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Contemporary OB/GYN®

SEPTEMBER 2023
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Expert Advice for Today's Ob/Gyn For Doctors by Doctors

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How to Have Difficult Discussions

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* A positive HPV screening result may lead to further evaluation with cytology and/or colposcopy.

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PUBLISHER'S NOTE

Reducing harm to infants

September is National Alcohol and Drug Addiction Recovery Month, a good time to remind your patients who are trying to get pregnant, are pregnant, or are postpartum about the facts on alcohol and breastfeeding. According to the Centers for Disease Control and Prevention (CDC), although moderate alcohol consumption (up to 1 drink per day) by a parent who is breastfeeding is "not known to be harmful to the infant, especially if the mother waits at least 2 hours after a drink before nursing," the CDC also states that "not drinking alcohol is the safest option for breastfeeding mothers."[1]

The CDC also notes the following:

- Exposure to alcohol above the levels considered moderate can affect the child's development, growth, and sleep patterns.
- Alcohol levels in breast milk are at their highest 30 to 60 minutes after drinking. Alcohol can be detected in breast milk 2 to 3 hours after being consumed. The more alcohol the parent drinks, the longer it remains in the milk.
- Pumping breast milk after drinking and then discarding it will not reduce the amount of alcohol present in the parent's milk more quickly.[1]

Additionally, in the past year, the Foundation for Alcohol Education & Research in Australia sent out a press release noting the findings of a Kantar Public study of women who had breastfed or were recently breastfeeding and drank alcohol when not pregnant or breastfeeding. In the release, they noted that nearly 70% of women felt they did not fully understand the risks of alcohol use while breastfeeding and 65% were not aware of the National Health and Medical Research Council's alcohol guidelines for women who are breastfeeding.[2] Let's keep educating pregnant parents and new parents on the facts, share findings from the latest studies with them, and keep them informed on this important subject. ■

Mike Hennessy Jr
President and CEO, MJH Life Sciences®

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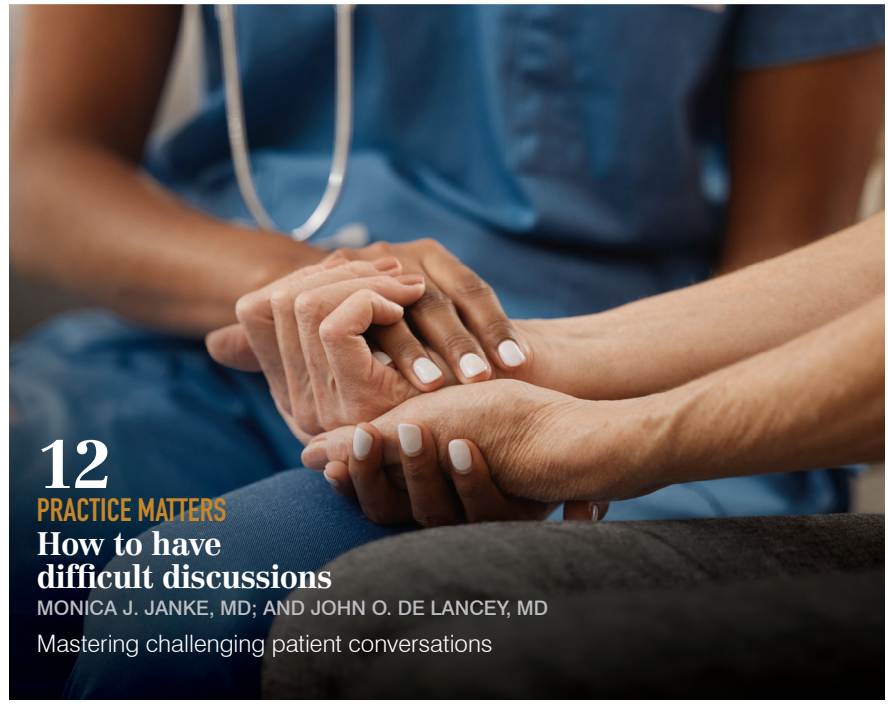
IN THIS ISSUE

september 2023 VOLUME 68 | NUMBER 9



COVER IMAGE: KAY ABRAHAMS/PEOPLEIMAGES.COM@STOCK.ADOBE.COM

PIPELINE NEWS

Study investigates vaginal estrogen for urinary symptoms of menopause

Contemporary OB/GYN Assistant Editor Celeste Krewson sat down with Monica Christmas, MD, associate professor at the University of Chicago, to discuss the findings of a study on how vaginal estrogen may be used to treat urinary symptoms in postmenopausal women.

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*Patients with a broad range of anatomical conditions: Uterine cavity lengths > 10 cm (up to 12 cm), cavities with certain types of myomas up to 4 cm, and in the presence of Essure®

References: 1. Johns DA, Garza-Leal JG. Post-Ablation Cavity Evaluation: A Prospective Multicenter Observational Clinical Study to Evaluate Hysteroscopic Access to the Uterine Cavity 4 Years after Water Vapor Endometrial Ablation for the Treatment of Heavy Menstrual Bleeding. *J Minim Invas Gynecol.* Published Online Sept 2019. **2.** Mara Water Vapor Ablation System Instructions For Use.

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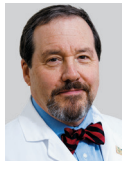


EDITORIAL

by CATHERINE Y. SPONG, MD

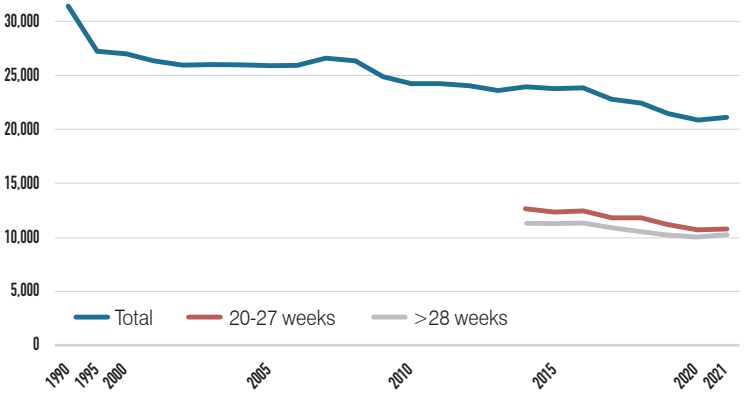
The impact of stillbirths on patients and providers

The latest United States statistics on stillbirth have been released, reporting an essentially unchanged rate since 2020 for fetal deaths, with 5.7 per 1000 live births and 2.9 per 1000 live births for fetal deaths at 20 to 28 weeks' gestation.[1] Although essentially unchanged from 2020, the overall trend has declined over the past decade (**Figure**).[1]

Stillbirths are one of the most tragic situations we encounter as obstetrician-gynecologists. The emotional toll both for the families and practitioners is immeasurable and results in a unique grief. Unlike deaths that occur later in life, stillbirth results in a lack of shared memories and experiences that can help in the healing process. The absence of tangible moments spent with the baby, combined with societal hesitations to discuss the topic openly, can lead to a sense of isolation and misunderstood pain. Moreover, the psychological toll on parents can be long-lasting and may affect their mental health and relationships for years.

As our patients' care providers, not only are we entrusted with their medical care and responsible for their physical well-being, but we are also first-line witnesses to the emotional turmoil following a stillbirth. This affects us all, and despite the emotional toll on us as providers, we continue to provide not only medical expertise but also compassionate support.

Figure. Stillbirths in the United States[1]



There has been a gradual decline in fetal deaths since 1990. Beginning in 2014, the obstetric estimate of gestation at delivery was used as the standard for measuring gestational age.

The impact of stillbirth extends beyond individual families and health care providers. From a public health perspective, the stillbirth rate serves as a crucial indicator of maternal and fetal well-being. Its rate within a country reflects the effectiveness of prenatal care, access to medical resources, and the overall state of maternal health. Addressing stillbirth demands a comprehensive approach that involves not only improving access to medical practices but also wide societal awareness and support systems.

To address the silent epidemic of stillbirth requires a multifaceted approach. Raising awareness is paramount. Open conversations about stillbirth can help shatter the stigma surrounding this topic, fostering a more understanding and empathetic society. Families who have endured stillbirth should find a supportive community that acknowledges their pain and provides resources for healing.

Furthermore, investment in research is essential. Building on the legacy work of the Stillbirth Collaborative Research Network, in-depth studies into the

CONTINUED ON PAGE 32

HHS launches tour for maternal health

by CELESTE KREWSON, ASSISTANT EDITOR

The US Department of Health & Human Services (HHS) launched its Maternal Outcomes Matter Showers (MOMS) Tour in Detroit, Michigan, on August 12, 2023.

Mental health has been an ongoing priority of President Joe Biden's administration. The HHS has encouraged pregnant women, new moms, and families to participate in the tour and receive educational information and health care services such as mental health services, health care coverage, and local support services.

The United States has the highest maternal mortality rate among developed nations, with the risk of death during childbirth 2.3 times more likely in Black, American Indian, and Alaska Native women than non-Hispanic White women, according to the HHS press release. In a blueprint calling for action against the mental health crisis, the Biden administration encouraged continuous, comprehensive maternal health insurance coverage throughout pregnancy.

Medicaid covers approximately 42% of births, but postpartum coverage is often lost 60 days after delivery. The HHS extended Medicaid postpartum benefits to 12 months during the Biden administration, and 35 states have begun efforts to decrease maternal mortality and morbidity rates and address disparities in maternal health.

In the 2024 fiscal budget from the Biden administration, over $471 million is dedicated to implementing strategies reducing maternal morbidity and mortality, expanding maternal health care in rural communities, implementing implicit bias training for health care providers, addressing perinatal health disparities, and creating pregnancy medical home demonstration projects.

