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Pregnancy Prevention Toolkit Helps Prevent Spread of Zika Virus

By Wayne Shields, President and Chief Executive Officer, Association of Reproductive Health Professionals, Washington, DC

All healthcare providers, especially family planning professionals, should integrate Zika virus prevention into their standard clinical care, according to a new health provider toolkit from the CDC and Office of Population Affairs (OPA).

This new resource has been developed to bring urgently needed, evidence-based guidance to providers to help stem the spread of the Zika virus, a mosquito-borne and sexually transmitted illness that can result in adverse fetal outcomes such as microcephaly, neurological complications, and Guillain-Barre syndrome.

The new toolkit, which is available at <http://bit.ly/29Tq9LR>, advises that all healthcare providers should be able to screen for the Zika virus; integrate Zika

into counseling on contraception and sexual health; recommend prevention strategies to women who do not want to become pregnant; and help women understand how to reduce the risk of becoming infected with the Zika virus, including transmission through vaginal, anal, and oral sex.



"... WE NEED TO EMPHASIZE EVERY OPPORTUNITY FOR PREVENTION."
— LORRIE GAVIN,
PHD, MPH, OFFICE OF POPULATION AFFAIRS

Helping non-pregnant women and men of reproductive age mitigate the impact of Zika by providing contraceptive and pregnancy planning services is a critically important component of the response, says **Lorrie Gavin**, PhD, MPH, senior health officer at the Office of Population Affairs. "Since there are so few treatments for microcephaly and other consequences to infant health from Zika, we need to emphasize every

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opportunity for prevention," Gavin
states. "We are especially focused on
reducing the risk of Zika to pregnant
women and women of childbearing
age, because of the severity of adverse
pregnancy outcomes we've seen
globally among pregnant women
with Zika."

The CDC issued two updated
resources for guidance and
information to prevent Zika virus
transmission and its health effects.^{1,2}
The first one is interim guidance
for healthcare providers caring for
pregnant women with possible
exposure to the Zika virus. Because
the diagnosis of Zika infections
can be complicated, the updated
information expands the timeframe,
up to 14 days, that testing for
Zika virus particles in the blood of
pregnant women can be offered. This
expansion will provide a definite
diagnosis for more pregnant women
who have become infected with the
Zika virus.¹

The second resource is interim
guidance for the prevention of the
sexually transmitted Zika virus. It
expands the CDC's definition of
sexual exposure to Zika to include sex
without a barrier method (including
male or female condoms, among
other methods) with any person —
male or female — who has traveled
to or lives in an area with Zika.²

As of mid-July 2016, there is only
one unconfirmed report of a Zika-
virus transmission by a mosquito
in the United States. However,
it is only a matter of time before
we see many more, according to
Christine Dehlendorf, MD, MAS,
associate professor in residence at
the Departments of Family and
Community Medicine, Obstetrics,
Gynecology and Reproductive
Sciences, and Epidemiology and
Biostatistics, University of California,
San Francisco. Screening for risk

should focus on travel by women and
their partners to affected areas, says
Dehlendorf.

"The number of travel-associated
cases of Zika is growing rapidly in
the U.S. As of early July, there were
over 600 pregnant women in the
U.S. states and territories who have
evidence of Zika virus infection,"
she notes. "Far less is known about
Zika than other flaviviruses like the
dengue virus, because implications
such as length of active infection are
not yet evident."

Although the current priority
is on prevention and screening in
the United States, federal and state
policymakers need to plan for the
care and support of those who will
be affected by the virus over time,
especially those caring for children
who are born with microcephaly,
neurological complications, and
Guillain-Barre syndrome, says
Dehlendorf.

Helping women to maintain their
sexual and reproductive autonomy
is a primary consideration for health
professionals, she states. "People
come first in healthcare, and we need
to remember to respect their decision
making during this urgent time,"
Dehlendorf advises.

Zika does bring an important
opportunity to the family planning
field, says Gavin. "Although there
is a need to respond to Zika on an
emergency basis, this also provides
a chance to solidify and reinforce
recent advances in the delivery of
family planning services, so that there
is a more sustained and widespread
impact."

The CDC/OPA toolkit does
not address abortion services,
another important consideration for
healthcare related to the Zika virus.
Healthcare professionals who wish
to counsel on abortion services can
look to information provided by

the National Abortion Federation at prochoice.org and to information from the Abortion Care Network at abortioncarenetwork.org. ■

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Suspected Sexual Transmission of Zika Virus Reported from Female to Male

It's time to raise the index of suspicion when it comes to the Zika virus: The New York City Department of Health and Mental Hygiene recently reported a suspected female-to-male sexual transmission of Zika virus.¹

According to information from the CDC, a woman engaged in sex without a condom with a male partner the day she returned to New York City from travel to an area with ongoing Zika virus transmission. Tests of her serum and urine later tested positive for Zika virus RNA. Seven days after intercourse with the woman, the male partner developed Zika-related symptoms. Zika virus RNA was detected in his urine, but not serum, the CDC said. An interview indicated the man had not traveled outside the United States during the year before his illness, had any other recent sexual partners, or been bitten by a mosquito.¹

On July 19, the Florida Department of Health announced that it was conducting an investigation with the CDC into a possible non-travel related case of Zika virus in Miami-Dade County. The CDC also is assisting in the investigation of a case of Zika in a Utah resident who is a family contact of an elderly Utah resident who died in late June. The deceased patient had traveled to an area with Zika. Lab tests showed he had uniquely

high amounts of virus. Laboratories reported evidence of Zika infection in both Utah residents.

The CDC has awarded \$25 million in funding to support efforts to protect Americans from Zika virus infection and associated health outcomes, including microcephaly and other serious birth defects.

