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INSIDE

Contraceptive vaginal ring: Researchers examine new option 76

HIV: ART prevents sexual transmission in discordant gay male couples 77

HPV vaccination: How clinicians can overcome barriers 79

Endometriosis: Research focuses on use of metronidazole for treatment 80

Guest Column: Contraception is more than birth control 82

Enclosed in this issue:

STI Quarterly: Time to close gaps in HIV testing, treatment; drug combination examined for treatment-resistant gonorrhea

RELIAS MEDIA

LARC Contraceptives: Remove the Barriers

Survey indicates many clinicians still are not offering same-day insertions

Use of long-acting reversible contraceptives (LARCs) has grown in the United States, but new research indicates that many practitioners still are not providing LARC methods on the same day women choose them.[1] Findings from the new study also suggest providers are failing to provide LARC options immediately postpartum.[1]

According to the latest data, LARC methods now account for 10.3% of women currently using contraception, compared to 12.6% for the Pill and 18.6% for sterilization.[2] Whether a patient chooses the intrauterine device (IUD) or contraceptive implant, she should be offered the option to begin her chosen LARC birth control method at the time of the office visit rather than waiting for her next period or returning for another appointment.[3] There is no medical reason for providers to routinely require multiple visits to begin any contraceptive method if the U.S. Selected Practice Recommendations for Contraceptive Use criteria for excluding pregnancy are met.[4]

The use of LARC in the postpartum period is safe, according to the *US Medical Eligibility Criteria for Contraceptive Use*. This guidance classifies immediate postpartum initiation of IUDs and implants as Category 1 (no restriction for use) or Category 2 (advantages generally outweigh theoretical or proven risks).[3]

However, not all clinicians are putting the guidance into practice. Findings from a recent survey of American College of Obstetricians and Gynecologists (ACOG) members indicate that although 91% of respondents said they provided IUDs, just 29% provided same-day placement. Nineteen percent indicated they offered immediate postpartum IUD placement and 21% said they offered immediate postpartum implant placement.[1]

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These results mirror those of a similar telephone survey of Family PACT providers' offices in Los Angeles County, where only about 5% of telephone respondents said clinics offered same-day placement, notes **Anita Nelson**, MD, professor and chair of the obstetrics and gynecology department at Western University of Health Sciences in Pomona, CA.

Robert Hatcher, MD, MPH, professor emeritus of gynecology and obstetrics at Emory University School of Medicine in Atlanta, notes that Eva Lathrop, MD, MPH, and Denise Jamieson, MD, MPH, trained physicians and their office staff to provide contraceptives to 29,000 women throughout Puerto Rico. A remarkable 96% of women received their contraceptive on the first day they were seen by the clinic; 70% of women received an implant, a levonorgestrel IUD, or a copper IUD.

"If access to contraceptives the first time a patient is seen becomes a priority for a family planning program, the percentage of women receiving their contraceptives the day they indicate they want it will rise dramatically," Hatcher states.

Are Political Moves Driving Interest?

Will clinicians be seeing more women choosing LARC methods in light of President Donald Trump's promise to make the 2020 election a referendum on the Affordable Care Act (ACA)? To check this hypothesis, researchers from the University of California San Diego monitored Google searches from the United States for the three most popular reversible methods of contraception (oral contraceptives, IUDs, and condoms) from Jan. 1, 2004, through Oct. 31, 2017.

The results indicate that IUD searches were cumulatively 15% higher (95% confidence interval [CI], 10-20) than expected in the year after the 2016 election, which reflected 10 million to 21 million extra searches. Searches for IUDs were statistically significantly higher in all states except Nevada, and they were consistent across states won by Trump or Clinton. The researchers reported that following the election, searches for oral contraceptives and condoms were stable (0%; 95% CI, -2 to 1) or decreased (-4%; 95% CI, -5 to -2), respectively.[5]

Under the ACA, most private insurance plans have been required to cover all Food and Drug Administration-approved contraception methods without cost-sharing since the 2013 plan year. A recent analysis of private insurance claims from 2006 to 2014 for women 13 to 45 years of age identified a small but statistically significant increase in LARC device insertions after the contraceptive mandate went into effect.[6]

"Women's interest in IUDs appears to be a hedge against ACA repeal by providing long-term family planning," says **Alicia Nobles**, PhD, MS, a data scientist at the University of California San Diego and lead author of the research.

The patterns in search trends for contraception revealed by this research appear to mirror the political debate on Capitol Hill. For instance, searches for IUDs reached a record high in May 2017, with 8.3 million searches, when legislation for a repeal of the ACA advanced in the House of Representatives, said Nobles in a press statement.

Research Examines Long-Term Effectiveness

Women who choose LARC methods may find that their

EXECUTIVE SUMMARY

Despite guidance stating that a patient should be offered the option to begin her chosen long-acting reversible contraception birth control method at the time of the office visit rather than waiting for her next period or returning for another appointment, just 29% of clinicians say they provide same-day placement.