The budget will also support the National Maternal Mental Health Hotline and screening and treatment for maternal depression because mental health conditions are the most common complication of pregnancy and childbirth.

The MOMS Tour was developed with the goal of improving maternal health outcomes, focusing on outcomes in marginalized racial and ethnic populations that experience high rates of maternal morbidity and mortality. Other locations the MOMS Tour will visit include Houston, Texas; Dallas/Fort Worth, Texas; Memphis, Tennessee; Albuquerque, New Mexico; Tulsa, Oklahoma; Oklahoma City, Oklahoma; Little Rock, Arkansas; and San Juan, Puerto Rico.

Mental health professionals, medical professionals, birth workers, and community workers will come together for the MOMS Tour, creating valuable discussions on maternal health disparities. These individuals will also design ways of supporting women at increased risk for adverse outcomes. ■

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Cervical excision treatment increases intra-amniotic infection risk

ACCORDING TO FINDINGS from a recent study published in the *American Journal of Obstetrics & Gynecology*, the risk of intra-amniotic infection is greater in women with a history of cervical excisional treatment.

Preterm premature rupture of membranes (PPROM), a leakage of amniotic fluid due to fetal membrane rupture occurring before 37 weeks' gestational age, is seen in 2% to 3% of pregnancies. This has caused debate among clinicians on prevention, prediction, and management strategies.

Microbial invasion of the amniotic cavity (MIAC), characterized by microorganism presence in the amniotic fluid, is seen in 23% to 63% of PPROM cases. MIAC presence may coincide with changes in inflammatory mediators' concentration, leading to certain clinical scenarios of PPROM.

Clinical scenarios of PPROM include intra-amniotic infection, sterile intra-amniotic inflammation, MIAC without

inflammation, and amniotic fluid that shows a negative result for infection. Data have indicated that cervical excisional management of cervical intraepithelial neoplasia increases PPROM risk by approximately 250%.

There are few data on the association between PPROM cases and intra-amniotic infection. To compare MIAC and intra-amniotic infection rates among women with PPROM during pregnancy with and without cervical excision treatment history, investigators conducted a retrospective study including women with singleton pregnancies complicated by PPROM.

Participants included pregnant women admitted to the Department of Obstetrics and Gynecology at the University Hospital Hradec Králové in the Czech Republic from January 2014 to December 2021. Eligibility criteria included singleton pregnancy, PPROM between 24+0 and 36+6 weeks, being 18 years or older, and the receipt of transabdominal amniocentesis.

An ultrasound scan during the first trimester was used to determine gestational age, whereas PPROM was determined using observation of amniotic fluid pooling in the vaginal fornix.

Antibiotics were used to manage PPROM, with intra-amniotic inflammation being managed with a 7-day regimen of clarithromycin and PPROM without intra-amniotic inflammation being managed with a 7-day regimen of intravenous benzylpenicillin. A positive test result of MIAC led to modification of antibiotic therapy.

Five investigators determined cervical excisional treatment history by reviewing maternal and perinatal medical records. When cervical excisional treatment history was found, the patient was contacted by phone to request permission to collect further medical information. This included procedure data and technique, cone length, and cervical dysplasia severity.

Cone length, specified as cone height or cone depth, was measured in millimeters. Data on cone length were collected from pathologic reports. Short-term neonatal morbidity was also evaluated using neonatal medical records.

MIAC was determined by microorganism presence in amniotic fluid cell cultures, whereas intra-amniotic inflammation was determined by IL-6 in the amniotic fluid of 745 pg/mL or more. Intra-amniotic inflammation without MIAC was defined as sterile intra-amniotic inflammation.

There were 765 women included in the final analysis, including 26% with MIAC and 20% with intra-amniotic inflammation. Of the women included, 14% presented with intra-amniotic inflammation, 6% with sterile intra-amniotic inflammation, 12% with MIAC without inflammation, and 68% with negative amniotic fluid for infection.

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Of the women included

14% presented with intra-amniotic inflammation

6% with sterile intra-amniotic inflammation

12% with MIAC without inflammation

68% with negative amniotic fluid for infection

Cervical excisional treatment was found in 10% of women. These women often had increased maternal age, rates of chronic hypertension, acute histologic chorioamnionitis and funisitis, and corticosteroid administration. However, lower birth weights, gestational ages at admission and delivery, and smoking rates were seen in these women.

Rates of polymicrobial findings in the amniotic fluid did not significantly differ between women with and without cervical excisional treatment history. However, higher rates of MIAC, intra-amniotic infection, and MIAC without inflammation as well as lower rates of negative amniotic fluid for infection were seen in women with a history of cervical excisional treatment.

A higher rate of intra-amniotic infection was also seen in women with a cone length of 3 to 8 mm, whereas a higher rate of sterile intra-amniotic inflammation was seen in women with a cone length of 13 to 17 mm. Those with a cone length of 18 to 32 mm had higher rates of MIAC, intra-amniotic infection, and MIAC without inflammation.

An increased rate of early-onset neonatal sepsis was seen in PPROM pregnancies with cervical excisional treatment history compared with PPROM pregnancies without that history. An association between cone length and the rate of early-onset neonatal sepsis was only seen in women with cone lengths of 18 to 32 mm.

These results indicated increased risks of intra-amniotic infection, MIAC without inflammation, and early-onset neonatal sepsis from cervical excisional treatment history. Investigators recommended the increased risk of intra-amniotic complications be considered in PPROM cases. ■

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Parents' stigmatizing beliefs about HPV vaccine

by **BOB KRONEMYER**

Stigmatizing beliefs that parents hold about the human papillomavirus (HPV) vaccine could discourage them from pursuing information about the vaccine, according to results from a survey published in the journal *Human Vaccines & Immunotherapeutics*.

The authors noted that although vaccination against HPV is safe and highly effective, only 59% of teenagers in the United States are up-to-date on HPV vaccination. Besides financial concerns, vaccine safety concerns, and a low perceived risk of HPV infection, stigmatizing beliefs about the HPV vaccine remain a common barrier that affects parents' decision-making.

The survey of 512 parents of vaccine-eligible children (girls and boys aged 11 -17 years) was conducted at Texas Children's Pediatrics, a network of 51 clinics in the greater Houston area. The average age of parents was 41 years. Participants were mostly women, White, college educated, and privately insured.

Despite 80.5% of parents having positive attitudes toward vaccines in general, 31.6% of parents listed "My child is too young" and 21.3% listed "My child is not having sex" as reasons for not yet vaccinating their child against HPV. Only 3.1% of parents listed "My child might think it's OK to have sex" as a reason for delaying vaccination.

No statistically significant differences existed in mean self-efficacy scores between parents who did and did not endorse 1 of these 4 stigmatizing beliefs: "My child is too young," "My child is not having sex," "It might make my child think it's OK to have sex," and "If my child gets the HPV vaccine, he/she may be more likely to have sex." On the other hand, parents who agreed or strongly agreed with the belief "My child is too young to get a vaccine for a sexually transmitted infection" were significantly more likely to report lower self-efficacy scores in speaking with their physician than parents who disagreed with the belief.

Two stigmatizing beliefs were linked to specific sources of information about the HPV vaccine. Parents who reported the stigmatizing belief "My child is not having sex" were much more likely to rely on health care providers as a source of information than parents who did not report this belief. But parents who reported the stigmatizing belief "It might make my child think it's OK to have sex" were much more likely to use social media as a source of information.

Parents who hold the belief "My child is too young to get a vaccine for a sexually transmitted infection" may greatly benefit from educational materials they can consult without a physician. One helpful intervention is the HPcancerFree app, which can raise awareness about HPV and reduce vaccine hesitancy by easing barriers to vaccination.

Findings from the current study are "significant because [they] further highlight the importance of doctor recommendations to all patients at recommended ages; doctor visits may represent one of the few opportunities to normalize HPV vaccination and address parents' stigmatizing beliefs about the HPV vaccine," the authors wrote. However, because only 29 of the 512 parents who participated in the study were men, results may not be generalizable to male parents. ■

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PHICHAK@STOCK.ADOBE.COM

HPV genotype screening improves cervical cancer prediction

by CELESTE KREWSON, ASSISTANT EDITOR

According to findings from a recent study published in *JAMA Network Open*, models for predicting cervical cancer among women with a diagnosis of high-risk human papillomavirus (hrHPV) are improved with the inclusion of HPV genotypes.

There were approximately 604,000 new cases of cervical cancer and 342,000 deaths from cervical cancer worldwide in 2020, making it the fourth most common cancer in women and a severe threat to women's lives. A decrease in cervical cancer incidence and mortality has been associated with well-established screening programs, but implementing these programs is an issue in developing countries.

Although screening programs have been implemented in China, the country has a coverage rate below 30%. Many countries are also facing a lack of medical resources and skilled health care personnel. This has made it difficult for cervical cancer screening programs to cover all women.

HrHPV is associated with an increased risk of cervical cancer, and different HPV genotypes are associated with different cervical cancer risks. However, few models consider including HPV genotypes.

Investigators conducted a study to develop a model for cervical cancer screening that included HPV genotypes. A cervical cancer screening program occurred in Xiangyang, China, from January 15, 2017, to February 28, 2018.

Participants included women 30 years or older with more than 1 year of sexual activity and no pregnancy, prior HPV vaccination, or hysterectomy or pelvic radiation therapy history. All participants had a positive test result for hrHPV infection and were evaluated by pelvic examination, HPV genotype testing, and questionnaires.

Data collected included participant demographic characteristics, medical history, menstrual status, sexual behavior factors, and family cancer history. Patients underwent a visual vulva inspection, internal vagina and cervix speculum examination, and bimanual adnexa and uterus palpation during pelvic examination.

