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INSIDE

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Reproductive health forecast: Look for more options for women

As *Contraceptive Technology Update* enters its 35th year, what new methods can clinicians look to add to their arsenal of family planning options?

The need for new contraception options is clear. In the United States, about half of the some 3.4 million pregnancies each year are unintended.[1] At current rates, more than half of all U.S. women will have faced an unintended pregnancy by age 45, and almost a third will have had an abortion by that age.[1]

Increased use of long-acting reversible contraceptive methods (LARC methods), such as implants and intrauterine devices (IUDs), has the potential to lower unintended pregnancy rates, says **Lisa Haddad**, MD, MS, MPH, assistant professor of gynecology and obstetrics at Emory University School of Medicine in Atlanta. Haddad spoke on LARC methods at the recent Contraceptive Technology conference in Atlanta.[2]

"IUDs and the contraceptive implant are the best reversible methods for preventing unintended pregnancy, rapid repeat pregnancy, and abortion in young women," says Haddad, who points to recommendations from the American College of Obstetricians and Gynecologists on the subject.[3] "LARC methods should be first-line recommendations for all women and adolescents."

Clinicians soon might see an

CTU celebrates 35th anniversary

This issue marks the 35th anniversary of *Contraceptive Technology Update*. In keeping with its ongoing coverage of emerging birth control methods, this issue gives a forecast of upcoming contraceptive options. What can clinicians expect to see when it comes to prevention and treatment of sexually transmitted infections? Stay tuned for a special focus article in the February 2015 issue.

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additional levonorgestrel IUD: The Food and Drug Administration (FDA) is reviewing a New Drug Application for Levosert, a hormonal intrauterine contraceptive. The device is under development by Medicines360, a San Francisco-based non-profit women's health pharmaceutical company, and Actavis plc, a global specialty pharmaceutical company. The two companies entered into a partnership in 2013 to make the Levosert commercially available in the United States and at an affordable price for U.S. family planning clinics. The device is a T-shaped polyethylene frame with a steroid reservoir around its vertical stem. The reservoir contains 52 mg levonorgestrel, which provides a daily release rate of 20 mcg. (*To read more about the device, see the* CTU *article, "New intrauterine device now is in research," September 2013, p. 104.)*

While not yet in U.S. development, a spherical IUD developed by OCON Medical of Modiin, Israel, won European marketing approval in 2014. Due to its form and deployment process, the SCu300A copper uterine device is expected to ease insertion and reduce perforation, malposition, and expulsion rates, and it also might reduce dysmenorrhea and menorrhagia.[4] The company has begun a North American clinical trial of a second device, which is designed with a larger copper surface area than the original model.

New patch in sight?

Advanced research is looking at a new contraceptive patch for women. Agile Therapeutics, a Princeton, NJ-based women's health specialty pharmaceutical company, initiated a Phase 3 study in September 2014 to assess the efficacy, safety, and tolerability of Agile's investigational once-weekly transdermal contraceptive patch, Twirla (AG200-15).

The Phase 3 study, a single-arm, open-label, multicenter investigation, will enroll approximately 2,100 women who will use the patch for up to one year to determine its contraceptive effectiveness. As of November 2014, approximately 50 of the planned 70 clinical sites had been activated, states company spokesperson Mary Coleman. The company anticipates completing the trial at the end of the first quarter of 2016, she says.

The investigational patch is designed to deliver 120 mg/day levonorgestrel with 25 mg/day ethinyl estradiol. The patch is under FDA review. *(To read more about the patch, see the* CTU *article*

EXECUTIVE SUMMARY

The need for new contraception options is clear. In the United States, about half of the some 3.4 million pregnancies each year are unintended.

- At current rates, more than half of all U.S. women will have faced an unintended pregnancy by age 45, and almost a third will have had an abortion by that age.
- The Food and Drug Administration is reviewing a New Drug Application for Levosert, a hormonal intrauterine contraceptive.
- Advanced research is looking at the efficacy, safety, and tolerability of Agile Therapeutics' investigational once-weekly transdermal contraceptive patch, Twirla.

"Options being eyed for transdermal contraception," March 2014, p. 31.)