- Although use of long-acting reversible contraception in the postpartum period is safe, 19% of providers say they offer immediate postpartum IUD placement, with 21% offering immediate postpartum implant placement.
- Scientists have just presented new six-year data from an ongoing multicenter clinical trial of the Liletta IUD, indicating that the device provides effective contraception for that time period. The IUD's manufacturer is seeking approval for a new label indication for the device.

devices provide effectiveness past their labeled indications. Scientists have just presented new six-year data from an ongoing multicenter clinical trial of the Liletta IUD at ACOG's 2019 Annual Clinical and Scientific Meeting in Nashville.[7] The device, which is similar in size to the Mirena IUD, was approved by the federal Food and Drug Administration (FDA) in February 2015. Initially labeled for three years of effective use, Liletta gained FDA approval for five years of effective use in 2018. The newly presented research is part of the company's efforts to seek approval to relabel the device for six years of effective use.

Investigators shared Pearl Index and life-table analysis information from the ongoing ACCESS IUS (A Comprehensive Contraceptive Efficacy and Safety Study of an IUS) trial. Data indicate the pregnancy rate, calculated as the Pearl Index, in the first year was 0.15 among women who were 16 to 35 years of age when they enrolled in the study. At six years, the cumulative life-table pregnancy rate was 0.87.[7]

The ACCESS IUS trial includes U.S. women ages 16 to 45 years, women who have given birth and those who have not, as well as obese and non-obese women. According to the presented information, two perforations following IUD placement were diagnosed within the first year, with no additional perforations reported in the trial to date. Expulsions have occurred in 4% of patients (68 participants), with most (73.5%) diagnosed during the first year. Fifteen women (0.9%) were diagnosed with pelvic infection, with most of the infections (73.3%) occurring after six or more months of device use. Forty women (2.3%) discontinued use because of bleeding complaints, with 75% of these discontinuations occurring in the first two years.[7]

"These latest clinical findings from ACCESS IUS are encouraging as they further reinforce Liletta's effectiveness and safety for pregnancy prevention in a broad range of women," said **Jessica Grossman**, MD, chief executive officer of Medicines360. "These data were included in our recent U.S. regulatory submission requesting approval of Liletta for up to six years of use." ■

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Researchers Investigate Contraceptive Vaginal Ring

When it comes to contraception, more women are considering the contraceptive vaginal ring. According to national statistics, 6% of U.S. women had used the contraceptive ring during 2006-2010, behind the contraceptive injectable and the contraceptive patch.[1]

Currently available contraceptive rings offer effectiveness rates that are similar to or slightly better than the Pill. The rings also do not require the user to remember to take them daily and allow the user to control initiation and discontinuation of the contraceptive.[2] Two contraceptive rings currently are available in the United States. Annovera, a soft, reusable, flexible silicone ring containing segesterone acetate and ethinyl estradiol, was approved by the U.S. Food and Drug Administration (FDA) in 2018. Left in place for 21 days and removed for seven days each cycle, it is indicated to prevent pregnancy for up to one year. Clinicians are more familiar with NuvaRing, which was approved in 2001. NuvaRing releases a combination of etonogestrel and ethinyl estradiol from a ring made of ethylene vinyl acetate copolymers. Each ring is designed for three weeks of continuous use, with a one-week break, followed by insertion of a new ring.

Scientists are investigating a nonhormonal monthly ring (Ovaprene) as a potential contraceptive. The device involves a permeable mesh in the center of the ring that creates a partial barrier to sperm and locally acting spermiostatic agents to create an inhospitable environment for sperm. Daré Bioscience of San Diego has received a grant providing up to $1.9 million for research of the ring from the Eunice Kennedy Shriver National Institute of Child Health and Human Development.

The company initiated a post-coital clinical trial in 2018 designed to assess general safety, acceptability, and effectiveness in preventing progressively motile sperm from reaching the cervical canal following intercourse. The study's design calls for enrollment of 50 couples, with the woman to be evaluated over the course of five menstrual cycles; investigators plan to have at least 25 women complete a total of 21 visits. Each woman's cervical mucus will be measured at several points during the study, including a baseline measurement at the first menstrual cycle that excludes the use of any product. Subsequent cycles and visits will include the use of a diaphragm for the second menstrual cycle, and the Ovaprene vaginal ring for the third, fourth, and fifth cycles. Data from the study are expected to be available in the second half of 2019.

Many women are seeking alternatives to traditional hormone-based options, notes study investigator **Andrea Thurman**, MD, professor of obstetrics-gynecology at CONRAD/Eastern Virginia Medical School. Although an effective long-acting, implanted, nonhormonal contraceptive is available, half of contraceptive users prefer a short-acting method, she notes.

"We don't have an effective short-acting, nonhormonal method that does not require intervention at the time of intercourse to offer these women," said Thurman in a press statement. "The opportunity to address this unmet need is compelling."

