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2 studies show monthly vaginal ring protects women against HIV

International Partnership for Microbicides to seek approval for device

Results presented at the 2016 Conference on Retroviruses and Opportunistic Infections from two large Phase III clinical trials suggest that a monthly vaginal ring containing the antiretroviral drug dapivirine (and no contraceptives) can safely help prevent HIV-1 infection in women.[1-2]

Developed by the Silver Spring, MD-based nonprofit International Partnership for Microbicides (IPM), the monthly ring is the first long-acting HIV prevention method designed for women, who bear the greatest burden of the global HIV/AIDS epidemic. Results from the Ring Study, led by IPM, indicate that the monthly dapivirine ring safely reduced HIV infection overall by 31% compared to a placebo.[1] Similar results were seen in the second study dubbed ASPIRE, headed by the Microbicide Trials Network (MTN), which was funded by the U.S. National Institutes of Health. Data from the ASPIRE study suggest the ring safely reduced infection by 27% overall.[2] *(Contraceptive Technology Update reported on the genesis of both studies. Access the story "Dapivirine vaginal ring eyed for HIV prevention," which was in the October 2012 issue, at http://bit.ly/1pEMTG3.)*

"THE HIGH HIV INCIDENCE RATES WE SAW IN WOMEN OF ALL AGES IN BOTH RING STUDIES UNDERSCORE THE GREAT RISK WOMEN IN THESE COMMUNITIES FACE EVERY DAY... "
— ZEDA ROSENBERG, SCD, INTERNATIONAL PARTNERSHIP FOR MICROBICIDES

The Ring Study enrolled 1,959 HIV-negative women ages 18-45 at seven sites in South Africa and Uganda, while the ASPIRE study enrolled 2,629 HIV-negative women ages 18-45 at 15 sites in Malawi, South Africa, Uganda, and Zimbabwe. The ASPIRE

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study began in 2012 and ended in 2015. While the Ring Study also began in 2012, it released its results early after its independent data safety and monitoring board recommended the study proceed to final analysis.

The Ring Study employed a 2:1 randomization design: For every two women who used the dapivirine ring, one woman used the placebo. Of the 1,300 participants who used the dapivirine ring and were included in the study's final analysis, 77 acquired HIV. Of the 650 who used a placebo ring, 56 acquired HIV (31% efficacy). In the ASPIRE study, which used a 1:1 randomization design, of the 1,308 participants who used the dapivirine ring and were included in the final analysis, 71 acquired HIV. Of the 1,306 who used a placebo, 97 acquired HIV (27% efficacy). All women in both studies received regular HIV testing and counseling, treatment for sexually transmitted infections, and condoms. Participants were instructed on how to insert and remove the ring, which they replaced every four weeks.

Both studies saw differences in efficacy by age and consistency of ring use, or adherence. Results from the ASPIRE study indicate the ring cut HIV risk by 61% in women older than age 25 and by 56% in women older than age 21 in a post-hoc analysis.[2] These findings were statistically significant and supported by a trend in The Ring Study, which also showed higher efficacy (37%) for women older than age 21.[1]

However, scientists in both studies saw little to no protection in women ages 18-21; just 15% in the Ring Study and no protection in ASPIRE.[1-2] The lack of protection seen in this age group, which is likely due to lower adherence, is not unique to these two studies, scientists believe. Previous ARV-based prevention efficacy trials with tenofovir gel and tenofovir-based oral PrEP also saw lower protection among younger male and female participants due to lower adherence.[3-4] With daily oral PrEP, however, adherence increased for younger participants in subsequent post-trial studies, in which participants knew that PrEP already had been proven effective and that they were receiving the active product.[5]

Study may offer clues

IPM plans to conduct an open-label extension (OLE) study that will provide the dapivirine ring to

EXECUTIVE SUMMARY

Results presented at the 2016 Conference on Retroviruses and Opportunistic Infections from two large Phase III clinical trials suggest that a monthly vaginal ring containing the antiretroviral drug dapivirine (and no contraceptives) can safely help prevent HIV-1 infection in women.

- Developed by the nonprofit International Partnership for Microbicides, the monthly ring is the first long-acting HIV prevention method designed for women, who bear the greatest burden of the global HIV/AIDS epidemic.
- Results from the Ring Study indicate that the monthly dapivirine ring safely reduced HIV infection overall by 31% compared to a placebo. Similar results were seen in the second study, dubbed ASPIRE. Its data suggest the ring safely reduced infection by 27% overall.

previous Ring Study participants. How might such a study help to answer critical questions about the product?

