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Expert Advice for Today's Ob/Gyn For Doctors by Doctors

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THE STATE OF
Maternal Mortality
How can we prevent pregnancy-related deaths?

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References: **1.** Blatt AJ, et al. Comparison of cervical cancer screening results among 256,648 women in multiple clinical practices. Cancer Cytopathol. 2015;123(5):282-288. doi:10.1002/ cncy.21544 (Study included ThinPrep, SurePath and Hybrid Capture 2 assay). **2.** Austin RM, et al. Enhanced detection of cervical cancer and precancer through use of imaged liquid-based cytology in routine cytology and HPV cotesting. *Am J Obstet Gynecol.* 2018;150(5):385-392. doi:10.1093/ajcp/aqy114 (Study included ThinPrep Pap test, ThinPrep imaging, Digene HPV, Cervista HPV and Aptima HPV). **3.** Beavis AL, Gravitt PE. Hysterectomy-corrected cervical cancer mortality rates reveal a larger racial disparity in the United States. Cancer. 2017;123(6):1044-1050. **4.** HHS Office of Minority Health; Cancer and Hispanic Americans. Updated August 26, 2021. Accessed March 9, 2021. https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=61.

PUBLISHER'S NOTE

Paying it forward

As a health care communications company, MJH Life Sciences® is dedicated to partnering with nonprofits and charities who raise money for crippling diseases that do not yet have a cure. To that end, we work, across all our brands and departments, to raise awareness and bring much-needed funding to these various enterprises, an initiative that everyone at MJH embraces, and the numbers bear out. For example, in 2022, the company set a goal of raising $150,000 for the various charities and nonprofits we align with, and I was delighted to see that by year-end we had surpassed that goal, raising a total of $175,000.

One of the organizations I get most excited about is the Leukemia & Lymphoma Society (LLS). To give you some background, in 1944, Robert "Robbie" Roesler de Villiers, a 16-year-old teenager living in New York, New York, received a diagnosis of leukemia. He quickly succumbed to the disease and died a few months later. At the time, those with leukemia, who were often children, typically died within 3 months of receiving their diagnosis, as there were no viable treatments. Five years later, Robbie's parents, Rudolph and Antoinette de Villiers, frustrated by how little was being done for this devastating illness, began a fundraising program in their son's name. The foundation steadily grew, evolving into the LLS. Today it is the largest nonprofit health organization dedicated to funding blood cancer research, offering education and patient services throughout the United States.[1]

For more information on how you can get involved, please visit www.lls.org.

This past October, MJH was proud to once again be part of an annual LLS fundraiser in New Jersey and Ohio, where we maintain offices. LLS holds 140 Light the Night walks around the United States, and for MJH, Light the Night Walk New Jersey and Light the Night Walk Cleveland were a great success. Both events brought associates and their families out for a night of festivities, a short fundraising walk, and, as the day turned to dusk, a beautiful moment when illuminated lanterns floated up into the sky—white for survivors, red for supporters, and gold for the memory of loved ones lost to the disease. ■

Mike Hennessy Jr
President and CEO, MJH Life Sciences®

REFERENCE

1. Leukemia & Lymphoma Society. Accessed January 18, 2023. https://www.lls.org/

IN THIS ISSUE

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PIPELINE NEWS

Women's health predictions for 2023

Alison Cowan, MD, ob-gyn hospitalist and head of medical affairs at Mirvie, discusses the latest predictions for women's health in 2023. From maternal mortality to preterm birth, Cowan dives into what health conditions will affect women most in 2023 and how the specialty is trying to combat these issues.

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EDITORIAL

by CATHERINE Y. SPONG, MD

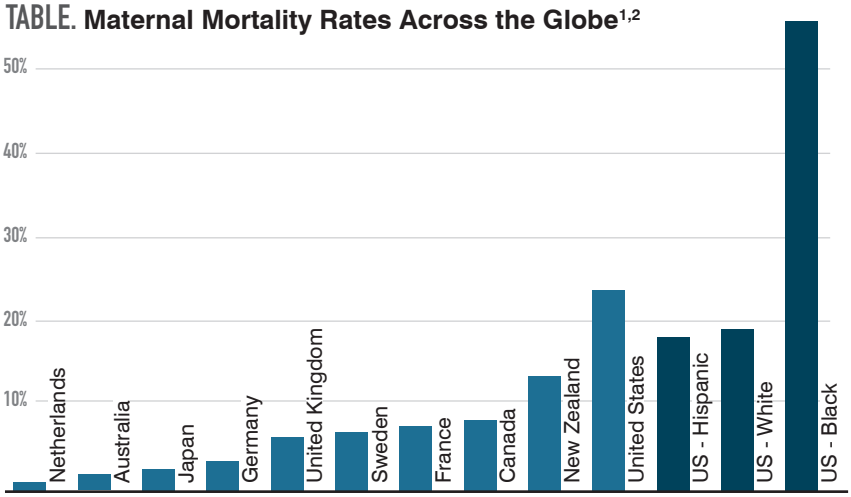
The rise of maternal mortality in the United States

Maternal mortality has long been regarded as a reflection of how important a population considers women and children to be. The rates in the United States have been troubling for years, increasing for over 2 decades. With the COVID-19 pandemic, where mortality rates increased across the board, maternal mortality also increased, as one would expect with a severely morbid virus.

The question is why does the United States have such a high rate (**Table**[1,2])? Is it because of enhanced reporting systems whereas other countries might not attribute a death to pregnancy simply because of the ability to link it to a pregnancy? Alternatively, is it because of the practices and availability of care for certain populations? As the United States has wrestled with unconscious bias and racism, it is relevant to examine how these factors affect the care and outcomes for pregnant women.

In this issue, our cover story chronicles the recent challenges with ascertaining maternal mortality data. For example, using the death certificate checkbox to assign pregnancy has been an earnest attempt at data collection; however, run-in over 20 years across 50 states at differing times has blurred national rates. Despite these challenges, the importance of maternal health is now at the forefront of national, state, and local programs.

TABLE. Maternal Mortality Rates Across the Globe[1,2]



These data—regardless of analysis—clearly demonstrate health disparity among non-Hispanic Black pregnant individuals. Identifying tangible action items in response to this crisis is now underway through state-based maternal mortality review committees and local health programs. In as many as 80% of cases, pregnancy-related deaths are determined to be preventable.[3] From these efforts, the importance of community-based organizations and social support mechanisms are increasingly being recognized as the next step for care beyond the hospital to neighborhoods of patients living in underserved communities.

The journey to improving maternal health across the United States begins with these important steps. To advance the national effort in improving both maternal mortality and morbidity, especially among minority pregnant patients, it is critical that accurate, relevant clinical data are reported and used to guide decisions for health care policy. Ultimately, these efforts can lead to safer deliveries for mothers and their infants for the future generations of our country. ■

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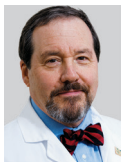

Caring for the gynecologic needs of the adolescent patient

by CELESTE KREWSON

The gynecologic needs of the adolescent patient can differ from the needs of adult patients, warranting a different approach to care, according to Carri Holton, MSN, WHNP-BC, who presented at the Annual Premier Women's Healthcare Conference held during fall 2022 in Houston, Texas.

Holton, of the Department of Pediatric and Adolescent Gynecology at Children's Hospital Colorado in Aurora, first outlined how health care providers can provide preventive health screenings and offer guidance to adolescents, teens, and parents in pediatric gynecology. Conditions such as pediatric vulvovaginitis, lichen sclerosis, genital injuries, labial adhesions, congenital anomalies in the reproductive system, menstrual suppression, tumors, premenstrual syndrome and premenstrual dysphoric disorder, and breast problems in youths are treated via pediatric gynecology. Needs such as fertility preservation and hormone replacement therapy are also included.

During an office evaluation, there should be a welcoming environment for adolescent patients, according to Holton. Health care providers will require technical skills to complete hymen exams and single-digit exams and will need smaller speculums. They also must have the patience to listen to adolescents and parents, along with learning about the history of their patients.

Holton also discussed confidentiality, noting that adolescents must be made aware of instances when information is not confidential, such as when individuals have suicidal or homicidal thoughts. Providers should be familiar with minor consent laws, as many states allow minors to consent to family planning, pregnancy care, substance use–related care, and outpatient mental health services. All states allow minors to consent to sexually transmitted infection testing.

The decision to arrange an adolescent exam should be between the adolescent and the provider, although a chaperone should be present during the exam. Providers should explain all components of the exam to the patient and parent. Patients should be reassured that they are in control of their body and that the exam can be stopped at any time.

At the exam, before moving on to the next step, providers should ask permission to pull the patient's sheet back. Holton reminded conference attendees to explain female anatomy with proper terms, educating parents and patients. Breasts and pubic hair should be examined for Tanner staging, and external genitalia should be examined.

During an office evaluation, there should be a welcoming environment for adolescent patients.

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During her presentation, Holton discussed normal pubertal development along with abnormalities, and encouraged attendees to learn this information so that they may recognize signs of abnormal development. Providers need to first identify the cause, then determine treatment. This could include hormone replacement therapy in cases of primary ovarian insufficiency.

Holton also outlined instances of physiologic anovulation—when slow maturation occurs in anovulatory cycles. This can lead to noncyclic, unpredictable, and inconsistent bleeding. In cases where there is too much bleeding, adolescents should see an oncologist for testing, especially in cases of concerning history with bleeding disorders in the individual or family.

In cases of mild bleeding without anemia, providers should reassure patients, provide them with prophylactic iron supplementation, and offer hormonal contraceptives if desired. In moderate bleeding with anemia, providers should give patients combined oral contraceptives, micronized oral progesterone, medroxyprogesterone acetate (Depo-Provera) injection, levonorgestrel an intrauterine device, and iron supplementation.

Further treatments, along with hospitalization and blood transfusion, may be needed in cases of severe bleeding. In all cases, Holton stated that iron supplementation should be given.

Holton also discussed polycystic ovary syndrome (PCOS), reminding attendees that every case is different. She also noted that PCOS is not caused by ovarian cysts or being overweight, and that much is still unknown about the disorder. Diagnoses may be given as "irregular periods," and the condition can present as amenorrhea, oligomenorrhea, and chaotic periods.

Treatment for PCOS will vary based on concerns, as it can lead to metabolic issues, acne, dermatologic concerns, and nutrition concerns. When these concerns arise, screenings should establish a rapport with the patient in the first visit. Repeated screenings should initially take place every 3 months, then every 3 to 12 months depending on the patient.

Holton lastly talked about dysmenorrhea and endometriosis. Dysmenorrhea is painful menstruation, which often increases the risk of anxiety and depression. It can be managed with dietary, vitamin, and herbal treatments; exercise, including yoga; or pharmacologic interventions.

Dysmenorrhea is often caused by endometriosis. Risk factors of endometriosis include early-onset menarche, nulliparity, shorter menstrual cycles, childhood sexual and physical abuse, and more. To treat endometriosis, Holton recommended both surgical and pharmacological treatments. Complementary and alternative therapies may also reduce symptoms. ■

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Digital therapeutic device for urinary incontinence

by ROBERT KRONEMYER

The prescription leva Pelvic Health System (Renovia) is the first device to offer a digital therapeutic therapy for pelvic floor muscle training to improve symptoms of urinary incontinence and fecal incontinence.

In study findings published in *Obstetrics & Gynecology*, leva achieved significantly greater urinary incontinence symptom improvement than did a standard home pelvic floor muscle training program at 6 and 12 months.

"Unlike biofeedback devices that provide information on pressure readings when placed into the vagina, leva uses accelerometers to provide visual information about muscle elevation and thus emphasizes the main action of the pelvic floor muscle contraction," said principal coinvestigator **Milena M. Weinstein, MD**, an associate professor of obstetrics, gynecology, and reproductive biology at Harvard Medical School. "The device also helps a woman track her progress, including monthly reports to the prescribing physician."

The virtual trial was conducted from

October 2020 to March 2021 among 363 women with stress urinary incontinence or stress-predominant mixed urinary incontinence. Participants were randomly assigned to either complete pelvic floor muscle training with leva (intervention group) or a standard home pelvic floor muscle training program (control group) for 8 weeks.

Of the 299 participants analyzed at 8 weeks, 95.7% returned 6- and 12-month data: 151 in the control group and 135 in the intervention group. Patients' mean age was 51.9 years and mean body mass index was 31.8. Overall, 84.6% of participants were parous and 54.9% were postmenopausal.

The mean change in Urogenital Distress Inventory-6 Short Form (UDI-6) score from baseline to 6 and 12 months was significantly greater in the intervention group than in the control group: 20.2 vs 14.8 ($P = .03$) and 22.7 vs 15.9 ($P = .01$), respectively.

Participants in the intervention group were also more than twice as likely to report improvement on the Patient Global Impression of Improvement (PGI-I) scale than the control group (odds ratio, 2.45; 95% CI, 1.49-4.00).

"This is the first trial of leva to show that its use is significantly better in improving symptoms of urinary incontinence than a home program with pelvic floor muscles exercises alone, such as Kegel exercises," Weinstein told *Contemporary OB/GYN®*. "Doing those exercises for an initial period with results that last at least 1 year is something we did not previously know about any conservative, nonsurgical therapy."

Pelvic floor physical therapy (PFPT) is currently used as a guided approach to pelvic floor muscle training. However, barriers to PFPT include a national shortage of trained therapists, patient time constraints to attend appointments, and embarrassment, as most visits require a pelvic exam.