Method Offers a Simple Regimen

While the contraceptive vaginal ring offers comparable efficacy, risks, and benefits as other combined hormonal methods, it also provides the simplest regimen.[3] In clinical trials of the etonogestrel and ethinyl estradiol ring, 85% of women were satisfied with the ring, and 90% would recommend its use to others.[4]

Adverse effects associated with the method also are similar to hormonal methods, with the additional vaginal symptoms of discharge, discomfort, and problems related to the device.[5] Clinicians may consider the etonogestrel and ethinyl estradiol ring for extended use. Although it is labeled

EXECUTIVE SUMMARY

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• Currently available contraceptive rings offer effectiveness rates that are similar to or slightly better than the Pill. Users can control initiation and discontinuation of the ring and they do not have to remember to take the ring on a daily basis.

for 28 days of use, the ring contains enough medication to be used for up to 35 days, allowing it to be replaced once every calendar month.[6]

Results of studies presented at the recent American College of Obstetricians and Gynecologists 2019 Annual Meeting indicate that the segesterone acetate/ethinyl estradiol ring is a highly effective contraceptive option that lasts for an entire year and can be inserted and removed by the patient each cycle.[7,8] Data show a high level of user satisfaction. Women who used the device for up to 13 cycles did not experience any unexpected safety findings, and only 1.7% of women discontinued use because of irregular bleeding.[7,8] ■

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Antiretroviral Treatment Prevents Sexual Transmission of HIV in MSM

New research indicates that antiretroviral treatment that leads to viral suppression prevents sexual transmission of HIV between discordant gay male couples as well as it does among heterosexual couples.[1] While earlier studies had provided evidence of the effect of antiretroviral therapy (ART) on the risk of HIV transmission between heterosexual mixed-status couples (where one partner was HIV-positive and the other was HIV-negative), limited data have been available on ART's effectiveness at preventing HIV transmission in discordant gay couples.[2,3]

The new results reported from the PARTNER2 trial mirror those observed in previous studies, which indicated that antiretroviral treatment that leads to viral suppression prevents sexual transmission of HIV between discordant gay male couples as well as it does among heterosexual couples. Investigators noted that the current study offers an important finding, since anal sex carries a higher risk of transmission than vaginal sex.

The current study "unequivocally" demonstrates the concept of Undetectable = Untransmittable (U=U), which is integral to the four strategies of the national campaign for ending the HIV epidemic in the United States, says **Carl Dieffenbach**, PhD, director of the Division of AIDS at the National Institute of Allergy and Infectious Diseases.

"These strategies include getting more people tested and, if they test positive, into HIV care and on treatment," said Dieffenbach in a press statement. "When a person with HIV is in care and HIV treatment durably suppresses their viral load, three important things happen — he or she can live a long and healthy life, he or she won't transmit the virus, and finally, the stigma that has long been associated with HIV diminishes."

Review the Results

The PARTNER2 trial was launched following the 2016 report of the initial PARTNER study, in which researchers enrolled 1,166 serodifferent couples at 75 sites in 14 European countries between 2010 and 2014.[3] The original study included 340 gay couples. Since the estimate for HIV transmission among gay couples was less precise than the estimate of transmission for heterosexual couples because of the lower number of

EXECUTIVE SUMMARY

New research indicates that antiretroviral treatment that leads to viral suppression prevents sexual transmission of HIV in discordant gay male couples as well as it does among heterosexual couples.

- While earlier studies had provided evidence of the effect of antiretroviral therapy (ART) on the risk of HIV transmission between discordant heterosexual mixed-status couples (where one partner was HIV-positive and the other was HIV-negative), limited data have been available on ART's effectiveness for preventing HIV transmission in discordant gay couples.
- A total of 782 couples provided results over 1,593 couple-years of follow-up. The investigators reported no episodes of HIV transmission from the HIV-positive partners to their HIV-negative sexual partners.

accrued couple-years of follow-up, the investigators launched the PARTNER2 study.

From 2014 to 2017, the researchers continued recruiting 495 additional gay couples to participate in the PARTNER2 study. In the PARTNER2 trial, the HIV-positive partner in each couple was on treatment and had regular laboratory tests to confirm a viral load of less than 200 copies/mL. Investigators checked that the HIV-negative partner was tested regularly for HIV. All couples engaged in sex without condoms and without the HIV-negative partner using HIV pre- or post-exposure prophylaxis.

A total of 782 couples provided evaluable results over 1,593 couple-years of follow-up. This included 76,088 self-reported episodes of anal intercourse without using condoms. The researchers reported no episodes of HIV transmission from the HIV-positive partners to their HIV-negative partners.[1] Although 15 people became infected with HIV during the study, virus screening showed that none of the new infections were linked to the HIV-positive partners in the study, but came from a sexual partner outside of the couple. Investigators estimated that within the study, which took place across 14 European countries, around 472 HIV transmissions were averted over the eight years of the trial.[1]

Time to Act Is Now

Alison Rodger, MD, professor at the University College London's Institute for Global Health and lead author of the study, says the current paper provides "conclusive evidence" for gay men that the risk of HIV transmission with suppressive ART is zero.

"Our findings support the message of the international U=U campaign, that a suppressed viral load makes HIV untransmittable," said Rodger in a press statement. "This message has been endorsed by more than 780 HIV organizations in 96 countries and can help end the HIV pandemic by preventing HIV transmission, and tackling the stigma and discrimination that many people with HIV face."

Public health officials now must strive to make sure that all HIV-positive people have access to testing, treatment, support for adherence, and linkage to care to help patients maintain an undetectable viral load, Rodger said.