"First, the OLE study would demonstrate how women would use the monthly dapivirine ring now that they know it can safely help prevent HIV when it is used consistently, and help us to better support adherence," says **Zeda Rosenberg**, ScD, IPM chief executive officer. "In an open-label research setting, we could follow women's ring use patterns individually and talk to them directly about their experiences, which would help us fully understand what factors discourage adherence and, just as importantly, what motivates it."

In addition, the study will help scientists understand why women age 21 and younger had such low protection in the Phase III ring studies, notes Rosenberg. Was it solely because they were not able to use the ring consistently, or are there other biological factors at play? Results from the OLE study will help develop methods to overcome barriers to protection for the youngest women, she states.

"The high HIV incidence rates we saw in women of all ages in both ring studies underscore the great risk women in these communities face every day — and the urgent need to find effective solutions they can use to protect their health," states Rosenberg.

As sister studies, ASPIRE and the Ring Study were designed to provide the strength of evidence to support potential licensure of the dapivirine vaginal ring for preventing HIV in women. Because at least two Phase III efficacy trials usually are needed for a product to be considered for regulatory approval, ASPIRE and the Ring Study were conducted in parallel to accelerate the timeline to the ring's potential approval. IPM is compiling all data on the ring to submit it for product licensure in the first quarter of 2017.

Woman have control

Dapivirine belongs to a class of antiretroviral drugs referred to as non-nucleoside reverse transcriptase inhibitors that bind to and disable HIV's reverse transcriptase enzyme, a key protein needed for HIV replication. The ring, made of a flexible silicone material, slowly releases the drug over a month, with minimal absorption elsewhere in the body.

> "... IT IS SAFE, WITH VERY LITTLE SYSTEMIC ABSORPTION OF THE MEDICATION. THE DRUG IS CONCENTRATED IN THE VAGINA ..."

The ring's development was made possible by a public-private partnership with Dublin-based Janssen Sciences Ireland UC, a Janssen pharmaceutical company of Johnson & Johnson, which granted IPM a royalty-free license in 2004 to develop dapivirine as a microbicide for women in developing countries. The license has been expanded since then to a worldwide rights agreement.

What characteristics of the dapivirine ring might make it an attractive option for HIV prevention, particularly for at-risk women? Two characteristics stand out, says **Jared Baeten**, MD, PhD, vice chair of global health and professor of allergy and infectious diseases, public health, and epidemiology at the Seattle-based University of Washington School of Public Health.

"First, the ring is under a woman's control and can be used discretely," says Baeten, who served as protocol chair for the ASPIRE study. "Second, it is safe, with very little systemic absorption of the medication. The drug is concentrated in the vagina, where it is needed."

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Food and Drug Administration takes steps to ensure safety of Essure

The Food and Drug Administration (FDA) has taken steps to ensure the safety of the Essure method of permanent birth control. The agency has issued a new, mandatory clinical study to determine heightened risks for particular women. It also plans to change product labeling to include a boxed warning and a patient decision checklist to help to ensure women understand information regarding the device's benefits and risks.

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

The Essure System includes an implantable insert and a delivery system for the placement of the insert. In contrast to other permanent sterilization procedures, Essure inserts are placed into each fallopian tube through the cervix using a hysteroscope. Once in place, the fibers within the insert elicit a local, fibrotic reaction, which causes fibrous tissue to grow in and around the implant, thus blocking the fallopian tubes.

As part of the Essure procedure, patients undergo a radiologic confirmation test via hysterosalpingography or ultrasound three months after insert placement to ensure the proper placement and/or occlusion of the fallopian tubes. Women are advised to use alternate contraception for the first three months until the confirmation test ensures tubal occlusion.

The Essure System was approved by the FDA in 2002 as a permanent birth control option for women who have completed their families. Originally brought to market by Conceptus of Mountain View, CA, Essure was acquired by Bayer in June 2013. According to the FDA, in late 2013, it received a significant increase in the number of adverse event reports related to Essure, particularly from patients who had received the device.

EXECUTIVE SUMMARY

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- The agency also plans to change product labeling to include a boxed warning and a patient decision checklist to help to ensure women receive and understand information regarding the device's benefits and risks.
- The action follows a September 2015 meeting of the agency's Medical Devices Advisory Committee's Obstetrics and Gynecology Devices Panel. The meeting included expert scientific and clinical opinions, as well as reports from women who have used the device. The panel meeting was called to weigh all evidence following complaints regarding the sterilization option.

The 2016 regulatory action follows a September 2015 meeting of the FDA Medical Devices Advisory Committee's Obstetrics and Gynecology Devices Panel. The meeting included expert scientific and clinical opinions, as well as reports from women who have used the device. The panel meeting was called to weigh all evidence following complaints regarding the sterilization option.

