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< Up to 90% of VTEs occur in the left iliofemoral vein. In this anterior view, the lower great vessels are shown, with emphasis on bifurcation of the aorta and femoral veins.
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References:

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Up to 90% of VTEs occur in the left iliofemoral vein. In this anterior view, the lower great vessels are shown, with emphasis on bifurcation of the aorta and femoral veins.
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INDICATIONS
• SUPRAX® (cefixime) is a cephalosporin antibacterial drug indicated in the treatment of adults and pediatric patients six months of age and older with the following infections when caused by susceptible isolates of the designated bacteria: Uncomplicated Urinary Tract Infections; Otitis Media; Pharyngitis and Tonsillitis; Acute Exacerbations of Chronic Bronchitis; Uncomplicated Gonorrhea (cervical/urethral).

IMPORTANT SAFETY INFORMATION
SUPRAX should only be used to treat infections that are proven or strongly suspected to be caused by bacteria.

CONTRAINDICATIONS
• SUPRAX (cefixime) is contraindicated in patients with known allergy to cefixime or other cephalosporins.

WARNINGS & PRECAUTIONS
• Hypersensitivity reactions: Anaphylactic/anaphylactoid reactions (including shock and fatalities) have been reported with the use of cefixime. Before therapy with SUPRAX is instituted, careful inquiry should be made to determine whether the patient has had previous hypersensitivity reactions to cephalosporins, penicillins, or other drugs. Discontinue use if a reaction occurs.
• Clostridium difficile associated diarrhea: Evaluate if diarrhea occurs.
• Dose Adjustment in Renal Impairment: The dose of SUPRAX should be adjusted in patients with renal impairment and those undergoing continuous ambulatory peritoneal dialysis and hemodialysis.
• Coagulation Effects: Cephalosporins, including SUPRAX, may be associated with a fall in prothrombin activity. Prothrombin time should be monitored in patients at risk and exogenous vitamin K administered as indicated.
• Phenylketonurics: SUPRAX Chewable Tablets contain aspartame, a source of phenylalanine.

ADVERSE REACTIONS
• Most common adverse reactions are gastrointestinal such as diarrhea (16%), loose or frequent stools (6%), abdominal pain (3%), nausea (7%), dyspepsia (3%), and flatulence (4%).
• Adverse reactions during postmarketing experience occurred at rates of less than 2%. Some serious adverse reactions included: pseudomembranous colitis, hypersensitivity reactions including Stevens-Johnson syndrome and serum sickness, acute renal failure, seizures, agranulocytosis, and toxic epidermal necrolysis.

DRUG INTERACTIONS
• Elevated carbamazepine levels have been reported in postmarketing experience when cefixime is administered concomitantly.
• Increased prothrombin time, with or without clinical bleeding, has been reported when cefixime is administered concomitantly with warfarin and anticoagulants.
• A false positive reaction for ketones and glucose in urine may occur with certain test kits. A false positive direct Coombs test has also been reported.

USE IN SPECIAL POPULATIONS
• Efficacy and safety in infants aged less than six months have not been established.
• Cefixime should be used during pregnancy only if clearly needed.
• Consideration should be given to discontinuing nursing temporarily during treatment with cefixime.

Please note this information is not comprehensive. Please see Brief Summary of Prescribing Information on the following page.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088, or contact Lupin Pharmaceuticals, Inc. at 1-800-399-2561.


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Pharmaceuticals Inc.

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111 South Calvert Street, Baltimore, MD 21202. PP-SPX-0047
SUPRAX® (cefixime)

BRIEF SUMMARY: This summary does not include all the information needed to use SUPRAX safely and effectively. Consult Full Prescribing Information for complete product information.

SUPRAX should only be used to treat infections that are proven or strongly suspected to be caused by bacteria.

INDICATIONS AND USAGE
SUPRAX (cefixime) is a cephalosporin antibacterial drug indicated in the treatment of adults and pediatric patients six months of age or older with the following infections when caused by susceptible isolates of the designated bacteria:

- Uncomplicated Urinary Tract Infections caused by Escherichia coli and Proteus mirabilis.
- Otitis Media caused by Haemophilus influenzae, Moraxella catarrhalis, and Streptococcus pyogenes. (Note: For patients with otitis media caused by Streptococcus pneumoniae, overall response was approximately 10% lower for cefixime than the competitor. Efficacy for Streptococcus pyogenes in this organ system was studied in fewer than 10 infections.)
- Pharyngitis and Tonsillitis caused by Streptococcus pyogenes. (Note: Penicillin is the usual drug of choice in the treatment of Streptococcus pyogenes infections. SUPRAX is generally effective in the eradication of Streptococcus pyogenes from the nasopharynx; however, data establishing the efficacy of SUPRAX in the subsequent prevention of rheumatic fever is not available.)
- Acute Exacerbations of Chronic Bronchitis caused by Streptococcus pneumoniae and Haemophilus influenzae.
- Uncomplicated Gonorrhea (cervical/urethral) caused by Neisseria gonorrhoeae (penicillinase-and non-penicillinase-producing isolates).

CONTRAINDICATIONS
SUPRAX (cefixime) is contraindicated in patients with known allergy to cefixime or other cephalosporins.

WARNINGS AND PRECAUTIONS
Hypersensitivity Reactions: Anaphylactic/anaphylactoid reactions (including shock and fatalities) have been reported with the use of cefixime. Erythema multiforme, Stevens-Johnson syndrome, and serum sickness-like reactions have also been reported. Before therapy with SUPRAX is instituted, careful inquiry should be made to determine whether the patient has had previous hypersensitivity reactions to cephalosporins, penicillins, or other drugs. Discontinue SUPRAX if an allergic reaction occurs.

Clostridium difficile-Associated Diarrhea: Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including SUPRAX.

Dose Adjustment in Renal Impairment: The dose of SUPRAX should be adjusted in patients with renal impairment.

Coagulation Effects: Cephalosporins, including SUPRAX, may be associated with a fall in prothrombin activity. Prothrombin time should be monitored in patients at risk and exogenous vitamin K administered as indicated.

Phenylketonurics: SUPRAX (cefixime) Chewable Tablets contain aspartame, a source of phenylalanine. 100 mg, 150 mg and 200 mg strength contains 3.3 mg, 5 mg and 6.7 mg of phenylalanine, respectively.

ADVERSE REACTIONS
The most commonly seen adverse reactions were gastrointestinal events, which were reported in 30% of adult patients on either the twice daily or the once daily regimen. Five percent (5%) of patients in the U.S. clinical trials discontinued therapy because of drug-related adverse reactions. Individual adverse reactions included diarrhea 16%, loose or frequent stools 6%, abdominal pain 3%, nausea 7%, dyspepsia 3%, and flatulence 4%. The incidence of gastrointestinal adverse reactions, including diarrhea and loose stools, in pediatric patients receiving the suspension was comparable to the incidence seen in adult patients receiving tablets.

DRUG INTERACTIONS
Carbamazepine: Elevated carbamazepine levels have been reported in postmarketing experience when cefixime is administered concomitantly. Drug monitoring may be of assistance in detecting alterations in carbamazepine plasma concentrations.

Warfarin and Anticoagulants: Increased prothrombin time, with or without clinical bleeding, has been reported when cefixime is administered concomitantly.

Drug/Laboratory Test Interactions: A false-positive direct Coombs test has been reported during treatment with other cephalosporins; therefore, it should be recognized that a positive Coombs test may be due to the drug.

USE IN SPECIFIC POPULATIONS
Pregnancy: Pregnancy Category B. Reproduction studies in mice have revealed no evidence of harm to the fetus due to cefixime. There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Labor and Delivery: Cefixime has not been studied for use during labor and delivery and should only be given if clearly needed.

Nursing Mothers: It is not known whether cefixime is excreted in human milk. Consideration should be given to discontinuing nursing temporarily during treatment with this drug.

Pediatric Use: Safety and effectiveness of cefixime in children aged less than six months old have not been established.

Geriatric Use: Clinical studies did not include sufficient numbers of subjects aged 65 and older to determine whether they respond differently than younger subjects. Other reported clinical experience has not identified differences in response between the elderly and younger patients. A pharmacokinetic study in the elderly detected differences in pharmacokinetic parameters, but they were small and do not indicate a need for dose adjustment.

Renal Impairment: Dose adjustment is advised in patients with renal impairment as well as those undergoing continuous ambulatory peritoneal dialysis (CAPD) and hemodialysis (HD). Patients on dialysis should be monitored carefully.

DOSEAGE AND ADMINISTRATION
Adults: The recommended dose of cefixime is 400 mg daily. This may be given as a 400 mg tablet or capsule daily or the 400 mg tablet may be split and given as one half tablet every 12 hours. The capsule and tablet may be administered without regard to food.

Pediatric Patients (6 months or older): The recommended dose is 8 mg/kg/day of the suspension. This may be administered as a single daily dose or may be given in two divided doses, as 4 mg/kg every 12 hours. Children weighing more than 45 kg or older than 12 years should be treated with the recommended adult dose. SUPRAX (cefixime) Chewable Tablets must be chewed or crushed before swallowing.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088, or contact Lupin Pharmaceuticals, Inc. at 1-800-399-2561.

Please note that this information is not comprehensive. Please visit www.supraxrx.com for Full Prescribing Information.

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111 South Calvert Street, Baltimore, MD 21202. NP-SPX-0005
Putting surgical site infection bundles into practice

Rates of post-hysterectomy infection have been shown to be lower in hospitals that have adopted evidence-based guidelines for preventing postsurgical infections.

Surgical site infections (SSI) are the most common type of health-care associated infections.1 Hysterectomy, the most common gynecologic surgery, has been reported to have an SSI rate of 2.7%.2 SSIs are further categorized by The Centers for Disease Control and Prevention (CDC) into both incisional SSI and organ-space SSI.3 Two-thirds of gynecological SSIs are superficial incisional infections (vaginal cuff cellulitis)4 with a 1.1% rate of deep and organ-space SSI (vaginal cuff abscess, peritonitis, and pelvic abscess) following hysterectomy.2 The morbidity and mortality associated with SSI have driven efforts to recognize and address risk factors.5 In addition, the Centers for Medicare and Medicaid Services (CMS) now publicly report SSI rates and use them to determine CMS reimbursement by penalizing hospitals if a Medicare patient develops an SSI.6 With this additional incentive many hospitals are turning to surgical site infection bundles, which are a compilation of evidence-based and existing guidelines that can be implemented rapidly to facilitate prevention.

Maternal Mortality and VTE Rates of VTE are increasing and ob/gyns need to be familiar with tactics to reduce maternal death. Read more on page 14.

Adenomyosis and its impact on fertility Adenomyosis is now being seen in younger asymptomatic women and an association with infertility has emerged. Read more on page 28.

Surgical site infection prevention resources

The American College of Surgeons has developed a free resource, Strong for Surgery, which is a public health campaign to evaluate evidence-based practices to optimize preoperative care prior to surgery and minimize SSI.7 The Strong for Surgery website, (https://www.facs.org/quality-programs/strong-for-surgery/about) provides resources including a toolkit for development of presurgical checklists. The focus of the checklists is on four key areas: nutrition, smoking, blood sugar, and medication.

In addition, Pellegrini et al., developed a mnemonic for a gynecologic-specific SSI bundle: WASHING (weight, antibiotic-resistant skin flora, smoking cessation, hygiene, immune deficiency status, nutritional status, glycemic control) to provide assistance in identifying key factors to prevent gynecologic SSI.8

Weight

Body mass index (BMI) positively correlates with infections in women undergoing abdominal hysterectomies.9 Rates of wound infection range from 8.9%, 4.1%, and 1.4% in morbidly obese, obese, and normal-weight patients, respectively.10 Although weight loss should not restrict access to an indicated surgery, physicians may counsel patients regarding the benefits of weight loss prior to surgery.11 Obese patients may require a larger dose of prophylactic antibiotics to exceed the same serum and tissue minimum inhibitory concentrations required as in a normal-weight patient. Although clinical data are limited to support a benefit of weight-
based dosing, pharmacokinetic studies have demonstrated decreased serum and tissue levels in obese patients who were administered 1 or 2 g of cefazolin. Therefore, the recommended dosage of cefazolin is 3 g if a patient weighs > 120 kg.

Regardless of weight, antibiotics should be administered within 60 minutes before a surgical incision, which is typically part of most surgical time-outs. Re-dosing of antibiotics is necessary for any procedure that lasts longer than 2 to 3 hours or when blood loss exceeds 1500 mL. Antibiotic selection is based on type of surgery and wound classification. Prophylactic antibiotic coverage for abdominal gynecologic surgeries includes a cephalosporin to cover *Staphylococcus aureus* and *Streptococcus* species. In addition, we recommend adding the surgical wound classification (SWC) during a structured operative debrief after a gynecologic surgery. SWC is an important predictor of postoperative surgical site infections and this will ensure that correct classification is recorded (e.g., clean contaminated).

### Table 1: Surgical wound classification

<table>
<thead>
<tr>
<th>Class</th>
<th>Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Clean</td>
<td>An uninfected operative wound in which no inflammation is encountered and the respiratory, alimentary, genital, or uninfected urinary tracts are not entered. In addition, clean wounds are primarily closed and, if necessary, drained with closed drainage. Operative incisional wounds that follow nonpenetrating (blunt) trauma should be included in this category if they meet the criteria.</td>
</tr>
<tr>
<td>II</td>
<td>Clean-contaminated</td>
<td>Operative wounds in which the respiratory, alimentary, genital, or urinary tracts are entered under controlled conditions and without unusual contamination. Specifically, operations involving the biliary tract, appendix, vagina, and oropharynx are included in this category, provided no evidence of infection or major break in technique is encountered.</td>
</tr>
<tr>
<td>III</td>
<td>Contaminated</td>
<td>Open, fresh, accidental wounds. In addition, operations with major breaks in sterile technique (for example, open cardiac massage) or gross spillage from the gastrointestinal tract, and incisions in which acute, nonpurulent inflammation is encountered, including necrotic tissue without evidence of purulent drainage (for example, dry gangrene), are included in this category.</td>
</tr>
<tr>
<td>IV</td>
<td>Dirty-infected</td>
<td>Includes old traumatic wounds with retained devitalized tissue and those that involve existing clinical infection or perforated viscera. This definition suggests that the organisms causing the postoperative infection were present in the operative field before the operation.</td>
</tr>
</tbody>
</table>


### Antibiotic-resistant skin flora, and MRSA

Evaluation of a preoperative history for methicillin-resistant *Staphylococcus aureus* (MRSA) infection or colonization may reduce risk of postoperative SSI, as 50% of hospital-acquired *S. aureus* infections in the United States are due to MRSA. If a history of MRSA colonization is identified prior to surgery, it can be treated with a single preoperative dose of vancomycin, 15 mg/kg up to a maximum of 2 g/dose.

### Smoking

Many complications, including SSI, are more prevalent in smokers. Because smoking has a detrimental effect on all phases of wound healing, smoking cessation prior to surgery reduces SSI. Physiologically, smoking cessation may cause increased secretions and more reactive airways in the first 48 to 72 hours, which can interfere with anesthesia. However, recent data have not demonstrated increased surgical risks during acute preoperative smoking cessation. Therefore, we encourage our patients to quit smoking as soon as possible, regardless of their surgical date.

