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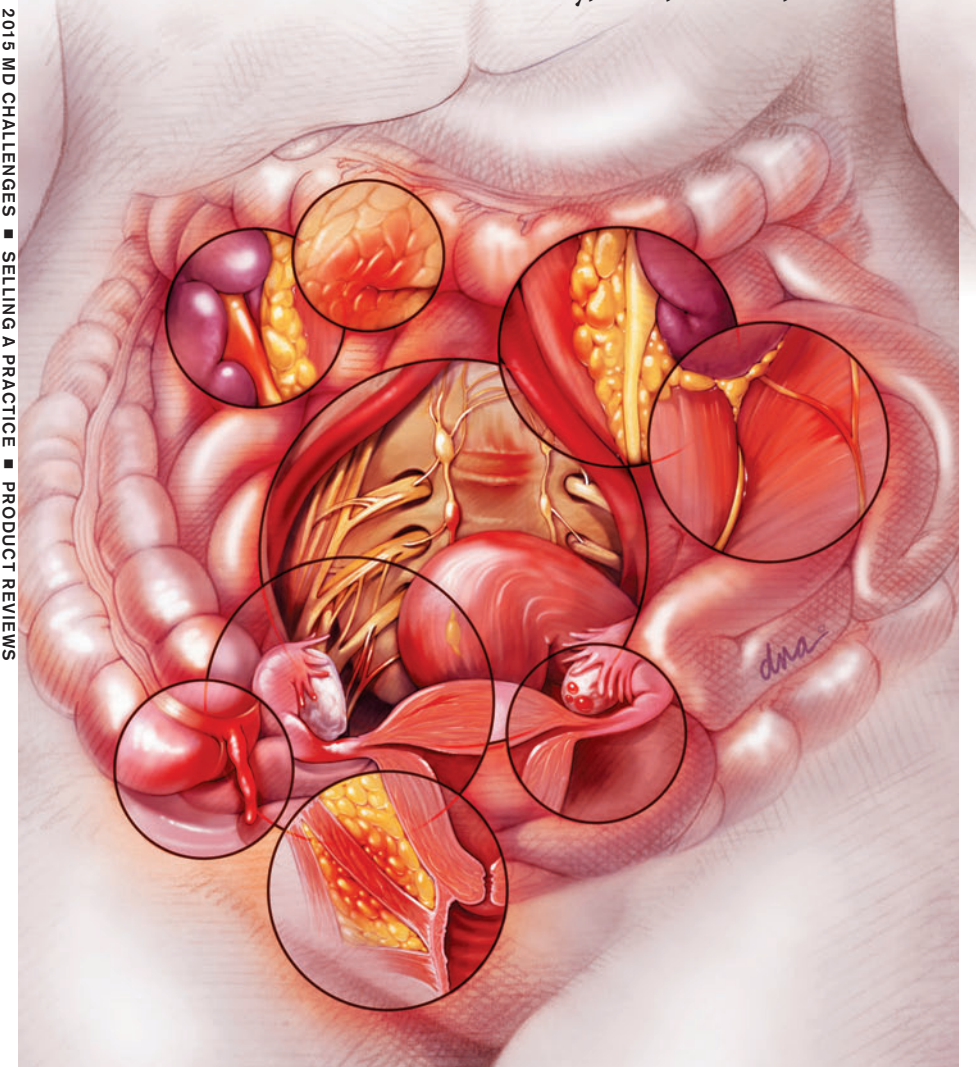
Contemporary OB/GYN®

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

CARING FOR PATIENTS WITH CHRONIC PELVIC PAIN

Erin T. Carey, MD, MSCR, and Austin Findley, MD



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Lo Loestrin® Fe (norethindrone acetate and ethinyl estradiol tablets, ethinyl estradiol tablets and ferrous fumarate tablets)

BRIEF SUMMARY: Consult the Package Insert for Complete Prescribing Information

WARNING: CIGARETTE SMOKING AND SERIOUS CARDIOVASCULAR EVENTS

Cigarette smoking increases the risk of serious cardiovascular events from combination oral contraceptive (COC) use. This risk increases with age, particularly in women over 35 years of age, and with the number of cigarettes smoked. For this reason, COCs should not be used by women who are over 35 years of age and smoke *[see Contraindications (4)]*.

