listed as Category 2 (benefits theoretically outweigh risks) for insertion less than 10 minutes following delivery of placenta, as well as 10 minutes after placenta delivery up to less than four weeks. The ParaGard is listed as Category 1 (no restrictions on use) for insertion less than 10 minutes after placenta delivery and Category 2 for 10 minutes after placenta delivery to less than four weeks.[4]

Although IUD expulsion rates are somewhat higher when insertion occurs within 28 days of delivery, continuation rates at six months are similar among women who receive an IUD postpartum and those who plan for delayed insertion, the guidance notes.[5,6] A 2009 review of evidence indicates that there is no increase in risk of complications among women who had an IUD inserted during the postpartum period.[5] The review notes some increase in expulsion rates occur with delayed postpartum insertion when compared to immediate insertion, and with immediate insertion when compared to interval insertion.[5]

Regret is real

While many new moms may gravitate to sterilization as a birth control option following hospital

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- Researchers found that women had an IUD inserted in one in every 37,000 post-deliveries, while tubal sterilizations were performed one in every 13 postpartum circumstances.
- While sterilization regret among younger women has been well-documented, procedures continue to be performed in this age range. In the current study of postpartum procedures, 15% of tubal sterilizations occurred among women who were 24 years old or less.

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Editorial Questions

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delivery, clinicians should pay close attention to age of the mother when explaining contraceptive choices.

In a 2006 review of available data, analysts report that the younger women are at the time of sterilization, the more likely they are to report regretting that decision.[7] Women undergoing sterilization at the age 30 years or younger were about twice as likely as those over 30 to express regret, and they were from 3.5 to 18 times as likely to request information about reversing the procedure, researchers note.[7]

While sterilization regret among younger women has been well-documented, procedures continue to be performed in this age range. In the current study of postpartum procedures, 15% of tubal sterilizations occurred among women who were 24 years old or less.[1]

What can you do?

What can clinicians do to expand contraceptive options for new mothers? Bring up the IUD as a safe, effective option, says **Barbara Clark,** MPAS, PA-C, DFAAPA, a clinician at Knox OB/GYN Ltd., a private obstetric/gynecology practice in Galesburg, IL. Clark, who terms herself as a "huge fan of IUDs," says intrauterine contraception is the number one recommended postpartum option in her practice.

"My comment to any patient, including postpartum, is that intrauterine contraception is as effective as sterilization, but it is not permanent, and it is not surgery," says Clark. "I also tell patients that it is one of the most cost-effective options as well, if used for two years or more."

Most young pregnant women are unsure about the IUD's characteristics. When asked to rank how safe/effective IUDs are compared to pills, injections, or tubal sterilization, 71% were unsure of the device's safety, while 58% were unsure of its efficacy.[8]

In summary, IUDs are significantly underutilized for contraception in the United States, notes Clark, a participant in the Association of Reproductive Health's (ARHP's) "A Clinical Update on Intrauterine Contraception." *(Get slide sets and patient handouts from the ARHP web site, www.arhp.org. Click on "Professional Education," then "View More." Select "A Clinical Update on Intrauterine Contraception.")*

"Most patients are very interested when this option is discussed with them, and I frequently have patients ask for an IUD because a friend has recommended it," says Clark. "I think the largest barrier to use is cost, if there is no third-party coverage." Total costs for the Copper T 380A IUD are $647, with total costs for the levonorgestrel IUD at $930; total cost for tubal ligation is $2,978.[9]

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Just in: IUDs reduce cervical cancer risk

Add more research to your database of information on intrauterine devices (IUDs): Results of a new international analysis indicate that using an IUD might lower cervical cancer risk in device users.[1]

To perform the study, researchers designed a

EXECUTIVE SUMMARY

Results of a new international analysis indicate that using an intrauterine device (IUD) might lower cervical cancer risk in device users.

- After controlling for health and behavioral factors, the researchers report that using an IUD reduced the risk of cervical cancer by 45%, compared with never using one. The protective effect was apparent in the first year of use and continued for as many as 10 years, the researchers note.
- Previous studies have associated IUD use with a reduced risk of endometrial cancer, but the device's effect on the risk for cervical cancer had not been determined previously.

pooled analysis of individual data from two large studies by the International Agency for Research on Cancer, an international collaboration on cancer research, and the Institut Català d'Oncologia, a Spanish-based oncology research program. One study included data from 10 case-control studies of cervical cancer done in eight countries, and the other included data from 16 human papillomavirus (HPV) prevalence surveys of women from the general population in 14 countries. A total of 2,205 women with cervical cancer and 2,214 matched control women without cervical cancer were included from the case-control studies, and 15,272 healthy women from the HPV survey.

After controlling for health and behavioral factors, the researchers report that using an IUD reduced the risk of cervical cancer by 45%, compared with never using one. The protective effect was apparent in the first year of use and continued for as many as 10 years, the researchers note.[1]

Previous studies have associated IUD use with a reduced risk of endometrial cancer, but the device's effect on the risk for cervical cancer had not previously been determined. The new study is the largest one to examine the association between IUDs and cervical cancer risk, and it also is the first one to include HPV in its analysis.

Check possible causes

While researchers report IUD use did not affect the risk of HPV infection, it was associated with a lower risk of cervical cancer for both major cervical cancer types, the researchers report. The likelihood of developing squamous-cell carcinoma was reduced by 44%, with risk for adenocarcinoma or adenosquamous carcinoma reduced by 54%. While study data suggest that IUD use does not modify the likelihood of prevalent HPV infection, it might affect the likelihood of HPV progression to cervical cancer, researchers note.[1]

What are possible explanations for the protective effect of IUDs? The researchers suggest the process of device insertion or removal might destroy precancerous lesions. IUD use might also induce chronic mucosal inflammation and a long-lasting immune response that might reduce the likelihood of HPV progression, the researchers note.[1]

Seven case-control studies around the world have examined the potential association between non-medicated or copper IUD use and development of endometrial cancer, with six of the seven finding protection against endometrial cancer from the devices, points out **David Grimes**, MD, author of the chapter on intrauterine contraception in *Contraceptive Technology*.[2] The protective effect was statistically significant in two of those studies.[3] The only study that did not find a benefit related to a steel ring used in China, which is not available in Western countries.[3]

Clinicians will need to be careful in interpretation of claim that IUD use reduces cervical cancer risk, because there might be a selection bias, says **Anita Nelson**, MD, professor in the Obstetrics and Gynecology Department at the David Geffen School of Medicine at the University of California in Los Angeles. Women at high risk for sexually transmitted diseases (STDs) generally are not given IUDs, Nelson notes. This potential bias in the current study was supported by the fact that the IUD did not protect against cervical cancer in women with HPV infection, she states.

