Perineal Lacerations

Diagnosis and management of severe injuries

Sara Cichowski, MD, and Rebecca G Rogers, MD
EVEN WHEN IT’S NOT YOUR PATIENT’S PERIOD

HER ENDOMETRIOSIS IS IN ATTENDANCE¹

In an international multicenter survey of patients treated in tertiary care centers, it was reported that endometriosis patients experience unresolved pain despite management¹.

Could your endometriosis patients be suffering in silence? Discover resources at HerEndometriosisReality.com that can help your patients open up about the true impact of their endometriosis pain.

Reference:

VISIT HerEndometriosisReality.com
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September 2017

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Our Mission

For nearly a half century, busy practitioners have trusted Contemporary OB/GYN to translate the latest research into outstanding patient care. We are dedicated to providing them with evidence-based information on scientific advances in a clinically useful format.

Don’t forget to check out our app for Apple and Android devices!

Illustration by Alex Baker, DNA Illustrations, Inc.
Severe maternal morbidity affects over 60,000 women each year\(^1\)
Every 10 minutes a woman in the US nearly dies of pregnancy-related complications\(^1\)

Start with IM and transition to Oral Tablets*
Ensure your patients are protected from Hospital to Home
*In appropriate patients who are at risk of PPH.

**INDICATIONS**
Methergine\(^\circledast\) (methylergonovine maleate) is indicated for routine management of uterine atony, hemorrhage and subinvolution of the uterus following delivery of placenta and for control of uterine hemorrhage in the second stage of labor following delivery of the anterior shoulder.

**IMPORTANT SAFETY INFORMATION**
Methergine Tablets are contraindicated for patients with the following conditions: hypertension, toxemia, pregnancy, and hypersensitivity.

**WARNINGS**

**General:** This drug should not be administered I.V. routinely because of the possibility of inducing sudden hypertensive and cerebrovascular accidents. If I.V. administration is considered essential as a lifesaving measure, Methergine (methylergonovine maleate) should be given slowly over a period of no less than 60 seconds with careful monitoring of blood pressure. Intra-arterial or periarterial injection should be strictly avoided. Caution should be exercised in presence of impaired hepatic or renal function.

**Breast-Feeding:** Mothers should not breast-feed during treatment with Methergine. Milk secreted during this period should be discarded. Methergine may produce adverse effects in the breast-feeding infant. Methergine may also reduce the yield of breast milk. Mothers should wait at least 12 hours after administration of the last dose of Methergine before initiating or resuming breast feeding.

**Coronary Artery Disease:** Patients with coronary artery disease or risk factors for coronary artery disease (e.g. smoking, obesity, diabetes, high cholesterol) may be more susceptible to developing myocardial ischemia and infarction associated with methylergonovine-induced vasospasm.

**Medication Errors:** Inadvertent administration of Methergine to newborn infants has been reported. In these cases of inadvertent neonatal exposure, symptoms such as respiratory depression, convulsions, cyanosis and oliguria have been reported. Usual treatment is symptomatic. However, in severe cases, respiratory and cardiovascular support is required. Methergine has been administered instead of vitamin K and Hepatitis B vaccine, medications which are routinely administered to the newborn. Due to the potential for accidental neonatal exposure, Methergine injection should be stored separately from medications intended for neonatal administration.

**ADVERSE REACTIONS**
The most common adverse reaction is hypertension associated in several cases with seizure and/or headache. Hypotension and anaphylaxis has also been reported. Cerebrovascular accident, paraesthesia, ventricular fibrillation, ventricular tachycardia, angina pectoris, atrioventricular block were also reported post-marketing. Safety and effectiveness in pediatric patients have not been established.

Please note that this information is not comprehensive. See the full Prescribing Information at www.methergine.com

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.

**References:**

Please see Brief Summary of Prescribing Information on the next page.

Methergine\(^\circledast\) (methylergonovine maleate) tablets, USP 0.2mg

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All rights reserved. Methergine is a registered trademark of Novartis AG. PP-METH-US-0032
METHYLERGONOVINE MALEATE TABLETS

Brief Summary: Consult Full Prescribing Information for complete product information.

INDICATIONS AND USAGES

Methylergonovine Maleate is a semi-synthetic ergot alkaloid used for the prevention and control of postpartum hemorrhage. It is used following delivery of placenta, for routine management of uterine atony, hemorrhage, and subinvolution of the uterus as well as for control of uterine hemorrhage in the second stage of labor following delivery of the anterior shoulder.

CONTRAINDICATIONS

Hypertension, toxemia, pregnancy, and hypersensitivity are contraindications to Methylergonovine Maleate Tablets.

WARNINGS

General: This drug should not be administered intravenously routinely because of the possibility of inducing sudden hypertensive and cerebrovascular accidents. If intravenous administration is considered essential as a lifesaving measure, methylergonovine maleate should be given slowly over a period of no less than 60 seconds with careful monitoring of blood pressure. Intravenous or perianal injection should be strictly avoided. Caution should be exercised in presence of impaired hepatic or renal function.

Breast-Feeding: Mothers should not breast-feed during treatment with Methylergonovine Maleate Tablets, USP. Milk secreted during this period should be discarded. Methylergonovine Maleate Tablets, USP may produce adverse effects in the breast-feeding infant. Methylergonovine Maleate Tablets, USP may also reduce the yield of breast milk. Mothers should wait at least 12 hours after administration of the last dose of Methylergonovine Maleate Tablets, USP before initiating or resuming breast-feeding.

Coronary Artery Disease: Patients with coronary artery disease or risk factors for coronary artery disease (e.g., smoking, obesity, diabetes, high cholesterol) may be more susceptible to developing myocardial ischemia and infarction associated with methylergonovine-induced vasospasm.

Medication Errors: Inadvertent administration of Methylergonovine Maleate Tablets, USP to newborn infants has been reported. In these cases of inadvertent neonatal exposure, symptoms such as respiratory depression, convulsions, cyanosis, and oliguria have been reported. Usual treatment is symptomatic. However, in severe cases, respiratory and cardiovascular support is required. Methylergonovine Maleate Tablets, USP has been administered instead of vitamin K and Hepatitis B vaccine, medications which are routinely administered to the newborn. Due to the potential for accidental neonatal exposure, methylergonovine maleate should be stored separately from medications intended for neonatal administration.

PRECAUTIONS

General: Caution should be exercised in the presence of sepsis, obliterator vasculardisease. Also use with caution during the second stage of labor. The necessity for manual removal of a retained placenta should occur only rarely with proper technique and adequate allowance of time for its spontaneous separation.

Drug Interactions

CYP3A4 Inhibitors (e.g., Macrolide Antibiotics and Protease Inhibitors): There have been rare reports of serious adverse events in connection with the coadministration of certain ergot alkaloid drugs (e.g., dihydroergotamine and ergotamine) and potent CYP3A4 inhibitors, resulting in vasospasm leading to cerebral ischemia and/or ischemia of the extremities. Although there have been no reports of such interactions with methylergonovine alone, potent CYP3A4 inhibitors should not be coadministered with methylergonovine. Examples of some of the more potent CYP3A4 inhibitors include macrolide antibiotics (e.g., erythromycin, troleandomycin, clarithromycin), HIV protease or reverse transcriptase inhibitors (e.g., ritonavir, indinavir, nelfinavir, delavirdine) or azole antifungals (e.g., itraconazole, voriconazole). Less potent CYP3A4 inhibitors should be administered with caution. Less potent inhibitors include saquinavir, nefazodone, fluconazole, grapefruit juice, fluoxetine, fluvoxamine, zileuton, and clotrimazole. These lists are not exhaustive, and the prescriber should consider the effects on CYP3A4 of other agents being considered for concomitant use with methylergonovine.

CYP3A4 Inducers: Drugs (e.g. nevirapine, rifampicin) that are strong inducers of CYP3A4 are likely to decrease the pharmacological action of Methylergonovine Maleate Tablets, USP.

Beta-Blockers: Caution should be exercised when Methylergonovine Maleate Tablets, USP is used concurrently with beta-blockers. Concomitant administration with beta-blockers may enhance the vasocostrictive action of ergot alkaloids.

Anesthetics: Anesthetics like halothan and methoxyflurane may reduce the oxytocic potency of Methylergonovine Maleate Tablets, USP.

Glyceryl Trinitrate and Other Antianginal Drugs: Methylergonovine maleate produces vasoconstriction and can be expected to reduce the effect of glyceryl trinitrate and other antianginal drugs. No pharmacokinetic interactions involving other cytochrome P450 isoenzymes are known. Caution should be exercised when methylergonovine maleate is used concurrently with other vasoconstrictors, ergot alkaloids, or prostaglandins.

Carcinogenesis, Mutagenesis, Impairment of Fertility: No long-term studies have been performed in animals to evaluate carcinogenic potential. The effect of the drug on mutagenesis or fertility has not been determined.

Pregnancy: Category C: Animal reproductive studies have not been conducted with methylergonovine maleate. It is also not known whether methylergonovine maleate can cause fetal harm or can affect reproductive capacity. Use of methylergonovine maleate is contraindicated during pregnancy because of its uterotonic effects. (See INDICATIONS AND USAGE).

Pediatric Use: Safety and effectiveness in pediatric patients have not been established.

Geriatric Use: Clinical studies of methylergonovine maleate did not include sufficient number of subjects aged 65 and over to determine whether they respond differently from younger subjects. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

ADVERSE REACTIONS

The most common adverse reaction is hypertension associated in several cases with seizure and/or headache. Hypotension has also been reported. Abdominal pain (caused by uterine contractions), nausea and vomiting have occurred occasionally. Rarely observed reactions have included: acute myocardial infarction, transient chest pains, vasoconstriction, vasospasm, coronary arterial spasm, bradycardia, tachycardia, dyspnea, hematura, thrombophlebitis, water intoxication, hallucinations, leg cramps, dizziness, tinnitus, nasal congestion, diarrhea, diaphoresis, palpitation, rash, and foul taste. There have been rare isolated reports of anaphylaxis, without a proven causal relationship to the drug product.

Nervous System Disorders: Cerebrovascular accident, paraesthesia.

Cardiac Disorders: Ventricular fibrillation, ventricular tachycardia, angina pectoris, atrioventricular block.

DRUG ABUSE AND DEPENDENCE

Methylergonovine maleate has not been associated with drug abuse or dependence of either a physical or psychological nature.

OVERDOSE

Symptoms of acute overdose may include: nausea, vomiting, abdominal pain, numbness, tingling of the extremities, rise in blood pressure, in severe cases followed by hypotension, respiratory depression, hypothermia, convulsions, and coma.

Because reports of overdose with methylergonovine maleate are infrequent, the lethal dose in humans has not been established. The oral LD50 (in mg/kg) for the mouse is 187, the rat 93, and the rabbit 4.3. Several cases of accidental methylergonovine maleate injection in newborn infants have been reported, and in such cases 0.2 mg represents an overdose of great magnitude. However, recovery occurred in all but one case following a period of respiratory depression, hypothermia, hypertonicity with jerking movements, and convulsions.

Also, several children 1-3 years of age have accidentally ingested up to 10 tablets (2 mg) with no apparent ill effects. A postpartum patient took 4 tablets at one time in error and reported paresthesias and clamminess as her only symptoms.

Treatment of acute overdose is symptomatic and includes the usual procedures of: 1. Removal of offending drug by inducing emesis, gastric lavage, catharsis, and supportive diuresis. 2. Maintenance of adequate pulmonary ventilation, especially if convulsions or coma develop. 3. Correction of hypotension with pressor drugs as needed. 4. Control of convulsions with standard anticonvulsant agents. 5. Control of peripheral vasospasm with warmth to the extremities if needed.

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 call Lupin Pharmaceuticals, Inc. at 1-800-399-2561.

Please note that this information is not comprehensive. Please see the full Prescribing Information at www.methergine.com.
Indication and Limitations of Use
ADDYI is indicated for the treatment of premenopausal women with acquired, generalized hypoactive sexual desire disorder (HSDD) as characterized by low sexual desire that causes marked distress or interpersonal difficulty and is NOT due to: a co-existing medical or psychiatric condition, problems within the relationship, or the effects of a medication or other drug substance.

Acquired HSDD refers to HSDD that develops in a patient who previously had no problems with sexual desire. Generalized HSDD refers to HSDD that occurs regardless of the type of stimulation, situation, or partner.

ADDYI is not indicated for the treatment of HSDD in postmenopausal women or in men. ADDYI is not indicated to enhance sexual performance.

WARNING: HYPOTENSION AND SYNCOPE IN CERTAIN SETTINGS
See full prescribing information for complete boxed warning.

• Use of ADDYI and alcohol increases the risk of severe hypotension and syncope; therefore alcohol use is contraindicated. Before prescribing ADDYI, assess the likelihood of the patient abstaining from alcohol. Counsel patients prescribed ADDYI about the importance of abstaining from alcohol.

• Because of the increased risk of hypotension and syncope due to an interaction with alcohol, ADDYI is available only through a restricted program called the ADDYI REMS Program.

