VULVOVAGINAL DISEASE
Fractional CO₂ laser therapy proves effective in treating vulvovaginal atrophy

LIFE TRANSITIONS
Transdermal estrogen therapy and resistance training build muscle mass

GYNECOLOGY
Better research into reproductive health of transgender and gender diverse individuals is needed

WELL WOMAN
Two recent, consecutive mammography scans prior to breast cancer diagnosis increase survival rates
REDEFINE LONG-TERM CONTRACEPTION

MEET ANNOVERA.

ANNOVERA (segesterone acetate and ethinyl estradiol vaginal system) is the only long-lasting, reversible birth control that doesn’t require a procedure.

Empower her to be in control of her fertility and menstruation with a predictable bleeding profile.

The only hormonal birth control with a non-androgenic progestin, segesterone acetate, and 13 mcg of ethinyl estradiol—making it one of the lowest dose combination hormonal contraceptives on the market.

97.3% effective and high patient satisfaction: ~90% of women in the clinical trial were satisfied with ANNOVERA.

IMPORTANT SAFETY INFORMATION

WARNING: CIGARETTE SMOKING AND SERIOUS CARDIOVASCULAR EVENTS

See full prescribing information for complete boxed warning.

- Females over 35 years old who smoke should not use ANNOVERA.
- Cigarette smoking increases the risk of serious cardiovascular events from combination hormonal contraceptive use.

CONTRAINDICATIONS

ANNOVERA (segesterone acetate and ethinyl estradiol vaginal system) is contraindicated and should not be used in women with a high risk of arterial or venous thrombotic diseases; current or history of breast cancer or other estrogen- or progestin-sensitive cancer; liver tumors, acute hepatitis, or severe (decompensated) cirrhosis; undiagnosed abnormal uterine bleeding; hypersensitivity to any of the components of ANNOVERA; and use of Hepatitis C drug combinations containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir.

WARNINGS AND PRECAUTIONS

- Stop ANNOVERA if a thrombotic or thromboembolic event occurs, and at least 4 weeks before and through 2 weeks after major surgery. Start ANNOVERA no earlier than 4 weeks after delivery, in females who are not breastfeeding. Consider cardiovascular risk factors before initiating in all females, particularly those over 35 years.
- Discontinue if jaundice occurs.
- Stop ANNOVERA prior to starting therapy with the combination drug regimen ombitasvir/paritaprevir/ritonavir: ANNOVERA can be restarted 2 weeks following completion of this regimen.
- Do not prescribe ANNOVERA for females with uncontrolled hypertension or hypertension with vascular disease. Monitor blood pressure and stop use if blood pressure rises significantly in females with well-controlled hypertension.
- Monitor glucose in pre-diabetic or diabetic females taking ANNOVERA. Consider an alternate contraceptive method for females with uncontrolled dyslipidemias.
- Patients using ANNOVERA who have a significant change in headaches or irregular bleeding or amenorrhea should be evaluated. ANNOVERA should be discontinued if indicated.
- Other warnings include: gallbladder disease; depression; cervical cancer; increased serum concentrations of binding globulins; hereditary angioedema; chloasma (females who tend
to develop chloasma should avoid exposure to the sun or UV radiation while using ANNOVERA; toxic shock syndrome (TSS) (if a patient exhibits symptoms of TSS, remove ANNOVERA, and initiate appropriate medical treatment); vaginal use (ANNOVERA may not be suitable for females with conditions that make the vagina more susceptible to vaginal irritation or ulceration).

ADVERSE REACTIONS
The most common adverse reactions reported in at least 5% of women who received ANNOVERA were: headache/migraine, nausea/vomiting, vulvovaginal mycotic infection/candidiasis, lower/upper abdominal pain, dysmenorrhea, vaginal discharge, urinary tract infection, breast pain/tenderness/discomfort, bleeding irregularities including metrorrhagia, diarrhea, and genital pruritus.

DRUG INTERACTIONS
Drugs or herbal products that induce certain enzymes, including CYP3A4, may decrease the effectiveness of ANNOVERA or increase breakthrough bleeding. Counsel patients to use a back-up or alternative method of contraception when enzyme inducers are used with ANNOVERA.

INDICATION
ANNOVERA is a progestin/estrogen combination hormonal contraceptive indicated for use by females of reproductive potential to prevent pregnancy.

Limitations of Use: ANNOVERA has not been adequately studied in females with a body mass index >29 kg/m².

Please note this information is not comprehensive. Please see Brief Summary of the Full Prescribing Information on the next page, including BOXED WARNING, or visit Annovera.com/pi.pdf.


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ANNOVERA-201423 12/2020
ANNOVERA® (segesterone acetate and ethinyl estradiol vaginal system)

BRIEF SUMMARY OF PRESCRIBING INFORMATION

This Brief Summary does not include all the information needed to use ANNOVERA safely and effectively. Please read ANNOVERA.com/mx.pdf for Full Prescribing Information (PI).

**WARNING:** CIGARETTE SMOKING AND SERIOUS CARDIOVASCULAR EVENTS

Cigarette smoking increases the risk of serious cardiovascular events from combination hormonal contraceptive use. This risk increases with age, particularly in females over 35 years of age, and with the number of cigarettes smoked. For this reason, CHCs should not be used by females who are over 35 years of age and smoke.

INDICATIONS AND USAGE

ANNOVERA is indicated for use by females of reproductive potential to prevent pregnancy.

Limitations of Use: ANNOVERA has not been adequately studied in females with a BMI >29 kg/m².

DOSAGE AND ADMINISTRATION

One vaginal system is inserted in the vagina. The vaginal system must remain in place continuously for 21 days (1 cycle) followed by a 1-week (7-day) vaginal system-free interval. One vaginal system provides contraception for 28 days (1 cycle).

**INDICATIONS AND USAGE**

Females are at increased risk for a venous thrombotic event (VTE) when using ANNOVERA.

ANNOVERA is contraindicated in females who are known to have a high risk of arterial or venous thrombotic disease. Some conditions associated with an increased risk of arterial or venous thrombotic disease are summarized in Table 2.

ANNOVERA is contraindicated in females with a history of deep vein thrombosis or pulmonary embolism; have cerebrovascular disease, have coronary artery disease; have thrombocytopenia or thrombocytopenic purpura, other bleeding disorders, or bleeding disorders associated with drugs, antithrombotic therapy, or systemic lupus erythematosus.

ANNOVERA is contraindicated in females with a history of stroke and myocardial infarction. The risk is greater among females who are over age 35, diabetes mellitus with hypertension or vascular disease; have diabetes mellitus and hypertension; and females who are taking ANNOVERA.

ANNOVERA is contraindicated in females who are known to have a high risk of arterial or venous thrombotic disease (including females with a history of deep vein thrombosis or pulmonary embolism).

ANNOVERA is not indicated for use in women who are pregnant or breastfeeding.

**DRUG INTERACTIONS**

No studies were conducted in subjects with renal impairment; Renal Impairment on the disposition of ANNOVERA. Acute or chronic renal impairment on the disposition of ANNOVERA.

**CONTRAINDICATIONS**

ANNOVERA is contraindicated in females who are known to have the following conditions:

- A high risk of arterial or venous thrombotic disease. Examples include females who are known to be smokers, aged ≥35 years, have a history of deep vein thrombosis or pulmonary embolism; have cerebrovascular disease, have coronary artery disease; have thrombocytopenia or thrombocytopenic purpura, other bleeding disorders, or bleeding disorders associated with drugs, antithrombotic therapy, or systemic lupus erythematosus.

- Thromboembolic Disorders and Other Vascular Conditions

- Females are at increased risk for a venous thrombotic event (VTE) when using ANNOVERA.

- One vaginal system provides contraception for thirteen 28-day cycles (1 year).

- Follow the recommended use after abortion, miscarriage, or childbirth

- Females are at increased risk for a venous thrombotic event (VTE) when using ANNOVERA.

- One ANNOVERA is inserted in the vagina. The vaginal system is used continuously for 21 days, followed by a 7-day system-free interval.

- Use of contraceptive vaginal devices. In some cases, the ring is associated with lower systemic exposure of SA and EE.

- Cardiovascular Events

- Females are at increased risk for a venous thrombotic event (VTE) when using ANNOVERA.

- Females who are not pregnant and use ANNOVERA may experience unscheduled bleeding and breakthrough bleeding.

- Metrorrhagia, menorrhagia, and abnormal withdrawal bleeding. Based on subject diaries from the two clinical efficacy trials of ANNOVERA, 5–10% of females experienced unscheduled bleeding.

- Metrorrhagia, menorrhagia, and abnormal withdrawal bleeding. Based on subject diaries from the two clinical efficacy trials of ANNOVERA, 5–10% of females experienced unscheduled bleeding.

- Hyperglycemia

- Females using ANNOVERA may experience unexplained breakthrough bleeding and/or breakthrough bleeding, especially during the first month of use. If unscheduled bleeding occurs or persists, check for causes such as pregnancy or malignancy. Based on subject diaries from the two clinical efficacy trials of ANNOVERA, 5–10% of females experienced unscheduled bleeding per 28-day cycle. A total of 41 subjects (1.7%) discontinued use due to menstrual disorders including menorrhagia, menometrorrhagia, and abnormal withdrawal bleeding.

- Females who use ANNOVERA may experience amenorrhea. Based on subject diary data from two clinical trials for up to 13 cycles, amenorrhea occurred in ≥3–5% of females per cycle using ANNOVERA and in <0.9% of females in all 13 cycles. If scheduled bleeding does not occur, consider the possibility of pregnancy.

- Depression

- Carefully observe females with a history of depression and discontinue ANNOVERA if depression recurs to a serious degree.

- Cerebral Cancers

- Some studies suggest that CHCs are associated with an increase in the risk of cerebral cancer or intracranial neoplasm.

- Effect on Birth Defects

- The estrogen component of ANNOVERA may raise the serum concentrations of thyroxine-binding globulin, sex hormone-binding globulin, and serum cholesterol. The dose replacement thyroid hormone or cortisol therapy may need to be increased.

- Hereditary Angiodyplasia

- Females with the hereditary angiodyplasia, exogenous estrogens may induce or exacerbate symptoms of angiodyplasia.

- Chloasma

- Chloasma may occur with ANNOVERA use, especially in females with a history of chloasma gravidarum. Advise females who tend to develop chloasma to avoid exposure to the sun or ultraviolet radiation while using ANNOVERA.

**ADVERSE REACTIONS**

**Clinical Trial Experience**

**Most Common Adverse Reactions**

The most commonly reported adverse reactions are nausea, vomiting, menstrual disorders, skin disorders, vaginitis, and breast disorders.

**Adverse Reactions Leading to Discontinuation**

Among subjects using ANNOVERA for contraception, 12% discontinued from the clinical trials due to an adverse reaction.

**Serious Adverse Reactions**

Serious adverse reactions occurring in ≥2 subjects were: VTEs (deep vein thrombosis, cerebral vein thrombosis, pulmonary embolism), drug hypersensitivity reactions, and spontaneous abortions. DRUG INTERACTIONS

Drugs or herbal products that cause certain enzymes, including CYP3A4, may decrease the effectiveness of ANNOVERA or increase breakthrough bleeding. Counsel patients to use a backup or alternative method of contraception when enzyme inducers are used with ANNOVERA. Do not co-administer ANNOVERA with HCV drug combinations containing ombitasvir/ paritaprevir/ritonavir, with or without dasabuvir, due to potential for ALT elevations.

**USE IN SPECIFIC POPULATIONS**

**Pregnancy**

Discontinue ANNOVERA if pregnancy occurs.

**Lactation**

Not recommended for nursing mothers; can decrease milk production.

**Pediatric Use**

Safety and efficacy of ANNOVERA have been established in women of reproductive age. Efficacy is expected to be the same for postpubertal adolescents under the age of 18 as for users 18 years and older. Use of ANNOVERA before menarche is not indicated.

**Geriatric Use**

ANNOVERA has not been studied in females who have reached menopause and is not indicated in this population.

**Hepatic Impairment**

No studies have been conducted to evaluate the effect of hepatic impairment on the disposition of ANNOVERA. Acute or chronic disturbances of liver function may necessitate the discontinuation of CHC use until markers of liver function return to normal and CHC causation has been excluded.

**Renal Impairment**

No studies were conducted in subjects with renal impairment; ANNOVERA is not recommended in patients with renal impairment.

**Body Mass Index (BMI)/Body Weight**

The safety and efficacy of ANNOVERA in females with a BMI >29 kg/m² have not been adequately evaluated because this subpopulation was excluded from the clinical trials after 2 VTEs occurred in females recommended a BMI > 29 to 34. Weight loss is associated with lower systemic exposure of SA and EE.

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Take Note: Lessons From a Doctor

A young general practitioner in New York was on the front lines of an epidemic that was as mysterious in its pathology as coronavirus disease 2019 (COVID-19). Some patients would develop only mild symptoms, but others would get the worst of it, ultimately succumbing to the disease, as medical professionals and other scientists rushed to understand how the disease was being spread.

The doctor was Alexander Anderson, and the epidemic was yellow fever, which plagued New York, New York, beginning in 1795 and returning in 1798. He would end up losing 8 of his relatives, including his parents and wife, to the disease, and ultimately he would leave the field of medicine to become an acclaimed engraver.

An astute writer researched the doctor’s diaries, which are housed at the Rare Book & Manuscript Library at Columbia University. The writer, Carolyn Eastman, penned an article about the diaries in the March issue of Smithsonian magazine, taking readers on a trip from the perspective of this young doctor whose life was forever changed by the experience.

We are fortunate to have such diaries to look back on, to see what our fellow humans experienced and what was learned. All of us know how profoundly life-changing the COVID-19 pandemic has been. We will be affected for years to come in ways we do not yet even realize. Yellow fever still exists in the world in parts of Africa and South America. Years from now, COVID-19 still will exist, and we will continue to learn so much from the writings of doctors who bothered to take note during this pandemic time. With today’s technologies, there are many ways to record your experiences, including voice memos, the notes function on an iPhone, or social media postings. There also is old-fashioned note-taking with a pen and paper. Anderson included drawings, and his voice and experience came alive for Eastman, more than 2 centuries later.