In March 2014, Bayer AG of Leverkusen, Germany, successfully concluded the registration procedure in the European Union for a new transparent low-dose contraceptive patch, FC-Patch Low. The patch is transparent and contains 0.55 mg ethinyl estradiol and 2.1 mg gestodene. Results of a recently published study indicate the patch is effective in preventing pregnancy.[5] Menstrual bleeding pattern was favorable and within the ranges expected of a healthy female population, findings suggest.[5] While gestodene has been in use as a contraceptive agent in European countries for more than 20 years, no U.S.-approved birth control method contains it.

Researchers also are looking at a new progestin-only pill for women who cannot take estrogen-containing medications. The Women's Health Research Unit at Oregon Health Sciences University in Portland is researching use of ulipristal acetate as a potential contraceptive. Clinicians might be familiar with ulipristal acetate in its use as ella (Afaxys, Charleston, SC), approved for emergency contraception.

Several European and Latin American countries have seen the launch of a combined oral contraceptive (OC) containing a natural estrogen and a new progestin, nomegestrol acetate (NOMAC). Research indicates the combination pill is well-tolerated and provides effective contraception and acceptable cycle control.[6] The pill is being marketed in approved countries as Zoely. Teva Pharmaceutical Industries Ltd. of Jerusalem, Israel, holds exclusive marketing rights for Zoely in France, Italy, Belgium, and Spain. MSD of Whitehouse Station, NJ, markets Zoely in all other European Union and other European countries. The drug is under review by the FDA. *(To read more on the drug, see the* CTU *article, "New OC formulation now in research focus," July 2012, p. 78.)*

In 2012, the European Commission approved Bayer HealthCare's new low-dose combined oral contraceptive, Flexyess. The drug, which contains 3 mg drospirenone and 0.02 mg ethinyl estradiol, relies on a flexible extended regimen. Research indicates the flexible dosing regimen of the drug combination is tied to good contraceptive efficacy and fewer bleeding/spotting days than the conventional 24/4 regimen.[7]

What's the right method?

A 2013 report from the Centers for Disease Control and Prevention notes that among women of reproductive age who had had sexual intercourse, 47% of those who had ever used at least one contraceptive method had discontinued a method due to dissatisfaction.[8]

"While it should be possible to improve effective use, most interventions designed to improve compliance and continuation rates have proved surprisingly disappointing," stated **Anna Glasier**, MD, professor of obstetrics and gynecology at the University of Edinburgh, Scotland, at a presentation made at the Society for the Study of Reproduction 2014 annual meeting. "Contraception is most effective when the method makes no demands on compliance and when motivation to avoid pregnancy is high."[9]

What's the next step? Those in reproductive health must be more imaginative in the strategies to improve patterns of contraceptive use and more rigorous in the research to evaluate them, stated Glasier.

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New year, new device — Offer barrier method option to your patients

With market clearance from the Food and Drug Administration (FDA) in hand, the German company licensed to market the Caya contoured diaphragm is seeking distribution and marketing partners to introduce the device in the United States.

Women in Europe and Canada already are familiar with the single size device. It received European regulatory approval in June 2013, with Canadian access granted in early 2014. It was designed through a unique collaboration between Seattle-based PATH (a global health nonprofit), Norfolk-based CONRAD (a nonprofit entity that operates as a Division of the Department of Obstetrics and Gynecology at Eastern Virginia Medical School), the United States Agency for International Development, and other partners. The device, called the SILCS diaphragm in its design and clinical validation stages, was licensed in 2010 to Frankfurt, Germany-based Kessel medintim GmbH (Kessel) to accelerate women's access to the technology. *(To read more about the device, see the* Contraceptive Technology Update *article "Diaphragm: update on this barrier contraceptive," June 2014, p. 66.)*

Caya is the first new cervical barrier method to enter the market in more than 10 years, says **Kate Grindlay,** MSPH, executive director of the Cervical Barriers Advancement Society (CBAS) and senior project manager at Ibis Reproductive Health. As a one-size-fits-most product, the Caya diaphragm should be easier to provide than diaphragms in multiple sizes since a clinician fitting to determine size is not required. Thus, the Caya diaphragm represents an important move forward in diaphragm access, with the potential to reinvigorate interest in and use of the method, and to expand women's contraceptive options, she says.

"Diaphragms are a good option for women who want a safe, effective, non-hormonal birth control method, They are also beneficial for women who have intermittent sex and may want a method they can use as needed rather than continuously," observes Grindlay. "Finally, new multipurpose prevention technologies that protect against both pregnancy and HIV and other sexually transmitted infections are greatly needed, and diaphragms are a promising delivery system for new microbicides under development."

