CONTRACEPTIVE TECHNOLOGY UPDATE®

2015 Index

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CONTRACEPTIVE TECHNOLOGY UPDATE®
35TH ANNIVERSARY

DECEMBER 2015 Vol. 36, No. 12; p. 133-144

INSIDE

FDA panel weighs Essure complaints — How to counsel on options

The Essure method of permanent birth control (Bayer HealthCare Pharmaceuticals, Wayne, NJ) was the subject of a September 2015 meeting of the FDA Medical Devices Advisory Committee's Obstetrics and Gynecology Devices Panel. The daylong meeting included expert scientific and clinical opinions, as well as reports from women who have used the device. The panel meeting was called to weigh all evidence following complaints regarding the sterilization option.

The Essure System was approved by the FDA in 2002 as a permanent birth control option for women who have completed their families. Originally brought to market by Conceptus of Mountain View, CA, Essure was acquired by Bayer in June 2013. According to the FDA, in late 2013, it received a significant increase in the number of adverse event reports related to Essure, particularly from patients who had received the device. The agency conducted a review of data related to the Essure System and determined that the information should be vetted and discussed in an open forum panel meeting. *(All material presented at the panel meeting may be viewed at http://1.usa.gov/1Jl92dI.)*

Essure represents a "high-priority issue" for the agency, says **Eric Pahon**, FDA press officer. "We are reviewing the panel recommendations and docket to determine the best course of action," states Pahon. "After considering the recommendations of the advisory committee, and the public comments made at the meeting and submitted through the docket, the FDA will

Next month: *CTU* Salary Survey Results

Where do you stand when it comes to your professional income? Review the results of the 2015 *Contraceptive Technology Update* annual salary survey, included in the upcoming January 2016 issue of the newsletter.

Financial Disclosure: Consulting Editor **Robert A. Hatcher**, MD, MPH, Editor **Rebecca Bowers**, Executive Editor **Joy Dickinson,** and guest columnists **Anita Brakman** and **Taylor Rose Ellsworth** report no consultant, stockholder, speaker's bureau, research, or other financial relationships with companies having ties to this field of study. **Melanie Deal**, nurse reviewer, discloses that she formerly was on the speakers bureau for Merck & Co. **Melanie A. Gold**, guest columnist, discloses that she is on the speaker's bureau for Novatis Pharmaceutical Co.

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CONTRACEPTIVE TECHNOLOGY UPDATE®

Contraceptive Technology Update®
ISSN 0274-726X, is published monthly by
AHC Media, LLC
One Atlanta Plaza
950 East Paces Ferry Road NE, Suite 2850
Atlanta, GA 30326.
Periodicals Postage Paid at Atlanta, GA 30304 and at additional mailing offices.

POSTMASTER: Send address changes to:
Contraceptive Technology Update
P.O. Box 550669
Atlanta, GA 30355.

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determine what additional actions, if any, are necessary to assure the safety and effectiveness of the device; the FDA intends to issue communications to inform the manufacturer and the public of any further actions."

Essure is commercially available in the United States, Canada, Australia, several European countries, and several Latin/South American and Asia Pacific countries. About one million Essure systems have been distributed worldwide, according to information presented at the FDA hearing.[1]

The Essure System includes an implantable insert and a delivery system for the placement of the insert. In contrast to other permanent sterilization procedures, Essure inserts are placed into each fallopian tube through the cervix using a hysteroscope. Once in place, the fibers within the insert elicit a local, fibrotic reaction, which causes fibrous tissue to grow in and around the implant, thus blocking the fallopian tubes. As part of the Essure procedure, patients undergo a radiologic confirmation test via hysterosalpingography (HSG) or ultrasound three months after insert placement to ensure the proper placement and/or occlusion of the fallopian tubes. Women are advised to use alternate contraception for the first three months until the confirmation test assures tubal occlusion.

The Essure System is contraindicated for those women who:

- are uncertain about ending fertility;
- can have only one insert placed;
- have previously undergone a tubal ligation;
- are pregnant or suspect pregnancy;
- have delivered or terminated a pregnancy less than six weeks prior to the Essure procedure;
- have an active or recent upper or lower pelvic infection;
- have a known allergy to contrast media.[2]

In clinical trials, 9.3% of women experienced mild to moderate pain during the insertion process. Following the insertion procedure, some of the women in clinical trials experienced mild to moderate pain (12.9%) and/or cramping (29.6%), vaginal bleeding (6.8%), and pelvic or back discomfort for a few days. Some women experienced nausea

EXECUTIVE SUMMARY

The Essure method of permanent birth control was the subject of a September 2015 FDA panel meeting held to weigh all evidence following complaints regarding the sterilization option.

- Essure was approved by the FDA in 2002 as a permanent birth control option for women who have completed their families. The FDA says it saw a significant increase beginning in late 2013 in the number of adverse event reports related to the device.
- The American College of Obstetricians and Gynecologists submitted a letter to the FDA prior to the panel meeting and stated its support for less-invasive tubal occlusion options such as Essure. The FDA is reviewing the panel recommendations to determine the best course of action regarding the device.

and/or vomiting (10.8%) or fainting (1.3%).[3]

The FDA looked at postmarket surveillance data sources to monitor the safety and effectiveness of Essure. In its review, the agency analyzed Essure patient reports of problems, including Web-based testimonials, and reports of problems submitted from other sources, including doctors, patients, and the device manufacturer.

The agency conducted a search of its Manufacturer and User Facility Device Experience (MAUDE) database. Prior to June 1, 2015, the FDA received 5,093 medical device reports related to Essure. Most reports were voluntary reports, mostly from women who received Essure implants.

The most frequently reported patient problems during this period were pain/abdominal pain (3,353), heavier menses (1,408), headache (1,383), fatigue (966), and weight fluctuations (936). Most of the reports received listed multiple patient problems.

The most frequent device problems reported were patient device incompatibility (941), such as possible nickel device allergy, migration of the device or migration of a device component (482), device operating differently than expected (301), device breakage (259), and malposition of the device (133). Multiple device problems also can be listed in each report, the FDA notes.[4]

Seventeen of the reports received by the FDA were coded as death reports; however, six of these reports were mistakenly coded as death, but no death occurred. Five reports involved fetal deaths that occurred in women who became pregnant following placement of Essure. The remaining six death reports were related to a total of four adult deaths:

- one death due to Group A Strep infection post-procedure;
- one death reportedly due to uterine perforation during device placement;
- one death related to an air embolism during device removal surgery;
- one death from suicide.