• Severe hypotension and syncope can occur when ADDYI is used with moderate or strong CYP3A4 inhibitors or in patients with hepatic impairment; therefore, ADDYI use in these settings is contraindicated.

Please see IMPORTANT SAFETY INFORMATION on next page.

In premenopausal women with acquired, generalized HSDD
In the pivotal trials that led to FDA approval, ADDYI was proven to:

• Increase sexual desire
• Increase satisfying sexual events
• Decrease associated distress

WARNING: HYPOTENSION AND SYNCOPE IN CERTAIN SETTINGS
See full prescribing information for complete boxed warning.

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Please see IMPORTANT SAFETY INFORMATION on next page.

Prescription savings available for your patients—exclusively at Walgreens and other participating pharmacies—through the Valeant Access Program.

$25 CO-PAY
Discounted pricing available for eligible uninsured patients*

Start the conversation with your patients about ADDYI.
Visit www.addyi.com

*Through the Valeant Access Program. Not all patients are eligible. Visit valeantaccessprogram.com to see eligibility criteria and terms and conditions.
ADDYI is contraindicated:
- With use of alcohol.
- With concomitant use with moderate or strong CYP3A4 inhibitors.
- In patients with hepatic impairment.

Summary of Warnings and Precautions:
- **Hypotension and Syncope due to an Interaction with Alcohol.** An interaction between ADDYI and alcohol increases the risk of severe hypotension and syncope. Alcohol use is contraindicated. Before prescribing ADDYI, the healthcare provider should assess the likelihood of the patient abstaining from alcohol use.
- **ADDYI Risk Evaluation and Mitigation Strategy (REMS) Program.** ADDYI is available only through a restricted program called the ADDYI REMS Program, because of the increased risk of severe hypotension and syncope due to an interaction between ADDYI and alcohol. The ADDYI REMS requires that prescribers are certified by enrolling and completing training; and, pharmacies are certified and will not dispense ADDYI unless it is prescribed by a certified prescriber. More information is available at www.ADDYIREMS.com.
- **Hypotension and Syncope with CYP3A4 Inhibitors.** Moderate and strong CYP3A4 inhibitors significantly increase ADDYI concentrations, which can lead to hypotension and syncope. Concomitant use of ADDYI with a moderate or strong CYP3A4 inhibitor is contraindicated. Concomitant use of multiple weak CYP3A4 inhibitors that may include herbal supplements (e.g., ginkgo, resveratrol) or non-prescription drugs (e.g., cimetidine) could also lead to clinically relevant increases in fibanserin concentrations that may increase the risk of hypotension and syncope.
- **Central Nervous System Depression.** ADDYI can cause CNS depression (e.g., somnolence, sedation). In five 24-week, randomized, placebo-controlled, double-blind trials of premenopausal women with HSDD the incidence of somnolence, sedation, or fatigue was 21% and 8% in patients treated with 100 mg of ADDYI at bedtime and placebo, respectively. The risk of CNS depression is increased if ADDYI is taken during waking hours, or if ADDYI is taken with alcohol or other CNS depressants, or with medications that increase fibanserin concentrations.

Patients should not drive or engage in other activities requiring full alertness until at least 6 hours after taking ADDYI and until they know how ADDYI affects them.

- **Hypotension and Syncope with ADDYI Alone.** The use of ADDYI – without other concomitant medications known to cause hypotension or syncope – can cause hypotension and syncope. In five 24-week, randomized, placebo-controlled, double-blind trials of premenopausal women with HSDD, hypotension was reported in 0.2% and <0.1% of ADDYI-treated patients and placebo-treated patients, respectively; syncope was reported in 0.4% and 0.2% of ADDYI-treated patients and placebo-treated patients, respectively. The risk of hypotension and syncope is increased if ADDYI is taken during waking hours or if higher than the recommended dose is taken. Consider the benefits of ADDYI and the risks of hypotension and syncope in patients with pre-existing conditions that predispose to hypotension. Patients who experience pre-syncope should immediately lie supine and promptly seek medical help if the symptoms do not resolve. Prompt medical attention should also be obtained for patients who experience syncope.
- **Syncope and Hypotension in Patients with Hepatic Impairment.** Any degree of hepatic impairment significantly increases fibanserin concentrations, which can lead to hypotension, syncope, and CNS depression. Therefore, ADDYI is contraindicated in patients with hepatic impairment.

Most Common Adverse Reactions
- The most common adverse reactions (ADDYI incidence > 2% more than placebo, respectively): dizziness (11.4%; 2.2%), somnolence (11.2%; 2.9%), nausea (10.4%; 3.9%), fatigue (9.2%; 5.5%), insomnia (4.9%; 2.8%), and dry mouth (2.4%; 1.0%).

Summary of Drug Interactions
- ADDYI is primarily metabolized by CYP3A4 and, to a lesser extent, by CYP2C19.
- ADDYI is contraindicated in women taking a moderate (e.g., fluconazole) or strong (e.g., ketoconazole) CYP3A4 inhibitor.
- The concomitant use of ADDYI with CNS depressants (e.g., diphenhydramine, opioids, hypnotics, benzodiazepines) may increase the risk of CNS depression (e.g., somnolence) compared to use of ADDYI alone.
- Patients using ADDYI with combined oral contraceptives or with weak CYP3A4 inhibitors may experience a higher incidence of adverse reactions.
- Strong CYP2C19 inhibitors (e.g., proton pump inhibitors, selective serotonin reuptake inhibitors, benzodiazepines, antifungals) may increase ADDYI exposure, which may increase the risk of hypotension, syncope, and CNS depression.
- Do not use ADDYI with strong CYP3A4 inducers (e.g., rifampin, St. John’s Wort) as this will substantially reduce the concentration of ADDYI.
- ADDYI inhibits P-glycoprotein (P-gp). Monitoring of drug concentrations of any narrow therapeutic index drugs that are substrates for P-gp (e.g., digoxin, sirolimus) should be increased if co-administered with ADDYI. The concomitant use of ADDYI with digoxin, a drug that is transported by P-gp, increases the digoxin concentration. This may lead to digoxin toxicity.

Please see Brief Summary of FULL PRESCRIBING INFORMATION on following pages.
**INDICATIONS AND USAGE**

ADDYI® (flibanserin) 100mg tablets is indicated for the treatment of premenopausal women with acquired, generalized hypoactive sexual desire disorder (HSDD), as characterized by low sexual desire that causes marked distress or interpersonal difficulty and is NOT due to:

- A co-existing medical or psychiatric condition,
- Problems within the relationship, or
- The effects of a medication or other drug substance.

**CONTRAINDICATIONS**
ADDYI is contraindicated with use of alcohol, with concomitant use with moderate or strong CYP3A4 inhibitors, and in patients with hepatic impairment.

**WARNINGS AND PRECAUTIONS**

**Hypotension and Syncope due to an Interaction with Alcohol**

Use of ADDYI and alcohol increases the risk of severe hypotension and syncope; therefore, the use of ADDYI in patients with any degree of hepatic impairment significantly increases flibanserin concentrations, which can lead to hypotension and syncope. Therefore, the use of ADDYI is contraindicated in patients with hepatic impairment.

**Indications and Usage**

ADDYI is not indicated to enhance sexual performance.

ADDYI is not indicated for the treatment of HSDD in postmenopausal women or in men.

ADDYI is not indicated to enhance sexual performance.

**Use of ADDYI and alcohol increases the risk of severe hypotension and syncope; therefore, alcohol use is contraindicated.** Before prescribing ADDYI, assess the likelihood of the patient abstaining from alcohol. Counsel patients prescribed ADDYI about the importance of abstaining from alcohol.

**Severe hypotension and syncope can occur when ADDYI is used with moderate or strong CYP3A4 inhibitors or in patients with hepatic impairment; therefore, ADDYI use in these settings is contraindicated.**

**Hypotension and Syncope In certain Settings**

See full prescribing information for complete boxed warning.

- Use of ADDYI and alcohol increases the risk of severe hypotension and syncope; therefore, alcohol use is contraindicated. Before prescribing ADDYI, assess the likelihood of the patient abstaining from alcohol. Counsel patients prescribed ADDYI about the importance of abstaining from alcohol.

**ADDYI is available only through a restricted program called the ADDYI REMS Program.**

**Severe hypotension and syncope can occur when ADDYI is used with moderate or strong CYP3A4 inhibitors or in patients with hepatic impairment; therefore, ADDYI use in these settings is contraindicated.**

**ADVERSE REACTIONS**

**Most Common Adverse Reactions**

<table>
<thead>
<tr>
<th>Placebo (N=1556)</th>
<th>ADDYI (N=1543)</th>
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<tr>
<td>Dizziness</td>
<td>2.2%</td>
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<tr>
<td></td>
<td>11.4%</td>
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<tr>
<td>Somnolence</td>
<td>2.9%</td>
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<td></td>
<td>11.2%</td>
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<tr>
<td>Nausea</td>
<td>3.9%</td>
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<td></td>
<td>10.4%</td>
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<tr>
<td>Fatigue</td>
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<td></td>
<td>9.2%</td>
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<tr>
<td>Insomnia</td>
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<td></td>
<td>4.9%</td>
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<tr>
<td>Dry mouth</td>
<td>1.0%</td>
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<td>2.4%</td>
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* Adverse reactions reported in ≥2% of patients receiving 100 mg ADDYI at bedtime and at a higher incidence than placebo-treated patients.

**Less Common Adverse Reactions**

In four trials in premenopausal women with HSDD treated with 100 mg ADDYI at bedtime, less common adverse reactions (reported in >1% but <2% of ADDYI-treated patients and at a higher incidence than with placebo) included: anxiety (ADDYI 1.8%; placebo 1.0%), constipation (ADDYI 1.6%; placebo 0.4%), abdominal pain (ADDYI 1.5%; placebo 0.9%), metrorrhagia (ADDYI 1.4%; placebo 1.4%), rash (ADDYI 1.3%; placebo 0.8%), sedation (ADDYI 1.3%; placebo 0.2%), and vertigo (ADDYI 1%; placebo 0.3%).
### DRUG INTERACTIONS

**Clinically Significant Drug Interactions (DI) with ADDYI**

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### OVERDOSAGE

Overdosage of ADDYI may cause an increase in the incidence or severity of any of the reported adverse reactions. In the event of overdosage, treatment should address the symptoms and supportive measures, as needed. There is no known specific antidote for flibanserin.

### PATIENT COUNSELING INFORMATION

See FDA-Approved Patient Labeling (Medication Guide).

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.medwatch.com or call 1-800-FDA-1088.

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Based on 9513300

6/2016 ADDYX.0059.USA.17
Are hysterectomy volumes in the US really falling?

Reexamination of the data implies previous reports may have been incomplete.

Hysterectomy is the most common nonobstetric surgical procedure performed on women, with 1 out of 9 women undergoing it in their lifetime. Recent reports have indicated a sharp decline in the number of hysterectomies performed annually in the United States. According to Wright et al,1 annual hysterectomy volume declined from 681,234 in 2002 to 433,621 cases in 2010. This was based on data from the National Inpatient Sample (NIS), which is the largest publicly available national inpatient care database and represents approximately 20% of discharges from hospitals within the United States. Another study from Desai et al reported further reduction in hysterectomy numbers in 2012, with only 311,820 cases performed that year based on query of data from the National Inpatient Sample (NIS), which is the largest publicly available national inpatient care database and represents approximately 20% of discharges from hospitals within the United States. Another study from Desai et al reported further reduction in hysterectomy numbers in 2012, with only 311,820 cases performed that year based on query of data from the NIS.2 According to that report, abdominal hysterectomy (AH) accounted for 52.8% of cases, while vaginal hysterectomy (VH) accounted for 14.7% and laparoscopic hysterectomy (LH) for 32.4% of cases for all nonobstetric indications. The reduction in number of hysterectomies has been attributed to a variety of alternative uterine-sparing treatment options for uterine fibroids and abnormal uterine bleeding, which are the 2 leading indications for hysterectomy.

These estimates, however, may reflect only part of the picture. Databases most commonly used to monitor hysterectomy rates, including those maintained by the federal government such as NIS and privately maintained samples, do not account for hysterectomies performed in outpatient surgical centers. A report by Cohen et al in the July issue of Obstetrics & Gynecology sheds some light on this issue.3 The authors queried data from the US Healthcare Cost and Utilization Project State Ambulatory Surgery and Services Database (SASD). Thirty-five states contributed data to the SASD with 16 states reporting all key variables in question for 2011. Based on the observed numbers in those 16 states, extrapolation to nationwide estimates indicates that there are approximately 100,000 to 200,000 hysterectomies performed in an outpatient setting yearly. Furthermore, 81.5% of them are performed laparoscopically or robotically and 16% are performed transvaginally. The SASD administrators confirmed that there was no overlap between these data and the inpatient databases. Although the data were drawn from only 16 of 50 states, they represent 41% of US women aged 18 or older, according to 2010 Census data.