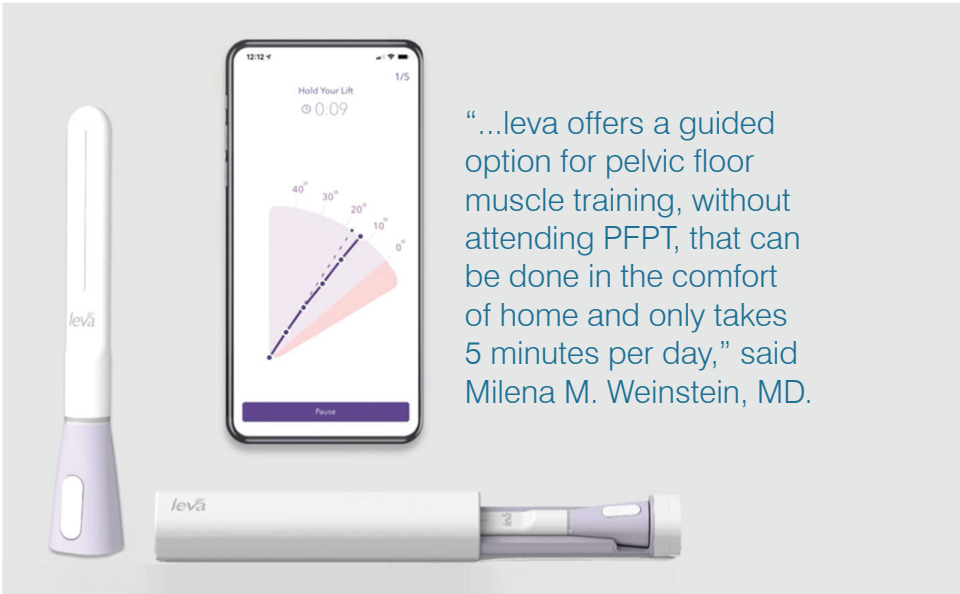
"By contrast, leva offers a guided option for pelvic floor muscle training, without attending PFPT, that can be done in the comfort of home and takes only 5 minutes per day," said Weinstein, who is also program director of the Female Pelvic Medicine and Reconstructive Surgery Fellowship at Massachusetts General Hospital in Boston.

But leva requires the use of a smart phone and knowing how to use it. Users also need to insert leva into the vagina during the exercises, "so women without a vaginal canal or those who feel uncomfortable or embarrassed may not be able to benefit, though the device is very small and comfortable for most women," Weinstein said.

In addition, insurance coverage is not consistent for leva, which has a list price of $1200.

"Despite these potential hurdles, leva is an ideal way to get women started in first-line care for urinary incontinence that is both nonsurgical and nonpharmacologic," Weinstein said. "The device is an easy and effective treatment."

Leva was originally approved by the FDA in 2014, with the most recent clearance being for fecal incontinence in July 2022. ■



"...leva offers a guided option for pelvic floor muscle training, without attending PFPT, that can be done in the comfort of home and only takes 5 minutes per day," said Milena M. Weinstein, MD.

DISCLOSURE Weinstein is the author of a section on obstetric anal sphincter injuries in UpToDate.

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Weinstein MM, Dunivan GC, Guaderrama NM, Richter HE. Digital therapeutic device for urinary incontinence: a longitudinal analysis at 6 and 12 months. *Obstet Gynecol.* 2023;141(1):199-206. doi:10.1097/AOG.0000000000005036

How can we prevent pregnancy-related deaths?

Interventions before and after birth can reduce rising maternal mortality ratio

by DAVID B. NELSON, MD; AND YEVGENIA Y. FOMINA, MD

The United States is facing a grim reality in maternal health. In 2020, more than 800 women died in the United States from pregnancy-related complications,[1] and this number continues to grow. The maternal mortality ratio (MMR) in 2020 was 23.8 deaths per 100,000 live births compared with 20.1 in 2019.[1,2] The ratio of pregnancy-related deaths in the US is in stark contrast to other high-income countries where pregnancy-related deaths are declining.[3] By highlighting some of the challenges of current data collection and reviewing contemporary data trends, we can pinpoint gaps in health care and focus on measures that make a tangible positive impact on maternal health outcomes.

Issues with data collection

The World Health Organization (WHO) defines the maternal mortality ratio (MMR) as the number of maternal deaths per 100,000 live births within 42 days of pregnancy termination, regardless of the cause of death.[3] Although MMR is a commonly used indicator for international comparisons of maternal health, it is unknown what proportion of the mortality ratio is related to pregnancy. The CDC subcategorizes pregnancy death as related to or associated with the pregnancy within 1 year of pregnancy, regardless of pregnancy duration or location. A pregnancy-associated death is defined as the death of an individual while pregnant or within 1 year of pregnancy regardless of cause. A pregnancy-related death is defined as the death of an individual while pregnant or within 1 year of pregnant from a pregnancy complication **(Table 1)**. These differing definitions and subcategorizations among organizations complicate comparisons among states and countries.

In the United States, maternal mortality declined from 800 deaths per 100,000 live births in 1920 to 9.8 deaths per 100,000 live births in 2000.[4] This dramatic drop in mortality during the 20th century is attributed to the advent of antibiotics, infection prevention, prenatal care, and transfusion services.[3] In the early 2000s, however, the MMR began to steadily rise—doubling in the past 2 decades **(Figure 1)**.[4] Appreciation for this contemporary rise in maternal mortality

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can be traced to reports by MacDorman et al in 2016 when they described an increase in the US maternal mortality ratio across states—specifically Texas, where the ratio increased from 18.6 per 100,000 live births in 2010 to 38.7 in 2012.[5,6] To explain this temporal increase in maternal mortality, some have suggested it is due to a growing prevalence of chronic medical conditions, delayed childbearing age, higher cesarean delivery rates, and the opioid epidemic. These trends, however, may also be influenced by an artifact of data ascertainment. The rise in maternal mortality coincides with staggered implementation of a pregnancy checkbox on death certificates in 2003 and introduction of the *International Classification of Diseases, Tenth Revision* (*ICD-10*) codes in 1999.[7,8]

To further elucidate the impact of the pregnancy checkbox on MMR trends, the National Center for Health Statistics (NCHS) released a 3-part report in 2020 detailing how the use of nonstandard pregnancy-related questions on death certificates and staggered implementation among states resulted in inconsistent reporting between 2003 and 2017.[9] The NCHS also reported a high degree of misclassification of pregnancy status on death certificates because of incorrect documentation and limitations of *ICD-10* code accuracy.[10] Validation studies found that for 21% to 50% of death certificates marked as pregnant-postpartum, the woman was not pregnant or postpartum at the time of death.[11,12] For instance, a review of 50% of obstetric-coded deaths in Texas showed no evidence of pregnancy within 42 days.[12] In another review of 4 states, 31% of death certificates with a registered pregnancy checkbox had no verifiable evidence of pregnancy.[11]

TABLE 1. Key Definitions of Terms Related to Maternal Mortality

Term	Definition
Pregnancy-associated death	The death of a person while pregnant or within 1 year of pregnancy, regardless of cause (may be related or unrelated to pregnancy).
Pregnancy-associated, but not-related, death	The death of a person while pregnant, or within 1 year of pregnancy, from a cause that is unrelated to pregnancy.
Pregnancy-related death	The death of a person while pregnant or within 1 year of pregnancy from pregnancy complications, a chain of events initiated by pregnancy, or the aggravation of an unrelated condition by the physiologic effects of pregnancy.
Maternal death (WHO definition)	The death of a person while pregnant or within 42 days of pregnancy, regardless of the duration and site of the pregnancy and from any cause related to or aggravated by the pregnancy and its management, but not from accidental or incidental causes.

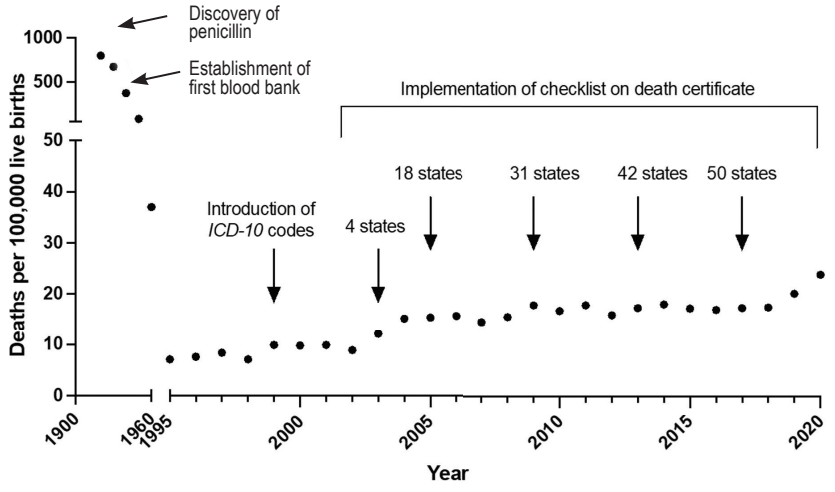
WHO, World Health Organization.

Because of the challenges of interpreting these trends from actual measurements, the National Center for Health Statistics did not publish an official maternal mortality ratio from 2007 to 2017. This led to a deficit of information at a time when the international community was focusing on maternal outcomes. To account for these checkbox discrepancies, MacDorman et al used correction factors and regression analysis to reevaluate maternal mortality across 48 states. They reported an adjusted MMR of 18.8 per 100,000 live births in 2000, which steadily rose to an MMR of 23.8 in 2014, an increase in 27%.[6] Taken together, these data suggest that although the MMR may not have doubled in the past 2 decades, it continues to rise.

Causes of maternal mortality

The varying causes of maternal mortality have evolved over time. Hemorrhage, infection, and hypertensive disorders were the leading causes of maternal death in the 1990s but improved management of these conditions has decreased their mortality risk. Indeed, use of stage-based responses has demonstrated clinical effectiveness in addressing these common obstetric complications.[13,14] Today, cardiovascular disease and mental health conditions are the leading causes of maternal death.[15] In October 2022, the CDC's Maternal Mortality Review Committees (MMRCs) released a report reviewing 987 pregnancy-related deaths across 36 states between 2017 and 2019.[16] Analysis of these data concluded that cardiac and coronary conditions are the leading causes of death in non-Hispanic Black women and mental health conditions are the leading cause of death among Hispanic and non-Hispanic White women **(Figure 2)**.[16] Additionally, 21.6% of these deaths occurred

FIGURE 1. Maternal Mortality Ratios 1920-2020 and Timeline of Associated Interventions and Data Ascertainment[4]



during pregnancy, 13.2% occurred on the day of delivery, and 65.3% occurred between 1 and 365 days postpartum.[16] These data highlight the importance of continued postpartum care.

In state-level reporting, cardiovascular conditions comprise nearly one-third of the mortality related deaths.[17] From 2003 to 2012, there was a 24.7% increase in the number of women entering pregnancy with preexisting heart disease. Congenital and valvular heart disease account for 70% of those cases.[18] Cardiomyopathy and pulmonary hypertension are less prevalent but have highest in-hospital mortality. The increasing trend of pregnancy in patients with heart disease may result from more patients with congenital cardiac disease surviving to adulthood, rising advanced maternal age, rising comorbidities, and increased surveillance.

Another important emerging contributor to maternal mortality is self-harm by suicide or accidental overdose. In Texas, mental health conditions were the second leading cause of pregnancy-related death, accounting for 17% of the cases reviewed in 2019 by the Maternal Mortality and Morbidity Taskforce.[14] In Philadelphia, Pennsylvania, assessment of pregnancy-associated deaths between 2010 and 2014 found that substance use disorders were related to 46% of nonoverdose deaths and drug overdose was the direct cause of 27% of deaths.[19] Similar findings were identified in California with drug overdose as the second leading cause of death in a postpartum cohort of more than 1 million women.[20] Mental health, substance use disorders, and intimate-partner violence are common risk factors for suicide and overdose.

Recommendations for preventing pregnancy-related mental health deaths range from individual patient-level changes to larger community- and systems-based changes that address social determinants of health. Providers should establish standardized screening protocols for anxiety, substance use, domestic violence, depressive symptoms, and suicidal ideation to identify at-risk mothers. The American College of Obstetricians and Gynecologists encourages providers to complete a full assessment of mood and emotional well-being for all patients at least once in the perinatal period.[21]

Next, providers should coordinate access to mental health counselors, domestic violence shelters, and substance use disorder clinics. Importantly, integrating mental health services into routine prenatal care by placing mental health counselors and obstetrics providers in the same clinics can significantly increase utilization of these resources.[22] Because unintentional overdose comprises nearly one-fourth of mental health-related deaths, expanding accessibility to naloxone will help combat deaths from opioid overdose.[23] In the community, clinical outreach educators can be trained to increase public awareness about signs and symptoms of postpartum depression and opioid overdose. Nationally, the Health Resources and Services Administration has created a free, confidential, 24/7 hotline available to pregnant and new mothers (1-833-9-HELP4MOMS) that offers professional counselors, real-time support, and referrals to local providers.[24]

Non-Hispanic Black women are at highest risk for maternal death, with 55.3 deaths per 100,000 live births, 2.9 times the ratio for non-Hispanic White women.[1] Inequalities in the maternal health outcomes of non-Hispanic Black women have persisted for more than a decade regardless of socioeconomic status or comorbidities. The root causes of these inequalities are complex, but they may include structural racism, distrust in the health care system, variation in quality of care, and inconsistent availability of community resources.

