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INSIDE

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Dual-purpose Vaginal Ring Moves to Clinical Trial

Study will assess ring's safety and pharmacokinetics in two U.S. centers

The push to increase women's ability to protect themselves from simultaneous sexual and reproductive health risks, including HIV, unintended pregnancy, and other sexually transmitted infections, continues with the start of a clinical trial of a three-month vaginal ring.

The ring slowly releases dapivirine, an antiretroviral drug designed to prevent HIV, and levonorgestrel, a contraceptive hormone. Dapivirine, also known as TMC-120, is a non-nucleoside reverse transcriptase inhibitor, which binds to and disables HIV's reverse transcriptase enzyme, a key protein needed for HIV replication.

"WOMEN'S SEXUAL AND REPRODUCTIVE HEALTH NEEDS DO NOT EXIST IN ISOLATION, AND NEITHER SHOULD THEIR PREVENTION OPTIONS." — ZEDA ROSENBERG, SCD, INTERNATIONAL PARTNERSHIP FOR MICROBICIDES FOUNDER AND CHIEF EXECUTIVE OFFICER

The nonprofit research group International Partnership for Microbicides (IPM) has joined Microbicide Trials Network (MTN), funded by the National Institutes of Health, to conduct this study. Researchers will assess the ring's safety and pharmacokinetics. Results of the trial, including the product's acceptability to women and their willingness to use it in the future, will be used to guide the ring's formulation and future research efforts.

Women's sexual and reproductive health needs do not exist in isolation, and neither should their prevention options, says **Zeda Rosenberg**, ScD, International Partnership for Microbicides founder and

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chief executive officer. A long-acting product that gives women two prevention methods in one may be "quite appealing," she says.

"The only way to end the HIV epidemic is to offer women product options that meet their various needs, and IPM remains committed to making this a reality," Rosenberg notes. One way to diminish the HIV epidemic is to offer women product options that meet their various needs, Rosenberg offers.

Two U.S. Sites to Conduct Study

The MTN-030/IPM 041 will take place at two sites: The University of Alabama at Birmingham and Magee-Womens Hospital, a teaching hospital affiliated with the University of Pittsburgh.

The Phase I randomized, double-blind study marks the first time a vaginal ring containing a combination of dapivirine and levonorgestrel will be tested in humans.

Researchers will randomly assign 24 healthy women 18-45 years of age who are not pregnant to one of two groups over a 14-day period. Women will use either a vaginal ring containing 200 mg dapivirine and 320 mg levonorgestrel or a ring containing 200 mg dapivirine alone.

All women participating in the study will undergo testing and receive counseling to reduce their risk of acquiring HIV and other sexually transmitted infections, and will be provided male condoms and other health services. Results are expected by mid-2018.

"Many of the women who have participated in our studies have told us that they want a single product that can provide both contraception and HIV prevention," said **Sharon Hillier**, PhD, professor and vice-chair for faculty affairs, and director of reproductive infectious disease research, department of obstetrics, gynecology, and reproductive sciences, at the University of Pittsburgh School of Medicine and principal investigator for the research. "We are excited about the next-generation microbicide products that we hope will address that unmet need."

What researchers will learn from this study will set the course for the future of the dual-purpose dapivirine vaginal ring, according to **Sharon Achilles**, MD, PhD, MTN-030/IPM 041 protocol chair and a lead investigator at the Magee-Womens Hospital clinical research site.

"If all goes well, we would then proceed to studies involving more women who would use the ring longer, for up to three months, as it was intended," says Achilles, an assistant professor of obstetrics, gynecology, and reproductive sciences at the University of Pittsburgh School of Medicine and director of the Magee-Womens Research Institute Center for Family Planning Research. "This study is a critical first step on a pathway that we hope will ultimately enable us to provide women with an easy-to-use product that can provide safe and effective, long-acting protection against both HIV and unintended pregnancy."

