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INSIDE

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Progesterone After Mifepristone to Halt Medication Abortion: Is It Safe?

Study of progesterone stopped due to safety issues

In the past four years, legislators in at least 14 states have introduced bills that would require clinicians to inform patients during pre-abortion counseling that medication abortion can be "reversed" if the patient changes her mind after taking the first of two drugs needed for the procedure. However, results of a new study indicated that women who opt to stop in the middle of treatment may be at risk for serious blood loss.[1]

RESULTS OF A NEW STUDY INDICATED THAT WOMEN WHO OPT TO STOP IN THE MIDDLE OF TREATMENT MAY BE AT RISK FOR SERIOUS BLOOD LOSS.

Medication abortion involves the use of two drugs, mifepristone and misoprostol, usually taken 24 to 48 hours apart. Mifepristone acts to block the pregnancy hormone, progesterone, while the misoprostol causes a woman's body to expel the pregnancy. Approved by the FDA for medical abortion during the first 70 days of pregnancy, the abortion regimen is highly effective and safe. The complication rate for medication abortion is less than 0.5%, whether it is provided in-person or by telemedicine.[2]

A case study was published in 2012 that detailed the experience of six abortion patients who received high doses of progesterone after taking only mifepristone, the first of the two drugs needed to complete the regimen.[3] Co-authored

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by an acknowledged antiabortion activist, George Delgado, MD, a San Diego physician, the study did not conform to minimum standards for medical research, according to a 2015 systematic evidence review. The study authors did not apply for ethical approval and did not use a control group.[4] Results of a 2018 observational study, published by some of the same authors, reported the experience of 500 abortion patients who underwent medication abortion "reversal."[5] The 2018 study also did not follow a uniform course of treatment, and was not designed with a control group.

To estimate the efficacy and safety of mifepristone antagonization with high-dose oral progesterone, a research team led by **Mitchell Creinin**, MD, professor in the department of obstetrics and gynecology and director of family planning at the University of California, Davis, enrolled women who were planning a surgical abortion and willing to delay the procedure for two weeks. Participants ingested 200 mg of mifepristone and initiated 400 mg of oral progesterone or placebo 24 hours later twice daily for three days, then once daily until their planned surgical abortion 14-16 days after enrollment. Women were followed for up to two weeks after taking mifepristone to identify if the pregnancy continued to develop. Those with continuing pregnancies underwent a surgical abortion as scheduled.

Researchers reported that after enrolling 12 women in the study, three participants experienced severe bleeding, requiring ambulance transport to an ED. One woman received progesterone, and two had received placebo. Because of such safety issues, the research team stopped the study early.

"Without any evidence of efficacy, the findings of serious safety concerns in our study participants who received progesterone or placebo means that we should not be providing such treatment unless it is under strict research oversight," states Creinin. "This treatment is experimental, and persons who [are] undergoing an abortion and may want this treatment deserve to be treated in the same safe manner as anyone receiving any new potential therapy."

In 2015, Arkansas was the first state to implement mandatory

EXECUTIVE SUMMARY

Results of a new study indicated that women who initiate medication abortion but opt to stop in the middle of treatment may be at risk for serious blood loss.

- In the past four years, legislators in at least 14 states have introduced bills that would require clinicians to inform patients during pre-abortion counseling that medication abortion can be "reversed" if the patient changes her mind after taking the first of two drugs needed for the procedure.
- The American College of Obstetricians and Gynecologists does not support the use of progesterone for "reversal" of medication abortion because the treatment does not meet clinical standards and is not based on scientific evidence.

abortion reversal counseling; Idaho, South Dakota, and Utah have adopted similar laws. Other states have pushed back against legislation. Bills introduced in California, Colorado, Georgia, and North Carolina failed to pass, and the Indiana Senate stopped a bill that had been passed by the House. In 2019, legislators in Kansas, Kentucky, North Dakota, and Nebraska also considered bills that would require abortion providers to tell their patients about abortion reversal.

In 2017, the Louisiana Department of Health performed a review of the effectiveness of "reversal" at the state legislature's request. The review concluded that "there is insufficient evidence to suggest that there is a sound method to reverse a medication-induced abortion."[6]

The American College of Obstetricians and Gynecologists (ACOG) does not support the use of progesterone for "reversal" of medication abortion because the treatment does not meet clinical standards, and is not based on scientific evidence.[7] The use of progesterone for reversing a medication abortion has not been reviewed by the FDA. Such use in medication abortion "reversal" is considered off-label, since it has not been approved by the agency for such purposes.

"It is very concerning that states are passing laws to encourage women to participate in an unmonitored experiment," says Creinin. "When a study is monitored, as ours was, we have the ability to stop if safety concerns arise."