How does it work?

How does the device work? In documentation submitted to the FDA, the device's function is described as a mechanical barrier that prevents sperm from entering the cervical canal. The spring within its perimeter causes the device to create a seal against the vaginal wall, covering the cervix and preventing sperm from entering the cervical canal. The silicone cup-shaped device also serves as a repository for contraceptive gel.[1]

The historical control for the SILCS diaphragm pivotal study was a multi-center contraceptive study conducted by the National Institute for Child Health and Human Development (NICHD), according to the FDA. The design of the SILCS pivotal study was modeled after the NICHD study. It used a historical control analysis to compare the contraceptive effectiveness and safety of SILCS used with a contraceptive gel to the Ortho diaphragm used with contraceptive gel. In the SILCS pivotal study, the six-month Kaplan-Meier cumulative typical-use pregnancy probabilities per 100 women (with 95% confidence intervals) was 10.4 (6.9, 14.0) for all SILCS users.[1] Results of the device's contraceptive effectiveness study were presented at the 2011 Reproductive Health Conference[3] and

EXECUTIVE SUMMARY

With clearance from the Food and Drug Administration in hand, the German company licensed to market the Caya contoured diaphragm is seeking distribution and marketing partners to introduce the device in the United States.

- The device, called the SILCS diaphragm in its design and clinical validation stages, was designed through a unique collaboration between the global health nonprofit PATH, the reproductive health product development organization CONRAD, the United States Agency for International Development, and other partners. The device was licensed in 2010 to Kessel medintim GmbH to accelerate women's access to the technology.
- As a one-size-fits-most product, a fitting exam is not required to determine diaphragm size. The Caya diaphragm represents an important move forward in diaphragm access in the United States.

have been submitted for publication by CONRAD, which implemented the study, says **Maggie Kilbourne-Brook**, PATH program officer and team leader of the SILCS project.

Stay tuned for launch

Kessel is evaluating potential marketing and distribution partners in the United States, says Kilbourne-Brook. Because Kessel doesn't currently market any products in the United States, it is reviewing potential partners for those who are best positioned to take on a new nonhormonal barrier method that will be available by prescription, she states. The company's goal is to offer U.S. distribution in 2015, says Kilbourne-Brook.

With the discontinuation of the Ortho All-Flex diaphragm in December 2013, which had been the most popular diaphragm prescribed in the United States, women are left with few diaphragm options, says Grindlay.

"There is only one diaphragm currently available on the U.S. market, the Milex Wide Seal, and anecdotal information suggests that some women may face barriers when trying to access that product," states Grindlay. "Women need a variety of contraceptive options to be able to choose the one that is best for them."

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New STD guidance on way: Be prepared

As 2015 rolls out, look for the publication of the newly updated *Sexually Transmitted Diseases Treatment Guidelines* from the Centers for Disease Control and Prevention (CDC). The proposed new guidance, which replaces information published in 2010,[1] will provide the latest evidence-based treatment recommendations, says **Gail Bolan**, MD, director of the CDC's Division of Sexually Transmitted Disease Prevention. Bolan presented information at the recent Contraceptive Technology Atlanta 2014 conference.[2] The proposed new guidance is available for review at http://1.usa.gov/11f6Kzf. Release is projected by late 2014 or early 2015, Bolan told conference attendees.

Included in these updated guidelines is new information on such topics as:

- alternative treatment regimens for *Neisseria gonorrhoeae;*
- use of nucleic acid amplification tests for diagnosis of trichomoniasis;
- alternative treatment options for genital warts;
- the role of *Mycoplasma genitalium* in urethritis/cervicitis and treatment-related implications;
- five updated human papillomavirus (HPV) counseling messages;
- a new section on the management of transgender individuals;
- recommendations for annual testing for hepatitis C in persons with HIV infection;
- updated recommendations for diagnostic evaluation of urethritis;
- retesting to detect repeat infection.

For uncomplicated gonococcal infections of the cervix, urethra, and rectum, the new recommended regimen includes ceftriaxone 250 mg in a single intramuscular dose **plus** azithromycin 1g orally in a single dose. Previous guidance called for 100 mg of doxycycline twice a day for seven days as the recommended second drug in dual therapy. As dual therapy, ceftriaxone and azithromycin should be administered

EXECUTIVE SUMMARY

Publication of the newly updated *Sexually Transmitted Diseases Treatment Guidelines* from the Centers for Disease Control and Prevention is on its way. The proposed new guidance, which replaces information published in 2010, will provide the latest evidence-based treatment recommendations.

