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INSIDE

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What Effect Do Antibiotics Have on Hormonal Contraception?

Data do not support drug interactions with non-rifamycin antibiotics

Results of a new systematic literature review suggest that existing evidence does not support drug interactions between hormonal contraceptives and non-rifamycin antibiotics.[1] The review should help clear misconceptions regarding hormonal contraception and drug interactions; for example, a majority of pharmacists recommend backup contraception for women who use antibiotics with hormonal birth control.[2] Misconceptions can lead to interruption of a woman's use of hormonal contraception or poor compliance with antibiotic regimens, either of which could increase the risk for treatment failure with either drug.[1]

"THERE ARE MISPERCEPTIONS AMONG HEALTHCARE PROVIDERS AND PATIENTS ABOUT THE POTENTIAL FOR DRUG INTERACTIONS."
— KATHRYN CURTIS, PHD, NATIONAL CENTER FOR CHRONIC DISEASE PREVENTION AND HEALTH PROMOTION, CDC

Investigators with the Centers for Disease Control and Prevention (CDC), Emory University, University of North Carolina at Chapel Hill, and FHI 360 conducted the systematic review to assess new evidence on the safety and effectiveness of hormonal contraceptive use among women using broad-spectrum antibiotics, says **Kathryn Curtis**, PhD, a CDC health scientist in the agency's National Center for Chronic Disease Prevention and Health Promotion's Division of Reproductive Health.

"We found that the current recommendations remain consistent with the updated evidence that suggests most women can expect no reduction in the effectiveness of hormonal contraception with the

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concurrent use of non-rifamycin antibiotics," says Curtis, who served as a review co-author. "This is an important finding because there are misperceptions among healthcare providers and patients about the potential for drug interactions between broad-spectrum antibiotics and hormonal contraception."

The *US Medical Eligibility Criteria for Contraceptive Use* (*US MEC*) provides recommendations for safe use of contraceptive methods for women with various medical conditions or characteristics, including recommendations for women using medications such as broad-spectrum antibiotics.[3] According to the *US MEC*, women using broad-spectrum antibiotics are eligible to use all contraceptive methods, says Curtis. (*Review the US MEC chart at:* http://bit.ly/2sCkUcB; *all methods are listed as Category 1 – no restrictions on use.*)

Other guidance also reflects the latest evidence, the review notes. The most recent guidance for dental practitioners and dermatologists no longer advises use of additional contraceptive protection during use of non-rifamycin antibiotics.[4,5]

Check the Results

In performing the review, researchers identified 29 reports that looked at pregnancy rates, serum progesterone levels and/or sonographic evidence of ovulation, change in bleeding patterns, or pharmacokinetics in women using hormonal contraceptives along with non-rifamycin antibiotics.

Results of the review indicate that concomitant use of antibiotics, such as penicillins, cephalosporins, quinolones, tetracyclines, macrolides, trimethoprim sulfamethoxazole, metronidazole, dapsone, and isoniazid/streptomycin, was not associated with changes in pregnancy rates, ovulation, unscheduled bleeding, or significant declines in serum progestin levels in women using combination pills, the vaginal ring, or emergency contraceptive tablets.

Researchers note that only one study examined a non-oral formulation – the contraceptive vaginal ring.[6] No data are available on the combination of antibiotics with other non-oral formulations that include the transdermal patch, injectables, or progestin implants.[1] Also, studies of oral contraceptives in the review included a range of doses and progestins, but none included the lowest-dose pills, such as those containing less than 30 mg ethinyl estradiol or less than 150 mg levonorgestrel.[1]

The concerns about antibiotics that supposedly reduced hormonal effectiveness by inactivating the entero-hepatic resorption hormones that had already been absorbed but had been conjugated and excreted back into the bowel should have been put to rest years ago, says **Anita Nelson**, MD, professor and chair of the obstetrics and gynecology department at Western University of Health Sciences in Pomona, CA.

"Women who have had complete colectomies and can never resorb hormones from the large intestine do not have higher failure rates with combined oral contraceptives," says Nelson. "The focus should always be on initial absorption differences and on the liver — how fast does it metabolize sex steroids."

Counsel on Effective Use

What are appropriate contraceptives for women using rifamycin antibiotics? Options include injectable depot medroxyprogesterone

EXECUTIVE SUMMARY

Results of a new systematic literature review suggest that existing evidence does not support drug interactions between hormonal contraceptives and non-rifamycin antibiotics.