Vaginal status was assessed by vaginal bacteria, miscellaneous bacteria, and number of white blood cells. Four categories were created, with categories 1 and 2 considered normal and categories 3 and 4 considered abnormal.

The cobas 4800 HPV test (Roche Diagnostics) was used to detect HPV genotypes. Categories included HPV 16, HPV 18, other hrHPV genotypes, HPV 16 plus HPV 18, HPV 16 plus other hrHPV genotypes, HPV 18 plus other hrHPV genotypes, and HPV 16 plus HPV 18 plus other hrHPV genotypes.

Microorganism infection in the vaginal microenvironment was also considered during evaluation. The primary outcome of the study was cervical intraepithelial neoplasia of grade 3 or above (CIN3+), whereas the secondary outcome was cervical intraepithelial neoplasia of grade 2 or above (CIN2+).

There were 314,587 women who received cervical cancer screening, 7.8% of whom had hrHPV and 11% of whom were excluded because of dropout. The remaining women were assigned to a training data set group or a validation data set group. Of the patients in the training data set group, 2.4% received a CIN3+ diagnosis and 4.6% received a CIN2+ diagnosis compared with 2.3% and 3.2% of patients, respectively, in the validation data set group.

The highest set of genotypes observed were other hrHPV genotypes, seen in 77.2% of patients in the training group. Other genotypes observed in this group included HPV 16 in 11.8% of patients, HPV 16 plus other hrHPV genotypes in 5.2%, HPV 18 in 3.5%, HPV 18 plus other hrHPV genotypes in 1.6%, HPV 16 plus HPV 18 in 0.3%, and HPV 16 plus HPV 18 plus other hrHPV genotypes in 0.3%.

When predicting CIN3+, models saw an area under the receiver operating characteristic (AUROC) curve value improvement of 35.9% when including HPV genotypes. For CIN2+, the AUROC value improved by 41.7% when including HPV genotypes.

These results indicated improved cervical cancer prediction from models including HPV genotypes. Investigators concluded these models may allow for early cervical cancer diagnoses in low-resource settings. ■

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A RESIDENT'S REFLECTION

How to have difficult discussions

by MONICA J. JANKE, MD; AND JOHN O. DE LANCEY, MD

During residency training, I often found myself taking care of patients experiencing loss, serious illness, and end of life. I was in the oncology clinic with a patient who came in to see their oncologist for the last time. She was frail because the disease had progressed despite chemotherapy and experimental trials. I was trying to gather the necessary information before the attending came in, when she asked me, "How long do you think I have to left to live?" I wasn't sure how to answer because no one had ever taught me how.

The oncologist entered and breezed past the patient's reports of fatigue, nausea, neuropathy, and abdominal pain. Instead, the oncologist explained that conventional treatment options had been exhausted, and the only remaining option was to try another clinical trial. The patient's eyes widened, as some required invasive procedures, lab values that were already unattainable, or moving away from home entirely.

A silence washed over the room. There was a palpable presence lurking,

MONICA J. JANKE, MD, is a gynecologic oncology fellow at University of Michigan in Ann Arbor, Michigan.

JOHN O. DE LANCEY, MD, is a Norman F. Miller Professor of Gynecology, the founding director of the Pelvic Floor Research Group, and director of Female Pelvic Medicine and Reconstructive Surgery at the University of Michigan in Ann Arbor, Michigan.

looming over all of us—an elephant in the room. Death. When would it come? An ideal moment arose to acknowledge it, and I waited for the oncologist to state the obvious to the patient: that she was dying, and would soon die from the cancer, and that it may be time to start making arrangements. But the silence passed, and nothing was said. The patient was given information on clinical trials, and like that, the appointment was over.

This was the experience my mother had at her last appointment with her oncologist. Despite having debilitating symptoms and a progressive cancer unresponsive to therapy, the difficult discussion to acknowledge the terminal nature of her disease was never even broached. A few days after the appointment, my mother decided to transition to hospice, and she died 2 months later. Though I accompanied my mother to her last appointment as her daughter, as a resident physician, I couldn't help think of all the other patients and families I had observed throughout my training experiencing similar interactions with their providers.

This scenario highlights an essential part of our practice as physicians: Patients deserve honest, compassionate, and effective communication from their doctors so that they can be empowered to make well-informed treatment decisions for themselves and their families. Yet few of us are trained in how to do this well. Whether it is end of life, serious illness, grief, or loss, we as doctors should be able to acknowledge the situation—not only to name it, but to deeply enhance our patients' understanding of it.

TAKE AWAYS

- Honesty, compassion, and effective communication are the key components to having a successful difficult discussion.
- Obstetricians and gynecologists should be prepared to conduct difficult discussions so that patients are empowered to make well-informed treatment decisions.
- Themes encountered in difficult discussions include prognosis, values, relationships, emotions, symptoms, and goals of care.
- Strategies to implement difficult discussions include determining candidacy; optimizing mindset, setting, and participants involved; respecting the nature of the therapeutic relationship; systematically documenting; and using a stepwise approach.
- Properly addressing these communication issues have the potential to improve patient quality of life, reduce rates of depression, and increase satisfaction with goal-concordant care.

Difficult discussions in obstetrics and gynecology

As obstetricians and gynecologists, we face clinical scenarios that require difficult conversations: a fetal anomaly diagnosed at a routine anatomy scan, a fetal demise discovered in labor and delivery triage, a reproductive abnormality preventing conception found during an infertility workup, or a new diagnosis of cancer on endometrial biopsy. It is our responsibility to meet these challenges alongside our patients, even if it feels hard or uncomfortable.

A key to successfully navigating these challenging situations with patients is to be familiar with an approach to initiating difficult discussions. Once the conversation is started, conducting the discussion with honesty, compassion, and effective communication is fundamental. Looking to oncologic care as an example, we know that conducting end-of-life discussions and early palliative care involvement can lead to improved quality of life, reduced rates of depression, and increased satisfaction with goal-concordant care for patients and caregivers.[1-3] It also lowers rates of aggressive medical care near death as well as health care costs and resource utilization.[4-7] Benefits such as these can be translated to other patients we care for in obstetrics and gynecology if we are able to utilize similarly timely and effective techniques for serious illness discussions.

Few of us have had formalized education and training in conducting difficult discussions. In a series of survey studies, only 18% of medical students indicated having received formalized training in end-of-life care and up to 53% felt unprepared to address end-of-life issues at the time of graduation.[8,9] Recalling their first experience giving bad news, residents reported faculty supervision only 5% of the time, and 88% of residents reported little to no in-class instruction on end-of-life care.[10,11] This article will help explain basic principles of communication and provide available resources we can use to improve the process of initiating and conducting difficult discussions.

Thinking about the discussion: Common themes

Breaking down the discussion into digestible pieces may make broaching the topic less intimidating. Whether in a clinical scenario involving serious illness, loss, or end of life, there are common themes encountered that we can preemptively prepare for. **Figure 1** shows the themes that arise in difficult discussions.

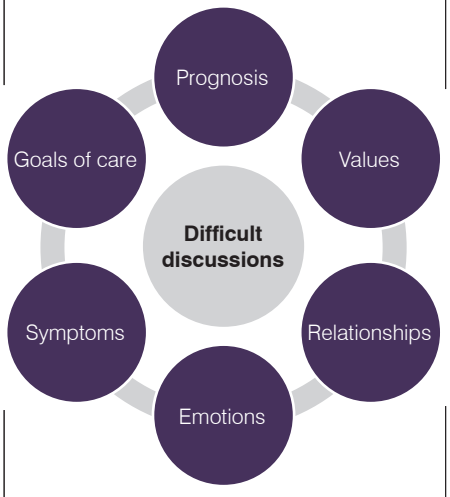
PROGNOSIS

Whether a patient is wondering if pregnancy is possible after treatment of a ruptured ectopic pregnancy or their likelihood of giving birth to a healthy baby after previable rupture of membranes, providers should be prepared to discuss prognosis. Though it may be easier to keep a prognosis vague, addressing it clearly and directly is crucial in helping patients make informed health decisions. Discussing prognosis requires the synthesis of clinical knowledge and interpersonal skills such as eliciting patient expectations and understanding, identifying emotions, and responding empathetically. Most studies show that patients want to discuss prognosis and receive detailed information, but it can be daunting for providers to know how to relay that information sensitively and accurately. A good place to start is by simply asking your patient what they already know and what they want to know—asking can facilitate an explicit discussion that matches an individual's values and needs.[12,13]

VALUES

Medical decision-making is influenced by patient values. Personal ethics, sociocultural background, and religious or spiritual beliefs may all have implications in how a patient interacts with health care. For example, a patient with cancer may be unwilling to transition to hospice due to cultural principles regarding death and dying, or a patient with infertility may oppose assisted reproductive technology due to a religious belief. Values also dictate what is most important to patients, such as spending time with family, advancing a career, or being active in the garden. Identifying and understanding your patients' values is essential to being able to provide a medical recommendation that aligns with their goals and prioritizes what is most important to them.

FIGURE 1.
Common Themes That Arise in Difficult Discussions



RELATIONSHIPS

Experiencing serious illness, loss, or end of life may affect your patient's relationships with family, friends, partners, or coworkers. Whether or not a patient opts for a certain treatment option is often intimately linked with how that choice will affect those around them. Understanding your patient's social web is imperative to enhancing shared decision-making and providing comprehensive care.

EMOTIONS

Though frequently avoided, minimized, or suppressed, emotions undoubtedly play a role in the experience of serious illness, loss, and end of life for both patient and provider. Accepting and acknowledging the presence of emotion with empathy and support can develop trust, encourage honesty, and reveal what matters most to patients.