- New information will be included on such topics as alternative treatment regimens for *Neisseria gonorrhoeae*, use of nucleic acid amplification tests for the diagnosis of trichomoniasis, and alternative treatment options for genital warts.
- The new guidance will include new sections on transgender men and women, as well as emerging issues, such as *Mycoplasm genitalium* and hepatitis C.

together on the same day, preferably simultaneously and under direct observation, the 2014 proposed guidance advises.

If ceftriaxone is not available, the new alternative regimen is cefixime 400 mg in a single oral dose **plus** azithromycin 1 g orally in a single dose. When there is an allergy to azithromycin, doxycycline (100 mg orally twice a day for seven days) can be used as an alternative second antimicrobial in place of azithromycin when used in combination with cefixime.

Review treatments

Genital warts are soft, moist, pink or flesh-colored bumps caused by HPV infection. In women, the warts usually occur in or around the vagina, on the cervix, or around the anus. While genital warts are less common in men, they may appear on the tip of the penis.

While most genital warts are asymptomatic, patients might experience itching, pain, and bleeding with them. For patient-applied therapy, the proposed new guidelines call for use of imiquimod in 3.75% or 5% cream. Imiquimod 5% cream should be applied once at bedtime, three times a week for up to 16 weeks, while imiquimod 3.75% cream should be applied once at bedtime but is applied every night for up to eight weeks.

Use of podophyllin resin 10-25% has been moved to "alternative therapy" for genital warts, due to case reports of adverse effects with misuse, says Bolan.

For treatment of chlamydia, the proposed new guidance recommends azithromycin 1 g orally in a single dose or doxycycline 100 mg orally twice a day for seven days. Alternative regimens include erythromycin base 500 mg orally four times a day for seven days, or erythromycin ethylsuccinate 800 mg orally four times a day for seven days, or levofloxacin 500 mg orally once daily for seven days, or ofloxacin 300 mg orally twice a day for seven days.

In patients who have erratic healthcare-seeking and follow-up behavior, or poor treatment adherence, azithromycin might be more cost-effective in treating chlamydia because it enables the provision of a single dose of directly observed therapy, the proposed guidance states.[2]

Due to concerns over amoxicillin use in pregnancy due to chlamydia persistence in vitro, use of the drug is listed only as an alternative regimen.

New sections added

The new guidance will include new sections on transgender men and women, as well as emerging issues, such as *Mycoplasm genitalium* and hepatitis C.

While the transgender population is relatively small, studies of HIV among transgender women suggest that the prevalence of HIV is the highest among subpopulation groups in the United States: 27.7% among all transgender women, and 56.3% among African American transgender women.[3]

Mycoplasma genitalium has become recognized as a cause of male urethritis. Research indicates it is responsible for approximately 15-20% of non-gonococcal urethritis (NGU) cases, 20-25% of non-chlamydial NGU, and approximately 30% of persistent or recurrent urethritis, says **Kimberly Workowski**, MD, professor of medicine in the Division of Infectious Diseases at Emory University in Atlanta.[4] It also might play a role in pelvic inflammatory disease (PID). There is no commercially available test for the infection. It should be suspected in cases of persistent or recurrent urethritis, and it may be considered in persistent or recurrent cases of cervicitis and PID.

Hepatitis C virus (HCV) infection is the most common chronic bloodborne infection in the United States, with an estimated 2.7 million persons with chronic infection.[5] Recent data indicate that sexual transmission of hepatitis C can occur. All HIV-infected individuals should be tested at initial evaluation and at least annually and more frequently depending on local circumstances. Screening should be performed using HCV antibody assays.

HCV testing is recommended by the CDC and the U.S. Preventive Services Task Force for all persons born during 1945-1965 and others based on their risk for infection or on a recognized exposure, including past or current injection drug use, receipt of a blood transfusion before 1992, long-term hemodialysis, status as the child of a mother with HCV infection, intranasal drug use, receipt of an unregulated tattoo, and other percutaneous exposures, the new guidance states.

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Drug interactions and the Pill: Clincians need to check the facts

The next patient in your office is a 32-year-old mother of two who is using oral contraceptives (OCs) for family planning. She tells you she also is using ampicillin for bronchitis. Should she be concerned about the antibiotic's impact on her Pill's efficacy?