### Hygiene/skin preparation

Preoperatively, patients should be counseled regarding hygiene. They should not shave the operative site, as this increases risk of infection. They should also be instructed to shower or bathe the entire body with either a soap or an antiseptic agent such as chlorhexidine at least the night before the surgery. Intraoperatively, hair should not be removed from the incisional site unless it interferes with the surgery. If so, it should be removed.
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immediately before the operation with electric clippers. Most institutions have policies regarding these preoperative recommendations.

Antisepsis of the surgical site is integral to prevent SSI. Only povidone-iodine preparation is currently approved by the US Food and Drug Administration for vaginal surgical site antisepsis. However, vaginal surgical site antisepsis can be performed with either 4% chlorhexidine gluconate or povidone-iodine before a hysterectomy or vaginal surgery based on patient allergies or surgeon preference.

Immune deficiency status
Patients with immune deficiency have increased rates of infection and surgery itself can cause immune suppression. Administering immune-modulating diets preoperatively with supplements such as arginine and fish oil may reduce risk of postoperative infections. One evidence-based immune modulating supplementation technique is to prescribe patients an oral supplement (Impact Advanced Recovery®, Nestlé, 237 mL) three times daily for a total of 5 days prior to surgery.

Nutritional status
Malnourished patients have higher rates of complications including postoperative complications, increased mortality, length of hospital stay, and costs. Strong for Surgery has a presurgical checklist available to review nutritional interventions. The key focuses of these checklists include measurement of preoperative albumin, assessment of nutritional status, and use of evidence-based nutritional support. An albumin of less than 3 g/dL is associated with a 200% to 300% increase in rates of reoperation and/or death in patients postoperatively. However, albumin may not accurately predict all patients with malnutrition; using the presurgical checklist with assessment of nutritional status can identify patients that require further evaluation by a trained dietician.

Glycemic control
It is important to identify patients pre-operatively that may have undiagnosed diabetes as, by some estimates, there are over 8 million undiagnosed cases of diabetes in the United States. In addition, known diabetic patients should have adequate glycemic control and blood sugar levels no higher than 200 mg/dL prior to surgery. Preoperative hemoglobin A1C levels of greater than 8.0% may be associated with increased morbidity and longer hospital length of stay. Although there are no American Diabetes Association (ADA) recommendations regarding A1C thresholds prior to elective surgical management, Strong for Surgery recommends further diabetes management and evaluation if A1C values are > 7.0% or the patient has had a fingerstick reading > 200 mg/dL in the past 2 weeks. Currently at our institution, patients with known diabetes have an A1C checked prior to surgery, and if it is > 8.0%, elective surgery is delayed. In addition, all patients without a known history of diabetes have a fingerstick blood sugar checked in the preoperative unit the day of surgery, if the blood glucose is > 200 mg/dL, elective surgery is canceled.

Medications
In the perioperative period, it is imperative to review all medications a patient is taking.

This includes review of anticoagulants, beta-blockers, aspirin, immunosuppressive and herbal medications. Review of medication is a critical component of not only SSI prevention but also patient perioperative safety. Perioperative medications checklists are also available at Strong for Surgery.

Impact of SSI bundles and checklists
The use of perioperative “bundles” reduces readmission rates and morbidity for surgery including gynecologic surgeries. One study demonstrated that implementation of gynecologic perioperative bundles, which included chlorhexi-
The use of perioperative "bundles" reduces readmission rates and morbidity for surgery including gynecologic surgeries.

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DISCLAIMER This guest editorial does not necessarily reflect the views of all members of the editorial staff or the board of Contemporary OB/GYN.

FOR REFERENCES VISIT contemporaryobgyn.net/SurgicalBundles

BENCH TO BEDSIDE
YOUR MONTHLY MUST READS

How valuable is a second opinion for breast cancer diagnosis?
This study reveals how getting a second opinion at an NCI-designated cancer center impacts outcomes.
Contemporaryobgyn.net/SecondOpinionValue

Is immediate or delayed pushing better in spontaneous vaginal delivery?
This multicenter study looked at how pushing in the second stage affects delivery and complications.
Contemporaryobgyn.net/pushing

Do contemporary hormonal contraceptives reduce ovarian cancer risk?
New contraceptive formulations and dosages were evaluated in this NICHD-supported study.
Contemporaryobgyn.net/ContraceptionOvarianCa

What makes hospitals safe for mothers and babies?
Low rates of maternal death don’t necessarily mean low rates of neonatal death, according to results of a new study.
Contemporaryobgyn.net/SafeHospitals

What’s behind postpartum opioid prescribing patterns?
A new study reveals characteristics of health care providers—and patients—that may be linked with postpartum opioid prescribing.
Contemporaryobgyn.net/SafeHospitals

Does HPV vaccination affect teens’ sexual behavior?
Results from a new study casts doubt on the assumption that teens who are vaccinated may practice unsafe sex.
Contemporaryobgyn.net/HPVvaccination

Each month, Contemporary OB/GYN sorts through the enormous pile of published research, bulletins, and releases to find the advances of most importance to clinicians.
A simple step to reduce maternal death: Improve VTE prevention

As rates of VTE in pregnancy are increasing in the United States, ob/gyns must be vigilant in identifying women at risk and promptly instituting measures recommended by ACOG and other organizations.

by ROBERT M. SILVER, MD, AND TORRI D. METZ, MD

The death of a mother is a devastating obstetric complication. In 2015, there were an estimated 303,000 maternal deaths throughout the world,\(^1\) which reflects a maternal mortality ratio of 216 per 100,000 live births. Maternal death is far less common in high-resource settings, but it still affects 12 per 100,000 live births.\(^1\) In the United States in 2014, the maternal mortality ratio was 23.8 per 100,000 live births.\(^2,3\) That is considerably higher than other countries with similar resources and represents a recent increase in maternal mortality.\(^1\) Although the increase is largely due to increased ascertainment,\(^7\) there is no doubt that it is possible to decrease maternal mortality in the United States.

Given the numerous causes of and risk factors for maternal death, often missing or vague available data in vital records, and variability among studies, it is difficult to precisely determine the proportion of deaths due to any single cause. Nonetheless, it is estimated that about 10% to 15% of maternal deaths in high-resource settings including the United States are due to venous thromboembolism (VTE).\(^4,5\) VTE is an attractive target for reducing maternal deaths because, in theory, many are preventable. Indeed, in the UK, a concerted effort has been made to lower the rate of maternal death due to VTE. There, a comprehensive program was instituted involving better risk assessment and increased use of thromboprophylaxis.\(^8\) The result was an apparent 50% reduction in maternal deaths due to VTE from 2006 to 2008 compared to 2003 to 2005.\(^7\)

In the United States, in contrast, the proportion of maternal deaths due to VTE remained relatively stable from 1987 through 2010.\(^5\) Recent data indicate a maternal mortality ratio due to VTE of 1.01/100,000 in the UK versus 1.5/100,000 in the United States.\(^6\) That may be a consequence of less aggressive recommendations for and implementation of VTE prophylaxis in the United States compared to the U.K., although it also may be due to chance. However, it is difficult to prove cause and effect since VTE, and especially death due to VTE

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is relatively uncommon. Thus, properly designed trials are difficult to conduct, and recommendations are largely based on expert opinion and theoretical benefits, rather than high-quality empirical evidence.

In addition, and despite prevention efforts, the rate of pregnancy-associated VTE may be increasing in the United States. For example, data from the Nationwide Inpatient Sample note that VTE associated with hospitalizations for childbirth increased 72% from 1998 to 2009.9,10 This may be due to an increased prevalence of risk factors such as obesity, advanced maternal age, cesarean delivery and comorbid conditions such as diabetes and hypertension.

Most maternal deaths associated with VTE occur after pulmonary embolism (PE). This is most often associated with cesarean delivery. However, recent data from the UK show that reductions in fatal PE can also occur in the antepartum period and after vaginal delivery.7 Accordingly, prevention strategies must focus on both the antepartum and postpartum periods and after both vaginal and cesarean delivery.

### Recommendations for antepartum thromboprophylaxis
Some data exist with which to guide antepartum thromboprophylaxis. For example, women with prior VTE—especially if the episode was associated with pregnancy or use of estrogen-containing oral contraceptives—are at increased risk for recurrent VTE during pregnancy or postpartum. VTE risk also is increased in women with high-risk thrombophilias such as antithrombin deficiency, antiphospholipid syndrome, and homozygosity for

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**TABLE 1**

Royal College of Obstetricians and Gynaecologists recommendations for antenatal and postpartum venous thromboembolism prophylaxis

<table>
<thead>
<tr>
<th>Clinical recommendations for thromboprophylaxis with low molecular weight heparin</th>
</tr>
</thead>
<tbody>
<tr>
<td>• If total score ≥ 4 antenatally, consider thromboprophylaxis from the first trimester</td>
</tr>
<tr>
<td>• If total score 3 antenatally, consider thromboprophylaxis from 28 weeks</td>
</tr>
<tr>
<td>• If total score ≥ 2 postnatally, consider thromboprophylaxis for at least 10 days</td>
</tr>
<tr>
<td>• If admitted to hospital antenatally, consider thromboprophylaxis</td>
</tr>
<tr>
<td>• If prolonged admission (≥ 3 days) or readmission to hospital within the puerperium consider thromboprophylaxis</td>
</tr>
</tbody>
</table>

**Scoring system**

**4 points**
- Previous venous thromboembolism (except for a single event related to major surgery)
- Ovarian hyperstimulation syndrome (first trimester only)

**3 points**
- Previous venous thromboembolism provoked by major surgery
- Known high-risk thrombophilia
- Any surgical procedure in pregnancy or puerperium except immediate repair of the perineum, e.g., appendectomy, postpartum sterilization
- Hyperemesis
- Medical comorbidities, e.g., cancer, heart failure, active systemic lupus erythematosus, inflammatory polyarthropathy or inflammatory bowel disease, nephrotic syndrome, type 1 diabetes mellitus with nephropathy, sickle cell disease, current intravenous drug user

**2 points**
- Cesarean in labor
- Obesity (BMI > 40 kg/m)

**1 point**
- Family history of unprovoked or estrogen-related venous thromboembolism in first-degree relative
- Known low-risk thrombophilia (no venous thromboembolism history)
- Age (> 35 years)
- Obesity (BMI > 30 kg/m)
- Parity ≥ 3
- Smoker
- Gross varicose veins
- Preeclampsia in current pregnancy
- Assisted reproductive technology, in vitro fertilization (antenatal only)
- Multiple pregnancy
- Elective cesarean
- Mid-cavity rotational operative birth
- Prolonged labor (> 24 hours)
- Postpartum hemorrhage (>1 liter or blood transfusion)
- Preterm birth < 37 weeks in current pregnancy
- Stillbirth in current pregnancy
- Current systemic infection
- Immobility, dehydration

the factor V Leiden or prothrombin G2010A mutations. Women with prior VTE and low-risk thrombophilias such heterozygosity for the factor V Leiden or prothrombin G2010A mutations also are at increased risk. These data led to clear recommendations from the American College of Obstetricians and Gynecologists (ACOG) for antepartum and postpartum prophylaxis for women with prior VTE and/or thrombophilias.11,12

Less guidance is available for prevention of VTE during pregnancy in women with no prior history of or known risk factors for VTE. US guidelines (based on ACOG and American College of Chest Physicians [ACCP] recommendations) only advise using pharmacologic prophylaxis in women at highest risk for VTE.11-13 In contrast, the Royal College of Obstetricians and Gynaecologists (RCOG) guidelines emphasize broad, risk factor-based assessment and widespread use of thromboprophylaxis. Their recommendations for antenatal and postpartum pharmacologic VTE prophylaxis are summarized in a “Green-top” guideline published in 2015 (Table 1).4 These guidelines use a risk-scoring system to determine recommendations for prophylaxis with low-molecular-weight heparin (LMWH).

They account for less profound but more common risk factors such as obesity, maternal age > 35 years and smoking.

Pharmacologic options

Pharmacologic thromboprophylaxis is typically accomplished with prophylactic doses of heparin or LMWH. Examples include 5,000 units twice daily of unfractionated heparin or a daily dose of LMWH such as 40 mg daily of enoxaparin. This is typically administered during pregnancy and through six weeks postpartum. Discussion of the timing of anticoagulant therapy peripartum and intrapartum is beyond the scope of this article but reviews are available.11-13 Data from a large US-based health care corporation noted a reduction in maternal deaths from VTE after universal use of pneumatic compression devices at cesarean delivery.14 There were seven deaths from 2000 to 2006 prior to use of the devices. After implementation of mechanical prophylaxis, there was only one VTE maternal death between 2007 and 2012. In contrast, data from the nationwide Centers for Disease Control and Prevention Pregnancy Mortality Surveillance System failed to show a meaningful reduction in maternal deaths due to VTE from 1987 to 2010.5 However, it is unknown what percentage of cesareans in the United States used mechanical thromboprophylaxis during this time.

### Table 2: National Partnership for Maternal Safety recommendations for antepartum outpatient prophylaxis

<table>
<thead>
<tr>
<th>Clinical history</th>
<th>Anticoagulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multiple prior VTE episodes</td>
<td>Treatment-dose LMWH or UFH</td>
</tr>
<tr>
<td>Prior VTE with high-risk thrombophilia</td>
<td>Treatment-dose LMWH or UFH</td>
</tr>
<tr>
<td>Prior VTE with acquired thrombophilia</td>
<td>Treatment-dose LMWH or UFH</td>
</tr>
<tr>
<td>Idiopathic prior venous thromboembolism</td>
<td>Prophylactic-dose LMWH or UFH</td>
</tr>
<tr>
<td>Prior VTE with pregnancy or oral contraceptive</td>
<td>Prophylactic-dose LMWH or UFH</td>
</tr>
<tr>
<td>Prior VTE with low-risk thrombophilia</td>
<td>Prophylactic-dose LMWH or UFH</td>
</tr>
<tr>
<td>Family history of VTE with high-risk thrombophilia</td>
<td>Prophylactic-dose LMWH or UFH</td>
</tr>
<tr>
<td>High-risk thrombophilia (including acquired)</td>
<td>Prophylactic-dose LMWH or UFH</td>
</tr>
<tr>
<td>Low-risk thrombophilia</td>
<td>No treatment</td>
</tr>
<tr>
<td>Prior VTE provoked</td>
<td>No treatment</td>
</tr>
<tr>
<td>Low-risk thrombophilia and family history of VTE</td>
<td>No treatment</td>
</tr>
</tbody>
</table>


Data are scant with which to guide thromboprophylaxis for vaginal or cesarean delivery. Most authorities including ACOG advise uniform and routine use of mechanical thromboprophylaxis placed prior to cesarean delivery, as well as encouragement of early ambulation.12 Data from a large US-based health care corporation noted a reduction in maternal deaths from VTE after universal use of pneumatic compression devices at cesarean delivery.14 There were seven deaths from 2000 to 2006 prior to use of the devices. After implementation of mechanical prophylaxis, there was only one VTE maternal death between 2007 and 2012. In contrast, data from the nationwide Centers for Disease Control and Prevention Pregnancy Mortality Surveillance System failed to show a meaningful reduction in maternal deaths due to VTE from 1987 to 2010.5 However, it is unknown what percentage of cesareans in the United States used mechanical thromboprophylaxis during this time.
Mechanical devices

Although they are of unproven efficacy, pneumatic compression devices are now used for virtually all cesarean deliveries in many hospitals. There is relatively little downside, other than cost and inconvenience. The devices are easily placed in a timely fashion prior to scheduled cesareans when the risk of VTE is low. However, they may be difficult to place in a timely fashion for emergency cases, when the risk of VTE is often higher. In addition, effectiveness is uncertain and may be adversely influenced by the lower-extremity edema that often occurs at the end of pregnancy. Also, many women dislike the devices, compliance is imperfect, and they may hinder early ambulation.15 A cost-effectiveness analysis noted that the cost for the devices is $39,545.00 for each quality-adjusted life year.16 It would be ideal to obtain high-quality data regarding the true benefits of mechanical thromboprophylaxis.