According to this new information, the reduction in number of hysterectomies appears be mainly caused by a shift in surgical venue rather than in absolute numbers. It is admittedly difficult to know the exact numbers of hysterectomies from any of these databases, but there are probably

### Table: Estimation of mode access of hysterectomy in the United States

<table>
<thead>
<tr>
<th>Mode of access</th>
<th>Inpatient databases only</th>
<th>All databases</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>Abdominal</td>
<td>164,640</td>
<td>52.8%</td>
</tr>
<tr>
<td>Vaginal</td>
<td>45,838</td>
<td>14.7%</td>
</tr>
<tr>
<td>Laparoscopic/robotic</td>
<td>101,030</td>
<td>31.8%</td>
</tr>
<tr>
<td>Total</td>
<td>311,820</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

Continued on page 38
Nonpainful vulvar mass in a 42-year-old woman

What’s your diagnosis for this mass of the labium majus?

by DIANA CURRAN, MD, JOHN O. DELANCEY, MD, AND HOPE K. HAEFNER, MD

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is Associate Professor, Department of Obstetrics and Gynecology, Michigan Medicine, University of Michigan, Ann Arbor.

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is Norman F. Miller Professor of Gynecology, Director, Pelvic Floor Research, Group Director, Fellowship in Female Pelvic Medicine and Reconstrutive Surgery at the University of Michigan Medical School, Ann Arbor, and a member of the Contemporary OB/GYN editorial board.

Hope K. Haefner MD
is Professor in the Department of Obstetrics and Gynecology, Michigan Medicine, University of Michigan, Ann Arbor.

PRESENTATION
A 42 y.o. woman presents for her annual gynecologic exam and complains of a non-painful mass on her right vulva. On examination, there is a 6-cm right-sided, mobile, non-tender mass just lateral to her right labium majus. It is bothersome when sitting and she cannot comfortably ride her bicycle. On physical examination, the mass is not compressible.

YOUR MOST LIKELY DIAGNOSIS IS:
A. Hernia  
B. Lipoma  
C. Vulvar abscess  
D. Bartholin cyst

YOUR TREATMENT PLAN:
A. Nothing  
B. Excision  
C. Wide local excision  
D. Biopsy

FIGURE 1
Vulvar mass of right labium majus

FOR THE DIAGNOSIS, TREATMENT PLAN, AND DISCUSSION TURN TO PAGE 12
**Lipoma**

**DIAGNOSIS:**
B. Lipoma

**TREATMENT PLAN:**
C. Wide local excision

**Discussion**

Lipomas are benign masses that may occur on the vulva. Those that are asymptomatic and not enlarging can be monitored. Treatment for tumors that become bothersome or interfere with movement or enlarge significantly consists of a simple wide local excision. Liposuction is another option if the lipoma is soft and has a small connective tissue component. The procedure typically results in less scarring but with large lipomas, it may fail to remove the entire tumor, which can lead to regrowth.

Liposarcomas are found in 1% of lipomas and are mostly well-differentiated. Other cell types that can be found include dedifferentiated, myxoid, round, and pleomorphic. Lipoblastomas have also been reported in the literature but they are very rare.

Vulvar lipomas can be confused with hernias, but unlike hernias, they cannot be compressed. A cyst of the Canal of Nuck can sometimes mimic an inguinal hernia. At times it can be difficult to distinguish a lipoma from a hernia. Radiologic studies such as magnetic resonance imaging or ultrasound may be helpful in these situations. Fibromas can also occur on the vulva and are usually easily excised.

In this case, a vulvar abscess is unlikely due to lack of pain, erythema, or fluctuance of the mass. The patient’s history does not seem to point in that direction. However, surgical management would elucidate the diagnosis.

A Bartholin duct cyst is located more medially on the vulva than is seen in this patient. The labium minus is located in the middle of the Bartholin duct cyst. Patients with this diagnosis complain of discomfort with sitting, inserting tampons, and intercourse. The bottom line is that if a patient is symptomatic and there is uncertainty as to the exact diagnosis, then once a hernia is ruled out, biopsy and/or excision is warranted and will guide any further management.

**FOR REFERENCES VISIT**
contemporaryobgyn.net/201709quiz
Fetal Fibronectin: The Benefits of a High Negative Predictive Value in Management of Preterm Labor

Introduction
Of women who present with preterm contractions, only 10% of deliveries are preterm,1 highlighting the imprecise nature of correlating symptoms with true preterm labor (PTL).2 This dilemma results in unnecessary hospitalizations and interventions, contributing to a drain on resources within the health care system and possibly overexposing patients to treatments such as antenatal corticosteroids and tocolytics. Thus, an important challenge when attempting to reduce the spontaneous preterm birth (PTB) rate is to differentiate patients who are in PTL from those in false labor.3

Many strategies for diagnosis of PTL based on clinical factors alone have led to disappointing results, and the clinical diagnosis of PTL has up to a 50% false-positive rate.3,4 This may be due in part to the somewhat subjective nature of clinical assessment. A significant advance in the work up of women with symptoms of PTL is the inclusion of objective tools, such as transvaginal ultrasound (TVUS) to measure cervical length (CL) and diagnostic testing for fetal fibronectin (fFN) as a component of standardized protocols.

fFN, a glycoprotein component of the extracellular matrix of the decidua basalis near the intervillous space,5,6 is typically absent from cervicovaginal fluid between 22 and 34 weeks of gestation; thus, its presence is considered a possible marker of pathologic disruption of the maternal-fetal interface and its absence is reassuring that PTL is not imminent.7 Rupture of membranes, moderate or gross vaginal bleeding and cervical dilatation greater than 3 cm are contraindications for the test. It is also important to collect the specimen with a swab for fFN testing prior to any cervical manipulation (digital cervical exam, TVUS, etc.). A specimen swab can be discarded without cost if subsequent clinical or TVUS findings are not appropriate for fFN utilization.

While the positive predictive value (PPV) of fFN is low, the negative predictive value (NPV) of fFN is high (99.5% for delivery within 7 days and 99.2% for delivery within 14 days) in women with symptoms of PTL.8 Therefore the clinical value of fFN is in identifying those women who are at minimal risk of imminent PTB and providing reassurance that the patient does not require any interventions or hospital admission. Studies suggest that women with preterm contractions and a negative fFN test result can be expectantly managed and spared corticosteroids, tocolytics, the stress and negative financial impact of ongoing hospitalization, or transfer to a facility capable of caring for a preterm infant.9,10 Inclusion of fFN testing in the evaluation of PTL facilitates efficient triage of patients and allocation of resources to those in true PTL.3
An additional tool for assessing PTL is CL, measured by TVUS, for evaluating cervical changes beyond those determined from a digital exam, such as shortening and funneling of the cervix. While CL is inversely related to the likelihood of delivery within 7 days, the cutoff value associated with imminent PTB varies widely among studies. This results in a “gray area” in which inclusion of an additional objective measurement such as fFN as part of a standardized PTL assessment can help clarify patient management. Additionally, accurate CL values require careful imaging by a highly trained technician skilled in the use of specialized equipment, which may not be available to all providers.

The PPV of either fFN or CL is low for either test alone, and as such, the American Congress of Obstetricians and Gynecologists (ACOG) recommends that a positive fFN test or a short CL should not be used alone as a predictor of PTB. However, studies have demonstrated that combining fFN and CL results can yield an improved PPV up to 45.4% for delivery within 7 days. In a direct comparison of frequency of PTB within 7 days for women with CL 1.5-2.9 cm (TVUS alone) compared with women with CL 1.5-2.9 cm plus a positive fFN result (TVUS + fFN), combining the two tests yielded a 4-fold increase in frequency of PTB within 7 days compared to TVUS alone.

Due to the high NPV associated with fFN and the improved PPV when combining fFN with CL by TVUS, we have incorporated these tools into a standardized protocol at our institutions for managing patients with suspected PTL.

The Value of Standardization

The ACOG Committee on Patient Safety and Quality Improvement has officially called for development of clinical guidelines and standardization of practice to improve patient outcomes. They note that checklists and protocols improve outcomes and strongly encourage their use. Similarly, the American College of Nurse-Midwives (ACNM) issued the following position statement: “Evidence-based methods of identifying women at risk for premature labor, including ongoing risk assessment at each visit, screening women with PTL contractions using fFN testing, and screening using CL measurement techniques should be accessible in all practice settings.”

Finally, the Association of Women’s Health, Obstetric and Neonatal Nurses (AWHONN) issued a call to action for quality patient care in labor and delivery for structured systems to help optimize communication about and response to rapid changes in patient status. Among the strategies they list are checklists and standard order sets.

An evidence-based protocol evaluated by Rose and colleagues and used at the Mayo Clinic (see Figure 1) offers an opportunity for a standardized evaluation for women with symptomatic PTL. The protocol prescribes a triage evaluation whereby fFN is collected (but not immediately processed) from women presenting with >4 contractions/hr and without evidence of Preterm premature rupture of the membranes (PPROM) or placental abruption. Following specimen collection for fFN testing, a digital exam is performed, and women with cervical dilatation ≥3 cm are admitted for interventions such as antenatal corticosteroids, prophylactic antibiotics and possible tocolytics. For women found to have cervical dilatation <3 cm, transvaginal CL assessment is performed. Women found to have a CL ≤1.5 cm are considered at increased risk for PTB and admitted for intervention. Women with a transvaginal CL of ≥3 cm are discharged to home for expectant management. FFN is used to triage women with cervical dilatation of <3 cm and CL by TVUS between 1.6 and 2.9 cm. Women who test positive for fFN are observed and given steroids, but other interventions are withheld pending further cervical change. Women who test negative for fFN are discharged home. When this protocol was utilized in a prescribed manner, the authors found a 56% reduction in hospital admissions and associated expenses without “compromise of patient care.”

For obstetrical facilities that do not have 24/7 access to providers skilled at performing transvaginal CL measurement, we recommend considering a protocol that relies on a negative fFN result alone for discharging patients and a positive fFN result for further observation and clinical assessment to determine if interventions are warranted (Figure 2). A meta-analysis published in 2016 by Berghella and colleagues20 called into question the usefulness of fFN in assessment of PTL. The authors included 6 studies for a total of 546 singleton gestations with symptoms of PTL, and concluded that women tested with fFN had a similar incidence of PTB compared with control patients who were not tested with fFN, with comparable incidences between groups at various time points of gestation. No differences were found in the number of women who delivered within 7 days, the mean gestational age at delivery, the rate of maternal hospitalization, the use of tocolytics and antenatal steroids, the mean duration of the triage evaluation, and neonatal outcomes that included respiratory distress syndrome and admission to the neonatal intensive care unit. Management that incorporated fFN screening resulted in higher hospitalization charges. The authors concluded that fFN testing in singleton gestations with symptoms of PTL was not associated with an improvement in perinatal outcomes and was associated with higher costs.

While the meta-analysis suggested that fFN alone is not an effective screening tool, it did not address the overall utility of fFN in PTL assessment for the following reasons:

- Trials that utilized CL measurements for decision-making were excluded. As noted, the cost savings and efficiency of fFN is higher when used in conjunction with TVUS.
- Treatment was at the discretion of the providers, who were not consistently aware of or required to consider the results of fFN testing.
- The meta-analysis did not evaluate the association of clinical interventions, including the use of steroids and tocolytics, with the results of diagnostic fFN testing or perinatal outcomes.
- The finding that fFN testing increased cost by $153 reflects only one study which compared the cost of the test ($153) versus observation, and failed to consider the cost of unnecessary hospital admissions or interventions.

Evidence Regarding Use of fFN Alone for Diagnosis of Preterm Labor

The 6 studies that were included in the meta-analysis are

Studies Included in the Meta-Analysis

The 6 studies that were included in the meta-analysis are further described and are summarized in Table 2.

Additional Studies Evaluating the Cost-Effectiveness of fFN

Giles and colleagues sought to determine whether fFN...
testing impacted costs, admission, and transfer rates from referral hospitals to a tertiary obstetric hospital. An 18-month prospective audit of fFN use was conducted in 9 referral hospitals and one university maternal-fetal medicine unit (N=151 patients). Overall, 90% of patients admitted to a referral hospital with threatened PTL and who had a negative fFN were not transferred, with cost savings of $30,297.

In a prospective cohort study, Joffe and colleagues evaluated the impact of fFN testing and reported a significant reduction in the number of admissions, number of prescriptions for tocolytics, and LOS, with an estimated cost savings of $486,000 over the 12 month study period.\(^{31}\)

As described above, Rose and colleagues conducted a 12-month retrospective observational study to look at the effect of a standardized evidence-based protocol for

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**Figure 1**

*Protocol for Evaluation of Preterm Labor: Combined use of fFN + TVUS*

(Permission granted by Rose, Mayo Clinic)
Figure 2: Protocol for Evaluation of Preterm Labor When Access to TVUS is Limited

Permission for reprint granted by Ochsner Baptist Division of Maternal Fetal Medicine
PTL evaluation on outcomes and resource use. All 201 patients underwent triage evaluation per protocol with a combination of fFN and CL measurement (Figure 1). The hospital admission rate was reduced by 56% compared with the previous year, in which no standardized algorithm was used for PTL assessment. This resulted in a total yearly cost savings of $39,900.

van Baaren and colleagues evaluated the cost-effectiveness of combining CL measurement and fFN for symptomatic women between 24 and 34 weeks gestation. They concluded that fFN testing saved between €2.4 and 7.6 million per year compared with treating all symptomatic patients, resulting in a cost savings of €3,919 per patient.