Response to maternal mortality crisis

More than 80% of pregnancy-related deaths in the US between 2017 and 2019 were determined by the CDC's MMRCs to be preventable.[16] Evaluation of these cases has identified interdisciplinary strategies and multilevel interventions to help prevent future pregnancy-related deaths. All states are encouraged to create MMRCs that comprehensively review maternal deaths, determine the underlying cause, and provide future recommendations for prevention.[25] Communication failure among members of a health team is a leading factor in maternal mortality sentinel events.[26] Implementation of structured team training simulations can facilitate interprofessional communication and teamwork in obstetrical emergencies. For example, scheduled multidisciplinary postpartum hemorrhage simulations at Parkland Health in Dallas, Texas, were associated with faster times for medication and blood transfusion administration as well as a decreased estimated blood loss after delivery.[27] Real-time simulation provides training for low-probability but high-risk events often associated with maternal deaths.[25]

Utilization of safety bundles and checklists can facilitate adherence to evidence-based guidelines. The Alliance for Innovation on Maternal Health (AIM) has developed several safety bundles that hospitals can implement to address the most common causes of maternal mortality.[28] California has developed a Maternal Quality Care Collaborative that demonstrated a reduction in maternal morbidity from postpartum hemorrhage after implementing a comprehensive hemorrhage bundle.[29] Interdisciplinary staff meetings and huddles are additional measures hospitals can take to identify women at risk of adverse outcomes.

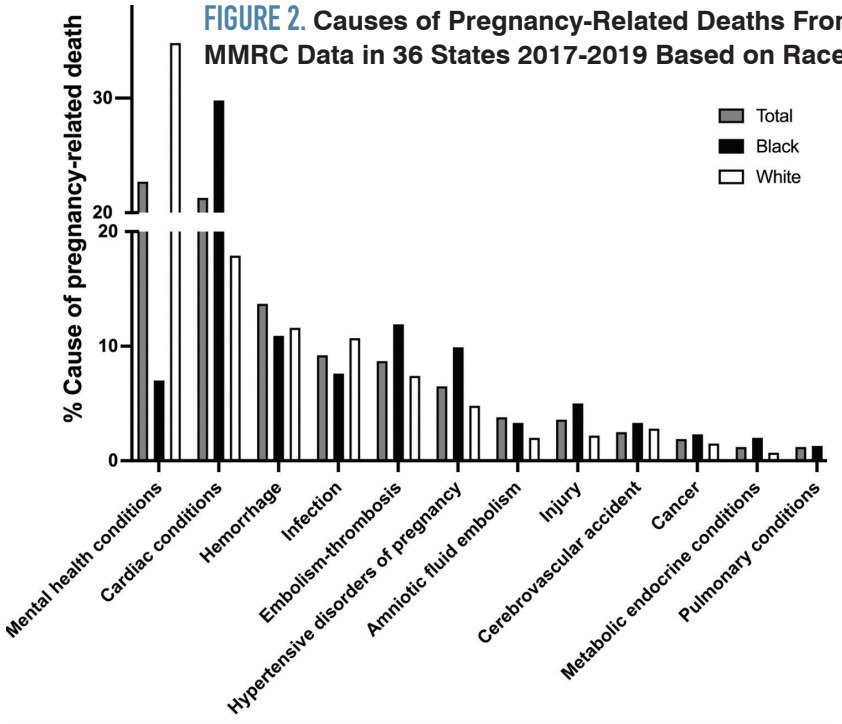


FIGURE 2. Causes of Pregnancy-Related Deaths From MMRC Data in 36 States 2017-2019 Based on Race[16]

MMRC, Maternal Mortality Review Committee.

At the national level, the White House released a blueprint in June 2022 addressing the maternal health crisis.[30] It urges legislatures to increase access and coverage of mental health services, advance data collection and standardization, expand diversity in the workforce, and strengthen economic and social support systems for expectant mothers.[30] States can decrease maternal mortality by increasing access to comprehensive medical care for a year after pregnancy, improving behavioral health access, and developing statewide infrastructure to address intimate-partner violence and the opioid epidemic.[14] At a local hospital systems level, health care facilities can adopt levels of care to ensure proper and prompt triage of pregnant and postpartum patients. To combat considerable racial and ethnic disparities, hospitals can train providers in recognizing implicit bias. To standardize evidence-based practices, hospitals can develop protocols for management of severe-range hypertension, sepsis, hemorrhage, and massive blood transfusions.[31] Implementation of the strategies summarized in **Table 2** are some approaches to decreasing preventable maternal deaths in the United States.[14,32,33]

Targeting health care disparities at the community level has been one of the most efficient ways of improving health care outcomes. A systematic review of MMR interventions by the New York MMRC identified a community-based initiative that provided doulas to non-Hispanic Black women in Brooklyn between 2010 and 2015, which resulted

in lower rates of preterm birth (6.3% vs 12.4%) and lower rates of low birthweight (6.5% vs 11.1%).[32] Similarly, the New Jersey MMRC stresses the importance of community-based resources dedicated to suicide prevention, domestic violence, and substance use disorders.[34]

Local organizations can perform individualized health needs assessments and address the specific social needs of vulnerable populations.[35] Parkland Health has developed the eMCAP (extending Maternal Care After Pregnancy) community-based program. The goal of eMCAP is to provide 12 months of postpartum care to women living in southern Dallas County, an area of substantial health disparity. eMCAP has a multidisciplinary team of advanced practice providers, community health workers, and nurses who use virtual visits and a mobile health unit deployed to areas in southern Dallas to reach patients too far from physical clinic locations.

Preliminary results from eMCAP show promise. Compared with matched controls outside the program, patients enrolled in eMCAP demonstrated an improvement in attendance to postpartum appointments up to 12 months after giving birth for management of chronic hypertension and diabetes mellitus. Moreover, patients with diabetes mellitus had significant improvement in hemoglobin A_{1c} levels more than 6 months after giving birth. Importantly, this program also led to increased completion of mental health referrals for those with symptoms of depression and anxiety. By focusing on these social determinants of health, eMCAP addresses the modifiable nonmedical factors that drive 80% of health care outcomes.[30] This program gained national recognition as one of the winners of the US Department of Health and Human Services Racial Equity in Postpartum Care Challenge. It also received a 2022 John M. Eisenberg Patient Safety and Quality Award.[36,37] eMCAP is an example of how community-based efforts can make a tangible impact on social determinants of health.

TABLE 2. Recommendations for Action and Strategies for Prevention[14,32,33]

National level
Expand Medicaid coverage to include 1 year of postpartum care
Expand economic and social support programs
Advance MMRC data collection, standardization, and research
State level
Establish maternal levels of care designations to properly triage patients
Improve public transportation services
Improve access to perinatal addiction services
Expand perinatal behavioral health support
Establish a maternal mortality task force
Community level
Engage communities of color
Establish mobile health units
Implement telemedicine use
Perform community health care needs assessments
Health care facility level
Train providers on implicit bias
Recruit a diverse workforce
Implement obstetric emergency simulation training
Implement interdisciplinary huddles
Implement evidence-based safety bundles
Develop sepsis, hemorrhage, and massive transfusion protocols
Establish an MMRC

MMRC, Maternal Mortality Review Committee.

Conclusion

Although data may be affected by differences in definition, ascertainment, and inconsistent collection systems, pregnancy-related deaths *have* been rising in the United States. This trend cannot be explained solely by these inconsistencies. Regardless of limitations, maternal mortality disproportionally affects non-Hispanic Black patients. Cardiovascular disease and mental health conditions are important emerging leading causes of maternal death. Interventions at the hospital, community, and legislative levels are necessary to make a tangible impact on maternal health. Nationally, a call to action for health care policies that expand postpartum medical coverage for 1 year is necessary to address inequalities in our health care system. Clinically, implementation of multidisciplinary simulations, safety bundles, and standardized management protocols will improve communication among providers and lead to improved clinical outcomes. Locally, support of community-based initiatives that focus on modifiable nonmedical needs and prioritize social determinants of health are central to the well-being of new families. Together, these measures offer important first steps to curb the trend of increasing preventable maternal deaths. Indeed, there is much work still to be done. ■

FOR REFERENCES VISIT
contemporaryobgyn.net/maternal-mortality

Model estimates the optimal number of oocytes for ART treatment

by ROBERT KRONEMYER

A model to estimate the optimal number of oocytes to try to fertilize during assisted reproductive technology (ART) treatment predicted that 43.4% of oocyte retrievals were day 3 transfers; hence, exposing all oocytes to sperm is recommended.

The results of the diagnostic study also showed that 57.6% of cycles predicted as day 5 transfers proceeded to the next stage, to estimate the number of oocytes to expose to sperm. The findings were published in *JAMA Network Open*.

The authors noted that surplus cryopreserved embryos present a challenge for in vitro fertilization patients and clinics. For instance, with the overturn of *Roe v Wade*, some states may decree illegal the discarding of surplus embryos.

"An evidence-based tool would help limit surplus embryo creation," the authors wrote.

Responding to the challenge, the authors developed a prediction tool to determine how many oocytes should be exposed to sperm to create embryos. The tool would help to conserve the chance of live birth while minimizing surplus embryos.

The study authors gleaned data spanning from 2014 to 2019 from member clinics of the Society for Assisted Reproductive Technology Clinic Outcome Reporting System.

The data comprised 410,719 oocyte retrievals and 460,577 embryo transfer cycles from 311,237 patients, aged 18 to 45 years, who initiated their first oocyte stimulation cycle between January 2014 and December 2019.

The final models included patient age, anti-Müllerian hormone level, diminished ovarian reserve diagnosis, number of oocytes retrieved, and which US state the clinic was located in.

The algorithm was based on 3 models with outcomes: day of transfer, proportion of retrieved oocytes that become usable blastocysts, and number of blastocysts needed for transfer for 1 live birth to occur. The median (IQR) age at stimulation cycle start was 35 years and the median (IQR) number of oocytes retrieved was 10 (range, 6-17).

THE REMAINING
57.6%
of cycles predicted as day 5 transfers proceeded to the next stage, to estimate the number of oocytes to expose to sperm.

The likelihood of recommending that all oocytes be exposed to sperm increased with age; for example, less than 20% of retrievals in patients younger than 32 years received recommendations that all oocytes be exposed to sperm, compared with more than 99% of retrievals among patients older than 42 years.

For cycles recommended to expose fewer than all oocytes, the median (IQR) numbers for 1 live birth were 7 oocytes (7 or 8) for patients younger than 32 years, 8 oocytes (7 or 8) for patients aged 32 to 34 years, and 9 oocytes (9-11) for patients aged 35 to 37 years. The prediction tool should reduce the number of unused embryos created and immediately address current patient and clinician concerns.

Overall, 47.8% of oocyte retrievals from the study population indicated that fewer of these oocytes underwent fertilization attempts than the actual number of oocytes retrieved. But this percentage varied by age: more than 80% for patients younger than 32 years and less than 2% for patients aged 41 or 42 years.

"If all patients in the test set had used this tool, 990,394 fewer oocytes would have been exposed to sperm," the authors wrote.

The authors have created an interactive website that clinicians and patients can use to compute the recommended number of oocytes to expose to sperm, based on the algorithm. ■

REFERENCE

Correia KFB, Missmer SA, Weinerman R, Ginsburg ES, Rossi BV. Development of a model to estimate the optimal number of oocytes to attempt to fertilize during assisted reproductive technology treatment. *JAMA Netw Open*. 2023;6(1):e2249395. doi:10.1001/jamanetworkopen.2022.49395

Impact of cannabis legalization on prenatal marijuana use

by LINDSEY CARR

All but 4 states in the United States have legalized some form of cannabis use, and 19 states have fully legalized it for adult recreational use.[1] Although providers and national organizations recommend against prenatal cannabis use, the frequency with and rate at which pregnant women are using the drug continues to increase in the United States, with most using cannabis to prevent nausea and vomiting.[2]

Prenatal cannabis use may result in adverse fetal outcomes, including low birth weight and neurodevelopmental issues in childhood.[2] Understanding the impact of cannabis legalization and its role in prenatal cannabis use from the perspective of pregnant women is crucial for obstetrician-gynecologists (ob-gyns) so they can offer effective, personalized care and counsel patients. It can also help with the development of educational materials, public health campaigns, and policy adaptations in the future.

Findings from a study from Kaiser Permanente Northern California (KPNC)—a large integrated health care delivery system with more than 4 million members—were published recently in *JAMA Network Open*. These provided valuable insight into how women who use cannabis during pregnancy perceive the effects of cannabis legalization.[3]

In general, the findings showed that women perceived legalization to mean greater access and exposure to cannabis, increased acceptance of its use, and more trust in cannabis retailers. Perhaps the most important finding, however, was the idea that legalization gave women greater confidence and willingness to discuss cannabis use during pregnancy with their provider. One woman said legalization empowered her to have an honest discussion with her doctor that ultimately led to her quitting use for the duration of her pregnancy.[3]

Researchers from KPNC conducted the qualitative study using data from the system's universal prenatal screening questionnaire that women receive on entrance to prenatal care at approximately 8 weeks' gestation. They prioritized women who reported daily or weekly prenatal cannabis use and focused their efforts primarily on non-Hispanic Black and non-Hispanic White pregnant women—the populations with the highest prevalence of prenatal cannabis use in KPNC in recent years.[4] Researchers also reviewed electronic health records for any documented pregnancy loss to confirm that the women were still pregnant. Eligible women were invited to participate in or opt out of a focus group, then asked to consent to schedule their participation in the group. More than 60% of the eligible women did not schedule focus group participation for various reasons, including those who opted out or had time conflicts or whose consent process was incomplete.

Over the course of 4 weeks (November 17-December 17, 2021), 51% of women scheduled (n = 104) participated in 1 of 18 virtual focus groups. Each group had 1 to 6 participants

and met for a duration of 90 minutes. Researchers grouped women and focus group leaders together based on race and ethnicity for congruency and to recognize the role race and ethnicity play in the experiences of pregnant women. The focus groups comprised 43% non-Hispanic Black women and 57% non-Hispanic White women with a mean age of 30.3 years. At the time of recruitment, most women (70%) reported daily prenatal cannabis use, 25% reported weekly use, and 6% reported monthly or less use.