- The review should help clear misconceptions regarding hormonal contraception and drug interactions; for example, a majority of pharmacists recommend backup contraception for women who use antibiotics with hormonal birth control. Misconceptions can lead to interruption of a woman's use of hormonal contraception or poor compliance with antibiotic regimens, either of which could increase the risk for treatment failure with either drug.
- According to the *US Medical Eligibility Criteria for Contraceptive Use*, women using broad-spectrum antibiotics are eligible to use all contraceptive methods.

acetate and intrauterine devices, says **Andrew Kaunitz**, MD, University of Florida term professor and associate chairman of the Department of Obstetrics and Gynecology at the University of Florida College of Medicine-Jacksonville.

Women who use more common antibiotics can be counseled that such drugs will not reduce the effectiveness of their hormonal contraception, he notes.

What does *Contraceptive Technology* have to say on the subject? Research indicates that hormone levels in women using combined oral contraceptives are not lowered by the use of ampicillin, amoxicillin, clarithromycin, metronidazole, quinolones (ciprofloxacin, ofloxacin), doxycycline, tetracycline, or fluconazole. Almost all combined pill users taking these antibiotics have hormone levels that remain well within the therapeutic range for contraceptive efficacy.[7-10] Backup methods should **NOT** be necessary unless a patient has problems taking pills, such as an underlying medical condition that interferes with pill-taking or absorption, it advises.

Long-term use of broad-spectrum antibiotics, such as in the case of erythromycin or tetracycline for acne, also is compatible with COC use.[10] While rifampin is used routinely in tuberculosis treatment, it also is used with other antibiotics to treat skin infections with methicillin-resistant *Staphylococcus aureus* (MRSA).[11]

No matter which antibiotic may be used, to maximize the effectiveness of user-dependent methods like oral contraceptives, providers should encourage correct and consistent use at all times, including during illness.[1] ■

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Cervical Cancer Screening May Be Less Effective in Obese Women

Results from a large retrospective study of women undergoing cervical cancer screening indicate that overweight and obese women had an increased risk of cervical cancer compared to normal weight women.[1] The study analyzed screening data from about 1 million women ages 30 to 64 undergoing routine cytology and human papillomavirus (HPV) DNA testing in the Kaiser Permanente Northern California healthcare system.

Although obesity is a strong risk factor for other female reproductive cancers, its relationship with cervical cancer has been less clear, says **Megan Clarke**, PhD, a postdoctoral fellow in the National Cancer Institute's Division of Cancer Epidemiology & Genetics, Clinical Genetics Branch. Some studies have reported an association of obesity with increased risk of cervical cancer incidence and death, she notes. Through a clinical observation during chart reviews of women with cervical cancer, a Kaiser Permanente Northern California technologist noted that many of the cancers were diagnosed in obese women, says Clarke.

"We undertook a study to test whether this clinical observation was a true association in our population of women participating in cervical cancer screening," explains Clarke, lead author of the current paper. "Our study was large enough so that we were able to analyze the effects of body weight on all stages of the disease process, including infection with human papillomavirus (the cause of cervical cancer), cervical precancer, and cancer."

Body mass index, defined as weight in kilograms divided by height in meters squared, was categorized as normal/underweight (below 25 kg/m^2), overweight (25 to less than 30 kg/m^2), or obese (30 kg/m^2 or greater). Researchers were able to confirm the clinical observation in the epidemiologic analysis, says Clarke. Data show that obese women had the lowest five-year risk of precancer (0.51%; 95% confidence interval [CI], 0.48-0.54% vs. 0.73%; 95% CI, 0.70-0.76% in normal/underweight women; $P < .001$). However, obese women had the highest five-year risk of cancer (0.083%; 95% CI, 0.072-0.096% vs. 0.056%; 95% CI, 0.048-0.066% in normal/underweight women; $P < .001$).[1]

The evidence suggests that obesity may increase risk for cervical cancer due to reduced effectiveness of cervical cancer screening in women with a high body mass index, Clarke states.

Andrew Kaunitz, MD, University of Florida term professor and associate chairman of the Department of Obstetrics and Gynecology at the University of Florida College of Medicine-Jacksonville, observes that compliance with screening does not explain the findings in the current study. If obesity serves as a risk factor for invasive cancer, it also should increase precancer as well, he says. Adequate visualization and sampling of the cervix can be challenging in women with higher BMI; this may explain the study's findings.