Conclusion
In summary, the available evidence verifies the cost savings and utility of a diagnostic protocol which includes fFN for identifying patients who have symptoms of PTL but are likely experiencing false labor. The test is easy to administer, non-invasive, and has no related side effects. The NPV of fFN is high, with a negative test associated with a <1% chance of giving birth within the next two weeks. The test itself is objective, and its benefits with respect to costs and decreased healthcare utilization are well-documented. A standardized, evidence-based protocol for evaluation of symptomatic PTL should ideally include CL and fFN to avoid unnecessary interventions for patients unlikely to progress to active PTL (Figure 1). However, in the absence of reliable access to TVUS, an alternative algorithm can be used in which a negative fFN test alone can provide reassurance against imminent delivery (Figure 2). Thus, objective evaluation of patients with symptoms of PTL can help direct critical resources to those patients most likely to need them.

Author Biographies
Dr. Brigid McCue is the Lead Ob/Gyn Hospitalist at Ochsner Baptist Hospital, specializing in the care of the hospitalized woman on the labor floor, emergency department, and in-patient floors. She earned a Doctor of Medicine degree and a Doctor of Philosophy in Immunology degree from Albert Einstein School of Medicine. Dr. McCue went on to complete an Ob/Gyn Residency at Brown University, and she is board certified in Obstetrics and Gynecology. Dr. McCue is the immediate past-president of the Society of Ob/Gyn Hospitalists, treasurer of the New England Ob/Gyn Society.

Dr. Vanessa Torbenson is an Ob/Gyn Hospitalist currently practicing at the Mayo Clinic where she also serves as an associate program director for the residency program. She earned a Doctor of Medicine degree from the University of Chicago Pritzker School of Medicine and completed her residency at Western Pennsylvania Hospital. Dr. Torbenson is board certified in Obstetrics and Gynecology and serves as the Chair of the Simulation Committee for the Society of Ob/Gyn Hospitalists.

Table 2 Studies Included in Meta-Analysis

<table>
<thead>
<tr>
<th>Study</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lowe et al.26</td>
<td>• Investigated the effect of fFN on length of stay (LOS) and use of PTL interventions in a tertiary care center.</td>
</tr>
<tr>
<td></td>
<td>• Randomized, non-blinded comparison of symptomatic women who were tested with fFN (n=48) versus women who were not (n=51).</td>
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<tr>
<td></td>
<td>• Concluded that a negative fFN test was associated with fewer hospital admissions and a shorter LOS.</td>
</tr>
<tr>
<td>Grobman et al.28</td>
<td>• Compared whether the knowledge of fFN results affected treatment and costs.</td>
</tr>
<tr>
<td></td>
<td>• Powered to find a 20% reduction in total health care-related costs.</td>
</tr>
<tr>
<td></td>
<td>• Found no differences between groups; however, physicians were not obligated to use the fFN results to provide care for patients.</td>
</tr>
<tr>
<td>Nguyen et al.25</td>
<td>• Evaluated cost for fFN testing versus observation only.</td>
</tr>
<tr>
<td></td>
<td>• As expected, testing was more expensive ($153 per test), although the study did not consider the costs of hospital stay, delivery, or other outcomes.</td>
</tr>
<tr>
<td>Plaut et al.29</td>
<td>• Use of fFN resulted in no difference in LOS; however, if the patient had been observed for at least 6 hours and the physician knew that the fFN results were negative, LOS was shortened by 40%.</td>
</tr>
<tr>
<td></td>
<td>• Treatment was at the discretion of the physician and was not determined by fFN results.</td>
</tr>
<tr>
<td>Lee et al.24</td>
<td>• Evaluated length of stay in triage, admission rate, and number of births before 34 or 37 weeks for symptomatic women between 24 and 34 weeks gestation.</td>
</tr>
<tr>
<td></td>
<td>• Diagnosis was made by digital cervical exam only or cervical exam plus fFN. Physicians were required to discharge the patient if the fFN was negative.</td>
</tr>
<tr>
<td></td>
<td>• Detected no differences in outcomes; however, to demonstrate significance, the fFN test would have needed to reduce triage time by 50% to 1.4 hours, a reduction that was highly unlikely given that the test itself requires one hour to conduct.</td>
</tr>
</tbody>
</table>
References


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NICE guidelines on menopause

Helping women make wise choices to meet the challenges of menopause

BY JUDITH M. ORVOS, ELS

Guidelines from the National Institute for Health and Care Excellence (NICE) offer a unique perspective on diagnosis and management of menopause, designed to help women stop suffering in silence. Aimed at health care providers in the UK but also relevant to US ob/gyns, the recommendations focus on ways to determine if menopause has started, what drug and non-drug options might be useful for a patient’s physical and psychological symptoms, and clarifying the risks and benefits of hormone replacement therapy (HRT).

THE NICE GUIDELINE:

Diagnosis and Management of the Menopause contains 10 key messages:

1. Management of estrogen deficiency needs to be individualized because women respond differently to the condition and to treatment for it.
2. Inappropriate use of testing of FSH for diagnosis of menopause in women older than age 45 should be eliminated. The testing is rarely required and expensive.
3. Women need information about menopause in a variety of formats.

Key topics for counseling include the stages and consequences of menopause and about use of contraception during perimenopause.

4. For management of symptoms of menopause, diet and lifestyle should be considered. HRT should be offered for vasomotor symptoms with full consideration of benefits and risks. Clonidine or antidepressants should not be routinely offered.
5. Women with a history of breast cancer should be counseled about all treatment options for menopausal symptoms. Those taking tamoxifen should not be given fluoxetine or paroxetine.
6. Vaginal estrogen can be used long-term in patients with urogenital atrophy due to estrogen deficiency. It can also be considered for women who are not candidates for HRT because of medical conditions.
7. Follow-up with a health care provider is recommended 90 days after a patient starts HRT and annually thereafter. Referral to a provider with experience in menopause may be necessary for a patient with a complex medical history.
8. There should be no arbitrary limits for duration of use of HRT. Health care providers should provide support for women who want a trial cessation of HRT to see if they still need it to control their symptoms.
9. Benefits and risks of HRT vary from patient to patient and are strongly influenced by baseline risk, which is affected by diet, lifestyle, and past medical and family history.
10. Blood tests should be used to confirm premature ovarian insufficiency (POI). For women with POI, HRT or combined oral contraceptives are appropriate at least until they reach the average of menopause.

NICE is an independent body responsible for driving improvement and excellence in the UK health and social care system. The organization develops guidance, standards and information on high-quality health and social care and advises on ways to promote healthy living and prevent ill health.

The NICE guideline on menopause for health care providers is available at http://www.nice.org.uk/guidance/NG23.

WHEN TO REFER TO SECONDARY CARE

- Persistent side effects
- Poor symptom control
- Complex medical history
- Past history of hormone-dependent cancer
- Bleeding problems
- Sequential HRT — if increase in heaviness or duration of bleeding, or if bleeding irregular
- Continuous combined — if bleeding beyond 6 months of therapy, or if after a spell of amenorrhoea.
How has expanded genetic screening evolved from traditional carrier screening?

Expanded carrier screening is changing the way we think about genetic diseases. Any patient, regardless of ethnicity, can be a carrier of a severe genetic disorder. Traditionally, we would only screen for likely disorders based on ethnicity, because we realized certain diseases—such as Tay-Sachs disease in the Jewish population, and sickle cell disease in the African-American population—were more present in particular ethnic groups. So, we would test those at-risk populations for a few likely disorders that were of higher prevalence within that ethnicity.

However, carrier screening defined by ethnicity can overlook important insights that you and your patients need. Today, advances in next-generation sequencing (NGS) have led to expanded carrier screening, making it easier to screen for a greater number of disorders—regardless of ethnicity.

“Ethnicity nowadays is not as straightforward as it used to be,” said Lisa Pike-Buchanan. “The population is such a mixture of different ethnic groups that sometimes people are unaware of their ancestry. Utilizing pan-ethnic expanded carrier screening panels allows us to test individuals, regardless of their self-identified ancestry, and get a true snapshot of their genetic risk for the diseases we are testing for.”

The benefits of expanded carrier screening: helping your patients make more informed decisions

Following the American Congress of Obstetricians and Gynecologists’ (ACOG) recommendation in March 2017 that expanded carrier screening be offered to all women, regardless of ethnicity, many OB/GYNs are revisiting their practice’s standard approach to carrier screening for their patients.

In March, ACOG provided updated guidelines on carrier screening. Who should be screened?

ACOG, the American College of Medical Genetics and Genomics (ACMG), and advocacy groups have highlighted the many advantages of providing expanded carrier screening to all patients, including:

• Overcoming inaccurate knowledge of ancestry in our increasingly multi-ethnic society
• Identifying the genetic conditions that do not occur solely in specific ethnic groups
• Accounting for the diverse genetic makeup of different ethnicities

With advances in NGS, certainly you must be able to test for many genetic disorders. How does an OB/GYN determine which disorders a patient should be screened for?

Expanded carrier screening gives patients valuable information about their pregnancy, or as they begin to discuss family planning with their OB/GYN. But despite the benefits of expanded carrier screening, the volume of results it can yield, and knowing how they apply in a clinical setting, can become overwhelming and therefore of diminishing value. OB/GYNs need guidance from the companies administering these tests so that when they see the genetic information, they know how to interpret it in an actionable way for the patient.

Dr. Lacbawan observed, “We can certainly test for so many conditions—but we have a responsibility to only test for those disorders that are quite severe and debilitating, and that are associated with a clear phenotype so that we have some clear information on how to handle a positive result.”

“To minimize the potential for harm, the number of conditions included in the screening panel needs to be considered…”

The American Congress of Obstetricians and Gynecologists
Quest Diagnostics recently launched a new test panel, QHerit™ Expanded Carrier Screen. What benefits does it offer for OB/GYNs and their patients?

QHerit Expanded Carrier Screen is a pan-ethnic testing panel for 22 heritable diseases. QHerit is the test that OB/GYNs have been asking for, rolling up testing for some of the most impactful diseases into a single, easy-to-order panel. It’s a panel built on national guidelines, recommendations, and testing criteria from groups including ACOG, ACMG, National Society of Genetic Counselors, and other advocacy groups, to include clinically relevant tests and results.

QHerit is ideal for anyone considering starting a family or already pregnant, regardless of ethnic background. QHerit is well-suited to provide highly accurate insights about heritable risk in a wide variety of patients.

Interpreting genetic screening can be challenging for the OB/GYN who may be seeing a positive test result for the first time. How can labs help OB/GYNs have an informed conversation with their patients?

You can take advantage of the latest advances in carrier screening to help you and your patients make more informed decisions. QHerit is fully supported by Quest’s genetic experts, including MDs, PhDs and genetic counselors, available to help OB/GYNs with test selection and results interpretation. Pike-Buchanan noted, “Genetic counselors like me are available to help OB/GYNs understand the impact of the results on their patients, so that the OB/GYN can determine approximate next steps for the family.”

Ordering QHerit is easy

- Request test code 94372(X)
- For assistance in test selection or result interpretation, contact 1.866.GENE.INFO (1.866.436.3463) 8:30 AM to 8:00 PM EST
- To learn more about QHerit, including testing specifications, please visit QHerit.com

Quest Diagnostics is a leader in women’s health. They provide a broad continuum of care for fetal aneuploidy testing by offering an extensive menu of first trimester screens as well as comprehensive diagnostic testing. In addition, they provide a wide range of prenatal testing options backed by proven science, from routine to highly specialized, including over 700 genetic tests. QHerit may be ordered by physicians as a component in the spectrum of testing, including pregnancy confirmation testing, general health screening panels, non-invasive prenatal screening, and maternal serum screening that supports healthy pregnancies.

What does QHerit test for?

QHerit tests for 22 diseases, including Spinal Muscular Atrophy, Cystic Fibrosis, Fragile X Syndrome, Tay-Sachs and other disorders that play an important role in patients’ healthcare and family planning. QHerit focuses on disorders that:

- Have potentially devastating consequences
- Result in early death
- Create a need for significant early intervention

In line with ACOG guidelines, we chose diseases that are approximately 1% carrier frequency or greater and specifically chose not to include ultra-rare conditions to help mitigate the risk of unnecessarily increasing patient anxiety. QHerit Expanded Carrier Screen provides a clear picture, testing only clinically relevant variants within genes.