In this month’s issue, we are fortunate to have esteemed, peer-reviewed content from Emily H. Adhikari, MD, who writes about evaluating and managing COVID-19 during pregnancy, and the extra challenges and risks it brings. That article begins on page 20. On page 28, ob/gyns from the Albert Einstein College of Medicine in Bronx, New York, also provide insight from their experiences. Erika E. Levi, MD, MPH; Molly Findley, DO, MPH, MS; Alexandra Woodcock, MD; and June Hoi Ka Ng, MD, have written “Fresh Ideas, Workarounds During Pandemic Can Increase Access to Contraception.” Separate from the pandemic-related articles, a group of dermatologists have written about skin conditions that can afflict pregnant women. The article begins on page 10 and is part of a new series called Curbside Consults. As always, we ask that you let us know your thoughts on these articles. We appreciate reader feedback, which can be sent to us at COGeditorial@mmhgroup.com. Thank you.

Mike Hennessy Sr
Chairman and Founder, MJH Life Sciences™

**CONSORTIUM FOR WOMEN’S HEALTH EQUALITY**

**THE CONSORTIUM FOR WOMEN’S HEALTH EQUALITY** is an online resource for practicing ob/gyns who want to better understand issues around racial and gender disparities affecting themselves and their patients. Topics will be viewed through this lens and help educate ob/gyns more fully around practice management issues, including payer disparities.

The consortium is built for you and will feature articles, podcasts, and video interviews with a variety of leading thought leaders in the field. It will provide resources to important information, along with access to forms on how to appeal insurance decisions - a tool that can help you as you help your patients.
DILAPAN-S®
The versatile, non-pharmacologic option for cervical ripening¹

DILAPAN-S TODAY
for planned inductions tomorrow

Gentle enough for her to sleep through, predictable enough for you to schedule around²

Indications for Use: Dilapan-S is for use by healthcare professionals trained in OB-GYN and is for use whenever cervical softening and dilation is desired, such as cervical ripening during term labor induction or gynecological procedures that require cervical preparation.

IMPORTANT SAFETY INFORMATION
Contraindication: Dilapan-S is contraindicated in the presence of clinically apparent genital tract infection.
Warnings & Precautions: Dilapan-S is intended for single use only. Do not re-use, re-sterilize, reprocess, or use if primary packaging has been opened or damaged. Discard after use.

Please see Instructions for Use.


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* Genius Digital Diagnostics is CE-marked for diagnostic use in Europe and is not currently available for sale in the U.S. May not be available in all markets. Contact your local Hologic representative for availability in your country.

Scan with your phone
Stay in the know
Rarely a day goes by without a post, article, or email about physician burnout. New variants of coronavirus disease 2019 (COVID-19) and slow vaccination rates are prolonging the quarantine, and there is no certain end in sight. Without a clear path to a semblance of normalcy for our careers, families, and communities, it should be no surprise that our well-being is in jeopardy.

From private practice to academic medicine, strategies to proactively address physician wellness are urgently needed. Results from a survey of 1122 academic faculty across the nation reported that individuals feeling very or extremely stressed more than doubled from 2019 (32%) to 2020 (70%), and almost 3 times as many had increased anger (12% vs 35%).

During the same time frame, more than 12,000 physicians surveyed reported their rate of being “somewhat” or “very” happy declined from 82% to 58%, with a similar decline reported for ob/gyn physicians (81% to 57%). Female faculty members reported a dramatic increase in feeling stressed, from 34% to 75%, and they experienced stress at higher rates than men, 75% to 59%. Since May 2020, 40% of women reported symptoms of anxiety or depression (Figure), which is almost 4 times higher than the 11% reported in 2019.

A FIRST STEP, ALTHOUGH CLEARLY NOT A SOLUTION, IS HAVING SOMEONE TO TALK TO, SOMEONE TO SHARE THE REALITIES OF LIFE WITH.

THIS CAN HELP US TO ADDRESS OUR BURNOUT AND PROVIDE AN OUTLET.

Given the predominance of female ob/gyns—83% of residents are women—these statistics really hit home. The shift to remote learning and limited child care options have affected these colleagues, as women disproportionally shouldered the burden. For women, the dual role of being the family’s primary caregiver and practicing medicine has made the balancing act untenable for many, affecting both their mental health and career.

Many accept—often request—night and/or weekend shifts to maximize time at home to assist with child care and remote learning. In return, they have no down time, time to accomplish academic goals, or opportunity to recharge. Remote working has resulted in busier schedules and often longer hours for many, with fewer breaks as virtual meetings are stacked one on top of another. As eloquently stated in a recent Womxn’s Health Collaborative online post, the effort “comes at the expense of our own health and well-being.”

Solutions are not obvious, especially for ob/gyns. Early responses have been to encourage us to take care of ourselves, but when can we do this? Others have recommended taking time off; this burdens our colleagues and often results in insurmountable amounts of catch-up when we return. Physician burnout as a critical topic predates the pandemic. The National Academy of Medicine launched a resource repository on clinical burnout and well-being.

WE WANT TO HEAR FROM YOU

Want to let Contemporary OB/GYN know what you thought of this month’s cover story? Feel like telling Dr. Spong what you thought of her editorial or how your practice is responding to COVID-19?

*Email Dr Spong at CSpong@mjlifesciences.com.*

*Comment online at the bottom of any Contemporary OB/GYN article.*

*Leave comments on our Facebook page: facebook.com/ContempOBGYN.*

*Follow us and tweet to @ContempOBGYN.*

*The editors reserve the right to shorten or edit letters and comments.*
There is a wealth of information on causes, effects, and solutions for clinical burnout available. Solutions include organizational and individual strategies, such as fostering communication, cultivating teamwork, and practicing mindfulness; however, data demonstrating their effectiveness are limited. Ultimately, system changes to address the inequity are needed to adjust metrics and support women in all roles: career, family, and community.

Physician burnout and the need for wellness will not be resolved once the pandemic is behind us. The American College of Obstetricians and Gynecologists has 5 warning signs of burnout: dread, increased complaining, irritability, lapses in confidentiality, and loosening boundaries. For ourselves and our colleagues, let’s keep these in mind and work with each other to identify and address burnout proactively. A first step, although clearly not a solution, is having someone to talk to, someone to share the realities of life with. This can help us to address our burnout and provide an outlet. Although we cannot eliminate the current emphasis on virtual working, remote learning, and limited child care, we can enhance our support for each other.

Catherine Y. Spong, 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.

FOR REFERENCES VISIT contemporaryobgyn.net/Smoldering

Catherine Y. Spong, 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.
The Itchy Stretch Marks

A 28-year-old primigravid patient presents for her routine prenatal visit. She is 36 weeks pregnant and complains that the stretch marks on her abdomen have become extremely itchy, red, and bumpy. She has no other obstetric complaints. Vital signs and fetal monitoring are within normal limits. On physical exam you see this (Figure 1).

Figure 1. Multiple pink to red papules coalescing into plaques within striae on abdomen, consistent with polymorphic eruption of pregnancy.¹

WHAT SHOULD YOU DO?

This scenario describes polymorphic eruption of pregnancy (PEP), also known as pruritic urticarial papules and plaques of pregnancy (PUPPP). Clinically, this presents as an abrupt onset of pruritic urticarial papules and plaques, targets, and vesicles within and around abdominal striae distensae, trunk, buttocks, and thighs. It typically spares the umbilicus, palms, and soles. There are no associated maternal or fetal morbidities. Risk factors for development of PEP include rapid weight gain, multiple gestation pregnancy, nulliparous, and primigravid.² It usually self-resolves in the postpartum period and does not recur with subsequent pregnancies.

Recommended initial management by obstetrician:

1. Order complete blood count (CBC), liver function tests (LFTs), thyroid function tests (TFTs), and bile acids to rule out other dermatoses of pregnancy.²
2. If necessary, perform two 3-0 punch biopsies, one from a papule or plaque for hematoxylin and
eosin (H&E) staining and the other on perilesional uninvolved skin for direct immunofluorescence (DIF) studies. DIF will show nonspecific C3 staining of basement membrane and scant immunoglobulin (Ig) G staining in the epidermis, whereas H&E will show nonspecific lymphohistiocytic infiltrate in dermis, edema, and eosinophils.3

3. Start mild to moderate topical corticosteroid and pregnancy-safe sedating or nonsedating oral antihistamines (diphenhydramine, chlorpheniramine, loratadine, cetirizine) to manage rash and pruritus.2

4. Refer to dermatologist if rash becomes intractable.

Recommended initial management by obstetrician:
1. Take two 4-0 punch biopsies, one from a vesicle for H&E staining and the other from perilesional uninvolved skin for DIF. H&E will show a subepidermal blister and eosinophilic spongiosis, whereas DIF will show linear C3/IgG staining along the basement membrane.6

2. Check TFTs to monitor for maternal risk of Graves disease, and perform a fetal non-stress test ultrasound for fetal monitoring.

3. Treat with moderate- to high-potency topical corticosteroids and oral antihistamines. The mainstay of treatment is 20 to 60 mg oral prednisone equivalent daily, with taper after blisters disappear.6

4. Refer to dermatology and endocrinology departments for further management.

WHAT SHOULD YOU DO?
This scenario describes pemphigoid gestationis, also known as herpes gestationis, which typically presents in late pregnancy or the postpartum period as an abrupt onset of PUPP that progress to tense vesicles and bullae on an erythematous base. Of note, these lesions involve the umbilicus or are immediately adjacent to it and spread to extremities, including palms and soles. Fetal risks include prematurity and small for gestational age.3 Maternal risks include Graves disease.2 Early-onset disease correlates with disease severity. This usually self-resolves during the postpartum period but can recur in subsequent pregnancies.

Herpes gestationis typically presents in late pregnancy or the postpartum period.
Itchy Rash From Head to Toe
A 21-year-old woman at 12 weeks of pregnancy presents with a complaint of new itchy bumps that started a week ago on her face and neck, under her arms, under her breasts, and on her arms and legs. She reveals she has never had a rash like this but did have eczema as a child. She does not complain about any other symptoms. Vital signs and fetal monitoring are within normal limits. On physical exam you see the following (Figure 3).

WHAT SHOULD YOU DO?
This scenario describes atopic eruption of pregnancy, which is the most common rash seen in pregnancy. Onset is typically before the second or third trimester. It is a spectrum of conditions that includes prurigo of pregnancy, eczema of pregnancy, and pruritic folliculitis of pregnancy. Clinically, it presents as excoriated papules or nodules, eczematous papules and plaques, or monomorphic follicular-based papules on the abdomen, flexural areas, and extremities. It typically occurs in patients with a history of atopic dermatitis but could be of new onset. It is due to an immune system shift from a T-helper (Th)1-predominant to a Th2-predominant system during pregnancy. Patients who already have this imbalance due to atopic dermatitis experience flares. It is self-limited and there are no maternal or fetal risks.

Recommended initial management by obstetrician:
1. Rule out other potentially severe conditions such as intrahepatic cholestasis of pregnancy and pemphigoid gestationis, scabies, pityriasis rosea, drug eruptions, and viral exanthems, which can present similarly.
2. Perform punch biopsies for H&E staining and DIF. Order CBC, comprehensive metabolic panel (CMP), and TFTs. CBC will show elevated IgE.
3. Treat rash with moisturizers and emollients rich in ceramides, mild to moderate topical corticosteroids, oral antihistamines, and narrow band UV-B.
4. Culture lesions if any sign of infection is present and prescribe daily topical mupirocin once infection is confirmed.

The Itchy Arms and Legs
A 22-year-old gravida 2 para 1 woman at 33 weeks of pregnancy presents with the complaint that she has been itchy all over her body for the past 3 days. She states that itching prevents her from sleeping at night and she experienced something similar during her first pregnancy but not as intensely. She reports that her first child was born at 35 weeks. Physical exam shows normal-appearing skin without any rash or secondary lesions.

WHAT SHOULD YOU DO?
This scenario describes intrahepatic cholestasis of pregnancy, which is characterized by extreme pruritus in absence of rash, followed by secondary excoriation and prurigo papules and nodules. There is no long-term morbidity to the mother, but fetal risks include premature birth, meconium staining of amniotic fluid,
WHAT SHOULD YOU DO?

This scenario presents a case of impetigo herpetiformis, also known as generalized pustular psoriasis of pregnancy. This presents in the third trimester of pregnancy as eczematous scaly plaques surrounded by 1- to 3-mm pustules in flexural areas, which then extend to the trunk and extremities. Patients usually have no prior history of psoriasis.

Maternal risk includes seizures, tetany, delirium, and cardiac arrhythmias secondary to hypocalcemia. Fetal risk includes placental insufficiency. The condition typically self-resolves in the postpartum period, and it recurs with earlier onset and a more severe course in subsequent pregnancies.

Recommended initial management by obstetrician:
1. Check CBC for elevated white blood cell count; check CMP for hypocalcemia and hypoalbuminemia.
2. Perform 2 punch biopsies for DIF and H&E. DIF will be negative for any immunoglobulins.
3. Counsel patient on natural progression of disease, with potential for early delivery if condition becomes life-threatening.
4. Treat rash with systemic corticosteroids with a starting dose of prednisone 15 to 80 mg oral equivalent daily; replace deficient electrolytes; prescribe 1.25 hydroxyvitamin D₃ 0.5 µg/d for hypocalcemia; and supplements for hypoalbuminemia.
5. Consider referral to dermatologist for refractory cases.
6. Follow up in 2 weeks to a month for fetal monitoring.

The Pus-Filled Rash

A 25-year-old woman at 30 weeks of pregnancy presents with complaint of new-onset rash located in her axilla and groin, as well as malaise and fever. She states that she has never had a rash like this. On physical exam you note the following (Figure 4).

Figure 4. Multiple pink, annular, scaly plaques with surrounding sterile pustules on arms, chest, and abdomen, consistent with impetigo herpetiformis.

SCENARIO

Figure 4. Multiple pink, annular, scaly plaques with surrounding sterile pustules on arms, chest, and abdomen, consistent with impetigo herpetiformis.

Recommended initial management by obstetrician:
1. Check CBC; CMP, with a focus on aspartate aminotransferase, alanine aminotransferase, and bilirubin; prothrombin time; activated partial thromboplastin time; international normalized ratio; hepatitis C; and genetic testing for genetic mutations in various hepatobiliary bile transporters.
2. Monitor fetus for fetal anoxia caused by toxic bile crossing the placenta.
3. Prescribe ursodeoxycholic acid 10 to 20 mg/kg/d and increase to maximum dose of 2 g/d.
4. Prescribe anti-itch over-the-counter emollients and moisturizers and topical corticosteroids.
5. Culture erosions if infection is suspected and prescribe topical mupirocin ointment once infection is confirmed.
WHAT SHOULD YOU DO?
This case scenario describes a pyogenic granuloma, also known as pregnancy granuloma, which is a vascular lesion composed of multiple capillary hemangiomas. Its development is associated with increasing hormonal levels in pregnancy, as well as trauma. It presents as a dome-shaped, painful, hemorrhagic papule usually on the gingiva, but it can also occur on the lips and other bodily sites. Their presence can cause pain, anxiety, difficulty eating, and, though rarely, life-threatening hemorrhage if poorly controlled.