What is the next step in research in examining the protective role of the IUD against cervical cancer? **Xavier Castellsagué**, MD, MPH, PhD, a researcher at Bellvitge Biomedical Research Institute, L'Hospitalet de Llobregat, Spain, and lead author of the current research, sees two kind of further studies:

- Mechanistic studies to explore and measure the potential local changes in the endometrium as well as in the cervix induced by the device, including local immune markers, hormonal receptors changes, and inflammatory markers, among others.
- Prospective studies recruiting a cohort of IUD users and a matched cohort of non-IUD users measuring HPV and cytological changes every six months to assess HPV incidence, clearance, persistence, and progression to cervical abnormalities and cervical intraepithelial neoplasia 2 (CIN2) in

the two cohorts.

"These two study designs would allow to firmly establish whether the protective effect if due to the device or not and explore the underlying mechanisms of such a potential effect," explains Castellsagué.

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Qualitest pulls suspect OCs

EXECUTIVE SUMMARY

A nationwide recall of multiple lots of Qualitest oral contraceptives (OCs) has been issued after the Huntsville, AL-based manufacturer detected a packaging error that could lead to incorrect administration of pills. The company issued the voluntary, nationwide retail-level recall.

- Select blister packs were rotated 180 degrees within the card, reversing the weekly tablet orientation and making the lot number and expiry date no longer visible, according to information issued by the company.
- Products affected by the recall include Cyclafem 7/7/7, Cyclafem 1/35, Emoquette, Gildess FE 1.5/30, Gildess FE 1/20, Orsythia, Previfem, and Tri-Previfem.

Check your pharmacy stock, and review patient pill choices: A nationwide recall of multiple lots of Qualitest oral contraceptives (OCs) has been issued after the Huntsville, AL-based manufacturer detected a packaging error that could lead to incorrect administration of pills.

The voluntary, nationwide retail-level recall of the multiple lots was issued by the company Sept. 15, 2011. Qualitest is a wholly owned subsidiary of Endo Pharmaceuticals of Chadds Ford, PA.

Select blister packs were rotated 180 degrees within the card, reversing the weekly tablet orientation and making the lot number and expiry date no longer visible, according to information issued by the company. Products affected by the recall include Cyclafem 7/7/7, Cyclafem 1/35, Emoquette, Gildess FE 1.5/30, Gildess FE 1/20, Orsythia, Previfem, and Tri-Previfem. A list of the lot numbers in question is available by accessing http://www.qualitestrx.com/pdf/OCRecall.pdf. Lot numbers may be checked by looking at the bottom of the product box or the individual blister card.

"As a result of this packaging error, the daily regimen for these oral contraceptives may be incorrect and could leave women without adequate contraception, and at risk for unintended pregnancy," states information released by the company. "These packaging defects do not pose any immediate health risks; however, consumers exposed to affected packaging should begin using a non-hormonal form of contraception immediately and consult their health care provider or pharmacist."

Pharmacies have been instructed to contact consumers who have received affected product. Clinicians, pharmacists, or women seeking more information on this recall, or who have affected products, should contact Qualitest toll free at (877) 300-6153, from 8 a.m. to 5 p.m. Central Time Monday through Friday. Return of any affected product may be arranged by calling the toll-free number.

Adverse reactions or quality problems associated with the use of the affected products may be reported to Qualitest toll-free at (877) 300-6153 or to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online at www.fda.gov/medwatch/report.htm, by regular mail using a postage-paid, pre-addressed Form FDA 3500 available at www.fda.gov/MedWatch/getforms.htm, or by faxing the Form FDA 3500 to (800) 332-0178. *(To check FDA recalls, see the Resource listing at the end of this story.)*

Recalls happen

Family planning clinicians have experienced similar recalls in 2000 (Norplant contraceptive implant), 2002 (Lunelle contraceptive injection), and 2003 (Nortrel 7/7/7 OC).

The recall for the suspect lots of the Qualitest pills might not have as much as an impact on clinics, since the Qualitest pills are relatively new. The two most established Qualitest pills are Previfem, a generic equivalent to Ortho Cyclen, and Tri-Previfem, an equivalent to Ortho Tri-Cyclen. Both received FDA approval in 2004. FDA approvals fol-

lowed in 2005 for Gildess (generic for Loestrin) and Gildess FE (equivalent to Loestrin FE). Cyclafem 1/35 (generic to Ortho Novum) and Cyclafem 7/7/7 (equivalent to Ortho Novum 7/7/7) gained approval in late 2010, with Emoquette (generic for Ortho-Cept) and Orsythia (equivalent to Alesse) approvals issued in 2011.

RESOURCE

To review Food and Drug Administration (FDA) recalls, go to the FDA web site, www.fda.gov. On the lower right side of the page, click the "Recalls & Safety Alerts" link. Click on the "Drugs" tab to see all information on drugs. The database can be sorted by brand name and company. Citizens also can sign up for free recall, withdrawal, and safety alerts from the FDA on this same page.' ■

FDA schedules review of drospirenone pills

The Food and Drug Administration (FDA) has scheduled a Dec. 8, 2011, meeting of its Reproductive Health Drugs Advisory Committee and Drug Safety and Risk Management Advisory Committee to review the risks and benefits of oral contraceptives containing the progestin drospirenone. The agency is weighing evidence regarding the risk of increased blood clots in users of such pills.

The federal regulatory agency has completed its review of the two 2011 studies that evaluated the risk of blood clots for women who use drospirenone-containing birth control pills.[1,2] It is continuing to analyze a separate FDA-funded study that evaluated the risk of blood clots in users of several hormonal contraceptives.

Preliminary results of the FDA-funded study suggest an approximately 1.5-fold increase in the risk of blood clots for women who use drospirenone-containing birth control pills compared to users of other hormonal contraceptives.[3]

Although advisory committees provide recommendations to the agency, the FDA makes the final decisions regarding drug use, says **Lisa Kubaska**, PharmD , a spokesperson for the agency's Center for Drug Evaluation and Research. The agency posts transcripts of public advisory committee meetings 2-4 weeks after the conclusion of a meeting. (They may be accessed by visiting the FDA web site, www.fda.gov. Under "About FDA" on the lower left side of the page, select "Advisory Committees," then under the "Advisory Committees" heading, select "Drugs," then "Reproductive Health Drugs Advisory Committee." Click on "2011 Meeting Materials" to see material related to each committee meeting.)

What to keep in mind?

Drospirenone is the progestin contained in the Yaz/Yasmin line of oral contraceptives from Bayer HealthCare Pharmaceuticals of Wayne, NJ. The progestin also is found in generic equivalents: North Wales, PA-based Teva Pharmaceuticals' Ocella and Gianvi; Princeton, NJ-based Sandoz's Loryna and Syeda; and Morristown, NJ-based Watson Pharmaceuticals' Zarah. In 2010, Bayer received FDA approval for two drospirenone pills with added folate: Beyaz and Safyral. Beyaz contains 20 mcg of ethinyl estradiol, while Safyral contains 30 mcg of ethinyl estradiol; both pills contain 3 mg of drospirenone.