Intrapartum and postpartum care

Data regarding pharmacologic thromboprophylaxis and delivery are also lacking. Thromboprophylaxis is almost always initiated after vaginal delivery or cesarean, typically at least six hours later. This allows for safe administration of neuraxial analgesia or anesthesia and removal of a catheter. However, VTE may already have formed by that time, in which case, prophylaxis may be useless or less effective compared to when it is used prior to and during surgery. Indeed, other than small pilot studies, there are no data from high-quality studies regarding the efficacy of thromboprophylaxis for cesarean delivery. Another knowledge gap is the optimal duration of thromboprophylaxis. Heparin or LMWH may be continued until the patient is ambulatory, until she is discharged from the hospital, through 10 days after delivery or 6 weeks after delivery.6 The relative merits of each time interval are uncertain. The same is true for various doses and drugs used for thromboprophylaxis. Although knowledge gaps exist, ACOG has a practice bulletin summarizing available regimens.12 As with mechanical prophylaxis, downsides include expense, inconvenience, and lack of compliance. In addition, these medications may irritate skin and are associated with an increased risk for complications such as wound separation.17 Unfortunately, high-quality studies assessing the efficacy and safety of pharmacologic thromboprophylaxis are unlikely to be performed. Such studies would be difficult to accomplish given the expense, large sample size required and reluctance on the part of clinicians to not use prophylaxis despite unproven efficacy.

VTE safety bundle

We are currently faced with a dilemma in trying to balance the pros and cons of strategies intended to decrease VTE-
associated maternal deaths in the absence of quality data. The desire to do everything we can that might work to reduce VTEs is understandable but theoretical benefits must be weighed against potential harms and costs. To address this issue, the National Partnership for Maternal Safety (NPMS) published a consensus bundle on VTE in 2016. The bundle includes recommendations intended to reduce VTEs, and it considers the lack of available high-quality data. As with other safety bundles, it is composed of four action domains: readiness, recognition, response, and reporting.

The readiness component involves establishment of risk assessment strategies or tools for several time points during pregnancy. These time points include the first prenatal visit, all antepartum admissions, immediately postpartum, and on discharge home after delivery. The Caprini and Padua risk scoring systems are highly predictive of VTE risk in surgical patients and can be modified for use during pregnancy. That strategy is also endorsed by ACOG. Recognition refers to the recognition of maternal risk after routine screening at the four time points, or in other words, the “use of the tool.” Recognition involves thromboprophylaxis in “high-risk” women. Recommendations from the NPMS for antepartum and postpartum thromboprophylaxis are summarized in Tables 2 and 3.

The last part of the bundle involves reporting and systems learning. Each institution should conduct audits of risk factors, use of screening tools and implementation of prevention strategies. Adverse events also should be tracked and reported. A goal is to make this a “core measure” for quality. The NPMS document acknowledges a paucity of quality data and uncertainty regarding the specific population warranting thromboprophylaxis. Given the relatively low rate of pregnancy-associated VTE, indirect measures such as screening and prophylaxis may be preferable metrics to assess than actual VTEs. Also, since most serious postpartum VTEs occur after the delivery hospitalization, it is important to implement a system to ascertain events through at least 6 weeks postpartum.

Along with prevention of VTE, prompt recognition and treatment of VTE, especially PE, can potentially reduce mortality. Diagnosis can be difficult during pregnancy owing to the preponderance of non-specific symptoms such as leg swelling and shortness of breath. Also, there is a reluctance to use imaging studies during pregnancy due to concerns for possible untoward fetal effects. Given the increased risk of VTE and PE associated with pregnancy, all symptoms of DVT and PE should be fully and promptly evaluated. Although useful in non-pregnant individuals, D-dimer levels are not advised for screening pregnant women for VTE.

Data from the Nationwide Inpatient Sample note that VTE associated with hospitalizations for childbirth increased 72% from 1998 to 2009.

Conclusion

In summary, tactics to reduce maternal death from VTE should include recognition of risk and prevention, as well as prompt diagnosis and treatment. Specific protocols may vary among institutions but should utilize the guidelines put forth by ACOG, NPMS, the Society for Maternal-Fetal Medicine, RCOG, ACCP and others. Most importantly, quality data are desperately needed to address the numerous knowledge gaps regarding VTE prevention. It is paramount to track the benefits and downsides of interventions in each institution and support the conduct of high-quality clinical trials regarding VTE prevention in pregnancy.

DISCLOSURES The authors report no potential conflicts of interest with regard to this article.

FOR REFERENCES VISIT contemporaryobgyn.net/VTEprevention
ACOG Practice Bulletin No. 196: Thromboembolism in Pregnancy

Reducing the Risk of Venous Thromboembolism during Pregnancy and the Puerperium
Revised guidelines and recommendations from the Royal College of Obstetricians and Gynaecologists to reduce complications from VTE.

Thromboembolic Disease in Pregnancy and the Puerperium
Revised guidelines and recommendations from the Royal College of Obstetricians and Gynaecologists to manage VTE.

Risk Assessment Tool for Venous Thromboembolism in Pregnancy and the Puerperium
Two multi-professional guidance and documentation tools for the implementation of thromboprophylaxis in pregnancy and the puerperium.

Consensus Statement National Partnership for Maternal Safety Consensus Bundle on Venous Thromboembolism
This bundle supports routine thromboembolism risk assessment for obstetric patients, with appropriate use of pharmacologic and mechanical thromboprophylaxis
https://pdfs.semanticscholar.org/5018/187f4a38f717a68b8995c4400d02189d97cb.pdf

Improving Health Care Response to Maternal Venous Thromboembolism
A toolkit from the California Maternal Quality Care Collaborative to help facilitate implementation of VTE risk assessment.

Patient Safety Bundle: Maternal Venous Thromboembolism (+AIM)
Resources from the Council on Patient’s Safety in Women’s Health Care to evaluate a unit’s readiness, ability to recognize and prevent, response, and reporting.

SMH’s VTE Implementation Guide
A “quick read” resource on VTE treatment from the Society of Hospital Medicine.
https://shm.hospitalmedicine.org/acton/media/25526/download-shm-s-vte-guide

We want to hear from you. Have you implemented tactics to prevent VTE in pregnancy? Tell us about your experience and share with your colleagues what you and your patients found beneficial. Which aspects of your prevention strategy do you feel could be improved? Email us your thoughts at COGeditorial@ubm.com
Help your patients understand both of their LARC location options

LARC = long-acting reversible contraceptive

NEXPLANON is indicated for use by women to prevent pregnancy.

SELECTED SAFETY INFORMATION

Who is not appropriate for NEXPLANON

• NEXPLANON should not be used in women who have known or suspected pregnancy; current or past history of thrombosis or thromboembolic disorders; liver tumors, benign or malignant, or active liver disease; undiagnosed abnormal genital bleeding; known or suspected breast cancer, personal history of breast cancer, or other progestin-sensitive cancer, now or in the past; and/or allergic reaction to any of the components of NEXPLANON.

WARNINGS and PRECAUTIONS

Complications of insertion and removal

• NEXPLANON should be inserted subdermally and be palpable after insertion. Palpate immediately after insertion to ensure proper placement. Undetected failure to insert the implant may lead to unintended pregnancy. Failure to remove the implant may result in continued effects of etonogestrel, such as compromised fertility, ectopic pregnancy, or persistence or occurrence of a drug-related adverse event.

• Insertion and removal-related complications may include pain, paresthesias, bleeding, hematoma, scarring, or infection. If NEXPLANON is inserted too deeply (intramuscular or in the fascia), neural or vascular injury may occur. Implant removal may be difficult or impossible if the implant is not inserted correctly, inserted too deeply, not palpable, encased in fibrous tissue, or has migrated. If at any time the implant cannot be palpated, it should be localized and removal is recommended.

• There have been postmarketing reports of implants located within the vessels of the arm and the pulmonary artery, which may be related to deep insertions or intravascular insertion. Endovascular or surgical procedures may be needed for removal.

NEXPLANON and pregnancy

• Be alert to the possibility of an ectopic pregnancy in women using NEXPLANON who become pregnant or complain of lower abdominal pain.

• Rule out pregnancy before inserting NEXPLANON.

Educate her about the risk of serious vascular events

• The use of combination hormonal contraceptives increases the risk of vascular events, including arterial events (stroke and myocardial infarction (MI)) or deep venous thrombotic events (venous thromboembolism, deep venous thrombosis (DVT), retinal vein thrombosis, and pulmonary embolism). Women with risk factors known to increase the risk of these events should be carefully assessed. Postmarketing reports in women using the nonradioactive etonogestrel implant have included pulmonary emboli (some fatal), DVT, MI, and stroke. NEXPLANON should be removed if thrombosis occurs.
SELECTED SAFETY INFORMATION (continued)

- Due to the risk of thromboembolism associated with pregnancy and immediately following delivery, NEXPLANON should not be used prior to 21 days postpartum.
- Women with a history of thromboembolic disorders should be made aware of the possibility of a recurrence. Consider removing the NEXPLANON implant in case of long-term immobilization due to surgery or illness.

Counsel her about changes in bleeding patterns
- Women are likely to have changes in their menstrual bleeding pattern with NEXPLANON, including changes in frequency, intensity, or duration. Abnormal bleeding should be evaluated as needed to exclude pathologic conditions or pregnancy. In clinical studies of the non-radiopaque etonogestrel implant, changes in bleeding pattern were the most common reason reported for stopping treatment (11.1%). Counsel women regarding potential changes they may experience.

Be aware of other serious complications, adverse reactions, and drug interactions
- Remove NEXPLANON if jaundice occurs.
- Remove NEXPLANON if blood pressure rises significantly and becomes uncontrolled.
- Prediabetic and diabetic women using NEXPLANON should be carefully monitored.
- Carefully observe women with a history of depressed mood. Consider removing NEXPLANON in patients who become significantly depressed.
- The most common adverse reactions (>10%) reported in clinical trials were headache (24.9%), vaginitis (14.5%), weight increase (13.7%), acne (13.5%), breast pain (12.8%), abdominal pain (10.9%), and pharyngitis (10.5%).
- Drugs or herbal products that induce enzymes, including CYP3A4, may decrease the effectiveness of NEXPLANON or increase breakthrough bleeding.
- The efficacy of NEXPLANON in women weighing more than 130% of their ideal body weight has not been studied. Serum concentrations of etonogestrel are inversely related to body weight and decrease with time after implant insertion. Therefore, NEXPLANON may be less effective in overweight women.
- Counsel women to contact their health care provider immediately if, at any time, they are unable to palpate the implant.
- NEXPLANON does not protect against HIV or other STDs.

Please read the adjacent Brief Summary of the Prescribing Information

CONTRAINDICATIONS
NEXPLANON should not be used in women who have:
- Known or suspected pregnancy
- Current or past history of thrombosis or thromboembolic disorders
- Liver disease or abnormal liver function tests
- Unexplained vaginal bleeding
- Known or suspected breast cancer, personal history of breast cancer, or other estrogen-sensitive neoplasms or in the family
- Allergy reaction to any of the components of NEXPLANON [see Adverse Reactions]

WARNINGS AND PRECAUTIONS
The following information is based on experience with the etonogestrel implants (IMPLANON® [etinoestrogel implant] and NEXPLANON), other progestin-only contraceptives, or experience with combination (estrogen plus progestin) oral contraceptives.

1. Complications of Insertion and Removal
NEXPLANON should be inserted subdermally so that it is palpable after insertion, and this should be confirmed by palpation immediately after insertion. Failure to insert NEXPLANON properly may go unnoticed until the implant is removed immediately after insertion. Unexpected failure to insert the implant may lead to an unintended pregnancy. Complications related to insertion and removal procedures, such as pain, paresthesia, breathing, hematomata, scarring, or infection, may occur.

If NEXPLANON is inserted deeply (intramuscular or submuscular), neural injury or vascular injury may occur. To reduce the risk of neural or vascular injury, NEXPLANON should be inserted at the inner side of the non-dominant upper arm about 8–10 cm (3–4 inches) above the medial epicondyle of the elbow. NEXPLANON should be inserted subdermally just under the skin avoiding the groove (between the biceps and triceps muscles) and from large blood vessels and nerves that lie deep to the neurovascular bundle deep in the subcutaneous tissues. An implant inserted more deeply than subdermally (deeplyinsertion) may not be palpable and may not be removed (see Dosage and Administration and Warnings and Precautions). NEXPLANON must be inserted by the expiration date stated on the packaging. NEXPLANON is a long-acting (up to 3 years), reversible, hormonal contraceptive method. The implant must be replaced at the third year and may be replaced by a new implant at the time of removal, if continued contraceptive protection is desired.

2. Changes in Menstrual Bleeding Patterns
After starting NEXPLANON, women are likely to have a change from their normal menstrual bleeding pattern. These may include changes in bleeding frequency (absent, less, more frequent or continuous), intensity (reduced or increased) or duration. In clinical trials of the non-erogestone etonogestrel implant (IMPLANON), bleeding patterns ranged from amenorrhea (11% in 5 women) to frequent and/or prolonged bleeding (1 in 5 women). The bleeding pattern experienced during the first three months of NEXPLANON use is broadly predictable of the future bleeding pattern for many women. Women should be counseled regarding the bleeding pattern changes they may experience so that they know what to expect. Abnormal bleeding should be evaluated as needed to exclude pathologic conditions or pregnancy.

Clinical studies of the non-erogestone etonogestrel implant, reports of changes in bleeding patterns were the most common reason for stopping treatment (31%). Irregular bleeding (10.8%) was the single most common reason women stopped treatment, while amenorrhea (0.3%) was cited less frequently. In these studies, women had an average of 17.7 days of bleeding or spotting every 90 days (based on 3.315 intervals of 90 days recorded by 780 patients). The percentages of patients having 0, 1–7, 8–21, or >21 days of spotting or bleeding over a 90-day interval while using the non-erogestone etonogestrel implant are shown in Table 1.

Table 1: Percentages of Patients With 0, 1–7, 8–21, or >21 Days of Spotted or Bleeding Over a 90-Day Interval While Using the Non-Ethogestone Etonogestrel Implant (IMPLANON)

<table>
<thead>
<tr>
<th>Total Days of Spotted or Bleeding</th>
<th>Treatment Days 91–100 (N = 745)</th>
<th>Treatment Days 271–300 (N = 657)</th>
<th>Treatment Days 631–720 (N = 547)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 Days</td>
<td>24%</td>
<td>37%</td>
<td>33%</td>
</tr>
<tr>
<td>1–7 Days</td>
<td>12%</td>
<td>16%</td>
<td>12%</td>
</tr>
<tr>
<td>8–21 Days</td>
<td>15%</td>
<td>30%</td>
<td>37%</td>
</tr>
<tr>
<td>&gt;21 Days</td>
<td>30%</td>
<td>32%</td>
<td>35%</td>
</tr>
</tbody>
</table>

Blending patterns observed with use of the non-erogestone etonogestrel implant for up to 2 years, and the proportion of 90-day intervals with these bleeding patterns, are summarized in Table 1.