Recommended initial management by obstetrician:
1. Evaluate for size, pain, and frequency of bleeding to guide the next best step in treatment.
2. Noninvasive treatment options include cryotherapy with liquid nitrogen, intralesional injection of triamcinolone 2.5 mg/mL, sclerotherapy, pulse dye laser, or neodymium-doped yttrium aluminum garnet laser treatment. Advise patient that multiple treatment sessions may be necessary.
3. Invasive treatment options include surgical excision, which is considered the standard of care but bears the risk of morbidity, deformity, and incomplete excision.
4. Advise patient about the importance of maintaining good oral hygiene to prevent secondary infection of the lesion.

FOR REFERENCES VISIT contemporaryobgyn.net/dermatosesofpregnancy
Non-opioid EXPAREL, powered by DepoFoam® technology, delivers precise pain control for the critical first few days after surgery to enable enhanced recovery.

**INDICATION**
EXPAREL is indicated for single-dose infiltration in adults to produce postsurgical local analgesia and 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 with an incidence greater than or equal to 10% following EXPAREL administration via infiltration were nausea, constipation, and vomiting; adverse reactions reported with an incidence greater than or equal to 1% following EXPAREL administration via interscalene brachial plexus nerve block were nausea, pyrexia, and constipation. 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 population: patients ≥18 years old 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 intravenous 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 anesthetic and paresthesia. CNS reactions are characterized by excitation


**ORAEs:*** opioid-related adverse events (such as vomiting, itching, sweating, freezing, and dizziness).

**Non-opioid EXPAREL**

NEW DATA
ENHANCED RECOVERY
AFTER C-SECTION

52% REDUCTION IN OPIOIDS* vs bupivacaine HCl through 72 hours (P=0.0117).1
0.7 DAY REDUCTION in readiness to discharge from hospital (P=0.008).2
54% OPIOID-SPARED* Women took ≤10 mg of oxycodone with no bother or stress from ORAEs through 72 hours (P=0.0015).4

ORAEs=

Opioid-related adverse events (such as vomiting, itching, sweating, freezing, and dizziness).

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

A prospective, multicenter, randomized, double-blind clinical trial of 1818 patients who underwent an elective C-section with a multimodal pain management protocol, including a transversus abdominis plane (TAP) block using either 20 mL EXPAREL 266 mg, 30 mL 0.25% bupivacaine HCl, and 20 mL normal saline for a total volume of 80 mL (30 mL volume on each side); or 20 mL 0.25% bupivacaine HCl and 40 mL normal saline for a total volume of 80 mL (30 mL volume on each side); or a multimodal pain management protocol alone. Mean hospital length of stay was 2.9 days with EXPAREL (n=87) vs 3.9 days without EXPAREL (n=88). Time to ambulation was 18.7 hours with EXPAREL (n=87) and 30.7 hours without EXPAREL (n=82).7

§Defined as patients who took no more than 10 mg of oxycodone (15 mg of morphine or equivalent) with no bother or stress from vomiting, itching, sweating, freezing, or dizziness through 72 hours.

Learn more at: www.EXPAREL.com/obgyn
EXPAREL
Bupivacaine Loxene injectable suspension

Brief Summary
(Further information referring to package insert)

INDICATIONS AND USAGE
EXPAREL is indicated for single-dose infiltration in adults to produce postsurgical regional analgesia. EXPAREL can be administered in a setting where trained personnel and equipment are available to provide for resuscitation and treatment of methemoglobinemia. EXPAREL may be administered in a setting where trained personnel and equipment are available to provide for resuscitation and treatment of methemoglobinemia.

CONTRAINDICATIONS
EXPAREL is contraindicated in obstetric paracervical block anesthesia. While EXPAREL has not been evaluated in obstetric paracervical block procedures, the use of a local anesthetic in this location has resulted in maternal and fetal cardiac arrest, hypotension, convulsions, and death.

WARNINGS AND PRECAUTIONS

Use of EXPAREL

There is a potential for severe life-threatening adverse events associated with local anesthesia using EXPAREL. EXPAREL should be administered in settings where trained personnel and equipment are available to provide for resuscitation and treatment of methemoglobinemia. EXPAREL should be administered in settings where trained personnel and equipment are available to provide for resuscitation and treatment of methemoglobinemia. EXPAREL should be administered in settings where trained personnel and equipment are available to provide for resuscitation and treatment of methemoglobinemia. Patients should be monitored for at least 120 hours after administration of EXPAREL.

Do not dilute EXPAREL with water or other hypotonic agents, as it will result in dilution of the local anesthetic potency.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

There are no studies conducted with EXPAREL in pregnant women. In reproduction studies, reproduction at the ratio of the milligram dose of bupivacaine HCl solution to EXPAREL was 1.5 and 4.0 times the MRHD, respectively, based on the BSA comparisons and a 60 kg human weight (85 mg/mL) of EXPAREL was administered with 7 mL infiltrated into the tissues surrounding the incision site. In pregnant women, there is a risk for neonatal toxicity from hypertension and tachycardia to myocardial depression, hypotension, and death.

Non-bupivacaine Local Anesthetics

In patients undergoing hemorrhoidectomy, a total of 266 mg (20 mL) of EXPAREL was administered with 7 mL infiltrated into the tissues surrounding the incision site. In pregnant women, there is a risk for neonatal toxicity from hypertension and tachycardia to myocardial depression, hypotension, and death.

Pediatric Use

Pediatric use of EXPAREL is not recommended for single-dose administration only.

Different formulations of bupivacaine are not bioequivalent even if the milligram dose is the same. Therefore, it is not possible to convert dosing from any other formulation of bupivacaine to EXPAREL.

DOSE AND ADMINISTRATION

Important Dose and Administration Information

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 formulation of bupivacaine to EXPAREL.
- DO NOT DILUTE EXPAREL with water or other hypotonic agents, as it will result in dilution of the local anesthetic potency.
- Use suspensions of EXPAREL diluted with preservative-free normal (0.85%) saline, 5% dextrose solution, 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 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 use if particulate matter, discoloration, or abnormal condition is noted.

Recommended Dosing in Adults

Local Anesthesia via Infiltration

The recommended dose of EXPAREL for local infiltration in adults is up to a maximum dose of 240 mg (16 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 dose, two examples of infiltration dosing are provided:

- In patients undergoing hemorrhoidectomy, a total of 106 mg (6 mL) of EXPAREL was administered with 7 mL infiltrated into the tissues surrounding the incision site. In pregnant women, there is a risk for neonatal toxicity from hypertension and tachycardia to myocardial depression, hypotension, and death.
- In patients undergoing hemorrhoidectomy, a total of 266 mg (20 mL) of EXPAREL was administered with 7 mL infiltrated into the tissues surrounding the incision site. In pregnant women, there is a risk for neonatal toxicity from hypertension and tachycardia to myocardial depression, hypotension, and death.

Regional Anesthesia via Interscalene Brachial Plexus Block

The recommended dose of EXPAREL for interscalene brachial plexus nerve block in adults is 133 mg (10 mL), and is based on one study of patients undergoing other total or partial/complete arthroplasty or calf cutdown procedures.

Compatibility Considerations

Administering EXPAREL with other drugs such as EXPAREL prior to administration of EXPAREL is not recommended.

- Non-bupivacaine based local anesthetics, including lidocaine, may cause an immediate release of bupivacaine from EXPAREL and result in adverse events related to local anesthetic systemic toxicity.
- Bupivacaine HCl administered together with EXPAREL may impact the pharmacokinetic and/or pharmacodynamic properties of EXPAREL, and this effect is concentration-dependent. Therefore, bupivacaine HCl administered together with EXPAREL may impact the pharmacokinetic and/or pharmacodynamic properties of EXPAREL, and this effect is concentration-dependent. Therefore, bupivacaine HCl administered together with EXPAREL may impact the pharmacokinetic and/or pharmacodynamic properties of EXPAREL, and this effect is concentration-dependent. Therefore, bupivacaine HCl administered together with EXPAREL may impact the pharmacokinetic and/or pharmacodynamic properties of EXPAREL, and this effect is concentration-dependent.

Non-Interchangeability with Other Formulations of Bupivacaine

Different formulations of bupivacaine are not bioequivalent even if the milligram dose is the same. Therefore, it is not possible to convert dosing from any other formulations of bupivacaine to EXPAREL.

CLINICAL PHARMACOLOGY

Pharmacokinetics

Administration of EXPAREL results in significant systemic plasma levels of bupivacaine which can persist for 96 hours after local infiltration and 120 hours after intravenous administration. EXPAREL may not be administered as it will result in dilution of the local anesthetic potency. EXPAREL may not be administered as it will result in dilution of the local anesthetic potency. EXPAREL may not be administered as it will result in dilution of the local anesthetic potency. EXPAREL may not be administered as it will result in dilution of the local anesthetic potency. EXPAREL may not be administered as it will result in dilution of the local anesthetic potency.

Pregnant women that use local anesthetics may cause methemoglobinemia, a condition when more than 15% of the red blood cells have a methemoglobin. Patients with a history of methemoglobinemia or patients with a family history of methemoglobinemia are at increased risk for methemoglobinemia. EXPAREL may cause methemoglobinemia in patients with a history of methemoglobinemia or patients with a family history of methemoglobinemia.

PATIENT COUNSELING

Inform patients that use of local anesthetics may cause methemoglobinemia, a condition when more than 15% of the red blood cells have a methemoglobin. Patients with a history of methemoglobinemia or patients with a family history of methemoglobinemia are at increased risk for methemoglobinemia. EXPAREL may cause methemoglobinemia in patients with a history of methemoglobinemia or patients with a family history of methemoglobinemia.

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Patients with breast cancer who had 2 recent, consecutive mammography scans before receiving their diagnosis saw a 49% reduction in mortality and a 50% lower chance of death after 10 years than patients who did not have screenings, according to a study published in *Radiology*. Twice-screened women also had a 22% to 33% death reduction range compared with women who had a single screening prior to receiving a diagnosis of breast cancer.1 The study was funded by the American Cancer Society. Previous studies had examined only the effect of a single screening on death rates following breast cancer diagnosis.2,3

Investigators examined participation data from 549,091 Swedish women from 1992 to 2016 from 9 counties who were eligible for mammography. The participants ranged in age from 40 to 69 years, with mean age of 58.9 years. These data were connected to data from registries and regional cancer centers, which included breast cancer diagnosis, cause, and date of death, according to the authors. Breast cancer mortality data were obtained from the Swedish Cause of Death Register of the Swedish National Board of Health and Welfare.

During the study period, participants received a letter inviting them for mammography with a prebooked appointment. In Sweden, women aged 40 to 54 years are recommended to get a scan once every 18 months, and women aged 55 to 69 years are recommended to be screened once every 24 months. However, investigators noted that screening age ranges can vary by county. Urban screening participation rates in mammography screening are 70%, whereas in more rural areas there is a 90% participation rate, investigators said.

Investigators calculated breast cancer mortality based on the number of screenings and the timing of the scans. Participants were divided into 4 screening groups prior to receiving a diagnosis of breast cancer: serial participants (392,135), who had their last 2 scheduled screenings before receiving a diagnosis; intermittent participants (41,746), who went to their last scan but not the next-to-last screening; lapsed participants (30,945), who had their next-to-last scan but not the last scan; and serial nonparticipants (84,265), who did not have their last 2 screenings.

Breast cancer mortality data were obtained from the Swedish Cause of Death Register.

Investigators calculated breast cancer mortality based on the number of screenings and the timing of the scans. Participants were divided into 4 screening groups prior to receiving a diagnosis of breast cancer: serial participants (392,135), who had their last 2 scheduled screenings before receiving a diagnosis; intermittent participants (41,746), who went to their last scan but not the next-to-last screening; lapsed participants (30,945), who had their next-to-last scan but not the last scan; and serial nonparticipants (84,265), who did not have their last 2 screenings.

Investigators calculated rate data using Poisson regression and produced relative risks (RRs) and 95% CIs for 9 combined counties, according to the authors. A significant difference was considered to be $P < .05$. “The 2 end points were analyzed according to the different participation groups and were offset by the person-years of observation,” the study’s authors wrote.1

Investigators reported 3995 deaths during the study period. Participants who attended both screenings had a 49% reduction in the risk of death and 50% lower risk of death after 10 years, according to the authors. “We found substantial and significant reductions for both mortality from breast cancer (relative risk [RR], 0.51; 95% CI, 0.48-0.55; $P < .001$) and incidence of breast cancers proving fatal within 10 years (RR, 0.50; 95% CI, 0.46-0.55; $P < .001$) for [those] who had participated in both of their previous 2 screening examinations (serial participants) compared with [those] who did not attend either of their last 2 screening examinations (serial nonparticipants),” the authors wrote.1 While reductions were smaller in intermittent (33%) and lapsed participants (28%), the investigators noted the decrease was still significant.

“Missing even 1 screening examination confers a significant increase in risk. This is an important message for women in the screening age groups, their referring physicians, and public health decision makers,” the authors concluded.1

Sandra Fyfe is a freelance writer for Contemporary *Ob/Gyn*.

FOR REFERENCES VISIT contemporaryobgyn.net/screening1
Gynecologic Care Needs to Improve in Women With Down Syndrome

by ANGIE DEROSA

A team of investigators has found that women with Down syndrome received gynecologic care at lower-than-recommended rates and at substantially lower rates than other forms of health care. The investigators have called for efforts to improve gynecologic care for this vulnerable population.

The study, based upon findings from a National Registry, appeared in Obstetrics & Gynecology, the journal of the American College of Obstetricians and Gynecologists (ACOG). The investigators’ goal was to estimate receipt of recommended gynecologic care, including cancer screening and menstrual care, among women with Down syndrome in the US. For the research, investigators used patient-reported data from DS-Connect, which is a national registry of individuals with Down syndrome. It is a centralized national registry funded by the Eunice Kennedy Shriver National Institute of Child Health and Human Development, the investigators said.