"It is crucial to implement science with importance for the involved community and people living with HIV," said **Jens Lundgren**, MD, professor of infectious diseases at Rigshospitalet, University of Copenhagen and co-investigator in the PARTNER study. "We have now provided the conclusive scientific evidence for how treatment effectively prevents further sexual transmission of HIV." ■

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Overcome Barriers to HPV Vaccination

What are the barriers to human papillomavirus (HPV) vaccination, and what strategies work best to increase vaccine uptake? A new analysis of a national survey underscores the importance of continued efforts to strengthen practitioner adoption of evidence-based approaches to recommending the HPV vaccine.[1]

Although more teens are receiving the HPV shot, public health officials say there is room for improvement. Data indicate that a little over half (51%) of adolescents have not received the full series of injections. Location plays an important role: Results of a 2018 analysis indicate that fewer teens in rural areas are getting the HPV shot compared to adolescents in urban areas. Statistics suggest that the number of rural teens who received the first dose of the HPV vaccine lagged 11 percentage points lower than the number in urban areas.[2]

To perform the current study, investigators examined responses in a sample of pediatricians and nurse practitioners from 19 states who participate in the American Academy of Pediatrics' (AAP) primary care practice-based research network. As part of the National Institutes of Health's STOP HPV trial, respondents completed an online, confidential survey that measured office characteristics, standard office procedures for and communication about HPV vaccination, and use of evidence-based strategies such as performance feedback, prompts, reminder-recall, and standing orders.

Results of the survey indicate that all respondents reported more than one barrier to HPV vaccination. More than 80% of respondents said that parental refusal or parental influence to delay was their major barrier to immunization. About 30% (range, 5% to 75%) of parents of children ages 11-12 years who were due for an HPV vaccine refused and 15% (range, 5% to 60%) hesitated without refusing. Other major barriers included the time required to discuss HPV vaccination with families (17% of practitioners), a low proportion of adolescents coming in for well visits (13%), a lack of training in providing a strong recommendation (11%), respondents' sense that others may think that HPV vaccination can wait (9%), and challenges associated with administering the HPV vaccine during acute or chronic care visits (7%).[1]

Put Improvements Into Place

Many providers already are implementing strategies to improve HPV vaccination rates, the new analysis indicates. The most commonly reported strategy was use of prompts when HPV vaccination is needed (89%). Respondents also reported that their practices commonly use tools to improve communication about HPV vaccination with parents and adolescents (87%) and they receive performance feedback about HPV vaccination rates (83%). However, just 17% of respondents indicated that their practice uses reminder-recall messages specific to the HPV vaccine.[1]

Although clinicians are using various strategies to improve HPV vaccine delivery, room for improvement remains. The ongoing STOP HPV trial is evaluating distinct strategies, alone or in combination, to overcome vaccination barriers, says **Alexander Fiks**, MD, FAAP, MSCE, primary care pediatrician at Children's Hospital of Philadelphia, AAP Pediatric Research in Office Settings (PROS) Director, associate director of the Center for

EXECUTIVE SUMMARY

A new analysis of a national survey underscores the importance of continued efforts to strengthen practitioner adoption of evidence-based approaches to recommending the HPV vaccine.

- More than 80% of respondents said that parental refusal or parental influence to delay was their major barrier to immunization. About 30% of parents of children ages 11-12 years who were due for an HPV vaccine refused and 15% hesitated without refusing.
- Other major barriers included the time required to discuss HPV vaccination with families, a low proportion of adolescents coming in for well visits, and a lack of training in providing a strong recommendation.

Pediatric Clinical Effectiveness, and researcher at PolicyLab.

Offer Vaccines Same Day, Same Way

The Centers for Disease Control and Prevention (CDC) continues to recommend routine immunization for girls and boys at age 11 or 12 years; the series can be started at age 9 years. Immunization also is recommended through age 26 years for females and through age 21 years for males. Males 22-26 years of age may be immunized.[3] Although the Food and Drug Administration has approved the use of the nine-valent HPV vaccine in women and men 27-45 years of age, the Advisory Committee on Immunization Practices is reviewing further information toward a potential vote on the matter.

The CDC advises that clinicians recommend HPV vaccination in the same way and on the same day that they recommend other vaccines for adolescents.

One way to approach the matter is to say, "Now that your son is 11, he is due for vaccinations today to help protect him from meningitis, HPV cancers, and whooping cough. Do you have any questions?"

Also, remind parents about the needed follow-up shots for their child and ask them to make those appointments before they leave the office.

Explain to parents that the HPV vaccine is important because it prevents infections that can cause cancer. That's why the immunization series needs to be implemented during the current office visit. If parents question why the vaccine is given at such a young age, the CDC advises clinicians to say that vaccines protect children before they are exposed to a disease. The HPV vaccine is given earlier rather than later so that it can protect children long before they are exposed to the virus.

(*The CDC offers helpful information sheets; visit https://bit.ly/2dj9dTt.*) ■

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Science Focuses on the Use of Metronidazole for Endometriosis

Researchers are exploring the use of metronidazole for treatment of endometriosis, which affects up to 10% of U.S. women between the ages of 25 and 40.[1] The current options for treatment include hormone therapy and surgery, but these approaches involve significant side effects and recurrence of the condition after treatment.