"My clinical impression is that a vaginal speculum exam is often more uncomfortable for obese women than for other patients," says Kaunitz. "Maintaining good communication with patients during the pelvic examination and employing appropriately sized vaginal speculums may pay off with improved cervical cancer screening efficacy in an increasing obese patient population."

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Results from a large retrospective study of women undergoing cervical cancer screening indicate that overweight and obese women had an increased risk of cervical cancer compared to normal weight women.

- The study analyzed screening data from about 1 million women ages 30 to 64 undergoing routine cytology and human papillomavirus DNA testing in the Kaiser Permanente Northern California healthcare system.
- In 2017, the U.S. Preventive Services Task Force issued draft guidance that states that for average-risk women ages 30-65, cervical cancer testing may be conducted with either cervical cytology alone every three years or with high-risk human papillomavirus (HPV) testing. Co-testing no longer is required.

Check Your Practice

In 2017, the U.S. Preventive Services Task Force issued draft guidance that states that for average-risk women ages 30-65, cervical cancer testing may be conducted with either cervical cytology alone every three years or with high-risk human papillomavirus (HPV) testing. Co-testing no longer is required.[2] The Task Force recommends screening for cervical cancer in women

ages 21-29 every three years with cervical cytology alone. For women ages 30-65, the advisory group recommends either screening with cervical cytology alone every three years or screening with high-risk human papillomavirus testing alone every five years. (Contraceptive Technology Update *reported on the guidance; see the December 2017 article, "Task Force Issues Cervical Cancer Screening Guidance: What Changes Can Clinicians Expect?" available at:* http://bit.ly/2ErPxud.)

The American College of Obstetricians and Gynecologists (ACOG) continues to affirm its clinical guidance, which recommends that for women ages 30-65, co-testing with cytology and high-risk HPV testing every five years is preferred, and screening with cytology alone every three years is acceptable. The Task Force recommends against screening for cervical cancer in women younger than 21 years of age.[3]

The Task Force's draft recommendations for routine cervical cancer screening in women younger than 21 years of age, for women ages 21-29, and for women older than age 65 who have been screened adequately previously have not changed and remain the same as ACOG's current guidance.

Regular screening for women ages 21 to 65 greatly reduces the rate of cervical cancer and the number of deaths resulting from cervical cancer.[4] The most effective screening method depends on the woman's age, according to the USPSTF evidence search. For women 21-29 years of age, many infections with HPV will resolve on their own, so the Pap test is most effective for this age group.[5] For women from 30-65 years of age, HPV infections are more likely to lead to cancer, so either Pap tests or high-risk HPV tests are effective for screening in this group, the evidence review noted.[1] ■

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Women Who Breastfeed for Six Months or Longer Found to Have Reduced Diabetes Risk

Breastfeeding for six months or longer cuts the risk of developing type 2 diabetes nearly in half for women throughout their childbearing years, according to results of a long-term observational study.[1]

To conduct the analysis, researchers focused on 1,238 women from the Coronary Artery Risk Development in Young Adults study, a national, multi-center investigation of cardiovascular disease risk factors. Women in the current analysis were ages 18-30 without diabetes during 1985-1986, the start of the study. Participants had one or more live births, reported their lactation duration, and were screened for diabetes up to seven times during 30 years of follow-up (1986-2016).

Findings from the investigation indicate that the women who breastfed their babies for six months or more across all births had a 47% decrease in risk of developing type 2 diabetes in comparison to women who did not breastfeed at all. Those women who breastfed for six months or less had a 25% decline in diabetes risk, figures suggest.[1]

"We found a very strong association between breastfeeding duration and lower risk of developing diabetes, even after accounting for all possible confounding risk factors," said **Erica Gunderson**, PhD, MS, MPH, lead author and senior research scientist with the Kaiser Permanente Division of Research, in a statement accompanying the paper's publication.

Although previous research on breastfeeding relied on self-reporting of diabetes onset and started to follow older women later in life, researchers involved in the current analysis followed women specifically during the period of childbearing and regularly screened them for diabetes before and after their pregnancies, Gunderson said. Scientists also accounted for pre-pregnancy metabolic risk, including obesity and fasting glucose and insulin,

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lifestyle behaviors, family history of diabetes, and perinatal outcomes, she noted.

What Could Lead to Benefits?