Until the FDA issues further communication, what should clinicians keep in mind regarding drospirenone pills? The agency lists five points:

- The risks and benefits of drospirenone-containing pills should be considered for a specific patient in light of her risk for developing blood clots before prescribing such a pill.
- Counsel patients about the current information regarding risk of venous thromboembolism (VTE) with drospirenone-containing oral contraceptives compared to levonorgestrel-containing oral contraceptives.
- Factors for increased risk of VTE in users of birth control pills include smoking, obesity, and family history of VTE, in addition to other factors that contraindicate use of combination oral contraceptives.
- The studies that have looked at the risk of blood clots have evaluated only the specific drospirenone-containing product that combines 3 mg of drospirenone with 0.03 mg of ethinyl estradiol. It is not known whether these study results apply to other drospirenone-containing products with a lower dose of estrogen, the FDA notes.
- Clinicians should report adverse events involving oral contraceptives to the FDA MedWatch program at www.fda.gov/medwatch.

What should women do?

What should women do if they are taking birth control pills containing drospirenone? The FDA advises that these women should continue taking their pills as directed unless told otherwise by their healthcare professional.

Staying the course on pills is an important mes-

sage, according to **Anita Nelson**, MD, professor in the Obstetrics and Gynecology Department at the David Geffen School of Medicine at the University of California in Los Angeles. All pills are safer than pregnancy, she notes.

Teach women to recognize the symptoms of blood clots, including persistent leg pain, severe chest pain, or sudden shortness of breath. Advise them to contact your office immediately if they develop any of these symptoms.

Explain to women that the risk of VTE also increases with age and is higher in women who smoke, are overweight, or have a family history of blood clots. Women with a history of blood clots, heart attack, or stroke should not take any type combination birth control pills. Because drospirenone, in contrast to other progestins used in combination oral contraceptives, has the potential to increase serum potassium levels, women with kidney or adrenal disease should not use birth control pills containing drospirenone.[4]

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New data emerges on one-size diaphragm

Effectiveness rate rivals traditional devices

The contraceptive options for women who cannot use hormonal methods might soon expand if regulatory approval is given to a new single-size diaphragm. Results of a two-year multi-site study of 450 U.S. couples indicate the effectiveness rates of the SILCS single size, contoured diaphragm, now in development, are similar to traditional diaphragms. Results of the pivotal trial were presented at the 2011 Reproductive Health Conference in Las Vegas.[1]

The device's single-size design, developed by PATH, a Seattle-based international health advocacy organization, eliminates the need for a clinical fitting. The SILCS diaphragm, made of silicone, was developed to improve reproductive health in low-resource settings. In those low-resource settings, women have a limited range of contraceptive methods, and diaphragms are not available. It also might provide another option for women in developed countries, particularly for those who cannot or do not want to use hormonal methods or an intrauterine device.

"High rates of unintended pregnancy and discontinuation of current contraceptive methods suggest that existing contraceptive methods do not adequately meet the reproductive health needs of all women," said **Michael Free**, PhD, PATH's vice president and senior advisor for technologies in a press release accompanying the study results. "This newly designed, discreet, and reusable cervical barrier could expand women's options for nonhormonal protection, thereby improving women's reproductive health especially in low resource settings."

Not your mother's device

The device is "not your mother's diaphragm." Those words come from **Jill Schwartz**, MD, medi-

EXECUTIVE SUMMARY

Results of a two-year multi-site study of 450 U.S. couples indicate the effectiveness rates of the SILCS single-size, contoured diaphragm, in development, are similar to traditional diaphragms.

- The device's single-size design, developed by PATH, a Seattle-based international health advocacy organization, eliminates the need for a clinical fitting.
- Made of silicone, the device was developed to improve reproductive health in low-resource settings, where women have a limited range of contraceptive methods and where diaphragms are not available. It also might provide another option for women in developed countries, particularly for those who cannot or do not want to use hormonal methods or an intrauterine device.

cal director at Arlington, VA-based CONRAD, an international reproductive health research organization and study principal investigator.

Development of the SILCS diaphragm arose as a response to women calling for a broader choice of contraceptive methods that are under their control, can be easily stopped and started, and nonhormonal, thus eliminating side effects. Health advocates also are interested in its potential as a dual protection method, providing protection against pregnancy and such sexually transmitted infections as HIV.

The pivotal trial was designed as a multi-center trial, looking at 450 U.S. couples using the SILCS device with gel for six months. Study visits were held at baseline, after one cycle, three cycles, and six cycles (190 days). The study was modeled in a similar design to an earlier investigation that looked at use of a fitted diaphragm.[2]

Couples were randomized into two study arms; 300 couples used the SILCS device with BufferGel, a microbicidal spermicide under development, while 150 couples used the device with Gynol II (Revive Personal Products, Madison, NJ), a nonoxynol-9 spermicide. The study objectives included a six month typical use pregnancy probability; a safety analysis of the SILCS device, including colposcopy and microflora subset; and an analysis of the feasibility of its over-the-counter use and fit.

In comparing the SILCS against the Ortho All-Flex diaphragm (Ortho-McNeil-Janssen Pharmaceuticals, Titusville, NJ) six-month typical use pregnancy rates (with 95% confidence interval), couples using the SILCS with Buffer Gel recorded a rate of 9.6 (5.5-13.6), compared to the All-Flex/Buffer Gel rate of 10.1 (7.1-13.1). For those who used the SILCS device with Gynol II spermicide, a rate of 12.5 (5.4-19.5) was recorded. This number compares to 12.3 (7.7-16.9) for the All-Flex diaphragm with similar spermicide.[1]

Ease of use eyed

How easy is it for healthcare providers to instruct women on proper use of the SILCS diaphragm? So far, women have only used the SILCS diaphragm in clinical trials in which they were given instructions that are similar to a standard sized diaphragm, says Schwartz. The next step will be to see how clinicians and women interact with the SILCS diaphragm once it becomes commercially available, she notes.

"The biggest difference with this device is that since it is a single-size, a pelvic exam to assess size is not required," Schwartz notes.

In the pivotal study, women were introduced to the device using printed instructions only, Schwartz notes. Most women were able to correctly insert, remove, and check correct position of the device by simply using the instructions. For women who had difficulty positioning the device or were not confident, counseling by the clinician helped most women achieve successful fit, she states.

"The clinician and the woman can assess the correct SILCS position according to four simple criteria: cervix covered, device behind pubic bone, device does not protrude from the vagina, and device comfort," says Schwartz. "These simple fit criteria should help women to feel confident using this method."