SYMPTOMS

Symptoms can be a source of great stress for patients, whether it is related to a fear of developing them or difficulty coping with or controlling them. Anticipating what types of symptoms may arise and knowing how to manage them is a skill that can empower patients and improve quality of life. Proper management could also include appropriate referrals to other specialists such as physical therapy, palliative care, or social work.

GOALS OF CARE

At the conclusion of a difficult discussion, the hope is that prognosis, values, relationships, emotions, and symptoms have all been touched on so that the patient's individualized goals of care can be determined. Goals of care could revolve around certain desires, the acceptability of specific treatments or intensity of care, or advance care planning such as durable power of attorney,

At the conclusion of a difficult discussion, the hope is that prognosis, values, relationships, emotions, and symptoms have all been touched on so that the patient's individualized goals of care can be determined.

living will, or resuscitative preferences. Whether it is a patient with cancer deciding between "full code" and "do not resuscitate" status, a couple with infertility choosing between known or unknown sperm donor, or a mother with a second trimester loss weighing the pros and cons of evacuation versus induction, defining a patient's goals of care is universally vital.

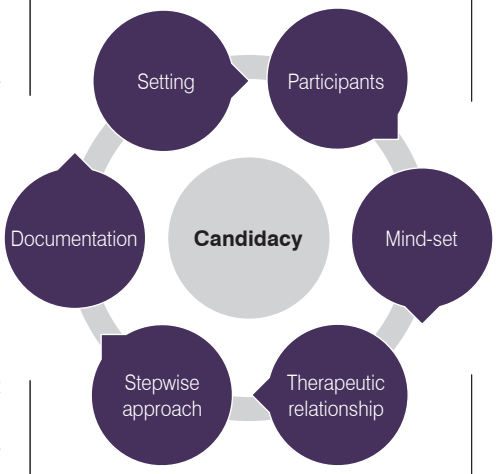
Conducting the discussion: Implementation strategies

Armed with the knowledge of what themes will likely arise in a difficult discussion, let's now explore techniques for setting up and conducting the conversation. **Figure 2** shows the different components of conducting difficult discussions.

CANDIDACY

You may ask yourself, which patients are appropriate candidates to have difficult discussions or address goals of care with? Goals of care discussions are relevant to more areas than just end of life—they should be a part of every clinical encounter that involves a decision. Disease-based triggers can also be used to identify patients. Some examples of disease-based identification include diagnoses such as a fetal anomaly incompatible with life, previable rupture of membranes, intrauterine fetal demise, hereditary breast and ovarian cancer syndrome, or platinum-resistant ovarian cancer.

FIGURE 2.
Components of Conducting Difficult Discussions



SETTING

Timing and place matters. If possible, choose a time of day that is convenient for the patient and a place that is comfortable for them. For example, initiating difficult discussions should be avoided when awakening patients on rounds before the sun rises or calling late in the day when there may not be support people available to them. If it is in clinic, consider a space like a consultation room, away from treatment-related disruptions, or a video visit where they can be in the comfort of their own home.

PARTICIPANTS

Who would the patient want with them when hearing difficult news or making big decisions? Figure out which family members or friends the patient feels supported by most and ask if it is OK to invite them to the conversation. Loved ones can often assist in processing information and creating a psychologically safe space.

MIND-SET

Consider where both you and your patient are coming from. It is likely you are in 2 very different mind-sets, and the closer you can come to understanding your patient's way of thinking, the better. Take a moment to walk in your patient's shoes to appreciate their situation. This includes considering their background and clinical scenario, as well as eliciting their current understanding of their condition. Check in with yourself to cultivate focus and calm. Try your best to eliminate other work distractions and be present when having the discussion.

THERAPEUTIC RELATIONSHIP

Consider the context of the clinical relationship: Is this a longitudinal relationship, or are you just meeting this patient for the first time as a consult? Your language and approach should be tailored accordingly. Acknowledging and respecting any potential limitations to the relationship contributes to credibility and may help build a bridge more swiftly. Additionally, it is important to partner with any specialists who may be involved in the patient's care to achieve a unified message.

STEPWISE APPROACH

Information delivery during a difficult discussion should be approached in a stepwise fashion. First, don't expect the discussion to necessarily occur all in 1 sitting. Rather, it is more likely that the discussion will need to occur in increments—possibly over multiple meetings—so that the patient and their family have time to process the information and make decisions. Second, using a "talking map" or conversation guide with patient-tested language to facilitate the discussion can be helpful. Some user-friendly and easily accessible frameworks include the Serious Illness Conversation Guide from Ariadne Labs and quick guides from the training organization VitalTalk. VitalTalk quick guides include tools on breaking bad news, discussing prognosis, responding to emotion, defusing conflicts, addressing goals of care, and more. VitalTalk also offers evidence-based skills training courses, as well as a smartphone tips app, which can be easily referenced just prior to having a difficult discussion no matter where you are.

DOCUMENTATION

We document clinical encounters in certain ways to streamline our processes in many areas of our practice, and documentation for difficult discussions should be no different. Though each scenario is unique, systematically documenting or using documentation templates helps us prepare, practice, and ensure we hit on the absolute essentials. Documenting difficult discussions also shares the patient's values and goals with other providers, which further supports goal-concordant care.

Conclusion

Conducting difficult discussions is part of what we do as obstetricians and gynecologists. Use the principles outlined in this article to help you implement difficult discussions with honesty, compassion, and effective communication and to empower patients to make well-informed treatment decisions. These general principles of thoughtful communication are simple to adhere to and can make a world of difference in your patient's life. Use simple, everyday language. Share what you know and admit what you don't know. Be transparent and vulnerable. Ask clarifying and open-ended questions. Listen. Allow for pauses and silence to create space. Respond to emotions when they come. Be direct yet considerate. Be truthful but sustain spirit. ■

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First OTC oral contraceptive approved by FDA

Norgestrel is the first nonprescription oral contraceptive approved for use in the United States.

by **CELESTE KREWSON, ASSISTANT EDITOR**

Norgestrel (Opill; HRA Pharma) has become the first nonprescription daily oral contraceptive approved by the FDA for preventing pregnancy.

"Today's approval marks the first time a nonprescription daily oral contraceptive will be an available option for millions of [individuals] in the United States," said Patrizia Cavazzoni, MD, director of the FDA's Center for Drug Evaluation and Research. "When used as directed, daily oral contraception is safe and is expected to be more effective than currently available nonprescription contraceptive methods in preventing unintended pregnancy."

There are 6.1 million pregnancies annually in the United States, of which approximately 50% are unintended. Adverse outcomes of unintended pregnancies include negative maternal and perinatal outcomes, such as increased preterm birth risk and decreased odds of receiving early prenatal care.

Individuals seeking contraception will be able to access norgestrel without consulting a health care provider, reducing barriers to contraception access. This may reduce the prevalence of unintended pregnancies and associated adverse outcomes.

In 1973, norgestrel received FDA approval for prescription use, highlighting its contraceptive efficacy. The manufacturer, HRA Pharma, later applied for norgestrel to become an OTC method of contraception. This required proof of safety and efficacy when used by consumers without support from a health care professional.

Research on norgestrel showed a significant percentage of consumers were capable of comprehending information on the Drug Facts label. Proper use of norgestrel is safe and effective, indicating that it can be used as an OTC product.

Efficacy of norgestrel is achieved when the product is used at the same time once daily, with efficacy decreasing if patients use medications that interact with norgestrel. Common adverse effects include dizziness, headaches, nausea, irregular bleeding, abdominal pain, cramps or bloating, and increased appetite.

Norgestrel is not effective as emergency contraception and should not be used in patients with breast cancer or patients who have a history of breast cancer. It also should not be used alongside other hormonal birth control products, and use should be discontinued if pregnancy has been confirmed.

HRA Pharma will determine the price and availability timeline of norgestrel. Consumers will be able to purchase the product at convenience stores, grocery stores, drug stores, and online. ■

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TOWFIQU BARBHUIYA@STOCK.ADOBE.COM

Curcumin does not impact bleeding from contraceptive implant

by CELESTE KREWSON, ASSISTANT EDITOR

According to a recent study published in the *American Journal of Obstetrics and Gynecology*, daily curcumin use does not improve bleeding patterns in etonogestrel (ENG) contraceptive implant users.

The ENG subdermal contraceptive implant has strong efficacy for preventing pregnancy but is associated with abnormal bleeding patterns that lead to discontinuation. As the implant is 20 times more effective than oral contraceptives at preventing pregnancy, increasing satisfaction may reduce unplanned pregnancy rates.

Tamoxifen has been shown to reduce bleeding after contraceptive implant but is associated with an increased risk of venous thromboembolism (VTE) in long-term exposure. Alternatively, curcumin has been deemed safe by the FDA and is effective against cancer, cardiovascular disease, and autoimmune and inflammatory conditions, wrote the study authors.

Curcumin has not been formally studied for uterine bleeding. Its safety and biological plausibility for improving bleeding showcased a need to associate its effects in implant users. To determine the effects of curcumin in ENG contraceptive implant users, investigators conducted a study at Oregon Health & Science University in Portland.

Participants were aged 15 to 45 years, had been using the ENG 68-mg subdermal contraceptive implants for 30 days or more, and met the criteria for frequent or prolonged bleeding or spotting in the past month. Frequent bleeding was defined as 2 or more separate episodes, whereas prolonged bleeding was defined as episodes lasting 7 days.

Exclusion criteria included being less than 6 months post delivery, being less than 6 weeks post abortion, being allergic to the study medication, currently breastfeeding, using anticoagulation drugs, having bleeding dyscrasia or undiagnosed abnormal uterine bleeding, having a VTE history, using P540 pathway–inducing drugs, active cervicitis, or current implant use of more than 2 years and 8 months.