Is counseling on "reversal" necessary when women are seeking a medication abortion? Research indicates that most women who seek medication abortion are sure of their decision to have an abortion. In the days after an abortion, the majority of women report that it was the right decision.[7] Fewer than 1% of patients who took mifepristone between 2000 and 2012 ended up deciding to continue their pregnancies.[4]

Robert Hatcher, MD, MPH, professor emeritus of gynecology and obstetrics at Emory University School of Medicine, suggests that individuals who have been counseled on medication abortion reversal be informed that the practice is potentially dangerous, is not effective, and is not recommended by ACOG. ■

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Help Women Take Charge of Breast Cancer Risks

Breast cancer is the most common cancer in American women, according to the American Cancer Society. In 2019, an estimated 268,600 new cases of invasive breast cancer were diagnosed among women.[1]

About one in three breast cancer cases could be prevented by simple lifestyle modifications to weight management, exercise, diet, and alcohol consumption.[2] During the North American Menopause Society 2019 Annual Meeting, **Juliana Kling**, MD, MPH, a menopause specialist at the Mayo Clinic in Scottsdale, AZ, outlined several breast cancer prevention recommendations from the World Cancer Research Fund and the American Institute for Cancer Research to aid clinicians.

"Given the magnitude of breast cancer occurrence and the accumulated evidence supporting prevention as the most cost-effective, long-term strategy for reducing breast cancer risk, lifestyle education centered on the American Institute for Cancer Research cancer prevention recommendations should be a core component of routine patient visits," Kling said in a statement.[3]

The World Cancer Research Fund and the American Institute for Cancer Research updated their breast cancer prevention recommendations in 2018, adjusting for menopause status when possible. Researchers examined modifiable risk factors, such as exercise, diet, and alcohol.[4]

As of 2015-2016, the National Center for Health Statistics at the CDC estimated that 41.1% of U.S. women age 20 years and older were obese.[5] Postmenopausal women have a 1.5 to 2.0 times increased risk of breast cancer if they are obese. Body fat may increase the susceptibility to cancer as a result of hyperinsulinemia, increased estradiol, and inflammation.[6]

Physical activity may have a role in preventing breast cancer. Research indicates that five hours per week of brisk walking can reduce the risk.[7] The American Cancer Society advises that adults engage in 150 minutes of moderate intensity or 75 minutes of vigorous intensity activity each week.[8]

What About Alcohol?

In a 2011 large, prospective cohort study drawn from the Nurses Health Study, researchers observed an association between low levels of alcohol consumption and breast cancer risk. Cumulative average alcohol consumption over long periods of time, and both drinking earlier and later in adult life were independently associated with breast cancer risk.[9] The American Cancer Society advises that women drink no more than one alcoholic beverage per day. A drink is defined as 12 ounces of beer, five ounces of wine, or 1.5 ounces of hard liquor.[8]

Research surrounding diet and breast cancer risk is ongoing. Study results indicate that a diet rich in vegetables, fruit, poultry, fish, and low-fat dairy may be of benefit.[10] Researchers from the Women's Health Initiative clinical trial studied the effects of dietary modification in 49,000 postmenopausal women with no previous history of breast cancer. They found that women who followed a balanced diet that was low in fat and included daily servings of fruits, vegetables, and grains had a 21% lower risk of death from breast cancer than women in the control group.[11] ■

EXECUTIVE SUMMARY

Breast cancer is the most common cancer in American women, according to the American Cancer Society. In 2019, an estimated 268,600 new cases of invasive breast cancer were diagnosed among women.

- About one in three breast cancer cases could be prevented by lifestyle modifications inlcuding such as weight management, exercise, diet, and alcohol consumption, according to a recent presentation at the North American Menopause Society 2019 Annual Meeting.
- Breast cancer prevention recommendations from the World Cancer Research Fund and the American Institute for Cancer are available to aid clinicians.

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Postpartum LARC: Highly Effective, but Restricted by Some Hospitals

A new mother is seeking a long-acting reversible contraceptive (LARC) method. When asked why she did not seek immediate placement of an intrauterine device (IUD) following her delivery, she says that the hospital where she gave birth prohibited such practices.

Women who receive care in Catholic facilities may be denied postpartum LARC due to religious directives that ban such care. In 10 states, more than 30% of all hospital beds are in Catholic facilities. In about 50% of states, more than one in five hospital beds is in a Catholic facility.[1]

Refusal to offer postpartum LARC methods stems from the Ethical and Religious Directives, a set of rules written by the U.S. Conference of Catholic Bishops. The directives urge Catholic hospitals not to provide procedures and services the church deems immoral, such as abortions, contraception, and sterilization, with very few exceptions.