Participants in the study reported high ratings for ease of use and comfort for both females and their partners, which should be noted as an important feature, says Schwartz. "The only methods that work are the kind that women will actually use," she observes.

What's the next step?

The SILCS device is not yet approved by regulatory authorities, so it is not yet commercially available, says Schwartz. Developers are moving toward seeking such approval, though.

PATH licensed the SILCS Diaphragm design to Kessel Marketing & Vertriebs GmbH (Kessel) of Frankfurt, Germany, in late 2010, states Schwartz. Kessel is working toward CE Mark certification, which will allow the product to be introduced through the company's existing distribution network in European Union countries, she states.

Kessel, CONRAD, and PATH will work on the submission to the U.S. Food and Drug Administration after European regulatory approval is granted, Schwartz says.

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More condom use by teen males reported

The safer sex message is reaching adolescents. Results of a new Centers for Disease Control and Prevention (CDC) report shows the percentage of teen males ages 15-19 in the United States who used a condom the first time they had sex increased between 2002 and 2006-2010.[1]

The report shows eight in 10 teen males used a condom at first sex, an increase of 9 percentage points from 2002. More teen males also used a condom in combination with a female partner's hormonal method: 16% versus 10% in 2002.

Reproductive health advocates hailed the September 2011 release of the report, issued by the CDC's National Center for Health Statistics.

"The nation's teen pregnancy and birth rates are now at record lows and the credit for this truly extraordinary progress goes to teens themselves who are making better decisions about sex and contraceptive use," said **Sarah Brown**, chief executive officer of the Washington, DC-based National Campaign to Prevent Teen and Unplanned Pregnancy in a statement accompanying the report's release.

Take a closer look

According to the new report, from 2006-2010, about 43% of never-married female teen-agers (4.4 million), and about 42% of never-married male teen-agers (4.5 million) had had sexual intercourse at least once. These levels of sexual experience have not changed significantly from 2002, researchers note.

The majority of teens are using some form of pregnancy prevention at first sex: 78% of females and 85% of males used a method of contraception at first sex according to 2006-2010 data. The condom remains the most popular method.

More adolescent females are looking at other forms of hormonal contraception than the Pill. Six percent of teen females used a non-pill hormonal method at first sex in the latest survey, compared to 2% in 2002. The most common method at first intercourse was the condom (68%) followed by the pill (16%).

About 20% of females in 2002 and 2006-2010 reported using hormonal contraceptive injectables when asked whether they had ever used a birth control method. Use of the contraceptive patch by teenagers also is on the rise. About 2% said they used it in 2002, when it was newly introduced; that number rose to 10% by 2006-2010. About 5% of teenagers (5.2%) said they had used the contraceptive ring.

Use of emergency contraception (EC) is on the rise, statistics indicate. In 2002, the use of EC was recorded at 8% in 2002; that figure grew to 14% in 2006-2010.

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Teen TOPICS

EPT: Use it to reduce STI teen reinfection

By **Anita Brakman**, MS
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According to the Centers for Disease Control and Prevention, female adolescents have the highest number of cases of gonorrhea and chlamydia in the United States.[1] While the overall prevalence for these infections among individuals ages 14-39 are .24% and 2.2% respectively, these rates are .92% and 3.4% for those ages 14-19.[2]

Adolescents' consistently higher rates of chlamydia and gonorrhea are partially due to high rates of reinfection. Recent studies have found chlamydia reinfection rates as high as 26% within 12 months, and younger patients are most likely

to be reinfected, with girls ages 13 and under having reinfection rates as high as 39%.[3] While many clinicians instruct patients to return to be tested for reinfection three months after initial treatment, this step does not address the underlying problem of ongoing sexual contact with untreated partners.

The American College of Obstetricians and Gynecologists (ACOG) released a committee opinion in September 2011 supporting use of expedited partner therapy (EPT) for management of gonorrhea and chlamydia.[4]

EPT is the delivery of medications or prescriptions by persons infected with a sexually transmitted infection (STI) to their sex partner(s) without assessment of the partner(s) by a clinician. ACOG joins medical and legal organizations including the America Academy of Pediatrics, Society for Adolescent Health and Medicine, American Medical Association, and the American Bar Association in supporting EPT as a tool for combating sexually transmitted infections.[5-8]

Can teens access EPT?

Adolescents can consent to receive STI treatment in all 50 states without parental consent or involvement, so legally the practice is supported for minors living in any state where EPT is legal for adults.[9] This situation means adolescents can access EPT in the 30 states that now explicitly permit the practice. EPT is potentially allowable in 13 states: Alabama, Delaware, Georgia, Hawaii, Idaho, Indiana, Kansas, Maryland, Montana, Nebraska, New Jersey, South Dakota, and Virginia; it also is potentially allowable in the District of Columbia and Puerto Rico — meaning the practice may become explicitly permitted after additional actions are taken or policies clarified by state officials. Only seven states — Arkansas, Florida, Kentucky, Michigan, Ohio, Oklahoma, and West Virginia — prohibit EPT.[10]

While directly referring partners to see a clinician for care remains the frontline strategy, EPT can be useful for partners who are unlikely or unwilling to come in for treatment. Systematic reviews show EPT can reduce the risk of repeat positive chlamydia and gonorrhea tests in adult patients.[11] However, no large-scale reviews have been conducted on studies of EPT and adolescents.

Some clinicians might express concerns regarding the safety of dispensing antibiotics to sexual partners of patients diagnosed with chlamydia or gonorrhea without requiring an office visit. Fortunately, severe allergic reactions are rare with the recommended treatments for chlamydia and gonorrhea.[12-13] However, patients should be counseled and given information on mediations' potential side effects, such as transient gastrointestinal problems, to share with their partner.

In addition to discussing side effects, more in-depth counseling is essential when providing EPT. The index patient's needs for information and support should be prioritized before discussing the need to treat partners. Additionally, patients should be screened to find out if partner notification could put them in danger of physical abuse or intimate partner violence. If so, EPT would not be recommended. Furthermore, EPT would not be recommended to survivors of sexual assault or abuse.

If an adolescent can safely discuss the infection and treatment with his/her partner(s), clinicians should discuss when and how notification will take place. They should rehearse this conversation with the patient when possible. Adolescents should be given educational materials on the infections and treatments. Many states provide web sites and specific materials for distribution. The CDC STD web site at http://www.cdc.gov/std/default.htm and the online Center for Young Women's Health at http://www.youngwomenshealth.org/sexuality_menu.html#stds serve as useful tools for adolescents.

Adolescents should be advised to encourage partners to see a clinician for an evaluation even after filling an EPT prescription and taking the medication. Teens should inform their partners that the medication provided will not treat any STIs other than the ones diagnosed. Adolescents and their partners also should be instructed on the recommended seven-day waiting period after both partners have completed their treatment before engaging in sex.