While the FDA officials say Essure remains an appropriate option for most women seeking a permanent form of birth control, some women might be at risk for serious complications, according to its February 2016 announcement. Such complications may include persistent pain, perforation of the uterus or fallopian tubes from device migration, abnormal bleeding, and allergy or hypersensitivity reactions.

How will the proposed patient checklist help with counseling women about the risks and benefits of the device?

"FDA intends to require a boxed warning and Patient Decision Checklist be added to the Essure product labeling to help to ensure that a woman receives and understands information regarding the benefits and risks of this type of device," says **Deborah Kotz**, an FDA press officer. "The FDA has issued a draft guidance to provide the public an opportunity to comment on the proposed language to be included in these warnings." *(The draft guidance issued on March 4 is available at http://1.usa.gov/1U2pmeV. Comments are being accepted for 60 days.)*

The decision checklist should be provided by doctors to patients to

better communicate risks to support an informed decision-making process, says Kotz. The FDA recommends that the checklist be completed and signed by the patient and physician prior to proceeding with a permanent hysteroscopic sterilization procedure, such as Essure, she notes.

"The FDA believes that significant improvements in patient counseling are necessary and may be accomplished through the decision checklist and other information disseminated through professional medical societies, patient advocacy groups, and minority health organizations," states Kotz. "Patients should be informed of all their birth control options, including all forms of sterilization techniques, before making the decision to use Essure."

In its February 2016 announcement, the FDA also ordered Bayer HealthCare Pharmaceuticals of Wayne, NJ, the company that manufactures Essure, to conduct a new postmarket surveillance study on the device.

The study will provide data to help the agency to better understand the risks associated with Essure and compare them to laparoscopic tubal ligation, including rates of complications such as unplanned pregnancy, pelvic pain and other symptoms, and surgery to remove the Essure device. The study also will examine how much these complications affect a patient's quality of life, as well as collect information to identify reasons for why some patients don't have a confirmation test to ensure that Essure has been properly placed three months after insertion. The FDA will use the results of this study to determine what, if any, further actions related to the device are needed to protect public health.

Dario Mirski, MD, senior vice president and head of medical affairs Americas at Bayer, states, "Physicians who perform the Essure procedure will receive a communication from Bayer outlining the FDA action items and will continue to receive updates as we proceed. We will also continue to inform physicians on any labeling changes through our field personnel and other outreach." ■

Advocates press for wider access to female condoms

With recent action by the World Health Organization/ United Nations Population Fund (WHO/UNFPA) to prequalify two more female condoms, women's health advocates hope the move aids in expanding options for female-initiated methods of dual protection from pregnancy and sexually transmitted infections (STIs). The WHO/UNFPA decision allows United Nations agencies and other international purchasers to procure these pre-qualified products for public-sector distribution.

The two newly prequalified condoms include the Woman's Condom, which was developed by Seattle-based PATH, Norfolk, VA-based CONRAD, and local research partners through a user-centered process across four countries. It is now produced as the O'Lavie female condom by Shanghai, China-based Dahua Medical Apparatus Co. The second pre-qualified condom is the Velvet, produced by Karala, India-based HLL Lifecare.

The duo join two previously prequalified female condoms: the FC2, produced by the Chicago-based Female Health Company, and the Cupid, sold by Nashik, India-based Cupid.

Before they can be marketed in a specific country, any female condom product requires regulatory approval from national regulatory authorities, explains **Patricia Coffey**, PhD, MPH, leader of the Health Technologies for Women and Children group at PATH. The regulatory process shares some similarities across countries, but each country has its own specific requirements, she notes.

"For example, the CE mark, Europe's approval for a medical device, is very focused on safety and making sure that a device performs according to its intended use," states Coffey. FDA approval "places greater emphasis on evidence from human clinical studies," she says.

The WHO/UNFPA pre-qualification process is an internationally recognized certification that ensures the efficacy, safety, and quality of female condoms. Some countries that do not have their own regulatory process rely on WHO/UNFPA prequalification or approvals from Europe, the United States, or other stringent regulatory bodies before allowing product registration.

"Because of this, WHO/UNFPA prequalification and/or regulatory approvals from Europe and the United States are often seen as critical milestones for product access," says Coffey. "Specifically, WHO/UNFPA prequalification allows United Nations agencies, national governments, and other international purchasers to procure the product for public-sector distribution — an important aspect of expanding availability in low- and middle-income countries."

WHO/UNFPA prequalification is often a tender requirement of country governments, including South Africa, that procure female condoms for use in government-supported sexual and reproductive health programs. Achieving this certification allows prequalified products to be positioned to respond to global market opportunities, notes Coffey.