An in-person screening visit was performed to confirm implant use and conduct an implant examination. Urine pregnancy tests were performed at baseline, enrollment, study exit, and when there was a concern for pregnancy. Baseline bleeding patterns were established with help from study staff using a calendar to estimate bleeding and spotting days.

Satisfaction with bleeding patterns and implant use were determined using a visual analog scale (VAS) at baseline and study exit.

The primary outcome of the study was the number of days without bleeding or spotting since initiation of the study drug, the 600-mg Theracurmin HP (curcumin; Immunovites). Secondary bleeding outcomes were also evaluated, including number of bleeding-free days, number of bleeding or spotting days, number of spotting days, number of bleeding days, and number of bleeding episodes.

There were 58 individuals included in the analysis, 54 of whom completed all 30 days of treatment. Participants were aged a mean 24 years and had a mean body mass index of 24 kg/m^2. Implant use length was 579 days for the placebo group and 431 days for the curcumin group.

A significant difference in the number of days without bleeding or spotting was not found between both groups, with a mean 16.7±6.9 days for the curcumin group and a mean 17.5±4.8 days for the placebo group. Secondary outcomes also did not differ between the curcumin and placebo groups.

Sixty-five percent of participants said they would recommend the ENG implant to a friend, with rates not significantly changing between groups. The groups also did not significantly differ in satisfaction measured by VAS.

Of participants, 72% overall, 82% of the placebo group, and 62% of the curcumin group said they would keep the implant. A desire to continue using the study drug was reported by 81% of the curcumin group and 39% of the placebo group.

These results did not indicate an improvement in bleeding patterns for ENG implant users. Investigators recommended further research on bleeding associated with progestin-only contraception. ■

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Nanoparticles are effective for managing vulvovaginal candidiasis

by CELESTE KREWSON, ASSISTANT EDITOR

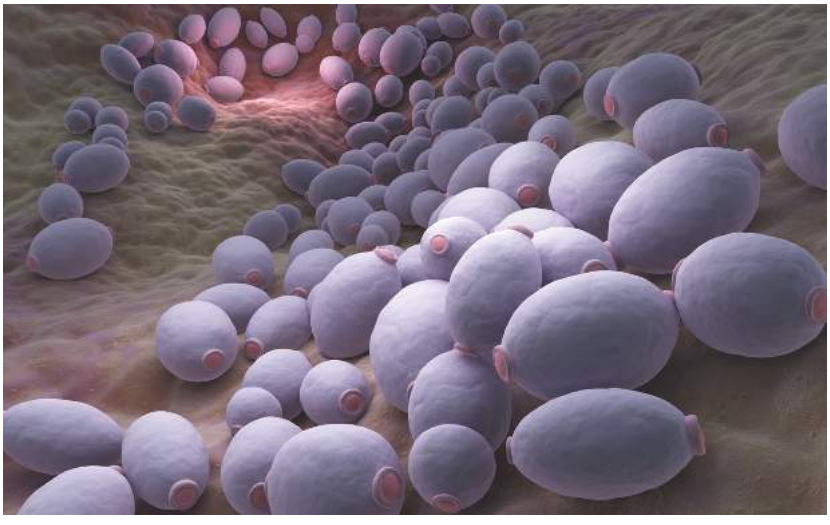
According to findings from a recent study published in the *European Journal of Pharmaceutical Sciences*, vulvovaginal candidiasis (VVC) may be effectively managed using miconazole-loaded nanoparticles coated with hyaluronic acid (HA).

Approximately 70% to 75% of women of reproductive age experience VVC, which presents as vulvar or vaginal inflammation. Recurrent VVC (RVVC), defined as 4 or more symptomatic episodes within 12 months, occurs in 40% to 50% of women who experience VVC. Approximately 138 million women are affected by RVVC annually.

Clinical symptoms of VVC and RVVC include vaginal discharge, vulvar erythema, vulvovaginal pruritus, edema, and soreness. More than 90% of VVC episodes are caused by *Candida albicans*. Infections by the *Candida* genus may be caused by the intestine, sexual activity, or remaining yeasts. Augmented estrogen levels also increase VVC risk.

Antifungal drugs including imidazoles, triazoles, polyenes, and ciclopirox olamine are used to manage VVC. However, dosage regimens are complex, last for months, and have high recurrence rates.

Scientists have developed antifungal drug delivery systems for VVC and RVVC management to overcome barriers on pharmaceutical therapies. These include miconazole-loaded nanoparticles with HA, which are employed to suppress *C albicans*. Investigators conducted a study to determine the efficacy of this treatment.



TATIANA SHEPELEVA@STOCK.ADOBE.COM

Emulsification and solvent evaporation techniques were modified for preparing uncoated miconazole-loaded nanoparticles. Miconazole concentrations of 0.5 mg/mL^{-1} and 1 mg/mL^{-1} and PCL masses of 25.9 mg and 36 mg were used to synthesize 4 total formulations.

To produce miconazole-loaded nanoparticles with HA, investigators first ultracentrifuged uncoated nanoparticles at 14 g for 30 minutes at 8 °C and then removed the supernatant. Afterward, investigators resuspended the pellet in 2 mL of purified water, then placed it in 5 mL of an aqueous solution with different concentrations of HA.

Photon correlation spectroscopy (Malvern S4700 PCS System; Malvern Instruments) was used to measure mean nanoparticle diameter and polydispersity index, with zeta potential measured by electrophoretic mobility. Miconazole encapsulation efficiency was determined using a high-performance liquid chromatographic (HPLC) method (HPLC-UV; Waters).

A standard buffer solution at a pH score of 4, 7, and 9.2 was employed when measuring pH, with measurements occurring at 25 ± 1 °C. Thermal analysis was performed by drying uncoated and coated miconazole-loaded nanoparticles at 25 °C and then keeping the nanoparticles in a dissector for 7 days.

Uncoated and coated nanoparticles

underwent in vitro miconazole release for 96 hours under sink conditions. The HPLC method was used to measure the release of miconazole from nanoparticles.

A higher PCL mass led to nanoparticles with a diameter of 300 to 400 nm. A higher polymer mass also caused higher polydispersity indexes.

Lower-diameter polydispersity index and zeta potential values were seen in nanosystems of a 25.9-mg PCL mass. Uncoated miconazole-loaded nanoparticles made with both drug concentrations and a lower PCL mass had a diameter of 200 nm.

A higher level of HA was associated with augmentation of diameter and polydispersity index. Because this risked affecting the formulation's physiochemical stability, only miconazole-loaded nanoparticles coated with 0.25% w/v HA were used for the remainder of the study. When presenting pH measurements, investigators wrote, "The pH of uncoated miconazole-loaded nanoparticles and miconazole-loaded nanoparticles [with] HA in suspension was 4.64 ± 0.03 and 3.06 ± 0.01, respectively."

Nanoparticles released about 36% of miconazole at 6 hours, 55% at 12 hours, and 100% at 72 hours. When evaluating the in vitro fungicidal activity against the *C albicans* of uncoated miconazole-loaded nanoparticles, significant increases in inhibition zones induced by the pure drug were found compared with those gathered from nanosystems in all concentrations.

These results indicated efficacy from miconazole-loaded nanoparticles with HA in managing VVC. Miconazole-loaded nanoparticles with HA may be effective as alternative local management for VVC and RVVC. ■

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Insurance coverage and postpartum care for immigrants

by **BOB KRONEMYER**

Immigrants in states that restrict public insurance coverage for undocumented and recent immigrants are less likely to receive postpartum care compared with immigrants in states without such restrictions, according to a cross-sectional analysis published in the *Journal of the American Medical Association*.

The analysis used data from the Pregnancy Risk Assessment Monitoring System (PRAMS) for 19 states and New York, New York, comprising 72,981 adults with low income who had a live birth between 2012 and 2019. Overall, 29% of these adults were immigrants and 71% were not.

States were divided into 3 categories of insurance coverage: full coverage (publicly funded postpartum care, regardless of immigration status), moderate coverage (publicly funded postpartum care to lawfully residing immigrants without a 5-year waiting period but no postpartum care to undocumented immigrants), and no coverage (no publicly funded postpartum care to lawfully present immigrants before 5 years of legal residence or to undocumented immigrants). Among the 19 states and New York City, 6 offered full coverage, 9 offered moderate coverage, and 4 offered no coverage. The remaining state, Oregon, converted from moderate coverage to full coverage during the study period.

Compared with states that offered full insurance coverage, receipt of postpartum care among immigrants was 7% lower in states that offered moderate

Compared with states that offered full insurance coverage, receipt of postpartum care among immigrants was 7% lower in states that offered moderate coverage and 11.3% lower in states that offered no coverage.

coverage and 11.3% lower in states that offered no coverage. Similarly, there was a 3.3 percentage point larger difference between immigrants and nonimmigrants in states that provided moderate coverage and a 7.7 percentage point larger difference in states that provided no coverage.

Neither principal investigator Maria Steenland, ScD, nor Laura Wherry, PhD, the major coresearcher on the study, are surprised by the findings. Steenland is an assistant professor of health services, policy, and practice at Brown University in Providence, Rhode Island, and Wherry is an associate professor of economics and public service at Robert F. Wagner Graduate School of Public Service at New York University in New York City. "[Findings from] most other studies have found that having insurance coverage is associated with increased health service use," Steenland told *Contemporary OB/GYN*.

Steenland noted that the size of the difference between states with the most and least restrictive policies was roughly 11 percentage points, "which is large, but not a huge difference. However, we compared all immigrants between state coverage categories, including both immigrants who would be affected by the policies—undocumented immigrants and legal permanent residents with fewer than 5 years with this status—and other immigrants who might be citizens or long-term permanent residents. Because some people in our study population would not be impacted by the policies, we knew that our findings were likely to be attenuated."