What are possible explanations for the lower risk of diabetes associated with lactation duration? Researchers in the current analysis note that lactating women have lower circulating glucose in both fasting and postabsorptive states, as well as lower insulin secretion, despite increased glucose production rates.[2]

Several plausible biological mechanisms could be responsible for breastfeeding's protective effects, researchers note. These include the influence of hormones associated with lactation on the pancreatic cells that control blood insulin levels and thereby affect blood sugar. In the current study, the incidence of diabetes decreased in a graded manner as the duration of breastfeeding increased, regardless of race, gestational diabetes, lifestyle behaviors, body size, and other metabolic risk factors measured before pregnancy.[1] This finding suggests that the underlying mechanism may be biological, Gunderson said.

Clinicians have known for a long time that breastfeeding provides many benefits to mothers and babies, but previous evidence indicated only weak effects on chronic disease in women, says **Tracy Flanagan**, MD, director of women's health for Kaiser Permanente Northern California.

"Now we see much stronger protection from this new study showing that mothers who breastfeed for months after their delivery, may be reducing their risk of developing type 2 diabetes by up to one half as they get older," said Flanagan in the press statement. "This is yet another reason that doctors, nurses, and hospitals, as well as policymakers, should support women and their families to breastfeed as long as possible."

What About Contraception?

According to the U.S. Selected Practice Recommendations for Contraceptive Use, postpartum women who are breastfeeding should not use combined hormonal contraceptives during the first three weeks after delivery (U.S. MEC 4 – should not be used) because of concerns about an increased risk for venous thromboembolism. During the fourth week postpartum, breastfeeding women generally should not use combined hormonal contraceptives (U.S. MEC 3 – use usually is not recommended unless other more appropriate methods are not available or acceptable) because of concerns about the potential effects on breastfeeding performance. New breastfeeding mothers with other risk factors for venous thromboembolism generally should not use combined hormonal contraceptives four to six weeks after delivery (U.S. MEC 3).[3] Use of progestin-only methods (contraceptive implant, contraceptive shot, and progestin-only pills) prior to 21 days is classified as Category 2 (benefits outweigh theoretical or proven risks). Between 30 and 42 days postpartum and beyond, these methods are classified as Category 1 (no restrictions on use).[4]

Women who are breastfeeding exclusively (meaning, they are nursing at least every four hours during the day and every six hours at night, and they feed their infants only breast milk) can rely on the Lactational Amenorrhea Method of contraception. The Lactational Amenorrhea Method is the proactive application of exclusive breastfeeding during lactational amenorrhea for the first six months after delivery. If used perfectly, two out of 100 people who use breastfeeding as birth control get pregnant in the six months it can be used after a baby is born.[5] ■

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More Women Opting for Outpatient Laparoscopy for Hysterectomies

Hysterectomy is the second most common procedure performed for women in the United States. Laparotomy followed by inpatient hospitalization has been the traditional surgical approach. A recent report suggests that fewer women are opting for traditional procedures; the rate of hysterectomies in the United States dropped 12% between 2010 and 2013, figures indicate.[1]

However, outpatient hysterectomy may be more common with the rise of laparoscopy, say researchers at the University of Michigan, authors of the current report. Since ambulatory data often are not included in large national claims datasets, declines in inpatient hysterectomy may be due to an overall decrease in hysterectomy utilization, or a shift toward outpatient care, they say.

To analyze the use of laparoscopy and outpatient hysterectomy, researchers looked at procedures between 2010 and 2013 in the Health Care Cost Institute, a national dataset with inpatient and outpatient private insurance claims for more than 25 million women. The researchers used procedure codes to categorize surgical approaches as abdominal, laparoscopic, laparoscopic assisted vaginal, or vaginal.

Investigators found that 386,226 women underwent hysterectomy between 2010 through 2013, with the rate of utilization decreasing 12.4%, from 39.9 to 35.0 hysterectomies per 10,000 women. The largest absolute decreases were in women younger than 55 years of age and among those with uterine fibroids, abnormal uterine bleeding, and endometriosis. Figures indicate that the proportion of laparoscopic hysterectomies increased from 26.1% to 43.4%, with decreases in abdominal (38.6% to 28.3%), laparoscopic assisted vaginal (20.2% to 16.7%), and vaginal (15.1% to 11.5%) hysterectomies. Researchers report a shift from inpatient to outpatient surgery. In 2010, the inpatient and outpatient rates of hysterectomy were 26.6 and 13.3 per 10,000 women, respectively. However, by 2013, the rates were 15.4 and 19.6 per 10,000 women.[1]

Researchers compared the costs of inpatient and outpatient procedures. They found that in each year of analysis, the average reimbursement for outpatient procedures was 44-46% less than for similar inpatient procedures. Total payments for hysterectomy decreased 6.3%, from $823.4 million to $771.3 million, they report.[1]

The findings suggest that minimally invasive procedures and other alternatives now are more common than traditional hysterectomies that require a hospital stay, notes lead author **Daniel Morgan**, MD, clinical associate professor in the Department of Obstetrics and Gynecology at the University of Michigan Medical School and Von Voigtlander Women's Hospital.