"These CDC funds will enable states and territories to strengthen their Zika preparedness and response plans," said **Stephen Redd**, MD, director of CDC's Office of Public Health Preparedness and Response in a prepared statement. "Although the continental United States has not yet seen local transmission of the Zika virus, mosquito season is here, and states must continue to both work to prevent transmission and prepare for their first local case."

A total of \$25 million in fiscal year 2016 preparedness and response funding has been awarded to 53 state, city, and territorial health departments in areas at risk for outbreaks of Zika. The funding became effective July 1 and can be used through June 2017.

Many online resources are becoming available to healthcare providers to help respond to the Zika virus challenge. A new health provider toolkit from the CDC and the Office of Population Affairs has been developed to bring urgently needed, evidence-based guidance to

clinicians.

The CDC offers a wide variety of materials for providers and patients at <http://bit.ly/2a4HOns>. Available resources include testing algorithms, fact sheets on testing, and information on preconception counseling. Other information pertinent to clinicians is available at <http://bit.ly/1VuapPd>.

The American College of Obstetricians and Gynecologists (ACOG) held a free webinar, "Biting Back: Contraception and Zika Prevention," July 21. Led by Melissa Kottke, MD, MPH, MBA, associate professor in the Department of Gynecology and Obstetrics at Emory University in Atlanta, the seminar is designed to review the latest guidance on Zika and the role of contraception, including long-acting reversible methods. (ACOG said the link to the webinar would be on the Zika information page at <http://bit.ly/2a257Pq>. The Association of Reproductive Health Professionals maintains a Zika Resource Center at www.arhp.org/zika. AHC Media offers coverage at AHCMedia.com/Zika.) ■

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U.S. Preventive Services Task Force Eyes Evidence For and Against Pelvic Exams

The United States Preventive Services Task Force has found insufficient evidence to recommend for or against performing pelvic exams in asymptomatic, nonpregnant adult women. While its recommendation statement and evidence review are out for comment, what will be the impact of its final guidance?

For the first time, the independent volunteer panel of national experts has reviewed the evidence on screening for gynecologic conditions with pelvic examination. The draft statement applies to women ages 18 years old and older who do not have any signs or symptoms of gynecologic conditions, are not at increased risk for these conditions, and who are not pregnant. This preliminary statement does not address screening for cervical cancer, chlamydia, and gonorrhea, which have been addressed previously by the Task Force.

In a prepared statement, task member **Francisco García**, MD, MPH, who serves as director of the Pima County Health Department in Tucson, said that the panel is calling for more research to better understand the benefits and harms

of performing screening pelvic exams in women without any complaints or symptoms.

Task Force member **Maureen Phipps**, MD, MPH, says, "There is not enough evidence to make a determination on screening pelvic exam in asymptomatic women for conditions other than cervical cancer screening, gonorrhea, and chlamydia. Women with gynecologic symptoms or concerns should discuss them with their clinicians." Phipps is department chair, Chace-Joukowsky professor of obstetrics and gynecology, and assistant dean for teaching and research on women's health at the Warren Alpert Medical School of Brown University in Providence, RI.

Thomas Gellhaus, MD, president of the American College of Obstetricians and Gynecologists (ACOG), said the national professional society is reviewing the Task Force's draft recommendation statement and the evidence upon which it is based. ACOG recommends annual pelvic examinations for patients 21 years of age or older, noted Gellhaus in a statement. However, the College

recognizes that this recommendation is based on expert opinion and limitations of the internal pelvic examination for screening should be recognized, he stated. "Notably, there are many women who are likely to benefit from a pelvic exam," said Gellhaus. "For example, women who report or exhibit symptoms suggestive of female genital tract problems, menstrual disorders, vaginal discharge, incontinence, infertility, or pelvic pain should receive a pelvic examination."

The draft recommendation statement concludes that there is not enough evidence to determine the benefits or harms of performing screening pelvic exams in asymptomatic, nonpregnant adult women for four conditions: ovarian cancer, bacterial vaginosis, genital herpes, and trichomoniasis, noted Gellhaus.

Part of wellness exam?

Women should see their obstetrician/gynecologists at least once a year, ACOG emphasizes. In addition to the screenings, evaluations, and counseling that clinicians can provide, the annual well-woman visit is an opportunity for the patient and her provider to discuss whether a pelvic examination is appropriate for her. The society promotes shared communication and decision making between the patient and the provider regarding the practice.

While most women who come in for a well-woman visit are prepared to have a pelvic examination, patients are best served by a clinician who performs pelvic examinations not

EXECUTIVE SUMMARY

The U.S. Preventive Services Task Force has found insufficient evidence to recommend for or against performing pelvic exams in asymptomatic, nonpregnant adult women. Its recommendation statement and evidence review are out for comment.

- The draft statement applies to women ages 18 and older who do not have any signs or symptoms of gynecologic conditions, are not at increased risk for these conditions, and who are not pregnant. This preliminary statement does not address screening for cervical cancer, chlamydia, and gonorrhea, which have been addressed previously by the Task Force.
- The American College of Obstetricians and Gynecologists recommends annual pelvic examinations for patients 21 years of age or older.

routinely, but for specific reasons, says **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.

Kaunitz offers the following observations from his practice:

- When seeing symptom-free adolescent patients, such as those presenting to initiate short-acting hormonal or implantable contraception, Kaunitz orders urine screening for chlamydia, but he does not perform a pelvic examination. These young women are so relieved to learn they will remain fully dressed and avoid the dreaded “pelvic,” he notes. For symptom-free patients in their 20s, Kaunitz performs pelvic examinations only when indicated for cervical cancer screening.
- When seeing new adult patients, Kaunitz says he prefers to proceed with a pelvic examination. Why? His concern is that failing to perform an exam in this setting may miss relevant conditions his history may have failed to detect, such as pelvic prolapse, genital atrophy, lichen sclerosis or

other vulvar conditions, and vaginitis.