Confirming whether a device actually caused a specific event can be difficult based solely on information provided in a given report, the FDA states.[4]

What is the next step?

Bayer HealthCare Pharmaceuticals has provided Essure-trained physicians with communication to keep them abreast of the issues involved, says **Tara DiFlumeri**, a Bayer spokesperson.

"We are working closely with FDA and will keep physicians updated if there are any actions to be taken based on the panel recommendations," she states.

The American College of Obstetricians and Gynecologists (ACOG) submitted a letter to the FDA prior to the panel meeting. In that letter, ACOG stated its support for less-invasive tubal occlusion options, such as Essure, to remain available to women.[5] To improve the use of hysteroscopic tubal occlusion in the future, the society called for the FDA to take steps toward obtaining more high-quality data on its safety and efficacy.

The ACOG letter to the FDA panel prior to its meeting called upon clinicians to obtain HSG confirmation of tubal occlusion three months after the operation, notes **Robert Hatcher**, MD, MPH, professor emeritus of gynecology and obstetrics at Emory University School of Medicine in Atlanta.

"I am concerned that people who perform tubal sterilization using the Essure technique may not get HSG confirmation for one of three reasons: First, the woman may not return (loss to followup)," notes Hatcher. "Second, the cost of the procedure may not have been included in the cost of the Essure placement, and this additional cost may discourage the patient or the program doing this procedure from obtaining HSG confirmation. And three, the clinician performing the placement of the Essure implants may be so secure in his or her excellence in placing the implants that he or she may deem HSG confirmation unnecessary."

The post-marketing evaluation of the effectiveness of Essure did not include women who became pregnant prior to the three-month HSG confirmation procedure. It included analysis only of the women whose HSG procedures found both tubes to be completely occluded, notes Hatcher.

"In other words, there was no typical use failure rate including all the errors clinicians and patients may make obtaining and following up this tubal sterilization procedure," Hatcher states.

Tubal sterilization and vasectomy represent safe, effective methods of permanent contraception. Some 15 million U.S. women rely on permanent female or male contraception, which makes it the most commonly used form of birth control.[6]

Essure initially was introduced to provide permanent contraception for women with contraindications or risk factors to more traditional approaches, and it still offers a viable option for women for when laparoscopy would be challenging, 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. Outside

of that situation, its superiority has not been established, especially its cost effectiveness, states Nelson.

"Of course, often implants, or intrauterine devices, or vasectomy can be better options," states Nelson. "Important questions about potential nickel allergies were discussed, but not answered, by the hearing."

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How to deal with IUD challenges: What are your strategies?

How do you deal with difficult intrauterine device (IUD) insertions, as well as diagnosis and treatment of infections and pregnancy with an IUD in place? A recent American College of Obstetricians and Gynecologists (ACOG) webinar, "LARC Challenges," looked at these issues.

The webinar reviewed such common concerns as management of non-palpable implants; non-fundal IUDs; management strategies for IUD malpositioning, expulsion, and perforation; and diagnosis and treatment of infections and pregnancy with an IUD in place. It was led by **Nikki Zite**, MD, MPH, professor and residency program director at the University of Tennessee Graduate School of Medicine in Knoxville, and **Nichole Tyson**, MD, an OB/GYN at Oakland, CA-based Kaiser Permanente, Northern California.

Often insertions and removals in nulliparous women are no more challenging than in multiparous women, notes Zite. A 2012 ACOG committee opinion echoes Zite's observation and noted "Intrauterine devices may be inserted without technical difficulty in most adolescents and nulliparous women. Little evidence suggests that IUD insertion is technically more difficult in adolescents compared with older women."[1] However, Zite offers tips that often can help in difficult cases:

- Although clinicians want to be flexible with timing of insertion so unnecessary barriers are not created, placing while on menses or on a withdrawal bleed ensures the woman is not pregnant and can make insertion easier.
- Always use a tenaculum, and have dilators readily available. Consideration can be given to placing the device with ultrasound guidance if clinicians meet more than expected resistance or an attempt already has been made without success, Zite notes.
- Misoprostol has not been shown to improve insertion success or decrease pain,[2] so it should not be used routinely, observes Zite. However, it can be reserved for

EXECUTIVE SUMMARY

A recent American College of Obstetricians and Gynecologists (ACOG) webinar, "LARC Challenges," reviewed such common concerns as management of non-palpable implants; non-fundal intrauterine devices; management strategies for IUD malpositioning, expulsion, and perforation; and diagnosis and treatment of infections and pregnancy with an IUD in place.

- Intrauterine devices may be inserted without technical difficulty in most adolescents and nulliparous women, according to an ACOG committee opinion.
- Recent data suggests that ketorolac, a nonsteroidal anti-inflammatory drug, can help with sounding, insertion, and post-procedure discomfort for nulliparous women and for post-procedure discomfort in all women.
- Pelvic inflammatory disease is rare in IUD users. However, when a patient does get PID with an IUD in place, it often might be possible to treat the patient with the IUD left *in situ*.

cases in which an attempt has been unsuccessful.

• Data on paracervical blocks are inconsistent,[3] notes Zite. They should be reserved for cases when dilation is needed, or the patient is not tolerating insertion but is motivated to continue to try inserting the device.

• Recent data suggest that ketorolac, a nonsteroidal anti-inflammatory drug, can help with sounding, insertion, and post-procedure discomfort for nulliparous women and for post-procedure discomfort in all women,[4] states Zite. It requires intramuscular dosing 30 minutes before the procedure, so it might not be an option in all settings. However, many women might appreciate this option, she says.

How about IUD removals in nulliparous women? Removals are typically not difficult unless the threads are missing, notes Zite. She advises that the "absolute first step" when considering a removal if threads are not present is to confirm the device is in the uterus. Once this presence is established, clinicians can proceed in the same manner for nulliparous and multiparous women in locating the threads: First, sweep the cervix with a cytobrush, says Zite. If that action is not successful, use an IUD hook, stone forceps, or long nose packing forceps to try to grasp the strings or device.

"Occasionally dilation will be needed, and then all the suggestions made for challenging placements apply here as well," states Zite. "As with insertions, a tenaculum helps straighten the angle between the cervix and uterus and often makes a difficult removal easier."