In 2016, MTN and IPM research teams reported results of two Phase III efficacy trials of the monthly 25 mg dapivirine vaginal ring, with findings indicating that the vaginal ring could deliver an antiretroviral drug to prevent HIV infection. Data suggested that overall risk of HIV infection was reduced by about 30% across both studies, with higher levels of protection observed in women

who used the ring most regularly.[1,2]

The two trials, MTN's ASPIRE and IPM's The Ring Study, investigated 4,588 women in four African countries where HIV rates for women continue to be among the highest in the world. *(For more information on this research, please visit: http://bit.ly/2twpOHi.)*

Two open-label studies involving former Phase III trial participants in the ASPIRE and Ring investigations are collecting additional safety, adherence, and efficacy data on the monthly dapivirine ring that will help inform its implementation as the ring moves toward potential regulatory approval.

A separate trial (MTN-034/IPM 045) will evaluate safety and adherence of the monthly vaginal ring and daily use of tenofovir as oral pre-exposure prophylaxis among adolescent girls and young women, as well as use in pregnant and breast-feeding women.

More Options in Pipeline

What other possible multipurpose technology (MPT) options are in the research pipeline? The Initiative for Multipurpose Prevention Technologies (IMPT), an international collaboration of researchers, advocates, and funders working together to advance the development and introduction of MPT options, was awarded a $4.5 million grant from the U.S. Agency for International Development in August 2016 to advance research in the field.

"Women worldwide tell us they need more prevention options that they can initiate and that fit the realities of their daily lives," **Bethany Young Holt**, PhD, MPH, IMPT director and co-founder, said in a statement accompanying the funding announcement. "The MPT field is committed to prevention approaches that women will want and be able to use."

There are a handful of MPT products in development at the same Phase I clinical trial stage as IPM's ring, according to **Kathryn Stewart**, MPP, IMPT deputy director. These include products that would combine protection against unintended pregnancy/HIV/HSV-2 (herpes), unintended pregnancy/chlamydia/gonorrhea/HIV/HSV-2 (herpes), and HIV/HSV-2 (herpes)/HPV. These methods include vaginal rings, gels, and fast-dissolving vaginal inserts and films. *(For more information about all methods now under development, please visit: http://www.theimpt.org.)*

A research organization called CONRAD has been developing MPTs to prevent unplanned pregnancies and protect against HIV/AIDS or other STIs. With funding from USAID and the National Institutes of Health, researchers at CONRAD pioneered a screening program designed to identify compounds with dual activity against sperm and HIV.

CONRAD's levonorgestrel/tenofovir-releasing intravaginal ring is under investigation in a Phase I study at Eastern Virginia Medical School in Norfolk and Profamilia in the Dominican Republic.

Evofem is developing Amphora, a non-hormonal vaginal gel that maintains a low vaginal pH, which creates an unfriendly environment for sperm and bacteria. Amphora uses lactic acid to maintain the acidic pH in the vagina. Its properties could offer many potential advantages for use, either alone or in combination with another active ingredient, such as tenofovir.

Amphora's potential applications could include use as a microbicidal product, a personal lubricant, or a vaginal contraceptive (alone or with a barrier method).[3] ■

EXECUTIVE SUMMARY

The push to increase women's ability to protect themselves from simultaneous sexual and reproductive health risks, including unintended pregnancy, HIV, and other sexually transmitted infections, continues with the start of a clinical trial of a three-month vaginal ring. The ring is designed to release dapivirine, an antiretroviral drug to prevent HIV, and levonorgestrel, a contraceptive hormone.

- The study will be conducted at the University of Alabama at Birmingham and Magee-Womens Hospital, a teaching hospital affiliated with the University of Pittsburgh.
- Other multipurpose technology options in the pipeline include other vaginal rings, gels, and fast-dissolving vaginal inserts and films.