Hormone levels in women using combined pills are not lowered by broad-spectrum antibiotics such as ampicillin, amoxicillin metronidazole, or doxycycline, 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. Nelson recently presented on the subject of drug interactions with hormonal contraceptives at the *Contraceptive Technology* Atlanta 2014 conference.[1]

"Don't worry about it, and advise patients not to worry," Nelson says of broad-spectrum antibiotics and estrogen-containing contraceptives. "There is no need for backup method, unless there are other problems with oral contraceptives."

To evaluate possible drug-drug interactions with combined pills, clinicians need to understand how the estrogen and progestin in pills are absorbed, distributed, metabolized, and eliminated. According to *Contraceptive Technology*, people used to worry about "enterohepatic circulation," but today we understand this process has only a slight impact on pill efficacy. The story goes like this: Sex steroids in combined OCs are absorbed by the small intestine and shunted primarily through the liver, known as first pass. About 60% of the absorbed ethinyl estradiol is conjugated to form glucoronic and sulfate conjugates, which are excreted through the gallbladder and back into the small intestine without entering the bloodstream. Bacteria in the large intestine unconjugate the estrogen compounds, which are then absorbed from the colon. They are then delivered to the liver through the enterohepatic circulation for additional hepatic passes for absorption into the bloodstream or for reconjugation and re-excretion back into the intestine. They are then eliminated in the feces. The sex steroids that enter circulation ultimately are conjugated hepatically and excreted in the urine. This is no longer considered a problem because the re-circulation contributes only slightly to serum levels.[2]

The real story, even for rifampin and griseofulvin, happens within the liver.[2] When ethinyl estradiol is in contact with the liver, it induces changes in hepatic enzyme and protein synthesis. It increases hepatic production of carrier proteins, and it also activates cytochrome P-450 enzymes. They boost the rate at which many drugs are cleared by the liver from the bloodstream.[2] Drugs that are metabolized more rapidly cannot work as thoroughly.

What drugs to flag?

Remember that rifampin also is widely used in treatment of skin infections associated with methicillin-resistant *Staphylococcus aureus*, notes Nelson.

Women with seizure disorders face special challenges when it comes to use of combined OCs, says Nelson. Enzyme-inducing anti-epileptic drugs (AEDs) increase clearance and decrease systemic levels of contraceptive hormones, as well as increase contraceptive failures and up the risk of teratogenicity. On the

EXECUTIVE SUMMARY

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- When ethinyl estradiol is in contact with the liver, it induces changes in hepatic enzyme and protein synthesis. It increases hepatic production of carrier proteins, and it also activates cytochrome P-450 enzymes, boosting the rate at which many drugs are cleared by the liver from the bloodstream.
- The only antibiotics that profoundly affect combined oral contraceptive potency are drugs that contain hepatic enzyme inducers: rifampin, used alone or with other drugs in treatment of tuberculosis, and griseofulvin.

other hand, the estrogen in combined OCs increases the clearance and decreases systemic levels of anticonvulsives, and it boosts seizure frequency.

Use of carbamazepine, phenobarbital, phenytoin, primidone, eslicarbazepine, oxcarbazepine, and topiramate will **decrease** serum concentrations of estrogen, while felbamate and rufinamide will increase serum concentrations of estrogen, explains Nelson. On the other hand, combined OC use results in reduced levels of lamotrigine and valproic acid (oxcarbazepine). Remember that many AEDs also are used in other applications, such as to reduce drug dependency and to treat depression.[2]

What are contraceptive management options for women using AEDs and combined hormonal contraception? Clinicians can look at either voiding systemic combined hormonal methods and progestin-only pills or can consider using 50 mcg ethinyl estradiol combined pills or adding barrier method usage to combined pills, advises Nelson. The contraceptive implant, injection, and intrauterine contraception all represent effective options for women who use AEDs.

Antiretrovirals and OCs?

What does the *U.S. Medical Eligibility Criteria for Contraceptive Use* (U.S. MEC) say about use of combined pills in women with HIV/AIDS? According to the U.S. MEC, all combined hormonal methods (the Pill, patch, and ring) are listed as "Category 1" (no restrictions on use) for women using nucleoside reverse transcriptase inhibitors for antiretroviral therapy.[3] However, for women using non-nucleoside reverse transcriptase inhibitors, the U.S. MEC classes combined hormonal method use as "Category 2" (advantages of using the method generally outweigh the theoretical or proven risks). For women who use ritonavir-boosted protease inhibitors, combined hormonal method use is classed as Category 3 (a condition for which the theoretical or proven risks usually outweigh the advantages of using the method).