STATES THAT HAVE EXTENDED POSTPARTUM COVERAGE REGARDLESS OF IMMIGRATION STATUS:


California


Illinois


Maryland


Massachusetts


Minnesota


Rhode Island


Washington

Reduced access to postpartum care for immigrants may decrease diagnosis and management of postpartum depression and other common causes of postpartum morbidity, according to Steenland. "Limited postpartum care could also result in less well-controlled diabetes and hypertension, [because] the postpartum visit is used to identify and refer patients for ongoing chronic disease care," she said. "Missed opportunities for the…management of chronic health conditions could have important implications for the long-term health of these immigrant parents and birth outcomes for any future pregnancies."

On the other hand, several states have recently extended Medicaid pregnancy coverage from 60 days postpartum to 12 months postpartum. "Although many immigrants are covered under this extension, undocumented postpartum immigrants will not be eligible in most states," Steenland said.

To date, 7 states (California, Illinois, Maryland, Massachusetts, Minnesota, Rhode Island, and Washington) have extended postpartum coverage regardless of immigration status. "In other states, excluding undocumented immigrants from the 12-month extension will likely exacerbate existing disparities in insurance coverage and health care access between US-born and undocumented individuals," Steenland said. ■

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Vaginal estrogen is effective against recurrent UTIs

by CELESTE KREWSON, ASSISTANT EDITOR

Vaginal estrogen is effective in preventing recurrent urinary tract infections (UTIs) in women with hypoestrogenism, according to a recent study published in the *American Journal of Obstetrics & Gynecology*.

Over 60% of women are impacted by UTIs in their lives, with health care costs reaching over $2 billion per year in the United States. Breakthrough infections, even while on active antibiotic suppression, are reported in 70% to 80% of recurrent UTI cases.

In women with hypoestrogenism, vaginal estrogen is considered the standard of care for preventing recurrent UTIs. However, the literature supporting vaginal estrogen use in this context is limited to small clinical trials, with the most common cited trial using a form of estrogen not available in the United States.

Investigators conducted a multicenter, retrospective cohort study to evaluate the association between vaginal estrogen and recurrent UTI. The study was conducted within Kaiser Permanente Southern California (KPSC), a large managed care organization with laboratory and pharmacy facilities.

Participants included women aged 18 years and older with a recurrent UTI diagnosis and a vaginal estrogen prescription given from January 1, 2009, to December 31, 2019. As vaginal estrogen is often prescribed to patients with vulvovaginal atrophy from estrogen deficiency, patients given vaginal estrogen for recurrent UTIs were considered to be hypoestrogenic.

As age or menopause diagnosis restrictions were not used in the study, women with other causes of estrogen deficiency such as oophorectomy, breastfeeding, suppression of the hypothalamic-pituitary-ovarian axis, or ovarian insufficiency were also included. Recurrent UTI was defined as 3 or more positive urine cultures within the 12 months before being prescribed vaginal estrogen.

Pharmacy databases were consulted for vaginal estrogen prescription information, with all forms of vaginal estrogen included. Exclusion criteria included not completing the initial vaginal estrogen prescriptions, using vaginal contraceptive hormones, not having continuous KPSC membership in the year before and after the index prescription date, and having a diagnosis which led to exclusion.

UTI frequency in the 12 months after index vaginal estrogen prescription was measured as the primary outcome of the study. A positive urine culture was defined by 1000 colony-forming units or more per milliliter in at least 1 uropathogen. A separation of 14 days between positive urine cultures was used to measure distinct events.

The frequency of postprescription UTIs was measured as the secondary outcome, compared between women adherent and nonadherent to vaginal estrogen application. Adherence was measured using the number of vaginal estrogen refills, with low adherence considered no refills, moderate adherence considered 1 refill, and high adherence considered 2 or more refills.

There were 5638 women in the final analysis, aged a mean 70.4 years. Urinary incontinence was the most common comorbidity in 40.1% of patients, followed by diabetes in 30.8%. An average 3.9 UTI episodes in the year before vaginal estrogen prescription were seen at baseline. This was reduced to 1.8 following the index prescription, decreasing by 51.9%.

> In women with hypoestrogenism, vaginal estrogen is considered the standard of care for preventing recurrent UTIs.

An association was found between the magnitude of UTI recurrence reduction and treatment adherence. One or less UTI experience in the 12 months following the index prescription was reported in 55.3% of women, and no UTI experiences in 31.4%. A decrease in the mean UTI frequency was observed across the 12 months.

Overall, these results indicated reduced rates of recurrent UTI following the use of vaginal estrogen. Investigators concluded this study supports the use of vaginal estrogen to treat women with recurrent UTIs. ■

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Infertility, miscarriage, and stillbirth increase early menopause risk

by CELESTE KREWSON, ASSISTANT EDITOR

According to findings from a recent study published in the *American Journal of Obstetrics & Gynecology*, infertility or miscarriage history increases risk of premature and early menopause.

Menopause begins at an average age of 51 years in White women and 48 to 49 years in Asian women, with menopause before the age of 40 years defined as premature menopause and menopause between the ages of 40 and 45 years defined as early menopause. Increased risk of menopause symptoms and noncommunicable diseases is seen in women with premature or early menopause.

Reproductive and health factors have been linked to age at natural menopause, but there are few data on how stillbirth, infertility, and miscarriage affect premature and early menopause. Because these reproductive outcomes are associated with shifts in sex hormones, they may affect age at menopause.

Early and premature menopause are more common in Asian women, making it possible there are differences in the associations of reproductive outcomes with age at menopause based on race. Investigators conducted a study to determine the associations of infertility, miscarriage, and stillbirth with age at natural menopause and whether these associations differ by race.

The study, known as InterLACE, pooled 27 observational studies from 12 countries with more than 850,000 women. Of the studies, 9 had data on at least 1 reproductive history and age at menopause. Seven of the studies recruited women at midlife, whereas the other 2 studies recruited women at birth. Studies were conducted between 1990 and 2010.

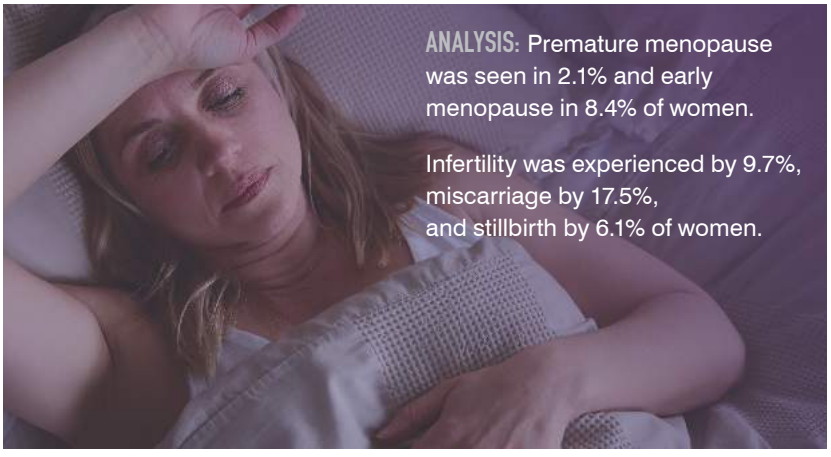
Study entry was defined as baseline in most studies. Participants included women who experienced natural menopause, with data on at least 1 reproductive history, possible confounders, and age at menopause available.

Baseline and follow-up questionnaires were used to gather data on infertility, stillbirth, and miscarriage. Infertility was determined by a lack of successful pregnancy after 12 months of regular, unprotected intercourse. Consolation, diagnosis, or treatment for infertility were also used to determine infertility.

Miscarriages and stillbirths were categorized by the number experienced. Categories included 0, 1, 2, and 3 or more. Recurrent miscarriages were defined as 3 or more, whereas recurrent stillbirths were defined as 2 or more.

Surveys were used to collect data on age at natural menopause, with categories including less than 40 years, 40 to 44 years, 45 to 49 years, 50 to 51 years, and 52 or more years. Baseline characteristics collected included education level, smoking status, race and ethnicity, alcohol intake, age at menarche, body mass index, and number of children.

There were 303,594 postmenopausal women included in the analysis, with a median age at natural menopause of 50 years. Premature menopause was seen in 2.1% of women and early



ANALYSIS: Premature menopause was seen in 2.1% and early menopause in 8.4% of women.

Infertility was experienced by 9.7%, miscarriage by 17.5%, and stillbirth by 6.1% of women.

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menopause in 8.4%. Infertility was experienced by 9.7% of women, miscarriage by 17.5%, and stillbirth by 6.1%.

Women without reproductive history data were excluded from the analysis. These included 13.8% of women for infertility, 3.9% for miscarriage, and 2.8% for stillbirth.

Higher risks of premature menopause and early menopause were seen in women with a history of infertility. Asian women with infertility had a definitive increased risk of premature menopause and possible increased risk of early menopause compared with White women with infertility.

Premature and early menopause risks also increased based on the number of miscarriages a woman experienced. Higher risks were seen in Asian women with miscarriage, especially those with recurrent miscarriages, compared with non-Asian women with an equal number of miscarriages.

A history of stillbirth, especially recurrent stillbirths, also increased premature and early menopause risks. Asian women were at increased risk of premature and early menopause compared with non-Asian women with an equal number of stillbirths.

These results indicated increased risk of premature and early menopause in women with a history of infertility, miscarriage, or stillbirth, with risk increased further in Asian women. Investigators recommended further studies on the causes of infertility or pregnancy loss be conducted. ■

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Breast cancer treatment increases biological aging

by **CELESTE KREWSON, ASSISTANT EDITOR**

According to findings from a recent study published by the National Institutes of Health, women receiving a diagnosis of and treatment for breast cancer may experience increased biological aging.