Down syndrome is one of the most common identified causes of intellectual disability in the U.S., the investigators reported. Women make up 40% of the population of those with the syndrome, also known as trisomy-21. The investigators noted that over the past two decades, the lifespan nearly has doubled for those with Down syndrome. This further underscores the need for patient-centered gynecologic care that takes into consideration the full lifetime needs of an individual.

“Our first outcome was receipt of all gynecologic components of ACOG-recommended, age-appropriate well-woman care among women with Down syndrome at least once during their lifetimes,” the investigators wrote. “We then measured lifetime receipt of specific components of recommended well-woman care: any gynecologic examination (for women age 18 years and older), Pap test (age 21 years or older), or mammography (age 40 years or older). We also measured breast examination by self or family member (age 18 years or older), although we did not include it in our estimate of guideline-adherent well-woman care because the breast self-examination was removed from ACOG guidelines during the study period. We compared receipt of recommended well-woman care to receipt of non-gynecologic care recommended for individuals with Down Syndrome, including physical examinations, vision, hearing, and dental care.”

Their second outcome was the receipt of menstrual regulation treatments, such as oral contraceptive pills, Depo-Provera injections, and intrauterine devices, they said. “The questionnaire distinguishes between use of contraceptives for intended menstrual regulation compared with pregnancy prevention,” they wrote. “We do not report use of contraceptives for pregnancy prevention, given the small number of respondents to this component of the questionnaire. We also characterized the age at menarche, regularity, and length of menstrual cycle.”

The results included the following: Of the 3,441 U.S. individuals enrolled in DS-Connect from 2013 to 2019, 1,625 were women, and 70 women (4% of female enrollees) had complete responses to the questionnaire on women’s health outcomes. The mean age of study participants was 33 years (95% CI, 30-36; range 19-74). The majority were White (94%; 95% CI, 89-100). Twenty-one percent had a history of physical abuse (95% CI, 12-31), and 24% (95% CI, 14-35) had experienced unwanted sexual advances. Six percent had potential or confirmed sexually activity (95% CI, 0-12) with no reported history of sexually transmitted infections. Fourteen percent of participants were postmenopausal (95% CI, 6-23) with a mean age of menopause of 40 (95% CI, 34-46).

Only 26% of age-appropriate women with Down syndrome reported ever having a Pap test, and 50% reported ever receiving a mammogram, the investigators wrote. By contrast, 89% of women with Down syndrome had received recommended non-gynecologic preventive care. Comparatively, according to the National Health Interview Survey, 93% of US women aged 21-65 years have ever received a Pap test, and 95% of US women aged 50-74 years have ever received a mammogram.

“Our research demonstrates considerable disparity in women with Down syndrome receiving the recommended preventative cancer screenings, on par with findings in women with other intellectual disabilities,” the investigators wrote.

Angie DeRosa is the senior editor for Contemporary OB/GYN®.

FOR REFERENCES VISIT contemporaryobgyn.net/Downsyndrome
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At the writing of this article in February 2021, severe acute respiratory syndrome coronavirus2 (SARS-CoV-2) cases ranging from asymptomatic infection to fatal respiratory illness have affected more than 100 million individuals and led to more than 2.4 million deaths worldwide. Although cases and hospitalizations have decreased from their winter peak, emerging variants threaten to intensify the epidemic. It is important to review the clinical evaluation and management of coronavirus disease 2019 (COVID-19) in pregnancy.

Although predominantly transmitted via respiratory droplets, SARS-CoV-2 can be transmitted through the air via aerosolized particles under some circumstances, such as during intubation prior to surgery, and in enclosed spaces. Asymptomatic or presymptomatic individuals account for 40% to 50% of transmissions. An estimated 95% of infected individuals have asymptomatic or mild illness, with approximately 5% developing severe or critical illness. Pregnant individuals with symptomatic COVID-19 may be at higher risk for intensive care unit admission, invasive ventilation, and death. Similar to nonpregnant individuals, obesity and diabetes may be risk factors associated with severe COVID-19 illness in pregnant individuals.

**Diagnosis of acute infection**

Active maternal infection is diagnosed by molecular (also known as polymerase chain reaction [PCR] tests) or antigen detection in nasopharyngeal, nasal, or saliva specimens. Several commercial PCR and antigen tests are available. Rapid antigen tests are inexpensive but not as effective at detecting infection in asymptomatic individuals.
Molecular test result interpretation depends on pretest probability, epidemiologic risk factors, and intended use for diagnostic or screening purposes in health care or congregate living settings. Serologic testing for presence of anti-SARS-CoV-2 immune globulin is used for epidemiologic and seroprevalence studies, but it is not useful for diagnosing active infection. At this time, there is no recommendation by the Centers for Disease Control and Prevention (CDC) for using antibody testing following vaccination to verify immunity.

**Clinical manifestations of COVID-19 in pregnancy**

Symptoms of COVID-19 in pregnant individuals are the same as those in nonpregnant individuals. An incubation period of approximately 5 to 14 days may be followed by fever, respiratory, gastrointestinal, or neurologic symptoms. Respiratory symptoms can vary from mild upper respiratory symptoms, such as pharyngitis and sneezing, to lower respiratory illness indicated by cough, dyspnea, tachypnea, and decreased oxygen saturation. Severe to critical respiratory illness manifests approximately 8 to 12 days after symptom onset in 5% to 14% of nonpregnant individuals, and approximately 5% of pregnant individuals. Acute respiratory failure, including acute respiratory distress syndrome (ARDS), is rare. Gastrointestinal symptoms are less common, although loss of smell (anosmia) and taste (ageusia) are reported in more than half of patients.

The National Institutes of Health (NIH) criteria for classifying the severity of respiratory illness from COVID-19 may generally be applied to pregnant patients, with additional considerations for how pregnancy physiology affects the progression and presentation of symptoms (Table 1). Physiologic changes in the pulmonary function during the third trimester include decreased functional residual capacity by approximately 20% to 30% and increased oxygen consumption by 20%, making lower respiratory infections less well tolerated. Because the respiratory rate in the third trimester remains relatively unchanged through gestation (with increased tidal volume accounting for increased minute ventilation), an increased respiratory rate above 30 breaths per minute—even if the oxygen saturation on room air is maintained at or slightly above 95%—is a sign of potentially severe respiratory compromise in symptomatic SARS-CoV-2 infection.

**Initial evaluation of respiratory symptoms**

Initial evaluation of a pregnant patient with reported mild symptoms such as sore throat or sneezing may be limited and focused. More thorough evaluation is warranted for those with fever, significant respiratory complaints, and systemic symptoms. This includes a thorough history and physical exam with an attempt to understand the timing of symptom onset relative to presentation and progression or improvement of symptoms. These details help the clinician determine the potential for worsening—ie, a patient with mild clinical illness improving on day 9 or 10 of symptoms is more likely to be near the end of the illness course, whereas a patient with mild, flulike symptoms at day 4 to 5 of illness may worsen and need to be monitored more closely, depending on maternal comorbidities and gestational age. In those with systemic findings or significant respiratory symptoms, auscultation of the lungs and documentation of oxygen saturation are necessary but not sufficient to assess respiratory status. The physician must also assess and document respiratory rate as well as objective signs of respiratory fatigue or respiratory distress, including accessory muscle use, work of breathing, and ability to speak without interruption due

<table>
<thead>
<tr>
<th>Table 1</th>
<th>National Institutes of Health COVID-19 Disease Severity Criteria12</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Asymptomatic</strong></td>
<td>Positive COVID-19 test result with no symptoms; unable to determine whether presymptomatic or asymptomatic</td>
</tr>
<tr>
<td><strong>Mild</strong></td>
<td>Cold symptoms to flulike illness (including fever, cough, myalgias, anosmia) without lower respiratory findings (dyspnea, abnormal chest imaging)</td>
</tr>
<tr>
<td><strong>Moderate</strong></td>
<td>Lower respiratory tract disease on clinical assessment (including dyspnea, crackles, CXR infiltrates) with oxygen saturation at 94% or greater on room air at sea level</td>
</tr>
<tr>
<td><strong>Severe</strong></td>
<td>Oxygen saturation less than 94% on room air, oxygen requirement, respiratory rate greater than 30 breaths per minute, ratio of ( \text{P}_{a}O_2/\text{Fi}_O_2 ) less than 300, chest imaging with greater than 50% lung involvement</td>
</tr>
<tr>
<td><strong>Critical</strong></td>
<td>Respiratory failure, requirement of mechanical ventilation or high-flow nasal cannula, multiorgan failure or dysfunction</td>
</tr>
</tbody>
</table>

Adapted from https://www.covid19treatmentguidelines.nih.gov/overview/clinical-spectrum/
to coughing or dyspnea. Assessment can be performed at rest and after walking in patients reporting significant symptoms but who appear comfortable at rest and without hypoxia. In these circumstances, the clinician may be uncertain about the need for admission. For nonpregnant adult patients, a 6-minute walk test is a low-cost assessment of functional status in patients with moderate to severe pulmonary disease. Although a full 6-minute walk test may not be feasible for nonlaboring obstetric patients, a brief assessment of ambulation may assist the clinician in determining whether the patient warrants closer observation. For patients with obvious increased work of breathing, chest pain, or desaturation following minimal ambulation, admission is warranted and supplemental oxygen should be considered. Given that approximately 40% of pregnant patients with initially moderate clinical illness may progress to severe pneumonia, observation for 24 to 48 hours should be considered.\(^3\)

Unlike other respiratory infections such as influenza, clinical decompensation secondary to COVID-19, if it occurs, happens relatively late in the course of illness.\(^5\) Early acute respiratory failure—ie, impaired gas exchange of oxygen and carbon dioxide—in a pregnant patient with COVID-19 should promptly lead to a consultation of maternal-fetal medicine (MFM) and critical care specialists experienced in treating COVID-19. Respiratory failure may be hypoxic, defined as partial pressure of oxygen (Pao\(_2\)) less than 60 mm Hg on room air, correlating approximately to an oxygen saturation (SpO\(_2\)) of less than 90%; or hypercapnic, defined as partial pressure of carbon dioxide (Pco\(_2\)) greater than 50 mm Hg.

Importantly, a compensated respiratory alkalosis is expected in the third trimester of pregnancy, and if arterial blood gas is obtained and reveals a normal or elevated Pco\(_2\), this is an ominous sign of hypercapnic respiratory failure. In the case of a pregnant patient without pre-existing cardiac or pulmonary disease admitted with severe pneumonia from COVID-19, early respiratory failure is commonly hypoxemic, although ARDS presents with cough and dyspnea is key so that appropriate triage takes place in coordination with specialists. This includes a thorough assessment of both oxygenation and ventilation, as well as an awareness of the pitfalls of using SpO\(_2\) as a single measure of clinical stability when the patient is tachypneic or describing shortness of breath.

Conditions other than COVID-19 (e.g., pulmonary embolus or pulmonary edema related to obstetric, pulmonary, or cardiac etiologies) should be considered in patients with hypoxia but without significant parenchymal opacities on chest radiography. It is unclear to what extent COVID-19 may exacerbate conditions such as sepsis from acute pyelonephritis or preeclampsia-related pulmonary edema.

Lab and imaging studies

For patients who are asymptomatic or with upper respiratory symptoms only, laboratory evaluation beyond COVID-19 testing typically is not necessary. For those with significant respiratory symptoms, systemic illness and fever who present to the hospital, laboratory evaluation following history and physical examination to rule out other causes of infection and hypoxia may be warranted. In our experience managing hospitalized, nonlaboring patients with moderate to severe viral pneumonia, measurement of daily C-reactive protein (CRP) aids in determining the clinical trajectory. While measurement of CRP performed well in discriminating disease severity and predicting adverse outcomes in nonpregnant patients with COVID-19, the predictive value has not been evaluated in a pregnant population.\(^5\) Furthermore, the level of CRP normally rises during pregnancy and with other states of inflammation or...
### Table 2: Oxygen Delivery Devices and Parameters for Use

<table>
<thead>
<tr>
<th>Order</th>
<th>Method</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low flow oxygen supplementation</td>
<td>Nasal cannula</td>
<td>Set between 1-6 L/min flow (at wall). ( \text{Fi}_2 ) increases approximately 4% with each liter increase in flow (e.g., room air is 21% ( \text{Fi}_2 ), 1L is approximately 24% ( \text{Fi}_2 ), 2L is 28%, etc)</td>
</tr>
<tr>
<td></td>
<td>Simple face mask</td>
<td>When set between 5-10 L/min flow, administers ( \text{Fi}_2 ) of 35-55%. Do not set below 5 L/min because it may result in exhaled ( \text{CO}_2 ) rebreathing.</td>
</tr>
<tr>
<td></td>
<td>Venturi mask</td>
<td>Different mask valve colors: When wall flow is set at the rate on the colored valve, it provides the listed ( \text{Fi}_2 ). (Colors may change depending on brand of mask.)</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Color of mask valves</strong></td>
</tr>
<tr>
<td></td>
<td>Blue</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Yellow</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>White</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>Green</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>Pink</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>Orange</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>Nonrebreather mask</td>
<td>When set between 10-15 L/min flow from wall, provides ( \text{Fi}_2 ) 80%. Do not set at lower flow rate.</td>
</tr>
<tr>
<td>High flow oxygen supplementation</td>
<td>Heated high-flow nasal cannula(HFNC)</td>
<td>Helps reduce dead space and oxygenate, thus avoiding mechanical ventilation. Provides PEEP. Has independent flow and oxygen concentration adjustments. • Flow starts around 30 L/min and is adjusted to reduce work of breathing (target RR &lt; 30). Flow can go as high as 65 L/min although patient may not tolerate. • Oxygen concentration (( \text{Fi}_2 )); adjust ( \text{Fi}_2 ) to target ( \text{SpO}_2 ) 95% in pregnancy (if postpartum, ( \text{SpO}_2 ) target can be lower as long as patient is comfortable and not dyspneic) • Frequent reassessment every 30 minutes is needed after initially starting HFNC until patient is stable with RR &lt; 30 and ( \text{SpO}_2 ) ≥ 95%. • If patient ( \text{SpO}_2 ) &lt; 95% and ( \text{Fi}_2 ) is near 100%, or flow is increasing above 50 L/min and patient is tiring, discuss controlled intubation with delivery planning if patient is in third trimester.</td>
</tr>
<tr>
<td>Noninvasive positive pressure ventilation</td>
<td>CPAP/BIPAP</td>
<td>Continuous positive airway pressure (CPAP) or bilevel positive airway pressure (BIPAP)</td>
</tr>
</tbody>
</table>

\( \text{Fi}_2 \), fraction of inspired oxygen; RR, respiratory rate; PEEP, positive end expiratory pressure; \( \text{SpO}_2 \), percent oxygen saturation. Adapted from Pacheco, et al. Obstet Gynecol. 2020;136(1):42-45
infection, so it would be considered less helpful in a laboring or recently delivered patient. Daily evaluation of liver function (aspartate aminotransferase, alanine aminotransferase [ALT]) also is warranted for patients hospitalized with severe illness and in those who receive remdesivir (Veklury). The Society for Maternal-Fetal Medicine (SMFM) recommends evaluation of ferritin in individuals with fevers higher than 39 °C despite acetaminophen in an effort to identify secondary hemophagocytic lymphohistiocytosis or cytokine storm syndrome, which may have a fulminant course.16 For critically ill patients with suspected respiratory failure, arterial blood gas evaluation may be indicated if clinical improvement is not rapid following initial oxygen supplementation. During initial evaluation, frequent clinical reassessment with respiratory support titration is more informative than arterial blood gas in awake patients. Obtaining serial arterial blood gas samples may delay escalating care, whereas frequent reassessment of the patient’s initial status and response to oxygen supplementation may help determine whether immediate placement in an intensive care setting or early transfer to a facility with a higher level of care is warranted. There is no evidence to support measurement of coagulation markers, including D-dimer, in nonhospitalized patients with COVID-19.22 Furthermore, there are limited data supporting the routine use of D-dimer in hospitalized pregnant patients to predict venous thromboembolism (VTE) in the setting of COVID-19, as interpretation may be confounded by physiologic increases during gestation, with certain pregnancy complications, and following delivery.22 Institutional protocols may call for the evaluation of certain laboratory indices as part of a standard panel ordered for patients with COVID-19. In this case, it may be helpful to consult with MFM specialists experienced in caring for pregnant patients hospitalized with COVID-19 before acting on abnormal laboratory results. When VTE is clinically suspected in the evaluation of a patient with COVID-19, appropriate diagnostic imaging studies should be considered.