The first female condom, the FC1 Reality condom, was approved by the FDA in 1993. The FC2, the successor to the original FC1 model, was approved by the FDA in 2009. It remains the only female condom on the U.S. market.

The female condom product category has evolved since the FDA first reviewed the FC1 female condom. Because the FC1 was the first of its kind, the FDA determined it should be classified as a Class III medical device, a category that is generally reserved for high-risk medical equipment that requires the highest level of regulatory scrutiny. Just 10% of all regulated medical devices fall under this category; examples include implantable pacemakers and breast implants. The classification has not changed since 1993.

"The Class III designation serves as a barrier to manufacturers seeking U.S. FDA approval and ultimately negatively impacts women and men who need more prevention options," states the Chicago-based National Female Condom Coalition, a group of U.S. advocates from the sexual health and reproductive justice, HIV/AIDS, and lesbian/gay/bisexual/transgender communities. "The high costs associated with a Class III product application prohibit manufacturers from submitting their products for review, thus limiting female condom options in the U.S. to a single product, the FC2, while women and men in other countries are able to access and choose from a number of female condom products to reduce their risk of HIV, STIs, and unintended pregnancy."

With the Woman's Condom and the Velvet condom now receiving WHO/UNFPA prequalification, the time for FDA down-classification of female condoms is "now," says **Jessica Terlikowski**, secretariat for the Coalition.

Eighty-eight organizations, including the American College of Obstetricians and Gynecologists and the National Coalition of STD Directors, joined the Coalition in 2015 to urge the FDA to re-classify female condoms as a Class II device and remove unnecessary barriers to female condom innovation. In 2015, the FDA announced that the FC2 is included in the list of Class III products under consideration for down-classification, an "important step in the right direction," says Terlikowski.

"However, given that female condoms remain the only dual purpose technology available for women, we urge the FDA to take swift action and down-classify female condoms so as to enable introduction of other female condom options into the U.S. market," says Terlikowski. "Women need more than one option." ■

Teen dating violence: Why you should screen

According to the Centers for Disease Control and Prevention (CDC), among high school students who date, 21% of females and 10% of males experience physical and/or sexual dating violence.[1] Among adult victims of rape, physical violence, and/or stalking by an intimate partner, 22% of women and 15% of men say they first experienced some form of partner violence between ages 11 and 17.[2]

How can clinicians screen and provide resources for at-risk teens?

First, understand what constitutes teen dating violence. Dating violence can be physical, emotional, or sexual. Physical violence occurs when a partner is pinched, hit, shoved, slapped, punched, or kicked. Psychological/emotional violence includes threatening a partner or harming his or her sense of self-worth by name-calling, shaming, bullying, embarrassing on purpose, or keeping him/her away from friends and family.

Because injuries are the most common preventable cause of morbidity and mortality among young women, safety questions are important facets of any preventive visit. All patients should be asked about abuse, neglect, and physical and sexual violence.[3] Sexual violence includes forcing a partner to engage in a sex act when he or she does not or cannot consent. Sexual violence can be physical or nonphysical. An example of nonphysical sexual violence is threatening to spread rumors if a partner refuses to have sex.

Another form of dating violence is stalking, which refers to a pattern of harassing or threatening tactics that are unwanted and cause fear in the victim. Dating violence can take place in person or electronically, such as repeated texting or posting sexual pictures of a partner online.

There are several reasons why healthcare providers should screen for partner violence in adolescents, says **Vijay Singh**, MD, MPH, MS, a University of Michigan Injury Center researcher and clinical lecturer in the Departments of Emergency Medicine and Family Medicine at the Ann Arbor-based university. Partner violence among adolescents is highly prevalent and creates a large burden of disease, notes Singh. In one study, more than one in three U.S. women in their lifetime experienced rape, physical violence, or stalking, and more than two-thirds of those women experienced partner violence before age 25.[4]

"Partner violence among adolescents is associated with unintended pregnancy, birth control interference, inconsistent condom use, and sexually transmitted infections including HIV," states Singh. "These reproductive health concerns may be the presenting reason for patients, but partner violence screening can uncover underlying risks for these health problems."