1 INDICATIONS AND USAGE

Lo Loestrin® Fe is indicated for use by women to prevent pregnancy.

The efficacy of Lo Loestrin Fe in women with a body mass index (BMI) of > 35 kg/m^2 has not been evaluated.

4 CONTRAINDICATIONS

Do not prescribe Lo Loestrin Fe to women who are known to have the following conditions:

- A high risk of arterial or venous thrombotic diseases. Examples include women who are known to:
  - Smoke, if over age 35 *[see Boxed Warning* and *Warnings and Precautions (5.1)]*
  - Have deep vein thrombosis or pulmonary embolism, now or in the past *[see Warnings and Precautions (5.1)]*
  - Have cerebrovascular disease *[see Warnings and Precautions (5.1)]*
  - Have coronary artery disease *[see Warnings and Precautions (5.1)]*
  - Have thrombogenic valvular or thrombogenic rhythm diseases of the heart (for example, subacute bacterial endocarditis with valvular disease, or atrial fibrillation) *[see Warnings and Precautions (5.1)]*
  - Have inherited or acquired hypercoagulopathies *[see Warnings and Precautions (5.1)]*
  - Have uncontrolled hypertension *[see Warnings and Precautions (5.4)]*
  - Have diabetes mellitus with vascular disease *[see Warnings and Precautions (5.6)]*
  - Have headaches with focal neurological symptoms or have migraine headaches with or without aura if over age 35 *[see Warnings and Precautions (5.7)]*
- Breast cancer or other estrogen- or progestin-sensitive cancer, now or in the past *[see Warnings and Precautions (5.2)]*
- Liver tumors, benign or malignant, or liver disease *[see Warnings and Precautions (5.3)]*
- Undiagnosed abnormal uterine bleeding *[see Warnings and Precautions (5.8)]*
- Pregnancy, because there is no reason to use COCs during pregnancy *[see Warnings and Precautions (5.9)* and *Use in Specific Populations (8.1)]*

5 WARNINGS AND PRECAUTIONS

5.1 Thrombotic and Other Vascular Events

Stop Lo Loestrin Fe if an arterial or deep venous thrombotic event occurs. Although use of COCs increases the risk of venous thromboembolism, pregnancy increases the risk of venous thromboembolism as much or more than the use of COCs. The risk of venous thromboembolism in women using COCs is 3 to 9 per 10,000 woman-years. The risk is highest during the first year of use of a COC. Use of COCs also increases the risk of arterial thromboses such as strokes and myocardial infarctions, especially in women with other risk factors for these events. The risk of thromboembolic disease due to oral contraceptives gradually disappears after COC use is discontinued.

If feasible, stop Lo Loestrin Fe at least 4 weeks before and through 2 weeks after major surgery or other surgeries known to have an elevated risk of thromboembolism.

Start Lo Loestrin Fe no earlier than 4 weeks after delivery, in women who are not breastfeeding. The risk of postpartum thromboembolism decreases after the third postpartum week, whereas the risk of ovulation increases after the third postpartum week.

COCs have been shown to increase both the relative and attributable risks of cerebrovascular events (thrombotic and hemorrhagic strokes), although, in general, the risk is greatest in older (> 35 years of age), hypertensive women who also smoke. COCs also increase the risk for stroke in women with underlying risk factors.

Oral contraceptives must be used with caution in women with cardiovascular disease risk factors.

Stop Lo Loestrin Fe if there is unexplained loss of vision, proptosis, diplopia, papilledema, or retinal vascular lesions. Evaluate for retinal vein thrombosis immediately.