"Hospitals have been reporting declines in hysterectomies for some time, but we wanted to learn how big the decrease actually was and the most common way hysterectomy is performed today," said Morgan in a press statement. "As more alternatives become available, more women seem to be choosing these other options."

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Researchers in the current study note that between 2010 and 2013, there were fewer hysterectomies among reproductive-age women and relatively stable rates among women older than 55 years of age. There was a marked decrease among the most common indications for hysterectomy in reproductive-age women, such as abnormal uterine bleeding, uterine fibroids, endometriosis, and chronic pelvic pain.

Clinicians and patients may be moving toward increased use of endometrial ablation and hormonal intrauterine devices to control bothersome abnormal bleeding and chronic pelvic pain. Such therapies have allowed many pre-menopausal women to control symptoms without resorting to invasive surgery.

The Duke Clinical Research Institute in Durham, NC, has been working with nine centers across the United States in a multi-year project to review the effectiveness of different treatment strategies for uterine fibroids. The project, a collaboration between the Patient-Centered Outcomes Research Institute and the Agency for Healthcare Research and Quality, is designed to help patients and clinicians make more informed choices about treatment options. (*Read more on the project; see the March 2016 article, "Elevated testosterone levels might increase risk of uterine fibroids," available at:* http://bit.ly/2mpiwC4.)

The study focuses on developing a multi-center registry of women who have undergone surgical treatments for uterine fibroids. This COMPARE-UF (Comparing Options for Management: Patient-centered REsults for Uterine Fibroids) registry will establish the necessary infrastructure to support comparative clinical effectiveness research that is patient-centered.

Therapies to treat isolated heavy menstrual bleeding associated with fibroids include tranexamic acid, an oral antifibrinolytic agent that is taken only on the days of heavy menstrual bleeding. This approach decreases bleeding and improves quality of life with minimal side effects.[3] Use of oral contraceptives or a levonorgestrel-releasing intrauterine device can decrease menstrual bleeding and provide birth control. ■

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Be Vigilant for Zika Infection

Clinicians are urged to maintain vigilance regarding the Zika virus in women of reproductive age. Areas with documented local transmission of Zika, such as southern Florida, parts of south Texas, and Puerto Rico, have seen a 21% jump in births with outcomes most strongly linked to Zika virus infection.[1]

Researchers at the Centers for Disease Control and Prevention (CDC) examined about 1 million births during 2016 in 15 U.S. states and territories, including portions of Florida, Georgia, North Carolina, and Texas, as well as Hawaii, Iowa, Illinois, Massachusetts, New Jersey, Puerto Rico, Rhode Island, South Carolina, Utah, Vermont, and New York (excluding New York City).

Their analysis indicates that about three out of every 1,000 babies in the focus areas exhibited a birth defect that possibly was associated with Zika virus infection in the mother. About 50% of the infants were born with brain abnormalities and/or microcephaly, while 22% exhibited nervous system damage, including joint problems and deafness, without brain or eye abnormalities. One-fifth had neural tube defects and other early brain abnormalities, while 9% had eye abnormalities without brain abnormalities. Another increase in birth defects possibly related to Zika could occur when 2017 data are analyzed, since many pregnant women exposed to the Zika virus in late 2016 subsequently delivered in 2017, researchers surmise.[1]

The CDC analysis notes that for the infants who had birth defects linked to Zika virus, the majority of the mothers did not exhibit laboratory evidence of Zika virus infection because they were not tested, they were not tested at the right time, or they were not exposed to Zika virus.

To track birth defects that might be associated with the virus, the CDC uses two systems. The U.S. Zika Pregnancy and Infant Registry tracks pregnancies with laboratory evidence of Zika virus infection, while the Zika Birth Defects

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Surveillance system records birth defects possibly associated with virus infection, regardless of exposure or laboratory testing.

