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INSIDE

RELIAS MEDIA

Revamping the Daily Pill: Research to Begin on Monthly Pill

Drug delivery platform will release medication for monthly dosing

Many scientific strides have been made in the past 25 years when it comes to combined oral contraceptives (OCs). Scientists have addressed the estrogen component, lowering the dose of ethinyl estradiol to reduce such side effects as bloating, breast tenderness, and nausea. Progestin doses, as well as associated endocrine and metabolic characteristics, also have changed. By improving originally manufactured progestins, such as those derived from 19-nor-progesterone, and developing new progestins, side effects such as acne and effects on high-density lipoprotein cholesterol levels have been reduced.[1,2]

> ONE OF THE BIGGEST CHALLENGES FOR PATIENTS IS ADHERING TO THE DAILY SCHEDULE OF THE ORAL CONTRACEPTIVE PILL.

Although lowering side effects plays an important role in oral contraceptive compliance, one of the biggest challenges for patients is adhering to the daily schedule of the pill. Forgetting one to three pills per cycle is a frequent problem among 15-51% of users, particularly among adolescents.[3] It is estimated that nine out of every 100 women will experience an unintended pregnancy within the first year of typical use of oral contraceptives.[4]

Lyndra Therapeutics has received a $13 million grant from the Bill & Melinda Gates Foundation and is setting out to remove the daily pill compliance challenge. The company is in early development of a monthly oral contraceptive to provide women with

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a discreet, noninvasive, reversible contraception option.

"This grant is special because it extends our focus on meeting unmet therapeutic need into women's health," said **Amy Schulman**, JD, chief executive officer and co-founder of Lyndra Therapeutics, in a statement. "We are proud to be part of the foundation's effort to improve lives and ensure better health outcomes by making it easier to access and benefit from family planning." *(View the statement online at: https://bit.ly/2ztNEIx.)*

Changing the Mechanics

Lyndra Therapeutics is developing a drug delivery platform that slowly releases medication in the stomach over a set period of time. This platform will help to make daily pills a thing of the past, according to company officials.

All current commercially available gastric resident dosage forms, and most in development, are limited to gastric residence of less than one day, according to Lyndra Therapeutics researchers.[5] The company is partnering with Gilead Sciences to develop and commercialize ultra-long-acting oral HIV therapies. Gilead's anti-HIV drug combination, Truvada, is the cornerstone of pre-exposure prophylaxis (PrEP) against HIV. The U.S. Preventive Services Task Force now recommends that PrEP be offered to all people at high risk of HIV.[6,7]

Lyndra's technology is based on a star-shaped structure with six arms, loaded with drug molecules. The arms fold inward, encasing the structure in a smooth capsule. After the capsule is swallowed, stomach acid dissolves the capsule's outer layer, unfolding the arms and releasing its drug molecules. Once the structure is expanded, it is large enough to stay in the stomach and resist being pushed down the digestive tract without blocking other items. Its arms are designed to break off eventually so that all pieces are expelled naturally.

Scientific tests in pigs indicate that a pill with such a structure could continue to release medicine in the stomach for two weeks.[8] Lyndra scientists are developing new versions of the capsule to provide one dose per month.

Researchers will conduct preclinical evaluation of the oral contraceptive in collaboration with Routes2Results, a nonprofit social and public health research

EXECUTIVE SUMMARY

Lyndra Therapeutics has received a $13 million grant from the Bill & Melinda Gates Foundation to develop a once-a-month oral contraceptive to provide women with a discreet, noninvasive, reversible option.

- Forgetting one to three pills per cycle is a frequent problem among 15-51% of users, particularly among adolescents. It is estimated that nine out of every 100 women will experience an unintended pregnancy within the first year of typical use of oral contraceptives.
- Scientists are developing a drug delivery platform that slowly releases medication in the stomach over a set period of time. This platform will help to make daily pills a thing of the past, researchers say.

organization based in the United Kingdom, through additional funding from the Gates Foundation. The foundation also awarded Lyndra Therapeutics a grant to develop a long-acting malaria drug. The company is using recently raised funding for Phase II clinical trials, expansion of its Phase I pipeline, and manufacturing scale-up.

Will Women Use It?