5.2 Carcinoma of the Breast and Cervix

Women who currently have or have had breast cancer should not use Lo Loestrin Fe because breast cancer is a hormonally-sensitive tumor.

There is substantial evidence that COCs do not increase the incidence of breast cancer. Although some past studies have suggested that COCs might increase the incidence of breast cancer, more recent studies have not confirmed such findings.

5.9 COC Use Before or During Early Pregnancy

Extensive epidemiologic studies have revealed no increased risk of birth defects in women who have used oral contraceptives prior to pregnancy. Studies also do not suggest a teratogenic effect, particularly in so far as cardiac anomalies and limb reduction defects are concerned, when oral contraceptives are taken inadvertently during early pregnancy. Lo Loestrin Fe use should be discontinued if pregnancy is confirmed.

Administration of oral contraceptives to induce withdrawal bleeding should not be used as a test for pregnancy *[see Use in Specific Populations (8.1)]*.

5.10 Depression

Women with a history of depression should be carefully observed and Lo Loestrin Fe discontinued if depression recurs to a serious degree.

5.11 Interference with Laboratory Tests

The use of COCs may change the results of some laboratory tests, such as coagulation factors, lipids, glucose tolerance, and binding proteins. Women on thyroid hormone replacement therapy may need increased doses of thyroid hormone because serum concentrations of thyroid binding globulin increase with use of COCs.

5.12 Monitoring

A woman who is taking COCs should have a yearly visit with her healthcare provider for a blood pressure check and for other indicated healthcare.

5.13 Other Conditions

In women with hereditary angioedema, exogenous estrogens may induce or exacerbate symptoms of angioedema. Chloasma may occasionally occur, especially in women with a history of chloasma gravidarum. Women with a tendency to chloasma should avoid exposure to the sun or ultraviolet radiation while taking COCs.

6 ADVERSE REACTIONS

The following serious adverse reactions with the use of COCs are discussed elsewhere in the labeling:

- Serious cardiovascular events and smoking *[see Boxed Warning* and *Warnings and Precautions (5.1)]*
- Vascular events *[see Warnings and Precautions (5.1)]*
- Liver disease *[see Warnings and Precautions (5.3)]*

Adverse reactions commonly reported by COC users are:

- Irregular uterine bleeding
- Breast tenderness
- Nausea
- Headache

6.1 Clinical Trial Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to the rates in the clinical trials of another drug and may not reflect the rates observed in practice.

A multicenter phase 3 clinical trial evaluated the safety and efficacy of Lo Loestrin Fe for pregnancy prevention. The study was a one year, open-label, single-arm, uncontrolled study. A total of 1,660 women aged 18 to 45 were enrolled and took at least one dose of Lo Loestrin Fe.

Common Adverse Reactions (≥ 2 percent of all Treated Subjects): The most common adverse reactions reported by at least 2 percent of the 1,660 women using Lo Loestrin Fe were the following in order of decreasing incidence: nausea/vomiting (7 percent), headache (7 percent), bleeding irregularities (including metrorrhagia, irregular menstruation, menorrhagia, vaginal hemorrhage and dysfunctional uterine bleeding) (5 percent), dysmenorrhea (4 percent), weight fluctuation (4 percent), breast tenderness (4 percent), acne (3 percent), abdominal pain (3 percent), anxiety (2 percent), and depression (2 percent).

Adverse Reactions Leading to Study Discontinuation: 10.7 percent of the women discontinued from the clinical trial due to an adverse reaction. Adverse reactions occurring in ≥1 percent of subjects leading to discontinuation of treatment were in decreasing order: menstrual irregularities (including metrorrhagia, irregular menstruation, menorrhagia and vaginal hemorrhage) (4 percent), headache/migraine (1 percent), mood disorder (including mood swings, depression, anxiety) (1 percent), and weight fluctuation (1 percent).

