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INSIDE

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Time to Update Your Knowledge of Long-Acting Reversible Contraceptives

Practice bulletin says intrauterine, implant options are safe and effective for almost all women

The American College of Obstetricians and Gynecologists (ACOG) has just issued an updated Practice Bulletin, "Long-Acting Reversible Contraception: Implants and Intrauterine Devices" outlining new key data on the safety of long-acting reversible contraception (LARC), such as intrauterine devices (IUDs) and implants.[1] What can family planning clinicians take away from the new guidance?

"The new LARC Practice Bulletin covers some changes since 2011, including better knowledge about effectiveness, candidates, and timing of LARC insertion," says Bulletin author **Eve Espey**, MD, MPH, professor and chair of the department of obstetrics and gynecology at the University of New Mexico School of Medicine. "Through the large amount of LARC research over the last few years, we have learned that IUDs are safe and effective for almost all women, including adolescents and women who have not had a baby, and that LARC methods are well tolerated by all groups of women."

"THROUGH THE LARGE AMOUNT OF LARC RESEARCH OVER THE LAST FEW YEARS, WE HAVE LEARNED THAT IUDS ARE SAFE AND EFFECTIVE FOR ALMOST ALL WOMEN."
— EVE ESPEY, MD, MPH

By reducing barriers to LARC access for appropriate candidates, family planning clinicians may aid in furthering the drop in unintended pregnancy rates in the United States, since

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gaps in contraception use and discontinuation of shorter-acting methods are associated with higher unintended pregnancy rates.[2] Research indicates that typical-use pregnancy rates for LARC methods are lower when compared with those for oral contraceptives.[3] A 2015 cost-effectiveness analysis from the public payer perspective suggests that LARC use becomes cost-neutral within three years of initiation when compared with use of short-acting methods.[4]

"LARC methods have been shown to be 20 times more effective than short-acting methods like the Pill in preventing unplanned pregnancy," observes Espey. "When available free of charge, they are widely chosen by women of all ages and result in a reduction in unintended pregnancy and abortion rates at the population level."[5]

New Data Support Extended Use

The new bulletin highlights recently released data that support extended use for some methods of LARC. Copper IUDs have been shown to be effective for up to 12 years.[6] While the Liletta levonorgestrel (LNG) IUD (18.6 IUD, Medicines360, San Francisco and Actavis, Dublin, Ireland) was approved in August 2017 by the Food and Drug Administration for four years of use, preliminary data suggest extended efficacy of up to five years. The device may be approved for use for up to seven years since its ongoing Phase III trial accumulates yearly effectiveness data. (*Review the data supporting the approval; see the September 2017* Contraceptive Technology Update *article, "Data Indicate Efficacy of Liletta IUD for Four Years' Use," at* http://bit.ly/2zK6cWI.) Data indicate that the Mirena IUD (LNG-20 IUD, Bayer HealthCare Pharmaceuticals, Whippany, NJ), is effective for at least seven years, with a seven-year pregnancy rate of 0.5 per 100 among women using the device.[7]

The Nexplanon etonogestrel implant (Merck, Whitehouse Station, NJ) is effective for at least four years, the bulletin states. Results of a 2016 study reported no pregnancies among 204 women using the etonogestrel implant for five years.[8] Data from a 2017 study reported no pregnancies among 102 study participants who used the implant for five years.[9]

Anita Nelson, MD, professor and chair of the obstetrics and gynecology department at Western University of Health Sciences in Pomona, CA, says that one of the most important take-home messages from the Practice Bulletin is the long-lasting use of the implant, with no caveats about the age of the user or her body mass index.

"This will undoubtedly change practice," states Nelson. "Based on this, women should be offered a fourth year of use, but if she is hesitant to go off-label, both providers and third party payors should be willing to give her a new implant at three years."

When to Initiate LARC Methods

When can women begin to use intrauterine or implant contraception? According to research, an IUD or an implant may be inserted at any point during the menstrual cycle as long as pregnancy may be reasonably excluded.[10] Insertion of LARC immediately after an induced or spontaneous abortion is safe and effective, the bulletin

EXECUTIVE SUMMARY

The American College of Obstetricians and Gynecologists (ACOG) has issued an updated Practice Bulletin, "Long-Acting Reversible Contraception: Implants and Intrauterine Devices," outlining new key data on the safety of long-acting reversible contraception, such as intrauterine devices and implants.