Partner violence screening among women starting at age 14 is recommended by the United States Preventive Services Task Force guidelines, as well as various medical societies, including the American College of Obstetrics and Gynecology, notes Singh, who served as lead author of a study looking at prevalence and correlates of dating violence, dating victimization, and dating aggression among adolescent teens seeking emergency department care.[5]

"Healthcare providers who screen youth for partner violence could prevent future intimate partner violence when adolescents reach adulthood," says Singh. (*See resources at the end of this article for screening information.)*

EXECUTIVE SUMMARY

Among high school students who date, 21% of females and 10% of males experience physical and/or sexual dating violence, according to the Centers for Disease Control and Prevention. Among adult victims of rape, physical violence, and/or stalking by an intimate partner, 22% of women and 15% of men say they first experienced some form of partner violence between ages 11 and 17.

- Dating violence can be physical, emotional, or sexual. Physical violence occurs when a person is pinched, hit, shoved, slapped, punched, or kicked by his or her partner.
- Psychological/emotional violence includes threatening a partner or harming his or her sense of self-worth by name-calling, shaming, bullying, embarrassing on purpose, or keeping him/her away from friends and family.

The CDC has launched an initiative, named Dating Matters: Strategies to Promote Healthy Teen Relationships, to promote respectful, nonviolent relationships among teens in high-risk, urban communities *(http://1.usa.gov/1nzQt2h).* The initiative supports prevention strategies in schools and neighborhoods and with families, using comprehensive, evidence-based, and evidence-informed practices to reduce the burden of teen dating violence.

The program, which began in 2011, is centered in four cities: Baltimore, Chicago, Fort Lauderdale, FL, and Oakland, CA. It focuses on young boys and girls ages 11-14 in high-risk, urban communities.

"It isn't enough to tell young people not to engage in violent behaviors; we have to teach young people what healthy relationship behaviors are and give them the skills to use them if we want to help them engage in respectful, safe relationships," said **Phyllis Holditch Niolon**, PhD, acting special assistant to the associate director of science in the CDC's Division of Violence Prevention. "As parents, educators, and community members, it's up to us to model respectful relationships and to give adolescents the skills and guidance needed to build respectful, violence-free relationships throughout their lives."

Use this mnemonic

Use the HEEADSSS method of interviewing to perform a psychosocial review of systems when talking with adolescent patients. HEEADSSS stands for:

- **H**ome environment;
- **E**ducation and employment;
- **E**ating;
- peer-related **A**ctivities;
- **D**rugs;
- **S**exuality;
- **S**uicide/depression;
- **S**afety from injury and violence.

The HEEADSSS method allows clinicians to explore a wide range of topics in an efficient manner during a visit. The questions in the HEEADSSS method give clinicians a key opportunity to spot risky behavior in adolescents, such as potential dating violence. *(To read more information about this approach, see the* Contraceptive Technology Update *article, "How to get into teens' heads in initial visit," January 2014, at http://bit.ly/22ywKzL.)*

RESOURCES

- Obtain guidance on screening from:
  — Moyer VA; U.S. Preventive Services Task Force. Screening for intimate partner violence and abuse of elderly and vulnerable adults: U.S. Preventive Services Task Force recommendation statement. *Ann Intern Med* 2013; 158(6):478-486.
  — ACOG Committee Opinion No. 518: Intimate partner violence. *Obstet Gynecol* 2012; 119(2 Pt 1):412-417.
- Offer teens a free handout on teen dating violence from the Centers for Disease Control and Prevention. Web: http://1.usa.gov/1yY40Sr.

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Management of your patients' menopause — Is your care on the right track?

By 2020, more than 50 million U.S. women will be older than 51, the mean age when menopause occurs.[1] Despite the availability of effective hormonal and nonhormonal treatments for menopausal symptoms, few women with menopausal symptoms are evaluated or treated, reports a new scientific perspective.[1] What can clinicians do to sharpen their clinical skills?

Providers who remain current regarding hormonal therapy can help their patients make sound choices regarding treatment of menopausal symptoms, observes **Andrew Kaunitz**, MD, University of Florida Research Foundation professor and associate chairman of the Department of Obstetrics and Gynecology at the University of Florida College of Medicine – Jacksonville. The current perspective was co-authored by Kaunitz and **JoAnn Manson**, MD, DrPH, NCMP, chief of the Division of Preventive Medicine at Brigham and Women's Hospital and professor of medicine and the Michael and Lee Bell professor of women's health at Harvard Medical School, both in Boston.

Since publication of initial findings from the Women's Health Initiative (WHI) in 2002, use of menopausal hormone therapy has declined steeply in U.S. women, notes Kaunitz. In contrast with current conventional wisdom, the best available evidence, which also comes from WHI findings, clarifies that for most women in their 50s or within one decade of the onset

EXECUTIVE SUMMARY

Despite the availability of effective hormonal and nonhormonal treatments for menopausal symptoms, few women with menopausal symptoms are evaluated or treated, reports a new scientific perspective.