Cell and tissue health are affected by biological aging, which is separate from chronological aging. The National Institute of Environmental Health Sciences (NIEHS) conducted the Sister Study (NCT00047970) to determine environmental risk factors associated with breast cancer and other biological conditions.

All 3 clocks indicated increased aging rates in women with a breast cancer diagnosis.

Participants were selected to have blood samples collected for measuring biological age. Investigators collected blood samples from 417 women at 2 time points separated by approximately 8 years. Of all participants, about half were recruited because of breast cancer development during the 8-year period.

Three methylation clocks were used to measure changes in biological age by evaluating natural chemical modifications to an individual's DNA. These were referred to as methylation changes. All 3 clocks indicated increased aging rates in women with a breast cancer diagnosis. No differences by race were reported.

Variations in aging rates were seen based on treatment type, indicating breast cancer development is not responsible for faster aging. Methods of breast cancer treatment include radiation therapy, chemotherapy, endocrine therapy, and surgery.

Radiation was the treatment method with the strongest associations with increased aging. According to Jack Taylor, MD, PhD, emeritus scientist at NIEHS and senior author of the paper, aging increases may be identified years after treatment.

Because radiation is a current effective method of breast cancer treatment, investigators urged women not to discard this option. Katie O'Brien, PhD, scientist in the NIEHS Epidemiology Branch and coauthor of the paper, recommended that women discuss all potential treatment methods with their physicians to determine which is best for them.

"Radiation is a valuable treatment option for breast cancer, and we don't yet know why it was most strongly associated with biological age," Dale Sandler, PhD, chief of the NIEHS Epidemiology Branch and coauthor of the paper, said. "This finding supports efforts to minimize radiation exposures when possible and to find ways to mitigate adverse health effects." ■

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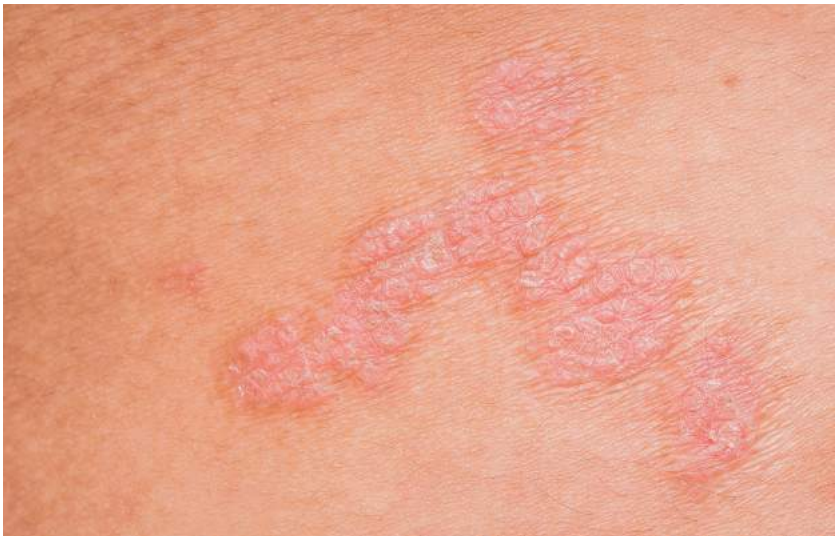
Curbside Consults features unique case reports from outside the obstetrics-gynecology specialty to provide insight into various health issues affecting women. This section is the brainchild of Editorial Advisory Board member Christine Isaacs, MD.

Sex differences in dermatologic conditions

by BERNARD COHEN, MD, FAAD, SOD, AAP; AND YAZMEEN TEMBUNDE



Editor's Note: This is part 1 of a series of articles on sex differences in dermatology. The next part will appear in the October/November 2023 issue of Contemporary OB/GYN.

INTRODUCTION Several dermatologic conditions have notable differences between the sexes in terms of prevalence and manifestation. For example, autoimmune dermatoses, pigmentary disorders, and hair disorders occur more often in female individuals, whereas predominance of infectious and malignant skin diseases is seen in male individuals.[1] Female individuals are more commonly affected by skin diseases in general.[2] The reasons for these differences have yet to be determined and are likely complex, with factors such as hormones, genetics, skin physiology, and lifestyle playing a part.[1,3] In this first part of our series, we discuss differences between the sexes in the manifestation of atopic dermatitis and psoriasis.

Atopic dermatitis

Atopic dermatitis (AD) is the most common chronic inflammatory skin condition, characterized by impairment of the skin barrier and pruritus.[4] Results from a study of patients older than 15 years with AD found no significant differences in AD duration or disease severity between male and female patients; however, female patients reported AD more frequently than male patients in all anatomical locations except the feet.[5] The greatest difference between male and female patients was AD being located in the usually visible areas of the head, neck, and hands; 78.3% of female patients reported that AD was present in these areas compared with 55.7% of male patients.[5] AD located in the areas that

Yazmeen Tembunde is a medical student at the University of Maryland School of Medicine in Baltimore.

Bernard Cohen, MD, FAAD, SOD, AAP, is a professor of pediatrics and dermatology at Johns Hopkins School of Medicine in Baltimore, Maryland.

are usually visible (head, neck, and hands) led to decreased quality of life in female patients more than in male patients.[5] There was a significant positive correlation between AD severity in female patients and impact on their quality of life but no such correlation in male patients.[5] These data show that visible areas of AD may have a more significant impact on female individuals compared with male individuals.

Results from a study on hand eczema found that women and men had no differences on the Hand Eczema Severity Index.[6] However, compared with men, it appeared that women had more variability in severity.[6] AD severity has been shown to increase with age in both men and women.[6,7] Women had a statistically significant higher mean score for burden of disease.[6] They also reported more itching and eczema-related fatigue than men, which may contribute to their higher scores for burden of disease.[6] Additionally, results from another study found that women with hand eczema had higher levels of anxiety than men ($P = .029$).[8]

Although no sex differences in eczema prevalence have been found in newborns,[9-11] the prevalence of AD is moderately higher in boys than in girls during early childhood.[12] This sexual difference is later reversed, with a higher prevalence of eczema in girls compared with boys in the preschool ages all the way to adolescence.[12-15] In addition to differences in sexual hormones, gender differences in indoor vs outdoor activity may be related to these findings. Girls have been found to play indoors more than boys,[16] and the prevalence of eczema is nearly twice as much in children who play more indoors than outdoors.[17,18] Within children aged 5 to 7 years, it has been shown that girls have a higher skin surface pH and decreased stratum corneum hydration compared with boys,[16] both of which are factors associated with an increased tendency for children to develop acute atopic eczematous lesions.[19]

> Female individuals are more commonly affected by skin diseases in general.[2]

Compared with girls, boys have eczema and concomitant respiratory allergies more often.[20] In contrast, nonatopic eczema, characterized by a low level of total IgE and undetectable specific IgE antibodies,[20,21] is present twice as often in girls compared with boys (5.9% vs 3.1%).[18]

Psoriasis

Psoriasis is a chronic inflammatory condition that can affect the skin, nails, and joints. The prevalence of psoriasis for US adults is estimated to be 3.2%, and prevalence is similar in men and women.[22] Findings from studies have shown that severe forms of psoriasis are more common in men compared with women after controlling for various possible confounders.[23,24] Results from a large Swedish cross-sectional study of 5438 patients with moderate to severe psoriasis found that across all ages, men had a higher median Psoriasis Area and Severity Index (PASI) score compared with women (7.3 vs 5.4; $P < .001$).[24] Women had significantly lower PASI scores than men in every body location except the head, where PASI scores were equal for women and men.[24] Results from a Swiss study that included 1979 patients with psoriasis found that more female patients were affected by psoriatic pruritus than male patients (36% vs 25.3%; $P < .001$).[25] Pruritus was identified by 39.7% of patients with psoriasis as the most quality of life–limiting or bothersome factor of their disease.[25]

Genital psoriasis can cause significant physical and emotional distress as well as negative impacts on quality of life and sexual health.[26,27] Anywhere from 33% to 63% of patients with psoriasis experience genital psoriasis during their disease course.[26] Results from a cross-sectional study conducted in Germany found that genital psoriasis was more prevalent in men compared with women (65.0% vs 52.5%; $P = .021$).[27] In results from another study, the scrotum was found to be the most common genital area involved in male patients and the labia majora was the most common genital area involved in female patients.[28] Findings from studies show that male sex, increased psoriasis severity, increased disease duration, and involvement of the scalp, flexure surfaces, and nails were associated with genital psoriasis.[28,29]

Results from most studies have found no gender bias in pediatric psoriasis.[30,31] The median age of diagnosis in children has been reported to be 10 to 11 years, with no significant difference between male patients and

TAKE-AWAYS

- Between the sexes, differences exist in the prevalence and manifestation of dermatologic conditions.
- The reasons for differences between sexes in dermatologic conditions have yet to be determined and are likely complex, with factors such as hormones, genetics, skin physiology, and lifestyle playing a part.
- Patient care should not drastically change simply because of a patient's gender; it should be tailored to each patient's specific needs.
- Many of the studies reviewed in this article were not randomized, controlled clinical trials; thus, findings may not be readily generalizable.
- Further investigation of sex-specific differences in dermatologic conditions and their causes is needed.

female patients.[30,32,33] Findings from studies have shown that among pediatric patients with psoriasis, 17% to 29% have nail involvement and 18% to 50% have scalp involvement.[30,34-36] Results from a multicenter, cross-sectional study found that nail psoriasis was significantly more common in boys and scalp involvement was significantly more common in girls.[37]

Conclusion

Our review of the literature has identified sex differences in some common dermatologic conditions that can help inform future patient care decisions. Nonetheless, patient care should not drastically change simply because of a patient's sex. Management of these conditions should be tailored to each individual patient's specific needs. Many of the studies reviewed were not randomized, controlled clinical trials; thus, findings may not be readily generalizable. Further investigation of sex-specific differences in dermatologic conditions and their causes is needed. ■

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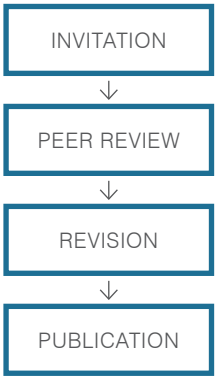


by HINDI STOHL, MD, JD; AND JIM M. SHWAYDER, MD, JD

Documentation saves the day

The case

A 29-year-old gravida 5, para 4 patient presented for her first prenatal visit at 10 weeks by her last menstrual period (LMP). She had a history of 4 prior vaginal deliveries: 3 were full-term and uncomplicated, and 1 was at 36 weeks in the setting of a stillborn fetus with trisomy 18 and multiple fetal anomalies. Her last pregnancy was notable for gestational hypertension but otherwise her pregnancies and deliveries were uncomplicated.