• Copper IUDs have been shown to be effective for up to 12 years, and while the Liletta levonorgestrel -18.6 IUD was approved recently for four years of use, preliminary data suggest extended efficacy of up to five years. Research also indicates the Nexplanon etonogestrel implant is effective for at least four years.

• Postpartum LARC insertion is recognized by ACOG as a best practice due to its role in preventing rapid repeat and unintended pregnancy. The copper IUD should be offered routinely to women who request emergency contraception and are eligible for IUD placement.

notes. The copper IUD should be offered routinely to women who request emergency contraception and are eligible for IUD placement.

Immediate postpartum LARC insertion is recognized by ACOG as a best practice, due to its role in preventing rapid repeat and unintended pregnancy.[11,12] Immediately postpartum is particularly favorable for IUD or implant insertion, the Bulletin states. Placing an IUD within 10 minutes after placental delivery in vaginal and cesarean births or inserting a contraceptive implant prior to discharge home after a hospital admission for delivering a baby has many benefits for the woman, observes Espey. Just-published research indicates that postpartum insertion of a hormonal IUD does not affect a woman's ability to lactate and breast feed.[13]

ACOG's LARC Program has established the Postpartum Contraceptive Access Initiative to provide clinical and operational support training for immediate postpartum LARC implementation. Clinicians can check the initiative's web site, https://pcainitiative.org, for details about the initiative, information about immediate postpartum LARC, and an application to become a participating hospital site.

The Centers for Disease Control and Prevention has established the 6/18 Initiative, a partnership between purchasers, payers, and providers, which considers insurance coverage of immediate postpartum LARC as a way to positively impact both health and costs. The initiative is working to ensure that both public and private payers reimburse for immediate postpartum LARC insertion by unbundling payment for LARC from other postpartum services. (CTU *reported on the move to increase postpartum LARC access; see the May 2017 article, "Implement Resources for Immediate Postpartum LARC to Cut Unintended Pregnancy," at* http://bit.ly/2reIWJ2.) ■

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Intrauterine Device Use Linked With Decrease in Cervical Cancer Incidence

Results of a just-published systematic review indicate that in women who used an intrauterine device (IUD), the incidence of cervical cancer was one-third lower.[1] The analysis is the first to combine data from multiple studies on IUDs and cervical cancer, and it includes data from 16 observational studies involving more than 12,000 women worldwide.

Researchers at the University of Southern California identified studies with individual-level measures of use of an IUD and incident cervical cancer. They extracted point and interval estimates of the association between use of an IUD and incident cervical cancer to develop a structured database, then implemented a random-effects meta-analysis to synthesize extracted estimates and assess likely influence of publication bias, residual confounding, heterogeneity of true effect size, and human papillomavirus prevalence and cervical cancer incidence. The findings suggest that women who used an IUD experienced less cervical cancer (summary odds ratio 0.64, 95% confidence interval, 0.53-0.77). Neither confounding by recognized risk factors nor publication bias seems to be a plausible explanation for the apparent protective effect, researchers note.[1]

Victoria Cortessis, PhD, lead author and associate professor of clinical preventive medicine at the Keck School of Medicine at the university, terms the pattern "stunning."

"The possibility that a woman could experience some help with cancer control at the same time she is making contraception decisions could potentially be very, very impactful," noted Cortessis in a press statement.

Check Previous Data

Results of a 2011 pooled analysis of individual data from two large studies by the International Agency for Research on Cancer, an international collaboration on cancer research, and the Institut Català d'Oncologia, a Spanish-based oncology research program, showed similar protective effects.[2] In that analysis, use of an IUD lowered the risk of cervical cancer by 45%, compared with never using an IUD. The researchers noted that the protective effect was seen in the first year of IUD use and continued for up to 10 years.

In the 2011 analysis, researchers pulled data from 10 case-control studies of cervical cancer done in eight countries and information from 16 human papillomavirus (HPV) prevalence surveys of women in 14 countries. A total of 2,205 women with cervical cancer and 2,214 matched control women without cervical cancer were included from the case-control studies, and 15,272 healthy women were included from the HPV survey.[2]

EXECUTIVE SUMMARY

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- The analysis is the first to combine data from multiple studies on IUDs and cervical cancer, and it includes data from 16 observational studies involving more than 12,000 women worldwide.