- Since publication of initial findings from the Women's Health Initiative in 2002, use of menopausal hormone therapy has declined steeply in U.S. women. However, clarification of the study's evidence indicates that for most women in their 50s or within one decade of the onset of menopause, hormone therapy is safe.
- Professional societies, including the North American Menopause Society, the American College of Obstetricians and Gynecologists, and the Endocrine Society, support the use of systemic hormone therapy in symptomatic, recently menopausal women who do not have contraindications, such as an excess risk of breast cancer or cardiovascular disease, and who have a personal preference for such therapy.

of menopause, hormone therapy is safe,[2] says Kaunitz. *(To review current treatment options, read the* Contraceptive Technology Update *article, "Update your treatment of menopausal symptoms," December 2015, at http://bit.ly/1Ufat91.)*

Notwithstanding the current evidence, hormone therapy (HT) is currently associated with such a "dark cloud of confusion and anxiety" that many symptomatic women who represent appropriate candidates for hormone therapy or nonhormonal management have difficulty finding clinicians who are knowledgeable and comfortable regarding treatment, states Kaunitz. "The purpose of our [article] was to signal the need for more education, (particularly for trainees, our next generation of providers) regarding menopause and appropriate strategies for treatment of symptoms, including HT and nonhormonal options," he states.

Professional societies, including the North American Menopause Society (NAMS), the American College of Obstetricians and Gynecologists, and the Endocrine Society, support the use of systemic hormone therapy in symptomatic, recently menopausal women who do not have contraindications, such as an excess risk of breast cancer or cardiovascular disease, and who have a personal preference for such therapy.[3-4] For patients in this category who present with moderate-to-severe vasomotor symptoms, a consensus has emerged that the benefits of hormone therapy are likely to outweigh the risks.[1]

For hot flashes, hormones are given in pills, patches, sprays, gels, or a vaginal ring for systemic therapy. For genitourinary symptoms, hormones are given in creams, pills, or rings that are inserted into the vagina.

The free MenoPro mobile app from NAMS facilitates personalized and shared decision-making for menopausal symptom management, notes Manson. *(More information is available at http://bit.ly/1X1eGyK.)*

The app allows the patient and the clinician to work together to personalize treatment decisions on the basis of the patient's personal preferences, hormone versus non-hormone options, while taking into account the patient's medical history and risk factor status. The app has two modes, one for clinicians and one for women, which facilitates shared decision-making.

THE FREE MENOPRO MOBILE APP FROM NAMS FACILITATES PERSONALIZED AND SHARED DECISION MAKING ...

This approach includes an assessment of whether the patient has moderate-to-severe menopausal symptoms, incorporation of the patient's preferences regarding hormonal compared with nonhormonal therapy, and evaluation of the presence of contraindications to HT, explains Manson. The app also looks at the patient's time since menopause onset and baseline risks of atherosclerotic cardiovascular disease, using an internal risk calculator that incorporates information on the patient's age, smoking status, systolic blood pressure level, antihypertensive therapy, presence or absence of diabetes, and total and HDL cholesterol measurements. Other issues also are addressed, including the patient's risk of breast cancer, osteoporosis, and other conditions relevant to clinical decision-making about HT initiation and duration of treatment. Information about treatment options, including regimens and doses, also is provided, notes Manson.

Other helpful features include links to NAMS education materials, such as a downloadable MenoNote on behavioral and lifestyle modifications to reduce hot flashes, as well as information pages on the pros and cons of hormone versus nonhormonal therapy options, a discussion of pill versus patch therapy, and information on treatment options for vaginal dryness and pain with sexual activities, with links to tables with information about different medications. These pages can be printed out or directly accessed from a phone or tablet.

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Counsel your patients on their risk for pregnancies that are exposed to alcohol

The latest statistics from Centers for Disease Control and Prevention (CDC) indicate that more than 3 million women between the ages of 15 and 44 are at risk of exposing their developing babies to alcohol because they are drinking and not using birth control to prevent pregnancy.[1] The report also found that three in four women who want to get pregnant as soon as possible do not stop drinking alcohol when they stop using birth control.[1]

Alcohol can permanently harm a developing baby before a woman knows she is pregnant, said **Anne Schuchat**, MD, CDC principal deputy director. About half of all pregnancies in the United States are unplanned,[2] and even if planned, most women won't know they are pregnant for the first month or so, when they still might be drinking, noted Schuchat in a press statement accompanying the new report.

Prenatal alcohol exposure is associated with a range of adverse reproductive outcomes and can cause fetal alcohol spectrum disorders that are characterized by lifelong physical, behavioral, and intellectual disabilities.[3] Such outcomes are completely preventable if a woman abstains from alcohol while pregnant.