Family planning clinicians seek to offer women the full range of contraceptive options in an effort for birth control success. As *Contraceptive Technology* points out, "the best method of contraception for an individual is one that is safe and that will actually be used correctly and consistently."[9]

Use of methods such as the contraceptive injectable, the vaginal contraceptive ring, and the transdermal contraceptive patch has grown over the past 20 years. The number of women who receive the injection grew from 5% in 1995 to 23% in 2006-2010. Ever-use of the contraceptive patch grew from less than 1% in 2002 to 10% in 2006-2010. Six percent of women in 2006-2010 reported using the contraceptive ring.[10]

In 2014, about 14% of women using a contraceptive reported using a long-acting reversible contraceptive (LARC) method — 12% used intrauterine devices, while 3% used the contraceptive implant.[11] Use of LARCs has grown from 2% in 2002 to 6% in 2007 and 9% in 2009.[12,13]

The increase in LARC usage has come in part due to the success of research demonstrating its effect on unintended pregnancy and abortion. In the Contraceptive CHOICE project, 9,256 women ages 14-45 years were offered their choice of contraceptive method without charge. About 75% of women chose long-acting methods, with significant results. The project identified a notable reduction in unintended pregnancies and abortion rates of study participants compared with a similar population from the same geographic area.[14] In the Zika Contraception Access Network (Z-CAN) — a program designed to prevent unintended pregnancies and reduce birth defects during the height of the 2016-2017 Zika virus outbreak in Puerto Rico — 67.5% of 21,124 women chose and received a LARC method at their initial visit.[15] In the Colorado Family Planning Initiative, investigators provided access to LARCs at no cost to clients in Title X-funded clinics in 37 of Colorado's 64 counties. Data indicate LARC use increased from 5% to 19% among low-income teenagers and young women. The increase in LARC use was accompanied by decreases in birth rates and abortion rates in both age brackets, results indicated.[16] ■

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Year-Long Supply of Pills Effective in Preventing Pregnancy, Cutting Costs

What is the common practice for providing multiple pill packs of oral contraceptives (OCs)? New research adds to the library of evidence that dispensing a year's worth of pills reduces the rate of unintended pregnancies as well as costs.[1]

Findings from the new paper, published by researchers at the University of Pittsburgh and the U.S. Department of Veterans Affairs, indicate that reducing birth control refills would be more effective for preventing undesired pregnancies among female veterans. The money saved on healthcare costs would more than outweigh the expense of providing multiple pill packs at one time.

"Medication dispensing limits are thought to be cost-saving because you're not wasting pills and medicines that people aren't going to use," lead author **Colleen Judge-Golden**, an MD/PhD student at Pitt's School of Medicine, noted in a statement. "Our analysis shows that concerns about wastage of contraceptive pills are overshadowed by the potential consequences of missed refills, and especially of unintended pregnancies." *(The statement can be viewed online at: https://upmc.me/328MQ8b.)*

Data supplied by the VA shows that 43% of women receiving three-month increments of birth control pills experience at least one gap between refills over the course of a year of use. Published data about civilian women who receive a year's supply of pills up front shows that they experience fewer gaps and fewer unintended pregnancies.[2-4]

Facilitate Access to Contraception

The VA system, the largest integrated healthcare system in the United States, currently stipulates a three-month maximum dispensing limit for all medications, including oral contraceptives. Judge-Golden worked with senior author **Sonya Borrero**, MD, MS, director of Pitt's Center for Women's Health Research and Innovation and associate director of the VA Center for Health Equity Research and Promotion, and other investigators to develop a decision model for the department.

The researchers' analysis estimated that among the 24,000 women receiving birth control pills from the VA, offering a year's supply of pills would prevent 583 unintended pregnancies and save the department about $2 million per year in prenatal, birth, and newborn care costs.

"This is a great opportunity for the VA to roll out this policy change on a national level and continue to be a leader and set an elevated standard for women's healthcare," Borrero noted in the statement with Judge-Golden.

The CDC's U.S. Selected Practice

EXECUTIVE SUMMARY

Findings from a new paper by researchers at the University of Pittsburgh and the U.S. Department of Veterans Affairs indicate that reducing birth control refills would better allow female veterans to prevent undesired pregnancies, with the money saved on healthcare costs more than outweighing the expense of providing multiple pill packs at one time.