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Analysis: One in Six Teen Births in 2015 was a Repeat Birth

Although the rate of teen births has decreased in recent years, results of a new analysis shows that that many teens continue to have repeat births. Most adolescent mothers are taking steps to prevent another pregnancy, but data indicate one in three uses either a least-effective contraceptive method or no contraception at all.[1]

Repeat teen births, defined as two or more live births before age 20, can affect mothers and babies in several ways. Repeat births can impede an adolescent mother's ability to take advantage of educational and workforce opportunities.[2] Babies that are born of repeat teen pregnancies are more likely to be preterm or of low birthweight than first teen births.[3]

In 2015, the national teen birth rate was 22.3 births per 1,000 females 15-19 years of age; however, many teens continue to have repeat births.[4] The Contraceptive CHOICE project in St. Louis, which was designed promote the use of LARC methods and provide contraception in an effort to reduce unintended pregnancies, has produced a significant decline in repeat abortions in the St. Louis region.[5]

Because repeat teen births are more likely than first teen births to be preterm and low birth weight, and giving birth more than once as a teenager can limit a mother's ability to attend school and obtain work experience significantly, it is important to assess patterns in repeat teen births and better understand contraceptive use within this population, according to **Deborah Dee**, PhD, lead author of the current research and an epidemiologist at the CDC's Division Of Reproductive Health.

"Our analysis found that, in 2015, one in six births to teens ages 15 to 19 was a repeat birth, a decline from one in five in 2004," Dee says. "We also found that about a quarter of teen mothers used one of the most effective methods of contraception (i.e., less than 1% failure rate) in 2013 — five times higher than in 2004."

However, overall contraceptive use among teen mothers did not change during this same period, and one-third of teen mothers used a least-effective contraceptive method (defined as a method with more than a 10% failure rate) or no contraception at all in 2013, Dee observes. There were geographic and racial/ethnic differences in both the trend in repeat teen births and in the use of postpartum contraception, she states. During the analysis period, researchers found 35 states experienced a significant decline in percentage of teen births that were repeat births. Among those 35 states, a dozen experienced declines of more than 20%.[1]

How to Stem Repeat Births?

Efforts are underway to help stem repeat teen births. Some states have implemented policies that provide enhanced reimbursement of immediate postpartum long-acting reversible contraception insertion for Medicaid-enrolled mothers, thereby removing healthcare system barriers.[6] Other states now provide support services to teen parents, such as home visiting programs, which have been found to reduce repeat teen births.[7]

Fighting teen repeat births can present challenges. According to the Texas Campaign to Prevent Teen Pregnancy, Texas leads the nation in repeat teen births. The campaign estimates one in four births among teens 15-19 years of age in Texas is a repeat birth.

In Texas, teen parents hold medical authority over their children, but do not have the ability to make decisions about their own healthcare. This means that teen mothers cannot get birth control without their parents' approval, even though they are

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already parents themselves, according to the campaign.

Robert Hatcher, MD, MPH, senior author of the newly-updated handbook, *Managing Contraception*, suggests that Texas' position as number one in repeat teen births is explained by its policies.

"This is a remarkably outrageous duet being orchestrated by a state that used to be a leader in family planning," Hatcher says. "The duet is denying teenagers the ability to choose their contraceptives, while permitting them to make health decisions about the children that may follow as a result of unprotected sex."

During the 2017 session of the Texas Legislature, Texas House Rep. Sarah Davis of Houston filed the Minor-Parental Consent to Contraception Bill (HB 1373), which sought to change policy to give teen parents the freedom to choose an effective contraceptive method, such as long-acting reversible contraception, without requiring parental consent. The House State Affairs committee considered the bill in March and approved it in May. However, lawmakers did not consider the bill on the floor and it died because of end-of-session deadlines, reports **Melanie Chasteen**, director of community engagement for the Texas Campaign to Prevent Teen Pregnancy. ■

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Researchers Affirm Effectiveness of Two-dose HPV Vaccine

Investigators have published clinical evidence that supports the CDC's recent recommendation for a two-dose human papillomavirus (HPV) vaccine to prevent genital warts, showing that the two-dose vaccine provides the same level of protection as three doses.[1]

Researchers studied nearly 400,000 U.S. females 9-18 years of age to find the rate of genital warts based on the number of vaccine doses received. Their analysis indicated that receiving two or three doses of the vaccine was effective. Both provided much more protection than receiving one or zero doses.[1]

The CDC recommends patients 11-12 years of age receive two doses of HPV vaccine at least six months apart, rather than the previously

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- The CDC recommends that girls and boys 11-12 years of age receive two doses of HPV vaccine at least six months apart, rather than the previously recommended three doses.