EPT may not be feasible for treatment of gonorrhea infections given that the most recent 2010 CDC guidelines for treatment of gonorrhea advise 250 mg intramuscular ceftriaxone (in addition to oral doxycycline or azithromycin) as part of the

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first-line treatment. However, one could substitute 400 mg of oral cefixime instead of the intramuscular medication.[14]

EPT is not appropriate for all adolescents. Sexual partners who might be pregnant should be seen by a clinician and not receive EPT. Likewise, there is inadequate research demonstrating the effectiveness of EPT for preventing reinfection among adolescent men who have sex with men because of the possible co-infection with HIV, syphilis, or other STIs.

Detailed information on the research supporting EPT, updates on legal status, and guidance on implementation can be found on the CDC's EPT website, http://www.cdc.gov/std/ept.

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CNE/CME INSTRUCTIONS

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

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

1. What *U.S. Medical Eligibility Criteria for Contraceptive Use* category is given to use of the Copper T 380A intrauterine device for insertion less than 10 minutes after placenta delivery?
   A. Category 1 (no restrictions on method use)
   B. Category 2 (advantages of using method generally outweigh theoretical or proven risks)
   C. Category 3 (theoretical or proven risks generally outweigh advantages of using method)
   D. Category 4 (unacceptable risk if method is used)

2. Why did Qualitest issue a voluntary recall of certain lots of its generic oral contraceptives?
   A. Select blister packs were rotated 180 degrees within the card, reversing the weekly tablet orientation and making the lot number and expiry date no longer visible.
   B. Suspect lots were formulated with just one hormonal component.
   C. The company received several reports of adverse events associated with pill use.
   D. Formulations were switched during packaging, resulting in incorrect labeling.

3. In which list of pills do all brands contain drospirenone?
   A. Yaz, Yasmin, Ocella, Gianvi, Loryna, Syeda, Zarah, Beyaz and Safyral
   B. Yaz, Yasmin, Errin, Gianvi, Loryna, Syeda, Zarah, Beyaz and Safyral
   C. Yaz, Yasmin, Ocella, Gianvi, Loryna, Cyclessa, Zarah, Beyaz and Safyral
   D. Yaz, Yasmin, Ocella, Gianvi, Loryna, Syeda, Zovia, Beyaz and Safyral

4. The SILCS diaphragm under development is made of:
   A. Latex.
   B. Silicone.
   C. Rubber.
   D. Non-silicone polymer.

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tion paper of the Society for Adolescent Medicine. *J Adolesc Health* 2009; 45:303-309.
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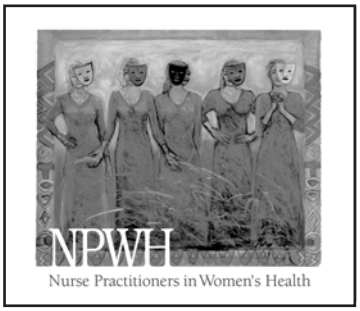

OB/GYN
QUARTERLY UPDATE

What healthcare providers should know about detecting thyroidal conditions

By **Sarah L. Berga**, MD
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Thyroid dysfunction and disease might present as reproductive compromise including oligomenorrhea, infertility, and miscarriage. Thyroid dysfunction and disease might complicate pregnancy and lead to compromised fetal neurodevelopment and preterm labor. Infertility procedures, particularly controlled ovarian hyperstimulation and ovulation induction with gonadotropins, increase the thyroxine requirement before the establishment of pregnancy. As such, the detection of thyroidal conditions may fall to any provider who cares for women.

Although we think of thyroid disease as a simple condition in which thyroxine is given when the thyroid-stimulating hormone (TSH) level is elevated and then TSH levels are monitored to see if the patient is getting the correct amount, it is a bit more complex than that. Indeed, the American Thyroid Association released a 45-page document titled "Guidelines of the American Thyroid Association for the Diagnosis and Management of Thyroid Disease during Pregnancy and Postpartum," which contains 76 recommendations.[1] The document was endorsed by the American Congress of Obstetricians and Gynecologists, among other groups.

The introduction highlights a few key points. During pregnancy, the thyroid gland increases 10%-20% in size and the production of thyroxine (T4) and triiodothyronine (T3) increases by 50% along with a 50% increase in the daily iodine requirement. The range of TSH is decreased throughout pregnancy because of the actions of hCG, and thus the upper and lower limits of TSH must be adjusted to detect and treat thyroidal disease. Approximately 10%-20% of pregnant women have antibodies to the thyroid gland during the first trimester and therefore are at high risk of developing overt hypothyroidism during pregnancy. I would add that it long has been known that symptoms such as fatigue are not a good way to screen for thyroid disease in the non-pregnant state, but fatigue is the sine qua non of pregnancy, so the only way to know if a pregnant patient's fatigue is partly related to subclinical or overt hypothyroidism is to screen.

Some of the recommendations of the report are highlighted below:

• Recommendation 2 states that "If trimester-specific reference ranges for TSH are not available, the following reference ranges are recommended: first trimester 0.1-2.5 mIU/L; second trimester 0.2-3.0 mIU/L; and

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third trimester 0.3-3.0 mIU/L.

• Recommendations 4 and 5 make the point that the wide variation in free T4 methodologies renders TSH a more reliable indicator of thyroidal status during pregnancy than FT4.

• Recommendation 6 is straightforward. Overt hypothyroidism should be treated in pregnancy using the TSH ranges above as guidance for how much thyroxine to give.

• Recommendations 8 and 9 grapple with the gray area of subclinical hypothyroidism (SCH), noting that SCH has been associated with adverse maternal and fetal outcomes. There is insufficient evidence from randomized controlled trials (RCTs) to recommend for or against universal levo-thyroxine replacement (LT4) in thyroid antibody negative women with SCH. However, women with SCH who are thyroid antibody positive should be treated with LT4.

• Treated hypothyroid patients already receiving LT4 who are newly pregnant should independently increase their dose of LT4 by 25%-30% immediately upon missed menses or positive home pregnancy test. There is great inter-individual variation in the amount of LT4 needed to maintain TSH below 2.5 mIU/L in the first trimester. (Recommendations 13 to 15).

• Euthyroid women who are thyroid antibody positive and not treated with LT4 should be monitored every four weeks during the first half of pregnancy and at least once between 26 and 32 weeks gestation (Recommendation 20).

• Recommendation 63 advises that women with postpartum depression should be evaluated for autoimmune thyroiditis with TSH, FT4, and thyroid peroxidase antibodies (TPOAb).