What is the risk of pelvic inflammatory disease (PID) in IUD users? Such infection is very rare: less than 1%,[5] says Tyson. As with any infection after a uterine procedure, the risk is increased in the first three weeks after insertion and then drops to baseline, she notes. "It is well-established that the old mythical thinking that an IUD causes PID is just that: old, mythical thinking," says Tyson. "IUDs do not cause PID."

However, when a patient does develop PID with an IUD in place, the patient can be treated with the IUD left *in situ*, notes Tyson. The treatment outcomes are the same whether the IUD is removed or left in place.[6]

"IUDs DO NOT CAUSE PID."

Bacterial vaginosis might be seen more often in IUD users, says Tyson. This condition might be due to the unscheduled bleeding or spotting that might increase vaginal pH, which makes the environment more susceptible to bacterial vaginosis, she notes. Because the irregular bleeding decreases over time, this problem is usually a short-term one, Tyson observes.

One common issue that comes up is the incidental finding of actinomyces-like organisms on routine cytology results, which occurs in about 7% of IUD users, says Tyson. Most of these women have no symptoms, and no treatment is needed, so there is no need to remove the IUD, she states.

What if a pregnancy occurs with an IUD in place? In women who have a desired pregnancy with an IUD in place, the best strategy is to remove the IUD if it can be done without an invasive procedure, says Tyson.

"Attempting removal with ultrasound guidance is not invasive and can be quite helpful," she says. "If the IUD is in a location that removal would lead to disruption of the pregnancy, it is best to just leave it in place and counsel that the pregnancy will be at higher risk for miscarriage, stillbirth, and preterm delivery."

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Women in the U.S. military are at risk of unintended pregnancy

Results of a recent study indicate the rate of unintended pregnancy among active-duty women in the U.S. military remains higher than that of the general population.[1] Data indicate 7% of servicewomen reported an unintended pregnancy during 2011, compared to 5% of women of reproductive age in the general U.S. population.[1]

To estimate unintended pregnancy rates among a representative sample of active-duty women ages 18-44 in the U.S. military, researchers from Cambridge, MA-based Ibis Reproductive Health, a non-profit research organization, analyzed cross-sectional data from the 2011 Department of Defense Health Related Behaviors Survey of Active Duty Military Personnel. A total of 9,038 women provided data on unintended pregnancy. To perform the study, unintended pregnancy rates were calculated for all women and by available background characteristics, including military branch, marital status (married versus unmarried), pay grade (enlisted versus officer), and deployment in the previous 12 months. Multivariable logistic regression testing for associations etween unintended pregnancy and subgroups also was performed.

The analysis indicated an unintended pregnancy rate of 72 per 1,000 women. Married women (odds ratio [OR] 1.30, 95% confidence interval [CI] 1.11-1.54) had higher odds of reporting unintended pregnancy compared to unmarried women, while enlisted women (OR 2.71, 95% CI 1.99-3.69) had higher odds of reporting unintended pregnancy compared to officers. Women in the Navy (OR 1.51, 95% CI 1.19-1.91) and Marine Corps (OR 2.38, 95% CI 1.92-2.95) had higher odds of reporting unintended pregnancy compared to women in the Air Force and women in the Army (OR 1.16 95% CI 0.89–1.50). Unintended pregnancy rates did not differ between women who were deployed in the previous 12 months and nondeployed women, the analysis reflects. A total of 10% of women who were deployed for 11-12 months in 2011 reported an unintended pregnancy in the previous year, suggesting that their pregnancies occurred during deployment.[1]

What prompted Ibis Reproductive Health to look into this particular line of research?

"Since 2009, Ibis has conducted research to better understand the reproductive health needs and experiences of servicewomen," says **Kate Grindlay**, MSPH, lead author on the study and a senior project manager at Ibis Reproductive Health. "Our interest in this area grew out of a desire to explore the impacts of federal policy limiting access to abortion services for servicewomen and military dependents." *(The "Washington Watch" column of* Contraceptive Technology Update *has reported on this issue. See "Abortion coverage alters for servicewomen," March 2013.)*

Ibis Reproductive Health conducted the first study of U.S. military women's experiences seeking abortion care during overseas deployment.[2] About the same time, it conducted a systematic literature review on contraceptive use, unintended pregnancy, and abortion in the military, and it found limited data on all of these issues.[3]

"We felt this was an important and overlooked area, and wanted to help fill in these gaps," says Grindlay.

Women play an integral role in the U.S. military, making up 15.7% of the active-duty and reserve forces and numbering more than 350,000.[4] In addition to the challenges faced by all women with unintended pregnancies, servicewomen might find that an unintended pregnancy compromises their career trajectory by removal from training exercises during pregnancy and postpartum, or through reassignment to a new unit or position outside of a primary occupation during and after pregnancy.[5] It might force them to

EXECUTIVE SUMMARY

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- Data indicate 7% of servicewomen reported an unintended pregnancy during 2011, compared to 5% of women of reproductive age in the general U.S. population.
- Women in the U.S. military make up 15.7% of the active-duty and reserve forces and number more than 350,000. In 2016, the U.S. military will lift restrictions on women in combat, which makes access to effective contraception even more important.

leave a military tour early, which makes career advancement more difficult.[5]

Unintended pregnancy is an important issue for servicewomen and for the military. A lack of contraceptive use, barriers to contraceptive access, and the high rate of sexual assault in the military all contribute to the levels of unintended pregnancy in the military. Federal Defense Department statistics for a single year, 2010, identified more than 3,000 reported sexual assaults, including roughly 875 rapes; however, the extent of the problem is considerably larger, because an estimated 86% of assaults go unreported.[6]

While some military branches have begun to improve access to pre-deployment contraception, a more comprehensive approach is needed to make sure that servicewomen who want to prevent pregnancy are able to access the contraceptive method of their choice, agree the researchers at Ibis Reproductive Health.

In 2016, the U.S. military will lift restrictions on women in combat. How important is it that military women have access to all forms of contraception, particularly long-acting reversible contraception?

One interesting finding from Ibis Reproductive Health's research is that the number one reason that deployed women choose to use contraception is for menstrual suppression, says **Daniel Grossman**, MD, director of advancing new standards in reproductive health and professor in the Department of Obstetrics, Gynecology, and Reproductive Sciences at the University of California, San Francisco, and senior advisor at Ibis Reproductive Health. Servicewomen also are interested in contraceptive methods that are discreet and long-acting, Grossman notes.