Chest radiography should be performed for patients with moderate to severe respiratory illness, and repeated if oxygen requirement increases, to evaluate the extent of parenchymal lung disease. Imaging indicative of moderate to severe viral pneumonia reveals opacities in a predominantly peripheral distribution, with a diffuse pattern demonstrated in early ARDS. CT pulmonary angiography (CTA) should be considered when hypoxia or tachycardia persist despite minimal opacities demonstrated on chest radiography or when clinical suspicion for pulmonary embolism is high. CTA is not routinely indicated for all pregnant patients with COVID-19 and classic symptoms of dyspnea and cough when parenchymal lung disease is demonstrated on chest radiography.

Respiratory support
For patients with asymptomatic or mild infection, supportive treatment is appropriate. For moderate illness, inpatient observation may be considered, as up to 40% may progress to severe illness.23 Furthermore, there are limited data supporting the routine use of D-dimer in hospitalized pregnant patients to predict venous thromboembolism (VTE) in the setting of COVID-19, as interpretation may be confounded by physiologic increases during gestation, with certain pregnancy complications, and following delivery.22 Institutional protocols may call for the evaluation of certain laboratory indices as part of a standard panel ordered for patients with COVID-19. In this case, it may be helpful to consult with MFM specialists experienced in caring for pregnant patients hospitalized with COVID-19 before acting on abnormal laboratory results. When VTE is clinically suspected in the evaluation of a patient with COVID-19, appropriate diagnostic imaging studies should be considered.
support, managing comorbid conditions, and coordinating safe delivery in coordination with specialists when indicated.16

Traditional (low-flow) nasal cannula may be initiated for patients with hypoxia but normal to mildly increased respiratory rate (Table 2). Frequent reassessment of both maternal oxygenation and ventilation in consultation with critical care specialists is warranted for patients requiring increasing oxygen supplementation. The goal of respiratory support is to maintain an oxygen saturation of 95% or more in pregnancy and at the same time reduce dyspnea and tachypnea; several oxygen delivery devices may be used.17 If significant mouth breathing is noted, a Venturi mask or nonrebreather mask may be needed to provide more controlled oxygen delivery. For patients with tachypnea or significant work of breathing despite appropriate oxygen supplementation, noninvasive ventilatory support with high-flow nasal cannula (HFNC) may be needed. Limited evidence in critically ill, nonpregnant patients suggests that HFNC may be more comfortable and potentially offer advantages over noninvasive positive pressure ventilation such as continuous positive airway pressure.18 Prone positioning to improve oxygenation with severe COVID-19 pneumonia has been used during pregnancy, though it may not be well tolerated.19 Managing dyspnea with intermittent intravenous opioids may be considered in coordination with critical care specialists. This may alleviate air hunger and facilitate oxygenation, potentially avoiding the need for intubation. Controlled intubation is considered when respiratory failure persists or worsens despite increasing support of maternal oxygenation and ventilation. This can be recognized as maximal fraction of inspired oxygen of 100% (with or without nonrebreather added) and increasing flow rate above 40 to 50 Liters per minute using an HFNC device.17

COVID-19 therapies
The efficacy of antiviral and biologic agents for COVID-19 in pregnancy remains unclear, and no clinical trials in pregnancy have been conducted. The decision to use currently available therapeutic agents approved under the US Food and Drug Administration’s Emergency Use Authorization (EUA) in coordination with critical care specialists is warranted for patients requiring increasing oxygen supplementation. The goal of respiratory support is to maintain an oxygen saturation of 95% or more in pregnancy and at the same time reduce dyspnea and tachypnea; several oxygen delivery devices may be used.17 If significant mouth breathing is noted, a Venturi mask or nonrebreather mask may be needed to provide more controlled oxygen delivery. For patients with tachypnea or significant work of breathing despite appropriate oxygen supplementation, noninvasive ventilatory support with high-flow nasal cannula (HFNC) may be needed. Limited evidence in critically ill, nonpregnant patients suggests that HFNC may be more comfortable and potentially offer advantages over noninvasive positive pressure ventilation such as continuous positive airway pressure.18 Prone positioning to improve oxygenation with severe COVID-19 pneumonia has been used during pregnancy, though it may not be well tolerated.19 Managing dyspnea with intermittent intravenous opioids may be considered in coordination with critical care specialists. This may alleviate air hunger and facilitate oxygenation, potentially avoiding the need for intubation. Controlled intubation is considered when respiratory failure persists or worsens despite increasing support of maternal oxygenation and ventilation. This can be recognized as maximal fraction of inspired oxygen of 100% (with or without nonrebreather added) and increasing flow rate above 40 to 50 Liters per minute using an HFNC device.17

COVID-19 therapies
The efficacy of antiviral and biologic agents for COVID-19 in pregnancy remains unclear, and no clinical trials in pregnancy have been conducted. The decision to use currently available therapeutic agents approved under the US Food and Drug Administration’s Emergency Use Authorization (EUA) is made in consultation with MFM and infectious disease experts and in accordance with institutional protocols following a discussion of potential benefits and risks with the patient.20 The NIH recommends that remdesivir, an intravenous nucleotide prodrug of an adenosine analogue, be offered to hospitalized patients with $SpO_2$ of less than 94% on ambient air (at sea level) or those who require supplemental oxygen.20 There currently are no available data to suggest harm in pregnant individuals. SMFM supports offering remdesivir for treatment of COVID-19 in hospitalized individuals who meet criteria, although no clinical trials have demonstrated efficacy in this population.20 Institutions may have protocols for use of EUA-approved therapies and compassionate use medications for COVID-19. For pregnant patients who meet clinical criteria and are offered remdesivir following counseling on the limited data available, daily liver function studies should be followed. NIH guidelines recommend discontinuing therapy if ALT levels increase to greater than 10 times the upper limit of normal or if signs or symptoms of liver inflammation are observed with ALT increase.20 Other COVID-19 therapies, such as antibody therapies and immunomodulators, have not been studied in pregnancy but may be considered in some individuals in consultation with infectious disease and MFM experts. Monoclonal antibodies bamlanivimab and the combination of casirivimab plus imdevimab are available through EUA to treat outpatients with mild to moderate COVID-19 who are high risk for progressing to severe disease or hospitalization.12

Finally, dexamethasone has been shown to reduce mortality in nonpregnant, hospitalized patients with COVID-19 who require supplemental oxygen.21 The dosing recommended based on the RECOVERY trial (NCT04381936) is 6 mg (intravenous or oral) for 10 days. SMFM recommends considering twice-daily dosing for 48 hours initially in patients who have an indication for corticosteroids for fetal lung maturity, followed by up to 10 days of daily dosing.20 Antibiotics for respiratory illness are rarely necessary unless bacterial coinfection is strongly suspected.

For patients with asymptomatic or mild infection, supportive treatment is appropriate.

Anticoagulation
There is no evidence to support empiric anticoagulation at therapeutic dosing in individuals without suspected or confirmed VTE.19 There is also little evidence to support prophylactic anticoagulation in individuals with asymptomatic or mild infection, whether inpatient or outpatient, without other indications for chemoprophylaxis. That said, clinicians should adhere to institutional protocols
when available. There is an increased risk for VTE in patients with COVID-19, but evidence suggests that this risk is concentrated in hospitalized patients with critical illness.\textsuperscript{2,3} For pregnant or postpartum individuals hospitalized with severe or critical COVID-19 pneumonia, VTE prophylaxis may be provided with either low molecular weight heparin or unfractionated heparin (if concern for potential delivery or at 35 weeks or later). Even in nonintubated patients, ambulation is typically very limited due to fatigue and supplemental oxygen requirement. For patients hospitalized for obstetric indications who have asymptomatic or mild COVID-19 illness, VTE prophylaxis is not routinely provided outside of other standard indications.

**Obstetric management**

Mild or asymptomatic COVID-19 illness is not an indication for delivery. There is no evidence to support inducing early term labor in patients with mild symptoms and no other indication for delivery. Although earlier evidence suggested potentially higher rates of preterm birth in patients with COVID-19,\textsuperscript{24} these data may be biased toward inclusion of individuals with severe pneumonia requiring hospitalization. Overall, there does not appear to be a risk of adverse pregnancy outcomes such as preterm birth, except in patients with severe or critical illness.\textsuperscript{3}

Delivery for maternal indication in individuals with preterm gestations should be considered only if adequate maternal oxygen and respiratory support have been provided. Delivery considerations include gestational age, fetal monitoring capabilities, and a discussion of potential benefits versus harms. SMFM provides guidance for considerations regarding delivery timing in pregnant individuals with COVID-19.\textsuperscript{25} Delivery does not always improve maternal ventilation or prognosis in a critically ill patient, so priority is given to providing adequate respiratory support with frequent reassessment for clinical worsening as long as fetal status is reassuring. If intubation with immediate proning is necessary after maximal noninvasive support is provided without improvement, delivery should be planned for pregnancies at or near term and considered for any patient in the third trimester.

**Mild or asymptomatic COVID-19 illness is not an indication for delivery. There is no evidence to support inducing early term labor in patients with mild symptoms and no other indication for delivery.**

**Prevention**

In addition to knowing how to manage COVID-19 illness during pregnancy, clinicians should be prepared to educate patients about evidence-based methods to prevent infection. Non-pharmaceutical interventions such as universal masking, physical distance kept at least 6 feet, and hand hygiene are mainstays for reducing the spread of SARS-COV-2 in both community and health care settings. In health care settings, airborne and contact isolation precautions are used to prevent nosocomial transmission, particularly when invasive procedures are planned.\textsuperscript{25}

Available mRNA vaccines appear to be highly protective against clinical disease in nonpregnant adults,\textsuperscript{26,27} and the American College of Obstetricians and Gynecologists and SMFM recommend that COVID-19 vaccines be accessible to pregnant and lactating individuals. Animal developmental and reproductive toxicity studies are ongoing, and clinical studies on safety and efficacy of vaccination in pregnancy are anticipated. As the writing of this article, February 16, 2021, the CDC’s V-safe After-Vaccination Health Checker’s data included more than 30,000 pregnant individuals who have received at least 1 dose of an mRNA vaccine.\textsuperscript{28} Pregnant and lactating individuals who accept vaccination are counseled that they may experience reactions such as pain, headache, fatigue, myalgia, and low-grade fever. Vaccinated individuals are encouraged to register with V-safe to track local and systemic reactogenicity.

Entering the second year of the pandemic, even with vaccination efforts ongoing and variant strains of SARS-COV-2 becoming more recognized, it is imperative that clinicians remain vigilant and up to date on the evaluation and treatment of a pregnant patient who presents with respiratory symptoms of COVID-19. Clinicians caring for pregnant patients with COVID-19 should be familiar with current CDC guidance and local institutional practices. They also should consider early consultation with specialists who are most experienced in managing this dynamic illness in pregnancy. As the virus evolves, so must clinicians’ approach to it; this illness likely will not disappear any time soon.

**FOR REFERENCES VISIT**

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Fresh ideas, workarounds during pandemic can increase access to contraception

The pandemic has forced us to get more creative in managing patients’ needs, especially when it comes to contraception.

by ERIKA E. LEVI, MD, MPH; MOLLY FINDLEY, DO, MPH, MS; ALEXANDRA WOODCOCK, MD; AND JUNE HOI KA NG, MD

Introduction

Although the coronavirus disease 2019 (COVID-19) pandemic has altered many health care practices, it has not changed the need for safe, efficient, and equitable contraception. In the United States, 45% of all pregnancies are unintended, and the rates of unintended pregnancy are highest in individuals with low income and those who are non-Hispanic Black or African American, populations known for reduced access to health care services.1 Because in-person contact with the health care system has been limited...
during the pandemic, ob/gyns should implement or expand upon methods to increase access to contraception. These strategies include same-day and immediate postpartum long-acting reversible contraception (LARC) initiation, home delivery of contraception, and virtual screening for self-start and/or administered contraceptives. Other items for ob/gyns to consider include accessible contraception discontinuation and the safety of contraceptive options for patients with COVID-19.

Contraception and telehealth

As the pandemic evolved, health care professionals had to pivot rapidly from in-person to remote models of care; 2020 saw the largest expansion of virtual health care (telehealth) services since the system’s inception. Providing health care remotely is not without its challenges, particularly in the field of obstetrics and gynecology, but is feasible and can be a valuable tool in reaching patients efficiently and effectively when it is not safe for them to be seen in person. In addition, telehealth has been embraced and supported by national health care organizations. Telehealth appointments have a high show rate and high patient and provider satisfaction. When providing virtual health care services, billing and coding will vary. If a patient is contacted via telephone only (no video), billing and coding will be based on time spent on the phone. If a patient is contacted via synchronous video, meaning that the patient encounter is live rather than viewing a prerecorded video of the patient, billing and coding will be at the same level as an in-person visit (Table).