The 2011 analysis indicates the chances of developing squamous-cell carcinoma were reduced by 44%, and the risk for adenocarcinoma or adenosquamous carcinoma was lowered by 54%. Although the data in the study suggest that IUD use does not modify the likelihood of prevalent HPV infection, it might affect the likelihood of HPV progression to cervical cancer, researchers note.[2]

More Research Needed

Scientists suggest the process of inserting or removing the device might destroy precancerous lesions. IUD use also might induce chronic mucosal inflammation and a long-lasting immune response that might decrease the likelihood of HPV progression, researchers note.[2] Seven case-control studies around the world have examined the potential association between non-medicated or copper IUD use and the development of endometrial cancer, with six of the seven studies finding protection against endometrial cancer from the devices, noted **David Grimes**, MD, author of the chapter on intrauterine contraception in the 19th revised edition of *Contraceptive Technology*.[3] The protective effect was statistically significant in two of the studies.[4] Two studies have addressed cervical cancer, noted Grimes; both found a 40% reduction in risk associated with IUD use, which was not statistically significant.[3]

"If we can demonstrate that the body mounts an immune response to having an IUD placed, for example, then we could begin investigating whether an IUD can clear a persistent HPV infection in a clinical trial," commented coauthor **Laila Muderspach**, MD, chair of obstetrics and gynecology at the Keck School of Medicine, in a press statement.

According to 2017 estimates from the Atlanta-based American Cancer Society, about 12,820 new cases of invasive cervical cancer will be diagnosed, while some 4,210 women will die from cervical cancer.[5] Although cervical cancer was once one of the most common causes of cancer death in U.S. women, the cervical cancer death rate has gone down by more than 50% during the past 40 years. The increased use of the Pap test, which can identify changes in the cervix before cancer develops, is the primary reason for the change in the cervical cancer death rate.[5]

Global statistics paint a sobering picture. According to the World Health Organization, about 528,000 women were diagnosed with cervical cancer worldwide in 2012, and 266,000 women died from the disease.[6]

In developing countries with rapidly-increasing populations and scarce cancer prevention resources, such as the HPV vaccine and regular cervical screenings, a contraceptive that offers protection against cervical cancer could have a "profound" effect, says Cortessis. Many women in the developing world are about to enter the age range where the risk for cervical cancer is the highest, she notes.

"Even if the rate of cervical cancer remains steady, the actual number of women with cervical cancer is poised to explode," Cortessis said in the release. "IUDs could be a tool to combat this impending epidemic." ■

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Research Update: Human Papillomavirus Vaccine Safe for Adult Women

In a study of more than 3 million adult women in Denmark and Sweden, results indicate that human papillomavirus (HPV) vaccination was not connected with 44 serious chronic diseases.[1] These findings expand the HPV vaccine knowledge base, since the majority of post-licensure evidence comes from young adolescents targeted by immunization guidelines.

"This is the most comprehensive study of HPV vaccination safety

in adult women to date," said lead author **Anders Hviid**, MSc, DMSc, senior investigator in the Department of Epidemiology Research at the Statens Serum Institut in Copenhagen, Denmark, in a press statement. "It is not unreasonable to expect different safety concerns in adult women compared with young girls, and our study is an important supplement to the safety studies in young girls."

In conducting the cohort study, researchers looked at Danish and Swedish nationwide healthcare registers to compare incidence rate ratios (RRs) of 45 preselected serious chronic diseases in quadrivalent HPV-vaccinated and unvaccinated adult women ages 18-44. A total of 3,126,790 women (1,195,865 [38%] Danish and 1,930,925 [62%] Swedish) were followed for 16,386,459 person-years. Scientists looked for diseases or conditions such as epilepsy, paralysis, lupus, psoriasis, type 1 diabetes, rheumatoid arthritis, thyroid issues, and Crohn's disease.

After taking multiple testing into account and conducting self-controlled case series analyses, celiac disease (RR 1.56; 95% confidence interval, 1.29-1.89) was the only remaining association, the analysis suggests.[1] The increased risk association with celiac disease, an autoimmune condition triggered by dietary gluten, was observed only in Denmark. Because previous research indicated that celiac disease is underdiagnosed in the general adult population in Denmark, scientists surmise the findings may be a result of unmasking a pre-existing disease.[2]

Immunize Adult Women

Adult women also are receiving HPV vaccination through catch-up programs or by choice at their own expense. How important is it that woman ages 18-26 be vaccinated for HPV?