"No single method is right for every servicewoman, but the levonorgestrel intrauterine system could be ideal for many women who desire amenorrhea and very effective contraception," he states. "The problem of unintended pregnancy among active-duty women should be addressable by improving counseling about and provision of the full range of contraceptive methods."

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Options for premenstrual dysphoric disorder

The patient in front of you says she has dealt with depression, marked anxiety, sudden mood shifts, persistent irritability, and bloating. While the symptoms disappear with the onset of her menstrual cycle, when they are present, they are severe enough to interfere with her relationships and work activities. What is your diagnosis?

Look at premenstrual dysphoric disorder (PMDD). Both premenstrual syndrome (PMS) and PMDD are marked by the cyclic nature of symptoms that begin in the late luteal phase of the menstrual cycle and remit shortly after the onset of menstruation. PMDD is distinguished from PMS by the severity of symptoms, predominance of mood symptoms, and role dysfunction, particularly in personal relationships and marital/family relationships.[1]

There are many proposed treatment options for premenstrual dysphoric disorder, but which are most effective? A comprehensive review of the evidence, including specific treatment guidelines, has just been published.[2]

Given the debilitating symptoms and impact associated with PMDD, healthcare professionals need to be able to identify and effectively treat patients with PMDD, says **Shalini Maharaj**, MPAS, PA-C, and **Kenneth Trevino**, PhD, both formerly affiliated with the University of Texas Southwestern Medical Center in Dallas. Maharaj, now a hospitalist physician assistant at Parkland Health and Hospital System in Dallas, and Trevino, now in private practice in Dallas, conducted an in-

EXECUTIVE SUMMARY

A comprehensive review of the evidence on premenstrual dysphoric disorder, including specific treatment guidelines, has just been published.

- Premenstrual syndrome (PMS) and premenstrual dysphoric disorder (PMDD) are marked by the cyclic nature of symptoms that begin in the late luteal phase of the menstrual cycle and remit shortly after the onset of menstruation. PMDD is distinguished from PMS by the severity of symptoms, predominance of mood symptoms, and role dysfunction, particularly in personal relationships and marital/family relationships.
- It is estimated that 3-9% of women of reproductive age meet the criteria for PMDD. Approximately two million to five million women have severe PMDD symptoms. Selective serotonin reuptake inhibitors have emerged as a first-line treatment option for PMDD.

depth review of the safety and efficacy of proposed treatments as an aid to clinical decision-making.

It is estimated that 3-9% of women of reproductive age meet the criteria for PMDD.[3] Approximately two million to five million women have severe PMDD symptoms.[4] The following symptoms might occur during days 14-28 in a 28-day menstrual cycle, and they notably subside within 2-3 days after menses begins:

- markedly depressed mood, feelings of hopelessness, or self-deprecating thoughts;
- marked anxiety, tension, feelings of being "keyed up" or "on the edge";
- marked affective lability;
- persistent and marked anger or irritability or increased interpersonal conflicts;
- decreased interest in usual activities;
- subjective sense of difficulty in concentrating;
- lethargy, easy fatigability, or marked lack of energy;
- marked change in appetite, overeating, or specific food cravings;
- hypersomnia or insomnia;
- subjective sense of being overwhelmed or out of control;
- other physical symptoms, such as breast tenderness or swelling, headaches, joint or muscle pain, a sensation of bloating, or weight gain.[5]

Obtaining prospective charting symptom information for a two-month period can help with diagnosis and treatment.

Selective serotonin reuptake inhibitors (SSRIs) such as sertraline, fluoxetine, and escitalopram have emerged as a first-line treatment option for PMDD, says Trevino. They have established efficacy and safety, which makes them an ideal treatment option, he says.

Although treatment with SSRIs might be continuous, semi-intermittent, or administered at the start of symptoms, further research is needed to determine which of these treatment schedules provide the best balance between effectiveness and side effects, according to the current analysis.

Clinicians also should be aware of the many other treatment options for PMDD, states Trevino. Such treatments offer an alternative option to women who are unable to achieve an adequate response to an SSRI.

Different types of antidepressants can be useful in treating PMDD, while some anti-anxiety drugs, such as alprazolam, are helpful for managing specific PMDD-related symptoms, the analysis states. Oral contraceptives containing drospirenone/ethinyl estradiol are an effective and recommended treatment option for women with PMDD who also are seeking contraception. Beyaz (Bayer HealthCare Pharmaceuticals, Wayne, NJ) carries a Food and Drug Administration indication for treatment of PMDD symptoms for women who choose an oral contraceptive for birth control. Research indicates continuous contraception with a combination levonorgestrel/ethinyl estradiol formulation might reduce the symptoms of PMDD, which provides an option for women who are appropriate candidates for a continuous pill as a contraceptive.[6]

When these options fail, various anovulatory treatments that decrease ovarian hormone production are effective, the analysis notes. Due to potential side effects and high cost, these are considered "third-line" alternatives, it states.[2] Some types of supplements and herbal-related treatments have been proposed, with some warranting further research, the analysis states. Only calcium supplementation has shown a consistent therapeutic benefit so far, it notes.[2]

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Update your treatment of menopausal symptoms

Most menopausal women experience vasomotor symptoms with bothersome symptoms often lasting longer than one decade. A new review looks at the options for treatment.[1]

Hormone therapy (HT) represents the most effective treatment for these symptoms, with oral and transdermal estrogen formulations offering comparable efficacy, according to review coauthors **Andrew Kaunitz**, MD, University of Florida Research Foundation professor and associate chairman of the Department of Obstetrics and Gynecology, University of Florida College of Medicine–Jacksonville, and **JoAnn Manson**, MD, DrPH, NCMP, chief of the Division of Preventive Medicine at Brigham and Women's Hospital and professor of medicine and the Bell Professor of Women's Health, Harvard Medical School, both in Boston.