<table>
<thead>
<tr>
<th>Disorder</th>
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<tbody>
<tr>
<td>Alpha-Thalassemia</td>
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<td>Beta-Hemoglobinopathies</td>
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<td>Bloom Syndrome</td>
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<td>Canavan Disease</td>
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<td>Cystic Fibrosis (CF)</td>
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<td>Dihydrolipoamide Dehydrogenase Deficiency (DLD Deficiency)</td>
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<td>Fragile X Syndrome</td>
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<td>Maple Syrup Urine Disease</td>
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<td>Niemann–Pick Disease Types A &amp; B</td>
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<td>Spinal Muscular Atrophy (SMA)</td>
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<tr>
<td>Tay-Sachs Disease</td>
</tr>
<tr>
<td>Usher Syndrome Type 1F</td>
</tr>
<tr>
<td>Usher Syndrome Type IIIA</td>
</tr>
<tr>
<td>Walker-Warburg Syndrome</td>
</tr>
</tbody>
</table>

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Post NICE guide for hormone replacement therapy

The safety of hormone replacement therapy (HRT) depends largely on the age of the patient. For most women, the risks are few and the potential benefits are many when HRT is given for clear indications and therapy is initiated within a few years of menopause.

### Vaginal Estrogen

<table>
<thead>
<tr>
<th>Indications</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>When vaginal and/or bladder symptoms of urogenital atrophy predominate, vaginal estrogen alone can be used.</td>
<td>Vaginal tablet: estradiol&lt;br&gt;Creams: estriol&lt;br&gt;Ring: estradiol</td>
</tr>
<tr>
<td>Vaginal estrogen may also be required in addition for some women taking systemic HRT. May be considered in women with urogenital atrophy in whom systemic estrogen is contraindicated, after seeking specialist advice.</td>
<td>Tablets and creams should be used nightly for 2 weeks and then twice weekly as maintenance. Maintenance can be continued long-term.</td>
</tr>
<tr>
<td></td>
<td>Rings should be changed every 3 months.</td>
</tr>
<tr>
<td></td>
<td>Systemic absorption is minimal and progestogen is not required.</td>
</tr>
<tr>
<td></td>
<td>Symptoms frequently recur on cessation of therapy.</td>
</tr>
</tbody>
</table>

### Systemic HRT

<table>
<thead>
<tr>
<th>Indications</th>
<th>Duration of Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptom control</td>
<td>As long as it is believed that benefits of symptom control and improvement in quality of life outweigh any risks, there are NO arbitrary limits</td>
</tr>
<tr>
<td>Treatment of premature ovarian insufficiency (POI) or premature induced menopause</td>
<td>At least until average age of menopause (51 in US and UK)&lt;br&gt;For POI or premature induced menopause symptom control start with low dose preparation but medium or higher doses are usually required. Consider addition of testosterone therapy after bilateral oophorectomy</td>
</tr>
<tr>
<td>Prevention and treatment of osteoporosis</td>
<td>Therapy for several years may be required, followed by consideration of other bone-protective therapy</td>
</tr>
</tbody>
</table>

**PROVEN BENEFITS**

- Control of menopausal symptoms
- Maintenance of BMD (bone mineral density) and reduced risk of osteoporotic fractures. Benefits reduce once treatment stops.
- Limited evidence suggest HRT may improve muscle mass and strength.

**KNOWN RISKS**

- **ENDOMETRIAL CANCER** if uterus is present and estrogen only is given. Reduced by addition of progestogen. Continuous progestogen provides better long-term protection than cyclical.
- **DVT/PE** background risk with oral estrogens, which is 1.7 per 1,000 women > age 50 after 7.5 years’ use by women > age 50. Greatest risk is in the first 12 months of use. Risk with transdermal estrogen is no greater than general population risk.
- **CVD** risk not increased when starting therapy in women < age 60
- **BREAST CANCER** combined HRT may be associated with 5 additional breast cancer instances per 1,000 women > age 50 after 7.5 years use. Overall mortality is not increased. Greatly decreased risk associated with estrogen alone. Risk returns to baseline after stopping HRT, suggesting HRT acts as a promoter rather than an initiator. *Postmenopausal obesity or 2 or more units of alcohol per day are associated with greater breast cancer risk than 5 years combined HRT.*

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SCREENING FOR FETAL ANEUPLOIDY

Prenatal genetic screening is designed to assess whether a patient is at increased risk of having a fetus affected by a genetic disorder. In contrast, prenatal genetic diagnostic testing is intended to determine, with as much certainty as possible, whether a specific genetic disorder or condition is present in the fetus. The purpose of prenatal screening for aneuploidy is to provide an assessment of the woman’s risk of carrying a fetus with one of the more common fetal aneuploidies. This is in contrast to prenatal diagnostic testing for genetic disorders, in which the fetal chromosomes are evaluated for the presence or absence of abnormalities in chromosome number, deletions, and duplications, or the fetal DNA is evaluated for specific genetic disorders. The wide variety of screening test options, each offering varying levels of information and accuracy, has resulted in the need for complex counseling by the health care provider and complex decision making by the patient. No one screening test is superior to other screening tests in all test characteristics. Each test has relative advantages and disadvantages. It is important that obstetrician–gynecologists and other obstetric care providers be prepared to discuss not only the risk of aneuploidy but also the benefits, risks, and limitations of available screening tests. Screening for aneuploidy should be an informed patient choice, with an underlying foundation of shared decision making that fits the patient’s clinical circumstances, values, interests, and goals.

The purpose of this Practice Bulletin is to provide current information regarding the available screening test options for fetal aneuploidy and to review their benefits, accuracy, and limitations. For information regarding prenatal diagnostic testing for genetic disorders, refer to Practice Bulletin No. 162, Prenatal Diagnostic Testing for Genetic Disorders.

COMMENTARY

Short course in genetics and screening

by JOSHUA A. COPEL, MD

Every pregnancy is at risk of chromosomal abnormalities, which are generally more common than most professionals and pregnant women appreciate, about 1 in 150 live births. With many early losses occurring due to aneuploidy, the prevalence is higher the earlier in pregnancy one looks. All ob/gyns are familiar with trisomy 21, which is an aneuploidy (abnormal number of chromosomes). However, many other types of chromosomal abnormalities (eg microdeletions and microduplications) are responsible for the difference between the frequency of trisomy 21 (1 in 800 live births) and the 1 in 150 number cited above.

While anomalies, maternal age, and a history of a prior affected pregnancy all increase risk of chromosomal abnormalities, nothing except a diagnostic test (ie, chorionic villus sampling or amniocentesis) can eliminate risk, at least to the limits of current technology.* Even then, I tell patients we can say that there is no chromosomal abnormality to the limits of current technology. (Affordable, rapid whole exome sequencing may eventually represent the ultimate test for this in the future).

Practice Bulletin #163 (PB) contains a short course in genetics and screening, with a great deal of important infor-
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Screening works in low-risk populations, where the detection rate (sensitivity) has to be balanced with avoiding false alarms (population false-positive rate). The false-positive rate is often confused with the positive predictive value (PPV). How often have we all heard a patient say she doesn’t want a screening test “because it’s almost always wrong”? That is a function of the low PPV of most of our tests. A screening test that shows a 1/100 risk of trisomy 21 essentially is “incorrect” 99% of the time.

When you perform multiple screening tests, unless they are designed to function together (eg, the quad test, where each of the 4 blood tests has been studied and found to be independent of the others), you risk increasing the number of false-positive results with an uncertain improvement in the actual detection rate for the abnormality.

Every pregnancy is at risk of chromosomal abnormalities, and “[a]neuploidy screening or diagnostic testing should be discussed and offered to all women…”

This PB contains a thorough review of the many screening tests available, by my count, with the advantages and disadvantages of each in a very helpful table. The limitations of ultrasound are also succinctly outlined: among others, low detection rate for trisomy 21 (likely 50% to 60% as a screening test), lack of standardization, and variable sonographer and sonologist experience.

Cell-free DNA (cfDNA) has been extensively marketed to professionals and patients alike. Despite some claims, the PB points out that they all have similar detection and false-positive rates, although there are limited data on direct comparisons in large patient samples. Each technique available has advantages and disadvantages. Perhaps the most important point in the PB on cfDNA is the reminder that patients with low fetal fractions leading to “no reportable result” have a heightened risk of fetal aneuploidy. Adding these patients to reported calculations would REDUCE the sensitivity of cfDNA tests. Conversely, considering these patients as screen-positive will decrease specificity and increase screen-positive rates.

**Risks of cfDNA testing:**

1. False reassurance of normality, because despite being very sensitive to trisomy 21, the test is only 80% in detecting all chromosomal abnormalities; and

2. Given the rarity of microdeletion syndromes like diGeorge (del22q11), and trisomy 13, it is uncertain what positive or negative screening test results mean. In fact, the PB recommends against screening for microdeletion disorders at present.

The PB contains a table that has recommendations for management of ultrasonographic markers for aneuploidy, some of which do not work well in the real world. Specifically, while it is useful in research protocols to define specific levels of risk as screen-positive or -negative, life is messier than that. One patient may consider 1 in 149 an acceptable risk and desire no further testing, while another may want invasive testing for a risk of 1 in 151. I would argue that the patient deserves to know as much as she can absorb about the risk number, not simply be told “you are screen-negative.”

Not addressed, and beyond the scope of a PB on screening, are other clinical dilemmas we now face with fetal anomaly detection. We increasingly face the scenario of women with very high risks for aneuploidy or microdeletion disorders, for example fetal tetralogy of Fallot, who decline diagnostic testing. cfDNA’s imperfect rate for detection of trisomy 21 is less of an issue, because > 99% of cases will be detected. The detection rate for del22q11, however, is only about 85%, so there will be far more false-positive and false-negative tests than with diagnostic testing.

As usual, the Summary of Recommendations and Conclusions contains the key bullet points for patient care, and there are too many to cite here specifically.

*Some minor microdeletions and epigenetic abnormalities are still not detected, and until economical and rapid whole exome sequencing is readily available, this is the current state of the art.*

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Managing complications of perineal lacerations

When perineal lacerations are severe, it’s important that ob/gyns know how to accurately diagnose and appropriately manage them.

by SARA CICHOWSKI, MD, AND REBECCA G. ROGERS, MD

Perineal lacerations occur in up to 80% of vaginal deliveries. Lacerations commonly occur on the perineum and vagina but can also occur on the labia, clitoris, urethra, and cervix. The severity of lacerations varies from minor lacerations that affect the skin or superficial structures of the perineum to more severe lacerations that damage the muscles of the anal sphincter complex and rectum. Laceration repair is not required for minor lacerations that are not bleeding or distorting anatomy. Obstetric anal sphincter injuries (OASIS) are severe perineal lacerations that extend into or through the anal sphincter complex. Major risk factors for severe lacerations include operative deliveries (forceps or vacuum), midline episiotomy, and larger birth weight. Additional risk factors for severe lacerations include labor induction and augmentation, Asian ethnicity, epidural anesthesia, persistent occiput posterior, and primiparity. Table 1 lists the classification of perineal lacerations.

Determining the extent of a perineal laceration sustained after delivery is critical for repair and postpartum counseling for, despite adequate repair, complications may arise. Some complications, such as anal incontinence, may develop years after the trauma. This article reviews complications that may occur following perineal trauma, techniques to help prevent these complications, and best practices for management using case vignettes.

**CASE VIGNETTE:** A 30-year-old G1P1 reports fecal incontinence 4 months after repair of a fourth-degree laceration.

**DIAGNOSIS:** Fecal incontinence

Fecal incontinence (FI) is a potential consequence of OASIS. Midline episiotomy (even without extension into the sphincter) is also a risk factor for FI and fourth-degree laceration has a higher risk compared to third-degree lacerations. Repair of a fourth-degree laceration begins with repair of the rectal mucosa with either a subcuticular running or interrupted suture of 4-0 or 3-0 polyglactin (Vicryl). Next, the internal anal

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**DR ROGERS** is Associate Chair for Clinical Integrations and Operations, Dell Medical School, The University of Texas at Austin.
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sphincter is identified and repaired with either a running or interrupted suture technique. The internal anal sphincter often has a whitish appearance with distant sheen from the striated, red appearance of the external anal sphincter. Overlapping repair of the sphincter requires complete sphincter disruption and 1 cm to 1.5 cm of torn muscle on either end. For this repair, grasp the ends of the torn anal sphincter with Allis clamps, pull the sphincter ends over each other in a double-breasted fashion and then suture them back together using either polyglaclin (Vicryl) or polydioxanone (PDS).

In contrast, with an end-to-end repair, the external anal sphincter is approximated and sutured, usually with 4 sutures to recreate the cylindrical shape of the muscle. No long-term differences are seen in FI rates for end-to-end versus overlapping repairs.9

Limited, retrospective data support an association between mediolateral episiotomy and decreased rates of OA-SIS. Theoretically, that in turn would decrease rates of FI. Evidence does not support routine episiotomy, although mediolateral may be preferred over midline when episiotomy is needed.9 Non-surgical treatment options for FI include increased intake of fiber and use of biofeedback, physical therapy, loperamide, and anal plugs. Women who develop postpartum FI may consider a cesarean delivery in subsequent pregnancies to help prevent deteriorating function.9

CASE VIGNETTE: A 23-year-old G1P1 with a fourth-degree laceration presents 6 weeks postpartum with a complaint that on defecation, stool is coming out of her vagina.