HPV vaccination is the best way to protect against cancers and other diseases caused by HPV infections, notes **Lauri Markowitz**, MD, HPV Team Lead in the Centers for Disease Control and Prevention's National Center for Immunization and Respiratory Diseases' Division of Viral Diseases.

"Every year in the United States, over 31,000 women and men are diagnosed with a cancer caused by persistent HPV infection," says Markowitz. "Most of these cancers could be prevented by HPV vaccination."

Vaccination also can prevent testing and treatment that is uncomfortable, even for cervical precancers, notes Markowitz. Each year in the United States, more than 300,000 women undergo invasive testing and treatment for lesions on the cervix that can develop into cancers.[3] Markowitz says that the testing and treatment for these precancers can have lasting effects.

"In the 10 years since HPV vaccine was introduced, we have seen that it works extremely well," Markowitz comments. "Since the vaccine was introduced, infections with the HPV types that cause most of these cancers and genital warts has dropped by 71% among teen girls ages 14-19 and 61% among young women ages 20-24."[4]

Follow the Schedules

Do you know the schedule when it comes to HPV vaccinations? Routine HPV vaccination is recommended at 11 or 12 years of age, says Markowitz. The vaccine will provide the most protection when it is administered in early adolescence before exposure to HPV, she says. HPV vaccination also is recommended for girls and women through age 26 who were not adequately vaccinated previously, says Markowitz.

"People who start the vaccination series after their 15th birthday need three doses instead of two to be protected against cancers caused by HPV," says Markowitz. "Women should also start getting regular Pap tests at age 21 to screen for cervical cancers and precancers."

In October 2016, the Advisory Committee on Immunization Practices approved the following HPV immunization schedule:

- Adult females through age 26 and adult males through age 21 who have not received any HPV vaccine should receive a three-dose series of HPV vaccine at zero, one to two, and

EXECUTIVE SUMMARY

In a study of more than 3 million adult women in Denmark and Sweden, results indicate that human papillomavirus (HPV) vaccination was not connected with 44 serious chronic diseases.

- These findings expand the HPV vaccine knowledge base, since the majority of post-licensure evidence comes from young adolescents targeted by immunization guidelines.
- Every year in the United States, more than 31,000 women and men are diagnosed with a cancer caused by persistent HPV infection. Adult women up to age 26 who have not previously received the HPV vaccine need three doses instead of two to be protected against cancers caused by HPV.

six months. Males ages 22-26 years may be vaccinated with a three-dose series of HPV vaccine at zero, one to two, and six months.

• Adult females through age 26 and adult males through age 21 (and males ages 22-26 years who may receive HPV vaccine) who the initiated HPV vaccination series before age 15 and received two doses at least five months apart are considered adequately vaccinated and do not need an additional dose of HPV vaccine.

• Adult females through age 26 and adult males through age 21 (and males ages 22-26 who may receive HPV vaccine) who initiated the HPV vaccination series before age 15 years and received only one dose, or two doses less than five months apart, are not considered adequately vaccinated and should receive one additional dose of HPV vaccine.[5] ■

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Counsel Women About Contraception Guidelines After Bariatric Surgery

Just-published research indicates that although women should avoid conception for the first 18 months following bariatric surgery, 42% of women participating in the 10-site study reported having unprotected intercourse during this at-risk post-surgical timeframe.[1]

The Centers for Disease Control and Prevention estimate that 36.4% of U.S. women 20 years of age and older are obese (body mass index [BMI] of 30 or higher).[2] Bariatric surgery is considered for those patients who have one of the following:

• BMI at or above 40;

• BMI 35 and up in association with major co-morbidities, such as severe sleep apnea, Pickwickian syndrome, or obesity-related cardiomyopathy;

• BMI of 35 and up in association with obesity-induced physical problems with lifestyle, including joint disease or body size problems interfering with employment, family function, and ambulation.[3]

The Gainesville, FL-based American Society for Metabolic and Bariatric Surgery recommends that women avoid conception for the first year and a half following weight-loss surgery so that the fetus is not affected by the woman's quick weight loss and so that the patient can reach her weight-loss goals.[4] However, in the current study, which used data collected through the National Institutes of Health-funded Longitudinal Assessment of Bariatric Surgery consortium, 4% of women were actively trying to become pregnant and an additional 42% reported having unprotected intercourse during the post-surgical timeframe.