Most of the time, endometriosis results from retrograde menstruation, where endometrial tissue flows back into the pelvic cavity, instead of out through the cervix. The endometrial tissue enters the abdominal cavity and attaches to organs in the abdominal and pelvic cavities. These areas include the outside of the uterus, the ovaries, the intestines, and other organs or tissues. The endometrial tissue follows the monthly menstrual cycle, resulting in bleeding and inflammation, scarring, and pain. Up to 30% to 50% of women with endometriosis may experience infertility.[2]

Using mice with surgically induced endometriosis, the researchers found that treatment with metronidazole reduced the size of lesions related to endometriosis in the gut of the animals. This finding held true when the treatment was begun before the lesions started forming and after endometriosis already was established.[1]

Previous research has suggested that gut microbes linked to bowel problems such as inflammatory bowel disease also feature prominently in endometriosis. In the current study, when investigators treated mice with metronidazole, endometrial lesions became smaller and inflammation was reduced.

"Our initial goal was to understand how these gut bacteria, or microbiota, might be connected to endometriosis, but in the process, we may have found a cost-effective treatment," notes **Ramakrishna**

EXECUTIVE SUMMARY

Researchers are exploring the use of metronidazole for the treatment of endometriosis, which affects up to 10% of U.S. women between the ages of 25 and 40. The current treatment options include hormone therapy and surgery, but these approaches involve significant side effects and recurrence of the condition after treatment.

- The Food and Drug Administration has approved elagolix, an oral gonadotropin-releasing hormone antagonist, for treating women with moderate to severe endometriosis pain. Initial pain management options begin with nonsteroidal anti-inflammatory drugs, such as ibuprofen, naproxen sodium, and mefenamic acid.
- Hormonal contraceptives, such as combined oral contraceptives, a contraceptive patch or vaginal ring, a single-rod contraceptive progestin implant, intramuscular or subcutaneous depot medroxyprogesterone acetate, or a levonorgestrel intrauterine device, also are options for treatment of the estrogen-dependent condition.

Kommagani, PhD, assistant professor of obstetrics and gynecology at Washington University School of Medicine in St. Louis's Center for Reproductive Health Sciences and principal investigator of the study.

Ampicillin, neomycin, and vancomycin, which also were tested in the study, did not lessen inflammation or shrink lesions. Since findings indicated very low levels of a protective type of gut bacteria in the mice with endometriosis, scientists surmise it may be possible to use probiotics in addition to antibiotics to increase levels of protective bacteria.

"This study is exciting as it opens new frontiers in identifying bacterial candidates that can promote endometriosis in reproductive-age women, and it enables us to conduct future studies aimed at developing simpler ways to diagnose endometriosis," notes paper coauthor **Indira Mysorekar**, PhD, the James P. Crane professor of obstetrics and gynecology and professor of pathology and immunology at Washington University School of Medicine in St. Louis. Mysorekar also serves as director of the Center for Reproductive Health Sciences at the university.

New Drug Available for Pain Treatment

Clinicians now have a new drug option in treating women with moderate to severe endometriosis pain. In July 2018, the Food and Drug Administration approved elagolix (Orilissa), an oral gonadotropin-releasing hormone receptor antagonist specifically developed for such an indication.

Patients with endometriosis pain have been treated with various forms of pain management, such as nonsteroidal anti-inflammatory drugs including ibuprofen, naproxen sodium, and mefenamic acid. Clinicians also may have used hormonal contraceptives, such as combined oral contraceptives, a contraceptive patch or vaginal ring, a single-rod contraceptive progestin implant, intramuscular or subcutaneous depot medroxyprogesterone acetate, or a levonorgestrel intrauterine device, for treatment of the estrogen-dependent condition.

Elagolix is available in tablet form in two strengths. The lower-strength tablet is taken once per day for no more than 24 months, while the higher-strength dosage is taken twice per day for no more than six months. Using the medication for a longer period is not recommended because of the potential for bone loss. In clinical trials, both dose strengths decreased pain during and between menstrual periods after three months of treatment.[3]

Endometriosis is the most common cause of secondary dysmenorrhea in adolescents.[4] It is not known whether elagolix is safe and effective in children younger than 18 years of age. The current treatment recommended for endometriosis in

adolescents is conservative surgical therapy for diagnosis and treatment, with suppressive medical therapies for preventing endometrial proliferation.[4]

The most common side effects associated with the use of elagolix are hot flashes and night sweats, headache, nausea, difficulty sleeping, absence of periods, anxiety, joint pain, depression, and mood changes. In addition to bone loss, potential serious side effects include suicidal thoughts or behaviors; worsening mood, including depression and anxiety; changes in menstrual bleeding that could make it difficult to detect pregnancy; and abnormal liver tests. The drug also may increase the risk of early pregnancy loss.

"Endometriosis is often characterized by chronic pelvic pain that can impact women's daily activities," says **Hugh Taylor**, MD, a study investigator and chair of the Department of Obstetrics, Gynecology and Reproductive Sciences at the Yale School of Medicine. "Women with endometriosis may undergo multiple medical treatments and surgical procedures seeking pain relief and this approval gives physicians another option for treatment based on a woman's specific type and severity of endometriosis pain." ■

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GUEST COLUMN

Legislators Listen Up, Learn, and Perhaps Beware

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While a legislative bill introduced in Ohio in April 2019 would ban most private insurance coverage of abortion, it also may touch on contraception as well. Since the legislation bans coverage for "drugs or devices used to prevent the implantation of a fertilized ovum," reproductive rights groups say it could eliminate coverage for some forms of contraception, such as birth control pills or intrauterine devices (IUDs).[1]

This is remarkable, since it is clearly these same contraceptives that most dependably prevent the NEED for an abortion.