Bleeding Patterns Definitions %
Infrequent Less than three bleeding and/or spotting episodes in 90 days (excluding amenorrhea) 33.6
Amenorrhea No bleeding and/or spotting in 90 days 22.2
Prolonged Any bleeding and/or spotting episode lasting more than 14 days in 90 days 17.7
Frequent More than 5 bleeding and/or spotting episodes in 90 days 6.7

Based on 3,315 recording periods of 90 days duration in 780 women, excluding the first 90 days after the implant insertion

1% = Percentage of 90-day intervals with this pattern

In case of undiagnosed, persistent, or recurrent abnormal vaginal bleeding, appropriate measures should be conducted to rule out malignancy.

3. Ectopic Pregnancies
As with all progestin-only contraceptive products, be alert to the possibility of an ectopic pregnancy among women using NEXPLANON. Women using NEXPLANON may be more likely to have an ectopic pregnancy occurring in a woman using no contraception.

4. Thrombotic and Other Vascular Events
The use of combination hormonal contraceptives (progestin plus estrogen) increases the risk of vascular events, including arterial events (strokes and myocardial infarctions) or deep venous thrombotic events (cerebral thromboembolism, deep venous thrombosis, retinal vein thrombosis, and pulmonary embolism). NEXPLANON is a progestin-only contraceptive. It is unknown whether this increased risk is applicable to etonogestrel alone. It is recommended that women who are known to increase the risk of venous and arterial thromboembolism be carefully assessed. There have been postmarketing reports of serious arterial and venous thrombotic events, including cases of pulmonary emboli (1 in 100,000), deep vein thrombosis, myocardial infarction, and strokes, in women using etonogestrel implants. NEXPLANON should be removed in the event of a thrombosis.

Due to the risk of thromboembolism associated with pregnancy and immediately following delivery, NEXPLANON should not be used prior to 21 days postpartum. Women with a history of thromboembolic disorders should be made aware of the possibility of a recurrence. Evaluate for retinal vein thrombosis immediately if there is unexplained loss of vision, proptosis, diplopia, papilledema, or retinal vascular lesions. Consider removal of the NEXPLANON implant in case of long-term immobilization due to surgery or illness.

5. Ovarian Cysts
If follicle development occurs, atresia of the follicle is sometimes delayed, and the follicle may continue to grow beyond the size it would attain in a normal cycle. Generally, these enlarged follicles disappear spontaneously. On rare occasion, surgery may be required.

6. Carcinoma of the Breast and Reproductive Organs
Women who currently have or have had breast cancer should not use hormonal contraception because breast cancer may be hormonally sensitive (see Contraindications). Some studies suggest that the use of combination hormones increases the risk of developing breast cancer; however, other studies have not confirmed such findings. Some studies suggest that the use of combination hormonal contraceptives is associated with an increase in the risk of cervical cancer or intraepithelial neoplasia. However, there is controversy about the extent to which these findings are due to differences in sexual behavior and other factors. Women with a family history of breast cancer or who develop breast nodules should be carefully monitored.

7. Liver Disease
Disturbances of liver function may necessitate the discontinuation of hormonal contraceptive use until markers of liver function return to normal. Remove NEXPLANON if jaundice develops. Hepatic adenomas are associated with combination hormonal contraceptives. Use of NEXPLANON may be considered. Women with liver disease using NEXPLANON should be monitored for signs of hepatic disease or liver cancer during NEXPLANON use. Use of NEXPLANON in women with active liver disease or liver cancer is contraindicated [see Contraindications].

8. Weight Gain
In clinical studies, mean weight gain in U.S. non-erogestone etonogestrel implant (IMPLANON) users was 2.8 pounds after 6 months and 3.2 pounds after 2 years. How much of the weight gain was related to the non-erogestone etonogestrel implant is unknown. In studies, 2.9% of the users reported weight gain as the reason for the non-erogestone etonogestrel implant removed.

9. Elevated Blood Pressure
Women with a history of hypertension-related diseases or renal disease should be discouraged from using hormonal contraception. For women with well-controlled hypertension, use of NEXPLANON can be considered. Women with hypertension using NEXPLANON should be closely monitored. If hypertension develops during the use of NEXPLANON, or if a significant increase in blood pressure does not respond adequately to antihypertensive therapy, NEXPLANON should be removed.

10. Gallbladder Disease
Studies suggest a small increased relative risk of developing gallbladder disease among combination hormonal contraceptive users. It is not known whether a similar risk exists with progestin-only methods like NEXPLANON. The progestin in NEXPLANON may be poorly metabolized with liver involvement. Use of NEXPLANON in women with active liver disease or liver cancer is contraindicated [see Contraindications].

11. Carbohydrate and Lipid Metabolic Effects
Use of NEXPLANON may induce mild insulin resistance and small changes in glucose concentrations of unknown clinical significance. Carefully monitor prediabetic and diabetic women using NEXPLANON. Women who are being treated for hyperlipidemia should be followed closely if they elect to use NEXPLANON. Some progestins may elevate LDL levels and may render the control of hyperlipidemia more difficult.

12. Depressed Mood
Women with a history of depressed mood should be carefully observed. Consideration should be given to removing NEXPLANON in patients who become significantly depressed.

13. Return to Ovulation
In clinical trials with the non-erogestone etonogestrel implant (IMPLANON), the etonogestrel levels, levels of blood decreased by 21% within the first 30 days postpartum. Women with a history of NEXPLANON should be given to restarting contraception immediately after removal of the implant. In addition, pregnancies were observed to occur as early as 7 to 14 days after removal. Therefore, a woman should re-start contraception immediately after removal of the implant if continued contraceptive protection is desired.
Substances increasing the plasma concentrations of HCs: Co-administration of certain HCs and strong or moderate CYP3A4 inhibitors such as itraconazole, voriconazole, fluconazole, grapefruit juice, or ketoconazole may increase the plasma concentrations of progestins, including etonogestrel.

Human Immuno deficiency Virus (HIV)/Hepatitis C Virus (HCV) protease inhibitors and non-nucleoside reverse transcriptase inhibitors: Significant changes (increase or decrease) in the plasma concentrations of progesterone have been noted in cases of co-administration with HIV protease inhibitors (decrease [e.g., nelfinavir, ritonavir, darunavir/ritonavir, fosamprenavir/ritonavir, lopinavir/ ritonavir, and tipranavir/ritonavir]) or increase [e.g., indinavir and atazanavir/ritonavir]) and HCV protease inhibitors (decrease [e.g., boceprevir and telaprevir]) or with non-nucleoside reverse transcriptase inhibitors (decrease [e.g., nevirapine, efavirenz]) or increase [e.g., efavirenz]. These changes may be clinically relevant in some cases. Consult the prescribing information for anti-viral and anti-retroviral concomitant medications to identify potential interactions.

Effects of Hormonal Contraceptives on Other Drugs
Hormonal contraceptives may affect the metabolism of other drugs. Consequently, plasma concentrations may either increase (for example, cyclosporin) or decrease (for example, lamotrigine). Consult the labeling of all concurrently-used drugs to obtain further information about interactions with hormonal contraceptives or the potential for enzyme alterations.

USE IN POPULATIONS
1. Pregnancy
Risk Summary
NEXPLANON is contraindicated during pregnancy because there is no need for pregnancy prevention in a woman who is already pregnant [see Contraindications]. Epidemiologic studies and meta-analyses have not shown an increased risk of genital or non-genital birth defects (including cardiac anomalies and limb-reduction defects) following maternal exposure to low dose CHCs prior to conception or during early pregnancy. No adverse development outcomes were observed in pregnant rats and rabbits with the administration of etonogestrel during organogenesis at doses of 315 or 781 times the anticipated human dose (60 μg/day). NEXPLANON should be removed if maintaining a pregnancy.

2. Nursing Mothers
Lactation
Risk Summary
Small amounts of contraceptive steroids and/or metabolites, including etonogestrel are present in human milk. No significant adverse effects have been observed in the production or quality of breast milk, or on the physical and psychomotor development of breastfed infants. Hormonal contraceptives, including etonogestrel, can reduce milk production in breastfeeding mothers. This is less likely to occur with NEXPLANON and is determined by breastfeeding status; however, it can occur at any time in some women. When possible, advise the nursing mother about both hormonal and non-hormonal contraceptive options, as steroids may not be the initial choice for these patients. The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for NEXPLANON and any potential adverse effects on the breastfed child from NEXPLANON or from the underlying maternal condition.

3. Pediatric Use
Safety and efficacy of NEXPLANON have been established in women of reproductive age. Safety and efficacy of NEXPLANON have not been established for postpubertal adolescents. However, no clinical studies have been conducted in women less than 18 years of age. Use of this product before menarche is not indicated.

4. Geriatric Use
This product has not been studied in women over 65 years of age and is not indicated in this population.

5. Hepatic Impairment
No studies were conducted to evaluate the effect of hepatic disease on the disposition of NEXPLANON. The use of NEXPLANON in women with active liver disease is contraindicated [see Contraindications].

6. Overweight Women
The effectiveness of the etonogestrel implant in women who weighed more than 130% of their ideal body weight has not been defined because such women were not studied in clinical trials. Serum concentrations of etonogestrel were inversely related to body weight. Generally, overweight women may be less effective in overweight women, especially in the presence of other factors that decrease serum etonogestrel concentrations such as concomitant use of hepatic enzyme inducers.

OVERDOSE
Overdose may result if more than one implant is inserted. In case of suspected overdose, the implant should be removed.

NONCLINICAL TOXICOLOGY
In a 24-month carcinogenicity study in rats with subcutaneous implants releasing 10 and 20 mcg etonogestrel per day (equivalent to approximately 1.6-3.8 μg/days for the human endogenous concomitant) for postpubertal adolescents. However, no clinical studies have been conducted in women less than 18 years of age. Use of this product before menarche is not indicated.

In a clinical trial of NEXPLANON, in which investigators were asked to examine the implant site after insertion, implant site reactions were reported in 8.6% of women. Erythema was the most frequent implant site complication, reported during and/or shortly after insertion, occurring in 3.2% of subjects. Additionally, hematomas (3.0%), bruising (2.0%), pain (1.0%), and swelling (0.7%) were reported.

Effects of Other Drugs on Hormonal Contraceptives
Substances decreasing the plasma concentrations of hormonal contraceptives (HCS) and potentially diminishing the efficacy of HCs: Drugs or herbal products that induce certain enzymes, including cytochrome P450 3A4 (CYP3A4), may decrease the plasma concentrations of HCs and potentially diminish the effectiveness of HCs or increase breakthrough bleeding. Some drugs or herbal products that induce the CYP3A4 system can induce breakthrough bleeding and/or contraceptive failure. Counsel women about the non-hormonal method of contraception or the back-up method when enzyme inducers are used with HCs, and to continue back-up non-hormonal contraception for 28 days after discontinuing the enzyme inducer to ensure contraceptive reliability.

Substances increasing the plasma concentrations of HCs: Co-administration of certain HCs and strong or moderate CYP3A4 inhibitors such as itraconazole, voriconazole, fluconazole, grapefruit juice, or ketoconazole may increase the plasma concentrations of progestins, including etonogestrel.

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Human Immuno deficiency Virus (HIV)/Hepatitis C Virus (HCV) protease inhibitors and non-nucleoside reverse transcriptase inhibitors: Significant changes (increase or decrease) in the plasma concentrations of progesterone have been noted in cases of co-administration with HIV protease inhibitors (decrease [e.g., nelfinavir, ritonavir, darunavir/ritonavir, fosamprenavir/ritonavir, lopinavir/ ritonavir, and tipranavir/ritonavir]) or increase [e.g., indinavir and atazanavir/ritonavir]) and HCV protease inhibitors (decrease [e.g., boceprevir and telaprevir]) or with non-nucleoside reverse transcriptase inhibitors (decrease [e.g., nevirapine, efavirenz]) or increase [e.g., efavirenz]. These changes may be clinically relevant in some cases. Consult the prescribing information for anti-viral and anti-retroviral concomitant medications to identify potential interactions.

Effects of Hormonal Contraceptives on Other Drugs
Hormonal contraceptives may affect the metabolism of other drugs. Consequently, plasma concentrations may either increase (for example, cyclosporin) or decrease (for example, lamotrigine). Consult the labeling of all concurrently-used drugs to obtain further information about interactions with hormonal contraceptives or the potential for enzyme alterations.
**Evaluation and management of polyhydramnios**

Idiopathic polyhydramnios requires extensive testing and surveillance.

**Introduction**

Polyhydramnios, or hydramnios, is an abnormal increase in the volume of amniotic fluid. Identification of polyhydramnios should prompt a search for an underlying etiology. The two most common pathologic causes of polyhydramnios are maternal diabetes mellitus and fetal anomalies. When no etiology for the excess amniotic fluid is identified, polyhydramnios is termed “idiopathic,” or unexplained. Idiopathic polyhydramnios accounts for approximately 60% to 70% of cases of polyhydramnios in published series and is identified in nearly 1% of pregnancies. This summary of SMFM Consult Series #46 reviews major considerations in evaluation and management of polyhydramnios (Table 1).

**Q** How is amniotic fluid volume assessed?

After 20 weeks’ gestation, amniotic fluid volume is assessed by using either the deepest vertical pocket (DVP) or the amniotic fluid index (AFI). In multiple gestations, the DVP is used. When the single DVP is used, polyhydramnios is defined as a measurement ≥ 8.0 cm. When AFI is used, the threshold is generally considered to be 24 cm or 25 cm, depending on whether a 95th or 97th percentile is selected.

Polyhydramnios is most often identified in the third trimester. Idiopathic polyhydramnios is usually detected in the third trimester, at a mean gestational age of 31 to 36 weeks across various series.

The degree of polyhydramnios is frequently categorized as mild, moderate, or severe, based on an AFI of 24.0 to 29.9 cm, 30.0 to 34.9 cm, and ≥ 35 cm, or a DVP of 8 to 11 cm, 12 to 15 cm, or ≥ 16 cm, respectively. Mild polyhydramnios accounts for approximately 65% to 70% of cases, moderate polyhydramnios for 20%, and severe polyhydramnios for < 15%.

**Q** What are the underlying causes of polyhydramnios?

When an etiology of polyhydramnios is identified, it is most commonly a fetal anomaly or maternal diabetes. Other potential causes of apparently isolated polyhydramnios in a structurally normal fetus include alloimmunization and congenital infection. Physiologically, the fluid increase in many of these cases can be attributed to either (1) impaired fetal swallowing or (2) overproduction of fetal urine due to a high-output cardiac state, renal abnormality, or osmotic fetal diuresis. In general, any anomaly severe enough to cause nonimmune hydrops fetalis (NIHF) may result in polyhydramnios, as these entities are often associated with each other. With maternal diabetes, maternal hyperglycemia leads to fetal hyperglycemia, with subsequent osmotic diuresis into the amniotic fluid compartment.
Alloimmunization can lead to fetal anemia with resultant NIHF and polyhydramnios. Congenital infections, such as parvovirus, cytomegalovirus, or syphilis, can lead to polyhydramnios by a variety of mechanisms, including anemia or cardiac dysfunction.