- Researchers estimate that among the 24,000 women receiving birth control pills from the VA, offering a year's supply of pills would prevent 583 unintended pregnancies and save the department about $2 million per year in prenatal, birth, and newborn care costs.
- The U.S. Selected Practice Recommendations for Contraceptive Use recommends providing up to a year's supply of pills when a patient initiates pill use.

Recommendations for Contraceptive Use recommends providing up to a year's supply of OCs when a patient initiates use.[5] Research shows higher continuation rates when more pill packs are given up to 13 cycles. Limiting pill packs distributed or prescribed can result in unwanted OC discontinuation and increased risk for pregnancy, the guidance states.[5] Eighteen states and the District of Columbia require that insurers cover the quantity of contraceptives dispensed in accordance with a prescription.

Power to Decide, a nonprofit campaign to prevent unplanned pregnancy, has worked with a panel of more than 50 experts to develop the Better Birth Control Framework, a collection of best practices that communities, states, and regions can use to make sure that policies, systems, programs, and financing are in place to ensure access to a full range of contraception. One of the platforms calls for public and private payers to cover a 12-month supply of self-administered hormonal contraception, such as pills, rings, or patches, at one time when prescribed and/or dispensed by a provider.

To expand access to contraception, a 2015 American College of Obstetricians and Gynecologists committee opinion calls for payment and practice policies that support provision of 3-13 month supplies of combined hormonal methods to improve contraceptive continuation.[6] ■

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Analysis Focuses on Testosterone Use in Postmenopause

Results of a comprehensive meta-analysis indicate that testosterone can improve sexual well-being for postmenopausal women.[1] According to the analysis, benefits included improved sexual desire, function, and pleasure, and fewer concerns about sex.

Testosterone contributes to female libido and and helps maintain normal metabolic function, muscle strength, cognitive function, and mood. Levels decline naturally over a woman's lifespan, and can decline after surgical menopause. Although evidence indicates that testosterone therapy can improve sexual function in women, available formulations have been designed for men, with little evidence available regarding safety or adverse side effects in women. **Susan Davis**, MBBS, FRACP, PhD, FAHMS, professor at Monash University in Melbourne, Australia, and senior author of the meta-analysis, said her research group's results suggested it is time to develop specific testosterone treatment tailored to postmenopausal women.

"Nearly a third of women experience low sexual desire at midlife, with associated distress, but no approved testosterone formulation or product exists for them in any country and there are no internationally agreed guidelines for testosterone use by women," said Davis in a press statement. "Considering the benefits we found for women's sex lives and personal well-being, new guidelines and new formulations are urgently needed." *(The statement can be found online at: https://bit.ly/2NzkIHu.)*

Take a Closer Look

Investigators reviewed 46 reports of 36 randomized controlled trials conducted between January 1990 and December 2018. The trials included 8,480 participants ages 18-75 years, with about 95% identified as postmenopausal. The trials compared testosterone treatment to a placebo or to an alternative hormone treatment

such as estrogen, with or without progestogen.

The analysis examined the effect of treatments on sexual function, as well as measures of heart, cognitive, and musculoskeletal health. Also studied were serious side effects, such as increased risk of heart disease or breast cancer; effect on mood and well-being; measures of breast health, such as mammographic density; metabolic effects; and lipid profiles. Investigators also looked for reports of development of androgenic effects, such as increased hair growth.

In 15 studies, including 3,766 naturally and surgically postmenopausal women, consistent beneficial effects were seen for all measures of sexual function. Testosterone treatment increased frequency of satisfactory sexual events, and increased sexual desire, pleasure, arousal, orgasm, responsiveness to sexual stimuli, and self-image. Women treated with testosterone also showed reduced measures of sexual concerns and sexually associated distress.[1]

"The beneficial effects for postmenopausal women shown in our study extend beyond simply increasing the number of times a month they have sex," said Davis. "Some women who have regular sexual encounters report dissatisfaction with their sexual function, so increasing their frequency of a positive sexual experience from never, or occasionally, to once or twice a month can improve self-image and reduce sexual concerns, and may improve overall well-being."