American women, their physicians, and their nurse practitioners are aware that the contraceptives women use also are being used to treat or prevent several medical conditions. Following are just a few examples of how contraception is more than just birth control.

Examine the Benefits

In a study of women with menorrhagia, findings suggest that the levonorgestrel (LNG) IUD is more effective than usual medical treatment in reducing the effect of heavy menstrual bleeding on quality of life.[2] Hormonal agents, such as combined oral contraceptives, the contraceptive patch or vaginal ring, the single-rod contraceptive progestin implant, intramuscular and subcutaneous depot medroxyprogesterone acetate injectables, and the LNG IUD, are first-line agents for treating dysmenorrhea.[3]

In the 1950s, birth control pills were used to treat endometriosis before they were approved in 1960 as a method of birth control. In later years, findings of a 2003 study indicate that insertion of an LNG IUD after laparoscopic surgery for symptomatic endometriosis is effective in reducing the medium-term risk of recurrence of moderate or severe dysmenorrhea.[4]

Combined oral contraceptives have been shown to provide health benefits beyond birth control. These benefits include treatment of menstrual migraine and other cyclical headaches, as well as treatment for severe premenstrual symptoms.[5] Pain and bleeding associated with uterine fibroids (the most common tumor in women, which usually are NOT cancerous), polycystic ovarian syndrome, acne, and painful sickle cell crises also are addressed by the use of hormonal contraceptives.

Decrease Cancer Risk With Contraception

Ovarian cancer is decreased by the use of pills and other hormonal contraceptives. The longer a woman has used oral contraceptives, the greater the protective effect. And the protective effect lasts for years after the pills have been discontinued.[6] Endometrial hyperplasia and endometrial cancer also are decreased by the use of pills and other hormonal contraceptives.[7]

Colon cancer is diminished by the use of pills and other hormonal contraceptives. The Nurses' Health Study reported a 40% reduced risk of colorectal cancer with eight years of previous use of oral contraceptives. Fritz and Speroff conclude that "steroid contraception should be offered to women with a strong family history of colorectal cancer."[8]

What Are the Implications?

Perhaps Kate Miller, PhD, of the University of Pennsylvania may have put it best when she wrote in an introduction to the book *Is Menstruation Obsolete?* that "this monthly discomfort (cramps, pain, fatigue, irritability) is simply not obligatory." Hormonal contraceptives are important now in the management of each of the above health problems affecting women during their reproductive years.

Contraceptives have contributed to a reduction in abortions, decreasing them to their lowest rate since shortly after the 1973 *Roe v. Wade* decision.[9] Contraceptives also have been major contributors to a decrease in teen births. In 2018, the birth rate for teenagers ages 15-19 years fell 7% to 17.4 births per 1,000 women.[10]

It was old white men who gave us the *Roe v. Wade* decision in 1973; now it is predominantly old white men who would see *Roe v. Wade* overturned. Younger (on average) women of all races and social groups are leading the charge to maintain the right of women to use contraceptives to prevent the need for abortion and, when necessary, abortion to prevent unwanted births. ■

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COMING IN FUTURE MONTHS

- New HIV vaccine strategy enhances immune response
- Check contraceptive options for new moms
- "Metabolic fingerprint" may prevent cervical cancer
- How to prevent pregnancy-related deaths

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CME/CE QUESTIONS

1. **The current label for the Liletta intrauterine device suggests how many years of effective use?**

   a. 3 years
   b. 4 years
   c. 5 years
   d. 7 years

2. **What is the current label indication for the segesterone acetate and ethinyl estradiol vaginal ring?**

   a. 1 year
   b. 3 years
   c. 5 years
   d. 7 years

3. **What drug was approved in 2018 for treatment of women with moderate to severe endometriosis pain?**

   a. Elagolix
   b. Zulresso
   c. Bijuva
   d. Ibrance

4. **What is the maximum time frame for initiating post-exposure prophylaxis (PEP), the use of antiretroviral drugs for people who are HIV-negative after a single high-risk exposure to stop HIV infection?**

   a. Initiation within 24 hours of a possible exposure
   b. Initiation within 36 hours of a possible exposure
   c. Initiation within 48 hours of a possible exposure
   d. Initiation within 72 hours of a possible exposure

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.

STI QUARTERLY™

A SUPPLEMENT TO CONTRACEPTIVE TECHNOLOGY UPDATE

Time to Close Gaps in HIV Testing, Treatment

Getting more people tested and into care is critical for new initiative

About 80% of new HIV transmissions can be linked to people whose infection is undiagnosed or not currently treated, according to findings from a just-published analysis.[1] With this information in hand, public health officials are moving to get more people tested and in care.

Admiral Brett Giroir, MD, assistant secretary for health at the U.S. Department of Health and Human Services, says there is an "unprecedented opportunity" now to stop the HIV epidemic in America. An effort must be made to close gaps in HIV prevention and care, Giroir said in a press statement.