According to a 2016 report published by the American Civil Liberties Union, 548 hospitals — 14.5% of all U.S. short-term care facilities — are urged to follow these directives, a 22% increase since 2001. These hospitals are owned by a Catholic health system or diocese, affiliated with a Catholic hospital or system through a business partnership, or are historically Catholic hospitals owned by a secular nonprofit or for-profit healthcare system.[1]

Government protections that allow religious hospitals to restrict care are limiting access to healthcare consumers, says **Maryam Guiahi**, MD, MSc, associate professor of obstetrics and gynecology at University of Colorado Denver School of Medicine. Guiahi is the author of a recent commentary on the subject.[2]

Many women once faced financial barriers to LARC access, such as lack of insurance coverage or high out-of-

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- Refusal to offer contraceptive care stems from the Ethical and Religious Directives, a set of rules written by the U.S. Conference of Catholic Bishops. The rules bar Catholic hospitals from providing procedures the church deems immoral, such as abortions, contraception, and sterilization, except in extreme situations.
- According to a 2016 report, 548 hospitals — 14.5 % of all U.S. short-term care facilities — are urged to follow these directives. These hospitals are owned by a Catholic health system or diocese, affiliated with a Catholic hospital or system through a business partnership, or are historically Catholic hospitals owned by a secular nonprofit or for-profit healthcare system.

pocket costs. The Affordable Care Act in 2012 instructed insurers to provide contraceptives without copays, leading to an increase in LARC use.[3]

Until 2012, most state Medicaid programs provided a single, bundled payment for all care during the delivery hospitalization.[4] Since this episode payment did not increase to cover the cost of immediate postpartum LARC-related care, providers were unable to receive separate payment for device placement in the inpatient setting. However, as of February 2018, 37 state Medicaid programs can bill separately for immediate postpartum LARC.[5]

Catholic hospitals may not choose to allow immediate postpartum LARC placement due to religious directives. According to information from the Wisconsin Hospital Association, one Catholic hospital, Ascension St. Joseph Hospital, billed for an IUD nine times for the fiscal year ending June 2019. Less than five miles away, a non-Catholic institution, Froedtert Memorial Lutheran Hospital, billed for more than 1,500 placements in the same time period.[6]

What can reproductive health providers do to help women get the reproductive healthcare they need in light of current directives governing Catholic hospitals?

"Reproductive providers in Catholic settings who are interested in providing appropriate options should consider several efforts when faced with this ethical dilemma," says Guiahi. "First, they should work toward improved efforts at transparency to help avoid conflicts in care and support patient autonomy."

For example, when patients call to request birth control appointments, Guiahi suggests they should be informed ahead of time of any relevant restrictions to care. Secondly, clinicians unable to provide this care should offer direct referrals for nearby providers who can deliver services that patients need or desire.

"Finally, they should work with their institutions to recognize when reproductive services are medically indicated, and create local policies that support provision," states Guiahi. "Many local ethicists are open to the medical considerations of reproductive experts in these settings."

Medical evidence backs the safety and efficacy of immediate postpartum LARC methods. The CDC's U.S. Medical Eligibility Criteria for Contraceptive Use classifies immediate postpartum use of IUDs and implants as Category 1 (no restriction for use) or Category 2 (advantages generally outweigh theoretical or proven risks).[7] ■

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Research Examines Effect of Pregnancy Preferences on Contraceptive Use

Do women who do not wish to become pregnant use more effective contraceptive methods than women who might welcome pregnancy? Results of a new study examine relationships between women's pregnancy preferences and contraceptive use using the Desire to Avoid Pregnancy (DAP) scale.[1]

Researchers found that women with a strong preference to avoid pregnancy were far more likely to use any contraceptive method. However, more than 50% of women who reported a low preference to avoid pregnancy used some form of birth control.

Among women who had sex in the last 30 days, about one-fifth reported not using any contraceptive method, while 17% used intrauterine devices or implants. About one-third used reversible contraception such as the pill, and 20% used condoms. Thirteen percent of women with a high preference to avoid pregnancy did not use contraception.[1]

While women's preferences about pregnancy contribute significantly to their use of birth control, features other than contraceptive effectiveness also play a part in their decision-making and use, say researchers.

The DAP scale prospectively evaluates a range of women's preferences and feelings about pregnancy and childbearing, and the degrees to which they prefer to avoid pregnancy. The scale examines three domains relevant to women's conscious and unconscious pregnancy desires, including cognitive desires and preferences, affective feelings and attitudes, and anticipated practical consequences.[2]

The scale includes current thoughts and feelings about the idea of becoming pregnant in the next three months and having a baby in the next year. Each of the 14 statements in the scale is ranked by the woman from "strongly agree" to "strongly disagree." *(The DAP scale can be found at: https://bit.ly/30gBEXy.)*

Scale Active in Research

The DAP measure is being tested and used in over a dozen studies with diverse populations, including students at community colleges, women in substance use treatment centers, individuals involved with the justice system, and immigrant women living near the United States-Mexico border, says **Goleen Samari**, PhD, assistant professor of population and family health at Columbia University Mailman School of Public Health and co-author on the current study. Outside of the United States, the scale is being translated and used in Kenya, Botswana, Ghana, the Philippines, and the United Kingdom.