The meta-analysis uncovered no beneficial effects on cognitive measures, bone mineral density, body composition, or muscle strength. No benefits were seen for depressive mood irrespective of menopausal status or in psychological well-being. Researchers noted that the number of women included in these studies was small, requiring further research.

Testosterone use had no serious adverse effects on postmenopausal women in terms of glucose or insulin in the blood, blood pressure, or measures of breast health, researchers reported. Limited data were available for breast cancer risk, and further research is needed to clarify the effects, researchers stated.

In studies of non-oral testosterone, researchers determined no effects on lipid profiles or metabolic variables such as cholesterol. However, use of oral testosterone increased LDL cholesterol, and reduced HDL cholesterol, overall cholesterol, and triglycerides. Postmenopausal women treated with testosterone were not more likely to experience a serious cardiovascular event, they reported.[1]

More Research Needed

In postmenopausal women, testosterone has been used with concurrent estrogen, estrogen plus progestogen, or on its own.[2-6] With the increasing use of compounded therapies that include testosterone, more research is needed. No current therapy including testosterone carries an approved indication from the FDA. A comment published with the meta-analysis indicates that adequate long-term studies can address benefits and risks of testosterone treatment in specific clinical conditions relevant to healthy female longevity.[7]

Two drugs carry indications for hypoactive sexual desire dysfunction. In 2015, the FDA approved flibanserin. Originally developed as an antidepressant, flibanserin works by increasing levels of dopamine and norepinephrine, while decreasing levels of serotonin. This drug interaction is intended to increase chemicals that help promote sexual desire and decrease one that can suppress desire. In June 2019, the FDA approved bremelanotide for treatment of hypoactive sexual desire dysfunction. Bremelanotide, a melanocortin 4 receptor agonist drug candidate, is a synthetic peptide analog of the naturally occurring hormone alpha-MSH (melanocyte-stimulating hormone). ■

EXECUTIVE SUMMARY

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- Testosterone contributes to female libido and helps maintain normal metabolic function, muscle strength, cognitive function, and mood. Levels decline naturally over a woman's lifespan, and can decline after surgical menopause.
- Although evidence indicates testosterone therapy can improve sexual function in women, available formulations have been designed for men, with little evidence available regarding safety or adverse side effects in women.

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Researchers Examine Use of Dapivirine Ring for HIV Prevention

In 2017, estimates indicated there were 37 million people living with HIV and 1.8 million new infections around the globe.[1] In hard-hit sub-Saharan Africa, where young women are disproportionately affected by HIV, new research from an open-label trial of a dapivirine vaginal ring confirms that women will use the device to prevent HIV.[2] The ring was estimated to reduce the risk of HIV by 39%, according to statistical modeling.

Results of the HIV Open Label Extension (HOPE) study were presented at the 10th International AIDS Society Conference on HIV Science in Mexico City. The study continued work begun by the ASPIRE clinical trial. The ASPIRE trial, along with a sister investigation called The Ring Study, demonstrated that the dapivirine ring reduced the risk of HIV infection by about 30% in women ages 18-45 years and was well-tolerated.[3,4] HOPE study researchers gathered additional data on the safety of the dapivirine ring and new data on whether and how women used it, since earlier trials had shown modest effectiveness.

HOPE Shows Results

Begun in 2016, HOPE study researchers enrolled 1,456 former ASPIRE study participants at 14 sites in Malawi, South Africa, Uganda, and Zimbabwe. The women, ages 20-49 years, were sexually active and HIV-negative. Study participants received free laboratory tests, physical and pelvic exams, HIV prevention counseling, and condoms. All participants were offered the dapivirine ring. During their first three months in the trial, participants attended monthly study visits where they could receive one new ring. After the first month, women attended quarterly visits where they could receive three new rings. This schedule was designed to more closely resemble how the ring might be distributed in a real-world setting.

Participants could remain in the trial even if they did not accept the ring. Analysis indicates that 92% of women accepted the ring at enrollment, and 90% accepted it at their first study visit. The proportion of participants who accepted the ring dropped at each subsequent visit, declining to 79% at the nine-month study visit.