• Recommendation 72 states that there is insufficient evidence to recommend for or against universal screening with TSH during the first trimester. However, recommendation 76 suggests that serum TSH be evaluated early in pregnancy to screen for those at high risk for overt hypothyroidism. High-risk factors include: history of thyroid dysfunction or prior thyroid surgery, age > 30 years, symptoms, goiter, TPOAb positive, type 1 diabetes, any autoimmune disorder, history of miscarriage or preterm delivery, history of head or neck radiation, family history of thyroid dysfunction, obesity > 39 kg/m2, use of amiodarone, lithium, recent iodinated radiologic contrast, infertility, and residing in an area of moderate to severe iodine insufficiency.

It would seem that all but the most straightforward of patients should be considered at risk and, therefore, screened. I suspect that by recommendation 72, you already were feeling that the detection and treatment of thyroidal conditions had morphed into a complicated topic. However, if recommendations 1 through 75 were not enough to convince you that this is not an entirely straightforward topic, then reading the rather long list of who is considered high risk and therefore eligible for screening probably was the drop that caused the flood. If all women > 30 years are at high risk, then it is starting to look far simpler and less time intensive to screen. TSH, with or without FT4, is inexpensive, particularly when compared to some of the screening tests we already perform universally. Also, as I noted earlier, if symptoms such as fatigue and goiter are used as criteria to determine who should be screened, then we are pushed even closer toward universal screening because which pregnant woman is not fatigued and which does not have an increase in thyroid size?

I remember an adage that a mind is a terrible resource to waste. What we know about fetal neurodevelopment and its dependence on appropriate maternal thyroxine supply shifts us in favor of accurate detection. Although we might lack sufficient evidence from RCTs to make a strong recommendation for universal screening, there is a lot of other evidence from the molecular and cellular investigations and even screening trials[2] to suggest that fetal neurodevelopment depends critically on appropriate maternal thyroxine. Let us not forget that the mother is the sole source of fetal thyroxine during the first trimester and the predominant source even in the second and third trimesters. Finally, I would be remiss to not mention another article released in July 2011 showing that the development of fetal goiter in mothers on antithyroid drugs for Grave's hyperthyroidism responds better to intra-amniotic thyroxine than discontinuing the anti-thyroid drugs.[3] The authors suggest that centralized care of pregnant women with Grave's disease is urgently needed to maintain optimal fetal development.

Screening guidelines are helpful, but they are a work in progress. When routine screening was conducted, 2%-3% of pregnant women had an elevated serum TSH. Also, if subclinical maternal HYPERthyroidism is not associated with adverse maternal or fetal outcomes[4] and maternal hypothyroidism is, then it would seem better generally to err on the side of too much thyroxine to the fetus than too little. Not only is TSH a relatively inexpensive test, thyroxine is a relatively inexpensive medication.

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ABSTRACT & COMMENTARY

Estimate the incidence of endometriosis

By **Jeffrey T. Jensen**, MD, MPH, Editor, Leon Speroff, Professor and Vice Chair for Research, Department of Obstetrics and Gynecology, Oregon Health and Science University, Portland, is Editor for OB/GYN Clinical Alert, also published by AHC Media.

Synopsis: The incidence of endometriosis diagnosed by magnetic resonance imaging (MRI) in a population-based cohort is 11%, similar to the amount detected by preoperative MRI in a surgically evaluated group. Although more than 40% of surgically evaluated women have visual endometriosis, most of this is minimal and mild in severity.

Source: Buck Louis GM, Hediger ML, Peterson CM, et al. Incidence of endometriosis by study population and diagnostic method: The ENDO study. Fertil Steril 2011; 96:360-365.

The objective of the Endometriosis: Natural History, Diagnosis, and Outcomes (ENDO) study funded by the National Institute of Child Health and Human Development was to estimate the incidence of endometriosis. The investigators used a matched-exposure cohort design to delineate the burden of endometriosis among women scheduled for surgical care and in the general population from the catchment areas of several surgical centers in the Salt Lake City and San Francisco areas. All subjects in both groups were menstruating women aged 18-44 years without a prior surgical diagnosis of endometriosis. Subjects were eligible to enroll in the surgical (operative) cohort if they were scheduled to undergo a diagnostic and/or therapeutic laparoscopy or laparotomy at one of the centers regardless of clinical indication; 495 women were enrolled in this group. The population cohort was obtained using population databases from the geographic catchment areas of the surgical centers. More than 2,000 households were contacted to enroll a group of 131 subjects matched to the exposed cohort by age and residence; all of the women in the population cohort were evaluated with pelvic magnetic resonance imaging (MRI). The primary outcome was a diagnosis of endometriosis by surgery (operative cohort) or pelvic MRI (population cohort). A subset of 96 women in the operative cohort also underwent preoperative pelvic MRI.

The incidence of endometriosis in the operative cohort was 41% for visualized disease. However, endometriosis staging was skewed toward minimal (58%) and mild disease (15%). Although the incidence of MRI-diagnosed endometriosis was lower (only 11%) in the population cohort, this was similar to the incidence seen in the subset of subjects in the operative cohort that underwent a preoperative MRI (7%).

The authors concluded that a diagnosis of endometriosis is dependent on the diagnostic method and choice of sampling framework and that approximately 11% of menstruating women have undiagnosed endometriosis.

Commentary

We have all heard of the story about the four blind men who are placed at different points around an elephant and asked to describe the animal. Just like those observers, our observations will be colored by the part we examine, the tenacity with which we hold on to our conclusions, and our willingness to reach out to explore alternatives. Let's try to look at the whole animal as we evaluate the ENDO study and consider how these data should influence our practice of medicine.

We all know that endometriosis is a highly prevalent condition, but surprisingly few studies have focused on defining incident cases. Unlike most operative studies of endometriosis, in the ENDO study, the surgical cohort enrolled women scheduled for a variety of procedures. Still, half of the surgeries were performed for pelvic pain (41%) and infertility (7%). More than 75% of the 2000 eligible women agreed to participate. Surgeons were not asked to change their practice in any way, but they were encouraged

to obtain specimens for histology (if endometriosis was suspected) and to complete a standardized operative report immediately after surgery to capture gynecologic and pelvic pathology and endometriosis staging (using the Revised ASRM classification). Endometriosis was diagnosed visually in 41% of the women evaluated surgically. Although some gynecologists will argue that this high yield provides justification for surgical evaluation of any woman in whom a diagnosis is suspected, it is important to recognize that most of the visual disease (71%) was rated as minimal or mild. Running the numbers, only 6% (29/473) of women in the operative cohort with a diagnosis of significant endometriosis (R-ASRM classification moderate or severe). Interestingly, this figure correlates almost exactly with the 7% incidence of endometriosis detected by preoperative MRI in the subset of surgical patients. These results are consistent with a prior study by Stratton et al that found the MRI was able to suggest endometriosis in 75% of those with at least mild disease.[1]