For women undergoing antiretroviral therapy, "pill burden" is real, notes Nelson. Non-daily delivery systems might reduce that burden and also avoid first pass metabolism issues, she states.

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Quality Family Planning (QFP) — Put it into practice

If you have attended a major national reproductive health conference in the last six months, chances are you have heard about the QFP — the acronym for *Providing Quality Family Planning Services — Recommendations of CDC and the U.S. Office of Population Affairs*.[1]

The QFP is the newest member in the "suite" of family planning recommendations from the Centers for Disease Control and Prevention (CDC), says **Michael Policar**, MD, MPH, clinical professor of obstetrics, gynecology, and reproductive science at the University of California, San Francisco. It joins the *U.S. Medical Eligibility Criteria for Contraceptive Use, 2010 (U.S. MEC)*, the *U.S. Selected Practice Recommendations for Contraceptive Use, 2013 (SPR)*, the *Recommendations for Improving Preconception Health Care*, the *Sexually Transmitted Diseases Treatment Guidelines, 2010*, and the *Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women In Health-Care Settings*.[2-6] (Contraceptive Technology Update *reported on the QFP. See "New guidance uses best evidence to direct family planning services," August 2014, p. 85.)*

According to Policar, the new guidance does the following:

- completes, and ties together, the CDC suite of family planning guidelines;
- defines and prioritizes the core content of contraceptive services;
- defines the borders between family planning and other preventive services;
- specifies which interventions are recommended for each of the seven family planning service types;
- emphasizes the role and content of contraceptive counseling;
- refines the content of male family planning services.[7]

The new recommendations integrate and fill in the gaps in the other guidelines for the family planning setting, explains Policar. The

recommendations include guidance on pregnancy testing and counseling, achieving pregnancy, basic infertility, preconception health, preventive health screening of women and men, and contraceptive counseling, including reproductive life planning, all of which constitute the core of family planning services.

How are core family planning services different from "well woman" care? Policar explains that core family planning services focus on three vital aspects: avoiding pregnancy or becoming pregnant, safe and effective contraceptive use, and protection of reproductive health.

More preventive services might be performed by the patient's primary care provider or family planning clinic, in the absence of a primary care provider. "Given limitations of time and resources, provision of core family planning services is our top priority," Policar states.

The National Clinical Training Center for Family Planning offers handy checklists of family planning and preventive services for women and men, says Policar. *(Access the checklists at http://bit.ly/11c4o4e.)*

Preconception health services should be offered to all female and male patients, says Policar. Priority populations include those who are trying to achieve pregnancy, including negative pregnancy test visits, those coming in for removal of an intrauterine device or implant to become pregnant, those seeking infertility services, and those at high risk of unintended pregnancy, he states.

Questions that can cover a patient's reproductive life plan include:

• Do you hope to have any (more) children?

• How many children do you hope to have?

• How long do you plan to wait until you next become pregnant?

• How much space do you plan to have between your pregnancies?

• What do you plan to do until you are ready to become pregnant?

• What can I do today to help you achieve your plan?

The "One Key Question" program advocated by the Oregon Foundation for Reproductive Health offers one way to enter into such a discussion, says Policar. By asking "Would you like to become pregnant in the next year?" healthcare providers can open the door to providing preconception, prenatal, or contraceptive care. *(Information on the program is at www.onekeyquestion.org.)*

EXECUTIVE SUMMARY

"*Providing Quality Family Planning Services — Recommendations of CDC and the U.S. Office of Population Affairs*" is the newest member in the "suite" of family planning recommendations from the Centers for Disease Control and Prevention.

• The new guidance defines and prioritizes the core content of contraceptive services, defines the borders between family planning and other preventive services, specifies which interventions are recommended for each of the seven family planning service types, emphasizes the role and content of contraceptive counseling, and refines the content of male family planning services.

• The recommendations include guidance on pregnancy testing and counseling, achieving pregnancy, basic infertility, preconception health, preventive health screening of women and men, and contraceptive counseling, including reproductive life planning.