recommended three doses. Those who start the series at 15-26 years of age will continue to need three doses of HPV vaccine to protect against cancer-causing HPV infection. The recommendation was issued shortly after the FDA approved the addition of a two-dose schedule for the nine-valent HPV vaccine (Gardasil 9) for adolescents 9-14 years of age age in October 2016. *(For more information, please visit: http://bit.ly/2li1dma.)*

Researchers, led by **Rebecca Perkins**, MD, an obstetrician at Boston Medical Center and the study's lead author, concluded that prospective effectiveness studies of recommended two-dose schedules against clinical endpoints such as persistent infection, genital warts, and cervical dysplasia are necessary to ensure long-term protection of vaccinated patients.

Although the data supporting a two-dose schedule is encouraging, the research focused only on genital warts, not cancer outcomes or cervical dysplasia. It's crucial for other researchers to collect such data, according to Perkins, who also is an associate professor of obstetrics and gynecology at Boston University School of Medicine.

"This study will be a stepping stone for future research into the effectiveness of the two-dose schedule of the HPV vaccine for other symptoms of the disease," Perkins said in a statement accompanying the publication.

Vaccine Effect on Oral HPV

New data have emerged, suggesting vaccine efficacy against oral HPV infections.[2] The findings were presented at the American Society of Clinical Oncology's June 2017 annual meeting in Chicago.

Maura Gillison, MD, PhD, professor at the University of Texas MD Anderson Cancer Center, and her team analyzed data collected between 2011 and 2014 in the National Health and Nutrition Examination Survey (NHANES), which was designed to assess the health and wellness of Americans.

In 2011, NHANES participants began self-reporting if they had received one or more HPV vaccines. Researchers studied responses from more than 2,600 young adults 18-33 years of age, comparing the prevalence of an oral HPV infection in those who received one or more doses of the vaccine to those who did not. At that time, about 18.3 percent of young adults in the U.S. reported receiving one or more vaccine dose by age 26, with vaccination more common in women than men (29.2% vs. 6.9%).[1]

The findings indicate that the prevalence (population-weighted) of oral HPV16/18/6/11 infections was significantly reduced in vaccinated vs. unvaccinated individuals (0.11% vs. 1.61%; $P = 0.008$), corresponding to an estimated 88.2% (95% confidence interval, 5.7-98.5%) reduction in prevalence.

The analysis suggests that oral HPV16/18/6/11 prevalence was reduced significantly in vaccinated vs. unvaccinated men (0.0% vs. 2.13%; $P = 0.007$). In contrast, prevalence for 33 non-vaccine HPV types was similar (3.98% vs. 4.74%; $P = 0.24$). Accounting for HPV vaccine-uptake, the population-level effectiveness of HPV vaccination on the burden of oral HPV16/18/6/11 infections was 17.0% overall, 25.0% in women and 6.9% in men.[1]

Previously, researchers found that HPV is responsible for several cancer types in men and women, including cancers in the oropharynx. It is estimated HPV is linked with approximately 70% of oropharyngeal cancers.[3]

According to Gillison, no one has conducted clinical trials that have prospectively evaluated whether the existing FDA-approved HPV vaccines will prevent oral infections that lead to the disease. Therefore, the vaccine is not approved for the prevention for head and neck cancers; it is approved for the prevention of cervical, vulvar, vaginal, and anal cancers in women and anal cancers in men.

"We don't know if there's a potential solution to these rising rates already existing on the shelves," Gillison said in a statement accompanying the presentation. "In the absence of that gold standard clinical trial, we looked at data from a study that we've been conducting in my lab to address the question as to whether or not existing HPV vaccines could be altering oral HPV infections in the U.S. population." ■

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Time to Increase Access to Postpartum LARC in All 50 States

Research indicates that while the number of women receiving immediate postpartum intrauterine devices and implants has increased dramatically in recent years, access to such services is unequal.[1]

To measure rates of long-acting reversible contraception (LARC), including intrauterine devices (IUDs), contraceptive implants, and tubal sterilization, investigators performed a retrospective cohort study, looking at the 2008-2013 National Inpatient Sample, an all-payer database that's available publicly. The authors identified delivery hospitalizations with the *International Classification of Diseases, 9th Revision, Clinical Modification* codes for intrauterine device insertion, contraceptive implant insertion, and tubal sterilization.