“Experienced clinicians recognize that some women may not understand that symptoms caused by these conditions are not normal; therefore, they do not report symptoms when providing a history,” Kaunitz states. “Embarrassment or lack of knowledge regarding their genital tract may also prevent some women from reporting symptoms.”

Kaunitz often sees adult patients returning for visits, including medication refill visits. When a focused history reveals no gynecologic symptoms or changes, he indicates that he doesn’t recommend performing a pelvic exam.

- For menopausal patients returning for well-woman visits, Kaunitz periodically performs external genital inspections without speculum or bimanual examinations. His rationale is that women benefit from recognizing that changes of genital atrophy are present, even if they do not choose to treat this condition.

“Pelvic examinations are unpleasant and intrusive,” says Kaunitz. “While some of my adult patients prefer to have a complete

pelvic exam with each well-woman visit, I note that more and more of my patients are delighted to avoid this time-honored, but not always indicated, ritual.”

The pelvic exam, as it is currently conducted, is not an efficient screening test, and with the increase in obesity, it is becoming increasingly insensitive, says **Anita Nelson**, MD, professor emeritus in the Obstetrics and Gynecology Department at the David Geffen School of Medicine at the University of California in Los Angeles. While there are more sensitive tests, such as ultrasound imaging, they are not cost-effective, she observes. Thus, for now, clinicians will do no examination, she observes.

“This may increase clinician liability; we will have to find ways to elicit complete histories to ensure that the woman is truly asymptomatic, and we will have to find ways to explain to women why we are not providing them this test without making them think we do not care about their health,” states Nelson. “And we need to make certain that our colleagues do not think that this diminishes the importance of women’s reproductive health.” ■

Use Effective Counseling Skills When Counseling on Choosing LARC Methods

Do you know how to counsel your young adult patients on selecting the right long-acting reversible contraception (LARC) method for their needs? The Association of Reproductive Health Professionals offers two informative web-based educational options to help clinicians fine-tune their counseling skills. Both options offer free CE credits.

A new *Clinical Minute*, “Counseling Young Women about

Long-Acting Reversible Methods,” is available at <http://bit.ly/2aoa7t6>. The brief presentation explains the difference between LARC methods and emphasizes their effectiveness. It covers effective counseling strategies and outlines appropriate candidates for intrauterine contraception.

The second option, a two-part webinar titled “Provider Education and Training to Increase Use of Intrauterine Contraception,” is available at

<http://bit.ly/29TFq1R>. The first section of the webinar explains the difference between the four forms of intrauterine contraception available in the United States, outlines the appropriate candidates for intrauterine contraception, and describes possible side effects of each type of intrauterine contraception. That section is conducted by **Amna Dermish**, an obstetrician/gynecologist with Planned Parenthood of Greater

EXECUTIVE SUMMARY

The Association of Reproductive Health Professionals offers two informative web-based educational options to help clinicians fine-tune their counseling skills on long-acting reversible contraception (LARC) methods.

- A new *Clinical Minute*, "Counseling Young Women about Long-Acting Reversible Methods," explains the difference between LARC methods and emphasizes the effectiveness of these methods. It also covers effective contraceptive counseling strategies and outlines appropriate candidates for intrauterine contraception.
- Also available is a two-part webinar "Provider Education and Training to Increase Use of Intrauterine Contraception." The first section explains the differences between the four forms of intrauterine contraception available in the United States, outlines appropriate candidates, and describes possible side effects of each type of intrauterine contraception. The second section covers pain management strategies during and after insertion, strategies for follow-up, and skills required for proper insertion techniques.

Texas in Austin. The second section covers pain management strategies during and after insertion, discusses strategies for follow-up of intrauterine contraceptive (IUC) users, and addresses skills required for proper insertion techniques for the four methods of intrauterine contraception. That section is led by **Wendy Grube**, PhD, CRNP, director of the Women's Health Nurse Practitioner Program at the University of Pennsylvania and director of its Center for Global Women's Health.

Approach patient counseling within a shared decision-making framework, notes Dermish. The steps of shared decision making include:

- query to identify preferences, using open-ended questions;
- provide information about side effects, effectiveness, and use of method, including written materials in the appropriate language and literacy level;
- give context about options, and allow patients to hold devices if possible;
- ensure access to method placement and removal;
- allow time for and encourage

questions.

Incorporate the "One Key Question," an initiative launched by the Oregon Foundation for Reproductive Health, at the start of counseling, advises Dermish. The initiative encourages providers to routinely ask women of reproductive age one simple question: "Would you like to become pregnant in the next year?" From there, a clinician can begin the discussion of what a woman's reproductive health plans are for the future, what is important to her about her contraceptive method, and what methods she has used in the past, Dermish explains. Open-ended questions help clinicians better understand what concerns patients have, as well as what they already know about their contraceptive options.

Use the contraceptive effectiveness chart (which can be accessed at <http://bit.ly/29K8XXD>) that illustrates the different tiers of effectiveness of birth control methods so patients can get a clear picture of the top-line effectiveness of LARC methods. LARC includes the contraceptive implant and

intrauterine contraception. Most women are LARC candidates, including adolescents, young women, and nulliparous women.

The *U.S. Medical Eligibility Criteria for Contraceptive Use (US MEC)* lists the following contraindications to use of the contraceptive implant:

- breast cancer — current or in the past;
- ischemic heart disease or stroke — current or in the past (for continuing method);
- lupus (systemic lupus erythematosus or SLE);
- migraine with aura (for continuing method);
- unexplained vaginal bleeding;
- severe cirrhosis;
- malignant liver tumor.¹

The *US MEC* lists the following contraindications to use of intrauterine contraception:

- known or suspected pregnancy;
- puerperal sepsis;
- immediate post-septic abortion;
- unexplained vaginal bleeding;
- uterine fibroids that interfere with placement;
- uterine distortion;
- active purulent cervicitis/pelvic inflammatory disease;
- active endometrial cancer (for initiating method);
- active cervical cancer (for initiating method).¹

Be prepared to discuss possible menstrual changes associated with LARC methods and how these will be managed, says Grube. Implants are associated with infrequent bleeding, amenorrhea, and prolonged bleeding. In many women, these changes improve over time. Most women using the Copper T intrauterine device (IUD) experience an increase in the duration and amount of menstrual bleeding, which often lessens by the first year of use. For

women who choose a hormonal IUD, the bleeding pattern is unpredictable. Many women have spotting and irregular bleeding during the first three to six months; most women have reduced bleeding or amenorrhea by 12 months after insertion.