Many women described cannabis retailers as being ubiquitous in their area and believed that the easy access and convenience increased their desire to use cannabis. Several women reported cannabis retailers being as accessible as liquor and corner stores, comparing the ease of accessibility with that of buying cigarettes or alcohol. Experiences with cannabis marketing and advertising varied among women, with many who had quit or cut down on use during pregnancy recalling that billboards and advertisements made them miss using or think about cannabis more often. Other women, however, reported little impact from cannabis marketing and advertising.

Evident among most women was the perception of reduced stigma around cannabis use, in general and during pregnancy. Such reduction may also be the reason they reported being more comfortable and open with their physicians. "I think that if it wasn't legal and I didn't feel comfortable speaking about it in the beginning with my doctor…I may still be smoking because if I didn't say anything and didn't have those conversations…I probably would have just kept doing it," said a woman in one of the focus groups.

Women expressed mixed concerns regarding Child Protective Services (CPS) investigations. Something for ob-gyns to consider may be reassuring patients that CPS would not be called because of prenatal cannabis use. Several women, however, reported continued strong concerns about potential CPS involvement after delivery. "I actually had a friend who has a CPS case out on her because she had tested positive for weed when she gave birth. So that's definitely a worry because some people are so against it. I don't know if…that would happen [in every case]. It's kind of scary…," one woman said.

Evident among most women was the perception of reduced stigma around cannabis use, in general and during pregnancy.

Another recurring theme among the focus groups was the idea that cannabis retailer staff are knowledgeable, caring, and nonjudgmental. Most women viewed budtenders in retail outlets as experts on the benefits of cannabis use, including during pregnancy, with one woman likening them to a doctor.

She said that budtenders "show you what's best for you.…It's kind of like the doctor, but not really." However, a few other women noted that advice can vary in quality and suggested going to a dispensary where "they know what they're talking about."

Ob-gyns and other prenatal care providers should leverage these findings, especially that legalization gave women greater confidence and willingness to discuss cannabis use during pregnancy with their doctors, according to the study's authors. They added that ob-gyns should be trained and empowered to screen for and initiate conversations about prenatal cannabis use. Additionally, the authors noted, ob-gyns should provide nonjudgmental counseling and information about potential health risks and refer women to alternative medicines or supplements that have been proved safe for pregnancy-related symptoms.

The issue regarding CPS involvement is also critical for ob-gyns to be aware of so they can provide accurate information to patients that is relevant in their state of practice. In California, for example, ob-gyns are not required to contact CPS or law enforcement when pregnant women screen positive for cannabis use; further, a positive toxicology test result at the time of delivery is not sufficient basis for reporting child abuse or neglect.[5] However, prenatal cannabis use is still included in definitions of child abuse or neglect that can lead to the termination of parental rights in many states,[5] even those with full legalization of cannabis use.[6]

According to other researchers, this further highlights the need to reform antiquated policies in states that criminalize prenatal substance use. Doing so, they say, may help avoid unintended negative public health consequences, such as fewer patient-provider conversations and missed opportunities for education and referrals for alternative treatments. ■

FOR REFERENCES VISIT
contemporaryobgyn.net/prenatal-marijuana-use

Positive data announced for intravaginal ring for menopause symptoms

by LINDSEY CARR

Daré Bioscience recently announced topline results from its phase 1/2 clinical trial of DARE-HRT1, an investigational intravaginal ring designed to deliver combination estrogen and progestogen hormone therapy over a 28-day period for the management of vasomotor and vaginal symptoms associated with menopause.

The intravaginal ring continuously delivers bioidentical 17β-estradiol and bio-identical progesterone for 28 days. The product's technology uses a solid ethylene vinyl acetate polymer matrix to release more than 1 active ingredient without the need for a membrane or reservoir—typically required to house the active drugs and control dosing—allowing for consistent dosing and sustained delivery.[1]

"The delivery of hormone therapy over a 12-week study via a 28-day intravaginal ring [that] requires no daily intervention supports DARE-HRT1's potential to be a first-in-category option, offering ease-of-use and consistent dosing to women suffering from menopausal symptoms," said Daré Bioscience Medical Director Annie Thurman, MD.

If approved, DARE-HRT1 would become the first FDA-approved monthly intravaginal ring to deliver both estrogen and progestogen hormone therapy.

The randomized, open-label phase 1/2 study evaluated DARE-HRT1 for safety, pharmacokinetics, and preliminary efficacy in improving vasomotor and vaginal symptoms of menopause in 20 healthy postmenopausal women aged 51 to 65 years with intact uteri over 3 consecutive months.

To calculate targets for hormone therapy, researchers reviewed the pharmacokinetics levels of currently available products with FDA approval to treat both vasomotor and vaginal symptoms of menopause. Results indicated that the levels of estradiol in both doses achieved or exceeded these established target levels. Progesterone levels in both doses proved successful as well, meeting the objective of releasing progesterone.

Results indicated that the levels of estradiol in both doses achieved or exceeded these established target levels. Progesterone levels in both doses proved successful as well, meeting the objective of releasing progesterone.

According to the study results, the levels of estradiol in the lower- and higher-dose formulations of DARE-HRT1 achieved statistically significant improvement in vasomotor and genitourinary symptoms of menopause, as well as vaginal pH and maturation index.

Researchers also found significant reductions in menopausal symptoms—including hot flashes and night sweats—among both DARE-HRT1 dose groups when compared with baseline. Participants showed significant improvements from baseline in all aspects surveyed on the Menopause-Specific Quality of Life survey, which expand beyond the parameters of vasomotor symptoms to the physical, psychosocial, and sexual symptoms associated with menopause ($P < .01$ on all domains). Compared with baseline, all participants showed significantly reduced vaginal pH ($P < .01$), increased superficial vaginal cells, increased intermediate cells, and decreased parabasal cells.

Vaginal dryness was reported by 70% of participants and was significantly improved in both DARE-HRT1 groups ($P < .01$). This same subset of women also experienced significant decreases in vaginal pain after usage. The most common adverse events included those found with other vaginal products.

All women said that DARE-HRT1 was comfortable to wear and did not come out during use. Over 94% also said they would be either somewhat or very likely to use the intravaginal ring for a women's health condition or unrelated disease in the future if needed. ■

FOR REFERENCES VISIT
contemporaryobgyn.net/dare-data

10+ MILLION PATIENTS HAVE RECEIVED EXPAREL

LOWER THE BARRIERS TO RECOVERY FROM WOMEN'S SURGERY

Non-Opioid EXPAREL Provides Long-Lasting Postsurgical Pain Relief to Help Women Recover Sooner

See more EXPAREL OB/GYN data

Patients who received multimodal pain management with an EXPAREL TAP block following C-section or hysterectomy had better outcomes compared with those who did not.[1,2]

46% LOWER
mean AUC of NRS pain scores up to 3 days[1]
(132.8 vs 246.3; *P*<0.001)

50% DECREASE
in total opioid use up to 3 days after surgery[2]*
(24.9 vs 51.7 [MED] mg; *P*=0.002)

39% SHORTER
time to ambulation[1]
(18.7 vs 30.7 hours; *P*<0.001)

1 DAY SHORTER
hospital LOS[1]
(2.9 vs 3.9 days; *P*<0.001)

AUC=area under the curve; LOS=length of stay; MED=morphine equivalent dose; NRS=numeric rating scale; OB/GYN=obstetrics and gynecology; TAP=transversus abdominis plane.

*The clinical benefit of the decrease in opioid consumption was not demonstrated in the pivotal trials.

Results from a retrospective chart review in patients who underwent C-section (N=201) with an EXPAREL TAP block (n=101) compared with those who did not receive an EXPAREL TAP block (n=100).[1]

Results from a randomized control trial in patients undergoing a robotic hysterectomy (N=60) who received an EXPAREL TAP block (n=30) compared with patients who received a bupivacaine HCl TAP block (n=30).[2]

Indication

EXPAREL® (bupivacaine liposome injectable suspension) is indicated for single-dose infiltration in patients aged 6 years and older to produce postsurgical local analgesia and in adults as an interscalene brachial plexus nerve block to produce postsurgical regional analgesia. Safety and efficacy have not been established in other nerve blocks.

Important Safety Information

EXPAREL is contraindicated in obstetrical paracervical block anesthesia. Adverse reactions reported in adults with an incidence greater than or equal to 10% following EXPAREL administration via infiltration were nausea, constipation, and vomiting; adverse reactions reported in adults with an incidence greater than or equal to 10% following EXPAREL administration via interscalene brachial plexus nerve block were nausea, pyrexia, and constipation. Adverse reactions with an incidence greater than or equal to 10% following EXPAREL administration via infiltration in pediatric patients six to less than 17 years of age were nausea, vomiting, constipation, hypotension, anemia, muscle twitching, vision blurred, pruritus, and tachycardia. If EXPAREL and other non-bupivacaine local anesthetics, including lidocaine, are administered at the same site, there may be an immediate release of bupivacaine from EXPAREL. Therefore, EXPAREL may be administered to the same site 20 minutes after injecting lidocaine. EXPAREL is not recommended to be used in the following patient populations: patients <6 years old for infiltration, patients younger than 18 years old for interscalene brachial plexus nerve block, and/or pregnant patients. Because amide-type local anesthetics, such as bupivacaine, are metabolized by the liver, EXPAREL should be used cautiously in patients with hepatic disease.

Warnings and Precautions Specific to EXPAREL

Avoid additional use of local anesthetics within 96 hours following administration of EXPAREL. EXPAREL is not recommended for the following types or routes of administration: epidural, intrathecal, regional nerve blocks **other than interscalene brachial plexus nerve block**, or intravascular or intra-articular use. The potential sensory and/or motor loss with EXPAREL is temporary and varies in degree and duration depending on the site of injection and dosage administered and may last for up to 5 days, as seen in clinical trials.

Warnings and Precautions for Bupivacaine-Containing Products

Central Nervous System (CNS) Reactions: There have been reports of adverse neurologic reactions with the use of local anesthetics. These include persistent anesthesia and paresthesia. CNS reactions are characterized by excitation and/or depression. **Cardiovascular System Reactions:** Toxic blood concentrations depress cardiac conductivity and excitability, which may lead to dysrhythmias, sometimes leading to death. **Allergic Reactions:** Allergic-type reactions (eg, anaphylaxis and angioedema) are rare and may occur as a result of hypersensitivity to the local anesthetic or to other formulation ingredients. **Chondrolysis:** There have been reports of chondrolysis (mostly in the shoulder joint) following intra-articular infusion of local anesthetics, which is an unapproved use. **Methemoglobinemia:** Cases of methemoglobinemia have been reported with local anesthetic use.

Full Prescribing Information is available at www.EXPAREL.com.

For more information, please visit www.EXPAREL.com or call 1-855-793-9727.

References: 1. Baker BW, Villadiego LG, Lake YN, et al. Transversus abdominis plane block with liposomal bupivacaine for pain control after cesarean delivery: a retrospective chart review. *J Pain Res.* 2018;11:3109-3116.
2. Hutchins J, Delaney D, Vogel RI, et al. Ultrasound guided subcostal transversus abdominis plane (TAP) infiltration with liposomal bupivacaine for patients undergoing robotic assisted hysterectomy: a prospective randomized controlled study. *Gynecol Oncol.* 2015;138(3):609-613.

PACIRA BIOSCIENCES, INC.

NON-OPIOID
EXPAREL®
(bupivacaine liposome injectable suspension)

EXPAREL®

(bupivacaine liposome injectable suspension)

Brief Summary

(For full prescribing information refer to package insert)

INDICATIONS AND USAGE

EXPAREL is indicated for single-dose infiltration in patients aged 6 years and older to produce postsurgical local analgesia and in adults as an interscalene brachial plexus nerve block to produce postsurgical regional analgesia.

Limitation of Use: Safety and efficacy has not been established in other nerve blocks.

CONTRAINDICATIONS

EXPAREL is contraindicated in obstetrical paracervical block anesthesia. While EXPAREL has not been tested with this technique, the use of bupivacaine HCl with this technique has resulted in fetal bradycardia and death.

WARNINGS AND PRECAUTIONS

Warnings and Precautions Specific for EXPAREL

As there is a potential risk of severe life-threatening adverse effects associated with the administration of bupivacaine, EXPAREL should be administered in a setting where trained personnel and equipment are available to promptly treat patients who show evidence of neurological or cardiac toxicity.

Caution should be taken to avoid accidental intravascular injection of EXPAREL. Convulsions and cardiac arrest have occurred following accidental intravascular injection of bupivacaine and other amide-containing products.

Avoid additional use of local anesthetics within 96 hours following administration of EXPAREL.

EXPAREL has not been evaluated for the following uses and, therefore, is not recommended for these types of analgesia or routes of administration.

- epidural
- intrathecal
- regional nerve blocks other than interscalene brachial plexus nerve block
- intravascular or intra-articular use

EXPAREL has not been evaluated for use in the following patient population and, therefore, it is not recommended for administration to these groups.

- patients younger than 6 years old for infiltration
- patients younger than 18 years old for interscalene brachial plexus nerve block
- pregnant patients

The potential sensory and/or motor loss with EXPAREL is temporary and varies in degree and duration depending on the site of injection and dosage administered and may last for up to 5 days as seen in clinical trials.

ADVERSE REACTIONS

Clinical Trial Experience

Adverse Reactions Reported in Local Infiltration Clinical Studies

The safety of EXPAREL was evaluated in 10 randomized, double-blind, local administration into the surgical site clinical studies involving 823 patients undergoing various surgical procedures. Patients were administered a dose ranging from 66 to 532 mg of EXPAREL. In these studies, the most common adverse reactions (incidence greater than or equal to 10%) following EXPAREL administration were nausea, constipation, and vomiting. The common adverse reactions (incidence greater than or equal to 2% to less than 10%) following EXPAREL administration were pyrexia, dizziness, edema peripheral, anemia, hypotension, pruritus, tachycardia, headache, insomnia, anemia postoperative, muscle spasms, hemorrhagic anemia, back pain, somnolence, and procedural pain.