Investigators used weighted multivariable logistic regression to examine associations between predictors, such as age, delivery mode, medical comorbidity, payer, hospital type, geographic region, and year, and likelihood of LARC and sterilization to compare characteristics of LARC and sterilization users.

The researchers found that the rate of IUDs or implants after childbirth increased sevenfold over five years, increasing from 1.86 per 10,000 deliveries in 2008 to 13.5 per 10,000 deliveries in 2013.

However, data indicate that about 96% of inpatient postpartum IUDs were placed at urban teaching hospitals, suggesting that the service is not available to women delivering at urban non-teaching and rural hospitals. The analysis also revealed that the rate of patients receiving reversible contraception while hospitalized for a delivery still remains less than 2% of the national sterilization rate in immediately postpartum women.

Getting an IUD right after childbirth may be more convenient and less painful than insertion at a later office visit for new mothers, according to the paper's lead author, **Michelle Moniz**, MD, MSc, assistant professor of obstetrics and gynecology and researcher at the University of Michigan Medical School.

However, the recent analysis indicates that access to this service varies greatly depending on where a woman delivers her baby, she said.

"Maternity clinicians and policymakers should strive to ensure that women have access to the full range of contraceptive options after childbirth and that they are able to make an informed, voluntary, personal choice about whether and when to have another child," Moniz noted in a statement accompanying the paper's publication.

Unplanned pregnancies can happen in the postpartum period. Data indicate 40–57% of women report engaging in unprotected intercourse before their routine six-week postpartum visit.[2,3] The LARC Program of the American College of Obstetricians and Gynecologists (ACOG) has just established the Postpartum Contraceptive Access Initiative (PCAI) to provide clinical and operational support training for immediate postpartum LARC implementation.

"Immediate postpartum LARC initiation is safe and effective, but is currently uncommon in U.S. hospitals," says **Eve Espey**, MD, MPH, professor and chair of the department of obstetrics and gynecology at the University of New Mexico in Albuquerque. "The aim of the Postpartum Contraceptive Access Initiative is to ensure all women have access to the full range of postpartum contraceptive methods before leaving the hospital after a delivery."

An important aspect of the initiative is to assist providers with the multiple aspects of initiating immediate postpartum LARC insertion, Espey says. First, barriers that prevent access to the full

EXECUTIVE SUMMARY

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- Data suggest that the rate of patients receiving reversible contraception while hospitalized for a delivery still remains less than 2% of the national sterilization rate.

range of contraceptive methods in the postpartum setting must be identified. Those specifically affecting LARC include lack of clinical training opportunities, complex billing and reimbursement requirements, and other administrative hurdles such as stocking and tracking devices, Espey notes.

"Through onsite training and support, ACOG will support implementation of IPP LARC provision at participating hospital sites, allowing women convenient access to the full range of postpartum contraceptive methods with the goal of assisting women in obtaining their desired contraceptive method and birth spacing with higher satisfaction and continuation rates with their choice of postpartum contraception," Espey says.

Evidence-based research supports the use of a tiered, stage-based approach for implementing immediate postpartum LARC. Current best practices have been incorporated into the initiative's three-pronged implementation model to support successful immediate postpartum LARC provision at participating hospitals. These phases include capacity building for implementation, onsite hands-on clinical simulation and operational support trainings, and ongoing support through a web-based resource hub and follow-up consultations with immediate postpartum LARC implementation experts.

The creators of the initiative are developing a website that will contain details about the initiative, information about immediate postpartum LARC, and an application to become a participating hospital site. Questions about PCAI can be directed to pcai@acog.org.