### Table 1: Classification of perineal lacerations

<table>
<thead>
<tr>
<th>Laceration Classification</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>First degree</td>
<td>Laceration of the vaginal epithelium or perineal skin only</td>
</tr>
<tr>
<td>Second degree</td>
<td>Involvement of the perineal muscles but not the anal sphincter</td>
</tr>
<tr>
<td>Third degree</td>
<td>Disruption of the anal sphincter</td>
</tr>
<tr>
<td>3a</td>
<td>&lt; 50% thickness of sphincter torn</td>
</tr>
<tr>
<td>3b</td>
<td>&gt; 50% of sphincter torn</td>
</tr>
<tr>
<td>3c</td>
<td>Internal sphincter also torn</td>
</tr>
<tr>
<td>Fourth degree</td>
<td>Disruption of anal epithelium</td>
</tr>
</tbody>
</table>

*Developed by Dr. Sultan9 and adopted at the revITALize Obstetric Data Definitions Conference that was convened by the American College of Obstetricians and Gynecologists in 2012 to develop and standardize national obstetric clinical data definitions in 2012.

**DIAGNOSIS:** Rectovaginal fistula/ perineal rectal fistulas

Rectovaginal fistulas (RVFs) may develop from poor-healing, unidentified, or unrepaird perineal lacerations. In the United States, fistula rates following perineal trauma have declined over the past 30 years.10 Patients with fistulas may complain of stool, gas, or foul discharge from a vagina. Women who have sustained a third- or fourth-degree laceration are at particular risk for RVF development, although the incidence remains low.1,10 Identification of a rectovaginal or perineal rectal fistula may be aided by dyeing the gel used during a rectal exam blue and attempting to push it up through the fistula tract. A dimple or indentation on the perineum may represent a fistula tract. Vaginoscopy and exam under anesthesia can help to make the diagnosis. Repair by physicians familiar with fistula repairs is recommended and for complex repairs, the involvement of multiple specialists such as urogyneologic and colorectal surgeons may be necessary.12 The type of repair should be tailored to the patient’s presentation.13

**CASE VIGNETTE:** A 34-year-old G1P1 at 24 hours post—vacuum-assisted delivery complains of increased perineal pressure and pain. She is tachycardic and visibly uncomfortable. On exam, there is an expanding 12 x 15-cm lental mass.

**DIAGNOSIS:** Puerperal genital hematomas

Puerperal genital hematomas (PGH), while rare (occurring in 1 per 500 to 1 per 12,500 deliveries),13 may become life-threatening obstetric emergencies. Risk factors for PGH include nulliparity, instrumental delivery, and mediolateral episiotomy.15 Rupture of the anterior branches of the internal iliac artery are frequently responsible for PGH.16 PGH may present as vulvar or vaginal damage to branches of the uterine artery and may dissect into the retroperitoneal...
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space, remaining clinically occult. In this situation an ultrasound, computed tomography, or magnetic resonance imaging may be useful in confirming the diagnosis. Vaginal-perineal hematomas may also dissect into the ischiorectal fossa. While not avoidable, identification and careful repair of all bleeding lacerations at the time of delivery helps to limit PGH.

Identification of PGH is paramount; careful vaginal and perineal examination will help decide further care as management of PGH depends on patient hemodynamic stability, PGH location and size. One option for a hematoma that appears stable (ie, non-expanding) is careful monitoring, which may include serial hematocrits, repetitive examinations, and transfusion or fluid resuscitation for the patient as appropriate. Other options to consider for unstable patients or expanding hematomas include exam under anesthesia with repair, packing, or drain placement. Interventional radiology to occlude the bleeding vessel may be helpful in the case of retroperitoneal hematomas. However, access to interventional radiology may be limited so careful attention to the stability of the patient is key to ensure transfer to a higher level of care if necessary.17

CASE VIGNETTE: A 38-year-old G2P2 smoker who had a mediolateral episiotomy to expedite delivery for fetal distress presents 5 days postpartum with increasing perineal pain and malodorous discharge.

DIAGNOSIS: Perineal infection/wound breakdown
Infections and wound breakdown may complicate laceration healing. Risk factors for breakdown of a perineal laceration include operative deliveries, mediolateral episiotomy, and mectonium-stained amniotic fluid.16 Severe third- and fourth-degree lacerations are more prone to infection and break down. A single dose of broad-spectrum antibiotics (such as cefotetan or cefoxitin) at the time of third- or fourth-degree laceration repair is recommended.19,20 Women who sustain a third- or fourth-degree laceration should return for early follow-up for wound evaluation and to aid early identification of wound breakdown/infection.20 Limited evidence-based guidelines exist for treatment of wound breakdown and infection.21 Careful examination of the wound should include rectal examination to evaluate for unrecognized fourth-degree laceration, which could further contribute to wound infection and breakdown. Some evidence indicates that early closure of dehisced episiotomy or laceration repair may also be an option, but only after all evidence of infection has resolved.22 Antibiotics that cover skin flora, such as amoxicillin or cephalaxin, should be given when signs of infection such as purulent exudate, erythema, or fever are present.

CASE VIGNETTE CONTINUED: After 3 days of oral antibiotics, the patient returns complaining of increased pain and fever. On examination, you see a black wound with foul smell and crepitus.

DIAGNOSIS: Necrotizing fasciitis
Perineal infection and breakdown is a rare cause of necrotizing fasciitis (NF). The reported incidence of NF postpartum has risen from 0.45% to 14.1%.23 Risk factors for PUR include nulliparity, longer labor, instrumental delivery, lacerations, and epidual anesthesia.24 A simple way to check for urinary retention is a bladder scanner (ultrasound). However, because a bladder scanner is not specific, sometimes a postpartum uterus or free fluid in the pelvis can falsely elevate the measured postvoid residual (PVR). If urinary retention is suspected, a catheter should be placed and continuous drainage initiated until the patient is ready for a voiding trial. One way to perform a voiding trial is to backfill the

CONTINUED ON PAGE 36
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The opioid pain reliever epidemic

What ob/gyns need to know about the devastating man-made epidemic of overdose deaths from medically prescribed opioids.

by DEBORAH COADY, MD, FACOG

Every day in this country, at least 40 people die from an overdose of prescription opioid pain relievers (OPRs). This is almost half of the 90 Americans that die each day from all opioid overdoses, including deaths from heroin and increasingly other very potent synthetic opioids such as fentanyl and carfentanil, a statistic that continues to rise. In 2015, the number of overdose deaths attributable to prescribed painkillers was over 15,000, a 3-fold rise since 2001. Even more unsettling, many of these deaths occur in people who receive their prescriptions from one doctor, meaning they were not doctor shopping to obtain the drugs, or taking or buying them from others.

These statistics likely underestimate this crisis due to under-reporting and difficulties such as lack of resources in certifying so many drug deaths. Statistics also do not take into account the contribution of OPRs to other injuries and deaths, such as from motor vehicle accidents. The development of very potent oral formulations increases the risk of sedation and respiratory depression, which may be heightened further by alcohol and some other medications such as diazepam. Overdose deaths in people with illnesses such as heart disease may not be investigated fully, with the cause of death deemed to be “natural causes.” I know of more than 1 patient who likely died in her sleep from inadvertently taking too many pills, but who did not undergo autopsy.

The aim of this article is to educate ob/gyns about what not to do for acute and chronic pain, in the hope that increased awareness will help us prevent suffering and loss of life from OPRs. Misconceptions about opioids are still commonly held by clinicians, and interfere with proper prescribing and monitoring of opioid treatment. I highly recommend the enlightened review by Volkow and McLelland, Opioid Abuse in Chronic Pain —Misconceptions and Mitigation Strategies.

Table 1 lists generic and brand names of commonly used OPRs. Most people who have had surgery or dental extraction have been prescribed one of

QUICK TAKE

- Obstetric patients need advice on safe, natural comfort measures for discomforts of pregnancy and postpartum,
- Setting treatment goals with patients will help assess the effectiveness of pain management measures.

DR COADY is Clinical Assistant Professor of Obstetrics and Gynecology at NYU Langone Medical Center, New York, New York.
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them. New formulations with different potencies and brand names continue to be developed and marketed.

**Historical perspective**

Chronic pain is a huge problem in the United States: 25.3 million adults report suffering from pain on a daily basis. Chronic pain patients are at high risk for OPR overdose death and adverse effects. Over the past 20 years, OPRs have been the main response of the medical system and the pharmaceutical industry (as well as the research it sponsors) to this very common problem of chronic pain. The steady increase in prescribing OPRs for chronic pain has paralleled the increase in the overdose death rate. In 2010, enough opioid painkillers were prescribed to medicate every American adult around-the-clock for a month; this was a 300% increase over the previous decade and 4 times the rate of OPR prescribing in Europe. Although OPRs are prescribed by us for a medical purpose, many patients purposefully or inadvertently misuse them, and some pills end up in the hands of people who abuse them; this may lead to progression to a chronic relapsing illness, which we now call opioid use disorder.

As a gynecologist focusing my practice on chronic pelvic pain, I became alarmed at seeing the rapidly rising use of OPRs in patients seeking my care as well as the increasing rate of overdose deaths in women. While more overdose deaths still occur in men, there has been a 400% increase in death rates for women since 1999, to almost 7000 currently, a number higher than female motor vehicle accident deaths. Because more women than men suffer from chronic pain, they are more likely to receive OPR prescriptions, and in higher doses and for longer periods of time; they also may become dependent on them more quickly than men. Women are more frequently prescribed benzodiazepines and antidepressants, medications frequently involved in OPR overdose deaths. In my practice, new patients sometimes came in already physiologically dependent on OPRs, and these medications were usually not providing any benefit to their pain or function. In some instances, the patients did not even realize that what they were taking were opioids that caused dependency. Two patients described emergency room visits for withdrawal symptoms that scared and puzzled them.

Amazingly, pregnant women are also increasingly being prescribed OPRs for pain during pregnancy, resulting in the rate of newborns with withdrawal symptoms, called neonatal abstinence syndrome, rising three-fold between 2000 and 2009. From 2008 to 2012, 28% of women aged 15 to 44 on private insurance and 39% of women on Medicaid filled a prescription written by a health professional for an OPR.

**Opioids for chronic pain**

Perhaps the risks of taking OPRs long-term, including death and the other serious adverse effects (AEs), would be worth it for some patients, if these medications actually helped chronic pain. Unfortunately, that is not the case. OPR use spread from the acute pain setting, to use in terminally ill and cancer patients, to use in chronic pain patients, without studies scientifically showing benefit. Clinically, I found this out the hard way, through experience, that OPRs really didn’t work well at all for my patients. Most reported back that their pain persisted, but they just didn’t care as much because their brains felt “out of touch with it.” I had a similar personal experience with Percocet for acute postoperative pain. It helped if I was just going to stay in bed, but not if I wanted to function and go on with my life. In 2014, a systematic analysis of 39 studies found no evidence of long-term benefit of OPRs for chronic pain, but did show an increased risk of serious harm. Why so many medical professionals continue to write these prescriptions for chronic pain, despite the evidence, is difficult to understand.

In addition, recent studies are casting doubt on whether OPRs are any better than non-opioid medications for acute pain. In an emergency department setting in the Bronx, a randomized, controlled study showed that patients with acute back pain who were assigned to take an OPR did not have improved functional outcomes or re-

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**TABLE 1 Common opioid pain relievers (OPRs) generic and brand names**

<table>
<thead>
<tr>
<th>Generic names</th>
<th>Brand names</th>
</tr>
</thead>
<tbody>
<tr>
<td>Codeine</td>
<td>TYLENOL® #3</td>
</tr>
<tr>
<td>Fentanyl</td>
<td>Duragesic patch</td>
</tr>
<tr>
<td>Hydrocodone</td>
<td>Vicodin</td>
</tr>
<tr>
<td>Morphine</td>
<td>MS Contin</td>
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Postpartum hemorrhage (PPH) is an obstetric emergency and a major cause of maternal mortality and morbidity, killing approximately 140,000 women each year worldwide.* This supplement identifies common causes of primary and secondary PPH, assesses the readiness of your practice to manage women who develop PPH, analyzes the clinical utility of methylergonovine maleate, and more.


read the supplement at contemporaryobgyn.net/pph
duced pain at 1-week follow-up compared to patients who were not treated with opioids. Much of what we have believed about the usefulness of these strong and dangerous medications is being called into question. An unanswered question I have is whether the use of OPRs for acute pain increases the risk of the pain becoming chronic, or is unrelieved pain a culprit in that process?

Because most OPRs that are misused and abused originate directly or indirectly from prescription medication, and 1 in 20 Americans admits to non-medical use of OPRs, how did we medical professionals let this tragic epidemic come about? I think one reason is that we did not question the pharmaceutical industry’s marketing and involvement. After all, the 23.4 million American adults that report “a lot of daily pain” needed our help. We began to consider that pain needed to be treated at all costs, even deeming pain level to be a vital sign, like pulse and blood pressure. We got into the habit of prescribing a week’s supply of pills “for the patient’s convenience” even if the need was only for 2 days postoperatively; in effect this supplied family medicine cabinets with leftover OPRs that could easily fall into the hands of teens and adults likely to abuse them. Most of us have heard of tragic accidental OPR overdose deaths in young people who may dangerously combine them with alcohol.