Adverse Reactions Reported in All Local Infiltration Clinical Studies in Pediatric Patients Aged 6 to Less Than 17 Years

The safety of EXPAREL in 110 pediatric patients between the age of 6 and 17 years old undergoing various surgical procedures was evaluated in one randomized, open-label, clinical study in which EXPAREL was administered by infiltration into the surgical site and one single-arm, open-label study in which EXPAREL was administered by infiltration into the surgical site. Patients were administered a weight-based dose of EXPAREL at 4 mg/kg (maximum dose of 266 mg) or bupivacaine HCl 2 mg/kg (maximum dose of 175 mg). In these studies, the most common adverse reactions (incidence greater than or equal to 10%) following EXPAREL administration were nausea, vomiting, constipation, hypotension, anemia, muscle twitching, vision blurred, pruritus, and tachycardia.

The common adverse reactions (incidence greater than or equal to 2% to less than 10%) following EXPAREL administration were bradycardia, muscle spasms, tachypnea, hypoesthesia oral, anemia postoperative, dizziness, pyrexia, diarrhea, hypoacusis, hypoesthesia, back pain, hematuria, incontinence, muscular weakness, and visual impairment.

Adverse Reactions Reported in Nerve Block Clinical Studies

The safety of EXPAREL was evaluated in four randomized, double-blind, placebo-controlled nerve block clinical studies involving 469 patients undergoing various surgical procedures. Patients were administered a dose of either 133 or 266 mg of EXPAREL. In these studies, the most common adverse reactions (incidence greater than or equal to 10%) following EXPAREL administration were nausea, pyrexia, and constipation.

The common adverse reactions (incidence greater than or equal to 2% to less than 10%) following EXPAREL administration as a nerve block were muscle twitching, dysgeusia, urinary retention, fatigue, headache, confusional state, hypotension, hypertension, hypoesthesia oral, pruritus generalized, hyperhidrosis, tachycardia, sinus tachycardia, anxiety, fall, body temperature increased, edema peripheral, sensory loss, hepatic enzyme increased, hiccups, hypoxia, post-procedural hematoma.

Postmarketing Experience

These adverse reactions are consistent with those observed in clinical studies and most commonly involve the following system organ classes (SOCs): Injury, Poisoning, and Procedural Complications (e.g., drug-drug interaction, procedural pain), Nervous System Disorders (e.g., palsy, seizure), General Disorders And Administration Site Conditions (e.g., lack of efficacy, pain), Skin and Subcutaneous Tissue Disorders (e.g., erythema, rash), and Cardiac Disorders (e.g., bradycardia, cardiac arrest).

DRUG INTERACTIONS

The toxic effects of local anesthetics are additive and their co-administration should be used with caution including monitoring for neurologic and cardiovascular effects related to local anesthetic systemic toxicity. Avoid additional use of local anesthetics within 96 hours following administration of EXPAREL.

Patients who are administered local anesthetics may be at increased risk of developing methemoglobinemia when concurrently exposed to the following drugs, which could include other local anesthetics:

Examples of Drugs Associated with Methemoglobinemia:

Class	Examples
Nitrates/Nitrites	nitric oxide, nitroglycerin, nitroprusside, nitrous oxide
Local anesthetics	articaine, benzocaine, bupivacaine, lidocaine, mepivacaine, prilocaine, procaine, ropivacaine, tetracaine
Antineoplastic agents	cyclophosphamide, flutamide, hydroxyurea, ifosfamide, rasburicase
Antibiotics	dapsone, nitrofurantoin, para-aminosalicylic acid, sulfonamides
Antimalarials	chloroquine, primaquine
Anticonvulsants	Phenobarbital, phenytoin, sodium valproate
Other drugs	acetaminophen, metoclopramide, quinine, sulfasalazine

Bupivacaine

Bupivacaine HCl administered together with EXPAREL may impact the pharmacokinetic and/or physicochemical properties of EXPAREL, and this effect is concentration dependent. Therefore, bupivacaine HCl and EXPAREL may be administered simultaneously in the same syringe, and bupivacaine HCl may be injected immediately before EXPAREL as long as the ratio of the milligram dose of bupivacaine HCl solution to EXPAREL does not exceed 1:2.

Non-bupivacaine Local Anesthetics

EXPAREL should not be admixed with local anesthetics other than bupivacaine. Nonbupivacaine based local anesthetics, including lidocaine, may cause an immediate release of bupivacaine from EXPAREL if administered together locally. The administration of EXPAREL may follow the administration of lidocaine after a delay of 20 minutes or more. There are no data to support administration of other local anesthetics prior to administration of EXPAREL.

Other than bupivacaine as noted above, EXPAREL should not be admixed with other drugs prior to administration.

Water and Hypotonic Agents

Do not dilute EXPAREL with water or other hypotonic agents, as it will result in disruption of the liposomal particles

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

There are no studies conducted with EXPAREL in pregnant women. In animal reproduction studies, embryo-fetal deaths were observed with subcutaneous administration of bupivacaine to rabbits during organogenesis at a dose equivalent to 1.6 times the maximum recommended human dose (MRHD) of 266 mg. Subcutaneous administration of bupivacaine to rats from implantation through weaning produced decreased pup survival at a dose equivalent to 1.5 times the MRHD [see Data]. Based on animal data, advise pregnant women of the potential risks to a fetus.

The background risk of major birth defects and miscarriage for the indicated population is unknown. However, the background risk in the U.S. general population of major birth defects is 2-4% and of miscarriage is 15-20% of clinically recognized pregnancies.

Clinical Considerations

Labor or Delivery

Bupivacaine is contraindicated for obstetrical paracervical block anesthesia. While EXPAREL has not been studied with this technique, the use of bupivacaine for obstetrical paracervical block anesthesia has resulted in fetal bradycardia and death.

Bupivacaine can rapidly cross the placenta, and when used for epidural, caudal, or pudendal block anesthesia, can cause varying degrees of maternal, fetal, and neonatal toxicity. The incidence and degree of toxicity depend upon the procedure performed, the type, and amount of drug used, and the technique of drug administration. Adverse reactions in the parturient, fetus, and neonate involve alterations of the central nervous system, peripheral vascular tone, and cardiac function.

Data

Animal Data

Bupivacaine hydrochloride was administered subcutaneously to rats and rabbits during the period of organogenesis (implantation to closure of the hard plate). Rat doses were 4.4, 13.3, and 40 mg/kg/day (equivalent to 0.2, 0.5 and 1.5 times the MRHD, respectively, based on the BSA comparisons and a 60 kg human weight) and rabbit doses were 1.3, 5.8, and 22.2 mg/kg/day (equivalent to 0.1, 0.4 and 1.6 times the MRHD, respectively, based on the BSA comparisons and a 60 kg human weight). No embryo-fetal effects were observed in rats at the doses tested with the high dose causing increased maternal lethality. An increase in embryo-fetal deaths was observed in rabbits at the high dose in the absence of maternal toxicity.

Decreased pup survival was noted at 1.5 times the MRHD in a rat pre- and post-natal development study when pregnant animals were administered subcutaneous doses of 4.4, 13.3, and 40 mg/kg/day buprenorphine hydrochloride (equivalent to 0.2, 0.5 and 1.5 times the MRHD, respectively, based on the BSA comparisons and a 60 kg human weight) from implantation through weaning (during pregnancy and lactation).

Lactation

Risk Summary

Limited published literature reports that bupivacaine and its metabolite, pipecoloxylidide, are present in human milk at low levels. There is no available information on effects of the drug in the breastfed infant or effects of the drug on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for EXPAREL and any potential adverse effects on the breastfed infant from EXPAREL or from the underlying maternal condition.

Pediatric Use

The safety and effectiveness of EXPAREL for single-dose infiltration to produce postsurgical local anesthesia have been established in pediatric patients aged 6 years and older. Use of EXPAREL for this indication is supported by evidence from adequate and well-controlled studies in adults with additional pharmacokinetic and safety data in pediatric patients aged 6 years and older.

Safety and effectiveness have not been established in pediatric patients aged less than 6 years old for local infiltration or less than 18 years old for interscalene brachial plexus nerve block.

Geriatric Use

Of the total number of patients in the EXPAREL local infiltration clinical studies (N=823), 171 patients were greater than or equal to 65 years of age and 47 patients were greater than or equal to 75 years of age. Of the total number of patients in the EXPAREL nerve block clinical studies (N=531), 241 patients were greater than or equal to 65 years of age and 60 patients were greater than or equal to 75 years of age. No overall differences in safety or effectiveness were observed between these patients and younger patients. Clinical experience with EXPAREL has not identified differences in efficacy or safety between elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Hepatic Impairment

Amide-type local anesthetics, such as bupivacaine, are metabolized by the liver. Patients with severe hepatic disease, because of their inability to metabolize local anesthetics normally, are at a greater risk of developing toxic plasma concentrations, and potentially local anesthetic systemic toxicity. Therefore, consider increased monitoring for local anesthetic systemic toxicity in subjects with moderate to severe hepatic disease.

Renal Impairment

Bupivacaine is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. This should be considered when performing dose selection of EXPAREL.

OVERDOSAGE

Clinical Presentation

Acute emergencies from local anesthetics are generally related to high plasma concentrations encountered during therapeutic use of local anesthetics or to unintended intravascular injection of local anesthetic solution.

Signs and symptoms of overdose include CNS symptoms (perioral paresthesia, dizziness, dysarthria, confusion, mental obtundation, sensory and visual disturbances and eventually convulsions) and cardiovascular effects (that range from hypertension and tachycardia to myocardial depression, hypotension, bradycardia and asystole).

Plasma levels of bupivacaine associated with toxicity can vary. Although concentrations of 2,500 to 4,000 ng/mL have been reported to elicit early subjective CNS symptoms of bupivacaine toxicity, symptoms of toxicity have been reported at levels as low as 800 ng/mL.

Management of Local Anesthetic Overdose

At the first sign of change, oxygen should be administered.

The first step in the management of convulsions, as well as underventilation or apnea, consists of immediate attention to the maintenance of a patent airway and assisted or controlled ventilation with oxygen and a delivery system capable of permitting immediate positive airway pressure by mask. Immediately after the institution of these ventilatory measures, the adequacy of the circulation should be evaluated, keeping in mind that drugs used to treat convulsions sometimes depress the circulation when administered intravenously. Should convulsions persist despite adequate respiratory support, and if the status of the circulation permits, small increments of an ultra-short acting barbiturate (such as thiopental or thiamylal) or a benzodiazepine (such as diazepam) may be administered intravenously. The clinician should be familiar, prior to the use of anesthetics, with these anticonvulsant drugs. Supportive treatment of circulatory depression may require administration of intravenous fluids and, when appropriate, a vasopressor dictated by the clinical situation (such as ephedrine to enhance myocardial contractile force).

If not treated immediately, both convulsions and cardiovascular depression can result in hypoxia, acidosis, bradycardia, arrhythmias and cardiac arrest. If cardiac arrest should occur, standard cardiopulmonary resuscitative measures should be instituted.

Endotracheal intubation, employing drugs and techniques familiar to the clinician, maybe indicated, after initial administration of oxygen by mask, if difficulty is encountered in the maintenance of a patent airway or if prolonged ventilatory support (assisted or controlled) is indicated.

DOSAGE AND ADMINISTRATION

Important Dosage and Administration Information

- EXPAREL is intended for single-dose administration only.
- Different formulations of bupivacaine are not bioequivalent even if the milligram strength is the same. Therefore, it is not possible to convert dosing from any other formulations of bupivacaine to EXPAREL.
- DO NOT dilute EXPAREL with water or other hypotonic agents, as it will result in disruption of the liposomal particles.
- Use suspensions of EXPAREL diluted with preservative-free normal (0.9%) saline for injection or lactated Ringer's solution within 4 hours of preparation in a syringe.
- Do not administer EXPAREL if it is suspected that the vial has been frozen or exposed to high temperature (greater than 40°C or 104°F) for an extended period.
- Inspect EXPAREL visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Do not administer EXPAREL if the product is discolored.

Recommended Dosing

Local Analgesia via Infiltration Dosing in Adults

The recommended dose of EXPAREL for local infiltration in adults is up to a maximum dose of 266mg (20 mL), and is based on the following factors:

- Size of the surgical site
- Volume required to cover the area
- Individual patient factors that may impact the safety of an amide local anesthetic

As general guidance in selecting the proper dosing, two examples of infiltration dosing are provided:

- In patients undergoing bunionectomy, a total of 106 mg (8 mL) of EXPAREL was administered with 7 mL infiltrated into the tissues surrounding the osteotomy, and 1 mL infiltrated into the subcutaneous tissue.

Complementary probiotics with clotrimazole may increase yeast infection cure rates

by **LINDSEY CARR**

Vulvovaginal candidiasis (VVC) is incredibly common and widespread among women of reproductive age. Its occurrence can be a result of several factors, including uncontrolled diabetes, long-term or repeat exposure to antibiotics, and unhealthy lifestyle habits.

Although clotrimazole (Lotrimin; Bayer) has established itself as a successful treatment method, providers still encounter women with antibiotic resistance, adverse effects, and VVC episode recurrences, which can be challenging in practice. Recent studies have begun exploring the complementary role of probiotics as a potential treatment option for VVC.[1]

To further understand the relationship between vaginal microflora and VVC induced by *Candida albicans*, researchers conducted a prospective, real-world study to explore treatment outcomes of uncomplicated VVC when combining probiotic lacidophilin vaginal capsules with clotrimazole vaginal tablets (500 mg).[2]

The study, for which researchers recruited 42 women, was conducted from March 2018 to December 2018 at a tertiary hospital in China: 27 women had normal vaginal flora and 15 had uncomplicated VVC. The women were between the ages of 20 to 50 years, and all had a history of sexual intercourse.