Since the drug level declines when the ring is worn, investigators

EXECUTIVE SUMMARY

In hard-hit sub-Saharan Africa, where young women are disproportionately affected by HIV, new research from an open-label trial of a dapivirine vaginal ring confirms that women will use the device as prevention against HIV.

- Dapivirine, also known as TMC-120, is an anti-HIV drug that binds to and disables HIV's reverse transcriptase enzyme, a protein needed for HIV to produce copies of itself.
- The nonprofit International Partnership for Microbicides, which developed the dapivirine ring, is seeking regulatory approval for the device.

assessed adherence by measuring how much dapivirine was left in returned rings. Results indicated that the amount of dapivirine left in 90% of the returned rings from HOPE study participants showed that the devices had been used for at least part of the prior month; in the ASPIRE trial, 77% of the returned rings indicated similar use.

"We wanted women to know that the decision was theirs to make, and theirs alone," says **Jared Baeten**, MD, PhD, professor of global health, medicine, and epidemiology at the University of Washington in Seattle. "As it turns out, most participants wanted the dapivirine ring — they accepted the ring being offered. Women in HOPE also appeared to use the ring more consistently than they did in ASPIRE."

Ring Under Review

Baeten, who presented the study findings at the IAS conference, is co-principal investigator of the National Institutes of Health-funded Microbicide Trials Network. He led the HOPE study with Thesla Palanee-Phillips, MMed Sci, PhD, MSc, of the Wits Reproductive Health and HIV Institute in South Africa, and Nyaradzo Mgodi, MBChB, MMed, of the University of Zimbabwe College of Health Sciences.

Dapivirine, also known as TMC-120, is an anti-HIV drug that binds to and disables HIV's reverse transcriptase enzyme, a protein needed for HIV to produce copies of itself.

The nonprofit International Partnership for Microbicides, which developed the dapivirine ring, is seeking regulatory approval for the device. It is under review by the European Medicines Agency. If approved, it would allow the agency, in cooperation with the World Health Organization, to provide a scientific opinion on the ring's use in low- and middle-income countries. The partnership also plans to submit applications to the South African Health Products Regulatory Authority and the FDA.

If approved, the ring would add another option to such women-controlled HIV prevention methods as oral pre-exposure prophylaxis. Women need choices that fit their needs and that they can initiate, noted **Anthony Fauci**, MD, director of the National Institute of Allergy and Infectious Diseases, which was the primary funder of the HOPE study. "With the invaluable contributions of thousands of study participants, the HOPE study has estimated the effectiveness of the dapivirine ring and examined its appeal to users," said Fauci in a press statement. "Additional efforts to develop HIV prevention options continue in the hope that one day, women will have a range of HIV prevention products from which to make an informed choice." *(The statement can be viewed online at: https://bit.ly/2ZkSFTm.)* ■

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Check Postpartum Opioid Use in New Moms

A new mother delivered her first child six months ago via cesarean delivery. Her medication list indicates she is continuing to use her peripartum opioid prescription.

Such incidents are not uncommon. In a new national cohort study of more than 300,000 deliveries, findings indicate that women who received a peripartum opioid prescription had rates of new persistent opioid use of 1.7% for vaginal delivery and 2.2% for cesarean delivery.[1]

Results of earlier studies show that 33% of women who give birth each year have a cesarean delivery; 66% receive a peripartum opioid prescription.[2,3] Two-thirds of women who give birth each year have a vaginal delivery, of whom approximately one-quarter receive an opioid prescription.[4]

University of Michigan (UM) obstetrician and health services researcher **Alex Friedman Peahl**, MD, and colleagues examined patterns of opioid prescribing to women with private insurance who had not received opioids for a year before delivering. The investigators limited the study to women who did not suffer major birth complications or have any other procedures in the year following a birth.

"Overall, we see rates of opioid persistence higher than previously documented for women having C-sections, at about 2%," Peahl said in a press statement. "For women who delivered vaginally, one-quarter received opioid prescriptions, although current guidelines call for a stepwise approach to pain management, starting with non-narcotic medications such as ibuprofen and acetaminophen; 1% of vaginal birth mothers were still receiving opioids months later." *(The statement can be viewed at: https://bit.ly/2ZxOj6y.)*

Peahl, a National Clinician Scholar at the UM Institute for Healthcare Policy and Innovation, collaborated with Institute members involved with the Michigan Opioid Prescribing and Engagement Network. Senior author Jennifer Waljee, MD, MPH, MS, worked with Peahl in using an approach previously used to study opioid prescriptions after inpatient surgery.