Advocacy continues growing for immediate postpartum LARC. The CDC established the 6/18 Initiative, a partnership between providers, payers, and purchasers that treats insurance coverage of immediate postpartum LARC as a way to affect health and costs positively. The creators of the initiative are working to ensure private and public payers reimburse for immediate postpartum LARC insertion by separating payment for LARC from other postpartum services. *(For more information on this issue, please visit: http://bit.ly/2reIWJ2.)* ■

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Treating Polycystic Ovary Syndrome May Prevent Infertility

Polycystic ovary syndrome (PCOS) is the most common hormonal disorder among women in their reproductive years. As many as 5 million women nationwide may suffer from PCOS, which is one of the leading causes of infertility.[1]

The FDA has approved few agents specifically for use in polycystic ovary syndrome; several other agents are contraindicated in pregnancy.[2] Insulin-sensitizing agents are indicated for most women with PCOS because they produce positive effects on anovulation, hirsutism, obesity, menstrual irregularities, and insulin resistance. Rosiglitazone and pioglitazone also are effective for ameliorating hirsutism and insulin resistance. Alone or in combination, metformin and clomiphene are first-line agents for ovulation induction. Insulin-sensitizing agents, oral contraceptives, spironolactone, and topical eflornithine can be used in patients with hirsutism.[2] About 98% of teens diagnosed with the disorder are prescribed an oral contraceptive (OC) for such symptoms as hirsutism and oligomenorrhea.[3]

Now, new research suggests reducing the amount of abdominal visceral fat and liver fat to normal restores ovulation, reduces the symptoms of androgen excess, and may help prevent subfertility.[4]

In a small study conducted at the University of Barcelona, **Lourdes Ibáñez**, MD, PhD, professor of pediatrics at the Institut de Recerca Pediàtrica Hospital Sant Joan de Déu and her colleagues enrolled 36 young women with PCOS who were, on average, 16 years of age, and were not pregnant, obese, or sexually active.

Study participants experienced their first menstruation at least two years before enrollment, and their excessive body hair and irregular menses could not be attributed to specific causes. Overall, 34 girls completed the study.

Study participants were randomized to receive one of two daily drug combinations: a combined oral contraceptive pill containing 20 mcg ethinyl estradiol plus 100 mg levonorgestrel or a novel drug, SPIOMET (spironolactone 50 mg, pioglitazone 7.5 mg, and metformin 850 mg). Researchers counseled study participants to exercise regularly and eat a Mediterranean diet. The teens took the study drugs for 12 months and were followed without intervention for another 12 months. The safety of SPIOMET in pregnant women was not addressed in this study.

Researchers counted the number of ovulations over two periods: between three and six months after treatment, and between nine and 12 months after treatment, by referring to menstrual diaries and weekly measurements of salivary progesterone. Assessments also were made of body composition; the amount of abdominal, visceral, and hepatic fat; circulating androgens; cholesterol and insulin; carotid artery thickness; and other markers of cardiovascular health.

Prior to treatment, young women with PCOS exhibited more visceral and hepatic fat than age-matched controls, as well as higher androgens and insulin and altered markers of cardiovascular health. Findings indicate that during treatment, those taking SPIOMET normalized more hepatic and visceral fat, insulin, and markers of cardiovascular health; and after treatment, these values remained more normal in the girls who took SPIOMET than in those on oral contraceptives. In comparison to oral contraceptives, SPIOMET was followed by a 2.5-fold higher ovulation rate and a six-fold higher prevalence of normal ovulation; the risk of experiencing abnormally few ovulations was 65% lower, according to the findings. The teens who lost the most hepatic fat were those who ovulated more after treatment, researchers noted.[4]

"If SPIOMET — the low-dose combination of an anti-androgen plus two insulin-sensitizers — can restore ovulation rates after reducing ectopic fat, later subfertility can potentially be prevented in many women who nowadays depend on expensive and time-consuming fertility techniques to conceive," Ibáñez said in a statement accompanying the presentation.

Anita Nelson, MD, professor and chair of the obstetrics and gynecology department at Western University of Health Sciences in Pomona, CA, says that the work is "interesting," but has questions regarding the chosen drug therapies.

"The choice of comparator pill was biased; women with PCOS are generally prescribed pills with low androgenicity or antiandrogenic activity [and] these women received pills with levonorgestrel," Nelson says. "The triple therapy with metformin, pioglitazone, and spironolactone leaves the women at risk for irregular bleeding, feminization of a male fetus, and substantial side effects as well as risks, such as hepatic failure."