Findings from the Women's Health Initiative and other recent randomized clinical trials have helped to clarify the benefits and risks of combination estrogen-progestin and estrogen-alone therapy, the review states. Absolute risks observed with HT tended to be small, especially in younger women, and neither regimen increased all-cause mortality rates. Given the lower rates of adverse events on HT among women close to menopause onset and at lower baseline risk of cardiovascular disease, risk stratification and personalized risk assessment appear to represent a sound strategy for optimizing the benefit-risk profile and safety of using hormone therapy for menopausal symptom treatment, the review notes.[1]

The North American Menopause Society (NAMS) recently published a position statement, *Nonhormonal Management of Menopause-Associated Vasomotor Symptoms*, on options.[2] These therapies include lifestyle changes, mind-body techniques, dietary management and supplements, and prescription therapies. The costs, time, and effort involved, as well as adverse effects, lack of long-term studies, and potential interactions with medications, need to be carefully weighed against potential effectiveness during decision-making, notes the position statement.[2]

For the best candidates for nonhormonal treatments, look at women with contraindications to estrogen use, particularly women with a history of breast cancer or other estrogen-sensitive tumors, venous thrombosis, elevated risk of cardiovascular disease, or those women with a personal preference for avoiding hormone therapy, advises Manson. Also, women who are more than 10 years past menopause onset, especially if they are at increased risk of cardiovascular disease, might want to avoid initiation of hormone therapy, she notes.

Cognitive-behavioral therapy and, to a lesser extent, clinical hypnosis, have been shown to be effective in reducing vasomotor symptoms, according to the statement. Paroxetine salt is the only nonhormonal medication approved by FDA for the management of vasomotor symptoms; however, other selective serotonin reuptake/norepinephrine reuptake inhibitors, gabapentinoids, and clonidine show evidence of efficacy, it notes.[2]

Therapies that might help alleviate symptoms include weight loss, mindfulness-based stress reduction, the S-equol derivatives of soy isoflavones, and stellate ganglion block, but more studies of these therapies are warranted, the statement says. There are negative, insufficient, or inconclusive data for cooling techniques, avoidance of triggers, exercise, yoga, paced respiration, relaxation, over-the-counter supplements and herbal therapies, acupuncture, calibration of neural oscillations, and chiropractic interventions.[2]

One-third of U.S. women who take hormones at menopause are using compounded hormones, results of a new national survey indicate.[3] The survey includes responses from 3,700 women ages 40-84 who were asked about their hormone use at menopause, what they thought the benefits would be, what benefits they received, and what side effects and health problems they experienced.

Survey results indicate 1,000

of the respondents had used or were using hormone therapy at menopause. Thirty-one percent of hormone therapy users were taking or had taken compounded hormones, and 34% were taking them at the time of the survey.

About 42% of the women who took compounded hormones thought that "natural" or "bioidentical" hormones are safer than other types of hormones, even though there are more than 30 tested and FDA-approved hormones for menopause, including many that are similar to human hormones.

Most of the women surveyed who used compounded or FDA-approved hormones (about 70% of each group) took them for hot flashes, which is the foremost, FDA-approved indication for menopausal hormone therapy. However, women who took compounded hormones more often expected unproven benefits that are not FDA-approved hormone therapy indications, such as to improve moodiness or irritability, sleep, low energy, depression, muscle mass, memory/concentration, sexual desire, and overall appearance, as well as to prevent aging and lose weight.

Kaunitz says that patients need to understand that compounded hormone formulations are not FDA-approved, are not standardized, with amounts of active drug varying substantially from one prescription to the next, and often are not covered by insurance.

"Fortunately, a number of FDA approved bioidentical formulations (including oral and transdermal estradiol, and oral progesterone) are available for the treatment of menopausal symptoms," Kaunitz notes in an email to *Contraceptive Technology Update*.

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TEEN TOPICS

Commercial sexual exploitation of children: What can healthcare providers do?

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Commercial sexual exploitation of children (CSEC) is a serious public health concern that results in immediate and long-term negative health consequences for affected youth. According to the federal Trafficking Victims Protection Act, sex trafficking of a minor does not require the use of fraud, force, or coercion to be deemed illegal. It includes pornography; trafficking of minors for a commercial sex act; street prostitution; exotic dancing; escort services; internet-based exploitation; and the exchange of sex for food, clothing, shelter, or other survival needs, also referred to as "survival sex."

As many as 325,000 U.S. children are estimated to be at risk of CSEC annually. However, there is no uniform method for data collection on this practice, and it is cited as the most under-reported form of child abuse.[1] Medical visits afford providers the opportunity for direct communication with CSEC youth, but most receive little training on their appropriate role in addressing this crisis.[2] One study assessing the CSEC population in New York City found that 75% of sexually exploited youth had accessed medical care within the last six months, primarily for general check-ups (42%), testing for sexually transmitted infections (STIs) (34%), and HIV tests (21%).These youth present to EDs, family planning clinics, urgent care, and community health centers.[3]

Risk factors for CSEC victims can include physical and sexual abuse; substance use; homelessness; foster care placement; juvenile justice involvement; identification as lesbian, gay, bisexual, transgender, or questioning; poor self-esteem;

gang involvement; and poverty.[4] The presence of risk factors does not clearly indicate CSEC, but CSEC should be considered as part of a more comprehensive medical assessment when these factors are present.

Sexually exploited youth are at greater risk for STIs, pregnancy, uncontrolled asthma, pelvic inflammatory disease, and drug abuse.[5] Other common problems include traumatic injuries, wound infections, posttraumatic stress disorder, depression, and suicide.[6]

Indicators of CSEC include depressed mood or flat affect; malnutrition; poor dentition; physical evidence of abuse, tattoos, or branding; and STI symptoms. Priority areas of focus during a visit with CSEC youth should be reproductive health, physical injuries, substance use, and mental health. Confidentiality concerns can have a deterrent effect on disclosure, which makes it imperative to know local laws and reporting requirements.

The National Human Trafficking Resource Center operates a hotline (888-373-7888) through which victims can seek help, and providers can request to be connected to local resources or training. HEAL Trafficking and Physicians Against the Trafficking of Humans (PATH) are led by clinicians working to address CSEC and human trafficking.

In March 2015, the American Academy of Pediatrics urged pediatricians to work to increase recognition of CSEC, provide direct care and resources, and engage in a multi-disciplinary effort with medical and nonmedical colleagues to meet the needs of CSEC patients.[7] Screening tools instituted by Asian Health Services and the Native American School Based Health Center in Oakland, CA, along with the Sexual Assault and Violence Intervention (SAVI) program at Mount Sinai Hospital in New York City, provide potential models for identifying CSEC youth. These organizations have implemented universal screening questions such as: "Over the years, we've noticed that more and more young people are turning to the streets to make money for themselves or for other people. Sometimes students tell us that they're trading sex or 'going on dates' for money, clothes, a place to stay, or drugs. Other students say they've been asked or forced to let other people do sexual things to them. Has this ever happened to you or to a friend?" This question is part of a larger protocol that involves multi-disciplinary staff, written assessments for risk factors, intervention steps, confidentiality guidelines, and community resources and referrals.[4,8]

Screen patients only when they are alone, and always offer hotline numbers and other resources directly to the patient.