"Our pregnancy and birth defects surveillance networks are a collaborative effort with state, local, and territorial health departments and are essential to protect mothers and babies affected by Zika virus," says **Margaret Honein**, PhD, MPH, acting director of the Division of Congenital and Developmental Disorders within the CDC's National Center on Birth Defects and Developmental Disabilities. "These networks can also be used as models to help track other known and emerging health threats for mothers and babies."

Drug May Find New Purpose

Researchers at University of California San Diego School of Medicine, working in conjunction with other international scientists, have published findings that suggest that an antiviral drug, sofosbuvir, currently used to treat and cure hepatitis C infections, may be repurposed as a potential treatment for adults, including pregnant women, infected with Zika.[2]

While much work has been done in addressing the Zika health threat, a large portion has been dedicated to developing a vaccine, notes the paper's senior author, **Alysson Muotri**, PhD, professor in the UC San Diego School of Medicine departments of pediatrics and cellular and molecular medicine. (*Results from two Phase I clinical trials now suggest that an experimental Zika vaccine developed by scientists at the National Institute of Allergy and Infectious Diseases is safe and induces an immune response in healthy adults; see the March 2018* Contraceptive Technology Update *article, "Zika Remains on Research, Public Health Radar," available at:* http://bit.ly/2EZwVii.)

"But there is also a great need to develop clinical strategies to treat Zika-infected individuals, including pregnant women for whom prevention of infection is no longer an option," said Muotri, who also serves as director of the school's stem cell program. "They represent the greatest health crisis because a Zika

Late-Breaking News

Preventing unintended pregnancy is a primary strategy to reduce adverse outcomes in pregnancy and birth related to Zika virus infection. A new report details the installation of a network of healthcare providers offering client-centered contraceptive counseling and the full range of reversible contraception at no cost to women in Puerto Rico during the 2016-2017 Zika virus outbreak.

The Zika Contraception Access Network provided services to 21,124 women, with almost all women (95%) receiving same-day provision of a reversible contraceptive method. More than half (68%) chose and received a long-acting reversible contraceptive method at their initial visit. Of the women who chose such a method, more than three-quarters had used no protection, condoms, or withdrawal before their visit.

The majority (93%) of women who participated in a follow-up survey said they were very satisfied with the services received, and 93% said they received the method that they were most interested in after receiving counseling.[1] ■

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infection during the first trimester confers the greatest risk of congenital microcephaly."

Both hepatitis C and Zika are part of the same family of viruses and have structural similarities, the scientists note. By using human neural progenitor cells, which generate neurons and other types of brain cells, researchers found that drug exposure rescued Zika-infected cells and restored the gene expression linked to their antiviral response. Researchers then followed up by studying an immunodeficient mouse model infected by Zika. Their analysis suggests that intravenous injections of sofosbuvir significantly reduced the viral loads in blood serum of those who received the injections compared to those in a placebo group. Also, fetuses of pregnant mice infected with Zika did not show detectable Zika virus amplification in the drug-treated group.[2]

While findings are preliminary, Muotri says they demonstrate the potential for repurposing a drug that is already in wide clinical use for a similar viral infection.

"Until there is approval of a Zika vaccine, we think this is an approach that needs to be pursued wholeheartedly," Muotri said in a press statement. ■

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WASHINGTON WATCH

Proposed 'Conscience' Rule Could Interfere With Patient Care

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In mid-January 2018, the Trump administration took two steps to expand and enforce federal "conscience" protections, which allow individuals and organizations in the healthcare field to refuse to provide or be involved with services, information, and referrals to which they have religious or moral objections. These steps have serious implications for patients' access to sexual and reproductive health services and other critical care.

On January 18, the U.S. Department of Health and Human Services (HHS) held a high-profile announcement that it was reorganizing its Office for Civil Rights (OCR), creating a new division that will focus on "conscience and religious freedom."[1] Administration officials, members of Congress, and conservative activists highlighted what they call rising intrusion into conscience rights. Among other things, they are objecting to laws requiring insurance coverage of contraception and abortion, public notice requirements for crisis pregnancy centers, attempts to require hospitals and healthcare professionals to provide abortion care when a woman's life is endangered, and anti-discrimination protections for LGBTQ individuals. Notably, OCR handled more than 30,000 total complaints on all issues in 2017,[2] but justified the creation of the new "conscience" division on the strength of just 34 such complaints.[1]