"In our culture, if you don't bleed when you think you should, then that's a problem, and if you're bleeding when you shouldn't, that's a problem," Grube observes.

By letting a patient hold an IUC or implant in her hand, and using a visual model to show where it will

be placed, patients gain a better understanding of the device and how it works. Go over insertion and removal procedures so women are well-prepared, says Grube. When it comes to IUC placement, many women may be concerned about pain at time of insertion. Review options for lessening pain, from use of ibuprofen prior to insertion, to use of lidocaine.

Be prepared to spend time with patients before they choose a LARC method, because these methods represent a potential commitment

of time from three to 12 years, says Grube. The patient needs to feel as if she knows everything there is to know, within reason, about this method and that she is in control of making the decision, she notes. "I truly believe that if you give women all the information that they need, they will make the right decision for themselves," states Grube. ■

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Physiology of Premenstrual Symptoms Examined

New data from the UC Davis Health System in Sacramento indicate that certain premenstrual symptoms, such as mood changes, breast pain, and abdominal cramps, are linked with inflammation.¹ C-reactive protein, a commonly accepted biomarker for inflammation, is elevated within most women with premenstrual symptoms, data indicate. Understanding the physiology of premenstrual symptoms could benefit patients and providers: About 80% of women experience premenstrual symptoms, and about 50% of women seek medical care for them.^{2,3}

Even though premenstrual symptoms affect most women, they are rarely studied, possibly because they are considered just a natural part of the menstrual cycle, says **Ellen Gold**, PhD, professor of epidemiology in the Department of Public Health Sciences at the UC Davis School of Medicine. In particular, very few studies have examined the role of inflammation, even though nonsteroidal anti-inflammatory drugs are one of the most-used treatments for

premenstrual symptoms, notes Gold, who served as lead author of the current research.

Gold and her colleagues at UC Davis used data from the Study of Women's Health Across the Nation (SWAN), a longitudinal, multicenter study of some 3,000 women in midlife from five racial/ethnic groups. Participants were eligible for inclusion in the cohort if they were ages 42–52 and premenopausal or early perimenopausal, had not undergone a hysterectomy or bilateral oophorectomy, were not pregnant, and were not using

menopausal hormone therapy or oral contraceptives at baseline. Because Gold serves as one of the SWAN investigators, she had access to extensive health data from the study, including results of blood analyses for an inflammatory marker (C-reactive protein) on a large and diverse group of women. This access allowed the researchers to look at the specific premenstrual symptoms women experienced and whether inflammation was associated with them.

"The results showed that this blood biomarker of inflammation was

EXECUTIVE SUMMARY

New data from the UC Davis Health System in Sacramento indicate that certain premenstrual symptoms, such as mood changes, breast pain, and abdominal cramps, are linked with inflammation. C-reactive protein, a commonly accepted biomarker for inflammation, is elevated within most women with premenstrual symptoms, data indicate.

- Understanding the physiology of premenstrual symptoms could benefit patients and providers: About 80% of women experience premenstrual symptoms, and about 50% of women seek medical care for them.
- Establishing premenstrual symptoms as an inflammatory condition may indicate that such symptoms may be a useful sentinel of future chronic disease risk, researchers believe.

associated with most premenstrual symptoms, but not headaches, after controlling for a variety of potentially confounding variables," notes Gold.

Establishing premenstrual symptoms as an inflammatory condition may indicate that those symptoms may be a useful sentinel of future chronic disease risk, notes **Elizabeth Bertone-Johnson**, ScD, assistant professor of epidemiology at University of Massachusetts, Amherst. C-reactive protein is a biomarker of inflammation that also is associated with increased risk of cardiovascular disease.

"This intriguing possibility also suggests that treatment of premenstrual symptoms with therapies targeting inflammation could have positive impacts on long-term chronic disease risk," states Bertone-Johnson in an accompanying editorial.⁴ Bertone-Johnson served as lead author of recent research which indicates that women with moderate-to-severe premenstrual symptoms had a 40% higher risk of developing high blood pressure over the following 20 years compared to women experiencing few menstrual symptoms.⁵ (Contraceptive Technology Update reported on the data. See the March 2016 article, "Could premenstrual syndrome be a flag for future risk of hypertension?"

available at <http://bit.ly/29O2Bdq>.)

UC Davis also plans to use SWAN data to determine the timing of inflammation relative to premenstrual symptoms and the role of hormonal factors. "Our hope is that our work will lead to treatment plans that can be targeted to specific symptoms or groups of symptoms, depending on each woman's experiences," notes Gold.