To compile the report, CDC researchers analyzed data from the 2011-2013 National Survey of Family Growth, which gathers information on family life, marriage, divorce, pregnancy, infertility, use of birth control, and men's and women's health.

Prevalence estimates of risk for an alcohol-exposed pregnancy were calculated for 4,303 nonpregnant, nonsterile women ages 15-44 by selected demographic and behavioral factors. A woman was considered to be at risk for an alcohol-exposed pregnancy if, in the past month, she was not sterile, her partner was not known to be sterile, she had vaginal sex with a male, she drank any alcohol, and she did not use birth control. A woman was considered to be trying to get pregnant if a desired pregnancy was the reason she and her partner stopped using contraception.

Overall, 3.3 million women (7.3% of women ages 15-44 who were having sex, who were non-pregnant and non-sterile) were at risk of exposing their developing baby to alcohol if they were to become pregnant, analysis data indicate.[1]

Every woman who is pregnant or trying to get pregnant, as well as her partner, want a healthy baby, but they might not be aware that drinking alcohol at any stage of pregnancy can cause a range of disabilities for their child, stated **Coleen Boyle**, PhD, director of the CDC's National Center on Birth Defects and Developmental Disabilities.

"It is critical for healthcare providers to assess a woman's drinking habits during routine medical visits; advise her not to drink at all if she is pregnant, trying to get pregnant or sexually active and not using birth control; and recommend services if she needs help to stop drinking," said Boyle in a statement accompanying the new report.

The U.S. Preventive Services Task Force recommends alcohol screening and brief intervention for all adults in primary care.[4] A single screening question about whether a patient recently has consumed more than five drinks in one day (more than four drinks for females) has been found to be effective in identifying at-risk drinking among primary care patients.[5]

The question "How many times in the past year have you had X or more drinks in a day?" (where X is five for men and four for women) can be included on an intake questionnaire or asked orally while collecting vital signs. Patients who score positive then should receive the full Alcohol Use Disorders Identification Test (AUDIT US) to determine their level of risk

EXECUTIVE SUMMARY

New statistics from the Centers for Disease Control and Prevention indicate that more than 3 million women between the ages of 15 and 44 are at risk of exposing their developing baby to alcohol because they are drinking and not using birth control to prevent pregnancy.

- The report also found that three in four women who want to get pregnant as soon as possible do not stop drinking alcohol when they stop using birth control.
- Prenatal alcohol exposure is associated with a range of adverse reproductive outcomes and can cause fetal alcohol spectrum disorders that are characterized by lifelong physical, behavioral, and intellectual disabilities. Such outcomes are completely preventable if a woman abstains from alcohol while pregnant.

and any signs of dependence.

The AUDIT exam, a 10-item screening instrument, was developed through international testing by the World Health Organization. It asks questions about alcohol consumption during the past year, symptoms of alcohol dependence, and alcohol-related problems or harm. It categorizes those taking the exam into four groups: those unlikely to be at risk, those at risk because they drink excessively, those who already have experienced problems related to their drinking, and those who are likely to have alcohol dependence. *(Find information about the AUDIT exam and guidance on implementing alcohol screening in "Planning and Implementing Screening and Brief Intervention for Risky Alcohol Use: A Step-by-Step Guide for Primary Care Practices" at http://1.usa.gov/1pU8wf5.)*

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Access resource on LARC reimbursement

Obtain appropriate compensation for long-acting reversible contraceptive (LARC) services with *Intrauterine Devices and Implants: A Guide to Reimbursement*, a new guide created by the American College of Obstetricians and Gynecologists' LARC Program, the National Health Law Program, the National Women's Law Center, the National Family Planning and Reproductive Health Association, and the Bixby Center at the University of California, San Francisco.

Go to http://bit.ly/1MhrmeA in order to access the guide.

The guide provides an overview of the landscape for coverage of LARC by public and commercial insurance. It also serves as a resource for healthcare practices that are navigating stocking, reimbursement, and other potential challenges to provision of LARC. ■

Check coding for intrauterine devices

As of Jan. 1, 2016, the Centers for Medicare & Medicaid Services has discontinued use of HCPCS code J7302 for 52 mg levonorgestrel-releasing intrauterine devices (IUDs).

The impacted devices are:

- Liletta (Medicines360, San Francisco and Actavis, Dublin, Ireland);
- Mirena (Bayer HealthCare Pharmaceuticals, Wayne, NJ).