During the pandemic, Medicare lifted its regulations on the provision of telehealth. Any qualified health care professional, including physicians and advanced-practice clinicians, can provide and bill for telehealth services. All clinical notes must include documentation that the patient agreed to conduct the visit virtually. Additionally, virtual visits cannot address the same problem as an in-person E/M service that occurred within the previous 7 days or lead to a visit with an E/M code in the following 24 hours. For example, if you perform a telehealth appointment for a patient seeking contraception you must see that patient more than 24 hours later to capture billing for both visits.

With the adjunct of a home pregnancy test with or without emergency contraception, many contraceptive methods can be initiated or continued without an in-person visit. Health care professionals can utilize telehealth as a screening visit to elicit the patient’s preferences for birth control and assess eligibility. If an in-person visit is deemed necessary—for example, the patient desires a contraceptive implant or intrauterine device (IUD)—the visit should be provided within a reasonable time frame. Many forms of contraception can be provided virtually, including pills, patches, rings, and self-administered subcutaneous medroxyprogesterone acetate. A simple medical screening can be conducted virtually to ensure eligibility. For estrogen-containing formulations, a blood pressure measurement within the last year is sufficient; if the patient has no documented blood pressure, a prescription for a home blood pressure monitoring kit can be provided with the prescription for contraception. Similarly, prescriptions for contraception should not be withheld due to lack of screening for cervical cancer or sexually transmitted infection (STI). Additionally, some pharmacists may be able to administer intramuscular medroxyprogesterone acetate. Although luteal phase pregnancies are unlikely, a shared decision-making approach is recommended when providing quick-start contraception virtually. The Centers for Disease Control and Prevention provides a mobile application with guidelines on how to be reasonably certain a patient is not pregnant, when to start contraception, and when to use backup contraception.

Mail-order pharmacies and mobile apps

Similar to the dramatic expansion of telehealth during the pandemic, mail-order pharmacies, often through mobile applications, have increased in
of contraception delivered at a time, with automatic refills available. Many of these apps also accept patients without insurance. However, not all companies operate in all 50 states, since these services are relatively new and implementation must follow state laws governing mail delivery of medication.

Although not much data exist on the provision of contraception via mail-order pharmacies, the American College of Obstetricians and Gynecologists (ACOG), the American Academy of Family Physicians, the American Medical Association, and the American Public Health Association support this access to hormonal contraception. In addition, a 2006 study found that patients’ self-assessment and provider assessment of contraindications to contraception agreed in more than 95% of cases. The pandemic and LARC access

Maintaining access to the most effective methods of contraception, such as IUDs and contraceptive implants, involves in-person contact. Luckily, there are a wealth of existing data and society recommendations supporting same-day initiation of LARC as a safe practice that leads to increased LARC uptake and decreased rates of unintended pregnancy. In order to decrease in-person contact, contraceptive options counseling can be done via telehealth, with the patient presenting for an in-person appointment only for the insertion of the device. IUDs and implants can be inserted at any point during the menstrual cycle as long as pregnancy can be reasonably excluded.

Postpartum contraceptive access during the pandemic

For patients who are newly postpartum during the pandemic, contraceptive counseling can be done either as part of antenatal care or during their admission for delivery. For short-acting methods such as pills, a prescription can be placed as part of a patient’s hospital discharge, ensuring they will have access when they need it, regardless of timing of the postpartum visit. Additionally, immediate postpartum IUDs and implants, placed after delivery but prior to discharge from the hospital, are evidence-based and safe methods of LARC initiation. These approaches allow women to initiate their preferred postpartum method of contraception without requiring an in-person postpartum visit. Immediate postpartum LARC initiation also has been shown to increase rates of LARC uptake and decrease rates of unintended and rapid repeat pregnancies.

LARC discontinuation

From a reproductive justice standpoint, efforts to provide seamless, reduced contact contraception during the pandemic must be balanced with a patient’s right to on-demand access to discontinuation of contraception, particularly of LARC. This comes within the context of a history in the United States of reproductive coercion and sterilization of individuals of color, low-income individuals, and other vulnerable populations. As part of this, self-removal of IUDs is growing in popularity. Likely exacerbated by the pandemic, patients have cited an inability to obtain an appointment for IUD removal and inappropriate cost for the removal as reasons they attempt to remove the devices themselves. In a study of women seeking IUD removal, a majority (59%) were willing to try self-removal after receiving instructions from their health care provider, and of those who attempted it, 1 in 5 were successful. Counseling by providers at the time of insertion about the potential of self-removal and/or telehealth counseling prior to attempting removal can help alleviate
both patient and provider concerns. For patients who are not interested in or are unsuccessful with self-removal, in-person appointments for IUD removal should be made available. Furthermore, these appointments should be made available for implant users, for whom self-removal is not an option. As with LARC placement, counseling can occur via telehealth, and the patient then can present for a focused in-person appointment for removal. When counseling patients on LARC removal, providers should consider extended use studies of various LARC methods beyond FDA-approved duration of use. Notably, the levonorgestrel-20 IUD has been shown to be effective for 7 years, the copper IUD up to 12 years, and the contraceptive implant up to 5 years.

Sterilization during the COVID-19 pandemic

Many hospital systems and providers have postponed or canceled elective or nonemergent surgical procedures during the pandemic. There are no existing data on what effect this may have had on access to sterilization procedures. Previous data have demonstrated that unfulfilled sterilization requests among postpartum women lead to high rates of unintended pregnancy: 47% were pregnant by 12 months postpartum. ACOG encourages continued provision of sterilization procedures when possible during the pandemic and discussions with patients to identify bridge methods of contraception when sterilization is not possible. Deciding to proceed with nonemergent surgery during the pandemic should be based on local and institutional policies, availability of local health care resources—including staffing and personal protective equipment (PPE)—and the prevalence of COVID-19 in the region.

The CDC has indicated that the risk of combined hormonal contraceptives and other estrogen-containing methods, particularly for cardiovascular and thromboembolic events, outweigh the benefits in patients with factors predisposing them to DVT or PE.

COVID-19 infection and contraceptive use

There are no published data on the safety profiles of contraceptive methods in patients with COVID-19, particularly the hormonal methods. However, there are studies documenting coagulation factor changes leading to a hypercoagulable state with COVID-19, including evidence of increased risk of thromboembolism with worsening severity of disease. The CDC has indicated that the risk of combined hormonal contraceptives (CHCs) and other estrogen-containing methods, particularly for cardiovascular and thromboembolic events, outweigh the benefits in patients with factors predisposing them to deep vein thrombosis (DVT) or pulmonary embolism (PE). These factors include current or prior DVT/PE, being within the 6-week postpartum period, hypertension, smoking, and known hypercoagulation disorder. By extension, shared decision-making should be employed when counseling patients with COVID-19 (particularly hospitalized patients or patients with severe disease) on CHCs and estrogen-containing methods. On the other hand, progestin-containing or hormone-free methods, including progesterone-only pills, progestin-containing or copper IUDs, and the contraceptive implant, have been shown to have minimal risk for coagulability and should be unrestricted.

Conclusion

Telehealth is critical for providing a means of counseling patients on contraception and screening to determine appropriateness of contraceptive initiation, continuation, and removal. If a patient still requires an in-person visit after a telehealth visit, particularly for LARC placement or removal, appointments should be made available within a reasonable time frame. For the postpartum patient, care should be taken to organize contraception prior to discharge from hospitalization for delivery. For patients desiring sterilization, bridge methods should be offered if there are restrictions on elective surgeries. The pandemic has led ob/gyns to implement new and different strategies to maintain access to care during this unprecedented time, and many are now established as best practices. Indeed, even beyond this pandemic, approaches that reduce the need for patients to interact in person with the health care system may be instrumental in lifting barriers to contraception for the most marginalized populations.

FOR REFERENCES VISIT contemporaryobgyn.net/covidcontraception
A scoping review of scientific literature on reproductive health of transgender and gender diverse individuals published in *Sexual and Reproductive Health Matters* indicates a need for additional and improved research.

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For the review, a research librarian gathered peer-reviewed journal articles that were published between 2000 and 2018 from Ovid MEDLINE, Embase, Cochrane Library, PubMed, Google Scholar, Gender Studies Database, GenderWatch, and the Web of Science Core Collection. All studies were on the topic of reproductive health and used the search terms: *reproductive health; reproductive health care; gynecology; obstetrics; pregnancy; contraception; abortion; fertility intentions; reproduction; family planning; birth; assisted reproduction; IVF* (in vitro fertilization); *surrogacy; prenatal care; postnatal care; gynecologic cancers; cervical cancer; and fertility.*

All selected studies were either qualitatively or quantitatively empirical, had human participants, were written in English, and contained disaggregated data for gender diverse and transgender individuals. According to the authors, studies were limited "to transgender and gender diverse people's own reproductive health experiences, preferences, concerns, needs, or priorities," rather than observations by others.1 Investigators collected 2197 unique articles with abstracts and citations.

A total of 75 articles were selected for full-text review by 2 independent screeners. Data were taken from 37 reviewed articles that were collated and summarized, then analyzed using a numerical summary and a thematic analysis approach, according to the authors.

Investigators observed that literature on reproductive health in transgender and gender diverse individuals was limited. Most studies focused on transgender and gender diverse individuals assigned female at birth. Investigators observed few articles completely about or including transgender and gender diverse individuals assigned male at birth (AMAB). "Similarly, no study exclusively focused on gender diverse (eg, nonbinary, gender fluid, gender nonconforming, genderqueer, agender) people and almost all of those that included both transgender and gender diverse participants aggregated the data for these distinct gender identity groups," the authors wrote.1

Investigators concluded that more studies need to be done, in addition to improvements in study design. Although the quantity of studies increased between 2010 and 2018, the authors said research was targeted toward specific countries, study designs, populations, and reproductive health topics. The authors observed that studies need to cover a wider range of reproductive health issues, including contraception, abortion, and birth.

According to the authors, more studies are needed for wider populations, including AMAB and gender diverse individuals. In addition, transgender
and gender diverse individuals who are from understudied and marginalized populations, such as minorities and low-income individuals, need more studies, the authors wrote. The authors noted that transgender and gender diverse individuals from the Global South need more focus, as most studies came from the Global North, and the United States, in particular. The Global South includes countries that are less economically developed such as Mexico, Brazil, China, and India whereas the Global North includes countries that have more developed economies such as the countries in Europe, Canada, Australia, Israel, and South Africa. Investigators stressed these studies need to be guided by intersectionality, which addresses overlapping challenges of gender, race, sexual orientation, and economic status, to be most effective.

**THE AUTHORS EXPLAINED THAT RESEARCH IS NEEDED THAT “USES INTERVENTION, IMPLEMENTATION SCIENCE, AND COMMUNITY-BASED PARTICIPATORY RESEARCH APPROACHES.”**

They added that practices, programs, and policies that cover the various barriers to reproductive health for these populations are needed. “Health care providers should receive ongoing training in transgender and gender-diverse reproductive health, person-centered care, gender-affirming care, transphobia, and other forms of bias, stigma, and discrimination in health care, structural competence, and shared decision-making in order to facilitate access to and utilization of high-quality reproductive health care that is inclusive and respectful of transgender and gender diverse people’s lived experiences and reproductive health needs,” the authors wrote.

They suggested rethinking branding reproductive health as only women’s health and encouraged practices to be inclusive and affirming of transgender and gender diverse individuals through educational materials, staff training, design of intake forms, response and language options, usage of patients’ correct names, and ways to report discrimination. The authors also encouraged funding for community-based care that specifically serves these transgender and gender-diverse populations. 

**Sandra Fyfe** is a freelance writer for Contemporary OB/GYN®.

**SOURCE**


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**LARC in the Time of COVID and Telehealth: Part 1**

This KCast features Dr. Rachel Phelps of the Rochester LARC Initiative and Dr. Amber Truehart of the University of Chicago Department of Obstetrics and Gynecology, Section of Family Planning and Contraceptive Research.

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Fractional CO₂ laser therapy is effective in treating vulvovaginal atrophy

by BOB KRONEMYER

Fractional microablative CO₂ laser therapy was found both effective and safe in treating vulvovaginal atrophy short term, according to results of a study published in *Menopause*.

The retrospective chart review was composed of 139 individuals with vulvovaginal atrophy symptoms who completed 3 laser sessions approximately 6 weeks apart at Waukesha Memorial Hospital in Wisconsin from January 2016 to December 2019.

All patients were 18 years or older (mean age, 62) and not pregnant. Concomitant topical estrogen was reported as used by 53% of patients (n = 74), breast cancer diagnosis was documented in 27% (n = 38), and lichen sclerosus was documented in 22% (n = 31).

Patients were surveyed prior to their first and third laser treatment via 2 validated questionnaires: the Female Sexual Function Index (FSFI) and the Vulvovaginal Symptoms Questionnaire (VSQ). Patients also filled out a visual analog scale (VAS).

Treatment was delivered vaginally using a vaginal probe followed by the vulvar treatment performed with a separate handpiece using a square pattern. Lidocaine 2% was applied to the vulvar tissue 20 minutes prior to treatment.

The mean follow-up was 13.8 weeks. All FSFI scores improved: pretreatment 12.7 vs posttreatment 19.0 (P < .001). The VSQ also showed that 18 of 21 questions significantly improved (P < .05). In addition, the VAS showed significant improvement in painful intercourse, as well as vulvar and vaginal dryness: pretreatment 12.7 and 4.6, respectively vs posttreatment 2.4 and 1.5 (both P < .001). Furthermore, 17 women became sexually active after the second laser treatment. There were no major adverse events reported among any of the study participants.

“We were surprised that patients improved as early as after 1 or 2 treatments,” said principal investigator Sarit Aschkenazi, MD, MS, medical codirector at Women’s Health Care Urogynecology at ProHealth Waukesha Memorial Hospital. “Improvement occurred even in women with severe symptoms not responding to conventional therapy, such as topical estrogens, or those on aromatase inhibitors for breast cancer prevention. We were especially thrilled to see women with lichen sclerosus with very advanced skin atrophy show signs of improvement.”