As products of our modern society, “magic pills” and quick fixes are very attractive to physicians and, also, desired by our patients. Many expect to be handed a prescription at every doctor’s visit. As we became “opiod-centric,” we neglected the importance of continuing to look for underlying root causes of pain in our chronic pain patients and forgot that our bodies have amazing self-healing abilities that can be enhanced by life-style changes and mind-body practices.

**Long-term use and adverse effects**

Although the use of OPRs for acute pain comes with serious AEs, long-term use is even more dangerous. When patients remain on these medications chronically, most develop tolerance, and need higher and higher doses to obtain the same effects. Even worse, most become physiologically dependent, and live in an uncomfortable state of almost constant withdrawal symptoms, as opioid blood levels fluctuate up and down over the course of the day. An estimated 25% become non-medical users, and 10% develop opioid use disorder. The most serious AE of OPRs is respiratory depression, which is how most overdose deaths occur, as breathing becomes more and more shallow and blood oxygen falls. Many women are co-treated on a variety of medications for medical conditions, are at increased risk.

Some OPR side effects actually make chronic pain worse. Constipation may be severe, resulting in more pelvic pain. Both male and female hormone levels decline, adding to genital tissue changes and discomfort. Opioids ironically lower pain thresholds, perhaps even forever after they are discontinued, causing pain intolerance and hyperalgesia (increased sensitivity to uncomfortable stimuli). OPR-induced “brain fog” puts patients at risk for inadvertently forgetting how many pills they already took that day, or misuse -- “not caring if I overdose” as one of my patients put it -- in her attempt to “get better pain relief” from her medications. Several of my patients admitted to this; 2 were found unconscious by family members after overdosing and they sustained serious musculoskeletal injury. Sadly, having a supply of potent OPRs on hand makes impulsive suicide attempts easier to carry out successfully. Recently, pharmacies in many states dispense kits of naloxone for emergency use, to reverse opioid-induced respiratory depression. It is now recommended that naloxone be kept in all households in which a person is using OPRs.

Many chronic pain patients who misuse opioids are actually trying to avoid opioid withdrawal symptoms, as opposed to looking for euphoric effects. These symptoms may be mild or severe, and range from anxiety, restlessness, insomnia, sweating, and stomach cramps, to muscle spasms, fever high blood pressure and heart rate, vomiting, and diarrhea. Patients react in varying ways to the experience of purposely withdrawing from their OPRs but many tolerate it well. I have helped patients wean slowly off their OPRs, once we determined together that the pills were not help-

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**One in 20 Americans admit to non-medical use of opioid pain relievers.**

with benzodiazepines, which heighten this risk: about one-third who die from OPR overdose also have diazepam or similar medications in their blood stream. Respiratory depression can occur very suddenly after an OPR dose; my 19-year-old daughter experienced a near-lethal overdose while under observation recuperating from surgery in the hospital! Elderly patients, and those...
ing and may even be worsening their chronic pain condition, and that there are other safer integrative approaches to use instead.12-14 Most chronic pelvic pain patients are motivated to stop OPRs, and with education and support are successful in discontinuing them by tapering down by 10% every week to minimize withdrawal symptoms, until they are finally off. With knowledge instead of fear, many tolerate a quicker regimen. My daughter decided to abruptly stop her OPR after her in-hospital overdose experience, and because she knew what to expect, handled the uncomfortable symptoms well. Utilizing mind-body therapies such as yoga and qigong help success with OPR discontinuation. Buprenorphine is a bridge medication that can be used to minimize withdrawal symptoms in difficult cases.1

Some opioid-dependent patients are, unfortunately, very prone to relapse after they discontinue OPRs due to genetic and environmental factors; a test to identify who these patients are ahead of time, before a prescription is ever written, would be life-saving, but does not yet exist.6 We need to consider all people to have this risk. Structural and functional changes occur in the brains of these patients, which may compromise for life their impulse control to take opioids.15 This brain disease model of addiction as a chronic relapsing brain illness helps explain the difficulties and behavior of people with opioid use disorder. Risk of overdose death is particularly high in patients who relapse, because their tolerance often decreases during the time they were opioid-free.

**Steps ob/gyns can take**

What can we do to halt this epidemic of death and injury from OPRs? Primary prevention is key, which means discouraging new use of opioids; “start at the beginning and keep opioid-naïve patients opioid-naïve,” as Nelson et al recently urged in *The Journal of the American Medical Association*.15 This means retraining medical professionals, patients, and society at large, so that expectations about preventing and treating pain are realistic. Education needs to include a reframed concept of acute pain as a necessary and important voice of our bodies, not something to avoid at all costs.

Our obstetric patients need our explanations on the many discomforts of pregnancy and our advice on safe natural comfort measures, so as not to resort to OPRs. After normal vaginal delivery, local vulvar measures usually suffice to soothe pain. I know of patients who have developed opioid use disorder after OPRs prescribed for mild episiotomy pain and after overly prolonged use post-cesarean delivery. For pregnant patients already on opioids, the American College of Obstetrician and Gynecologists has recently developed specific guidelines for care (Table 2).16

If pain is chronic, the root cause should be diligently searched for before giving up and falling back on OPRs. For example, chronic pelvic and vulvar pain

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**TABLE 2  Opioid Use and Opioid Use Disorder in Pregnancy**

Summarized from ACOG Committee Opinion 171. Recommendations and Conclusions.16

- Universal screening of pregnant women early in pregnancy and referral for treatment for opioid use and opioid use disorder improve both maternal and infant outcomes.

- Screening for substance use should be part of comprehensive obstetric care for all women at first prenatal visit.

- Routine screening should rely on validated screening tools such as questionnaires.

- For patients with chronic pain, strategies should avoid or minimize the use of OPRs.

- For patients with opioid use disorder, opioid agonist pharmacotherapy is recommended, as opposed to medically supervised withdrawal which leads to high relapse rates and worse outcomes.

- Infants born to women who used opioids during pregnancy should be monitored by a pediatric care provider for neonatal abstinence syndrome.
Determining When to Initiate or Continue Opioids for Chronic Pain

1 Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate.

2 Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how therapy will be discontinued if benefits do not outweigh risks. Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.

3 Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy.

Opioid Selection, Dosage, Duration, Follow-Up, and Discontinuation

4 When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting opioids.

5 When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when increasing dosage to $=50$ morphine milligram equivalents (MME)/day, and should avoid increasing dosage to $=90$ MME/day or carefully justify a decision to titrate dosage to $=90$ MME/day.

6 Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed.

7 Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids.

Assessing Risk and Addressing Harms of Opioid Use

8 Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages ($=50$ MME/day), or concurrent benzodiazepine use, are present.

9 Clinicians should review the patient’s history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months.

10 When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.

11 Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible.

12 Clinicians should offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder.

* All recommendations are category A (apply to all patients outside of active cancer treatment, palliative care, and end-of-life care) except recommendation 10 (designated category B, with individual decision making required); see full guideline for evidence ratings.
is often not fully evaluated by ob/gyns. Mowers et al recently studied almost 4000 women who had a hysterectomy for chronic pelvic pain: fewer than 25% had endometriosis at the time of surgery. In those with a preoperative diagnosis of endometriosis, almost half did not actually have endometriosis at surgery. In these patients without a clear surgical explanation for their pelvic pain, other causes such as musculoskeletal or neurological may not have been adequately assessed preoperatively, resulting in a treatment intervention that was likely to be inappropriate and ineffective. I have seen the disappointment when patients consulted me after “negative” surgery; the frustration of both patients and clinicians often leads to trying OPRs instead of evaluating for other etiologies. Table 3 lists CDC recommendations for prescribing OPRs for chronic pain.

For the millions of people already on OPRs, we must remove the societal stigma attached to addiction, which often interferes with access to potentially life-saving treatment programs. More strides need to be made to ensure that medical insurance covers opioid rehabilitation, as many patients remain underinsured and underserved. Mind-body therapies are being studied and utilized by the Department of Defense, and the Veterans Administration, for military veterans who were treated for chronic pain with OPRs and developed dependency, with benefit in rates of recovery. We need more Western research like this to convince medical professionals of the importance of not using OPRs for pain but instead offering safer medications and mind-body therapies that enhance self-care and self-responsibility for health. We all have a role to play in curbing this epidemic by declining OPRs ourselves and by advising and supporting our family, friends and patients to use alternate methods of pain relief. Changing the current mind-set may be difficult, but we can and must do it.

DISCLOSURES The author reports no potential conflicts of interest with regard to this article.

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bladder with 300 mL of normal saline, remove the catheter, and have the patient attempt to void. Other clinicians remove the catheter, wait for spontaneous voiding, and then check a PVR with bladder scan. While a normal PVR has not been determined, some providers use a cutoff of < 100 mL or 1/3 the voided volume. Women who develop PUR with a delayed or missed diagnosis may develop long-term voiding dysfunction. If there is ongoing voiding dysfunction or a patient is unable to pass a voiding trial or to resume spontaneous voiding, she should be managed with either an indwelling catheter or intermittent self-catheterization until referral to an appropriate specialist can be accomplished.

CASE VIGNETTE: A 27-year-old G1P1 complains of painful intercourse 8 weeks after a vaginal delivery of a 4-kg male complicated by a second-degree laceration.

DIAGNOSIS: Dyspareunia
Approximately 41% to 83% of women at 2 to 3 months postpartum report sexual dysfunction, including dyspareunia.²⁷ Risk factors for development of postpartum dyspareunia are not well known. Routine episiotomy is associated with more pain and slower time to first intercourse than when episiotomy use is restricted, or in women who sustain spontaneous lacerations.²⁸ A recent study revealed that OASIS was a strong predictor of delayed resumption of intercourse and the strongest predictor of dyspareunia postpartum compared to that in women without sphincter laceration.²⁹

Longer longitudinal data 6 to 11 years after first delivery suggest that women who deliver vaginally with perineal trauma either from a spontaneous laceration or episiotomy do not have increased rates of dyspareunia. However perineal trauma from forceps or a baby ≥ 4 kg remain associated with dyspareunia.²⁸,³⁰ Importantly, cesarean delivery carries the same risk of dyspareunia as vaginal delivery 6 to 11 years after first delivery.³⁰ Experts recommend assessing the perineum when dyspareunia is present and encouraging patients to use vaginal lubricants during intercourse.²⁷ Women with levator spasms following perineal laceration may benefit from physical therapy. Significant scarring that leads to vaginal stenosis may require surgical revision or use of vaginal dilators.

CASE VIGNETTE: A 32-year-old G3P3 reports urinary incontinence while jogging with her 4-month-old. She sustained only a minor first-degree laceration at the time of her delivery.

DIAGNOSIS: Stress urinary incontinence
The incidence of stress urinary incontinence (SUI) during pregnancy is 39.1% and increases with each trimester.³¹ Developing SUI during pregnancy is a risk factor for having postpartum SUI. Fortunately, the majority of women (72.4% in one study) have resolution of their symptoms over time.³² Options for management of persistent SUI include physical therapy, pessaries, incontinence tampons, and surgery. Most physicians would wait to perform an anti-incontinence procedure until a patient’s childbearing is complete, and delay surgical therapy until at least 6 months after delivery because symptoms may resolve.

CASE VIGNETTE: A 23-year-old G2P2 presents 1 week postpartum with foul-smelling vaginal discharge and fever. On vaginal examination with speculum, a purulent sponge is found posterior to the cervix and removed with ring forceps.

DIAGNOSIS: Pelvic organ prolapse
Multiple deliveries with spontaneous perineal lacerations have been associated with development of prolapse beyond the hymen.³³ Pelvic organ prolapse (POP) surgery is more common in women with a history of both non-instrumented and instrumented vaginal deliveries as compared to women with only cesarean deliveries.³⁴ No preventative strategies have been identified to prevent development of POP. Treatment options are individualized based on a patient’s age, surgical history, and desire for future childbearing. Postpartum pelvic floor muscle training has not been shown to help correct POP.³⁵

DIAGNOSIS: Unintended retention of foreign object
When sponges become soaked in blood they can be difficult to identify; the rare complication of unintended retention of foreign object (URFO) is preventable. Retained surgical sponges, needles, or instruments can cause both infection and psychological harm. The average cost related to a URFO is > $200,000, in-
cluding legal defense, indemnity payments and surgical costs.36 The Minnesota Department of Health reported that in 2006, retained sponges during vaginal delivery were more frequent than all other types of URFOs.37 Findings from an earlier 1996 study also showed that vaginal delivery was the most likely reason for a URFO and in that review, none of the 11 cases of vaginally retained sponges were associated with a sponge count.38

Operating room principles apply to the repair of perineal trauma. These principles include before and after counts of sponges and needles, use of radio-detectable sponges with safety features such as tags, and vaginal examination followed by pelvic radiograph when a retained sponge is suspected.39 Using sponges that are larger, such as 8 inches or 18 inches (mini-laparotomy sponge), rather than the 4×4-inch gauze may also help reduce URFO.37

URFO may also occur if packing is placed for bleeding. When this is done, we recommend placing an arm band on the patient that stays on until the packing is removed. If a foreign body is found, that should be disclosed to the patient as well as to the hospital. The Joint Commission considers URFO a sentinel event and accredited organizations are expected to respond as part of a patient safety program.