Serious Adverse Reactions: deep vein thrombosis, ovarian vein thrombosis, cholecystitis.

7 DRUG INTERACTIONS

No drug-drug interaction studies were conducted with Lo Loestrin Fe.

7.1 Changes in Contraceptive Effectiveness Associated with Co-Administration of Other Products

If a woman on hormonal contraceptives takes a drug or herbal product that induces enzymes, including CYP3A4, that metabolize contraceptive hormones, counsel her to use additional contraception or a different method of contraception. Drugs or herbal products that induce such enzymes may decrease the plasma concentrations of contraceptive hormones, and may decrease the effectiveness of hormonal contraceptives or increase breakthrough bleeding. Some drugs or herbal products that may decrease the effectiveness of hormonal contraceptives include:

- barbiturates
- bosentan
- carbamazepine
- felbamate
- griseofulvin
- oxcarbazepine
- phenytoin
- rifampin
- St. John's wort
- topiramate

HIV protease inhibitors and non-nucleoside reverse transcriptase inhibitors: Significant changes (increase or decrease) in the plasma levels of the estrogen and progestin have been noted in some cases of co-administration of HIV protease inhibitors or of non-nucleoside reverse transcriptase inhibitors.

Antibiotics: There have been reports of pregnancy while taking hormonal contraceptives and antibiotics, but clinical pharmacokinetic studies have not shown consistent effects of antibiotics on plasma concentrations of synthetic steroids.

Consult the labeling of all concurrently-used drugs to obtain further information about interactions with hormonal contraceptives or the potential for enzyme alterations.

7.2 Increase in Plasma Levels of Ethinyl Estradiol Associated with Co-Administered Drugs

Co-administration of atorvastatin and certain COCs containing ethinyl estradiol increase AUC values for ethinyl estradiol by approximately 20 percent. Ascorbic acid and acetaminophen may increase plasma ethinyl estradiol levels, possibly by inhibition of conjugation. CYP3A4 inhibitors such as itraconazole or ketoconazole may increase plasma hormone levels.

7.3 Changes in Plasma Levels of Co-Administered Drugs

COCs containing some synthetic estrogens (for example, ethinyl estradiol) may inhibit the metabolism of other compounds. COCs have been shown to significantly decrease plasma concentrations of lamotrigine, likely due to induction of lamotrigine glucuronidation. This may reduce seizure control; therefore, dosage adjustments of lamotrigine may be necessary. Consult the labeling of the concurrently-used drug to obtain further information about interactions with COCs or the potential for enzyme alterations.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

There is little or no increased risk of birth defects in women who inadvertently use COCs during early pregnancy. Epidemiologic studies and meta-analyses have not found an increased risk of genital or non-genital birth defects (including cardiac anomalies and limb reduction defects) following exposure to low dose COCs prior to conception or during early pregnancy.

The administration of COCs to induce withdrawal bleeding should not be used as a test for pregnancy. COCs should not be used during pregnancy to treat threatened or habitual abortion.

Women who do not breastfeed should not start COCs earlier than 4 weeks postpartum.

8.3 Nursing Mothers

When possible, advise the nursing mother to use other forms of contraception until she has weaned her child. Estrogen-containing OCs can reduce milk production in breastfeeding mothers. This is less likely to occur once breastfeeding is well-established; however, it can occur at any time in some women. Small amounts of oral contraceptive steroids and/or metabolites are present in breast milk.

8.4 Pediatric Use

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

8.5 Geriatric Use

Lo Loestrin Fe has not been studied in postmenopausal women and are not indicated in this population.

8.6 Renal Impairment

The pharmacokinetics of Lo Loestrin Fe has not been studied in subjects with renal impairment.

8.7 Hepatic Impairment

No studies have been conducted to evaluate the effect of hepatic impairment on the disposition of Lo Loestrin Fe. However, steroid hormones may be poorly metabolized in patients with impaired liver function. Acute or chronic disturbances of liver function may necessitate the discontinuation of COC use until markers of liver function return to normal and COC causation has been excluded *[see Contraindications (4)* and *Warnings and Precautions (5.3)]*.