Procedure and device coding changes for dates of service on or after Jan. 1, 2016, are 58300 (IUD Insertion) and J7297 (levonorgestrel-releasing intrauterine contraceptive system, 52 mg, three-year duration [Liletta]) OR J7298 (Levonorgestrel-releasing intrauterine contraceptive system, 52 mg, five-year duration [Mirena]). ■

Reader Survey has 2 options

This year, we offer you the option of taking the *2016 Reader Survey* in print, enclosed in this issue, or online, at svy.mk/1Pvdf1J.

Your responses will guide future issues of *Contraceptive Technology Update*. We look forward to receiving your feedback on how to make *CTU* as useful as possible. ■

COMING IN FUTURE MONTHS

- Counseling tips on cervical cancer screening
- Check menorrhagia treatment options
- One key question: Use it in contraceptive counseling
- New HIV prevention drugs in pipeline

CONTRACEPTIVE TECHNOLOGY UPDATE

CE/CME INSTRUCTIONS

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

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

2. Scan the QR code to the right or log on to the AHCMedia.com site to take a post-test. Go to "My Account" to view your available CE activities. Tests are taken after each issue. First-time users will have to 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.

CE/CME QUESTIONS

1. Which class of antiretroviral drugs includes dapivirine?

A. Entry inhibitors
B. Non-nucleoside reverse transcriptase inhibitors
C. Protease inhibitors
D. Fusion inhibitors

2. What are the two female condoms that received pre_qualification in 2016 from the World Health Organization/United Nations Population Fund?

A. The O'Lavie and the Velvet
B. The FC2 and the Cupid
C. The O'Lavie and the Cupid
D. The Velvet and the FC2

3. Which of the following is a contraindication for hormone therapy for symptomatic, recently menopausal women, according to professional societies?

A. Anorexia
B. Cardiovascular disease
C. Mood lability
D. Joint aches

4. How many women in the United States between the ages of 15 and 44 are at risk of exposing their developing baby to alcohol because they are drinking and not using birth control to prevent pregnancy?

A. 1 million
B. 2 million
C. More than 3 million
D. More than 7 million

CE/CME OBJECTIVES

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

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

Contraceptive Technology Update

2016 Reader Survey

In an effort to learn more about the professionals who read *Contraceptive Technology Update*, we are conducting this reader survey. The results will be used to enhance the content and format of *CTU*.

Instructions: Fill in the appropriate answers. Please write in answers to the open-ended questions in the space provided. Return the questionnaire in the enclosed postage-paid envelope by **July 1, 2016.**

In future issues of *CTU*, would you like to see more or less coverage of the following topics?

A. more coverage B. less coverage C. about the same amount

1. Emerging contraceptives	O A	O B	O C
2. Alternative therapies	O A	O B	O C
3. Women's health	O A	O B	O C
4. Depo-Provera (DMPA)	O A	O B	O C
5. Oral contraceptives	O A	O B	O C
6. Teens	O A	O B	O C
7. Existing contraceptives	O A	O B	O C
8. Intrauterine devices (IUD)	O A	O B	O C
9. NuvaRing	O A	O B	O C
10. Emergency contraception	O A	O B	O C

Please rate your level of satisfaction with the following items.

A. Excellent B. Good C. Fair D. Poor

11. quality of newsletter	O A	O B	O C	O D
12. article selections	O A	O B	O C	O D
13. timeliness	O A	O B	O C	O D
14. length of newsletter	O A	O B	O C	O D
15. overall value	O A	O B	O C	O D
16. customer service	O A	O B	O C	O D

17. On average, how many people read your copy of *CTU*?

O A. 1-3
O B. 4-6
O C. 7-9
O D. 10-15
O E. 16 or more

18. Do you plan to renew your subscription to *CTU*?

O A. yes
O B. no If no, why not? _____

_____

19. How would you rate your overall satisfaction with your job?

O A. very satisfied
O B. somewhat satisfied
O C. somewhat dissatisfied
O D. very dissatisfied

20. How would you describe your satisfaction with your subscription to *CTU*?

O A. very satisfied
O B. somewhat satisfied
O C. somewhat dissatisfied
O D. very dissatisfied

21. What is your title?

O A. administrator
O B. nurse practitioner
O C. registered nurse
O D. health educator
O E. MD
O F. nurse midwife
O G. physician assistant
O H. other _____

22. To what other publications or information sources about contraceptive technology do you subscribe?

23. Including *CTU*, which publication or information source do you find most useful, and why?

24. Which website related to your position do you use most often?

25. Please list the top three challenges you face in your job today.

26. What do you like most about *CTU*?

27. What do you like least about *CTU*?

28. What are the top three things you would add to *CTU* to make it more valuable for your money?

Contact information