Participants were treated with a single dose of clotrimazole tablets (500 mg) supplemented with 2 lacidophilin vaginal capsules for the following 7 days. Over the course of the study, participants were examined 4 times—once during the first visit, 8 to 10 days after the first visit, 30 days after the second visit, and finally 30 days after the third visit. Those in the control group of healthy, normal vaginal flora were examined a single time at the initial visit.

According to the results, 46.67% (7 of 15) of women were cured at the second visit, 61.54% (8 of 13) were cured at the third, and 72.73% (8 of 11) at the final visit.

Researchers ultimately analyzed 81 samples and found that those from women in the control group were exceedingly abundant in *Lactobacillus*, especially *Lactobacillus crispatus*, *L iners*, and *L jensenii*, and *Gardneralla vaginalis*.

Samples from women with VVC, on the other hand, were relatively few in bacterial composition and dominated by *L iners*. However, bacterial abundance in women with VVC increased gradually as treatment progressed.

At the final visit, the abundance of vaginal flora was further increased, with the dominant bacteria being *L crispatus* and *L iners*. ■

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Opioid use disorder and contraception

by JOHN JESITUS

Women covered under Medicaid who have opioid use disorder (OUD) and use medications for opioid use disorder (MOUD) are more likely to use contraception and to undergo female sterilization than peers not prescribed MOUD, according to study findings in *Contraception*.[1]

The fact that less than half of commercially insured and Medicaid-insured women were prescribed MOUD provides opportunities for improving contraceptive use and integrating contraception and MOUD services, the authors added.

Because of treatment and counseling requirements, the authors said, women with OUD prescribed MOUD likely have increased engagement with health professionals. "But our results showed no difference in odds of contraception use by MOUD status among commercially insured women."[1]

Investigators reviewed records from women with OUD aged 20 to 49 years in January 2018 who had at least 6 years of continuous commercial insurance (n = 3085) or Medicare (n = 3841). Authors set the 6-year cutoff to identify previously initiated long-acting reversible contraception (LARC) methods or use of female sterilization.

Within Medicare, the proportions of women who were and were not prescribed MOUD who were sterilized were 12.0% and 7.5%, respectively ($P < .0001$).

After controlling for age, women prescribed MOUD had significantly higher odds (adjusted odds ratio, 1.33) of using female sterilization vs no method than women not prescribed MOUD. Additionally, 79% of patients in Medicaid who were not prescribed MOUD used neither prescription contraception nor sterilization, vs 71.1% of Medicare peers prescribed MOUD ($P < .0001$).

After controlling for age, women prescribed MOUD had significantly higher odds (adjusted odds ratio, 1.33) of using female sterilization vs no method than women not prescribed MOUD.

Regarding commercial insurance, the proportions of women who were and were not sterilized were 3.3% and 3.1% ($P = .755$). Further, 65.8% and 66.1%, respectively, used no prescription contraception or female sterilization ($P = .847$).

"Further research is needed to assess reasons for the differential patterns of contraceptive use by insurance type," the authors wrote. Such reasons could include differences in consumer preferences and knowledge, provider influence or (lack of) prescribing behavior, coercive practices, and insurance coverage.

The authors moreover suggested improving delivery of recommended clinical care for women with OUD by integrating contraception and MOUD services in ways that align medical services and support with reproductive health goals. Such programs, they added, should ensure that all women are counseled and have access to the full range of methods, can make informed choices about whether to use contraception and which type, and can discontinue LARC at any time.[2,3]

The fact that only 41% of commercially insured and Medicaid-insured women with OUD were even prescribed MOUD also leaves room for improvement, the authors said. Among commercially insured women, those who lived in the South were less likely to be prescribed MOUD. Within Medicaid, Black women were less likely to be prescribed MOUD. These results mirror those from previous research that found racial and regional disparities in accessing, being prescribed, and continuing MOUD treatments.[4,5]

Altogether, the authors said, their findings highlight the need for social and structural interventions to provide more equitable and longer-term MOUD access to women with OUD. Along with fragmented services, such women face fear of criminalization and social stigma that may hinder them from accessing and using contraception and MOUD services. ■

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Hormonal contraceptives and adverse effects: What's the evidence?

by SANDRA FYFE

An umbrella review of meta-analysis studies on hormonal contraceptives, published in *JAMA Network Open*, found no high-quality evidence that they cause major adverse health outcomes such as stroke or cancer.[1]

Nathorn Chaiyakunapruk, PhD, of the Department of Pharmacotherapy at the College of Pharmacy, University of Utah College of Pharmacy, Salt Lake City, and School of Pharmacy, University of Wisconsin–Madison, and colleagues conducted the review.

The researchers reported that contraceptive use is increasing worldwide, with about 1.1 billion women in need of services.[1] Fifty percent of those women use hormonal contraceptives, which include skin patches, intravaginal rings, intramuscular injections, intrauterine devices, implants, and tablets.[1] These methods use either progesterone alone or a combination of estrogen and progesterone and are available in different doses. Are there risks involved for women who choose this family planning method?

Findings of some meta-analyses have shown major adverse health effects for women taking hormonal contraceptives, including cancer; cardiovascular, gastrointestinal, and metabolic issues; and fractures. Other findings indicate that hormonal contraceptives reduce certain risks.[1-3] The study authors evaluated the evidence in meta-analysis studies to clarify this conflicting information.

The researchers collected data from cohort studies and randomized clinical trials (RCTs) that looked at adverse health outcomes from hormonal contraceptive use in women. They used the Cochrane Database of Systematic Reviews, Medline, and Embase, from study inception through August 2020. They searched for terms such as meta-analysis and systematic review, including hormonal contraception, contraceptive agents, progesterone, desogestrel, norethindrone, megestrol, algestone, norprogesterones, and levonorgestrel.[1]

After screening 2996 studies, the researchers evaluated 310 full-text articles. Of these, 58 were selected for evidence analysis: 45 meta-analyses of cohort studies and 13 of RCTs. The authors used A Measurement Tool to Assess Systematic Reviews, version 2, to grade studies' methodologies; results were categorized as high, moderate, low, and critically low.[1]

"The Grading of Recommendation, Assessment, Development and Evaluations approach was used to assess the certainty of evidence in meta-analyses of RCTs, with evidence graded as very low, low, moderate, or high," the researchers reported.[1]

The researchers found 60 associations between hormonal contraceptive use and adverse outcomes described in meta-analyses of RCTs, and 96 associations described in meta-analyses of cohort studies.[1] They reported that none of the associations were supported by high-quality evidence. Of the 60 associations described in RCTs, only 14 were statistically significant, but none of these were supported by strong evidence.[1]

"The association between the use of a levonorgestrel-releasing intrauterine system and reductions in endometrial polyps associated with tamoxifen use (odds ratio [OR], 0.22; 95% CI, 0.13-0.38) was graded as having high-quality evidence, and this evidence ranking was retained in the subgroup analysis," the study authors reported.[1]

Of the 96 associations described in cohort studies, 40 were statistically significant, but none were supported by convincing evidence in the primary or subgroup analyses, the researchers said.[1] The risk of venous thromboembolism among those using oral contraceptives was initially supported by highly suggestive evidence. However, this was downgraded to weak in the sensitivity analysis.[1]

"The results of this umbrella review supported preexisting understandings of the risks and benefits associated with hormonal contraceptive use," the researchers said. They concluded that meta-analysis studies associating major adverse health outcomes such as cancer and increased cardiovascular events linked to hormonal contraceptives did not have high-quality evidence.[1] ■

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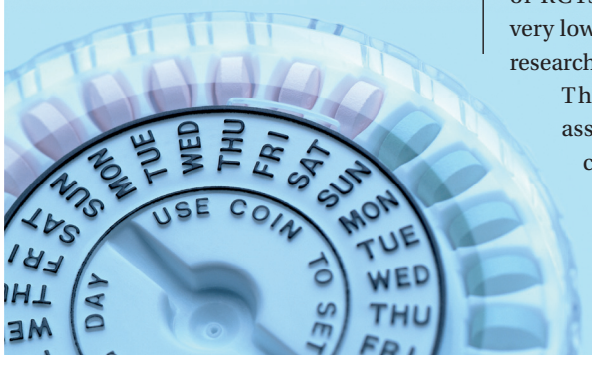

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Eating disorders can develop at any age

by LINDSEY CARR

Eating disorder prevention efforts are typically targeted to teens and adolescents, but new research data suggest women of all ages are susceptible, including those in menopause. Findings of a new study in *Menopause* showed body dissatisfaction to be a primary cause of eating disorders, especially during perimenopause.[1]

According to the North American Menopause Society (NAMS), the prevalence of any eating disorder especially for women older than 40 years is about 3.5%. Additionally, specific symptoms such as dissatisfaction with eating patterns is as high as 29.3%.[2]

Eating disorders can lead to serious deficiencies and other health concerns, which can then reveal their full effects later in life. The new study, unlike previous research, included participants at midlife, including premenopause, perimenopause, and postmenopause.

Growing evidence suggests that perimenopausal women have the highest rates of dysregulated eating behaviors—including counting calories, restricting food, using diet pills, skipping meals, and excessive physical exertion—of any reproductive stage. Further, they are vastly different from premenopausal women who express body dissatisfaction.

Findings such as these remain few and far between, but they confirm that perimenopause may be an especially risky time for developing eating disorders.

In this study, researchers wanted to investigate the structure of eating disorder symptoms specifically during perimenopause and early postmenopause. They included 36 participants aged 45 to 61 years from a larger clinical trial who had completed the Eating Disorder Examination Questionnaire at a baseline study visit.

Upon their evaluation, the researchers found that shape and weight dissatisfaction were the 2 most central symptoms of the questionnaire answers. Their findings reiterate the idea that dissatisfaction with body image is a core feature of eating disorder pathology across a woman's lifespan, from adolescence to postmenopause.[1]

"Dissatisfaction with body image remains a core feature of eating disorder pathology in midlife women. Specifically, fear of gaining weight and fear of losing control over eating habits are central symptoms of eating disorders in perimenopause and early postmenopause."

"[Data from] this study show that, similar to [that of] studies in young adults, dissatisfaction with body image remains a core feature of eating disorder pathology in midlife women. Specifically, fear of gaining weight and fear of losing control over eating habits are central symptoms of eating disorders in perimenopause and early postmenopause. These findings may help direct more targeted treatment strategies in women during midlife," said Stephanie S. Faubion, MD, MBA, NAMS medical director. ■

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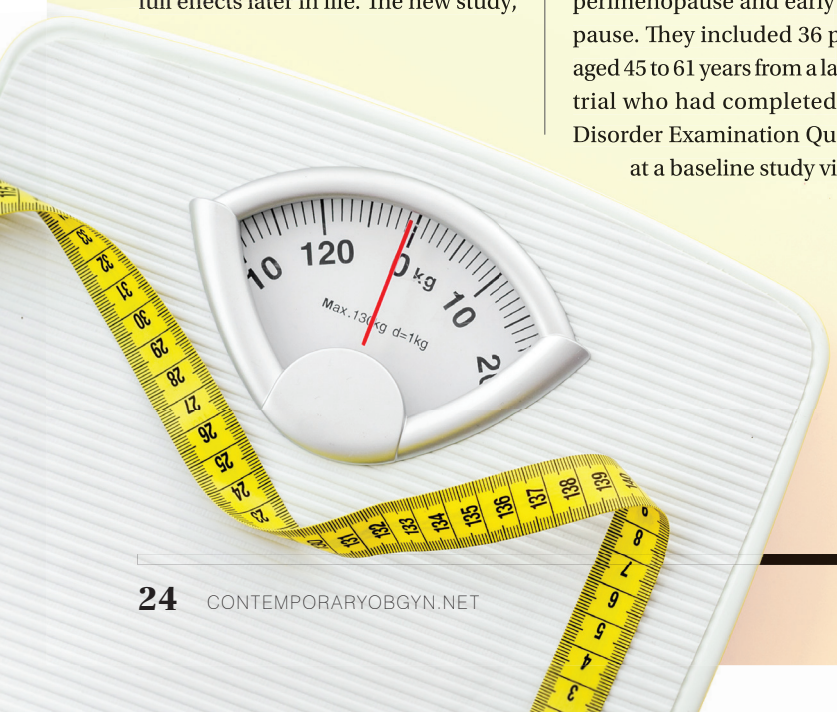

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Combating vaginal atrophy in menopause through the vaginal microbiome

"This small study shows that both systemic hormone therapy and ospemifene improve signs of vulvovaginal atrophy and induce favorable changes in the vaginal microbiome, with differing effects on vaginal bacterial composition."

– Stephanie S. Faubion, MD, MBA

by **MORGAN PETRONELLI**, MANAGING EDITOR

Ospemifene, a selective estrogen-receptor modulator as well as systemic hormone therapy, has shown an improvement in vulvovaginal atrophy (VVA) symptoms and vaginal microbiome in menopausal women through increasing healthy microorganisms and diminishing harmful bacteria, according to recently published study results in *Menopause*.

Approximately 50% of women experience VVA during menopause, according to the North American Menopause Society. VVA is caused by a decrease in circulating estrogen levels, leading to thinning of the vaginal walls and a reduction in lubrication of the vagina. As a result, women can experience symptoms such as pain during sex (dyspareunia) and vaginal dryness, as well as feelings of burning and itching.

Although relief of these symptoms can be seen with vaginal moisturizers and lubricants, and vaginal estrogens, the study researchers aimed to discover new methods for treatment of this chronic condition.