Taken together, these studies demonstrate that a noninvasive MRI can detect significant disease. Does this suggest that MRIs should be ordered on all of our pelvic pain patients? It seems like every imaging report I see these days recommends that we get another imaging test (just to be sure)! A couple of things to consider before we put down our scopes: First, I expect that most experienced gynecologists can also detect the significant findings of advanced endometriosis (cul-de-sac nodularity, adnexal mass) with a careful pelvic exam. Furthermore, MRI exams are expensive and cannot treat endometriosis, while the literature supports the benefits of surgical treatment.[2]

Recognizing that the initial approach to endometriosis should be medical, if your clinical judgment suggests a condition that will improve with surgery, move in that direction without additional testing. A true minority of patients will be helped with advanced imaging. As I tell my medical students, clinicians are constantly pressured to order more tests and imaging studies, but at the same time, the pool of money available for healthcare is contracting. Every test you order reduces the amount of money left to provide surgery or medical therapy for the condition, or to pay your fee. Good patient care always has begun with a careful history, thorough physical exam, and thoughtful assessment. Our training is expensive, and we should make good use of it.

What about the 11% incidence of endometriosis by MRI in the population cohort? Does this mean that we have a substantial burden of significant unrecognized disease? Should we be doing even more MRIs or surgeries to detect this prevalent condition? The population-based controls represent a group of typical reproductive-aged women. Although the investigators gathered information about baseline symptoms, they were not reported in this manuscript, so we don't know whether some had gynecologic pain or infertility, and whether these symptoms were associated with MRI-detected endometriosis.

It is important to remember that endometriosis is not ovarian cancer. Establishing a histologic diagnosis is not required to begin treatment. While surgical management of endometriosis appears to be superior to diagnostic laparoscopy alone,[2] there are no randomized studies comparing initial surgical treatment to medical management. We have excellent medical treatments for endometriosis: continuous-dosed combined hormonal contraceptives, depot medroxyprogesterone acetate, GnRH analogs, the levonorgestrel intrauterine system, and etonogestrel implants.[3] In my opinion, medical therapy is the first-line approach to therapy for pelvic pain and suspected endometriosis.

An interesting randomized controlled trial was performed more than 20 years ago in the Netherlands comparing a multidisciplinary approach to pelvic pain to an initial evaluation with laparoscopy.[4] The multidisciplinary group received medical management and supportive counseling. Not only were outcomes superior in the multidisciplinary group, but only 10% underwent laparoscopy over one year of follow-up (compared to 100% in the surgical group), so cost savings also were realized. If you hang on to the belief that endometriosis is best treated surgically, the ENDO study will provide reassurance that you have a lot of patients to treat. I hope you will look at it otherwise and avoid surgical evaluation and MRI exams in women with normal pelvic findings, and maximize medical treatments first.

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S · T · I
QUARTERLY

Seniors may be older and wiser, but don't assume they know STI risks

Risks have increased — only a minority use condoms

If your clinical practice includes the care of age 50-plus women, are you including information on risks for sexually transmitted infections (STIs)? You should. Results of a new study indicate that there is a critical need for improving communication between older women and their clinicians about sexual health and for providing senior women with tools on how to negotiate with partners about safe sex practices.[1]

> ***"There is a critical need for improving communication between older women and their clinicians about sexual health."***

Many older adults continue be sexually active well into their 80s, state results of a 2010 study.[2] Due to divorce or loss of a partner, many women over 50 years old are returning to the dating scene, where they become sexually active and thereby face STI risks. However, most STI prevention campaigns are designed to target younger generations, says **Cynthia Morton,** PhD, associate professor in the Department of Advertising in the College of Journalism and Mass Communications at the University of Florida in Gainesville. Morton served as lead author of the current research.

The "baby boomer" generation, defined as those who were born between 1946 and 1964, is redefining senior citizenship, much as it has reshaped every other age of life, says Morton. Case in point: statistics show this "new aged" group of people ages 50-plus as the fastest-growing segment for Internet dating services.[3,4]

"As the television series 'The Golden Girls' taught us, life goes on, dating goes on, and so too does sexual activity," notes Morton.

In conducting the current study, Morton and other researchers conducted focus groups among women age 50 years and older. In group discussions, women talked about the challenges in find-

EXECUTIVE SUMMARY

Results of a new study indicate that there is a critical need for improving communication between older women and their clinicians about sexual health and for providing senior women with tools on how to negotiate with partners about safe sex practices

- Due to divorce or loss of a partner, many women over 50 years old are returning to the dating scene, where they face risks for sexually transmitted infections (STIs). However, most STI prevention campaigns are designed to target younger generations.
- In recent years, there has been a noted increase in STI risk for older adults, yet only a minority of older adults report using a condom.

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ing male partners, negotiating condom use, and seeking credible information sources to help them make good choices about sexual health.

Older women uncomfortable

While older women are aware of STI risks, they are uncomfortable about seeking sexual health information from their clinicians, the study notes. And while older women might know the importance of condoms in preventing STIs, they might avoid negotiating condom use with their partners to avoid conflict or rejection.[1] In recent years, there has been a noted increase in STI risk for older adults, yet only a minority of older adults report using a condom, says **Vanessa Schick**, PhD, research scientist at Indiana University in Bloomington and co-author of Read My Lips: A Complete Guide to the Vulva and Vagina (Rowman & Littlefield Publishers, 2011). Statistics reinforce Schick's message: From 2005 to 2009, the number of reported cases of syphilis and chlamydia among those 55 and older increased 43%, according to an Orlando Sentinel analysis of data provided by the Centers for Disease Control and Prevention.[5]

Schick and other Indiana University researchers published a 2010 paper on sexual behaviors in those age 50 and above. Their data indicate about one-third of women and about 50% of the men reported their last sexual partner was not a relationship partner.[2] When researchers questioned single or newly partnered men and women whether they had used a condom the last time they had sex, the answer was an overwhelming 'no.' Just 20% of men and 24% of women reported they used a condom the last time they engaged in intercourse.[2]

Older adults should receive similar messages to those that younger adults receive, says Schick: that STIs are prevalent, that condoms remain the only effective device for reducing STI and HIV transmission among sexually active individuals, and that communicating with one's partner and seeking regular healthcare — including talking with one's healthcare provider about STI risk — are important.

How can you help?

What can clinicians do to help older patients protect themselves against STI risks? Schick suggests discussing the value of water-based lubricants and vaginal moisturizers. For older women who might be more likely to be dealing with issues of vaginal dryness, not only can lubricant use make sex more pleasurable and comfortable, but it can reduce the risk of vaginal tearing and condom breakage, both of which are relevant to STI risk. Advise against use of oil-based lubricants, such as petroleum jelly, which reduce condom integrity and might facilitate breakage.[6]

Also include a discussion and demonstration of different condom sizes and types, says Schick. Men and women who find themselves in new sexual partnerships after being in a long-term monogamous relationship need to know about the many technological advances in condoms, she notes.