**Q** What evaluation should be performed when polyhydramnios is detected?

Idiopathic polyhydramnios is a diagnosis of exclusion. While the cause may be unexplained during pregnancy, the underlying risk that a structural or genetic abnormality is identified after birth in a pregnancy associated with apparently idiopathic polyhydramnios is 9% in the neonatal period to as high as 28% when infants were followed up to age 1 year.

Initial evaluation for polyhydramnios involves targeted ultrasonography to assess for fetal abnormalities. It is important to assess fetal growth because idiopathic polyhydramnios may be associated with macrosomia, and fetal growth restriction associated with polyhydramnios presents a high risk for an underlying fetal abnormality, including trisomy 13 or 18.

Not all of the abnormalities associated with polyhydramnios are detectable by ultrasound. Fetal esophageal atresia and tracheoesophageal fistula are among the most common polyhydramnios-associated abnormalities and may be difficult to diagnose by ultrasound. Disorders associated with apparently isolated polyhydramnios also include genetic syndromes for which there may be no sonographic findings or no screening or diagnostic test available.

Diabetes, alloimmunization, and congenital infection should be considered in a structurally normal fetus with mild polyhydramnios. Routine prenatal care includes screening for diabetes and alloimmunization, as well as testing for syphilis. Congenital infection usually presents with additional sonographic findings, such as NIHF, hepatomegaly, splenomegaly, or placentomegaly. In cases of polyhydramnios associated with NIHF or additional sonographic features, evaluation for fetal anemia and congenital infection is recommended.

Severe polyhydramnios presenting earlier in gestation should raise a greater concern for an underlying etiology. In severe cases, especially early in gestation, it is important to review the medical and family history, in addition to obtaining a detailed ultrasound examination. Genetic counseling and consideration of testing for neurologic disorders such as congenital myotonic dystrophy should be considered, especially with decreased fetal movement.

**Q** How is a pregnancy with polyhydramnios managed?

**Treating polyhydramnios**

Polyhydramnios severe enough to cause maternal respiratory compromise, significant discomfort, or preterm labor often has an underlying etiology, whereas idiopathic polyhydramnios, because it is usually mild and does not present until the mid-third trimester, does not typically require treatment. In selected cases, however, amnioreduction may be considered in an effort to relieve maternal dyspnea or discomfort. Overall, in cases of severe polyhydramnios that results in maternal respiratory compromise such that amnioreduction is considered, an underlying fetal abnormality is usually present. In addition, polyhydramnios usually recurs after amnioreduction, making its efficacy somewhat limited.

Indomethacin, which is often used for tocolysis, decreases fetal urine production. Due to reported neonatal complications, and in the absence of data on improved maternal or neonatal outcomes, we recommend that indomethacin not be used for the sole purpose of decreasing amniotic fluid in the setting of polyhydramnios.

**Antepartum management**

Likelihood of an underlying fetal abnormality is significantly higher with greater degrees of polyhydramnios, and progression of the condition is suggestive of an underlying etiology. In pregnancies with an identified underlying etiology, the degree of polyhydramnios is associated with an increased likelihood of preterm birth (PTB), a small-for-gestational age infant, macrosomia, and perinatal mortality.

Rates of PTB are not generally increased with idiopathic polyhydramnios (which is usually mild) but PTB is associated with more severe polyhydramnios. Reported data on whether perinatal mortality is increased with idiopathic polyhydramnios have been

The two most common pathologic causes of polyhydramnios are maternal diabetes mellitus and fetal anomalies.
inconsistent. Idiopathic polyhydramnios is associated with infant birthweight > 4000 g in approximately 15% to 30% of cases.

The most recent guidance from the American College of Obstetricians and Gynecologists on antepartum fetal surveillance does not specifically address isolated polyhydramnios or list it as an indication for surveillance. Although antepartum surveillance is often performed in this setting, there are no data to suggest that such assessment decreases perinatal mortality. The role and frequency of follow-up ultrasonography is unclear, but the imaging may be warranted in cases where there is concern for progression of polyhydramnios or to evaluate fetal growth.

Regarding timing of delivery, there are no data to suggest that induction of labor or PTB are associated with an improved outcome in the setting of mild idiopathic polyhydramnios. Labor should be allowed to occur spontaneously at term and the mode of delivery should be determined based on usual obstetric indications. If an induction is planned, it should not occur at < 39 weeks’ gestation in the absence of other indications.

Intrapartum management

Rates of fetal nonvertex presentation are reported to increase as severity of polyhydramnios increases. Clinical or sonographic determination of the fetal presenting part should be performed upon presentation in labor. External version for nonvertex fetal presentation may be considered if there are no contraindications to this procedure.

Rates of dysfunctional labor are increased in the presence of polyhydramnios. Studies have also demonstrated that women with pregnancies complicated by idiopathic polyhydramnios are significantly more likely to undergo a cesarean delivery for failure to progress. Rates of caesarean delivery for women with pregnancies complicated by idiopathic polyhydramnios range from 35% to 55%. An increased risk of operative vaginal delivery in the presence of polyhydramnios has also been reported. Some investigators report a higher frequency of nonreassuring fetal heart rate tracings and postpartum hemorrhage.

Planning for care of the neonate is necessary in cases of polyhydramnios. As noted previously, there is an increased rate of structural abnormalities or genetic syndromes in the neonate following a gestation complicated by polyhydramnios. Idiopathic polyhydramnios has also been associated with an increased risk of neonatal intensive care unit admission. Pediatric support should be available at delivery for women with mild, idiopathic polyhydramnios; for women with severe polyhydramnios, delivery at a tertiary center is recommended.

### TABLE 1. SUMMARY OF RECOMMENDATIONS

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>GRADE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 We suggest that polyhydramnios in singleton pregnancies be defined as either a DVP ≥ 8 cm or an amniotic fluid index ≥ 24 cm.</td>
<td>2C Weak recommendation, low-quality evidence</td>
</tr>
<tr>
<td>2 We recommend that amnioreduction be considered only for the indication of severe maternal discomfort, dyspnea, or both in the setting of severe polyhydramnios.</td>
<td>1C Strong recommendation, low-quality evidence</td>
</tr>
<tr>
<td>3 We recommend that indomethacin not be used for the sole purpose of decreasing amniotic fluid in the setting of polyhydramnios.</td>
<td>1B Strong recommendation, moderate-quality evidence</td>
</tr>
<tr>
<td>4 We suggest that antenatal fetal surveillance is not required for the sole indication of mild idiopathic polyhydramnios.</td>
<td>2C Weak recommendation, low-quality evidence</td>
</tr>
<tr>
<td>5 We recommend that labor be allowed to occur spontaneously at term for women with mild idiopathic polyhydramnios; that induction, if planned, not occur at &lt; 39 weeks’ gestation in the absence of other indications; and that mode of delivery be determined based on usual obstetric indications.</td>
<td>1C Strong recommendation, low-quality evidence</td>
</tr>
<tr>
<td>6 We recommend that women with severe polyhydramnios deliver at a tertiary center.</td>
<td>1C Strong recommendation, low-quality evidence</td>
</tr>
</tbody>
</table>

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Adenomyosis and its impact on fertility

Comorbidities such as endometriosis can confound the picture in patients with adenomyosis, a condition that may lead to poor IVF outcomes.

by ANTHONY N. IMUDIA, MD, AND RACHEL G. SPRAGUE, MD

Introduction
Adenomyosis is a common gynecologic disorder, yet its etiology and association with infertility remains unclear. It is a benign disorder previously associated with multiparity. Recently, however, an association with infertility has emerged. Adenomyosis can be asymptomatic or present with menorrhagia, dysmenorrhea, and metrorrhagia with these symptoms usually occurring in patients aged 35 to 50.

Approximately 20% of cases of adenomyosis involve women younger than 40 and 80% are aged 40 to 50. On histological analysis, adenomyosis is defined by ectopic location of endometrial and stromal tissue distal to the endometrial-myometrial junction with associated myometrial smooth muscle hypertrophy. Histologic diagnostic criteria for adenomyosis have been debated and inconsistently applied, making studies unreliable and often incompatible.

The most accepted hypothesis for the etiology of adenomyosis stems from the invagination of the endometrial basalis layer into the myometrium. Adenomyosis can have a diffuse, haphazard distribution or more focal regions known as adenomyomas. Women with the condition, therefore, present with enlarged, boggy uteri.

How is adenomyosis diagnosed?
Traditionally, the diagnosis was made by means of histopathologic examination, usually on a hysterectomy specimen as the treatment of choice for the disease was hysterectomy. With the evolution of magnetic resonance imaging (MRI) and high-quality trans-...
Today, the diagnosis can be made with a level of accuracy of 80% to 90% without the need for excisional surgery (Figures 1a and 1b).\(^5\)\(^-\)\(^7\)

Criteria used to define adenomyosis on ultrasound include focal areas with diffuse hyperechogeneity and loss of a normal endo-myometrial interface; increased or decreased areas of echogenicity; or cystic structures within myometrium with increased color Doppler flow. On MRI, assessment of the thickness of the junctional zone (the subendometrial myometrium) is the mainstay of diagnosis. The consensus for diagnosis of adenomyosis is when the junctional zone is greater than 12 mm but the disorder can be suspected when the thickness is between 8 and 12 mm.\(^8\) The advantage of MRI over TVS is that MRI has a greater specificity and can differentiate adenomyomata from leiomyoma.\(^9\) When noninvasive diagnosis with MRI and TVS imaging became available, the role of adenomyosis in infertility and early pregnancy was better recognized.\(^10\)

**How is the condition linked with infertility?**

Most evidence that links adenomyosis to infertility is limited to case reports and small case series. There is also the potential for confounding in these studies as adenomyosis commonly coexists along with other pathologic processes linked to infertility, such as endometriosis, polyps, or leiomyoma.\(^11\) There is a significant association between pelvic endometriosis and adenomyosis, with estimates indicating that it occurs in 54% to 90% of cases.\(^12\)\(^,\)\(^13\) Because endometriosis is well-known to cause infertility, there is concern that findings of infertility were due to concurrent endometriosis rather than adenomyosis.\(^14\) However, a study in baboons showed a strong association between histological adenomyosis and lifelong infertility (20-fold increased odds) even in cases where coexisting endometriosis was excluded.\(^15\) In a study of women who received embryos created through oocyte donation rates of miscarriage were significantly higher in those who had adenomyosis alone versus those with co-existing endometriosis or controls.\(^16\)

A recent meta-analysis concluded that adenomyosis has a detrimental effect on clinical outcomes of in vitro fertilization (IVF). In women undergoing IVF, rates of implantation, clinical pregnancy per cycle, clinical pregnancy per embryo transfer, ongoing pregnancy, and live birth among women with adenomyosis were significantly lower than in those without adenomyosis.\(^17\) The miscarriage rate in women with adenomyosis was also higher than in those without adenomyosis.\(^17\) One of the confounding variables in this study was age, given that women with adenomyosis were older; however, even after controlling
How does adenomyosis impact infertility?

Proposed mechanisms of infertility in patients with adenomyosis focus on derangements of three putative pathways: uterotubal transport, endometrial receptivity, and implantation. In patients with adenomyosis, uterotubal transport is impaired due to intrauterine anatomical distortion that blocks the tubal ostia and potentially blocks sperm migration and embryo transport. Uterine hyperperistalsis has been seen on ultrasound in patients with adenomyosis due to destruction of normal myometrial architecture. These abnormal myometrial contraction waves lead to abnormal sperm transport through the uterine cavity and may also lead to increased intrauterine pressure.

Endometrial receptivity and function becomes altered via increased production of estrogens from aromatization of androgens and altered estrogen receptor/progesterone receptor expression. The inflammatory response in women with adenomyosis has also been shown to be increased. Patients with severe adenomyosis in whom implantation failed were found to have higher density of macrophages. This increased macrophage density subsequently increases intrauterine inflammatory response and release of reactive oxygen species that are thought to be embryotoxic.

Lastly, impaired implantation results from a lack of adequate expression of adhesion molecules, reduced expression of implantation markers, and altered function of the gene for embryonic development (HOXA10). In contrast to women with endometriosis, adenomyosis has not yet been shown to have an adverse influence on oocyte function or folliculogenesis. In patients with endometriosis, levels of activated macrophages, prostaglandins, interleukin (IL)-1β, tumor necrosis factor (TNF)α, and proteases were increased in peritoneal fluid and their high concentrations may adversely affect oocyte function. As of yet, there no association has been found between adenomyosis and oocyte quality or function.

Possible treatments for adenomyosis in infertility

Based on limited available evidence, patients with adenomyosis could be treated with medical and/or surgical therapies to improve pregnancy and live birth outcomes. Treatment with gonadotrophin-releasing hormone agonist (GnRH-a) serves to down-regulate the pituitary, exert an anti-proliferative effect, promote apoptosis, and reduce the anti-inflammatory and angiogenesis effect. Multiple case reports show conception and live birth in women with infertility and adenomyosis after pretreatment with GnRH-a for 3 to 5 months. In other retrospective studies, pretreatment with GnRH-a prior to fresh- or frozen-embryo transfer appears to increase pregnancy rates. Further prospective studies with larger sample size are needed to validate these findings.

In retrospective studies, conservative surgery or combination surgery with GnRH-a has shown to be more effective in controlling symptoms and also in increasing pregnancy and live birth rates when compared with GnRH-a alone in patients with extensive adenomyosis. In case reports and case series, multiple methods of fertility-sparing surgery for adenomyosis have been performed, with subsequent pregnancies. These techniques include classical adenomyomectomy, H-incision, triple-flap method, and laparoscopic cytoreductive surgery. No evidence as of yet points to superiority of one technique over another (Video). Surgical management of adenomyomas and adenomyosis can present an operative challenge, especially compared with myomectomy. Adenomyomas are less distinct given absence of well-defined borders and given protrusion into the myometrium. During dissection, the plane is identified mainly by recognizing healthy myometrium rather than simple enucleation as in myomectomies. This can lead to increased risk of intraoperative bleeding and weakening of the myometrium, which can increase risk of uterine rupture or abnormal placentation in future pregnancies. Uterine-preserving surgeries have shown benefit for women who have previously experienced IVF treatment failures, especially patients ≤ 39 years old.
A large prospective study showed that combination conservative surgery and medical treatment with GnRH-a for patients with severe symptomatic adenomyoma lowers symptom relapse rates and yields a trend toward improved reproductive outcomes.36 Therefore, for patients with presumed severe adenomyosis who want to retain fertility, surgical cytoreduction and GnRH-a combined may be desirable.