The investigators studied the effect of ospemifene and systemic hormone therapy on the composition of the vaginal microbiome by examining the vaginal microbiome profiles of women with VVA vs those of healthy postmenopausal women.

Results of the study showed that women with VVA had a significantly different vaginal microbiome from that of postmenopausal women. Additionally, both ospemifene and hormone therapy showed a reduction in harmful bacteria and an increase in healthy microorganisms, potentially promoting vaginal well-being.

The authors urged that further investigation is needed in this area to "confirm how the vaginal ecosystem is modified by this selective estrogen-receptor modulator."

"This small study shows that both systemic hormone therapy and ospemifene improve signs of vulvovaginal atrophy and induce favorable changes in the vaginal microbiome, with differing effects on vaginal bacterial composition, said Stephanie S. Faubion, MD, MBA, Penny and Bill George director for Mayo Clinic's Center for Women's Health and medical director for The North American Menopause Society.

She concluded, "Areas for future study include the assessment of changes in the vaginal microbiome, proteomic profiles, and immunologic markers with various treatments and the associations between these changes and genitourinary symptoms." ■

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Only about half of all breast cancer survivors seek gynecologic care

by RACHAEL ZIMLICH, RN, BSN

Fertility myths and declining sexual satisfaction may contribute to shortfalls in contraceptive use after cancer treatment, a new study concludes.

Contraception is a challenge after breast cancer because traditional hormone-based treatments are not an option. But limited choices in birth control are not the only things keeping breast cancer survivors from effective contraception.

The belief that cancer treatments can cause infertility, as well as an overall decline in sexual satisfaction, is a big deterrents in seeking effective birth control for many women who have beat breast cancer, data from a new study reveal. And the consequence is not just a lower quality of life. Premenopausal breast cancer survivors often turn to induced abortions or emergency contraceptives to handle unintended pregnancies, the findings show. This problem highlights the need for more attention on the sexual and reproductive health of women with a history of breast cancer.

As cancer treatments improve and lifespans for cancer survivors increase these and other new challenges are becoming clearer. Although there is concrete guidance on managing fertility associated with cancer treatment, there is less evidence to support decision-making about reproductive health issues such as pregnancy prevention.

ONLY ABOUT 45% OF PARTICIPANTS IN THE FIRST YEAR AND 65% OF PARTICIPANTS IN THE SECOND YEAR AFTER CANCER TREATMENT CONSULTED WITH A GYNECOLOGIST.

The new report by a research team in Italy, published in *JAMA Open Network*, reveals that many premenopausal women who survive breast cancer find themselves faced with unplanned pregnancies after using ineffective contraceptive methods or mistakenly assuming their oncology treatments had left them infertile. The goal of the report, according to the research team, was to identify how women use birth control after breast cancer, what barriers they face, and how to make contraception a bigger part of the post-cancer discussion.

Better contraceptive counseling is needed for women who survive breast cancer and want to prevent pregnancy, the report states. This issue may become even more important as the duration of some teratogenic breast cancer treatments like tamoxifen may be extended for as long as 5 to 10 years after diagnosis. The researchers used data from the CANTO cohort study to assess the use of birth control in premenopausal women who had survived breast cancer. The cohort was comprised of almost 3000 survivors

of stages I, II, and III breast cancer in France over a 5-year period. Among these study participants, researchers specifically examined their contraceptive use and the quality of their sexual health before menopause and in the first 2 years after cancer treatment.

According to the report by the Italian team, approximately 78.5% of the group studied reported being in a partnership or relationship at the time of their cancer diagnosis, and 96% already had children. In terms of treatment types, nearly 71% of participants received chemotherapy and 80% received endocrine therapy. Most of the cohort—80%—who received endocrine therapies were administered tamoxifen alone, whereas the other 20% received other hormonal therapies such as ovarian suppression treatments.

Despite these treatment results, the study findings revealed that just 54% of the women were using contraception at the time of their cancer diagnosis. That number dropped to about 40% in the 2 years after breast cancer treatment.

The type of birth control used after breast cancer treatment also changed. Even though nearly 63% of women were using hormonal contraceptives at the time of their diagnosis, only 5% to 6% were still using these types of birth control after treatment.

Instead, 95% of the breast cancer survivors polled turned to nonhormonal birth control options, including the following:

- **reversible mechanical methods** (89%-91%)
- **intrauterine devices** (75%-77%)
- **male condoms** (13%-14%)

Some participants reported using a combination of nonhormonal contraceptive strategies, and about 4% sought out nonreversible procedures such as hysterectomy to prevent pregnancy, according to the report. Additionally, only about 45% of participants in the first year and 65% of participants in the second year after cancer treatment consulted with a gynecologist.

The majority of the women the research team identified as using contraception after breast cancer treatment generally fell into the following demographic groups:

1. younger age (41 vs 43 years)
2. higher monthly household incomes
3. in a partnership or relationship
4. already have children
5. still experience leukorrhea
6. fewer reports of menopausal symptoms like hot flashes

Participants who sought contraceptive guidance also reported more positive perceptions of their body image, physical and emotional health, social functions, and sexual health and enjoyment, according to the report.

Generally, the researchers concluded, participants who already had children and were in a partnership, and who were still sexually functional with assumed signs of fertility were most likely to seek the help of a gynecologist and pursue contraception. Some deterrents to gynecologic guidance and birth control use most often appeared to be affected by things such as a lack of interest or engagement in sex after cancer treatment, or changes in menopausal signs.

Chemotherapy and adjuvant endocrine therapies also have been associated with adverse sexual health effects, including decreased libido and increased vaginal dryness, according to the report. This brings light to a separate issue concerning the sexual health of women after breast cancer treatment, the researchers added.

"Patients with cancer often report low rates of overall sexual satisfaction, and these problems are not always properly addressed," the authors stated. This lack of sexual satisfaction is likely a factor in lower rates of contraceptive use, as contraceptive use and better sexual health appear to have a positive association.

Whether better contraception leads to a better sex life or a better sex life increases the desire for reliable contraception after cancer treatment remains debatable. However, the research team stresses that in either case, gynecological support and follow-up care appears to be the strongest link to both sexual fulfillment and birth control use in premenopausal breast cancer survivors. Moving forward, the authors suggest that gynecological, contraceptive, and sexual health counseling become a larger part of the overall plan for living a full life after breast cancer. ■

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Cleveland Clinic reexamines syphilis testing strategies after rise in cases

by CELESTE KREWSON

The rate of syphilis cases has significantly increased in recent years, leading the Cleveland Clinic Ob/Gyn & Women's Health Institute to reexamine testing strategies.

The CDC has reported a 171.9% increase in the syphilis infection rate in female patients aged 15 to 44 years, which has caused congenital syphilis cases to rise 291.1%. This increases the risks of low birth weight, hydrops fetalis, cardiac and neurological defects, preterm birth, and stillbirth in infants.

Cleveland Clinic is located in northeast Ohio, where the number of syphilis cases per 100,000 individuals has risen since 2014 from 26.4 to 41.7. From 2016 to 2021, the rate of congenital syphilis rose by 82%.

Noting the alarming trend in rising rates of syphilis cases, the clinic's Ob/Gyn & Women's Health Institute and Center for Pediatric Infectious Diseases conducted a retrospective study of women who received perinatal care between 2014 and 2021 at facilities within the health system.

In traditional screening for syphilis, a nontreponemal test takes place first, followed by a confirmatory treponemal test when positive. In an alternative reverse-screening method, a treponemal test occurs first, followed by a nontreponemal test when positive. Patients then receive a second treponemal test if the results differ.

Further testing is needed to determine whether a test result is true positive (TP) or false positive (FP), with FP results being more common than TP results in many populations.

Among the Cleveland cohort patients there were 75,056 pregnancies and 77,410 infants delivered from June 2014 through February 2021. Initially, screening was recommended for women at the first prenatal visit, with an additional screen at the early third trimester and at delivery for high-risk women. Universal screening in the early third trimester was recommended from July 2019 onward. This strategy was implemented to address the rising rates of congenital syphilis.

There were 221 initial syphilis screens recorded, with an FP rate of 243.8 cases per 100,000 pregnancies and a TP rate of 50.6 cases per 100,000 pregnancies. The traditional algorithm was used for 46 screens, 38 of which were FP and 8 TP. The reverse algorithm was used for 175 screens, 145 of which were FP and 30 TP.

The CDC has reported a 171.9% increase in the syphilis infection rate in female patients aged 15 to 44 years.

Among women with a TP result, 55% received a past syphilis diagnosis whereas 45% had a new syphilis diagnosis. In TP screens, patients were more often likely to be Black, use marijuana, and have nonsyphilis sexually transmitted infections.

Data on potential harm from syphilis screening during pregnancy are lacking. These include time and expense associated with screening, FP results that lead to stress, incorrect labeling, and further diagnostic work-up.

Further evaluations and treatments because of syphilis concerns occurred in 2 women with FP results and 1 infant in the study: two high-risk patients were not rescreened at delivery, leading to diagnosis after their discharge from hospital, and 1 infant developed congenital syphilis. Cleveland Clinic has provided updated syphilis screening guidelines to address inadequate testing and treatment. In these guidelines, they recommend screening all patients as early as the first trimester during the first prenatal care visit. Patients at risk of developing syphilis during pregnancy should also receive serologic testing at delivery.

Testing should also be conducted in patients with a fetal death after 20 weeks' gestation, and screening at delivery should be carried out for patients who have not had prenatal care. Patients with a history of syphilis should receive a repeat test at 28 weeks and at delivery, and those at high risk of reinfection should receive monthly testing. ■

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by ANDREW I. KAPLAN, ESQ

Was this fourth-degree laceration properly repaired?

Case

A patient received prenatal care for the pregnancy at issue at Defendant Clinic. This was the patient's first pregnancy and it proceeded without issue. Defendant Obstetrician (Defendant OB) did not see the patient for any pre- or postnatal visits.

The patient was at 41 weeks, 4 days' gestation when she was admitted to the Labor and Delivery Department at the Codefendant Hospital on August 11, 2013. Her labor was managed by a nonparty obstetrician until the morning of August 13, when Defendant OB took over service. External fetal monitoring throughout this time was category 1, but with irregular contractions. Defendant OB's initial exam was at 7:27 AM on August 13, at which time the patient was still 3 cm dilated (no change since approximately 5:00 AM), 90% effaced, and still at –2 station above the spine.

She was started on oxytocin after verbal consent at 9:50 AM, as she continued to have category 1 tracings but irregular contractions and no progression of dilation. At 12:12 PM, she was 6 cm dilated, 100% effaced, and –1 cm above the spine with category 1 tracings. The patient was fully dilated at 10 cm with the head 2 cm below the spine when Defendant OB examined her at 3:09 PM, which ended the first stage of labor (16 hours, 44 minutes). The plan was for a normal vaginal delivery.

Pushing was effectively initiated at 3:56 PM, and at 4:00 PM, fetal tracings were category 2 with a single prolonged deceleration to 70 beats per minute for 2 minutes. The patient denied a strong urge to push, so she was told to rest. Oxytocin was continued (at a lower rate) and Defendant OB requested that her epidural be topped off. After pushing began again at 6:10 PM, at 6:18 PM, Defendant OB observed episodes of fetal bradycardia on the fetal monitoring strips.

Considering the strips, maternal exhaustion, and ineffective pushing, Defendant OB recommended a vacuum-assisted delivery and received verbal consent from the patient by showing her the vacuum and explaining the risks, benefits, and complications, including the risk of perineal tears. In anticipation of delivery, Defendant OB placed a straight catheter at 6:20 PM to empty the patient's bladder. The records document the

Andrew I Kaplan, Esq is a partner at Aaronson, Rappaport, Feinstein & Deutsch, LLP in New York City, specializing in medical malpractice defense and healthcare litigation. This case was handled by one of his partners.

patient's second stage of labor as 3 hours, 26 minutes (with pushing for less than 1.5 hours and rest for approximately 2 hours).

Defendant OB testified that the patient had a normal-sized perineum that was very swollen and edematous from labor. He placed the vacuum between the anterior and posterior fontanel, approximately 5 cm to 6 cm from the posterior and 2 cm to 3 cm from the anterior. He used a Kiwi vacuum, which includes a standard 4-mm cup and a hand pump. He pumped it up to 100 mm Hg and, in the direction of the plane of delivery, he pulled the vacuum out. The first application resulted in a "pop off" of the vacuum, whereas the second application resulted in the extraction of the infant without difficulty at 6:35 PM. Also, Defendant OB did not perform an episiotomy.

Defendant OB did see the perineum tearing during the extraction. Once the infant's head was out, he paused the procedure to reduce the cord from around the infant's neck before resuming the delivery. After delivery of the infant, during his postdelivery exam, Defendant OB observed a fourth-degree laceration. He testified that he informed the patient of the tear before repairing it, at which time he also discussed the risks of the laceration and repair, including the possibility of repair breakdown and fistula development.

Defendant OB's delivery note documents that, after the administration of cefazolin (Ancef, GlaxoSmithKline; Kefzol, Pfizer), he repaired the fourth-degree perineal laceration, noting "rectal mucosa 2 layers of running 3-0 Vicryl episiotomy in usual fashion, antibiotics given, betadine wash during procedure." He testified that the entire rectum was torn open, and that rectal tissue appeared healthy and normal. He placed a self-retaining Gelpi (a retraction device) for good exposure and then poured povidone-iodine (betadine) over the entire area. After finding the apex of the tear, he used 4-0 Vicryl sutures (he later stated 3-0), which are long-acting and self-absorbing sutures, to sew the rectal mucosa in 2 layers. As he placed the running sutures in the mucosa, he released the Gelpi to put less tension on the tissue. He tied the first suture and left it long at the apex and then sewed all the way down to the anal verge, where he left another suture. The 2 long sutures were guidelines for where he started and stopped.