The team that developed the measure, led by Corinne Rocca, PhD, MPH, associate professor and epidemiologist at the University of California, San Francisco, is using the DAP measure in the Attitudes and Decision-making After Pregnancy Testing (ADAPT) Study, states Samari. This study is recruiting about 2,000 women from reproductive and primary care health centers in four states, she explains. Women who become pregnant, as well as a subset of women who do not become pregnant, will be surveyed over two to three years.

"ADAPT's unique prospective study design and use of DAP will enable researchers to document women's pregnancy attitudes, decision-making processes, and experiences seeking prenatal or abortion care over time," Samari explains. "Comparing the health and well-being of women who have more and less intended pregnancies, as well as women who avoided unintended pregnancies, will illuminate the effects of unintended pregnancy on women's lives."

In talking with women about their desires to avoid pregnancy, two questions come to mind: Do

EXECUTIVE SUMMARY

Do women who do not wish to become pregnant use more effective contraceptive methods than women who might welcome pregnancy? Results of a new study examine relationships between women's pregnancy preferences and contraceptive use, using a new prospective measure, the Desire to Avoid Pregnancy (DAP) scale.

- Researchers found that women with a strong preference to avoid pregnancy were far more likely to use any contraceptive method.
- However, more than 50% of the women studied who reported a low preference to avoid pregnancy used some form of birth control.

women know what their real risk of pregnancy is? Do they know there are differences in method efficacy? **Anita Nelson**, MD, professor and chair of the obstetrics and gynecology department at Western University of Health Sciences in Pomona, CA, considers these questions.

"This lack of knowledge also might help explain the mismatch in method effectiveness and strength of desire to avoid pregnancy," observes Nelson. "Perhaps more education about this fundamental issue should be addressed in addition to the other features the authors recommend we explore." ■

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Check Your Practice: Are Unnecessary Pelvic Exams and Pap Tests Being Performed?

While pelvic examinations and cervical cancer screenings are no longer recommended for most women younger than age 21 years during routine health visits, results from a new national study indicate that millions of women are unnecessarily undergoing these tests.[1]

Since 2009, guidelines by the American College of Obstetricians and Gynecologists (ACOG) have recommended not performing Pap tests in women under age 21, and not performing routine pelvic exams in those without symptoms, says senior author **George Sawaya**, MD, professor of obstetrics, gynecology, and reproductive sciences at University Of California, San Francisco (UCSF) and director of the UCSF Center for Healthcare Value. The research team wanted to study how practice patterns have changed since these guidelines have been in place, Sawaya states.

Investigators used a cross-sectional analysis of data from September 2011 through September 2017 from the National Survey of Family Growth, focusing on a population-based sample of 3,410 young women ages 15 to 20 years. Survey weights were used to estimate prevalence and the number of people represented in the U.S. population.

Pelvic exams were classified by researchers into two types: medically indicated or potentially unnecessary. If performed during pregnancy or in association with use of an intrauterine device, or in the context of treatment for a sexually transmitted infection (STI), examinations were considered medically indicated.

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Since 2009, guidelines from the American College of Obstetricians and Gynecologists have recommended not performing Pap tests in women younger than age 21 years, and not performing routine pelvic exams in those without symptoms.

- While pelvic examinations and cervical cancer screenings are no longer recommended for most young women under age 21 years during routine health visits, results from a new national study indicate that millions of women are undergoing these tests unnecessarily.
- The analysis indicated that of the approximately 2.6 million young women who received a pelvic exam during the previous year, 54.4% were potentially unnecessary, affecting an estimated 1.4 million young women.

Check Current Recommendations

Analysis results indicated that of the approximately 2.6 million young women who received a pelvic exam during the previous year, 54.4% were potentially unnecessary, affecting an estimated 1.4 million young women.[1] One-fifth of females younger than the recommended age underwent a Pap test within the past year. Because almost three-quarters of Pap tests were performed as "part of a routine exam," they were potentially unnecessary, researchers said.