The laser therapy delivers energy to the subcutaneous tissue with minimal damage to the overlying epithelium. It stimulates the fibroblasts to produce more collagen and elastin fibers, as well as increases water content, skin folds, and epithelial thickness of the vaginal and vulvar skin, according to Aschkenazi.

“This is similar to the effects produced when the laser is applied to facial skin,” she said. “The laser has been used on facial skin for [more than] a decade and has been documented to be safe.”

The laser is a promising alternative treatment for a prevalent condition such as vulvovaginal atrophy. However, randomized control studies are needed to clearly determine its efficacy and establish the optimal number of treatment sessions, intervals, and boosters. Although the laser treatment was found safe for use in all study patients, Aschkenazi recommends using conventional treatment options for vulvovaginal atrophy symptoms first before adding laser therapy and following treatment parameters to avoid any adverse effects. Patients should maintain skin care by avoiding skin irritants, tight undergarments, scented soap, and scented feminine pads. “Adding nonhormonal moisturizers helps avoid the dryness associated with menopausal symptoms,” she said.

**DISCLOSURES** Aschkenazi reports no relevant financial disclosures.

Bob Kronemyer is a freelance writer for Contemporary OB/GYN®.

**SOURCE** Gardner AN, Aschkenazi SO. The short-term efficacy and safety of fractional CO₂ laser therapy for vulvovaginal symptoms in menopause, breast cancer, and lichen sclerosus. Menopause. Published online January 4, 2021. doi:10.1097/GME.0000000000001727
Cervical Cancer Screening Guideline Recommendations

Healthcare providers and real-world data support co-testing with the Pap test and HPV test together. These screening methods represent the most effective way to detect cervical cancer and precancer in women and should be retained in cervical cancer screening guidelines.

In this *Contemporary OB/GYN* Clinical Consult video series, expert Jessica Shepherd, MD, MBA, presents an authoritative overview of screening guidelines and discusses critical topics of cervical cancer prevention and control, including concerns over with HPV-alone testing, at-risk demographics, data supporting retention of the Pap test, her own perspective as a practicing clinician, and more.

Go to: [contemporaryobgyn.net/consult-screening](http://contemporaryobgyn.net/consult-screening)
Transdermal Estrogen Therapy and Resistance Training For Muscle Mass

by BOB KRONEMYER

Transdermal estrogen therapy (ET) significantly increased skeletal muscle mass in response to 12 weeks of supervised, progressive resistance training among early postmenopausal women, study results show.

The Danish double-blinded randomized controlled study found an increase in muscle cross-sectional area of 7.9% in the ET group vs 3.9% in the placebo group ($P < .05$).

Likewise, the increase in whole-body fat-free mass was 5.5% in the ET group vs 2.9% in the placebo group ($P < .05$).

“Women show an accelerated loss of muscle mass around menopause, possibly related to the decline in estrogen,” the study authors wrote. “Furthermore, the anabolic response to resistance exercise seems to be hampered in postmenopausal women.”

The investigators tested the hypothesis that ET amplifies the skeletal muscle response to resistance training in early postmenopausal women.

For the study, which was conducted at the Department of Public Health at Aarhus University in Denmark, 32 healthy, postmenopausal women no more than 5 years past menopause who were not doing resistance training were recruited.

The primary outcome was the impact of resistance training on a cross-sectional area of quadriceps femoris measured by MRI. Secondary parameters were fat-free mass determined by dual-energy x-ray absorptiometry, muscle strength, and functional tests.

Transdermal 17-$\beta$-estradiol or placebo patches were given to the participants in a closed, nontransparent envelope. The patch was placed on the skin on the lower part of the abdomen at the start of the intervention. The patch was renewed twice a week.

The ET patch released 100 $\mu$g 17-$\beta$-estradiol every 24 hours. After intervention, participants in the ET group were offered 10 days of treatment with progesterone. One participant did not attend the initial test and start of the intervention; the remaining 31 women (ET n = 15; placebo n = 16) completed the intervention period and tests.

The ET group receiving a somewhat substantial dose of estradiol, their follicle-stimulating hormone (FSH) and luteinizing hormone (LH) levels did not reach premenopausal levels (< 15 IU/L). “Thus, it can be speculated that a higher dose of estradiol would have led to even more pronounced effects on muscle mass and function,” the authors wrote.

The authors stated that future training studies should clarify if the combination of training and ET causes a greater positive effect on skeletal muscle mass and strength than training or ET alone.

Bob Kronemyer is a freelance writer for Contemporary OB/GYN®.
Evolving Management Strategies for Uterine Fibroids

In this Contemporary OB/GYN® K-Cast expert video series, Ayman Al-Hendy, MD, PhD, and Magdy Milad, MD, discuss the current challenges and standards of care, as well as future opportunities in the management of patients with uterine fibroids.

Watch the video series at: contemporaryobgyn.net/fibroid-management
Overactive bladder (OAB) is a clinical diagnosis characterized by urinary urgency, with or without urgency incontinence, usually with increased daytime frequency and nocturia with urinary incontinence (OAB-wet) or without (OAB-dry) in the absence of urinary tract infection or other detectable disease. The overall prevalence of OAB in the general population is as high as 12% to 17%, and it significantly impacts the quality of life of affected individuals.1–5 The underlying pathophysiology of OAB is detrusor overactivity (DO), a urodynamic diagnosis defined by involuntary detrusor contraction during filling cystometry.6 In patients desiring treatment for symptoms of OAB/DO, behavioral therapies, including fluid management, bladder training, urge suppression, and pelvic floor muscle strengthening, should be instituted first. If behavioral therapies do not control
Consideration should be given to use of anticholinergic medications to treat OAB in women older than 70 years.®

Recommendations

When behavioral therapies fail and pharmacologic treatment of OAB/DO is considered, providers should counsel on the associated risk of cognitive impairment, dementia, and Alzheimer disease associated with anticholinergic medications in comparison with the potential benefits related to improvement in quality of life or overall health of the individual patient.

To reduce overall anticholinergic burden, the lowest effective dose should be prescribed, and consideration should be given to alternative medications such as β-3 agonists.

- Consideration should be given to changing or decreasing the dosage of other anticholinergic medications that a patient may be taking.

As recommended by the American Urogynecologic Society’s “Choosing Wisely” campaign, use of anticholinergic medications to treat OAB in women older than 70 years should be avoided.

- When anticholinergic medications have to be used in elderly patients, consideration should be given to use those that have low potential to cross the blood-brain barrier, recognizing that there are limited clinical data.

- Third-line therapies such as intradetrusor onabotulinum toxin A or neuromodulation should also be considered in patients not desiring to use medications for OAB/DO because of their adverse effects.

REFERENCES


This was created in partnership with the American Urogynecologic Society (AUGS). AUGS was established in 1979 and represents more than 1,900 members, including practicing physicians, nurse practitioners, physical therapists, nurses and health care professionals, and researchers from many disciplines.
The Blame Game Becomes Real When Patient Unleashes Fury

As a doctor tackles the challenges of his senior year of residency, he learns how to balance the blame that can come with heightened responsibilities.

by LUKE BURNS, MD

A few months ago, I transitioned into my third year of residency, crossing that invisible line that demarcates the junior residents from the seniors. In my program, this means assuming the role of labor and delivery chief, managing a floor of laboring mothers and antepartum patients.

It was at around 3 AM on one of these nights, as I was sitting alone in the boardroom, that the silence was suddenly shattered by screams. A nurse burst into the room to tell me that the patient in room 11 had her amniotic sac rupture. Shouting from the hallway filled the room.

Room 11 held one of our high-risk antepartum patients. But which patient? As I sprang from my seat, I scanned through my mental Rolodex, desperately trying to remember which of the dozen high-risk patients I had assumed care for might now be imminently delivering.

It was only when I reached the hallway and saw the bed rolling past me toward the operating room that I remembered. Room 11 was a patient who was stable, primigravid with breech presentation, admitted several days ago for new cervical insufficiency and funneling. She was the one with daily reassuring nonstress tests (NSTs) and a cervical length that had not changed since admission. She was also the patient who summoned me every night to her room, convinced she might have felt a contraction, the one I had only just reassured that evening, despite her insistence that this time something was different. Her tocometry was reassuring, her physical exam unchanged, and so we had decided against any intervention. And now she was delivering a 27-week infant in her bed.

The patient was rolled toward me, guided by a swarm of nurses, and as she approached, my eyes found hers. In an instant she recognized me as the young doctor who had ignored her earlier pleas. She pointed a finger directly at me.

“I told you! I told you and you didn’t listen, and now you’ve killed my baby! This is your fault! You killed my baby!” I froze, speechless. Was she right? What subtle finding on her NST had I overlooked? Had I anchored myself in my own beliefs about her diagnosis? If so, I had missed an opportunity to initiate neuroprotective magnesium, to start ampicillin for her group B Strept–positive status, to move toward a calm and controlled cesarean delivery.

I grabbed my scrub cap and ran to the operating room.

Sometime later during the gynecology night service, a patient came in to the emergency department (ED) for management of her abnormally trending β-hCG levels. She was a single mother, and sitting beside her was her 4-year-old daughter. She had been waiting several hours and was weary of the mixed
messages she had received all week regarding a pregnancy that she had at first been told was a miscarriage and now was told might be ectopic. Now, she said, raising her voice, 1 doctor wants to give her chemotherapy, another wants to cut her open, and the third wants to do some kind of abortion procedure.

I took my time explaining her options. Throughout our conversation, her daughter napped quietly, even as my pager shrieked with incoming messages. Three new consults were waiting for me, including a gynecological oncology patient in the ED with a small bowel obstruction and an apparent non-ST-segment elevation myocardial infarction (NSTEMI).

The patient ultimately decided on a manual vacuum aspiration (MVA), but it would have to be tonight, she said. I leaped into action. My first step was to page the ED attending, asking if he would be willing to permit the procedure under general sedation in the patient’s room. While I waited for his response, I saw the pending consults. The patient with the small bowel obstruction had an outside CT scan that still needed to be read, and I contacted the radiology department to track it down.

Next I rushed upstairs to attend to patients on the floor and received a call from the ED on the way back down. They had decided not to let the patient have her MVA at the bedside, due to a new policy. This patient would need a dedicated operating room, despite the fact that with inadequate insurance she would likely receive a substantially greater bill as a result.

I updated my attending physician at home, then contacted the anesthesia team in the main operating room. The patient’s case fell somewhere between “elective” and “urgent,” but it was close enough to the former that the obstetric anesthesia resident I spoke to did not feel it warranted action tonight. She apologized and hung up.

My last option was to request the procedure be performed in a labor and delivery room. I begged the OB anesthesia resident over the phone, insisting that this patient was dangerously close to falling through the cracks, and she hung up to discuss it with her attending physician. Meanwhile, more gynecology consults had rolled in, and the gynecological oncology patient with the NSTEMI was becoming unstable.

When I returned to the emergency room, it was midnight. The OB anesthesia attending physician had approved the procedure. All of the ducks were in a row, and her MVA was ready to happen.

As I approached the room, I heard yelling from within. Something was wrong. Inside, I found an ED social worker trying her best to calm the patient down. The patient’s daughter sat wide-eyed in the corner.

“I mean I’ve been waiting here for 6 hours for this procedure, and now nobody is going to take care of my child?”

The social worker explained that a family member or friend would have to care for the patient’s daughter while she had her MVA.

I stayed silent, not sure what to say. “I’m going home now, and I’m going to take care of this problem myself. I’m going to end this pregnancy my own way, and you can read about it in the paper tomorrow.”

With that, she gathered up her daughter and left the room. Suddenly, the weight of the entire evening fell upon me, the lengths I had gone to secure this patient proper care, the many other problems I had been juggling, the dead ends I had reached, this accusation, and worst of all, the thought that this woman might hurt herself. In that moment, I lost it. Without knowing what I was doing, I felt my eyes fill with tears.

The social worker laid a hand on my shoulder as I buried my face in my hands. I’ve never cried in public before, certainly not in the hospital, but I could not stop. Even when I had done everything right, somehow things had gone wrong. What would happen to this patient? What was she going to do to herself? After a few minutes, I stepped outside again and the night carried on.

The following week I participated in a straightforward spontaneous birth. As
the family thanked me for delivering their child, I did what most doctors do in this situation, refusing the credit and sharing the gratitude among all the nurses and other staff involved in their care. Avoiding self-blame is not an easy task. It is impossible for physicians to be entirely hardened against the bad outcomes of our patients. When things go wrong, hindsight forces us to consider every possible choice we did or did not make. But to assume full responsibility for these outcomes is an act of egoism; blaming oneself for the failures of the human body is like taking credit for the miracle of birth. Biology marches on, no matter how closely you follow your American College of Obstetricians and Gynecologists Practice Bulletin.

This is a timely realization for me as I embrace my new role as a senior resident. Now with more responsibility than ever, I need to remember that when things go wrong—and they will—I must learn from these experiences without letting them drag me down.

And perhaps most importantly, I will remember to share them with other trainees. Every one of my role models has made a mistake, lost a patient, or cried quietly in the hospital. Attendings and senior trainees should know that it is not their stories of brilliant diagnoses or heroic interventions that most inspire their residents. It is the stories of times when they felt they were knocked down, either by a bad call or a bad outcome, but rose up again, wiser and stronger than before.

As I approached the room, I heard yelling from within. Something was wrong.

If I never accept full credit for a good outcome, why should I accept full responsibility for a bad one? If an upset patient lays blame at my feet, shouldn’t I stop to consider if I am truly at fault before I stoop to pick it up?
Was a laparoscopic approach to a salpingectomy proper?

The conditions the plaintiff had struggled with included uterine fibroids and primary infertility. What approach would you have taken in this situation?

**Factual summary**

On November 2, 2011, the plaintiff presented to the defendant hospital emergency department (ED) complaining of left-sided abdominal pain and nausea. A pelvic sonogram showed a large intramural fibroid at the fundus measuring 6.7 x 6.1 x 8.4 cm and a second small subserosal fibroid in the posterior uterine body measuring 1.2 x 1 x 1.5 cm. On November 9, 2011, the patient presented to the clinic for follow-up. The patient also stated that her menses were heavy, and she complained of dysmenorrhea, occasional dyspareunia, and urinary frequency.