Study findings suggested that women who gave birth in their teens or early 20s, as well as those with more medical issues at time of delivery, such as those related to pain or mental health, had higher rates of persistence. Mothers in the South and Midwest and women who used tobacco during pregnancy also were at higher risk for persistence, data indicated.

Researchers found two key factors: The larger the vial, the more likely women were to refill multiple prescriptions in the months after giving birth. Also, women who filled prescriptions prior to delivery were more likely to develop new persistent use.

Similar findings have been noted in surgical patients, according to previous research conducted by Waljee and colleagues.[5] The researchers created prescribing guidelines for surgical teams that are based on patient feedback on pain control. Their cesarean section recommendations call for women to receive up to 20 5-mg oxycodone tablets or the equivalent.

Check Prescribing Recommendations

While guidelines for postpartum prescribing from both the American College of Obstetricians and Gynecologists (ACOG) and the American Pain Society advocate for stepwise, multimodal approaches to pain management, neither guidance includes specific recommendations on whether women should be discharged with an opioid prescription after vaginal delivery or cesarean delivery and, if so, with how many tablets.[5,6]

Using long-lasting opioids for the height of birth pain as part of an epidural, and reserving oral opioids

EXECUTIVE SUMMARY

In a new national cohort study of more than 300,000 deliveries, findings indicate that women who received a peripartum opioid prescription had rates of new persistent opioid use of 1.7% for vaginal delivery and 2.2% for cesarean delivery.

- According to earlier studies, more than 33% of women give birth via cesarean delivery each year and 66% receive a peripartum opioid prescription. Two-thirds of women who give birth each year will have a vaginal delivery, of whom approximately one-quarter will receive an opioid prescription.
- National guidance calls for a three-step approach to postpartum pain relief, with nonopioid analgesics, such as acetaminophen or nonsteroidal anti-inflammatory drugs, to be used first.

for "breakthrough" post-birth pain, is possible, according to Peahl.

Acetaminophen and nonsteroidal anti-inflammatory drugs (NSAIDs) like ibuprofen can provide effective pain relief in the days after birth, Peahl said, especially if women receive education on proper use during birth preparation. This approach can reduce post-discharge opioid painkiller use, she noted. ACOG calls for a three-step approach to postpartum pain relief, with nonopioid analgesics, such as acetaminophen or NSAIDs, to be used first. Step two adds milder opioids such as codeine, hydrocodone, oxycodone, tramadol, and oral morphine, and step three incorporates stronger opioids, such as parenteral morphine, hydromorphone, and fentanyl. When pain cannot be managed adequately with step one nonopioid medications, milder, short-acting opioids are the preferred next option, ACOG guidance states.[6]

Peahl and colleagues are contacting new mothers who received opioid painkillers to find out how many pills they used out of the total prescribed number. The researchers also are examining a new protocol that includes more robust patient education and shared decision-making about opioid prescriptions at the time of discharge.

"No matter which way they deliver, women should be able to get up and spend time with their new baby," Peahl said in the statement. "Pain, and the effects of pain control medications, should not get in the way of their birth experience and bonding with their infant." ■

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New Tool May Identify People at Risk for HIV

A potential analytical tool may help providers identify those at risk for HIV in efforts to offer pre-exposure prophylaxis (PrEP). Using a machine-learning algorithm to predict who could become infected with HIV during a three-year period, researchers were able to flag 2.2% of 3.7 million patients as high or very high risk.[1]

Researchers at Kaiser Permanente San Francisco, the Kaiser Permanente Division of Research, Beth Israel Deaconess Medical Center, and Harvard Medical School analyzed a study population of HIV-negative adult members of Kaiser Permanente Northern California. The participants were not yet using PrEP and had at least two years of previous health plan enrollment with at least one outpatient visit from Jan. 1, 2007, to Dec. 31, 2017. The researchers discovered that 44 of 81 electronic health record (EHR) variables were most relevant for predicting HIV risk. A tool that used these 44 variables identified 2.2% of the population as having a high or very high risk of HIV infection within three years. The high-risk group included 38.6% of all new HIV infections; 32 of 69 men were diagnosed with HIV during the study period, but none of the 14 women were found to be infected during the same period.[1]