Researchers reported that young women who had been screened for an STI were 3.8 times more likely to receive a Pap test, and 60% more likely to receive a pelvic examination, compared with those who had not been screened.[1]

In 2018, the U.S. Preventive Services Task Force issued final recommendations for cervical cancer screening, including:

• Women ages 21 to 29 years should be tested every three years with cervical cytology;

• Women ages 30 to 65 years should undergo a Pap test every three years, a high-risk human papillomavirus test alone, or both tests, every five years;

• No screening in women younger than age 21, in women older than age 65 who have received prior screening and are not at high risk for the disease, and in women who have undergone a hysterectomy with removal of the cervix and do not have a history of precancerous lesions or cervical cancer.[2]

The American College of Physicians and the American Academy of Family Physicians do not recommend performing screening pelvic examinations in asymptomatic women.[3,4] While ACOG recommends annual pelvic exams for women age 21 years and older, it also states that the decision should be case by case.[5] Adolescent health experts discourage providers from requiring screening in asymptomatic adolescents, as this requirement creates unnecessary barriers.[6,7]

The study suggests that healthcare providers and patients should communicate clearly and often about the best time for these tests, lead author **Jin Qin**, ScD, an epidemiologist with the Division of Cancer Prevention and Control at the CDC, said in a statement.[8] ■

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Consensus Position Statement on the Use of Testosterone in Women

By Jeffrey T. Jensen, MD, MPH

Abstract

Clinicians lack clearly established guidance and indications for testosterone therapy for women, which has led to considerable variation in practice patterns. The absence of clear indications and approved products for women has resulted in the use of compounded therapies or off-label prescription of testosterone formulations approved for men. To address concerns regarding current prescribing practice, representatives from the International Menopause Society, the European Menopause and Andropause Society, the International Society for Sexual Medicine, and the Endocrine Society established a task force to conduct a systematic review and meta-analysis of the risks and benefits of testosterone therapy in women. The task force met in Berlin in May 2019 and drafted a consensus position paper that was published simultaneously in the journals *Climacteric*, *Maturitas*, *Journal of Sexual Health*, and *Journal of Clinical Endocrinology and Metabolism*.

The task force developed this consensus position statement to inform healthcare professionals of the known benefits and potential risks of testosterone therapy with the aim of providing clear guidance for treatment, considering benefit and risk. They also addressed conditions for which evidence does not support prescribing testosterone. Wherever possible, the task force based recommendations on findings from blinded placebo/comparator randomized controlled trials (RCTs) of at least 12 weeks' duration. They reported findings with Levels of Evidence (e.g., Level I, experimental studies [RCTs]; Level II, quasi-experimental studies [prospective studies]; Level III, non-experimental studies [case-control]; Level IV, opinion of respected authorities [clinical practice guidelines, consensus panels]; Level V, experiential and non-research [literature reviews, case reports]) and Grades of Recommendations (A = high quality [Level I] to recommend; B = good quality [Level II]; C = weak evidence).

Here are the highlights of the recommendations:

• **Measurement of testosterone, female sexual dysfunction, and endogenous androgen levels.** The task force noted that testosterone concentrations decline during the reproductive years, but are maintained during menopause (Level IIB). They found direct assays highly unreliable (Level A) for diagnosis within the normal female range of values, but useful to exclude high baseline concentrations in the setting of suspected pathology or to rule out supra-physiologic doses during treatment (expert opinion). The task force recommended the use of high accuracy liquid/gas chromatography and tandem mass spectrometry (LC/GC-MS/MS) assays for total testosterone.

• **Recommendations for the terminology for female sexual dysfunction (FSD).** Grade B evidence supports the categorization of hypoactive sexual desire disorder/dysfunction (HSDD) and female sexual arousal disorder (FSAD) as distinct conditions. They have different etiologies, risk factors, clinical features, and responses to psychological and biological interventions, including androgen therapy. The task force recommended basing the diagnosis of HSDD in clinical practice on a thorough clinical assessment[1] guided by diagnostic criteria, such as those proposed by the International Society for the Study of Women's Sexual Health (expert opinion).[2-4]

• **Recommendations pertaining to the associations between endogenous androgen concentrations and female sexual function.** The task force categorized the evidence for using androgen concentrations as a diagnostic test for sexual function as "insufficient," and found no cut-off blood level for any measured circulating androgen to differentiate women with and without sexual dysfunction (Grade C).

• **Recommendations regarding systemic testosterone therapy.** The task force found insufficient evidence to make any recommendations regarding the use of testosterone in premenopausal women for treatment of sexual function or any other outcome. In contrast, high-quality (Level I, Grade A) evidence supports the beneficial effect of testosterone replacement at physiologic levels on sexual function in naturally or surgically postmenopausal women with HSDD. The benefit over placebo includes an average of one satisfying sexual event per month, and increases in the subdomains of sexual desire, arousal, orgasmic function, pleasure, and sexual responsiveness, along with a reduction in sexual concerns including sexual distress. The group of experts found insufficient evidence to support the use of testosterone to enhance cognitive performance or delay cognitive decline in postmenopausal women. They found high-quality evidence that testosterone does not improve bone density or increase lean body mass (Level I, Grade A). They also found systemic testosterone therapy in postmenopausal women at physiologic levels associated with mild side effects in some women (acne, increased body/facial hair) but not with alopecia, clitoromegaly, or voice change (Level I, Grade A).