Starting a dialogue allows patients to disclose if they are ready to do so, and it lays groundwork for patients to seek help in the future.

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COMING IN FUTURE MONTHS

- Research examines oral HPV test
- Estetrol: A new hormone for contraception?
- HIV vaccine: Update on status
- Premenstrual breast discomfort: How to treat?

CONTRACEPTIVE TECHNOLOGY UPDATE®

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CNE/CME QUESTIONS

1. With Essure, what is the proper time period women are advised to use alternate contraception before confirmation testing is performed?

A. Six months
B. Four months
C. Three months
D. Two months

2. What drug recently has been shown to help with sounding, insertion, and post-procedure discomfort with intrauterine device for nulliparous women, and for post-procedure discomfort in all women?

A. Ketorolac
B. Cortisone
C. Lidocaine gel
D. Methotrexate

3. What class of medications is seen as first-line treatment for premenstrual dysphoric disorder?

A. Selective serotonin reuptake inhibitors
B. Tricyclics
C. Antianxiety drugs
D. Antipsychotics

4. What is the only nonhormonal medication approved by the Food and Drug Administration for the management of menopausal vasomotor symptoms?

A. Black cohosh
B. Soy isoflavones
C. Paroxetine salt
D. Clonidine

CNE/CME OBJECTIVES

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

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

STI QUARTERLY™

A SUPPLEMENT TO CONTRACEPTIVE TECHNOLOGY UPDATE

Young men who have sex with men have highest HIV infection risk — Just 1 in 5 is tested

Young men who have sex with men (MSM) have the highest risk for HIV infection, but only one in five has ever been tested for HIV, according to new research.[1]

Low levels of testing are a concern in this age group, because young gay and bisexual men ages 13-24 accounted for 72% of new HIV infections among all persons in that age group in 2010, and they represented 30% of new infections among all gay and bisexual men, according to statistics from the Centers for Disease Control and Prevention (CDC).[2] Black/African American or Hispanic/Latino gay and bisexual young men are especially affected, CDC data reflect.[3]

> ... YOUNG GAY AND BISEXUAL MEN AGES 13-24 ACCOUNTED FOR 72% OF NEW HIV INFECTIONS AMONG ALL PERSONS IN THAT AGE GROUP IN 2010...

Looking at 2007-2010 statistics, the CDC reports 89% of HIV/AIDS cases among young men ages 13-24 were attributed to male-to-male sexual contact; 58% of HIV/AIDS infections were in African Americans/blacks, 20% in Latinos/Hispanics, and 19% in whites. During this same time period, cases of HIV/AIDS among young African American/black MSM ages 13-24 increased by 48%. While diagnoses of HIV also increased among white and Hispanic men who have sex with men, rates rose less sharply, CDC data indicate.[4]

Little is known about testing rates among men ages 18 and younger or about the barriers that they face when contemplating an HIV test, say researchers at the Chicago-based Northwestern University Feinberg School of Medicine and the Center for Innovative Public Health Research (IMPACT Program), based in the School's Department of Medical Social Sciences. The IMPACT Program is focused on conducting translational research that improves the health of the lesbian, gay, bisexual, and transgender (LGBT) community and increases understanding of the development of sexual orientation and gender identity.

Supported by a grant from the National Institutes of Health's National Institute of Mental Health, the researchers examined testing behaviors and barriers among a diverse national sample of adolescent gay and bisexual men. They reported results in the current study.[1]

Between June and November 2014, scientists enrolled a national sample of 302 males ages 14-18 who identified themselves as gay, bisexual, or queer into a text messaging-based HIV prevention program. Questions about their HIV-testing behaviors were included in the study. Researchers report only 20% of the teen boys had ever been tested for HIV, a rate that is much lower than what other studies have found with adult gay and bisexual men. Nearly half (42.9%) of sexually active participants did not know where they could go to get tested for HIV.[1]

Researchers asked nine questions to assess potential barriers to HIV testing; these factored into three subscales: external factors, fear, and feelings of invincibility. Among sexually active participants, those who had never been

Financial Disclosure: Consulting Editor Robert A. Hatcher, MD, MPH, Nurse Reviewer Melanie Deal, Author Rebecca Bowers, and Executive Editor Joy Dickinson report no consultant, stockholder, speaker's bureau, research, or other financial relationships with companies having ties to this field of study.

EXECUTIVE SUMMARY

Young men who have sex with men (MSM) have the highest risk for HIV infection, but only one in five has been tested for HIV, according to new research.

- Low levels of testing are a concern in this age group, because young gay and bisexual men ages 13-24 accounted for 72% of new HIV infections among all persons in that age group in 2010, and they represented 30% of new infections among all gay and bisexual men.
- The greatest barriers to teen males getting tested are not knowing where to obtain an HIV test, worries about being recognized at a testing site, and to a lesser degree, thinking they are invincible and won't get infected, new research states.

tested for HIV had significantly greater scores on the external factors (odds ratio, 1.63; 95% confidence interval, 1.01-2.66) and fear (odds ratio, 1.88; 95% confidence interval, 1.11-3.19) subscale. Older youth ages 16-18 were especially likely to be affected by external factor barriers, and fear was associated with never testing among gay-identified individuals.[1]

Break down the barriers

The Chicago-based researchers found that the greatest barriers to teen males getting tested are not knowing where to obtain an HIV test, worries about being recognized at a testing site, and to a lesser degree, thinking they are invincible and won't get infected.

"Understanding the barriers to testing provides critical information for intervening, so we can help young men get tested," said **Gregory Phillips II**, PhD, a research assistant professor of medical social sciences at Northwestern University Feinberg School of Medicine and an investigator for the IMPACT LGBT Health and Development Program at Feinberg. Phillips served as the study's first author.

Rates of new HIV infections are increasing among young gay and bisexual men, noted **Brian Mustanski**, PhD, an associate professor of medical social sciences at Feinberg and director of IMPACT, in a press statement accompanying the publication.

"Testing is critical because it can help those who are positive receive lifesaving medical care," noted Mustanski, who served as the principal investigator of the project. "Effective treatment can also help prevent them from transmitting the virus to others."