The next day, HHS unveiled a massive set of proposed regulations to interpret and enforce more than 20 different statutory provisions related to the new division's mission.[3] That includes not only long-standing laws related to abortion and sterilization in the United States, but also laws related to global healthcare assistance, end-of-life care, and much more. The proposed regulations mirror and expand on controversial regulations put forth at the end of the George W. Bush administration. The 2008 regulations generated more than 300,000 public comments, were immediately challenged in court, and then were rescinded almost entirely during the Obama administration.[4]

Regulations Raise Numerous Questions

The 2018 version of the proposed refusal regulations, like the 2008 version, purports to clarify key terms, but in effect is redefining those terms to expand the laws' reach. In the process, the proposed regulations raise numerous questions over what have been long-settled standards of law and practice. For example:

- Under the Title X family planning program, all clients found to be pregnant must receive nondirective counseling on all of their legal options, including abortion, and referral upon request. Under the proposed regulations, could that requirement

be enforced? How would HHS ensure that every Title X client is able to receive this counseling and referral if individual providers and entire programs were allowed to refuse?

• Long-standing federal and state laws require healthcare institutions to provide care in an emergency. Could institutional healthcare providers, such as hospital emergency rooms, use the proposed regulations to refuse to provide emergency care, such as an abortion necessary to preserve the life a woman?

• Title VII of the Civil Rights Act has long governed religious discrimination in the workplace and balances the religious rights of workers with the practical needs of employers, including their ability to provide needed care to their patients. Would this balancing still be permitted under the proposed regulations, or would religious objections always take precedence over patients' needs? For example, could family planning clinics be forced to employ individuals unwilling to provide, discuss, or even schedule appointments for contraception?

• Healthcare professionals have ethical and legal responsibilities to ensure that patients have the information they need to provide informed consent to care. Yet, the new refusal regulations encompass the provision of counseling and information on topics and services that healthcare personnel find objectionable. How would healthcare institutions ensure that patients receive the information they need? Would personnel even be required to notify patients and employers when they refused to provide information or services?

• Federal and state civil rights laws protect against discrimination against patients based on a variety of characteristics, such as race, gender, sexual orientation, immigration status, disability, and HIV status. Would these civil rights laws always take precedence? Or could the proposed regulations allow personnel or institutions to refuse to provide some or all services to entire categories of patients?

• The proposed regulations appear to apply certain federal refusal laws to international, foreign, and multilateral organizations. How could large international agencies, such as the World Health Organization, require, monitor, and certify compliance by their numerous local sub-grantees? And could these laws conflict with the laws of other countries?

The proposed regulations also greatly expand the powers of OCR to investigate threatened, potential, or actual violations of the laws and to enforce their compliance. Advocates for sexual and reproductive health and rights and for LGBTQ health and rights are working to identify all the potential harms of the new regulations and to organize a robust campaign of public comments before a March 27, 2018, deadline. ■

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COMING IN FUTURE MONTHS

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- What affects teens' choices for contraception?
- FDA approves new HPV assay
- How to manage uterine fibroids

CONTRACEPTIVE TECHNOLOGY UPDATE®

Contraceptive Technology Update is endorsed by the **National Association of Nurse Practitioners in Women's Health** and the **Association of Reproductive Health Professionals** as a vital information source for healthcare professionals.

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CME/CE QUESTIONS

1. **According to the *U.S. Medical Eligibility Criteria for Contraceptive Use, 2016*, use of broad-spectrum antibiotics are classified as what category with all methods?**

   a. Category 1
   b. Category 2
   c. Category 3
   d. Category 4

2. **According to the *U.S. Selected Practice Recommendations for Contraceptive Use*, use of combined hormonal contraceptives during the first three weeks after delivery for postpartum women who are breastfeeding falls into which category?**

   a. Category 1
   b. Category 2
   c. Category 3
   d. Category 4

3. **In 2017, the U.S. Preventive Services Task Force issued draft guidance that recommended what type of cervical cancer screening in average-risk women ages 21-29 years?**

   a. Screening every other year with cervical cytology alone
   b. Screening every three years with cervical cytology alone
   c. Screening every three years with cervical cytology and high-risk human papillomavirus (HPV) testing
   d. Screening every year with cervical cytology and high-risk human papillomavirus (HPV) testing

4. **Which disease is in the same viral family as the Zika virus?**

   a. Hepatitis C
   b. Smallpox
   c. Norwalk virus
   d. Measles

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.