8.8 Body Mass Index

The safety and efficacy of Lo Loestrin Fe in women with a body mass index (BMI) > 35 kg/m^2 has not been evaluated.

10 OVERDOSAGE

There have been no reports of serious ill effects from overdose of oral contraceptives, including ingestion by children. Overdosage may cause withdrawal bleeding in females and nausea.

17 PATIENT COUNSELING INFORMATION

See FDA-approved patient labeling.

Based on Lo Loestrin Fe Prescribing information dated 06/2012.

Manufactured By:
Warner Chilcott Company, LLC
Fajardo, PR 00738

Distributed By:
Actavis Pharma, Inc.
Parsippany, NJ 07054

Some studies suggest that COCs are associated with an increase in the risk of cervical cancer or intraepithelial neoplasia. However, there is controversy about the extent to which these findings may be due to differences in sexual behavior and other factors.

5.3 Liver Disease
Discontinue Lo Loestrin Fe if jaundice develops. Steroid hormones may be poorly metabolized in patients with impaired liver function. Acute or chronic disturbances of liver function may necessitate the discontinuation of COC use until markers of liver function return to normal and COC causation has been excluded.

Hepatic adenomas are associated with COC use. An estimate of the attributable risk is 3.3 cases per 100,000 COC users. Rupture of hepatic adenomas may cause death through intra-abdominal hemorrhage.

Studies have shown an increased risk of developing hepatocellular carcinoma in long-term (>8 years) COC users. However, the attributable risk of liver cancers in COC users is less than one case per million users.

Oral contraceptive-related cholestasis may occur in women with a history of pregnancy-related cholestasis. Women with a history of COC-related cholestasis may have the condition recur with subsequent COC use.

5.4 High Blood Pressure
For women with well-controlled hypertension, monitor blood pressure and stop Lo Loestrin Fe if blood pressure rises significantly. Women with uncontrolled hypertension or hypertension with vascular disease should not use COCs.

An increase in blood pressure has been reported in women taking COCs, and this increase is more likely in older women with extended duration of use. The incidence of hypertension increases with increasing concentrations of progestin.

5.5 Gallbladder Disease
Studies suggest a small increased relative risk of developing gallbladder disease among COC users.

5.6 Carbohydrate and Lipid Metabolic Effects
Carefully monitor prediabetic and diabetic women who are taking Lo Loestrin Fe. COCs may decrease glucose tolerance in a dose-related fashion.

Consider alternative contraception for women with uncontrolled dyslipidemias. A small proportion of women will have adverse lipid changes while on COCs.

Women with hypertriglyceridemia, or a family history thereof, may be at an increased risk of pancreatitis when using COCs.

5.7 Headache
If a woman taking Lo Loestrin Fe develops new headaches that are recurrent, persistent, or severe, evaluate the cause and discontinue Lo Loestrin Fe if indicated.

An increase in frequency or severity of migraine during COC use (which may be prodromal of a cerebrovascular event) may be a reason for immediate discontinuation of the COC.

5.8 Bleeding Irregularities and Amenorrhea
Unscheduled (breakthrough or intracyclic) bleeding and spotting sometimes occur in patients on COCs, especially during the first three months of use. If bleeding persists or occurs after previously regular cycles, check for causes such as pregnancy or malignancy. If pathology and pregnancy are excluded, bleeding irregularities may resolve over time or with a change to a different COC.

The clinical trial that evaluated the efficacy of Lo Loestrin Fe also assessed unscheduled bleeding and/or spotting. The participants in this 12-month clinical trial (N = 1,582 who had at least one post-treatment evaluation) completed over 15,000 cycles of exposure.