With respect to cardiovascular health, oral testosterone therapy results in adverse changes in lipid profiles, but these effects are not seen with transdermal therapy (Level I, Grade A). Short-term transdermal testosterone therapy does not increase mammographic breast density or affect breast cancer risk (Level I, Grade A), but insufficient data exist to assess long-term breast cancer risk or to support safety in women with hormone-sensitive breast cancer (expert opinion). The experts found high-quality evidence supporting an absence of serious adverse events associated with physiologic testosterone replacement in postmenopausal women, but noted that safety data do not exist beyond 24 months of treatment.

• **Considerations for clinical care of postmenopausal women with FSD.** The task force noted that clinicians should consider the multiple biopsychosocial etiologies (neuroendocrine imbalance, health status, interpersonal difficulties, psychological distress, and sexually

repressive cultural or religious values) that contribute to FSD (Grade C). They offer treatments that follow this biopsychosocial model, including pharmacologic options (hormone therapies and other pharmacologic agents), psychotherapy, or multimodal treatments that combine both (Grade B). The only evidence-based female indication for the use of testosterone is HSDD in postmenopausal women (Level I, Grade A). Use of supra-physiologic doses of testosterone is not recommended (expert opinion). To keep levels in the physiologic range, the task force recommended measurement of a baseline total testosterone prior to initiation of treatment, and a repeat level three to six weeks later (Level II, Grade C). They further recommended monitoring patients for signs of androgen excess, monitoring testosterone levels every six months to screen for overuse (expert opinion), and discontinuing treatment at six months in the absence of benefit. The group found high-quality evidence to recommend against the use of systemic DHEA for the treatment of HSDD (Level I, Grade A).

Commentary

This statement by an international panel of experts provides useful guidance to clinicians considering the use of androgen therapy to treat FSD. The task force reviewed the available literature to determine the quality of evidence both for and against the use of testosterone. For many recommendations, little data exist, and for this reason, many recommendations are conservative and based on expert opinion only.

The take-home recommendation is that postmenopausal women with a diagnosis of HSDD benefit from testosterone (T) replacement in the physiologic range of normal premenopausal women. This recommendation is based on a meta-analysis of seven RCTs by Achilli and colleagues.[5] The testosterone-treated women reported significantly more satisfying sexual episodes, sexual activity, orgasms, and desire; a decrease in Personal Distress Scale score; and minor androgenic adverse events compared with the placebo group. Most of the studies used transdermal doses of T at 150-300 mcg per day.

As only postmenopausal women meeting the criteria of HSDD have been shown to benefit from T therapy, the task force cautioned clinicians not to generalize the findings to other groups. Another caveat is that more is not better, and, in fact, more T may be worse from the perspective of side effects. Measure T levels and keep these in the normal range of premenopausal women for your reference lab. Use a lab that measures T with state-of-the-art LC/GC-MS/MS methods if possible.

Another consideration is that RCTs of T therapy have excluded women at high risk for cardiovascular disease, and that most studies have included women taking concurrent estrogen therapy. Furthermore, all studies have been of relatively short duration. Therefore, we have much less information regarding risks and benefits of T therapy than we do with estrogen only or combined estrogen/progestogen treatment. Keeping up to date on this evolving literature remains important. ■

SOURCE

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- Abortion: Teens find roadblocks to access
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- Researchers support new HIV control strategies
- Science eyes potential male contraceptive

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1. **Which is the drug that has been suggested for use in "reversal" of medication abortion?**

   a. Progesterone
   b. Meloxicam
   c. Methotrexate
   d. Gonadotropin-releasing hormone

2. **Which is the U.S. Medical Eligibility Criteria for Contraceptive Use classification of immediate postpartum use of intrauterine devices and implants?**

   a. Category 1 or Category 2
   b. Both Category 1
   c. Both Category 2
   d. Both Category 3

3. **Final recommendations issued in 2018 by the U.S. Preventive Services Task Force suggest cervical cancer screening with cervical cytology every three years for women in which age group?**

   a. Women ages 18-21
   b. Women ages 21-29
   c. Women ages 30-45
   d. Women ages 45-65

4. **As of 2015-2016, the National Center for Health Statistics at the CDC estimated which percentage of U.S. women age 20 years and older were obese?**

   a. 25.4%
   b. 37.9%
   c. 41.1%
   d. 65%

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;
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STI QUARTERLY™

A SUPPLEMENT TO CONTRACEPTIVE TECHNOLOGY UPDATE

New Congressional Funding for STD Programs: Is It Enough?

$3.51 million added to CDC's STD prevention programs

Good news: Congress recently increased federal funding for sexually transmitted disease (STD) prevention for the first time since 2003, with a $3.51 million addition in base funding to the CDC's STD prevention programs. But is the funding enough to fully address the rise in national STD rates?