Findings from the study indicate that testing might be increased by providing young men with an easy way to find nearby testing sites via text messaging or online programs, as well as opening testing sites in high schools. Providing in-school testing would normalize the process, Phillips states. With the constant presence of on-site testing at schools, testing would seem less stigmatized, increase knowledge about the testing process, and make it less scary, he observes.

Increase testing access

Because young people spend a significant part of their day in school, education agencies and schools can play key roles in supporting HIV testing, states the CDC.[5]

School-based referral programs can help connect students to adolescent-friendly community healthcare providers.[6,7] According to the CDC, some schools might be able to offer on-site testing with a school-linked or school-based clinic, or in partnership with mobile testing programs.

Online information explaining the testing procedure also can calm young men's fears, note the Chicago-based researchers. Adolescents might not know that finger stick or cheek swabs are options for testing. To help young people understand the testing process, the IMPACT Program at Feinberg created a video to show what it's like to get an HIV test. *(See the video at http://bit.ly/1NVXpP1. Click on the link "video that shows young people what it's like to get an HIV test.")*

High schools can strengthen their HIV prevention curricula by including information on locations and procedures for obtaining free, or low-cost, confidential HIV testing, advises the CDC.

Support grows

Federal support for preventing HIV/AIDS in adolescents is growing.

The Department of Health and Human Services' Office of Adolescent Health awarded a $350,000 grant in June 2015 to Boston-based JSI Research and Training Institute to support an online National HIV/AIDS Resource Center. The center will promote practical strategies for community-based providers and youth-serving professionals. It will offer information and resources targeted to adolescents who might be at high risk for HIV infection and those living with AIDS. It also will have links to training and technical assistance. The online service also will include interactive media and social

media to help improve adolescent health and well-being.

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Results in your hand: Scientists develop hand-held chlamydia test

Researchers at Baltimore-based Johns Hopkins University (JHU) are testing a low-cost diagnostic tool that detects chlamydia within 30 minutes. The tool, tentatively called mobiLab, is made of a disposable cartridge for a genital swab sample and a heating unit that incubates the DNA to facilitate a reaction. The test results are delivered to and processed by a mobile app on a smartphone connected to the battery-powered device.[1]

National data indicate that an estimated 1.8 million Americans ages 14-39 are infected with chlamydia, with rates of infection highest among young women. An estimated 4.7% of women ages 14-24 were infected with the disease in 2012, data suggest.[2] *(*Contraceptive Technology Update's "*STI Quarterly" supplement reported on the data. See "Nearly 5% of young U.S. women have chlamydia," December 2014.)*

Since the beginning of the 21st century, healthcare providers have been able to expand chlamydia screening programs through development of nucleic acid amplification (NAAT) testing. However, NAAT testing is too complex to perform in point-of-care settings such as clinicians' offices, health fairs, school clinics, or other sexual health outreach venues.

Johns Hopkins University researchers, led by **Jeff Tza-Huei Wang**, PhD, from JHU's BioMEMS Lab, presented initial results of the first low-cost NAAT platform that can diagnose chlamydia at the point of care and that integrates sample preparation, DNA amplification, and data processing at the 2015 American Association for Clinical Chemistry Annual Meeting and Clinical Lab Expo in Atlanta. The battery-powered device, the size of a coffee mug, works by using a microfluidics cartridge to detect the DNA of chlamydia bacteria in genital swab samples. The DNA analysis unit is integrated with a smartphone, which enables the user to control the platform and process test data with a smartphone app.

EXECUTIVE SUMMARY

Johns Hopkins University researchers are testing a low-cost diagnostic tool that detects chlamydia within 30 minutes. The tool, tentatively called mobiLab, is made of a disposable cartridge for a genital swab sample and a heating unit that incubates the DNA to facilitate a reaction. The test results are delivered to and processed by a mobile app on a smartphone connected to the battery-powered device.

- The battery-powered device, the size of a coffee mug, works by using a microfluidics cartridge to detect the DNA of chlamydia bacteria in genital swab samples. The DNA analysis unit is integrated with a smartphone, which enables the user to control the platform and process test data with a smartphone app.
- The testing device costs about $200 to manufacture. Developers estimate the per-run cost of the platform at $2.

The testing device weighs as much as two or three iPhones and costs about $200 to manufacture. Developers estimate the per-run cost of the platform at $2.

Researchers now have fairly accurate, sensitive, and specific molecular assays to detect very few numbers of organisms in biological samples, said **Dong Jin Shin**, BME, one of the abstract's authors and a PhD student at Johns Hopkins. However, many of these technologies are confined to use in centralized lab settings.

"If we're able to bring molecular diagnostic technology closer to the clinic and deliver accurate results to clinicians sooner, then we'll be able to improve our standard of care for patients with chlamydia, while also saving costs," said Shin in a press statement accompanying the abstract presentation.

How does it perform?

The JHU researchers designed the heart of the mobiLab technology using magnetic particles as a mobile solid phase for DNA capture and transport. This simplified fluidic processing to particle translocation on a robust and scalable cartridge. Process integration facilitated by Bluetooth-enabled microcontrollers enable full control of the instrument by the user with a smartphone application, the researchers state.[1]

The mobiLab platform consists of three discrete units:

- a droplet microfluidic cartridge;
- a battery-powered instrument for droplet manipulation and amplification;
- a smartphone for user interface, data acquisition, and processing.

The microfluidic cartridge design uses open-surface magnetofluidic manipulation to enable bioassays requiring multiple buffer exchanges to be performed without complex instruments. The instrument uses a microcontroller that controls the rotary bead manipulator, thermal incubation, and Bluetooth-based communication with the smartphone application. Each assay consumes about 10% of the battery capacity, which allows up to 10 assays to be performed consecutively without access to a power outlet.

Researchers designed a single-stream loop-mediated isothermal amplification (LAMP) assay to operate in tandem with the mobiLab platform. Within this assay, polyhistidine-coated magnetic particles capture DNA targets from sample lysate via electrostatic interaction. The affinity between particles and nucleic acids is maintained at acidic pH, which is reversed when particles enter the LAMP buffer. The basic pH of LAMP mixture is compatible with the elution conditions for nucleic acids, which enables seamless integration between DNA extraction and amplification.

> THE TESTING DEVICE WEIGHS AS MUCH AS TWO OR THREE IPHONES AND COSTS ABOUT $200 TO MANUFACTURE.