Condoms now come in many shapes, sizes, and textures that were not available several decades ago, states Schick. Emphasize that patients' past experiences with condoms might be quite different from the experiences they would have with condoms today, notes Schick. Case in point: a 2010 study by Indiana University researchers found that some men and women have equally or more pleasurable experiences with condoms.[7]

Changes on the way

In 2009, the Centers for Medicare & Medicaid Services announced coverage for HIV screening for Medicare beneficiaries at increased risk for the infection. It is now assessing whether to include STI screening in Medicare-covered services.[8]

The University of Florida researchers plan a partnership with providers and public health officials in the health community to develop larger intervention programs, pilots, and opportunities to reach seniors, says Morton. "As health communication researchers, what we are looking at this point is message strategies, because there have been no campaigns that have been specifically targeted at the mature market," she notes.

Until more resources are developed specifically for seniors, start now by talking with your older patients about their sexual habits, says Morton. Your patients might be waiting for you to initiate the discussion.

"A consensus expressed across the participant pool was that, although they wanted answers to sexual health questions, they did not feel comfortable asking their doctors about sex or sexual health practices, even though some

women admitted to having the same family physician for many years," the University of Florida researchers report. "They also lamented the fact that the doctor never explored questions they might have about sex, presuming that women over 50 are already informed or not interested in knowing."

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Testing program to reach at-risk women

How can your clinic reach more women at risk for chlamydia and gonorrhea? Take a tip from the Sexually Transmitted Disease (STD) Program at the Los Angeles County Department of Public Health, which is expanding its popular "I Know" at-home testing program in a further outreach to the community.

Kicked off in 2009, the Don't Think Know Home Test Kit program provides a simple way for women in Los Angeles County to test for chlamydia and gonorrhea in the privacy of their own home. The free kit includes a swab for taking a test sample from the vagina, a swab collection tube, and an envelope for mailing purposes. The swab is tested at the Los Angeles County Public Health Laboratory. Results are available online or by phone one week after the kit is mailed. *(To read more about the program, see the* STD Quarterly supplement *article, "Program launches STD at-home testing kits,"* Contraceptive Technology Update, *September 2009, supplement p. 3.)*

The kits have been available free of charge to females ages 12 to 25 through a designated web site, www.DontThinkKnow.org, or by calling the county's STD telephone hotline, (800) 758-0880. In September 2011, public health officials announced enhancements to the program, with digital tablets and touch-screen kiosks making the kits more widely and immediately available to women.

An individual can order the kit from a kiosk or be provided a kit from an outreach worker using a digital tablet that requisitions the kit, explains **Peter Kerndt**, MD, MPH, director of the county's STD program. If women are at an outreach event where kits are available, they can take them home, collect their sample, and drop the results in the mailbox.

This point-of-service access might help reach younger women who might hesitate to have a kit mailed to their home, explains Kerndt. Even though the kit arrives via U.S. mail in a white 8 1/2 x 11 inch envelope with no external marks, some women might hesitate in placing an order, he notes.

Getting more young women tested is a public health priority: Los Angeles County reports the highest number of chlamydia cases and the second-highest number of gonorrhea cases of any county

EXECUTIVE SUMMARY

The Don't Think Know Home Test Kit program provides a simple way for women ages 12-25 in Los Angeles County (CA) to test for chlamydia and gonorrhea in the privacy of their own homes.

- The free kit includes a swab for taking a test sample from the vagina, a swab collection tube, and an envelope for mailing purposes. The swab is tested at the Los Angeles County Public Health Laboratory. Results are available online or by phone about one week after the kit is mailed.
- Public health officials are expanding the program to reach even more women by placing touch-screen kiosks in target at-risk areas and using community health workers to take kit orders with digital tablets.

in the nation. More than 30,000 women and girls acquire infections every year, with younger women most heavily affected. In 2010, there were 20,337 chlamydia cases and 2,136 gonorrhea cases reported in females ages 15-24.

Technology is the key

The rise of self-collected nucleic acid amplification testing now available for gonorrhea and chlamydia screening makes such at-home testing possible, says Kerndt.

The Los Angeles program draws from initial work by **Charlotte Gaydos**, MS, DrPH, and researchers at Johns Hopkins University (JHU), who launched the "I Want The Kit" program in Baltimore in 2004. Recent research published by the JHU research teams shows at-home testing is effective in reaching young women at risk. Over a five-year period in Maryland, the iwantthekit.org screening program detected more cases of chlamydia infection among young females than regular screening programs available at traditional family planning clinics. Infection rates for chlamydia ranged from 3.3% to 5.5% in local clinics to 4.4% to 15.2% with the Internet service.[1]

More than 30,000 women and girls acquire infections every year, with younger women most heavily affected.

While technology has greatly improved STI screening options, the reliability of specimens sent via mail must be verified by local laboratories. Los Angeles public health officials have worked with the Centers for Disease Control and Prevention to ensure that the quality of mailed samples would be sufficient for accurate testing.[2]

The Los Angeles program is cost-effective, data indicate. An analysis determined each requested kit at $6.50, with test processing cost at $17.75. When considering ongoing costs, saved patient travel, and clinic visit costs, the intervention is potentially cost-saving over clinic-based testing, the analysis suggests.[3]

In the last two years, the county has received over 3,700 orders; 57% of ordered kits have been returned to the public health lab, with almost all of them testable, says Kerndt. The kits have yielded an approximate 9% positive rate for chlamydia or gonorrhea, and public health officials have been able to confirm treatment on almost all of those patients, says Kerndt.

The system has the capacity to link tested women with health care services; there are about 60 clinical sites that are searchable, based on zip codes, where women can go to obtain treatment, Kerndt notes. Test results are available on the dontthinkknow.org web site or by telephone. Women can use the clinic locator service on the web site to locate a clinic for care. Women can print out their test results and take them with to their clinician. The printed results page explains that a home test was provided by the Department of Public Health and that the person needs treatment.

Extra effort is needed

The expansion of the Los Angeles program is needed to reach at-risk women, said **Mark Ridley-Thomas**. Thomas is supervisor of the county's Second Supervisorial District, site of the county's highest STD rates. Public health officials are linking with community organizations in the district, including faith-based organizations, to provide enhanced access to the kits, as well as other targeted areas of risk.

"The "I Know" program has a track record of success, so we come together today to encourage women who may be afraid — who likely have no symptoms, but who have made some choices that put them at risk — to take that first step toward getting help and taking a test right in the privacy of their own homes," said Ridley-Thomas in an announcement of the program expansion.

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