Researchers noted that the tool is limited in identifying women at risk of contracting HIV, since the risk for females may depend on risk factors of their partners, which are not captured by the variables included in the tool. The tool also does not perform as well among patients for whom the EHR contains

fewer data due to initial enrollment in the system or less use of healthcare services, investigators stated.

"It is critical that we identify our patients at risk of HIV acquisition," **Jonathan Volk**, MD, MPH, an infectious disease physician who treats patients with HIV at Kaiser Permanente San Francisco Medical Center, said in a statement. "We used our electronic medical record to develop a tool that could be implemented in a busy clinical practice to help providers identify patients who may benefit most from PrEP." *(View the statement online at: https://k-p.li/2ztfLaQ.)*

Recent data indicate that the majority of new HIV diagnoses are attributed to male-to-male sexual contact.[2] Injection drug use also is linked to HIV infection; the prevalence of HIV infection among those who inject drugs is estimated at 1.9%.[3] According to 2017 statistics, males ages 13 years and older represented 81% of new diagnoses of HIV infection.[4] While the majority of these new diagnoses were attributed to male-to-male sexual contact, about 10% were attributed to heterosexual contact, 4% to injection drug use, and 4% to both male-to-male sexual contact and injection drug use.[4] In adolescent females ages 13 years and older, 87% of all new diagnoses were attributed to heterosexual contact and 12% to injection drug use.[4]

PrEP Push Is On

The U.S. Preventive Services Task Force (USPSTF) issued final recommendations that providers screen for HIV in everyone ages 15-65 years and all pregnant women, as well as younger adolescents and older adults at greater risk for HIV. [5-7] PrEP also should be offered to people at high risk of HIV, USPSTF states.[8,9]

The new predictive tool directly addresses this gap and may be more effective than current efforts to identify those who may be good PrEP candidates, said Volk. While the tool does not replace the clinical judgment of medical providers, it could save them time and address misconceptions about HIV risk, he stated. While investigators were able to access a wide variety of patient information from Kaiser Permanente's electronic records system, other healthcare organizations could build similar algorithms using fewer EHR variables. Study findings indicated that simpler models that included only six variables still helped identify patients at risk for HIV.

Such a tool could be incorporated in EHRs to alert providers to speak with patients most likely to benefit from discussions about PrEP, researchers said. Clinicians also could explain the availability of drug manufacturer and publicly funded programs that may cover all or part of PrEP copays.

"Embedding our algorithm in the electronic health record could support providers in discussing sexual health and HIV risk with their patients, ultimately increasing the uptake of PrEP and preventing new HIV infections," lead author **Julia Marcus,** PhD, MPH, a former Kaiser Permanente Division of Research member who is now at Harvard Medical School and Harvard Pilgrim Health Care Institute, said in the statement. ■

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CME/CE QUESTIONS

1. **Research indicates how many women will experience an unintended pregnancy in the first year of typical use of oral contraceptives?**

   a. Seven out of 100 women
   b. Nine out of 100 women
   c. 12 out of 100 women
   d. 15 out of 100 women

2. **What are the two FDA-approved drugs for treatment of hypoactive sexual desire dysfunction?**

   a. Darifenacin and fesoterodine
   b. Durvalumab and darolutamide
   c. Flibanserin and bremelanotide
   d. Erdafitinib and solifenacin

3. **Dapivirine is in which class of drugs?**

   a. Integrase inhibitors
   b. Fusion inhibitors
   c. Chemokine receptor antagonists
   d. Non-nucleoside reverse transcriptase inhibitors

4. **What drugs are considered the first step in postpartum pain management, according to the American College of Obstetricians and Gynecologists?**

   a. Acetaminophen and non-steroidal anti-inflammatory drugs
   b. Muscle relaxants
   c. Corticosteroids
   d. Antianxiety drugs

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.