Getting more people tested and into HIV care is a critical part of the new federal initiative, "Ending the HIV Epidemic — A Plan for America," which was launched recently to end the HIV epidemic. Four key components comprise the initiative: diagnosing HIV as early as possible, treating infections quickly to achieve sustained viral suppression, protecting those at risk for HIV with prevention approaches such as pre-exposure prophylaxis (PrEP), and responding quickly to growing HIV clusters to halt new infections.

Although tools are available to end the HIV epidemic, they are useful only if put into practice, says **Jonathan Mermin**, MD, MPH, director of the Centers for Disease Control and Prevention (CDC) National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention.

"This is why it's vital to bring testing and treatment to everyone with HIV — and to empower them to take control of their lives and change the course of the epidemic," said Mermin in a press statement.

Get Going on Testing, Treatment

> "THIS IS WHY IT'S VITAL TO BRING TESTING AND TREATMENT TO EVERYONE WITH HIV — AND TO EMPOWER THEM TO TAKE CONTROL OF THEIR LIVES AND CHANGE THE COURSE OF THE EPIDEMIC."

Reducing new infections is imperative if the HIV epidemic is to be stopped. Efforts should be aimed at increasing the proportion of people who are aware of their HIV status, states the new report.

Be sure that all patients ages 13-64 have been tested at least once for HIV, says the CDC. Those at high risk should be tested at least annually, with sexually active gay and bisexual men benefitting from more frequent testing (every three to six months).

Be sure to help those with HIV get care. It is estimated that the 23% of people with HIV who have received a diagnosis but who are not receiving HIV care account for 43% of all HIV transmissions. According to the CDC, taking antiretroviral therapy, or ART, not only helps to achieve and maintain an undetectable viral load for patients with HIV, it also aids in preventing transmission of the virus to others.

Research indicates that treatment as prevention is very effective for preventing transmission of HIV through sexual contact. Strong evidence from recent studies demonstrates that such treatment works; in three studies,

EXECUTIVE SUMMARY

About 80% of new HIV transmissions can be linked to people whose infection is undiagnosed or is not currently treated, according to findings from a just-published analysis.

• Public health officials are now moving on this information to get more people tested and into care as part of the new federal initiative to end the HIV epidemic.

• The initiative entails four key strategies: diagnosing HIV as early as possible after infection, treating HIV rapidly and effectively to achieve sustained viral suppression, protecting people at risk for HIV using prevention approaches such as pre-exposure prophylaxis, and responding rapidly to growing HIV clusters to stop new infections.

data suggested that no linked HIV transmissions were observed between partners with mixed HIV status when the partner with HIV was virally suppressed.[2-5] More research is necessary to determine how well viral suppression prevents transmission of the virus by other routes.

For patients with HIV, be sure to stress the importance of taking medicine to maintain viral suppression. Data indicate that the 11% of people with HIV who were receiving care but were not virally suppressed account for 20% of all HIV transmissions.[1] When talking about patients continuing treatment, the CDC advises that it may be helpful to share information about research with patients, and then ask open-ended questions to encourage further conversation. Consider using the following approaches suggested by the CDC:

• We have evidence in hand of mixed-HIV-status couples who engaged in thousands of unprotected sex acts while the partner with HIV was taking ART to achieve viral suppression. There was no evidence that a single HIV-negative person got HIV from their sexual partner with a viral load that was undetectable. What does this information mean to you?

• To maximally reduce the risk of sexual transmission of HIV, you must achieve and then maintain an undetectable viral load. How do you feel about that?

• Good news: Your viral load continues to be undetectable. Tell me the methods you are using to prevent other STDs.[6]

Don't Forget PrEP, PEP, and Condoms

Prevention tools like condoms and PrEP are important for people who are at risk for HIV. Discuss the fact that correct use of male condoms and other barriers, such as female condoms and dental dams, can lower the risk of sexually transmitted infections, including HIV. Explain that, for the highest protective effect, condoms must be used correctly and consistently throughout the entire sex act, from the start of sexual contact to after ejaculation.

PrEP is a method of prevention used by people who are HIV-negative and at high risk for exposure to HIV through sexual contact or injection drug use. The Food and Drug Administration-approved PrEP medication is oral tenofovir disoproxil fumarate and emtricitabine (TDF-FTC), which is available as a fixed-dose combination in a tablet (Truvada). Explain to patients that when a person is exposed to HIV through sexual contact or injection drug use, these medicines can work to keep the virus from establishing an infection. Guidance calls for patients who take PrEP to commit to taking the drug every day, as well as to attend follow-up visits with their healthcare provider every three months.

Post-exposure prophylaxis, or PEP, is the use of antiretroviral drugs for people who are HIV-negative after a single high-risk exposure. This prevention method must be started as soon as possible to be effective; guidance calls for initiation within 72 hours of a possible exposure, with continued dosing for four weeks. PEP is recommended for potential exposures through sexual contact or injection drug use, and should be provided only for infrequent exposures. For patients who engage in behaviors that result in frequent, recurrent exposures, clinicians should advise the use of PrEP.

Get your patients ready to use PrEP and PEP with questions such as these:

• What do you do when a condom breaks?