David Harvey, executive director, National Coalition of STD Directors (NCSD), calls the increase a "crucial first step, and a down payment toward tackling this growing public health crisis."

Since 2003, STD programs have experienced a 40% decrease in spending power, which have led to staff cuts and clinic closures. NCSD is calling for an $82 million increase to ensure programs are equipped with the needed resources and manpower to mount a proper defense, Harvey states. While the funding increase is a welcome start, public health advocates will need to build on such momentum.

"Additional funding from Congress will ensure public health STD prevention programs are equipped with the resources they need to address the all-time highs of STDs in the U.S.," says Harvey. "As rates soar and millions continue to get sick, the time to act is now."

Added backing comes from the Congressional Caucus for Women's Issues, a bipartisan membership organization within the House of Representatives. The caucus has issued a letter to the Department of Health and Human Services and the CDC in an effort to develop new initiatives and resources to address the growing STD epidemics, as well as asking the Trump Administration to address these issues.

Public health officials are bracing against rising rates of STDs. According to the CDC's annual Sexually Transmitted Disease Surveillance Report, STD infections increased for the fifth consecutive year, with nearly 2.5 million combined cases of chlamydia, gonorrhea, and syphilis.[1]

> STD INFECTIONS INCREASED FOR THE FIFTH CONSECUTIVE YEAR, WITH NEARLY 2.5 MILLION COMBINED CASES OF CHLAMYDIA, GONORRHEA, AND SYPHILIS.

Figures for primary and secondary syphilis cases rose 14% to more than 35,000 cases, the highest number reported since 1991. Cases of syphilis in newborns increased 40% to more than 1,300 cases. Figures for gonorrhea rose 5% to more than 580,000 cases, also the highest number for the infection that have been reported since 1991. Numbers for chlamydia increased 3% to more than 1.7 million cases, representing the most ever reported to the CDC.[1]

Innerbody, an online medical and wellness testing guide, analyzed the CDC's latest statistics on a city-by-city basis to develop its list of the top 100 cities with the highest STD rates. According to its analysis, the top 10 cities include Baltimore; Jackson, MS; Philadelphia; San Francisco; Montgomery, AL; Augusta, GA; Milwaukee; Killeen, TX; Shreveport, LA; and Indianapolis. The five cities with the highest rates of total STD cases (HIV,

syphilis, chlamydia, and gonorrhea) are Los Angeles, Chicago, Houston, Phoenix, and Philadelphia. Nearly half of the top 25 cities with the highest rates of infection are in the South, according to the analysis. California led all states with the most cities in the top 100 with seven cities; Ohio and Texas tied for the second most cities, each with six cities.[2]

Congenital Syphilis Cases on the Rise

Public health concerns have been raised in light of the dramatic rise in congenital syphilis cases. While most states recorded at least one incident of congenital syphilis, five states — Texas, California, Florida, Arizona, and Louisiana — accounted for 70% of cases in 2018.[1]

The New Mexico Department of Health issued a statewide Public Health Order in January 2020, requiring medical professionals to test all pregnant women in their first and third trimesters, and again at delivery for congenital syphilis. In 2018, New Mexico had the eighth highest rate of infants born with congenital syphilis in the United States, with 10 cases reported to the state agency, resulting in two deaths. From 2012 to 2017, New Mexico reported an average of two cases of congenital syphilis per year; however, as of Dec. 30, 2019, 23 cases of congenital syphilis had been reported to the state health department.[3]

IN 2018, NEW MEXICO HAD THE EIGHTH HIGHEST RATE OF INFANTS BORN WITH CONGENITAL SYPHILIS IN THE UNITED STATES, WITH 10 CASES REPORTED TO THE STATE AGENCY.

"This order will assure medical practitioners, with patient consent, will make testing for syphilis part of the standard pre-natal care provided to their patients," New Mexico Department of Health Cabinet Secretary **Kathy Kunkel**, JD, MSW, said in a statement.[4]

What are some of the factors that continue to drive the increase in STDs? According to the CDC, some of the issues include:

- drug use, poverty, stigma, and unstable housing, which can reduce access to STD prevention and care;
- decreased condom use among vulnerable groups, including young people and gay and bisexual men;
- cuts to state and local STD prevention programs. Statistics indicate that more than 50% of local programs have experienced budget cuts, resulting in clinic closures, reduced screening, staff loss, and reduced patient follow-up and linkage to care services.[5]

More Funding Needed for STI Research

There are serious gaps in the research pipeline for the development of prevention and treatment options for gonorrhea, chlamydia, and syphilis, according to a 2019 report from Treatment Action Group. However, there are some positive movements on this front. Efforts to develop new gonorrhea treatment options are moving forward, while investigations of doxycycline as pre-exposure prophylaxis for chlamydia and syphilis are underway. Vaccine research funding also has increased: In 2018, the National Institutes of Health made a significant new investment in gonorrhea, chlamydia, and syphilis vaccine research.[6]

"Despite a few promising advancements, STI research is nowhere near where it needs to be," says **Jeremiah Johnson**, MPH, Treatment Action Group's HIV project director and lead author of the report. "I hope this report is an eye-opener for people working not just on STI prevention, but also other areas of sexual health." ■

EXECUTIVE SUMMARY

Congress recently increased federal funding for sexually transmitted disease (STD) prevention for the first time since 2003, with $3.51 million in additional base funding to the CDC's STD prevention programs.