Providers can help ease mild-to-moderate premenstrual symptoms by suggesting changes in lifestyle or diet. Regular aerobic exercise, such as brisk walking, running, cycling, and swimming, may help lessen premenstrual symptoms and reduce fatigue and depression. Relaxation therapy such as breathing exercises, meditation, and yoga, as well as massage therapy, also may help.⁶

When premenstrual symptoms interfere with daily life, women may decide to seek medical treatment. Treatment will depend on the severity of symptoms; in more severe cases, medication may be indicated. Family planning providers may suggest use of extended cycles of combined oral contraceptives or the contraceptive vaginal ring, levonorgestrel intrauterine contraception, or the contraceptive injection for lessening dysmenorrhea associated with premenstrual symptoms.⁷ ■

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Researchers' Index Could Help Detect Women at Risk for Rapid Bone Loss

Researchers have developed an index to predict which women may experience faster bone loss across the menopause transition.¹ Such a tool may prove helpful. Estimates indicate that as many as 50% of Americans older than 50 years will be at risk for osteoporotic fractures

during their lifetimes.² Osteoporosis has a fivefold greater prevalence in women than in men. In the United States, although women only have twice the fracture rate of men, they sustain 80% of hip fractures because older women outnumber older men.³

Osteoporosis is a medical

condition that causes bone density to diminish and fracture risk to increase. It often is referred to as a "silent" disease because individuals who have it experience few noticeable symptoms. Because gender and age are the factors most associated with the disease, the U.S. Preventive

Services Task Force recommends screening for women who are age 65 and older.⁴

"Whether an individual loses or gains bone mass is dependent on how much bone is being broken down by osteoclasts and being formed by osteoblasts; both processes occur simultaneously," explains **Albert Shieh**, MD, fellow physician in the Division of Endocrinology, Diabetes and Hypertension at the David Geffen School of Medicine, University of California, Los Angeles. "At present, we can measure markers of bone breakdown (resorption) and formation."

Shieh and researchers hypothesized that to better predict how fast bone will be lost, such markers should be combined in an "index" to reflect both processes, rather than being interpreted in isolation. In the current article, the scientists found that new "Bone Balance Index" predicted future bone loss across the menopause transition better than the bone resorption marker alone, Shieh notes. The scientists combined measurements of bone breakdown and bone formation in what they termed the "Bone Balance Index" to determine each individual's net bone balance before the final menstrual period.

To create the index, the researchers looked at data from the Study of Women's Health Across the Nation, a longitudinal, multicenter study of some 3,000 women in midlife from five racial/ethnic groups. The 685 women who participated in the current research were between the ages of 42 and 52, premenopausal or in early perimenopause when they enrolled in the study, and had their final menstrual periods during the follow-up portion of the study.

Urine and blood samples were taken from study participants to

EXECUTIVE SUMMARY

Researchers have developed an index to predict which women may experience faster bone loss across the menopause transition.

- Such a tool may prove helpful. Estimates indicate that as many as 50% of Americans older than 50 years will be at risk for osteoporotic fractures during their lifetimes.
- Osteoporosis has a fivefold greater prevalence in women than in men. In the United States, although women have only twice the fracture rate of men, they sustain 80% of hip fractures because older women far outnumber older men.
- Because gender and age are the factors most associated with the disease, the U.S. Preventive Services Task Force recommends screening for women who are age 65 and older.

measure for bone turnover markers, the proteins that reflect bone breakdown and bone formation. Participants also had their bone mineral density measured every year during the study.

The scientists found that the Index was a stronger predictor of bone loss from two years before the final menstrual period to three to four years later — a time when bone density typically declines — than a measurement of bone breakdown alone.¹

This approach to assessing bone health may help identify which women are at risk of losing vertebral bone mineral density across the menopause transition, notes Shieh. However, more studies are needed to test whether the index is useful for predicting bone loss after the menopause transition and if it is useful for predicting fractures, he states.

Bone health measures should begin early in life, according to *Contraceptive Technology*. Weight-bearing exercise in moderation is important to initiate the skeletal modeling and remodeling process. Clinicians should advise on the importance of smoking cessation, as

well as moderation in alcohol use.⁵

Bone mineral density testing is recommended for all women ages 65 years and older, with consideration for earlier testing in women with clinical risk factors for fracture, including low body weight, history of prior fracture, family history of osteoporosis, smoking, excessive alcohol intake, or long-term use of high-risk medications such as glucocorticoids.⁶

The Institute of Medicine recommends that adults age 19 to 70 get 600 IU (international units) of vitamin D a day. For calcium, the amount needed depends on age and sex. All adults ages 19-50 should get 1,000 mg; the recommendation for adult men ages 51-70 is 1,000 mg, while adult women in the same age bracket are advised to take 1,200 mg.⁷ (*The National Institutes of Health has a handout on calcium and vitamin D. Access it at <http://bit.ly/29w3l7z>.*) ■

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TEEN TOPICS

Having Providers Talk with Adolescents About Condom Use Remains Essential

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According to the 2015 Youth Risk Behavior Surveillance (YRBS) Survey, the percentage of sexually active high school students reporting condom use at last intercourse has declined from a peak of 63% in 2003 to 57% in 2015.¹ The 2015 YRBS found that just 57% reported using a condom at last intercourse. Overall, the percentage of students reporting condom use has increased since the YRBS started collecting data in 1991, when only 46% reported condom use at last intercourse. The decline in reported condom use at

last intercourse in recent years serves as a reminder that discussing condom use with adolescents should remain a priority for healthcare professionals.

Condoms provide excellent protection from STIs, and they have the added benefit of acting as a method of pregnancy prevention. As a contraceptive, latex male condoms have just a 2% failure rate with perfect use, but the failure rate for typical use is estimated to be as high as 18%.²

The American Academy of Pediatrics Committee on Adolescence statement on condoms encourages clinicians to actively support consistent, correct condom use. The statement also suggests providing condoms in healthcare providers' offices as well as in community settings, such as schools.³

It is appropriate and essential to discuss condom use with adolescents of all genders. Research suggests primary care providers are twice as likely to counsel female adolescents about condom use and are three times more likely to take sexual histories from females compared to male adolescent patients.⁴

When taking sexual histories or discussing sexual health with

adolescent patients, providers should ask not just "if" adolescents are using condoms, but how often. If adolescents are not consistently using condoms, explore and listen to the reasons, and respect concerns for such complaints such as sizing and comfort, as well as availability, impact on spontaneity, and perceptions of condom use as representing a lack of trust or infidelity. Explore each reason to use or not to use condoms, and use open-ended questions. Offer a variety of sizes of condoms.