EXECUTIVE SUMMARY

As many as 5 million women nationwide may have polycystic ovary syndrome (PCOS), which is one of the leading causes of infertility. Results of a small study suggest that reducing the amount of abdominal visceral fat and liver fat to normal restores ovulation, reduces the symptoms of androgen excess, and may help prevent subfertility.

- Few agents have been approved specifically for use in polycystic ovary syndrome, and several agents are contraindicated in pregnancy. Insulin-sensitizing agents are indicated for most women with PCOS because they produce positive effects on insulin resistance, menstrual irregularities, anovulation, hirsutism, and obesity.
- About 98% of teens diagnosed with the disorder are prescribed an oral contraceptive for such symptoms as hirsutism and oligomenorrhea.

Check Diagnosis, Treatment

Guidance issued in 2013 by the Washington, DC-based Endocrine Society directed clinicians to use the Rotterdam criteria for diagnosing PCOS, which calls for the presence of two of the following criteria: polycystic ovaries, androgen excess, or ovulatory dysfunction.[5]

Establishing a diagnosis of PCOS can be problematic in adolescents and menopausal women, according to the guidance. Hyperandrogenism is central to the presentation in adolescents, while there is no consistent phenotype in postmenopausal women, it notes. Providers should exclude alternate androgen-excess disorders and risk factors for endometrial cancer, mood disorders, obstructive sleep apnea, diabetes, and cardiovascular disease in their evaluation of women with PCOS.[5]

In a 2015 statement, the Endocrine Society called for further research on establishing diagnostic criteria for adolescents to track how PCOS develops throughout childhood and into reproductive years.[6] The authors of the statement argued that earlier diagnoses could lead to other longitudinal studies that could better evaluate targeted PCOS interventions and the metabolic, psychological, and reproductive conditions connected to it.

"If healthcare providers were armed with better strategies for diagnosing PCOS in teenage girls, they would be able to intervene sooner to address risk factors for diabetes and cardiovascular disease," **Richard Legro**, MD, vice-chair of research in the department of obstetrics and gynecology and professor of obstetrics and gynecology and public health sciences at Penn State College of Medicine and chair of the statement task force said at the time. "Earlier diagnosis is crucial for gaining a better understanding of the long-term effects of PCOS." ■

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States with EPT Laws May See Most Success in STI Treatment

States with the most permissible expedited partner therapy (EPT) laws may demonstrate the most success treating and preventing sexually transmitted infections (STIs), according to a new study.[1]

Although both young men and women are affected heavily by STIs, young women face the most serious long-term health consequences. The CDC estimates that undiagnosed STIs cause infertility in more than 20,000 women each year.[2] One factor that contributes to young women's high rates of STIs is reinfection from an untreated sexual partner.[3] These and other findings led the American College of Obstetricians and Gynecologists to issue a Committee Opinion in 2015 that called for providers to prescribe antibiotics for the male partners of their female patients diagnosed with chlamydia or gonorrhea to reduce high reinfection rate, as well as to push for legalization of EPT in those states and jurisdictions where it is illegal or where the legal status of EPT is unclear or ambiguous.[4]

According to lead author **Okeoma Mmeje**, MD, assistant professor of obstetrics and gynecology at Michigan Medicine and a member of the University of Michigan Institute for Healthcare Policy and Innovation, the research began as an offshoot of another project examining legislation and its interaction with patients.

"We saw expedited partner therapy as one of these types of legislation that may influence the patient and provider interaction," Mmeje says.

To perform the analysis of the ef-

EXECUTIVE SUMMARY

States with the most permissible expedited partner therapy (EPT) laws may demonstrate the most success treating and preventing sexually transmitted infections (STIs), results of a new study suggest.