Lead author **Marie Menke**, MD, assistant professor of obstetrics, gynecology, and reproductive sciences at the University of Pittsburgh School of Medicine and Magee-Womens Hospital, says the findings are "concerning," since recent research suggests that bariatric surgery increases the risk for small-for-gestational-age newborns, preterm deliveries, and neonatal intensive care unit admissions in the first 18 months after surgery.[5]

"Our findings highlight a public health issue that merits additional scrutiny regarding contraceptive counseling before and after surgery, and provision of contraceptive services for all reproductive-age women undergoing bariatric surgery," Menke said in a press statement.

Review the Results

To perform the study, University of Pittsburgh researchers examined post-surgery contraceptive practices and conception rates by gathering information from the Longitudinal Assessment, which includes adults seeking first-time bariatric surgery at 10 U.S. hospitals. Women ages 18-44 with no history of menopause, hysterectomy, or estrogen and progesterone therapy were enrolled between 2005 and 2009. Participants completed preoperative and annual postsurgical assessments for up to seven years until January 2015. Primary outcomes included self-reported contraceptive practices, overall conception rate, and early (less than 18 months) postsurgical conception.[1]

Among all women in the study, first-year prevalence of intrauterine contraception was 9%, researchers report. Oral contraceptives were used by 11%. Despite a Category 3 (risks outweigh benefits) ranking by the U.S. Medical Eligibility Criteria for Contraceptive Use, 21% of those with a Roux-en-Y gastric bypass reported use of pills. Within the first 18 months after bariatric surgery, the conception rate was 4.2 per 100 woman-years.[1]

Counsel Before and After Surgery

Contraceptive counseling both before and after bariatric surgery are critical pieces of the multidisciplinary needs of the bariatric patient, noted **Anita Courcoulas**, MD, MPH, FACS, director of minimally invasive bariatric and general surgery at Magee-Womens Hospital.

"This study clearly shows that early conception rates and contraceptive practices after bariatric surgery are not ideal," said study co-author Courcoulas in a press statement. "The findings highlight the need for more frequent referral to counseling for contraception guidance throughout the bariatric surgery process."

The two approaches to bariatric surgery are restrictive and restrictive/malabsorptive surgeries. The most common restrictive procedure is adjustable gastric banding. The Roux-en-Y gastric bypass is the most common restrictive/malabsorptive procedure. For women who have undergone restrictive bariatric surgery, the U.S. Medical Eligibility Criteria for Contraceptive Use, 2016, rates all methods (combined hormonal ring, patch, and pills; contraceptive injection; the Copper-T and levonorgestrel intrauterine devices; progestin-only pills and progestin implant) as Category 1: "a condition for which there is no restriction for the use of the contraceptive method."[6]

However, after malabsorptive bariatric surgery, for use of combined hormonal pills or progestin-only pills, the guidance issues a Category 3 rating: "a condition for which the theoretical or proven risks usually outweigh the advantages of using the method."[6] The reason for the Category 3 rating is that research suggests malabsorption of oral contraceptive hormones, as well as uncertainty about whether such malabsorption translates to decreased efficacy.[7] ■

EXECUTIVE SUMMARY

Just-published research indicates that while women should avoid conception for the first 18 months following bariatric surgery, 42% of women participating in the 10-site study reported having unprotected intercourse during the 18-month at-risk, post-surgical timeframe.

• Recommendations call for women to avoid conception for the first year and a half following weight-loss surgery so that the fetus is not affected by the woman's quick weight loss and so that the patient can reach her weight-loss goals. However, 4% of women in the current study were actively trying to become pregnant and an additional 42% reported having unprotected intercourse during the post-surgical timeframe.

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Griffithsin Considered as Potential Multipurpose Prevention Technology Option

Researchers now are focusing on an investigational multipurpose prevention technology comprised of griffithsin, a naturally occurring algae protein, in a carrageenan gel. While research is in the early stages, the combination approach may lead to a new option to prevent HIV and STIs in an on-demand or sustained use format.

Scientists at the New York City-based Population Council have begun enrolling women in a Phase I trial, conducted at the Albert Einstein College of Medicine in the Bronx, NY. A total of 27 women ages 18-49 will be enrolled. Seven women will take part in an open-label period and will receive a single dose of the griffithsin/carrageenan gel formulation. Data from this initial trial will inform the randomized, placebo-controlled safety, pharmacokinetics, and pharmacodynamics assessment of the formulation. Twenty women will be randomized to receive either the formulation or a placebo gel; all will use a gel product once daily for 14 days. Results are expected in 2018.