Other methods of fertility-sparing treatment for adenomyosis have recently generated interest. High-intensity focused ultrasound ablation (HIFU) has been used for leiomyoma and is now being used for patients with adenomyosis who want fertility.41 HIFU is a noninvasive thermal ablation technique in which high-intensity ultrasound energy is focused on a small focal region to increase tissue temperature sufficient to cause irreparable cell damage in the target at a certain depth within the body.42 Selection criteria for using HIFU ablation for adenomyosis vary depending on the center, but very strict selection criteria are required to improve efficacy and decrease risk of thermal injury.43,44 Patients typically must be 18 or older, premenopausal, have no history of pelvic inflammatory disease or severe pelvic endometriosis, and have symptomatic adenomyosis with junctional zone thickness > 3 cm for diffuse adenomyosis or a lesion diameter between 3 and 10 cm for focal adenomyosis.45 A recent retrospective study showed high rates of conception and live birth in HIFU-treated patients with adenomyosis, suggesting that it is a promising noninvasive fertility-sparing treatment option.44 In another study, pregnancies after HIFU resulted in 2 miscarriages and delivery of 4 healthy babies. One delivery was complicated by a major placenta previa and hemorrhage.45

Conclusion

Although adenomyosis is a common gynecologic disorder, its role in infertility is unclear. It previously was believed to be a symptomatic disease in older women but it is now being seen in an asymptomatic and younger population undergoing evaluation for infertility. Limited studies have found an association between adenomyosis and poor reproductive outcomes. However, other coexisting pathologies, such as endometriosis, may be significant confounders.

Proposed mechanisms of adenomyosis and infertility point toward derangements in uterotubal transport, endometrial receptivity, and intrauterine inflammation impairing implantation. No association with oocyte function has yet to be identified. Women with severe adenomyosis and in whom IVF previously failed who want fertility can be treated with GnRH-a and/or surgical resection. The strategy has produced promising outcomes in pregnancy and live birth along with symptom improvement. While definitive treatment with hysterectomy was previously the gold standard for adenomyosis, emerging conservative surgical interventions are gaining momentum. Alternatively, HIFU thermal ablation has been presented as another potential noninvasive option for fertility preservation. Large prospective trials are needed to confirm the clinical efficacy of these new fertility-sparing treatment modalities and to better understand their risk and safety profiles.

DISCLOSURES The authors report no potential conflicts of interest with regard to this article.

Treatments to consider for adenomyosis in women who want to preserve fertility include GnRH-a with or without surgical resection and HIFU.

FOR REFERENCES VISIT contemporaryobgyn.net/Adenomyoma

Visit our website to view a video of the authors’ technique for surgical management of adenomyoma.

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RESECTION OF ADENOMYOMA IN INFERTILITY PATIENT

NOVEMBER 2018
The hospitalist’s role in the critical care team

Contemporary OB/GYN sits down with a hospitalist to discuss the role hospitalists fill at her institution and how ob/gyns can improve efficiency in critical care situations.

by LINDA MARIE WETZEL, RN

CONTEMPORARY OB/GYN: Not all institutions have hospitalists on staff. Explain the role of the hospitalist in your institution during times of emergency.

RAKHI DIMINO, MD: The hospitalist team is the glue that makes a unit stick together and act like a team. It’s part of our duty to understand what the resources are in the hospital and how to rally them. The hospitalist is the one who knows exactly how long it takes to get anesthesia to open an OR, or how quickly our nurses can move into an emergency and take care of their other patients. It’s the hospitalist’s role to understand how to get support from the code blue team and communicate, “This woman is coding, you need to treat her like she’s not pregnant. I’m going to be your advisor on the pregnancy part, so let’s run this code together.” And in the OR, even when there’s a private physician there, somebody has to step back to the foot of the bed and determine the patient’s overall needs. A hospitalist might say “I need these particular blood products, somebody call the blood bank,” because when you’re focused inside the patient’s belly, you can’t see what’s happening in the rest of the room and coordinate the emergency. It’s that kind of coordination of resources during an emergency that makes hospitalists so incredibly vital for in terms of getting a great outcome for the patient.

CONTEMPORARY OB/GYN: How have that understanding and coordination worked in one of your cases?

DR DIMINO: In one of our hospitals, our team received a frantic call from a midwife at a birthing center. She had an extremely preterm patient who was bleeding. We actually had 5 minutes of warning before the patient arrived but that made all the difference in the world. We were able to alert anesthesia, neonatal intensive care unit (NICU) and the nursing staff. We opened the OR and had the room ready for her. In fact, we were waiting for her at the door when she arrived. We assessed the patient very quickly and were able to quickly take her to the operating room (OR) for an emergency delivery with a great outcome. If the midwife had not called and we did not have a hospitalist team preparing for her arrival, her outcome would not have been the same. Our team is faster now because we are conditioned to respond. When your team is always ready to respond together, especially mentally prepared, it decreases your time to respond and improves your outcomes. We are all striving for a healthy baby and healthy mom.

CONTEMPORARY OB/GYN: How can other teams achieve this level of efficiency, even if hospitalists are not part of the picture?

DR DIMINO: The best thing that you can do is to make sure your unit’s team has
practiced. And that you, as a physician, are part of that practice. The nurses tend to be really well-prepared but sometimes private physicians are too busy to practice. When you’re running a drill for your team, you need everybody to be part of it from the unit secretary who is calling out the code, to the operators who are ringing the code bells overhead, to your nursing staff and the people who are your runners to the blood bank. Your surgical techs opening your OR, your private staff, anesthesia with the certified nursing assistant team, and your NICU team need to be part of those rehearsals or practice drills because when it really happens, you don’t have the time to work all that stuff out. It’s not the time to learn how to swim when you are trying to get away from a shark. Your team on labor and delivery should have practiced enough that they work like a well-oiled, dependable machine when they are faced with a life-threatening situation. They should be in a constant state of readiness to react.

CONTEMPORARY OB/GYN: How can the team support each other through complicated emotions that come up as part of these intense and traumatic situations?

DR DIMINO: Supporting each other through traumatic events is the only way for your team to keep working together. The “second victim effect” is real and sometimes hits us when we least expect it. I’ve seen hospitalists and private physicians alike who have had a traumatic event with their patient and have trouble putting one foot in front of the other to keep going to take care of their other patients. Sometimes they can’t eat or sleep. Sometimes when they go home and hug their kids they feel guilty that their patient doesn’t have a baby to hug. Hospitals have really become better at supporting their nurses and others in the hospital, but physicians often miss this support. We as physicians should seek it out. Our organization has a second victim’s program where a colleague will reach out to you if you go through a traumatic event and then stay with you, supporting you emotionally for as long as you need it. As a hospitalist, when I see a private physician experience a traumatic event, I try to take it upon myself to call them the next day and check in with them periodically to make sure they are doing OK. This collegial support is important because ultimately it affects how future patients are cared for.

CONTEMPORARY OB/GYN: How can doctors prepare themselves for that moment when everyone in the room is looking to them to lead?

DR DIMINO: As physicians, we are often very adept at the clinical aspects of a case. We can recite how to run a clinical protocol and take care of the case medically, but we don’t always know how to coordinate a team. I think that is the part we are sometimes missing as physicians. Your team is looking for you to not just go through the motions of releasing a shoulder dystocia, but also to guide the team in a coordinated effort while maintaining a sense of calm.

Many physicians report that they go on autopilot when responding to an emergency. Physicians often say, “I get really quiet and I do talk but I’m focused on what is happening.” In serious emergencies many will get very quiet and seem to be lost in their own thoughts as they respond to their patient’s needs. When they do talk out loud, they often do not direct their requests to anyone on the team in particular. They might ask for a medication and someone leaves to get it. Then the physician makes the request again because he/she doesn’t know if someone actually went to get the medication or not. Then another person leaves the room to get the medication while the physician remains alone with the patient. Other times, everyone is standing in the room waiting for instructions and the physician, lost in thought, is wondering why no one else is helping the patient in the way they expect. This lack of communication makes the whole team suffer, and dramatically affects the patient.

When your team has rehearsed it and you know your team’s response inside and out, your demeanor changes. You become more directive. You don’t just talk, but you talk with purpose and clarity. You look to the person who is standing immediately to your right, where your team’s runner is designated to stand. You say to that person who is standing immediately to your right, where your team’s runner is designated to stand. You say to that particular person, “I need this medicine,” and that person responds with,
Lynch syndrome is an autosomal-dominant hereditary cancer syndrome that has the same incidence in the general population as the BRCA1/2 gene cancer syndrome: 1 in 400 people. But the public and physicians remain unfamiliar with this disorder partially because we have no public advocates as we have had with Angelina Jolie and the BRCA1/2 genes.

In the United States, it is projected that 1 million people have Lynch syndrome, yet only 5% of them have currently been diagnosed. Lynch syndrome is not rare, and yet it is under-diagnosed. To identify these high-risk families before they receive a cancer diagnosis is truly practicing preventive medicine. Ob/gyns are uniquely positioned to identify these families before they develop cancer.

Lynch syndrome and cancer risk
Lynch syndrome is caused by a mutation in a DNA mismatch repair pathway. The 5 genes associated with hereditary nonpolyposis colorectal cancer (HNPCC) and their prevalences are as follows: MSH2: 60%, MLH1: 30%, MSH6: 7% to 10%, and rarely PMS2 and EPCAM. Usually, our healthy genes can detect mistaken genes and repair them as they are growing and multiplying. However, with Lynch syndrome, the healthy cells cannot repair the errant cells, and the body continues to make more flawed cells, which will lead to a cancer.

The predominant risk associated with Lynch syndrome, named for Henry Lynch (see Origins of Lynch Syndrome) is colon cancer, which is the third most common cancer in the United States. Three to 5 of every 100 colon cancers are a consequence of Lynch syndrome. Patients with Lynch syndrome have a 50% to 80% chance of developing colon cancer during their lifetime, and they have a 25% risk of already having colon cancer at the time of starting/commencing routine colo-
noscopy screening at age 50. Lynch-associated colon cancers are often diagnosed in adults younger than age 50, which is a red flag for hereditary cancer syndromes. Thus, it is important that any colon cancer in the patient or in the family history be evaluated in the context of additional Lynch syndrome-related cancers (endometrial, ovarian, pancreatic, etc.) so as to not miss Lynch families. Colorectal screening protocols for patients with Lynch syndrome differ slightly based on the specific gene mutation, but in general, include annual colonoscopies beginning at age 20 to 25.

**Role of the ob/gyn**

For ob/gyns, it is especially important to diagnose patients with Lynch syndrome, as a study from MD Anderson in 2005 reported that up to 71% of women identified as having it will acquire endometrial cancer (20% risk by age 50) and 12% will acquire ovarian cancer. That same study also showed that the sentinel/first cancer diagnosed in nearly 50% of women eventually proven to have Lynch syndrome will be a gynecologic cancer. Interestingly, a significant proportion of women with Lynch syndrome presented with simultaneous gynecologic and colon cancers. For these women, mean age at diagnosis of colorectal cancer was 40 and at diagnosis of endometrial or ovarian cancer was 44.

Due to an increased risk of both endometrial and ovarian cancers, it is important that ob/gyns be aware of the cancers associated with Lynch syndrome when taking a cancer family history of their patients (Table 1). A woman who presents with abnormal uterine bleeding and has a family history of colorectal cancer could be at risk for having Lynch syndrome, particularly if the affected member is younger than age 50 (Table 2). Once a patient with Lynch syndrome has completed child-bearing, it is appropriate to counsel her to consider a prophylactic hysterectomy and bilateral salpingo-oophorectomy. Women with Lynch syndrome who have not completed child-bearing should be followed carefully with endometrial biopsies every 1 to 2 years, starting at age 30 to 35. In addition, the practitioner should be more concerned about risk of endometrial cancer as the cause of bleeding in a woman with Lynch syndrome than in a typical patient who presents with such bleeding.

It cannot be emphasized enough that taking a careful cancer family history is the most effective way for a clinician to evaluate a patient for risk of having Lynch syndrome. If a patient’s personal or family history is suggestive of Lynch Syndrome, diagnostic genetic testing should be considered to confirm the diagnosis (Table 3). Tumor testing (MSI and IHC) of colon or endometrial cancers can be performed to look at characteristics of the cancer itself to assess the likelihood of Lynch syndrome. However, such testing is not diagnostic for Lynch syndrome nor is it a substitute for germline genetic testing. Ordering a hereditary cancer panel that will test for multiple cancer syndromes at one time is now the standard of care. That is important because genetic testing can distinguish between Lynch syndrome and other colorectal cancer syndromes, such as familial adenomatous polyposis (FAP) or MAP syndrome (MUTYH-associated polyposis). This is a critical distinction for women’s health care providers as these syndromes are not believed to...
be associated with increased risk for gynecological cancers.

**Case studies**

Two cases illustrate key points for ob/gyns in identifying patients with Lynch syndrome.

**CASE 1: 73-YEAR-OLD WOMAN**

**Personal and family history:**
- **Patient** – endometrial cancer at age 45 and colorectal cancer at ages 51 and 72
- **Sister** – kidney/renal cancer at age 56
- **Mother** – endometrial cancer at age 45
- **Father** – colorectal cancer at age 65
- **Maternal aunt** – breast cancer at age 65

As you can see, this patient had a personal history of both colon and endometrial cancers, the hallmark cancers of Lynch syndrome. Her case is illustrative of the findings referenced in the MD Anderson article because she had a gynecologic cancer before her first colon cancer. Unfortunately, this woman underwent cancer treatment 3 times before her history was recognized and acted upon, at age 73. Surprisingly, it was a breast radiologist—not her oncologist, ob/gyn, or colorectal surgeon—who noticed the striking history during a routine mammogram. The radiologist then suggested that a Lynch Syndrome Panel be performed, which was subsequently positive. Rather than defer to geneticists or other specialists, it is important that physicians in all specialties recognize the importance of concerning cancer histories and act upon them, so that a lifesaving diagnosis is not delayed or missed completely in these high-risk families.

**CASE 2: 36-YEAR-OLD WOMAN**

In 2017, this patient with 5 children presented with a family history of breast and endometrial cancer in both her mother and her maternal grandmother. Because of this, she requested genetic testing. The test result came back as “negative” with a “variant of unknown significance – VUS” in the MLH1 gene. A VUS is not considered a positive result and should not clinically be acted upon. The majority of VUSs are later reclassified as benign, and responsible laboratories will monitor VUS results for a lifetime and send amended reports, should new information be obtained. ERRONEOUSLY, the patient was told that she had an increased risk for both breast and endometrial cancers. Based on that discussion, she underwent bilateral mastectomies as well as a hysterectomy.

Later, with subsequent interpretation of her genetic results, she brought a medical liability suit against both the ob/gyn and the breast surgeon.

For physicians who do genetic screening on a limited basis, it is prudent to send patients to an individual with expertise in evaluation of genetic

**Table 2**

KEYS TO IDENTIFYING PATIENTS WITH LYNCH SYNDROME

- Positive family history of colon cancer – especially if a member developed colon cancer before age 50
- Positive family history of extracolonic Lynch syndrome cancers such as endometrial, ovarian, small bowel, biliary, renal pelvis, ureter, or glioblastoma
- Abnormal uterine bleeding with diagnosis of complex endometrial hyperplasia or endometrial cancer in a woman younger than age 50

**Table 3**

AMSTERDAM II CRITERIA FOR DIAGNOSIS OF HNPCC (LYNCH SYNDROME)*

- Three or more relatives with histologically verified HNPCC-associated cancer (colorectal cancer, cancer of the endometrium, small bowel, ureter, or renal pelvis), one of whom is a first-degree relative of the other two. Familial adenomatous polyposis should be excluded.
- Cancer involving at least 2 generations.
- One or more cancer cases diagnosed before age 50.