- Since 2003, STD programs have experienced a 40% decrease in spending power, which have led to staff cuts and clinic closures. Public health advocates are calling for an $82 million increase to ensure programs are equipped with the needed resources and manpower to mount a proper defense against the epidemics.
- According to the latest national figures, STD transmission increased for the fifth consecutive year, with nearly 2.5 million combined cases of chlamydia, gonorrhea, and syphilis.

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More Young Adults Receiving HPV Vaccination, but There Is Room for Improvement

Results of a new report indicate that the percentage of adults ages 18-26 years who received one or more doses of human papillomavirus (HPV) vaccine nearly doubled between 2013 and 2018. The percentage of adults in the same age category who received the recommended number of doses of HPV vaccine increased from 13.8% to 21.5%.[1]

Authors of the report from the National Center for Health Statistics revealed that the percentage of women from 2013-2018 who received one or more doses increased from 36.8% in 2013 to 53.6% in 2018, while the percentage of men more than tripled from 7.7% to 27%.[1]

One Dose May Provide Protection

Among adults who received one or more doses of HPV vaccine, data indicated that women were more likely than men to have received their first dose of HPV vaccine at or before the recommended age of 12 years. Since vaccination recommendations were issued in 2006 for girls and 2011 for boys, researchers explained that the differences in dates may explain the differences in numbers.[1]

EXECUTIVE SUMMARY

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- Among adults who received one or more doses of HPV vaccine, data indicated that women were more likely than men to have received their first dose of HPV vaccine at or before the recommended age of 12 years.

Findings from a new study published by researchers at the University of Texas Health Science Center at Houston suggest that one dose of the HPV vaccine may prevent infection.[2] However, it is not time to change current practice, explained senior author **Ashish Deshmukh**, PhD, MPH, an assistant professor at the university's School of Public Health. Global HPV vaccine coverage rates currently register at less than 10% due to poor vaccine uptake rates in many resource-limited countries, notes Deshmukh. Even administering the initial dose to boys and girls is a "big challenge" in several countries, and many teens fail to complete the recommended series due to a lack of infrastructure needed to administer them, Deshmukh says.

"If ongoing clinical trials provide evidence regarding sustained benefits of a one-dose regimen, then implications of single-dose strategy could be substantial for reducing the burden of these cancers globally," said Deshmukh in a statement.[3]

Time to End HPV-Related Cancers

In July 2019, the Association of American Cancer Institutes, American

Association for Cancer Research, the Biden Cancer Initiative, and Moffitt Cancer Center hosted a congressional briefing, called Let's End HPV-related Cancers, in Washington, DC. The briefing served as a call to action for policymakers and other stakeholders to help eliminate cervical cancer and other cancers caused by HPV.

Through high vaccine coverage and widespread participation in cervical cancer screening and treatment programs, prevention specialists hope to meet the following Department of Health and Human Services "Healthy People 2020" goals:

- vaccinate more than 80% of females and males ages 13-15 years,
- screen 93% of eligible females for cervical cancer;
- provide prompt follow-up and treatment of females who screen positive for high-grade cervical precancerous lesions.

Diagnoses Across All Age Groups

People are being diagnosed with HPV-related cancers as early as their 20s, through their 40s and 50s, and even later, **Caroline Billingsley**, MD, a University of Cincinnati Health gynecologic oncologist and assistant professor of obstetrics and gynecology at the University of Cincinnati College of Medicine, said in a statement.[4] The FDA recently approved the expanded use of the HPV vaccine to include individuals through age 45, she stated.[5]

> "THE GOAL IS TO REDUCE THE HPV VIRUS AND PREVENT, OR LESSEN, THE INCIDENCE OF RELATED CANCERS IN MALES AND FEMALES OF CURRENT AND FUTURE GENERATIONS."

Recommendations from the CDC call for boys and girls ages 9-14 years to receive the two-dose HPV immunization. A three-dose schedule is recommended if the first dose was given on or after the 15th birthday.[6]

"The goal is to reduce the HPV virus and prevent, or lessen, the incidence of related cancers in males and females of current and future generations," said Billingsley.[4] ■

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