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Family planning issues might be in this Congress' crosshairs

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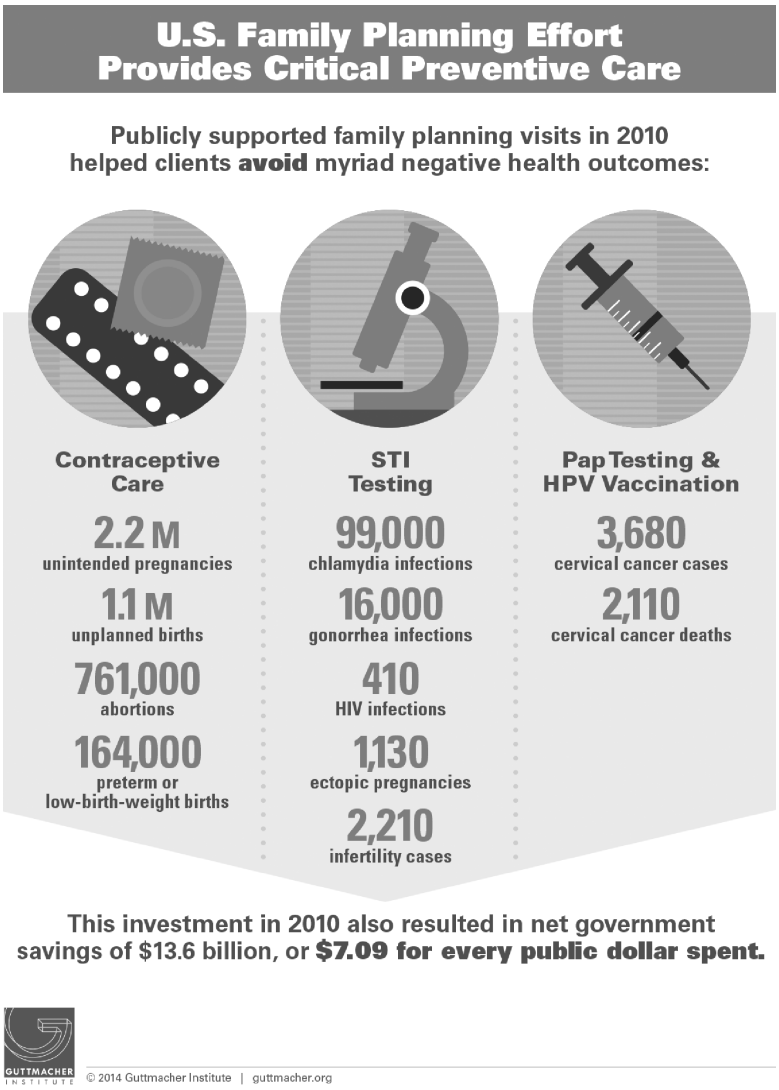
In the wake of the 2014 midterm elections, Congress has shifted decidedly to the political right. When the 114th Congress convenes in January 2015, Republicans will have their largest majority in the House of Representatives since World War II and will control the Senate for the first time since 2007. Most of the remaining Democratic moderates in the Senate have retired or were defeated, which helps to further align Republican office-holders in both chambers with opposition to reproductive rights and Democrats with support for reproductive rights.

Contraception was at issue in many of the congressional campaigns, but in a novel way. By latching onto the idea of moving oral contraceptives over-the-counter, a number of socially conservative politicians had success distracting voters and opinion leaders from their longtime opposition to programs and policies supporting access to affordable family planning care. With the election behind them, it is unclear whether conservatives in Congress have any intention of addressing the over-the-counter issue. That goal has considerable merit and has long been promoted by reproductive health advocates, although those advocates stress that it must be accomplished without compromising affordable access to the full range of contraceptive options and without politicizing the Food and Drug Administration's approval process.[1]

It is also unclear to what extent conservative leaders in Congress will prioritize their existing, hostile positions on family planning policy, such as undermining the Affordable Care Act's (ACA's) contraceptive coverage guarantee, defunding the Title X national family planning program, and barring federal funds from going to safety-net family planning centers that also provide abortion care. It is more certain that conservatives will make repeated attempts to repeal or cripple the ACA more broadly, which would endanger the health coverage that millions of women and men rely on for all of their healthcare, including family planning care. Policymakers



Source: Guttmacher Institute. Accessed at http://bit.ly/1EWc1tN.

and advocates supportive of family planning will spend the next Congress guarding against all of these potential attacks. They also will be working with the Obama administration to strengthen family planning coverage, funding, and programs.