Conclusion
Perineal lacerations are common and most resolve without sequelae. Good surgical technique helps prevent URFO and laceration repair should be conducted as any surgical procedure with good lighting, adequate analgesia, and appropriate help and equipment. Rectal examination at the time of vaginal delivery may help prevent missing fourth-degree lacerations. Avoiding routine episiotomy limits perineal trauma, which in turn may limit complications. For women with severe lacerations, including third- and fourth-degree lacerations, postpartum follow-up is important as these patients are at higher risk for FI, pain, and fistulae. Severe complications are rare and providers should be familiar with perineal complications following vaginal delivery.

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

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around 500,000 hysterectomies being performed annually in the United States. Further, the mode of access is now predominantly minimally invasive, which represents a significant shift from previous reports. If we assume that 150,000 hysterectomies are performed in ambulatory surgical centers with 81.5% of them being done laparoscopically/robotically and 16% transvaginally, then the proportion of mode of access can be estimated as shown in the Table.

These findings highlight the limitations of current understanding of hysterectomy volume and have important implications for resident education as well as medical device development. Although databases that are based on insurance data or hospital discharge information can be useful, they are limited in scope and often lack crucial information such as detailed perioperative outcomes and surgeon characteristics. The data we are looking at now are already several years old and may not accurately reflect current trends and realities. We need a more comprehensive prospective database to better understand what is actually happening in real time in our surgical environment.

That has important implications for policy makers, researchers, residency education, and medical device companies. A comprehensive prospective database of surgical procedures in gynecology is urgently needed.

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**Delay in timely delivery with placenta accreta**

A Georgia woman was diagnosed with placenta accreta during her pregnancy. About 10 days prior to the planned delivery date for 39 weeks gestation, she collapsed and died at home.

A lawsuit was filed and claimed the obstetricians made the decision to delay delivery to 39 weeks gestation instead of the standard of care, which required delivery no later than 36 weeks, and had she been delivered at that time it would have prevented her death.

**THE VERDICT** The case settled for $1.425 million.

**Oxytocin overdose and delivery delay blamed for CP**

A Pennsylvania woman was admitted to the hospital in 2012 for delivery of her baby. Oxytocin was ordered to accelerate the uterine contractions. The fetal heart rate (FHR) progressively slowed over the next hour, dropping to 60 bpm. The obstetrician took steps to expedite the delivery and 20 minutes later the head was crowning. Another 10 minutes went by and the obstetrician then cut an episiotomy and delivered the infant. The baby developed spastic quadriparesis cerebral palsy (CP). He experienced impaired cognition, seizures, and global aphasia.

The parents sued those involved with the delivery and claimed the obstetrician mishandled the delivery; failed to properly monitor the labor; started oxytocin when it was not necessary as the patient was progressing and used it at an inappropriately high dose; and failed to discontinue it when the FHR dropped. They also maintained that the obstetrician should have delivered the infant with forceps or vacuum when it was crowning.

The obstetrician countered that his treatment of the patient was proper, and he appropriately determined that vaginal delivery was the quickest route. He also testified that it was his practice to stop the oxytocin when the FHR dropped, but he had no independent recollection of stopping the oxytocin in this case. The obstetrician and hospital both argued that the infant’s CP stemmed from insufficiencies in the placenta, seizures, and meconium aspiration syndrome.

**THE VERDICT** The jury found in favor of the parents after a 2-week trial and a 4-hour deliberation, and they were awarded $14.48 million.

**Bowel perforation during robotic hysterectomy**

A New Jersey woman in her late 60s underwent a robotic sling procedure and hysterectomy, performed by her gynecologist. During the operation, she sustained a large perforation of the bowel outside the operative field. She developed sepsis and had multiple attempts at surgical repair. She ultimately required a colostomy.

**THE VERDICT** The woman sued the gynecologist claiming there was a failure to properly control the robotic device. She contended that she will require a permanent colostomy. The case settled for $6.25 million.

**Alleged failure to respond to FHR results in CP**

An Ohio woman filed a lawsuit against those involved in the 2010 delivery of her son. She originally presented to the hospital for delivery of her infant and the FHR tracings were reassuring. She claimed that, during the course of her labor, the FHR deteriorated and required intervention, but neither the obstetrician nor nurses recognized the need to expedite delivery. The infant was born not breathing and was then resuscitated. As a result of the lack of oxygen to his brain, he was diagnosed with CP. In the lawsuit, the parents claimed the child will need lifelong 24/7 care.

**THE VERDICT** The obstetrician settled with the parents for $1 million prior to trial. The case then proceeded against the nurse and hospital, and the jury returned a verdict for the child and parents, and $28.8 million that included $24.9 million in future care costs for the child, $2.9 million in lost earning capacity, and $500,000 each for non-economic damages to the parents.

**Neonatal death blamed on hypovolemia from double nuchal cord**

In 2006 an Illinois woman was at 40 weeks gestation when she was admitted to a local hospital in labor. A nurse midwife performed the vaginal delivery that evening. She noted a tight double nuchal cord as the head delivered and she reduced the cord at the perineum and delivered the rest of the infant. The baby was blotchy, limp, and extremely...
pale when she was placed on the mother’s chest. The nursing staff immediately realized the baby was not moving or crying and moved her to the warmer, initiated resuscitative measures, and called the special care nursery for assistance. The pediatrician immediately took charge of resuscitation and spent 38 minutes attempting to establish an airway and ventilation. Despite his efforts, the infant was pronounced dead at 40 minutes of life.

The parents sued all those involved with the delivery and resuscitation on behalf of the infant’s estate. They contended the midwife was negligent for failing to have a neonatal team present at the delivery due to the maternal fever and variable decelerations of the FHR. They claimed the tight nuchal cord prevented blood flow through the umbilical cord and the pediatrician was negligent for failing to replace the blood volume lost by the fetus due to complete umbilical vein occlusion, which caused hypovolemia, asphyxiation, and ultimately death.

The court granted the midwife’s motion for a directed verdict at the close of the plaintiff’s case. The pediatrician asserted that he performed a rigorous textbook resuscitation, that it was improbable that the nuchal cord completely occluded the umbilical vein, that volume administration would have been frivolous without first establishing an airway/ventilation and heartbeat, and, finally, that the baby’s death was due to complications of chorioamnionitis and funisitis, which were present prior to delivery.

**THE VERDICT** The jury found in favor of the defense.

### Urinary Injury During Hysterectomy

A 43-year-old South Carolina woman who suffered from multiple sclerosis (MS) underwent a hysterectomy performed by her gynecologist.

During the operation the ureter was injured, requiring additional surgery and leaving her with permanent incontinence.

The woman sued the gynecologist and claimed that he failed to notice that during the operation, he stitched around the ureter. She underwent a second surgery to remove the stitches and reimplant the ureter. She alleged it was the second surgery that left her permanently incontinent, and if the first surgery had been performed correctly, the second surgery would not have been necessary. She maintained the incontinence was not a part of her MS.

The gynecologist asserted there was no violation of the standard of care and there was no stitching around the ureter. He claimed the ureter was damaged by kinking and the second surgery was performed to address that. He contended the incontinence was a result of her MS.

**THE VERDICT** The jury deliberated for 2 hours after a 4-day trial and returned an award of $700,000 for the woman. This included $500,000 economic damages and $200,000 in non-economic damages.

### Claim that episiotomy was unnecessary

A 28-year-old Missouri woman had a stillbirth at 38 weeks gestation and underwent a vaginal delivery. The fetus had been diagnosed with a genetic cardiac problem and the pregnancy was managed by a maternal-fetal medicine specialist who performed the delivery. An episiotomy was done and resulted in a fourth-degree laceration during the delivery. A breakdown later occurred, necessitating a repair and an ileostomy. A third operation was done to remove the ileostomy.

The woman sued the physician who performed the delivery, claiming the episiotomy was unnecessary and that he failed to inform her of the risks of a fourth-degree laceration.

**THE VERDICT** The physician argued that the episiotomy was necessary and there was no need to obtain informed consent. The jury found in favor of the defense.
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To learn more about these and other opportunities, contact Heather Scott at 954.835.2844 or heather_scott@teamhealth.com, or visit www.teamhealth.com.

OB/GYN Physician needed near New York.

We have an opportunity for a physician to join our OB/GYN Hospitalist team at WCA Hospital in Jamestown, New York.

Enjoy working with a friendly team of professionals and put the passion back into your practice lifestyle by taking control of your time. The ideal candidate will be a Board Certified OB/Gyn physician (MD or DO) who demonstrates clinical excellence, superior communication skills, and a focus on providing quality care and placing the patient above all other considerations. Qualifications also include active and current skills in the full breadth of the OB/Gyn specialty, a current New York license to practice (all required licenses or certificates must be free from any past or current limitations and must not have been withdrawn, suspended, curtailed, placed on probation, or revoked). We ask that you have a willingness to drive patient safety and quality initiatives as required by the TeamHealth Patient Safety Organization, insurability for malpractice insurance, and at least 2 years of active practice with a successful track record.

This position also offers flexible scheduling providing excellent work/life balance, paid PLI with tail coverage and no responsibilities while off where full-time averages 8 (24-hour in-house) shifts per month.

To learn more about these and other opportunities, contact Heather Scott at 954.835.2844 or heather_scott@teamhealth.com, or visit www.teamhealth.com.

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Clinical Assistant Professor

ATTENDING PHYSICIAN

The Department of Obstetrics and Gynecology at SUNY Downstate, one of the nation’s leading urban medical centers, located in Brooklyn, NY is seeking to recruit an Attending Physician at the Clinical Assistant Professor level.

Core Responsibilities:

The responsibilities of this full-time faculty physician will include:

- Alternating services in: Labor and Delivery, Outpatient Clinic, Surgical Procedures, Supervision of Obstetrics and Gynecology Residents and teaching Medical Students.

Core Requirements:

Applicant must be Board Eligible/Board Certified in Obstetrics and Gynecology with a New York State License to practice Medicine.

To Apply: Please send CV and Cover Letter to:

Ovadia Abulafia, M.D.,
Professor and Chairman
Department of Obstetrics and Gynecology
SUNY - Downstate Medical Center
450 Clarkson Avenue - MSC 24
Brooklyn, NY 11203

Telephone: (718) 270-2081
Ovadia.Abulafia@Downstate.EDU

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WESTERN OHIO METRO UNIVERSITY COMMUNITY

Opportunities include joining well established hospital employed obgyn groups and clinical/faculty general obgyn positions with 800 bed health system with Level III NICU and top ranked medical school and obgyn residency program in dynamic family oriented metro of 400,000 population. 1-7 call. Very strong long term, negotiable mid $300K salary, generous signing/retention/student loan bonus, benefits including malpractice tail liability and relocation.

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ADVERTISER INDEX

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In 2004, a Kansas woman presented to the hospital for delivery of her baby. The nurse midwife managing the labor, sought an obstetrician’s intervention when the head did not descend easily. The obstetrician used forceps to assist the delivery. She applied traction, pulling gently with a contraction 3 times, then removed the forceps, and an 8 pound 8 ounce infant was delivered.

The parents sued the obstetrician after the delivery alleging the infant suffered a skull fracture, lacerated ear, bruising around his scalp, and bleeding in the brain as a result of the forceps. They attributed his cognitive impairment and epilepsy to the injuries he received at birth. The lawsuit claimed the obstetrician’s use of forceps was below the standard; the forceps were misplaced; and she should have delivered the infant by cesarean.

The obstetrician countered that the fact of the baby’s vaginal delivery negated the claim that he was too large for such a delivery, also there was some question as to whether the baby actually suffered a skull fracture. She maintained that she used proper procedure for application of the forceps and understood the position of the fetal head. She further argued that the normal forces of labor could account for the infant’s injuries at the time of birth, and that the epilepsy is not related to his delivery. The defense also argued the child’s developmental issues were mild - he participates in sports and is in the same grade as others his age.

With an appropriate indication for use of the instrument, it is possible to successfully defend a malpractice case.

The jury found in favor of the defense.

ANALYSIS
In malpractice cases involving instruments used to assist with delivery of an infant such as vacuum and forceps, the 2 issues that come up are usually the actual use and placement of the instruments and the indication for their use. It is often difficult to prove that the instrument was negligently placed unless the injury is a skull fracture or some other head trauma, and it is then assumed that the instrument caused the injury. So, the case then focuses on the indication for using the device. With an appropriate indication for use of the instrument, it is possible to successfully defend a malpractice case. It is imperative that the indication for using vacuum or forceps for delivery be documented in the medical record along with any or no difficulty in placing the device.

FOR MORE LEGALLY SPEAKING CASES TURN TO PAGE 39

Ms Collins is an attorney specializing in medical malpractice in Long Beach, California. She can be reached at dawncfree@gmail.com.
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We’re committed to telling it with the utmost accuracy.

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