On June 26, 2014, the patient, then 29 years old, presented to defendant obstetrician (OB) A’s office with her husband. She had been married for 2 years and was experiencing primary infertility. Her past surgical history included an abdominal myomectomy through Pfannenstiel incision 2 years earlier. The patient reported that she underwent a complete examination 2 weeks earlier and was scheduled to undergo a sonogram and hysterosalpingogram. Defendant OB A counseled the couple on infertility. The patient’s June 26, 2014, antimüllerian hormone (AMH) was low at 0.51. On July 2, 2014, the patient underwent a hysterosalpingogram, which showed a normal uterine cavity but a delayed filling of both fallopian tubes with suspicion of hydrosalpinx on the right.

On July 9, 2014, the patient returned to Defendant OB A’s office. He noted that her AMH was suspect for decreased ovarian reserve. He also documented that her hysterosalpingogram showed bilateral occlusion with probable bilateral hydrosalpinx. They discussed in vitro fertilization (IVF) and the need for a laparoscopy. Defendant OB A noted that if single or bilateral hydrosalpinx were found, removal would increase chances of IVF success. Defendant OB A documented that they discussed the procedure, risks, and benefits.

Furthermore, he noted that, depending on the scar tissue due to her prior abdominal myomectomy, he might transect rather than remove her tubes completely.

On March 31, 2015, the patient presented to defendant hospital’s ambulatory surgery unit. The surgery started at approximately 1:13 pm. Defendant OB A’s operative report lists the patient’s pre- and postoperative diagnosis as “bilateral hydrosalpinx,” and “extensive pelvic adhesions” was added to the postoperative diagnosis. During the procedure, Defendant OB A encountered extensive scar tissue and found omentum attached to the anterior abdominal wall, bowel, and uterus. The right fallopian tube was found to be a hydrosalpinx, “the vast majority of which was greatly adhered to the sidewall over the uterus,” according to the report.

Defendant OB A “decided to excise only the proximal portion near the uterus and enough down the tube to ensure that there was no communica-
tion between them." The left fallopian tube was severely kinked. There were other adhesions to it, as well, even though it had normal fimbria due to the strictures around it. A significant portion was hydrosalpinx, as well.

Defendant OB A wrote an office note indicating that the patient’s bowel and scar tissue completely obliterated the right sidewall of her pelvis. In addition, he noted extensive adhesions anteriorly of her uterus, both omentum and bladder, and subserosal fibroid at the fundus, as well. Her right tube was very dilated with hydrosalpinges with extensive adhesions, so he performed a partial salpingectomy to take down the 36.9 °C. At approximately 3:30 PM, the patient experienced an episode of Sao2 less than 90% and was cyanotic and nauseous. The PACU nurse increased O2 to 3 L. After 5 minutes, the patient’s O2 saturation was 100%. At 4:10 PM, her blood pressure was 87/47 mm Hg and she continued to have complaints of pain, which she graded 6 out of 10. The nurse’s note indicates a resident ordered 0.25 mg hydromorphone. By 4:30 PM, the patient’s nausea is noted to have subsided.

At 5 PM, the patient remained nauseated. At 5:20 PM, the patient still complained of nausea. Codefendant OB B ordered dexamethasone 4 mg intravenous (IV) and a scopolamine patch. At 5:30 PM, the patient tried to ambulate but was “too weak to walk” and was placed back in the recliner. Her vital signs at this time were blood pressure 88/46 mm Hg; pulse rate 72, Sao2, 100%. At this time, codefendant OB B noted that a moderate amount of blood was found on the patient’s sanitary pad. The nurse’s note also documented that the patient was evaluated by Defendant OB A and was to be transferred to the ED for further evaluation. At this time, her vital signs were blood pressure 105/44 mm Hg; Sao2, 100%, temperature, 36 °C.

At 7:45 PM, codefendant OB B noted that the patient’s abdomen looked more distended. The ED was called and report given. At 8:05 PM, the patient was transferred to the ED by emergency medical services via stretcher. Her vital signs at transfer were blood pressure 111/42 mm Hg; pulse rate 72, Sao2, 99%.

At 8:38 PM, the patient was examined at the defendant hospital’s ED. The patient was cold, clammy, and hypotensive with systolic blood pressure in the 70s and a diffusely tender and distended abdomen. The patient was responsive to pain but not answering questions. Her ECG reflected abnormal ST and shortened PR interval. A stat ob/gyn consult was requested. The patient, deemed critically ill with a diagnosis of abdominal

She had been married for 2 years and was experiencing primary infertility. Her past surgical history included an abdominal myomectomy through Pfannenstiel incision 2 years earlier.
hemorrhage, was admitted for urgent transfer to the operating room (OR). Defendant OB A was listed as the admitting physician.

At 9:03 PM, the patient was brought to the OR and underwent an exploratory laparotomy and evacuation of hemoperitoneum. The abdominal cavity was entered and a copious amount of blood and clots evacuated. All 4 quadrants of the abdomen were packed, and a systematic exploration of all quadrants performed. There was no evidence of active bleeding in the pelvis, and each site of surgery performed on the uterus was also examined, with no area of active bleeding noted. During surgery, the patient received 2 units of packed red blood cells as well as fresh frozen plasma and platelets. There were no complications.

On April 4, 2015, the patient was discharged home in stable condition to follow up in 1 week with the surgeon and with Defendant OB A; however, Defendant OB A never saw the patient again.

On April 13, 2015, she presented to the surgeon’s office. The surgeon noted that the patient’s incision was healing well and removed her staples. She was instructed “to return as needed.” On April 27, 2015, she returned to the surgeon’s office complaining of cramps after eating. Although she had regular bowel movements, she reported passing very little flatus. Again, her physical exam revealed that her incision was healing well and that her abdomen was soft, non-tender, and nondistended. The surgeon recommended a CT scan of her abdomen and pelvis to rule out obstruction. The patient never returned to the surgeon’s office.

On April 28, 2015, a CT with contrast revealed no bowel obstruction. Of note, there were small volume ascites in the pelvis with minimal faint peritoneal enhancement within the cul-de-sac and mild hazy/streaky changes within the pelvic fat. These findings represented mild inflammation or postoperative changes.

On August 19, 2015, the patient presented to the defendant hospital ED complaining of abdominal pain and pressure and leg numbness. A CT scan of the abdomen/pelvis revealed an increased amount of pelvic ascites moderate in size and of uncertain etiology, which the radiologist attributed to cyst rupture or leakage.

On September 8, 2015, the patient returned to the defendant hospital’s ED complaining of abdominal pain and nausea. She also reported that her 2 right-sided ovarian cysts had ruptured 2 weeks earlier. A CT scan of the abdomen/pelvis revealed fibroid uterus, moderate fluid in the pelvis, and mild displacement of the rectosigmoid colon on the right. The clinical impression was loculated fluid vs peritoneal inclusion cyst. The patient was given IV fluids. She eventually was discharged and advised to follow up with her private ob/gyn in 2 days. She also was referred to a urogynecologist.

Although they discussed options, the patient initially opted for nonsurgical treatment.

The patient also followed up with her physicians for her left ovarian cyst and lower left quadrant pain beginning October 14, 2015. Of note, the patient’s review of systems was unrevealing, and she denied a history of blood clots or increased risk for blood clots/PE/DVT. A transvaginal ultrasound on October 1, 2015, revealed extensive partially loculated pelvic collections suggestive of peritoneal inclusion cysts (normal) measuring 7.6 x 3.6 x 5.3 cm and a 2- to 2.5-cm posterior serosal leiomyoma. Her new ob/gyn gave her a diagnosis of chronic pelvic pain and a pseudocyst of pelvis. Given the finding of large fluid collection, he discussed possible drainage and future surgery if her symptoms did not improve.

Between November 2015 and July 2016, the patient underwent 2 interventional radiology drainages of pelvic fluid. Although she initially reported improvement of pelvic pain, she also complained of worsening
prolapse symptoms. During her July 20, 2016, appointment with urogynecology, the patient underwent a pessary trial to see if it would alleviate any pelvic pressure or bulge sensation; however, she reported no improvement and wanted a hysterectomy.

Defendant OB A wrote an office note indicating that the patient’s bowel and scar tissue completely obliterated the right sidewall of her pelvis. In addition, he noted extensive adhesions anteriorly of her uterus, both omentum and bladder, and subserosal fibroid at the fundus, as well.

On September 6, 2016, the patient underwent a hysterectomy and salpingectomy at the defendant hospital, along with a pelvic floor reconstruction. Dense adhesions to the anterior abdominal wall were encountered. A colonic serosal tear was repaired using 2-0 silk suture. Pathology revealed benign uterus, cervix, and fallopian tubes.

On September 20, 2016, she returned to the urogynecologist and reported doing well and that her pain was relieved by acetaminophen. She also denied incontinence or retention but complained of some episodes of dizziness and blurry vision. She also complained of incisional pain and musculoskeletal pain in her back and legs.

On November 19, 2016, she presented to the defendant hospital ED complaining of severe lower back and abdominal pain for 5 days after a hysterectomy. She underwent a CT scan of her abdomen and pelvis, which revealed a normal appendix and that she had had a hysterectomy. Of note, the report also indicated a 1.7-cm left adnexal lesion, likely representing a cyst, and that her right adnexa was unremarkable.

The patient continued to follow up with ob/gyn and urogynecology; however, her symptoms continued to persist despite the hysterectomy. During her November 29, 2016, visit, she continued to complain of severe pelvic, vaginal, and rectal pain, which she described as identical to the pain she had prior to the surgery. The urogynecologist recommended consultation with a pelvic pain specialist as well as evaluation with her ob/gyn. The urogynecologist also recommended trying amitriptyline.

Allegations

The plaintiff claimed that defendant OB A did not use the appropriate surgical technique in performing her surgery. Specifically, it was claimed that he should have performed an open/laparotomy or open laparoscopic approach. With respect to defendant hospital, the plaintiff alleged that there was a delay in obtaining an ambulance to take her from the PACU to the hospital.

As a result of the alleged malpractice, the plaintiff claimed she sustained fibroid with fundal myoma, peritoneal inclusion cysts, posterior serosal leiomyoma, vaginal prolapse, abdominal myomectomy, lacerated omentum, hemorrhagic and hypovolemic shock, chronic pelvic pain, and myomatous uterus, all of which allegedly required further surgical intervention. Plaintiff alleged that due to vaginal prolapse and continued pelvic pain, she had to undergo a hysterectomy and is now infertile. The plaintiff’s husband also alleged loss of consortium and services.

Trial

Defendant OB A testified that the laparoscopic approach to the surgery in question provided him with adequate visualization of the relevant anatomic structures. He maintained his position that the laparoscopic approach was appropriate, especially given the fact that the patient was expected to have significant adhesions from the prior myomectomy that she underwent through a Pfannenstiel incision.

The resident testified there was no evidence of abdominal bleeding during the time-period that she was involved with the patient in the initial postoperative period. She described the patient’s postoperative course as being completely within normal limits. Although the patient’s blood pressure was somewhat low, the resident testified that the patient’s baseline blood pressure also was low and it was not unusual for a patient’s blood pressure to be low in the immediate postoperative period.

On cross-examination, we were able to establish that the plaintiff was
told to return to the fertility office after Defendant OB A’s surgery but never did. This was in an attempt to refute the infertility claim by establishing that the plaintiff chose not to proceed with in vitro fertilization following the surgery performed by Defendant OB A. Notably, the fertility specialist confirmed that the patient’s adhesions were most likely the cause of her pain and that they were a natural consequence of any surgery. Finally, we pointed out that his chart contained a copy of the operative report from the plaintiff’s prior myomectomy, which states that surgery was done for chronic pelvic pain, suggesting the condition was preexisting. Her current ob/gyn opined on cross-examination that the vaginal prolapse was unrelated to Defendant OB A’s surgery.

The plaintiff and her husband both testified as to the impact that the plaintiff’s physical condition had on her personal life as well as her work life and their intimacy. On cross-examination we pointed out that the plaintiff had been treated for pelvic pain and constipation prior to the surgery in question, in an attempt to establish that she had preexisting conditions that could be responsible for her current complaints, including the vaginal prolapse. The plaintiff also maintained that she was unaware that her uterus was going to be removed before she agreed to undergo subsequent surgery, but she was confronted with the consent form that she admitted signing, as well as an entry in her urogynecologist’s chart 1 month before the surgery stating she no longer desired fertility.

The plaintiff’s ob/gyn expert initially stated that the use of a Veress needle during a laparoscopic procedure was within the standard of care and later tried unsuccessfully to correct himself. He was eventually able to opine that a laparotomy should have been done instead of a laparoscopic procedure. He also stated that it should have been performed through the same Pfannenstiel incision that was used for the prior myomectomy.

On cross-examination, he conceded that there would be more scar tissue near the incision site, and he agreed that a surgeon would want to avoid scar tissue during a subsequent procedure. He also had a difficult time establishing a causal relationship between the surgical complication and the claimed injuries, including the vaginal prolapse and the need for a hysterectomy.

Our urogynecology expert previously had written American College of Obstetricians and Gynecologists’ bulletins on pelvic organ prolapse and pelvic pain. He explained that a rectocele is not an acute problem but one that develops over years and sometimes decades. Because of that and because bleeding into the abdomen is not a risk factor, he said that, in his opinion, the bleeding complication that occurred in this case was not the cause of the rectocele. Similarly, he testified that the plaintiff’s other injuries, including the pelvic floor dysfunction and vaginal pain, were not caused by the bleeding complication at issue. Finally, he testified that the hysterectomy was not necessitated by the bleeding complication. Although it was certainly possible that some of the plaintiff’s pelvic pain was due to adhesions, he testified that adhesions are a risk of any surgery and are unavoidable. He also refuted the contention that the plaintiff was in hemorrhagic shock due to the estimated blood loss of approximately 2400 cc. In addition, he testified that the presence of blood in the patient’s abdomen was not, per se, dangerous to the patient since most of it would naturally be reabsorbed into the body.

Defendant OB A returned to the stand and explained that he did not perform a laparotomy through the Pfannenstiel incision from the prior myomectomy because he wanted to avoid the dense adhesions that were likely underneath that incision. Defendant OB A also was able to show the jury the difference between the omental adhesions and the dense adhesions around the other structures, including the uterus and bowel.

Our gynecology expert testified that no gynecologic surgeon would have performed the surgery in question via a laparotomy. He also stated that the use of a Veress needle was inappropriate and is, in fact, the method he uses during laparoscopic surgery. He refuted each of the opinions offered by plaintiff’s expert and said that use of the prior Pfannenstiel incision would not have been safer or easier than a laparoscopic approach.

**Result**
The jury returned a verdict in favor of the defendants.
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