**Origins of Lynch Syndrome**

Henry Lynch has been considered the “father of hereditary cancer” and a pioneer in the study of cancer and genetics. Dr. Lynch received his doctorate degree in human genetics at the University of Texas, Austin, in 1960, while completing medical school there. In 1966, while a professor at Creighton University, he characterized the syndrome and named it “Cancer Family Syndrome.” Later in 1984, the term Lynch syndrome was coined by other authors, and in 1985, Dr. Lynch named the condition HNPCC (hereditary nonpolyposis colorectal cancer). Since then the 2 names have been used interchangeably. Lynch syndrome families are born with a predisposition to develop colorectal, endometrial, ovarian, or other cancers.
“Given the number of surgical approaches one needs to learn and the decrease in surgical cases, I think the specialty (ob/gyn) should be split. With decreased surgical numbers, there is no way to adequately learn vaginal, abdominal and laparoscopic approaches.”

“I think ... gyn surgery will become a specialty. I have already stopped doing hysterectomies because my volume was so low.”

“Ambulatory gyn will become part of primary care called Women’s Health Services and gyn surgery will revert back to general surgery.”

“Residents receive less training in gyn surgery and office gynecology. Eventually, I think we will need to change ob/gyn residency programs from 4 years to 5 years in length.”

“Robotics use has and will dampen current resident training & surgical skills. While there is a robotics niche, the temptation to use the tool in an unethical manner is very great.”

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*From the Contemporary OB/GYN 2018 Readers Survey.*
Does surgery improve pregnancy odds for women with colorectal endometriosis?

by NANCY MONSON

Secondary analysis of results from a French trial investigating the effects of surgical management of colorectal endometriosis found that the intervention effectively improved postoperative fertility rates, including the ability to conceive naturally. The study is one of the first to evaluate the impact of first-line surgery on pregnancy rates in this population.

First-line assisted reproductive technology (ART) is the recommended strategy for improving pregnancy rates in women with endometriosis, but is a subject of controversy in the gynecological community due to a lack of high-quality data comparing it to surgical management. In addition, the European Society of Human Reproduction and Embryology (ESHRE) reported in 2014 that there was no evidence that surgical management of deep endometriosis would improve pregnancy rates prior to ART.

The study population consisted of 55 women from the ENDORE (Functional Outcomes of Surgical Management of Deep Endometriosis Infiltrating the Rectum) randomized trial conducted between March 2011 and August 2013 who wished to conceive. ENDORE was an unblinded, parallel-arms, controlled trial designed to determine if conservative rectal surgery was superior to segmental resection in women with colorectal endometriosis.

All of the women had deep endometriosis reaching into the rectum up to 15 cm from the anus with lesions measuring more than 20 mm in length. The endometrial lesions at minimum involved the muscular layer in depth and up to half of the rectal circumference. Twenty-five subjects underwent a conservative surgical procedure (shaving or disc excision) and 30 had radical rectal surgery (segmental resection). The surgeries were all performed by the same gynecologist. Subjects were followed for 50 to 79 months.

Of 36 patients who wanted to become pregnant after surgery, 23 (63%) had tried unsuccessfully prior to surgery for more than a year (the infertile group). After surgery, 29 patients became pregnant (81%), and some had more than one pregnancy, for a total of 37 pregnancies. Odds of postoperative conception improved over time (see Table).

<table>
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<td>At 12 months</td>
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In total, 24 of the 37 pregnancies occurred as a result of natural conception, and subjects who were advised by their physicians to try to conceive naturally got pregnant significantly earlier than subjects who were referred for ART ($P=0.008$).

Conclusions tempered by lack of data

Although the study had a small sample size, was subject to possible ascertainment bias and preoperative and postoperative fertility assessments were not performed for all women, the trial was prospective with long-term follow up. It showed that fertility and the ability to conceive naturally can be restored by first-line surgery in women who are infertile due to colorectal endometriosis, perhaps in part due to the ability of women with endometriosis-related severe dyspareunia to engage in regular sexual intercourse postoperatively.

The authors stopped short of recommending that surgery for infertility be recommended over ART until more studies are performed. They suggested that in the interim “Physicians should ultimately offer patients a balanced perspective of the potential benefits and potential harms of alternative options.”

Nancy Monson is a freelance writer and certified health coach. She reports no relevant financial disclosures.
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Medical malpractice insurance is one of the greatest expenses physicians face during their careers. A primary care doctor can expect to pay hundreds of thousands of dollars in premiums over the decades.

But knowing what to look for in a policy is a mystery for many physicians, as well as a time-consuming chore that rarely gets the attention it deserves. And buying the wrong type or incorrect amount of insurance—or buying it from the wrong carrier—can be extremely costly.

Physicians who take the time to understand how to buy malpractice insurance will not only save money, but ensure that they’ve got the right type and amount of liability coverage.

Types of insurance

Policies typically cover expenses incurred while defending and settling malpractice suits. These can include attorney fees, medical damages, arbitration and settlement costs, court costs, and punitive and compensatory damages. Liabilities incurred from criminal acts or sexual misconduct usually are not covered.

There are 2 basic types of malpractice insurance: claims-made and occurrence. A claims-made policy provides coverage only if the policy is in effect both when the incident took place and when a lawsuit is filed. Occurrence policies cover any claim for an event that took place during the period the policy was in effect, even if the claim is filed after the policy lapses.

Because a claim can be filed years after an event and after a claims-made policy expires, these policies often include a “tail” that extends coverage for a set number of years beyond the expiration date. If it’s not part of the original policy, tail coverage can be bought separately.

Tail coverage offers protection when a physician is changing jobs or carriers or retiring. Sometimes, the cost of tail coverage will be covered by a previous employer to protect itself or can be negotiated with a new employer. Occurrence policies generally don’t require tail coverage, but are not available in all states.

If buying a claims-made policy, be sure that the beginning date for coverage is accurate and matches the date on the prior policy to ensure there are no coverage gaps between policies, says Jennifer Richard, ARM, RPLU, vice president of sales and marketing, Professional Risk Associates, a Virginia-based malpractice insurance broker.
“Physicians should ensure all services they are providing have been fully disclosed and reviewed by their agent and underwriter to ensure there are no gaps in coverage in their practice,” she says.

“Additionally, it’s important they review all other professional liability exposures within cyber, regulatory, directors and officers, and employment practices liability. There are situations where these coverages could overlap, or come into play, based on the risk exposure of the practice.”

How much coverage?
The appropriate amount of coverage can vary by state, specialty, and contractual arrangements with hospitals and other healthcare organizations, says Richard. Some states require providers have minimum levels of coverage, but a physician can still need more.

In general, carriers’ standard coverage limits are $1 million per claim and $3 million aggregate, which is the most the policy will pay in a year for all claims. However, certain states require different limits based on medical malpractice caps on damages. States with more litigious climates might require more.

Richard cites the example of Virginia, which does not have a statutory requirement for medical liability insurance. However, the state has a medical malpractice cap of $2.35 million (which eventually will increase to $3 million). For that reason, hospitals require physicians to carry at least that amount with an aggregate that is three times higher ($2.35 million per claim/$7.05 million aggregate).

Some states have patient compensation or catastrophe loss funds, which provide an additional layer of coverage over the primary policy limits, says Eric Anderson, vice president of marketing and communications for Medical Professional Liability Associates, an industry group.

Providers pay into these state-run funds through a surcharge on medical malpractice insurance premiums. If a lawsuit is filed and found to be legitimate, malpractice insurance will cover the injured patient’s costs to a limit set by the state. The rest is paid by the fund.

What to look for in a carrier
Carriers must be licensed in each state in which they operate and follow that state’s rules and regulations. While many carriers operate in multiple states, not all do. Patrick Lawn, owner of Physicians Insurance Consultants in Pennsylvania, estimates that there is an average of 5 to 6 carriers in each state.

Price is an important factor, but it shouldn’t be the only one, says Lawn, adding that shopping on price alone can lead to hiring an unreliable or financially precarious carrier.

“You can’t just jump (carriers) for a penny; you’ve got to be able to rely on the carrier,” Lawn says.

Make sure the policy has a “consent to settle” clause, which prevents the insurer from settling a claim without permission of the insured doctor, Lawn advises.

The best carriers will act as resources for their clients, offering advice on how to avoid claims and other matters, says Kenneth Hertz, FACMPE, principal consultant at Medical Group Management Association (MGMA). "Partner with them as a resource. They’re the experts. They’re only too happy to help and they can help you stay out of trouble. It’s to their benefit as well,” he says.

Should you use a broker?
Virginia Kladder, MD, considers herself fortunate that she’s never had to shop for malpractice insurance. “If I had to go out on my own there is no way, as a physician, I could figure it out,” she says.

The Richmond, Va., internist works for PartnerMD, a concierge practice. Buying insurance for Kladder and 23 other physicians across 8 offices in 5 states is the responsibility of PartnerMD’s Chief Operating Officer Jack Bretcher, who, in turn, relies on insurance broker Professional Risk Associates.

A broker has the depth of knowledge and the experience to know the coverage a practice needs and the best insurers to provide it, Bretcher says.
“They help us keep abreast of what’s out there and what our needs are,” he says, adding that he’s bought extra layers of coverage, including cyber insurance, at the recommendation of his broker.

Even small practices are better off using independent brokers rather than spending the time to research policies and carriers, says MGMA’s Hertz, a former practice manager.

“If you can find a broker who is knowledgeable, it’s a lot easier to hire them to do the legwork, get the quotes, and educate you as a manager,” he says.

**Risk retention groups**

An alternative to traditional malpractice insurance is a risk retention group (RRG). These are liability insurance companies that require all company owners to be policyholders and vice versa.

All owners/policyholders must be in the same type of business, such as physicians. RRGs can offer lower premiums than traditional carriers and, if they are profitable, the owners are paid dividends, but there are some drawbacks as well, says Hertz. They must be incorporated in at least 1 state but can operate nationwide, largely exempt from the oversight of other state insurance departments.

Because they were created by federal law, they are not subject to the same level of state regulation as private carriers. They may not have to disclose as much financial information and they are not backed by state guaranty funds in case of financial troubles.

Practices should perform due diligence on RRGs before deciding to join one, Hertz says. Sources of information about them are Demotech and Risk Retention Reporter.

**Shopping and updating**

Shopping for malpractice insurance can be a time-consuming task, so it’s not surprising that physicians tend to stick with a carrier and policy unless something changes, such as a large increase in premiums or a contentious claim. That complacency can be costly, says Lawn.

“I’ve seen doctors who are looking to save expenses, but they don’t bother [comparison] shopping one of their highest overhead expenses. It makes no sense to me,” Lawn says.

But that doesn’t mean shopping every year, says Richard, who adds that practices should review their policies and compare prices every 2 to 3 years.

Ask carriers about ways to earn discounts, says Hertz, who adds that some insurers will offer discounts of up to 10 to 15% if doctors attend carrier-led risk management programs on how to avoid malpractice claims through such things as documentation and better patient communication.

Even if not shopping for a new carrier, physicians should periodically check if their coverage needs updating to account for developments since the policy was purchased.

“If you have any questions at all, you should reach out to your agent, as they can guide you through practice exposure changes,” she says.

**Should you use your own attorney to defend you?**

Should a physician who’s being sued for medical malpractice use a personal defense attorney instead of, or in addition to, the one provided by the insurer? In most cases the answer is no, according to the experts.

As part of the policy, the insurer provides a defense team with expertise in medical malpractice, a highly specialized area of the law. Attorneys who don’t specialize in medical malpractice would be at a significant disadvantage in preparing a defense, says Patrick Lawn, owner of Physicians Insurance Consultants in Lafayette Hill, Pa.

“You want someone who’s an expert,” Lawn says. “A lot of the malpractice attorneys are well-versed in the law, so there’s really no need to spend your own money.”

Private attorneys are at another disadvantage because they do not have a prior relationship with the carrier, which can lead to miscommunication, mistrust, and a disorganized defense, says Jennifer Richard, ARM, RPLU, vice president at Professional Risk Associates, a healthcare insurance brokerage in Midlothian, Va.

Involving a private attorney can even lead to penalties. “Some policies will deny coverage if you have retained your own attorney to handle the case without the carrier’s written permission and the case is adjudicated and/or settled without the carrier’s knowledge,” Richard says. She advises physicians to familiarize themselves with the part of their policy that dictates the
Identifying Lynch syndrome

Continued from Page 36

risk factors and genetic testing. In this case, a genetic counselor’s expertise could have been obtained by calling a teaching university in his/her state.

Conclusion
Ob/gyns are well-positioned to identify women who may have Lynch syndrome by routinely obtaining a cancer family history from their patients. They can then discuss the importance of genetic testing with patients who may possibly meet the criteria for Lynch syndrome. As noted earlier, Lynch syndrome is an extremely under-diagnosed genetic disorder as only about 5% of Lynch syndrome carriers have been identified. Compared to breast cancer, which has a very high awareness nationally with many newspaper and television discussions, Pink Ribbon marches and events, and greater philanthropic contributions, Lynch syndrome is not well known or discussed in the United States. In 1998, Katie Couric lost her first husband at age 42 to colon cancer. Over the next 10 years, she became a national spokeswoman for colonoscopies and colon cancer. Through physician-patient discussions and education, perhaps a new national awareness about the relationship between colon cancer, other cancers, and the under-appreciated Lynch syndrome can be developed.

Disclosure: Drs. Kirkpatrick and Cotton are medical consultants for Myriad Genetic Laboratories.

For references visit contemporaryobgyn.net/LynchSyndrome
Helping patients improve their decision-making

Using care in framing risk/benefit information is key to helping patients make rational choices about their healthcare.

by CATHERINE HAMBLEY, PHD

How a situation is framed affects the decisions that people make. For example, consider a situation where there is the opportunity to risk the loss of money so that one can gain a larger sum (much like we see in gambling). When framed as a loss, people respond more strongly to losing something than they do to a corresponding gain.

Now consider a similar situation that has health implications. A patient has to decide what treatment course to take and has been told that there is the potential for a fatal or catastrophic outcome, along with the potential benefit of that treatment. Patients often focus more strongly on the potential risk versus the potential benefit – a phenomenon known as the “loss aversion bias.”

As physicians, it is important to understand this predisposition so that you can better prepare patients for certain procedures, interventions, and health behaviors. There is actually an evolutionary basis to loss aversion bias. We are wired to avoid losses more than to seek gains because we are more likely to stay alive and reproduce if we perceive threats (losses) as more urgent than rewards. Therefore, patients will often make decisions based on the perceived negative risks or outcomes without giving sufficient weight to the potential benefits and/or risks of NOT pursuing a certain course of action.

Consider this example: A 57-year-old woman has refused a screening colonoscopy because she read on the internet that it could cause bowel perforation. When asked why she will not have a colonoscopy, she states, “they tear people’s bowels open.” Her bias towards loss aversion causes her to believe that the risks of the procedure far outweigh the benefits. The more someone perceives a potential loss (to life, limb, or in this case, bowel), the greater the loss aversion.

Loss aversion and the “framing effect” often work together and can get activated depending upon how information is framed. Our brains respond to minimize loss aversion, it is helpful to explain both the risks of the treatment or medical procedure AND the risks of not having the treatment (a reframe of the benefits).

Be aware that how you frame the situation will affect decision-making – avoid overuse of negative, emotionally-laden words.

If a patient appears overly reluctant, ask about what is fueling the hesitancy. There may be some associative effects (e.g., the person has had a negative experience or has a family member or friend who had a negative experience).