A total of 1,257 women (85.9 percent) experienced unscheduled bleeding and/or spotting at some time during Cycles 2 to 13 of this study. The incidence of unscheduled bleeding and/or spotting was highest during Cycle 2 (53 percent) and lowest at Cycle 13 (36 percent). Among these women, the mean number of days of unscheduled bleeding and/or spotting during a 28-day cycle ranged from 1.8 to 3.2 days.

Scheduled (withdrawal) bleeding and/or spotting remained fairly constant over the one year study, with an average of less than 2 days per cycle.

Women who are not pregnant and use Lo Loestrin Fe may experience amenorrhea (absence of scheduled and unscheduled bleeding/spotting). In the clinical trial with Lo Loestrin Fe, the incidence of amenorrhea increased from 32 percent in Cycle 1 to 49 percent by Cycle 13. If scheduled (withdrawal) bleeding does not occur, consider the possibility of pregnancy. If the patient has not adhered to the prescribed dosing schedule (missed one or more active tablets or started taking them on a day later than she should have), consider the possibility of pregnancy at the time of the first missed period and take appropriate diagnostic measures. If the patient has adhered to the prescribed regimen and misses two consecutive periods, rule out pregnancy.

Some women may experience amenorrhea or oligomenorrhea after stopping COCs, especially when such a condition was preexistent.

INDICATION AND USAGE for Lo Loestrin® Fe

Lo Loestrin Fe is an estrogen/progestin combination oral contraceptive (COC) indicated for use by women to prevent pregnancy. The efficacy of Lo Loestrin Fe in women with a body mass index (BMI) of >35 kg/m^2 has not been evaluated.

SELECTED SAFETY INFORMATION about Lo Loestrin Fe, including Boxed Warning

WARNING: CIGARETTE SMOKING AND SERIOUS CARDIOVASCULAR EVENTS

Cigarette smoking increases the risk of serious cardiovascular events from combination oral contraceptive (COC) use. This risk increases with age, particularly in women over 35 years of age, and with the number of cigarettes smoked. For this reason, Lo Loestrin Fe should not be used by women who are over 35 years of age and smoke.

Lo Loestrin Fe is contraindicated in pregnant patients, and those with a high risk of arterial or venous thrombotic diseases, liver tumors (benign or malignant) or liver disease, undiagnosed abnormal uterine bleeding, or breast cancer or other estrogen- or progestin-sensitive cancer, now or in the past.

Discontinue Lo Loestrin Fe if a thrombotic event occurs, and at least 4 weeks before and through 2 weeks after major surgery. Lo Loestrin Fe should not be started any earlier than 4 weeks after delivery, in women who are not breastfeeding. If jaundice occurs, treatment should be discontinued.

Lo Loestrin Fe should not be prescribed for women with uncontrolled hypertension or hypertension with vascular disease. Women who are pre-diabetic or diabetic, should be monitored while using Lo Loestrin Fe. Alternate contraceptive methods should be considered for women with uncontrolled dyslipidemia. Patients using Lo Loestrin Fe who have a significant change in headaches or irregular bleeding or amenorrhea should be evaluated.

In the clinical trial for Lo Loestrin Fe, serious adverse reactions included deep vein thrombosis, ovarian vein thrombosis, and cholecystitis. The most common adverse reactions (incidence ≥2%) were nausea/vomiting, headache, bleeding irregularities, dysmenorrhea, weight fluctuation, breast tenderness, acne, abdominal pain, anxiety, and depression.

Patients should be counseled that COCs do not protect against HIV infection (AIDS) and other sexually transmitted diseases.

To report a Suspected Adverse Reaction from one of our products, please contact Actavis Drug Safety Department at 1-800-272-5525.

References: 1. Lo Loestrin® Fe prescribing information. Rockaway, NJ: Warner Chilcott (US), LLC; 2012. **2.** Data on file. Rockaway, NJ: Warner Chilcott (US), LLC.