Reproductive coercion, birth control sabotage, or pressure to become pregnant also may be present in an adolescent's relationship. Ask each adolescent who decides if or how often to use condoms in their relationships as part of a larger discussion of healthy relationships. Adolescents of all genders and sexual orientations and identities may need support in considering condom discussions and negotiation with sexual partners.

One tool for helping adolescents and young adults initiate a behavior change is motivational interviewing (MI). Motivational interviewing is a collaborative, goal-oriented style of communication, with particular

attention to the language of change. It is designed to strengthen personal motivation for and commitment to a specific goal by eliciting and exploring the adolescent's own reasons for change within an atmosphere of acceptance and compassion. (*More information on MI can be found at motivationalinterviewing.org.*)

In a recent randomized controlled trial, an MI-based intervention was shown to decrease unprotected sex among young men who have sex with men living with HIV.⁵ Another randomized controlled trial found a computer-assisted MI intervention reduced unprotected sex among 572 predominantly minority female adolescents at risk for unintended pregnancy and STIs compared to didactic counseling.⁶

Outside of large studies, MI can be an effective method to facilitate condom use and enhance acquisition of other protective sexual health behaviors.

Many sexually active adolescents use condoms. When an adolescent reports condom use, an opportunity arises to affirm and applaud this behavior and also offer support, with positive feedback, for making healthy sexual decisions. Those using condoms also can benefit from discussing ways to practice consistent and correct usage by exploring potential barriers to use and solutions to these barriers. Most individuals do not use condoms consistently and correctly, which results in a much higher risk of failure with typical use.

When condoms are not used correctly, the likelihood of breakage or slippage increases, as does the risk for pregnancy and transmission of STIs. Several factors contribute to condom breakage and slippage, but one issue to consider when counseling adolescents is that breakage and slippage decrease significantly with

condom use experience. In one study that focused on condom failures, breakage rates were 7% for first-time users and just 2% for those who had used the method at least 15 times. Slippage rates had a similar drop from 3% to less than 1% after 15 or more uses.⁷

Most breakage and slippage is caused by user-side errors and problems, rather than device-side or structural problems, so better education about correct condom use has the potential to increase efficacy for individual users. A 2012 systematic review of more than 50 studies from 14 countries reported that the most common errors users make are putting the condom on too late; removing the condom early; not leaving room at the tip for ejaculate; not squeezing out air from the tip, which leads to condom rupture; putting it on inside out; and using lubricants that are not water-based, which leads to breakage.⁸ These points are all ones to review when instructing patients on correct usage.

For tips on starting conversations about birth control methods, bedsider.org offers resources for adolescent and young adult patients, as well as for providers. Visitors can read about how to correctly and consistently use various birth control methods and watch testimonials about young people's experiences using these methods. ■

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COMING IN FUTURE MONTHS

- Evidence evaluation improves teen pregnancy prevention
- Counseling tips on EC options and efficacy
- Research eyes anti-HIV meds for suppression and protection
- Strategies emerge to expand access to OCs

CONTRACEPTIVE TECHNOLOGY UPDATE

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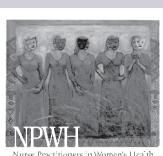
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CE/CME QUESTIONS

1. The American College of Obstetricians and Gynecologists recommends annual pelvic examinations for what age range?

- a. Patients 14 years of age or older
- b. Patients 16 years of age or older
- c. Patients 18 years of age or older
- d. Patients 21 years of age or older

2. What is the "One Key Question" that providers should routinely ask women of reproductive age?

- a. Are you currently involved in a sexual relationship?
- b. Do you have any sexual concerns you would like to discuss?

c. Would you like to become pregnant in the next year?

3. The U.S. Preventive Services Task Force recommends osteoporosis screening for what age range?

- a. Women who are age 21 and older
- b. Women who are age 45 and older
- c. Women who are age 55 and older
- d. Women who are age 65 and older

4. What is the treatment guidance for gonorrhea?

- a. An oral dose of azithromycin and single shot of ceftriaxone
- b. A single oral dose of azithromycin

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.

STI QUARTERLY™

A SUPPLEMENT TO CONTRACEPTIVE TECHNOLOGY UPDATE

Are antibiotics overprescribed for possible STIs? Check your practice

New CDC surveillance data indicate azithromycin resistance is emerging

With growing resistance to antibiotics noted in the United States, what's your practice when it comes to prescribing them? According to a recent study, three-quarters of ED patients who received antibiotics to treat suspected STIs tested negative for such diseases.¹

To perform the current study, researchers from St. John Hospital & Medical Center in Detroit looked at records of more than 1,103 patients who underwent STI testing in the ED to identify the extent of unnecessary antibiotic use. Genital cultures are commonly collected from patients with STI signs and symptoms; however, results are not immediately available, and antibiotics often are prescribed without a confirmatory diagnosis while patients are in the department.

The analysis indicates that of the 1,103 patients tested, 40% were treated with antibiotics for gonorrhea and/or chlamydia. However, of those treated, 76.6% ultimately tested negative for having an STI. Of the 60% who went untreated, 7% ultimately tested positive for either or both infections.

"We have to find the appropriate balance between getting people tested and treated for STDs, but not prescribing antibiotics to patients who don't need them," said **Karen Jones**, MPH, BSN, RN, infection preventionist at St. John Hospital & Medical Center in a statement accompanying the publication of data. "There is a tricky balance between not furthering antibiotic resistance by overprescribing, but also still getting people treatment for STDs they might have."

Further examination of the data yields clues about how certain symptoms were associated with positive STI

cultures. In male patients, 60.3% with penile discharge and 57.5% with inflammation of the urethra tested positive for gonorrhea and/or chlamydia. In female patients, 25% with inflammation of the cervix and 27% with cervical motion tenderness tested positive for gonorrhea and/or chlamydia. More than one-third (35%) of patients who disclosed that they had more than one sex partner also tested positive for gonorrhea and/or chlamydia.¹

"Focusing on these clinical predictors may improve unnecessary antibiotic prescribing in patients without true disease," said Jones, who served as lead author of the current paper.