Determine if your patient has read information from other sources (e.g., the Internet) and if this might be influencing their decision.

Stay alert for your own biases and assumptions when considering treatment options. Take the time to engage in rational analysis of the data.
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fairly quickly to emotion, thus, language that conveys emotion will get people’s attention. And if people hear words that have a negative connotation – “bad news,” “cancer,” “death,” “fatal,” “complications” – they pay even more attention to those words.

I am not suggesting that we avoid giving patients all the relevant information. What I am suggesting is that physicians be aware that the way in which information is presented has a strong influence on risk perception. When patients are told the potential risks and benefits of various treatment options, their ability to rationally reflect can be impacted (often unconsciously) by various factors. For example, there is the impact of associative memory – “my grandmother died during surgery.”

“If you think that physicians are immune to these effects, consider this experiment done at Harvard Medical School. Subjects (all physicians) were presented with treatment outcome statistics for surgery versus radiation for lung cancer. Half of the subjects were provided with survival rate statistics for surgery (the 1-month survival rate is 50%), while the other half received statistics on mortality rate of surgery (there is 10% mortality in the first month). The physicians were more likely to recommend the treatment associated with the survival rate statistics than the treatment associated with the mortality rate statistics (84% chose surgery while only 50% chose radiation). This experiment demonstrates that emotional words – “mortality” and “survival” – are enough to sway our rational decision-making.

The typical approach that physicians make when presenting treatment options is to present the risks of treatment alongside the benefits of treatment. When patients hear the potential risks of a procedure or treatment, the degree to which their aversion to risk is prominent will cause the risks to carry more weight than the benefits. This can lead to less effective treatment choices. As a physician, your awareness of this tendency can guide how you present information to patients so that they are more likely to engage their rational decision-making processes.

Catherine Hambley, PhD is a consulting psychologist who offers brain-based strategies to organizations, leaders, teams, and healthcare providers to improve their effectiveness and promote greater success. She can be reached at catherine.hambley@gmail.com

The hospitalist’s role CONTINUED FROM PAGE 33

“I’m getting this medicine,” and they leave the room. So you have your clinical checklist in your head and you’re directing your team members clearly to help you carry it out. When teams practice how they work together in an emergency, physicians are able to also practice how they communicate to their team to make sure the response is coordinated, and valuable minutes are not lost in assisting the patient and her baby.

CONTEMPORARY OB/GYN: Do you have any words of wisdom or advice that you think is the most important for all team members to remember when the emergency is hot?

DR DIMINO: One piece of advice to others is to make sure that everyone on the clinical team is able to speak up and contribute when they notice something. Thank goodness for experienced nurses who have lived through many emergency responses. They often know what to do and try to kindly prompt the physician, but an emergency is not the time to kindly prompt anybody. An emergency is not the time to ask permission from the physician to start weighing pads. If the nurse knows from the team’s rehearsals that this is the next correct step, just say, “We need to be doing this, I’m going to start weighing pads.” Or the nurse might say, “I’m going to go ahead and draw our complete blood count because we’re 500 ccs down.” In this scenario my response would be a simple, “Thank you.” Great teams have a culture that promotes everyone contributing the important information they are observing and every team member having the ability to keep the team on the right track. If you want your team to reach this level of collaboration you must create this type of culture, and that starts with respecting each team member as an equal member with particular expertise. Collaborative teams save moms and babies because they are working together toward a common goal.
salpingo-oophorectomy (LAVH-BSO), or an abdominal approach to these procedures. Options including a CA125, frozen section of the ovary at the time of surgery, and oncology backup were discussed at this appointment. Surgery was delayed for better diabetes control.

**Preoperative diagnosis**
The patient was seen 2 months later for a preoperative appointment by the chief resident and attending who would perform the surgery. The preoperative diagnosis was chronic pelvic pain unresponsive to medical therapy, and a right adnexal mass, most likely a dermoid of the right ovary. It was noted the patient wanted only removal of one or both tubes and ovaries and preferred to avoid hysterectomy. The attending’s note specifically documented her history of 5 prior C-sections; the possibility of conversion to laparotomy; the need for a bowel prep; the increased risk of bowel, bladder, vessel, or ureteral injury; and the potential need for surgical consultation and multiple surgical procedures.

**Surgery**
The patient underwent surgery 10 days later. A note documented the patient’s continued consent and desire to proceed with surgery. Findings included extensive adhesions of the omentum and uterus to the anterior abdominal wall. There were extensive adhesions of the bowel to the right and left ovary. Extensive adhesiolysis and BSO were performed. The procedure took approximately 2½ hours. The operative note performed immediately after surgery documented entry via the Hasson method. Also documented was lack of suspicion or clinical evidence of inadvertent injury to bowel, bladder, major blood vessels, or the ureters. The surgical note specifically documented that adhesiolysis was performed with laparoscopic scissors without use of energy. At the end of the surgery it was documented that all areas of surgical treatment were inspected with no evidence of bleeding or inadvertent injury identified. Blood loss was estimated at 50 cc. The patient was observed postoperatively with no untoward or unexpected post-operative findings. She was discharged home the day of surgery to be followed as an outpatient. The final pathology confirmed a 6.5-cm benign cystic teratoma with a segment of a normal fallopian tube. The left ovary revealed endosalpingiosis and a normal left tube.

**Postoperative follow-up**
The patient was called by the involved resident the day after surgery, as was the routine practice in this department. The patient reported she was doing well. However, over the next 4 days, several calls were made by the patient’s family stating she had continued complaints of pain and abdominal bloating. It was documented that at each call the family was advised to bring the patient to the emergency department (ED), either by their own transportation or via ambulance. However, there were some inconsistencies in the documentation, or lack thereof, of phone calls received from the patient’s family and the advice given. Ultimately, 6 days after the original surgery the patient was brought to the emergency department by ambulance for abdominal distension, constipation, and severe pain. She was seen by a partner of the original attending and by general surgery. Surgery admitted the patient to the hospital for surgical exploration for a bowel perforation and fecal peritonitis, with repair (over sewing) of the perforation and colostomy. On the day following the initial surgery to repair the bowel perforation, the physicians/surgeons and the hospital’s director of risk management met with the patient’s family to review the original surgery, the ensuing complications, and the expected course in recovery. They entertained any and all questions from the family. A hospital representative was assigned to the family to assist in their “navigating” the hospital areas and to be a consistent point of contact for the family. The attending gynecologist asked the pathologist for a re-review of the pathology. It was noted that the patient had a history of a previous dermoid cyst of the right ovary removed with complete resolution of symptoms afterwards.

**Bowel injury during BSO**
CONTINUED FROM PAGE 53

Several calls were made by the patient’s family stating she had continued complaints of pain and abdominal bloating.
original surgical specimen, particularly looking for bowel serosa in the specimen. The addendum stated that the findings are consistent with the original diagnosis of a cystic teratoma. No bowel was found on the ovarian surface or in the surgical specimen.

During the ensuing 4 months of hospitalization, the patient underwent 5 additional surgical procedures, spent 2 weeks in the surgical intensive care unit, had 3 months of rehabilitation and physical therapy services, and required readmission twice for gastrointestinal bleeding. During her hospitalizations the original attending gynecologist initially saw the patient daily, then every other day, and weekly thereafter, with brief notes documenting his visits in the patient’s record. At the time of the patient’s subsequent readmissions, the attending general surgeon alerted the attending gynecologist, allowing the gynecology attending to visit the patient during those hospitalizations.

Allegations
Suit was filed alleging inadequate preoperative evaluation, failure to obtain a CA125 to rule-out malignancy, failure to obtain an adequate informed consent, inappropriately continuing with a laparoscopic approach and not converting to an open procedure, failure to obtain a frozen section, failure to identify the bowel injury at the initial procedure, and that the care rendered was a substantial departure from physicians with the same level of skill as the attending gynecologist and resident.

Discovery
In preparation for litigation, at the request of the defense attorney, the attending surgeon prepared a summary of the case, addressed anticipated areas of concern, and provided justification for the treatment rendered, supportive documentation, and pertinent literature. The attending surgeon also provided documentation of his extensive experience in performing similar cases, as well as ultrasound expertise. This information was used to prepare the response to plaintiff interrogatories and case defense.

The defense attorney sent the case for review to an outside expert of comparable expertise. This gynecologist supported the surgical approach to this patient, the surgical technique described in the operative note, and management of the complications.

The patient’s deposition revealed several key factors for the defense:
1. The patient remembered the attending reviewing the operative procedure and its risks in the preoperative holding area;
2. She remembered the gynecology attending holding her hand when she went to sleep and saying, “We will take good care of you;”
3. She remembered the physician speaking with her prior to her discharge from the postoperative unit;
4. She remembered the attending coming to see her in the hospital on a number of occasions during her subsequent hospitalizations.

All of these statements supported excellent communication and demonstrated the caring demeanor of the gynecologic surgeons. The defense attorney felt this would be critical in “winning over” the jury. The defense attorney also secured an admission by the plaintiff’s husband that he had been advised to immediately bring the patient to the emergency department. The lack of their coming to the hospital immediately, with the ensuing delay in diagnosis, contributed to the adverse outcome of the patient.

Deposition of the plaintiff’s expert revealed a lack of experience in complicated laparoscopic procedures. Criticism regarding the lack of an adequate preoperative evaluation was countered with the imaging diagnosis of a dermoid on both ultrasound and CT, supported by the pathologic findings. Criticism regarding the lack of recognition of the bowel injury intraoperatively were countered by the specific documentation in the operative note.

Following deposition of the plaintiff’s expert, the defense attorney filed a motion to dismiss with prejudice. This means the court has made a final determination on the merits of the case. The literature demonstrates that many, if not most, bowel injuries are not recognized at the time of surgery. Thus, early
recognition is crucial in optimizing outcomes. In this case, the communication between the physician’s practice and the patient’s family, although not ideal in documentation, demonstrated a valid attempt to assess the patient’s clinical status. Further, the patient’s delay in presenting to the hospital contributed to the more severe outcome in this instance.

**Several areas warrant specific comment:**

**Preoperative management.**
The fact that there were documented attempts at medical management of the patient’s pain, and that the gynecologists did not immediately move to surgery, while addressing her other medical conditions, demonstrated a thoughtful approach to the patient’s care.

**Informed consent process.**
The documentation of informed consent was excellent in this case. Informed consent requires a discussion of the probable diagnosis, the options in management, including doing nothing, and the substantial risks of surgery. All of these areas were specifically addressed in the documentation. Of note, the attending’s note again confirming the patient’s understanding in the preoperative area further helped negate a claim of inadequate informed consent. Also of note is that this department schedules their preoperative clinics so that, in most instances, both the resident and the attending who will be performing the operation meet the patient prior to surgery. This allows for establishing rapport and trust with the patient and her family. This remains a particular challenge in many residency programs, particularly as residents who performed the preoperative evaluation may rotate off the service.

**Contemporaneous operative notes.**
It was critical that an operative note was completed immediately following the surgery documenting the surgeons concern for and efforts to avoid and identify a bowel injury. Had this note been entered after the diagnosis of a bowel injury, it would have been discredited by a skilled plaintiff’s attorney. Conversely, a note entered contemporaneously supports the prudent actions of the surgeon.

**Attending presence in a teaching hospital environment.**
The documented attending involvement in this case, both for the gynecology service and the surgical service, is commendable. This involvement laid the foundation for the defense of the patient’s care. The documented training and surgical experience of the attending gynecologist was critical in defending the surgical approach in the case.

**Attending communication.**
The communication between the surgery attending and the gynecology attending allowed for continued involvement of the gynecology attending, even on subsequent admissions. This continued involvement, particularly in the presence of major complications, demonstrates a caring approach which is embraced by a jury.

**Involvement and support of the hospital’s Risk Management department.**
This particular institution takes an aggressive approach to communicating with patients and their families, bringing together the involved providers and the patient and her family. Transparency regarding the patient’s care, the concerns of both the family and the physicians, and openness to questions from all parties enhances communication and trust. Often, patients and their families just want honesty and are less apt to pursue litigation if they feel they are being truthfully informed regarding the patient’s care and treatment. The additional support of a patient liaison for the family is always welcome and appreciated by the family, particularly those unfamiliar with a hospital system or coming from long distances for care.

**The approach of the defense attorney.**
This attorney asked the gynecologist to prepare a summary of the case, all foreseeable claims, and potential defenses, and supportive literature. Since this information was prepared at the defense attorney’s request, in most states, this information is protected by attorney-client privilege. The ability of an attorney to anticipate the claims and have a prepared answer is crucial in litigation. Although difficult, it is important to notify your attorney of concerns that may have little or no defense, so adequate preparations can be made to address these concerns and mitigate their damage. The information provided by the physician at the attorney’s request allowed the defense attorney to anticipate every claim levied at deposition and negate the validity of the claims. Attorneys prefer to be over-prepared and avoid surprises during deposition and trial.
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CASE DISSECTION

Bowel injury post-BSO for ovarian mass

Bowel injuries are not often recognized at surgery so communication with the patient following surgery is vital.

A 57-year-old G5P5005 was seen by gynecology at a teaching hospital outpatient facility for chronic pelvic pain. A review of the patient’s history revealed that 6 months earlier she had been admitted to the hospital for severe bilateral lower quadrant abdominal pain, crampy in nature with significant bloating. The patient had a history of an appendectomy and 5 prior cesarean deliveries.

She had an ultrasound in the emergency department revealing a 5.0 x 4.7 x 3.8 cm complex right adnexal mass consistent with a probable dermoid with no definitive evidence of torsion. A CT scan showed a right pelvic mass, probably a dermoid, with probable diverticulosis without abscess. Comment was made that there was inflammatory fat stranding that was probably related to diverticula through the sigmoid suggestive of diverticulitis. Gynecology and surgery were consulted during the hospitalization. Gynecology opined that although the patient had a pelvic mass, the stronger suspicion was that of diverticulitis. General surgery treated the patient with intravenous hydration and antibiotics, with improvement, and the patient was subsequently discharged home without the need for surgery.

The patient was treated in the following 6 months by her primary care physician for continued pelvic pain. This included nonsteroidal anti-inflammatory drugs (NSAIDs) and occasional narcotics over 4 months, without significant relief. Thus, she was referred for further gynecologic evaluation.

On a gynecology visit 6 months after the above evaluation the patient’s exam revealed moderate bilateral adnexal tenderness. Her BMI of 39 kg/m² prevented palpation of any adnexal masses. She was referred for a pelvic ultrasound, which revealed a unilocular, heterogeneous, solid cyst, involving the entire right ovary consistent with a dermoid. The ovary itself measured 5.74 x 5.28 x 3.36 cm. Doppler studies were performed which were normal (benign). The patient’s prior records were requested but were unavailable as her appendectomy and cesarean deliveries had been performed in another country. In addition, the patient was referred to her primary care physician for preoperative treatment of diabetes. She was seen 6 days after the initial gynecology outpatient appointment. It was noted that her diverticulosis was stable. However, the patient required further insulin adjustments to bring her diabetes under good control.

The patient was seen again by her gynecologist 1 week after the ultrasound to review the results and for further recommendations. With complaints of persistent pain, a recommendation was made to consider surgery, with the options presented for laparoscopic removal of the right ovary, both ovaries, a laparoscopic total hysterectomy with bilateral...
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