Initially discovered by scientists at the Center for Cancer Research at the National Cancer Institute, griffithsin is a potent anti-HIV agent that has been found to be safe and effective when tested against HIV and herpes simplex virus-2 (HSV-2) in animal studies.[1]

"Griffithsin's mode of action and the fact that it is not used in HIV treatment means there is no risk that users of a griffithsin-prevention product could develop cross-resistance to ARVs [antiretroviral drugs] that are used for treatment," said **George Creasy**, MD, medical director at the Population Council's Center for Biomedical Research, in a press statement. "This may increase the possibility that a griffithsin multipurpose prevention technology could become an over-the-counter product and increase access for people in high-demand, low-resource settings."

The Population Council plans to pursue multiple delivery methods for griffithsin, including inserts that dissolve quickly and intravaginal rings, to provide on-demand and sustained protection. Additional methods of delivery may be developed by agency scientists in the future.

"Multipurpose products that prevent sexually transmitted infections, including HIV, must be a research and development priority," said **James Sailer**, MPP, vice president and executive director of the Center for Biomedical Research at the Population Council. "We are excited to be enrolling participants in the first trial of a griffithsin-containing multipurpose prevention technology, which could be an important addition to the HIV and STI prevention toolbox."

HIV prevention efforts have proven effective in the United States: The number of new infections has dropped since the peak of the epidemic in the mid-1980s, and an overall stabilization of new infections has been seen in recent years.[2] Currently, methods to prevent HIV include abstinence, condoms, and pre- and post-exposure prophylaxis with antiretrovirals.

However, there is concern that using ARV-based products for HIV prevention could promote the development or spread of drug-resistant HIV strains that would compromise subsequent treatment with ARVs.[3] High rates of drug resistance in a population could make the spread of drug resistance

EXECUTIVE SUMMARY

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easier and eventually reduce the effectiveness of ARVs in treatment and prevention.

Griffithsin is one product in the early stages of development as a multipurpose option. Other potential products include protection against unintended pregnancy/HIV/HSV-2 (herpes), unintended pregnancy/chlamydia/gonorrhea/HIV/ HSV-2 (herpes), and HIV/HSV-2 (herpes)/human papillomavirus, formulated in vaginal rings, gels, and fast-dissolving vaginal inserts and films. (*See all methods now under development at the Initiative for MPTs' website,* http://www.theimpt.org.)

Young women in the United States are interested in multipurpose prevention technology (MPT) options that are safe and effective, with a preference for protection against HIV and HSV, according to results from a recent cross-sectional online survey.[4]

Women who participated in the survey were ages 18-29, U.S. residents, and had engaged in sexual activity with a male partner in the past three months. Results of the survey indicate that women desired protection from HIV (86.6%), followed by herpes simplex virus (HSV, 41.1%) and human papillomavirus (21.9%). Protection from gonorrhea (10.8%) and chlamydia (12.7%) were seen as least important.

What type of prevention options would women like? Survey findings indicate that many women would prefer injectables (45.6%), followed by vaginal gels (33.7%), vaginal rings (26.3%), and diaphragms (17.3%). Safety and efficacy in preventing pregnancy were the most important factors when choosing a multipurpose prevention option.[4]

"While injectables are most highly desired, many women would use vaginal/topical methods," researchers say. "These preferences must be considered as MPT development continues to ensure acceptance among young women, an important target demographic, in the United States." ■

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WASHINGTON WATCH

New Rules Undermine Federal Contraceptive Coverage Guarantee

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In October 2017, the Trump administration took long-expected steps to undermine the Affordable Care Act's (ACA) contraceptive coverage guarantee.[1,2] The pair of regulations it issued — which took effect immediately, before the standard public comment period — implemented part of President Trump's May 2017 executive order on "religious liberty."[3] The regulations leave the coverage guarantee in place, but greatly extend exemptions for employers, schools, individuals, and insurers that express religious or moral objections to some or all contraceptive methods and services.