Her medical history was notable for migraine headaches with aura and varicose veins in the left leg. She had no history of hypertension (aside from the gestational hypertension noted above) and no history of diabetes inside or outside of pregnancy. She denied having a history of blood clots, including no family history. She had used oral contraceptives prior to the current pregnancy without incidence. She was a nonsmoker. Her body mass index was 45 kg/m^2.

At her first prenatal visit at 9 weeks and 4 days of gestation, she noted some morning nausea but was able to tolerate food without difficulty. On review of systems, she reported no difficulty sleeping and no shortness of breath. She had no recent travel or long car rides and was able to climb stairs as she had before. However, she did note that her activity level was decreased because of her morning sickness, and she would remain in bed for several hours. She also complained of worsening pain in her legs, noting that although she has had long-standing varicose veins that made it difficult to walk, stand or put pressure on her legs, her symptoms on the left leg worsened significantly the day before. She described having a "shooting pain up and down" her left leg.

On physical examination, the patient was in no acute distress. She

DC STUDIO@STOCK.ADOBE.COM

Hindi Stohl, MD, JD, is director of the Division of Maternal Fetal Medicine and associate residency program director in the Department of Obstetrics and Gynecology at Harbor-UCLA Medical Center and clinical assistant professor at the UCLA David Geffen School of Medicine. She also chairs her hospital's Medicolegal Committee and serves as a medicolegal expert witness and consultant.

Jim M. Shwayder, MD, JD, is an adjunct professor at the University of Florida at Gainesville Medical Center. A recognized expert in gynecology ultrasound and minimally invasive surgery, he consults on legal matters in medicine, including liability in ultrasound and gynecologic surgery and issues surrounding privileging and insurance fraud.

was speaking in full sentences and did not have labored breathing. Her vital signs were within normal limits, with a blood pressure of 116/64 mm Hg and a heart rate of 76 beats per minute (bpm). She weighed 273 lbs. Her heart had a regular rate and rhythm, her abdomen was soft and nontender, and her lungs were clear bilaterally. Her pelvic exam was normal, noting an appropriately enlarged uterus. Examination of her extremities noted swelling of both legs, the left greater than the right. No erythema was noted, and no palpable cords could be appreciated.

A bedside transvaginal ultrasound was notable for an intrauterine pregnancy. Crown-rump length measured 9 weeks and 4 days, corroborating the gestational age by her LMP. Fetal heart tones were noted in the 150s, and no maternal adnexal masses were seen.

The patient was given prenatal education packets as well as an order for her prenatal labs, and a formal first trimester ultrasound. Because of the patient's symptoms and her leg edema on exam, she was also given an order for an urgent lower extremity ultrasound with Doppler. The provider's documentation included a differential diagnosis for causes of her symptoms and physical exam findings, including potential next management steps if the Doppler ultrasound of the leg was within normal limits.

The patient had her labs drawn in the laboratory on the first floor of the clinic and then proceeded out of the clinic building. While walking across the parking lot to the hospital to have her lower extremity ultrasound, she started feeling unwell and sat on a bench on the sidewalk. She then sustained a witnessed fall from the bench and 911 was called by bystanders on the street.

On arrival, paramedics noted she was initially unconscious. Her heart rate was 131 bpm and oxygen saturation was 75% on ambient air. Blood pressure was not able to be obtained and the patient was noted to have weak radial pulses but good pulses in the carotids. Intravenous access for fluids was established, an oxygen mask secured, and the patient regained consciousness. Her blood pressure was 166/122 mm Hg and heart rate was 153 bpm. The patient was taken emergently across the street to the hospital emergency department (ED).

In the ED, the patient complained of difficulty breathing and abdominal pain. She was very agitated and unable to follow complete commands. She described feeling dizzy and nauseated before sitting on the sidewalk bench but could not recall falling or the 911 response. She was on supplemental oxygen but was grabbing at the mask because of her agitated state.

Vital signs were notable for a blood pressure of 172/99 mm Hg and a heart rate of 160 bpm. Oxygen saturation was 90% on a nonrebreather face mask. Physical examination revealed labored but symmetric breathing, with clear lungs bilaterally to auscultation. The heart exam revealed a regular rhythm without extra heart sounds. Radial and femoral pulses were both weak. The patient was able to move all extremities. Lower extremities were notable for edema with left greater than right. A bedside ultrasound demonstrated no free fluid in the abdomen and an early intrauterine pregnancy was confirmed. Ultrasound of the lower extremities was planned.

A femoral line was placed, and labs were drawn. Shortly thereafter the patient became unresponsive and was noted to be grinding her teeth and biting her lip. Her pupils became fixed and dilated. Blood pressure at this point was 148/106 mm Hg and heart rate was 54 bpm. She was immediately intubated, and her airway was secured.

Within minutes, she went into pulseless electrical activity (PEA) cardiopulmonary arrest. Cardiopulmonary resuscitation (CPR) was initiated. Differential diagnosis at this point was a pulmonary embolism, intracranial hemorrhage, seizure, toxidrome, or unknown cause. Ultrasound of lower extremity revealed a superficial venous thrombus. The deep venous system could not be fully evaluated. Tissue plasminogen activator (tPA) was given as pulmonary embolism (PE) was presumed more likely than an intracranial bleed. Despite maximal efforts at resuscitation, the patient continued in PEA arrest, and she

On arrival, paramedics noted she was initially unconscious. Her heart rate was 131 bpm and oxygen saturation was 75% on ambient air.

was pronounced dead after 50 minutes of CPR. On autopsy, a PE of the main right pulmonary artery was found to be the cause of death.

Review

This case was reviewed by a medical expert for the plaintiff. Critical documentation during her prenatal visit noted several risk factors for venous thromboembolism. Her providers considered deep venous thrombosis in their differential diagnosis, ordering an urgent lower extremity ultrasound with Doppler. Her obstetrician documented that her status was stable, such that emergent transfer to the ED was not required. The obstetrician was unaware that the patient had become unresponsive outside of their clinic building.

Documentation and response by the ED physicians, particularly noting the acute change in her status, were appropriate. It was noted that thorough documentation occurred shortly after the patient was pronounced dead, which was considered appropriate under the circumstances.

After an extensive review it was determined that, although this was a tragic outcome of an infrequent, but very morbid condition, the documented care met the applicable standard of care. As such, a medical negligence suit was not filed.

> On arrival, paramedics noted she was initially unconscious. Her heart rate was 131 bpm and oxygen saturation was 75% on ambient air.

Discussion

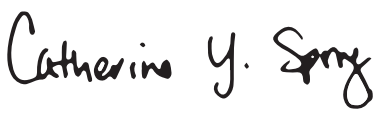
The lack of adequate and appropriate documentation is often cited as a root cause for medical malpractice actions. This case demonstrates how appropriate documentation avoided a negligence suit. Documentation included the pertinent historical and clinical information, and there was a complete and thoughtful physical examination with an appropriate differential diagnosis, including the actual diagnosis. Appropriate laboratory and imaging tests were ordered in a timely manner. Response at the ED was appropriate, administered in a timely and competent manner, with appropriate documentation. As such, the reviewer concluded that the providers acted reasonably under the circumstances and within the applicable standard of care. Documentation that is less complete and timely could have resulted in an allegation that the patient's complaints were not taken seriously or that the acuity of her condition was not recognized, with a subsequent delay in care resulting in the patient's death. The documentation addressed these concerns.

It was noted that the ED providers' documentation primarily occurred after the patient succumbed. Noting the acuity of the situation and the patient's in extremis status, documentation shortly after the event was acceptable. Timely documentation is critical in appropriate patient care and in avoidance of subsequent suit when there are adverse outcomes. It is also recommended that physicians and providers debrief with the nursing and support staff after an acute event, assuring consistent documentation by all involved parties. ■

EDITORIAL CONTINUED FROM PAGE 7

causes and risk factors of stillbirth can potentially lead to preventive measures that save lives. As health care professionals, we can benefit from ongoing training and support to navigate the emotional complexities associated with stillbirth.

These recent stillbirth rates, remaining constant, underline the continued impact of stillbirth on families and providers. By acknowledging its constant presence and committing to increased awareness, support, and research, we can collectively work toward prevention and a more accepting environment for affected families and providers. ■



Catherine Y. Spong, MD, editor in chief, is professor and vice chair in the Department of Obstetrics and Gynecology and chief of the Division of Maternal-Fetal Medicine at UT Southwestern Medical Center in Dallas. She holds the Gillette Professorship of Obstetrics and Gynecology.

Email her at cspong@mjhlifesciences.com

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