What are the latest developments when it comes to STI

EXECUTIVE SUMMARY

According to a recent study, three-quarters of ED patients who received antibiotics to treat suspected STIs tested negative for such diseases.

- New surveillance data from the CDC's Gonococcal Isolate Surveillance Program find that resistance is emerging to azithromycin, a first-line antibiotic used to treat gonorrhea. Clinicians are advised to continue with the current guidance for treatment: an oral dose of azithromycin and a single shot of ceftriaxone.
- Public health officials are focusing on reducing the number of unnecessary antibiotic prescriptions to combat antibiotic-resistant bacteria. Results from recently published national research indicate at least 30% of antibiotics prescribed in the United States are unnecessary.

treatment and antibiotic resistance?

New surveillance data from the CDC's Gonococcal Isolate Surveillance Program (GISP) find that resistance to azithromycin, a first-line antibiotic used to treat gonorrhea, is emerging, says **Robert Kirkcaldy**, MD, MPH, medical epidemiologist in the CDC's National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Division of STD Prevention. As GISP project officer, Kirkcaldy says findings show that the percentage of isolates showing signs of reduced susceptibility to azithromycin — an indicator of emerging resistance — increased between 2013 and 2014 (from 0.6% to 2.5%).²

"This is the largest percentage since monitoring of this drug began in 1992 and occurred in all geographic regions," states Kirkcaldy. (*For more about the rise of multi-drug resistance, readers can see the Contraceptive Technology Update article, "Threat up for gonorrhea that is multi-drug resistant," May 2012, at <http://bit.ly/29Ve4Yd>.*)

Neisseria gonorrhoeae, the bacteria that causes gonorrhea, has developed resistance to nearly all of the antibiotics used for gonorrhea treatment: sulfonilamides, penicillin, tetracycline, and fluoroquinolones, such as ciprofloxacin. The CDC recommends a combination gonorrhea therapy consisting of two antibiotics: an oral dose of azithromycin and single shot of ceftriaxone,³ notes Kirkcaldy. Because recent research indicates there were no isolates that exhibited resistance to azithromycin and ceftriaxone, clinicians should continue to use the recommended dual therapy to treat patients with gonorrhea.

However, signs that resistance to these antibiotics may be emerging is concerning, because dual therapy with ceftriaxone plus azithromycin

is the only recommended gonorrhea treatment, Kirkcaldy states. While the CDC has taken initial steps, more efforts are needed on multiple fronts to ensure clinicians preserve the last recommended treatment for as long as possible, he says. "It is critical that we ensure local prevention services are available to those who need them by strengthening STD prevention services at the state and local level," states Kirkcaldy. "Researchers and pharmaceutical companies must jump-start research on new, effective drugs or drug combos, [and] health departments and labs must also help us keep a watchful eye on emerging drug resistance."

To fight antimicrobial-resistant gonorrhea, the CDC is using the latest advances in genome sequencing techniques to unlock the DNA of the bacterium that causes gonorrhea. This information is critical to the development of new drugs to treat gonorrhea, as well as better tests to find out quickly if a patient's infection is resistant.

Public health officials believe that this advanced research will tell how the bacteria are changing and help scientists find better ways to prevent gonorrhea. Using these new approaches, CDC officials hope to keep untreatable gonorrhea from becoming a reality.

In the coming year, the CDC plans to identify gene mutations that are responsible for antimicrobial resistance in *N. gonorrhoeae*, begin developing molecular tests to detect antimicrobial resistance, provide support to state public health laboratories to pilot whole genome sequencing of *N. gonorrhoeae*, and upload genetic sequences into publicly accessible databases for further study.

According to recently published national research, at least 30% of

antibiotics prescribed in the United States are unnecessary.⁴ The data, published in May 2016 in the *Journal of the American Medical Association* by the CDC, analyzed the rates of outpatient oral antibiotic prescribing by age and diagnosis, and the estimated portions of antibiotic use that may be inappropriate.

Scientists used information from the 2010-2011 National Ambulatory Medical Care Survey and National Hospital Ambulatory Medical Care Survey to obtain a national overview of antibiotic use in doctors' offices and EDs throughout the United States. The analysis indicates that most unnecessary antibiotics are prescribed for respiratory conditions caused by viruses, including common colds, viral sore throats, bronchitis, and sinus and ear infections. These 47 million excess prescriptions each year put patients at needless risk for allergic reactions or the sometimes deadly diarrhea, *Clostridium difficile*.

In 2015, the White House issued The National Action Plan for Combating Antibiotic-Resistant Bacteria, which set a goal of reducing inappropriate outpatient antibiotic use by at least half by 2020. To reach this goal, 15% of antibiotic prescriptions (half of the 30% that are unnecessary) must be eliminated by 2020.

Upon the data release, **Lauri Hicks**, DO, director of the CDC's Office of Antibiotic Stewardship in the organization's National Center for Emerging and Zoonotic Infectious Diseases' Division of Healthcare Quality Promotion and commander in the U.S. Public Health Service, said, "Setting a national target to reduce unnecessary antibiotic use in outpatient settings is a critical first step to improve antibiotic use and protect patients. We must continue to work together across the entire

health care continuum to make sure that antibiotics are prescribed only when needed, and when an antibiotic is needed, that the right antibiotic, dose, and duration are selected.”

Money for the fight

In fiscal 2016, Congress appropriated \$160 million in new funding to aid the CDC in fighting the spread of antibiotic resistance by doing the following:

- accelerating outbreak detection and prevention in every state;
- enhancing tracking of antibiotic use and resistance mechanisms and resistant infections;
- supporting research to address knowledge gaps;
- informing providers and the general public about antibiotic resistance and appropriate antibiotic use;
- improving antibiotic use by supporting expansion and development of new programs and

activities at the local level.