• What works for you when you talk with partners about HIV prevention medicines, like PrEP? What doesn't work?

• When you party, are injecting drugs part of the action? If so, are you sharing needles or drug preparation equipment with others? ■

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Drug Combination Considered for Treatment-Resistant Gonorrhea

Gonorrhea is on the rise around the world. Following a decline in notification rates in 2016, the number of gonorrhea cases rose 17% in the European Union and associated countries, with more than 89,000 confirmed diagnoses in 2017.[1] The United States saw a similar rise, with a total of 555,608 cases of gonorrhea reported in 2017, an 18.6% increase since 2016.[2]

Current numbers do not even show the true extent of the sexually transmitted infection's (STI) epidemic in Europe, says **Gianfranco Spiteri**, MD, MPH, STI expert at the European Centre for Disease Prevention and Control.

"Many infections are not diagnosed due to lack of symptoms or limited access to diagnostics or simply are not reported," Spiteri said in a press statement.

Newly released research indicates that a certain combination of drugs, gentamicin and azithromycin, may work as well as ceftriaxone alone for cases of drug-resistant gonorrhea.[3] Scientists are pressing to find a reliable and affordable oral treatment option for gonorrhea since the bacteria has become increasingly antibiotic-resistant. (*Read the October 2018* Contraceptive Technology Update *article on investigation efforts, "Research Strides May Offer Keys to Battling Gonorrhea," at https://bit.ly/30a5IDM.*)

Check the Research

The new study is the first randomized controlled trial to compare the use of gentamicin and azithromycin amid concerns about growing resistance to ceftriaxone. For the trial, investigators recruited participants from 14 sexual health clinics in England and randomly assigned 720 participants to receive either injections of gentamicin or ceftriaxone, with both groups also receiving a single dose of oral azithromycin.

The results indicate that 98% of participants who received ceftriaxone were cleared of infection, compared to 91% of those who received gentamicin. Among the study participants, gentamicin achieved a 94% cure rate for genital gonorrhea, making it a possible useful choice if ceftriaxone is not available or inappropriate to use, scientists concluded.[3]

"Our current antibiotic treatment for gonorrhea is beginning to fail and experience with previous drugs strongly suggests that this could become a widespread problem," says **Jonathan Ross**, MD, professor of sexual health and HIV at the University of Birmingham. "Our trial has found that gentamicin combined with azithromycin works almost as well as ceftriaxone with azithromycin for genital gonorrhea, but did not clear throat or rectal gonorrhea as effectively."

Ceftriaxone should remain the first-line treatment for gonorrhea, with gentamicin as an alternative,

EXECUTIVE SUMMARY

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- Scientists are pressing to find a reliable and affordable oral treatment option for gonorrhea since the bacteria has become increasingly antibiotic-resistant.
- Gonorrhea is on the rise around the world. Following a decline in notification rates in 2016, the number of gonorrhea cases rose 17% in the European Union and associated countries, with more than 89,000 confirmed diagnoses in 2017. The United States saw a similar rise, with a total of 555,608 cases of gonorrhea reported in 2017, an 18.6% increase since 2016.

particularly for patients with genital infection and for those who are allergic or intolerant to ceftriaxone, notes Ross, who served as chief investigator of the Birmingham trial. However, further research is required to identify and test new alternatives to ceftriaxone for the treatment of the STI, he states.

On the Hunt for More Options

Scientists are looking for multiple alternatives for treatment-resistant gonorrhea, since cases are appearing across the globe. Public health institutions such as the National Institute for Health Research (NIHR), the largest national clinical research funder in Europe, are committed to research in areas of the greatest health need, such as antimicrobial resistance. The current research is one of a number of studies the NIHR has funded over the last few years in its sustained effort to tackle this worldwide threat, says **Hywel Williams**, PhD, professor of dermato-epidemiology at the University of Nottingham and director of the NIHR's Health Technology Assessment Programme.

Investigators say further research into developing a preventive or therapeutic vaccine is crucial because of increasing resistance and limited future antibiotic options. The samples collected in the current trial will help to develop a greater understanding of the immune response to infection, they note. Also, scientists plan to examine the frequency of multiple infections and their potential role in the spread of resistance. By using genome sequencing, investigators could identify genetic markers of gonorrhea resistance and provide insights into the mechanisms and predictors of resistance, they conclude.

Scientists recently have completed proteomic profiling on all the proteins produced by 15 gonorrhea strains; among the isolates were World Health Organization-maintained reference strains that show all known profiles of gonococcal antimicrobial resistance.[4] Nine new potential vaccine candidates were identified as a result of the research.

The National Institutes of Health recently awarded a $5.1 million grant to a team of Johns Hopkins University (JHU) scientists to develop a device that rapidly tests for gonorrhea and detects if a particular bacterial strain is resistant to antibiotics. Researchers from JHU's Whiting School of Engineering and School of Medicine, the World Health Organization, GE Global Research, and Stanford University also are involved in the inquiry. ■

> "OUR CURRENT ANTIBIOTIC TREATMENT FOR GONORRHEA IS BEGINNING TO FAIL AND EXPERIENCE WITH PREVIOUS DRUGS STRONGLY SUGGESTS THAT THIS COULD BECOME A WIDESPREAD PROBLEM."

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