To test the single-stream assay, researchers used plasmid targets and were able to capture and amplify 103 copies of gene targets. Specificity of the assay for *Chlamydia trachomatis* was tested, and the absence of cross-reactivity with human or other bacterial genomic DNA was verified. The mobiLab platform was validated by testing *Chlamydia trachomatis* infection from patient-collected vaginal swab samples.

Volunteers enrolled in an internet-based chlamydia screening program, where two sets of swabs were self-collected and mailed back to the JHU lab. One set of swabs was analyzed using the gold standard Gen-Probe AC2 CT assay (San Diego), while the second set was tested using the mobiLab platform. The two results were in agreement for 20 out of 20 samples after 30-minute incubation, which demonstrated that the droplet assay performance is comparable to the gold standard for the samples tested.[1]

At the present time, the mobiLab technology hasn't been tested for infections other than chlamydia; however, Wang says it could be used to test for other DNA/RNA-based infections. Researchers will continue looking at alternate uses for the technology, as well as confirm its use for possible commercial development.

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CONTRACEPTIVE TECHNOLOGY UPDATE®

OB/GYN Clinical [ALERT]
Evidence-based commentaries on women's reproductive health

2015 Contraception Survey

Please Give Us 9 Minutes of Your Time

Please circle your answers below. If you receive this survey through another channel, please do not fill out more than one.

1. Of the women leaving your clinic with combined pills, the percentage prescribed an extended or a continuous regimen of pills is:
   A. 0
   B. 1-10%
   C. 11-25%
   D. 26-50%
   E. More than 50%

2. Do you provide actual packages of emergency contraceptive pills (ECPs) in advance?
   A. Yes
   B. No

3. About what percentage of women leave your office using an intrauterine device (IUD) each month?
   A. 0
   B. 1-10%
   C. 11-25%
   D. 26-50%
   E. More than 50%

4. Would you (or a clinician in your program) prescribe combined oral contraceptives to a healthy patient age 35 to 39 who smokes 10 cigarettes/day?
   A. Yes
   B. No
   C. I don't know

5. Would you (or a clinician in your program) prescribe combined oral contraceptives to a healthy patient age 40 or older who smokes 10 cigarettes/day?
   A. Yes
   B. No
   C. I don't know

6. In the past year, how many intrauterine devices have you personally inserted?
   A. 0
   B. 1-5
   C. 6-10
   D. 11-25
   E. More than 25

7. In the past year, how many Nexplanon implants have you personally inserted?
   A. 0
   B. 1-5
   C. 6-10
   D. 11-25
   E. More than 25

8. Is your facility using the QuickStart method to initiate combined hormonal contraceptive use?
   A. Yes
   B. No

9. Are more women at your facility using long-acting reversible contraceptives (an implant or one of the two IUDs)?
   A. Yes, dramatically more
   B. Yes, slightly more
   C. No

10. After what period of time postpartum do you usually recommend that a woman who is not breast-feeding start taking combined oral contraceptives?
    A. On hospital discharge
    B. 1-3 weeks postpartum
    C. 4-6 weeks postpartum
    D. After first menses
    E. I don't know

11. After what period of time postpartum do you usually recommend that a woman who is breast-feeding start taking progestin-only oral contraceptives?
    A. On hospital discharge
    B. 1-3 weeks postpartum
    C. 4-6 weeks postpartum
    D. After first menses
    E. I don't know

12. A growing body of evidence suggests that oral contraceptives can be provided safely and effectively in a pharmacy without a woman needing to obtain a prescription from a clinician. What is your opinion about this? (You may choose more than one answer.)
    A. In some situations, I support over-the-counter availability of combined oral contraceptives (COCs)
    B. In some situations, I support over-the-counter availability of progestin-only contraceptives (POPs)
    C. I do NOT support over-the-counter availability of any oral contraceptives

13. Would you recommend Depo-Provera for a 14- to 17-year-old teenager?
    A. Yes
    B. No

14. Would you recommend an IUD for a 14- to 17-year-old teenager?
    A. Yes
    B. No

Survey continues on back of sheet.

15. Please mark the title that ***best*** describes you.
    A. Physician (your specialty) _____
    B. Nurse practitioner
    C. Nurse midwife
    D. Registered nurse (RN)
    E. Licensed practical nurse (LPN)
    F. Physician assistant (PA)
    G. Allied health professional
    H. Health educator or counselor
    I. Administrator
    J. Student (studying for what degree?) _____
    K. Other (specify)_____

16. Are you currently enrolled in a family planning fellowship?
    A. Yes
    B. No

17. Have you completed a family planning fellowship?
    A. Yes
    B. No

18. What is your primary role in your discipline?
    A. Care provider
    B. Case management
    C. Administrator or supervisor
    D. Faculty/teacher/student
    E. Other (specify)_____

19. In what type of facility do you work?
    A. Hospital/hospital-based clinic
    B. Private practice
    C. Public health clinic/agency/health department/community center
    D. Health professions academic institution/student health center
    E. Other health care (specify) _____

20. What is the location of your employment setting?
    A. Urban
    B. Suburban
    C. Rural
    D. other (specify) _____

21. If your program actually does provide pills to patients, how many packages of pills do you most commonly provide to women who have already been on pills and are experiencing no problems at all?
    A. 0
    B. 1
    C. 2
    D. 3-5
    E. 6-11
    F. 12 or 13

22. Assume you could prescribe any pill for a woman initiating combined pills and there were no formulary issues dictating which you could prescribe. Which pill would you (or a clinician in your program) prescribe for a 42-year-old nonsmoking woman who wants to use combined pills?

    _____

23. In your clinic, HMO, or office, there may be limits on the pills you prescribe to routine patients. Given the pills that are readily available to you, which pill would you (or a clinician in your program) prescribe for a 21-year-old nonsmoking woman?

    _____

24. My facility subscribes to:
    A. *Contraceptive Technology Update*
    B. *OB/GYN Alert*
    C. Neither of the above

May we contact you for further information? If so, please provide the following information:

Name: _____

Title: _____

Facility: _____

Address:_____

Phone: _____

E-Mail: _____

Thank you for participating in this survey. VERY IMPORTANT: Don't forget to return this form in the postage-paid envelope addressed "*Contraceptive Technology Update* Contraception Survey."

Our mailing address is AHC Media, One Atlanta Plaza, 950 East Paces Ferry Road, Suite 2850, Atlanta, GA 30326.