As Congress and the Obama administration evaluate their respective policy priorities heading into the next two years, they should consider the broad range of health benefits that come from publicly funded family planning services, along with the government savings that result. My colleagues and I at the Guttmacher Institute released new evidence in October 2014 to quantify this impact *(See chart, p. 10.)*[2,3]

Nearly nine million U.S. women received publicly supported contraceptive services in 2010.[4] These services helped women prevent an estimated 2.2 million unintended pregnancies and the abortions, unplanned births, and miscarriages that would otherwise have followed. These contraceptive services also helped to prevent poor birth outcomes, including an estimated 164,000 preterm or low-birth-weight births and 288,000 births that would have been spaced more closely than is medically recommended.[2]

Another core piece of publicly funded family planning visits, for female and male clients, is testing for sexually transmitted infections such as chlamydia, gonorrhea, and HIV. Testing leads to early detection and treatment of infections and reduced transmission to partners. These testing services in 2010 helped prevent an estimated 99,000 chlamydia infections,16,000 gonorrhea infections, and 410 HIV infections. Treating clients who tested positive for chlamydia or gonorrhea helped to avoid 13,000 cases of pelvic inflammatory disease, 1,100 ectopic pregnancies, and 2,200 cases of infertility.

Also central to the U.S. family planning effort are cervical cancer prevention services. Pap tests, often performed with human papillomavirus (HPV) tests, detect abnormal cervical cells and cases of precancer, which allows for early treatment that prevents cervical cancer cases and deaths. HPV vaccination protects clients against the most common HPV strains linked to cervical cancer. Combined, the tests and vaccines provided in 2010 prevented an estimated 3,700 cases of cervical cancer and 2,100 cervical cancer deaths.

> "IT IS ... UNCLEAR TO WHAT EXTENT CONSERVATIVE LEADERS WILL PRIORITIZE THEIR EXISTING, HOSTILE POSITIONS ON FAMILY PLANNING POLICY..."

In addition to the health benefits resulting from publicly funded family planning services, this investment resulted in an estimated net public savings of $13.6 billion, or $7.09 saved for every public dollar spent. Services provided at Title X-supported health centers alone account for more than half of the overall health benefits and savings. And because all of these estimates are for 2010, which predates the ACA's expansion to Medicaid and its other key provisions, there is every reason to believe that the impact of publicly funded services is rising. The bottom line should be obvious for Congress and the president: The U.S. investment in family planning services is a wise use of public funds, and it should be supported, not attacked, in 2015 and beyond.

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COMING IN FUTURE MONTHS

- Research eyes vitamin D for repeat vaginal infections
- HIV vaccines in research spotlight
- Contraception options for medically challenging patients
- Science focuses on HPV transmission

CONTRACEPTIVE TECHNOLOGY UPDATE®

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

CNE/CME INSTRUCTIONS

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

1. Read and study the activity, using the provided references for further research.

2. Until Jan. 4, log on to cmecity.com to take a post-test. First-time users must register on the site using the 8-digit subscriber number printed on your mailing label, invoice, or renewal notice. On and after Jan. 5, when logging onto the new AHCMedia.com, go to "MyAHC" and then "My Courses" to view your available CE activities.

3. Pass the online tests with a score of 100%; you will be allowed to answer the questions as many times as needed.

4. After successfully completing the test, your browser will be automatically directed to the activity evaluation form, which you will submit online.

5. Once the completed evaluation is received, a credit letter is e-mailed to you.

CNE/CME QUESTIONS

1. What is the daily release rate of the proposed Levosert intrauterine device?

A. 20 mcg
B. 15 mcg
C. 10 mcg
D. 5 mcg

2. What is the name of the new contoured diaphragm approved in 2014 by the Food and Drug Administration?

A. FemCap
B. Caya
C. Reality
D. Essure

3. What has become recognized as a cause of male urethritis?

A. *Pediculus humanus corporis*
B. *Tinea pedis*
C. *Mycoplasm genitalium*
D. Methicillin-resistant *Staphylococcus aureus*

4. Which two antibiotics impact combined oral contraceptive efficacy?

A. Ampicillin and amoxicillin
B. Metronidazole and doxycycline
C. Erythromycin ethylsuccinate and levofloxacin
D. Rifampin and griseofulvin

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.