As a reminder, the ACA provision requires that private health insurance plans in the United States cover dozens of preventive care services without copayments, deductibles, or any other patient out-of-pocket costs. This applies to plans sold to employers, schools or individuals, or those that are offered by employers that self-insure. The list of covered services includes 18 distinct contraceptive methods used by women, along with contraceptive counseling, services that are needed to start or stop a method, and follow-up care.[4] The largest exception to all of these coverage requirements is for "grandfathered" plans, which are plans that predated the ACA and have not changed substantively; just 17% of covered workers were enrolled in these grandfathered plans in 2017.[5]

Beyond that, the Obama administration had granted an exemption from the contraceptive coverage requirement to a limited group of religious employers, mainly houses of worship. Other

nonprofit employers and closely held for-profit employers that have religious objections were given an "accommodation," which allowed the employer to refuse to pay for contraceptive coverage, arrange for it, or even talk about it, but still ensured that employees and their dependents could receive that coverage from the insurance company directly. In response, dozens of companies filed lawsuits demanding broader exemptions on religious and, in a few cases, moral grounds.[6]

The new Trump administration regulations were designed to negate all of those lawsuits. Any employer with a religious objection now may exclude some or all contraceptive methods and services from the health insurance plans it sponsors. Almost any employer (as long as it is not publicly traded) with a moral objection may do the same. Colleges and universities have the same options for the health plans they sponsor for students. Employers and schools still may use the accommodation, but that is optional. The regulations also provide for limited exemptions for religious and moral reasons for individuals and insurance companies.

As of mid-November 2017, only a handful of employers and schools had publicly announced that they would make use of the new exemptions, and the potential impact of the Trump regulations was unclear. The clearest impact is for the employees, students, and dependents of the employers and schools that had sued the Obama administration. Shortly after the new regulations were issued, the Trump administration began settling those lawsuits and granting the plaintiffs a permanent exemption — even if the new regulations are eventually reversed.[7]

Less clear is what will happen with the numerous employers and schools that had been making use of the old accommodation: That includes 3% of U.S. nonprofits and 10% of the largest nonprofits, according to a 2015 study.[8] If those thousands of employers and schools decide to claim a full exemption, their employees, students, and dependents would lose contraceptive coverage.

Finally, under the old rules, publicly traded companies and entities with moral objections were not eligible even for the accommodation, but now may claim full exemptions. How many will do so is a complete unknown. Yet, without clear standards or procedures for claiming an exemption and without any mechanisms of oversight or methods that affected employees and students could use to appeal a claim, the new regulations offer considerable potential for abuse.

The possible harm of the new regulations might be mitigated by several factors. Notably, more than half of the states have their own contraceptive coverage requirements, and some of the most recent state laws echo the federal requirement by covering the full range of methods and barring out-of-pocket costs.[9] State laws cannot affect plans that are offered by employers that self-insure, but these protections will matter for people enrolled in other health insurance plans. Moreover, schools and employers will face pressures, both internal and external, to maintain contraception coverage, and might have financial incentives to help employees avoid the costs and disruption of unplanned pregnancies.

Finally, the regulations themselves could be changed or reversed. Although the regulations took effect immediately, the Trump administration still is required to offer a public comment period (closing on Dec. 5, 2017); however, if the administration does make changes in response to public comments, it seems more likely to expand the exemptions than to narrow them. Another potential avenue for change is via the courts: As of mid-November 2017, at least eight lawsuits had been filed against the new regulations, including two cases in which state attorneys general have requested preliminary injunctions. ■

(*Editor's Note: Adam Sonfield's employer, the Guttmacher Institute, filed a declaration in support of one of those lawsuits.*)

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CME/CE QUESTIONS

1. **What is the current approved effective use of the levonorgestrel–18.6 IUD (Liletta)?**
   a. Three years
   b. Four years
   c. Five years
   d. Seven years

2. **What is the U.S. Medical Eligibility Criteria for Contraceptive Use, 2016, rating of combined hormonal pills or progestin-only pills after malabsorptive bariatric surgery?**
   a. Category 1
   b. Category 2
   c. Category 3
   d. Category 4

3. **What is the recommended number of doses of the HPV vaccine for adult women through age 26 who have not received any HPV shots?**
   a. One
   b. Two
   c. Three
   d. Four

4. **What is the active agent in the multipurpose prevention technology option now in development by the Population Council?**
   a. Dolutegravir
   b. Lamivudine
   c. Tenofovir
   d. Griffithsin

CME/CE 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.