- The CDC estimates that undiagnosed STIs cause infertility in more than 20,000 women each year. One factor that contributes to young women's high rates of STIs is reinfection from an untreated sexual partner.
- Even after EPT legislation is enacted, there may be concurrent issues that need to be addressed to gain its full benefits. Many insurers may not cover medication costs for partners, and some clinicians may be hesitant to treat patients without an exam, citing liability concerns.

fect of EPT legal status (permissible, potentially allowable, or prohibited) on *C. trachomatis* infection rates for each state, researchers analyzed reported chlamydia cases from 2000-2013. Their analysis indicated that on average, disease incidence in states with prohibitive EPT legislation grew significantly faster than in states where EPT was allowed.[1]

In states that prohibit EPT, the analysis indicated that the average increase in the incidence of chlamydia infection is 17.5 cases per 100,000 per year, compared with 14.1 cases in states where EPT is legal.[1]

"There are many barriers preventing people from making an office visit, from transportation and inconvenience to access to a free clinic," Mmeje said a statement accompanying the report. "Allowing doctors to treat both patients and their partners in this way has proven to be effective at preventing reinfection and the spread of infections such as chlamydia and gonorrhea. Long term, there are many societal benefits both in health and cost."

Do you know the status of EPT legislation in your state? **Stephanie Arnold Pang**, director of policy and communications for the National Coalition of STD Directors, says clinicians can find out by checking out the EPT map, maintained by the CDC, at: http://bit.ly/2sofAfl. As of July 1, Georgia became the latest state to allow EPT. *(To read more about the state's enabling legislation, please visit: http://bit.ly/2rmUFcF.)*

Providers, public health officials, and legislators who wish to see pro-EPT legislation passed in their states can get information from the CDC's dedicated web page on the subject. *(http://bit.ly/2sxdbP9)*

The National Coalition of STD Directors also has been a part of the policy process in many states by helping facilitate coalitions, creating materials, and providing organizational support.

Even after lawmakers enact EPT legislation, there may be concurrent issues legislatures need to address to unlock EPT's full benefits.

Many insurers may not cover medication costs for partners, and some clinicians may be hesitant to treat patients without an exam, citing liability concerns. The University of Michigan research team continues to examine barriers to practicing EPT in Michigan, where legislation became effective in 2015.

"EPT helps circumvent some of the most common barriers to patients receiving the care they need," Mmeje said in the statement released with her team's report. "Our findings provide strong reasons to re-examine policies that make it difficult to access a public health measure that we know can help treat and prevent sexually transmitted diseases." ■

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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.

COMING IN FUTURE MONTHS

- Liletta intrauterine device eyed for four-year use
- New urinary tract infection test detects more bacteria than standard test
- Research eyes women's attitudes and beliefs on pelvic screening
- Estrogen loss: Risk factor for disc degeneration and lower back pain?

CONTRACEPTIVE TECHNOLOGY UPDATE®

CME/CE 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. Log on to the AHCMedia.com and click on My Account to view your available CE activities. Tests are taken after each issue. First-time users must register on the site using the subscriber number on their mailing label, invoice, or renewal notice.

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

4. After successfully completing the test, a credit letter will be emailed to you instantly.

5. Twice yearly after the test, your browser will be automatically directed to the activity evaluation form, which must be completed to receive your credit letter.

CME/CE QUESTIONS

1. **The two drugs contained in the vaginal ring now in Phase I clinical trials conducted by the International Partnership for Microbicides and the Microbicide Trials Network are:**

   a. dapivirine and levonorgestrel.
   b. tenofovir and levonorgestrel.
   c. dapivirine and norgestimate.
   d. dapivirine and ethinyl estradiol.

2. **Babies that are born of repeat teen pregnancies are more likely to:**

   a. experience more infections and be delivered in breech position than first teen births.
   b. result in more postpartum hemorrhage than first teen births.
   c. result in more prolonged labor than first teen births.
   d. be preterm or of low birthweight compared to first teen births.

3. **Rather than the previously recommended three doses, the CDC now recommends administering two doses of HPV vaccine at least six months apart in girls and boys:**

   a. 9-10 years of age.
   b. 10-11 years of age.
   c. 11-12 years of age.
   d. 12-13 years of age.

4. **Data indicate what percentage of women report engaging in unprotected intercourse before the routine six-week postpartum visit?**

   a. Between 15-20%
   b. Between 20-25%
   c. Between 30-46%
   d. Between 40-57%