What can healthcare professionals, health systems, and patients do to improve antibiotic use? The CDC outlines the following steps:

- Outpatient healthcare providers can evaluate their prescribing habits and implement antibiotic stewardship activities, such as watchful waiting or delayed prescribing, when appropriate, into their practices.
- Health systems can improve antibiotic prescribing in offices and outpatient facilities within their networks by providing communications training, clinical decision support, patient and healthcare provider education, and feedback to providers on their performance.
- Patients can talk to their healthcare providers about when antibiotics are needed and when they are not. These conversations should include information on patients' risk for infections by antibiotic-resistant

bacteria. ■

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Approach May Be Effective Against Genital Herpes

Researchers from the University of Illinois at Chicago, working with scientists from Germany, have shown that zinc oxide nanoparticles can prevent the herpes simplex virus from entering cells.

Based on their recent findings, the scientists believe that the particles could serve as a powerful active ingredient in a vaginal cream, which would be applied topically, that would provide immediate protection against herpes virus infection while simultaneously helping stimulate immunity to the virus for long-term protection.¹

Virtually all efforts to generate an effective protection against the lifelong, recurrent genital infections caused by HSV-2 have failed. Apart

from sexual transmission, the virus also can be transmitted from mothers to neonates, and it is a key facilitator of HIV coacquisition.¹

“We call the virus-trapping nanoparticle a microbivac, because it possesses both microbicidal and vaccine-like properties,” says

EXECUTIVE SUMMARY

Researchers from the University of Illinois at Chicago, working with scientists from Germany, have shown that zinc oxide nanoparticles can prevent the herpes simplex virus from entering cells.

- Based on their recent findings, the scientists believe the particles could serve as a powerful active ingredient in a topically applied vaginal cream that would provide immediate protection against herpes virus infection while simultaneously helping stimulate immunity to the virus for long-term protection.
- Research also is moving ahead on treatment of genital herpes. Recently released results of a Phase II clinical trial indicate that a new type of treatment for genital herpes, an immunotherapy called GEN-003, may reduce the activity of the virus and the number of days with recurrent herpes.

Deepak Shukla, PhD, professor of ophthalmology and microbiology & immunology in the University of Chicago College of Medicine and lead author of the current paper. “It is a totally novel approach to developing a vaccine against herpes, and it could potentially also work for HIV and other viruses.”

How it works

The tetrapod-shaped zinc-oxide nanoparticles, which are called ZOTEN by University of Chicago researchers, work through basic electrical charges.

The ZOTEN have negatively charged surfaces that attract the HSV-2 virus, which has positively charged proteins on its outer envelope, explains Shukla. When the herpes virus is bound to the nanoparticles, it cannot infect cells, because the nanoparticle/virus complex is too large to pass through the cell membrane.

The bound virus also is exposed to processing by immune cells, known as dendritic cells, that patrol the vaginal lining. The dendritic cells overtake and process the virus, presenting pieces of it to the immune cells that produce antibodies specific to the herpes virus. The antibodies then deactivate the virus and trigger the production of customized killer cells that identify infected cells and destroy them before those cells are able to spread.¹

The particles potentially could serve as a powerful active ingredient in a topically applied vaginal cream that would provide immediate protection against herpes virus infection while simultaneously helping stimulate immunity to the virus for long-term protection, explains Shukla.

Anita Nelson, MD, professor emeritus in the Obstetrics and

Gynecology Department at the David Geffen School of Medicine at the University of California in Los Angeles, says, “Beyond the science of whether zinc oxide works or not, I think that any research in this area may have profound implications for the work on HIV prevention strategies using PrEP/PEP [pre-exposure prophylaxis/post-exposure prophylaxis]. Will at-risk women really consistently use something to prevent HSV infection? Will they be motivated to protect themselves from HSV better than they use contraception or PrEP/PEP?”

Vaccine in the pipeline

Research also is moving ahead on treatment of genital herpes. Recently released results of a Phase II clinical trial indicate that a new type of treatment for genital herpes, an immunotherapy called GEN-003, may reduce the activity of the virus and the number of days with recurrent herpes.² This novel treatment, given by three injections, appears to last for up to at least one year, according to research presented at the 2016 *microbe* research meeting of the American Society for Microbiology.²

Kenneth Fife, MD, PhD, an investigator and professor of medicine at Indiana University in Indianapolis, said, “GEN-003 is believed to work through a different pathway from most vaccines by recruiting T cells, which are critical to controlling chronic infections such as herpes. In addition, GEN-003 is also designed to stimulate antibodies to help neutralize the virus.”

To conduct the current study, 310 participants with a history of chronic, recurrent genital herpes received three shots of one of six vaccine doses, 21 days apart. Over one year, participants were tested for

stimulation of the immune system against the herpes virus, the frequency that the herpes virus was detectable on the skin around the genital area (“viral shedding”), and the number of days that herpes outbreaks (“lesions”) were visible.

Data indicate the GEN-003 treatment resulted in reductions in the rate of viral shedding and lesion frequency compared to rates before treatment. Immune response data are being analyzed and will be the topic of a future presentation.²

The GEN-003 vaccine is a first-in-class immunotherapy composed of two immunogenic antigens and a matrix adjuvant, designed to induce T-cell and B-cell immune responses. The vaccine is under development by Genocea Biosciences of Cambridge, MA.

Treatments for HSV-2 include daily topical medications to suppress the virus and shorten the duration of outbreaks, when the virus is active and genital lesions are present. However, drug resistance is common, and little protection is provided against further infections. Efforts to develop a vaccine have been unsuccessful because the virus does not spend much time in the bloodstream, where most traditional vaccines do their work. ■

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