A perineal exam on the day of discharge indicated no redness, discharge, vulvar edema, or external hemorrhoids.

Defendant OB then repeated the same procedure with the second layer of mucosa. He cut the 2 sutures and identified the rectal sphincter. He placed Allis clamps on each side of the sphincter and repaired the internal rectal sphincter with 3 individual 2-0 Vicryl sutures before closing the external sphincter with the muscle capsule using 2-0 Vicryl. Finally, he closed the perineal tear. Defendant OB did not extend the perineal tear during the delivery or repair. With each layer of the repair, povidone-iodine was poured over the surgical site. Once the repair was complete, Defendant OB performed a rectal exam, finding that the rectal mucosa and sphincters were intact, there were no sutures in the rectum, and the vagina was put together properly. The repair was uncomplicated and took approximately 30 minutes. After the repair, Defendant OB ordered routine pain medication, including topical sprays for the perineum, and advised the patient to keep the area clean, take sitz baths, and use witch hazel and a stool softener, but take nothing per rectum.

Over the next few days, the patient reported low levels of pain (4-5/10) and received pain medication. A perineal exam on the day of discharge, August 14, 2013, indicated no redness, discharge, vulvar edema, or external hemorrhoids. It was also noted that the patient was voiding independently with no issues. The records were not clear on whether the patient had a bowel movement or flatus prior to discharge (the notes are written to state "no abdominal tenderness, bowel movement, passage of flatus, no vomiting/drainage, no external hemorrhoids"). However, there is nothing to suggest that the patient advised that anything other than urine was coming through her urethra (she testified to passing gas through her vagina prior to discharge but did not tell anyone). She was instructed to take sitz baths

A Kelly probe was used to identify the fistula before Dr Q transformed the connection "into a fourth-degree laceration" and placed Vicryl sutures on the 2 ends of the sphincter with a "0" Vicryl.

3 times per day and was advised on perineum care and demonstrated her understanding of these instructions.

The patient was seen for 3 postpartum visits at Defendant Clinic. At the first visit, on August 20, 2013, she complained of "odorous discharge like feces for 2 days and some discomfort." A Defendant Clinic physician noted a small rectovaginal fistula near the introitus, started her on an antibiotic, and asked her to return in 2 weeks.

Instead, she returned 1 week later, on August 26, at which time a small rectovaginal separation was noted, and she was referred to Dr Q. The patient saw Dr Q that same day and reported that she experienced gas passing through her vagina prior to discharge and then feces passing through her vagina after she went home. She did not report any issues with fecal incontinence.

On exam, Dr Q recorded the location of the fistula as "1 cm in diameter, and approximately 2 cm from the hymenal ring" and confirmed the presence of the fistula on rectal exam. Unspecified treatment was discussed, and the patient was asked to return, which she did on September 4. At that visit, Dr Q reported that the patient's vagina was less inflamed and that the defect was well delineated. Notably, while the patient continued to report feces passing through her vagina, there were no complaints of fecal incontinence.

Preoperative assessment was performed on October 2, 2013, and the patient reported no issues with fecal incontinence. She also did not report any issues of fecal incontinence on October 7, when she presented to Codefendant Hospital in anticipation of the fistula repair performed by Dr Q later that day. Dr Q's Operative Report noted the indication for the rectovaginal fistula repair as the failed repair of a fourth-degree laceration following vacuum delivery.

A Kelly probe was used to identify the fistula before Dr Q transformed the connection "into a fourth-degree laceration" and placed Vicryl sutures on the 2 ends of the "cut" sphincter. Dr Q then dissected the vaginal mucosa away from the rectal mucosa and excised scar tissue to ensure a well-vascularized rectal mucosal edge. The rectal opening was then closed by placing interrupted 4-0 Vicryl sutures on the prerectal fascia, "thus imbricating the rectal mucosa," but taking care to avoid suturing the rectal mucosa. Dr Q then placed a second layer of prerectal fascia to decrease the tension from the first layer of sutures before approximating the 2 ends of the sphincter with "0" Vicryl. Following this, Dr Q addressed the vaginal mucosa, placed levator stitches, and completed the perineorrhaphy. Dr Q performed a rectal exam that revealed no sutures in the rectal mucosa and well-approximated edges.

Per the Operative Report, Dr Q concluded the procedure by performing a "contra coup sphincterotomy to relieve the tension on the sphincters and to avoid rectal stricture." The repair was uncomplicated. Patient complained of rectal pain (5-8/10) postoperatively. She was passing flatus on postoperative days 2 and 3 and had 2 bowel movements by postoperative day 4. She was discharged home on October 11, 2013, on docusate sodium (Colace), ibuprofen (Advil), and oxycodone/acetaminophen (Percocet). Six weeks of pelvic rest was recommended to the patient and she later presented to Dr Q on October 30 for a single postoperative follow-up, at which time she reported external hemorrhoids. No review of systems was recorded, and Dr Q noted a well-healed perineum and "no fecal incontinence."

In April 2014, the patient complained that she was possibly passing gas through her vagina. In July 2014, a dye test ruled out a rectovaginal fistula. Instead, her complaints were due to a weak anal muscle/sphincter. Dr Q recommended a change in diet, Kegel exercises, and biofeedback physical therapy, which she did with improvement (able to hold stool for

10 seconds, an improvement from 1 second). However, she could still not control flatus and had post–bowel movement leakage due to issues with rectal emptying, so the patient started seeing a new doctor in January 2015.

Anorectal manometry showed normal involuntary resting tone of the internal anal sphincter, normal voluntary squeeze pressures of the external anal sphincter, and normal sensation. A pudendal nerve test was not performed because the assessment showed that the external anal sphincter was functioning. She underwent an endoscopic ultrasound in March 2015 that showed the "anterior portion of [the] anal sphincter [was] missing." As such, continued biofeedback therapy and a sphincteroplasty if improvement plateaued were suggested.

The patient did improve to being able to hold her stool for 40 seconds but was still having accidents. In December 2016, she tried a Solesta injection that was unsuccessful. As such, the patient agreed to the recommended sphincteroplasty, which was performed on February 6, 2018. Significantly, "after repair of sphincters at the delivery, the rectovaginal fistula was repaired; however, no attempt was made to repair the sphincter deficit that was associated with it." The new physician then went on to state that "at the time of this operation, [the patient] had [a] markedly attenuated external sphincter with marked scarring in the perineum, all making repair of sphincter quite difficult."

In November 2018, the patient testified that she was doing pelvic floor therapy and using a rented biofeedback machine at home. Her fecal incontinence had improved, but she continued to have 2 to 3 "accidents" per month and leakage 3 to 4 times a week (down from daily). The accidents made it difficult for her to go out.

The patient testified that she was afraid of vaginal intercourse but confirmed that her sexual relationship with her husband returned to normal after the placement of an intrauterine device in September 2015. At the patient's further deposition on January 12, 2021, she testified that she had stopped doing pelvic floor exercises and no longer used a biofeedback machine as she was not seeing any new results. The patient continued to experience fecal incontinence every other week and post–bowel movement leakage almost daily, for which she wears pads. She believed her condition had worsened since November 2018 because her pelvic floor was weakening with age.

Patient claimed damage to the anal sphincter, including decreased tone and weakness, perineal laceration, and nerve and muscle damage.

Allegations

Plaintiff claimed damage to the anal sphincter, including decreased tone and weakness, perineal laceration, nerve and muscle damage, fecal incontinence, flatulence, numbness, hypotonia, anxiety over public soiling, depression, inability to care for her child, and inability to engage in sexual and recreational activities, secondary to improper repair of a fourth-degree laceration resulting in the formation of a rectovaginal fistula. Plaintiff alleged that she would require cesarean sections for all future deliveries. She also included the rectovaginal fistula repair surgery, the overlapping sphincteroplasty, and the need for potential future surgeries as part of her injuries.

Discovery

The defense's obstetrics expert was supportive of the decision to perform a vacuum-assisted delivery, the decision to not perform an episiotomy, and the repair of the fourth-degree laceration that occurred during the delivery.

He agreed that a mediolateral episiotomy is more painful for the mother and the repair has a greater risk of breaking down, even though it is associated with a decreased risk of third- and fourth-degree perineal lacerations (although lacerations can still occur with episiotomy). The development of a rectovaginal fistula is a known and accepted risk of a fourth-degree laceration and can occur absent a negligent repair. However, it is possible that Defendant OB placed 2 sutures too far apart allowing the hole to persist and a fistula to form given Plaintiff's report of passing gas through her vagina while still in the hospital after delivery.

If this is the case, Defendant

OB's repair would be below the standard of care. However, based on Defendant OB's testimony and his experience, it is more likely that the fistula formed naturally from the normal pressure of postrepair bowel movements and/or Plaintiff straining too much with the first postpartum bowel movement. The expert also commented that even if Defendant OB's repair was subpar and allowed the fistula to develop, his layered repair of the anal sphincters was within the standard of care and was shown to be a good repair as Plaintiff had no complaints of fecal continence in the 2 months that followed the repair.

Our expert opined that the appropriateness of Dr Q's decision to re-create the fourth-degree laceration to address the rectovaginal fistula depended on where the fistula was located and whether it was visible during the surgery, but neither was described in Dr Q's Operative Report. The expert also indicated that the Operative Report did not clearly describe how Dr Q closed and repaired the sphincters after opening them back up. Nevertheless, given that no fistula remained with subsequent testing, the expert confirmed that Dr Q's fistula repair was successful. It was unusual for a sphincterotomy to be performed following a fistula repair and, given that Plaintiff had no complaints of fecal incontinence prior to Dr Q's repair, the expert believed that Dr Q's decision to cut the sphincter was the cause of Plaintiff's subsequently developed incontinence.

The colorectal surgery expert opined that Defendant OB's repair of Plaintiff's fourth-degree laceration was appropriately performed and that the breakdown and development of a rectovaginal fistula is a known and accepted complication of same. He also opined that the breakdown of the laceration repair had nothing to do with Defendant OB's "layered" repair of the anal sphincters, as fistula development is a known and accepted complication regardless of whether the anal sphincters are comingled or repaired in layers.

Although it is unclear what Dr Q did to the anal sphincters during the October 2013 surgery, the expert opined that Dr Q's performance of a sphincterotomy was not indicated and is below the standard of colorectal surgery care. He explained that a sphincterotomy is only performed by colorectal surgeons to treat anal fissure, which the plaintiff did not have. Although the expert speculated that Dr Q performed the sphincterotomy because he thought the repair made the sphincters too tight, the expert opined that the sphincter can always be dilated, whereas a sphincterotomy cannot be repaired without another surgery. He also pointed out that Plaintiff did not have complaints of fecal incontinence prior to Dr Q's October 2013 surgery and that impairment of control with leakage of feces/gas and soiling of undergarments, as Plaintiff described at deposition, is a known complication of sphincterotomy in 5% of patients. ■

Result

Codefendant Hospital moved for dismissal and was discontinued from the case as this was Defendant OB's patient and there were no direct allegations of negligence against them. Defendant Clinic was ultimately discontinued from the case as well. Although Defendant OB's care could be defended, Plaintiff focused on his repair of the external and internal sphincters and contended that in his repair he had "bunched" them together rather than repairing them separately and then bringing them together, resulting in breakdown and the patient's eventual fistula formation, incontinence, and need for subsequent surgeries.

Given the significant exposure in a case involving a young mother who underwent multiple corrective procedures without success, resulting in continued incontinence and the documented need to have all future deliveries performed by caesarean section, the decision was made to resolve the case reasonably rather than defend through trial. By depicting the ability to potentially apportion a significant percentage of responsibility for the injuries to the subsequent treating surgeon's repair, the defense lawyers were able to negotiate a more favorable result.

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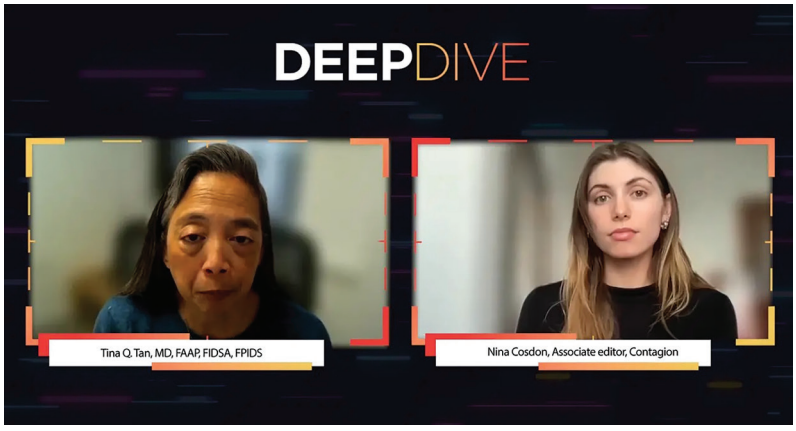

Respiratory syncytial virus (RSV) is a common respiratory virus that typically causes mild, coldlike symptoms. However, this season we have seen an unprecedented number of severe RSV cases in young children and older adults. Tina Q. Tan, MD, FAAP, FIDSA, FPIDS, a professor of pediatrics at Northwestern University Feinberg School of Medicine, and a pediatric infectious diseases attending, in Chicago, Illinois, explains why this past year's RSV season is so early and deadly. She also highlights the most promising candidates in the race to the first-ever RSV vaccine.

www.medicalworldnews.com/view/deep-dive-into-rsv

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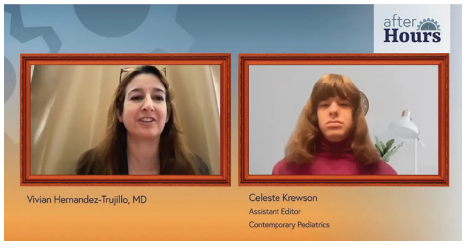

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