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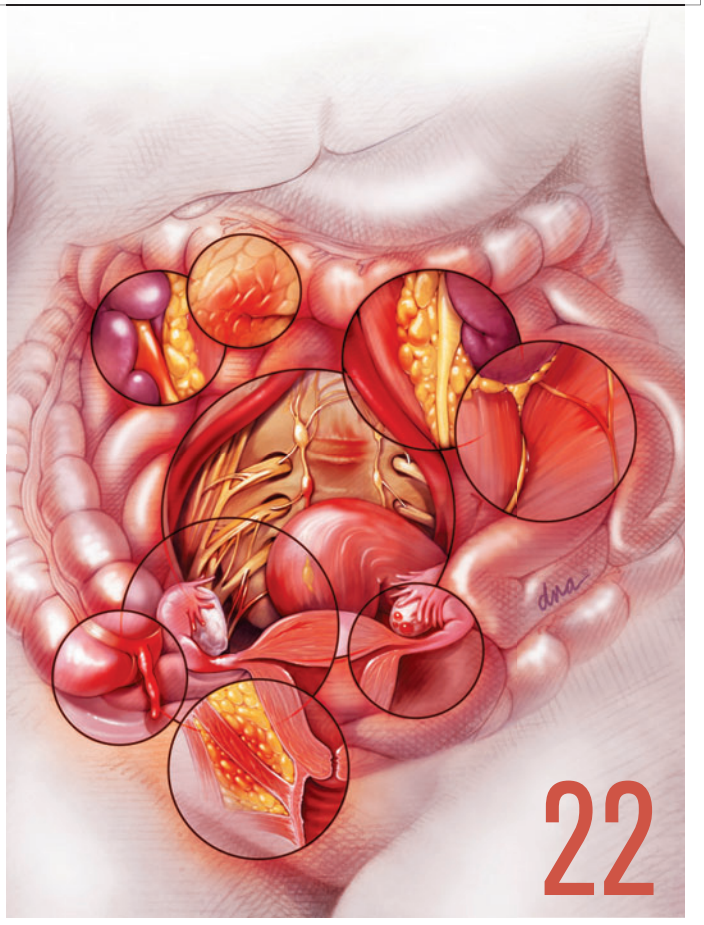

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The vaginal swab collection device is specifically validated to collect specimens for assays that require vaginal samples from **symptomatic** women for diagnostic testing for vaginitis (ie, NuSwab® VG and NuSwab VG+ for bacterial vaginosis.)

Vaginal swabs have been recognized by the CDC as the optimal specimen type for nucleic acid amplification (NAA) testing for *Chlamydia* and *Gonorrhea* detection in women with and without symptoms.[1] Vaginal swabs may also be used for high-quality NAA molecular tests for HSV1/2, *Trichomonas*, and *Mycoplasma*.

Liquid-based cytology specimens

Liquid-based cytology collection devices are used for cervical (endocervical) **screening** protocols and certain molecular tests, such as *Chlamydia, Gonorrhea*, HPV, and *Trichomonas*. These collection devices are not designed (or acceptable) for collecting and transporting specimens for tests that require vaginal samples.

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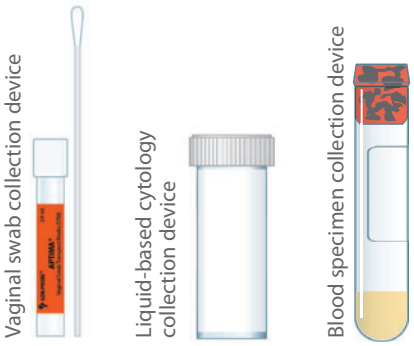
Acceptable specimens for other women's health-related tests

- **Cystic fibrosis carrier screening genetic test:** Blood or buccal swab
- ***Treponema pallidum*/syphilis:** Blood
- **Group B strep:** Vaginal/rectal specimen collected with a bacterial transport swab (screening according to CDC guidelines[2])
- **Bacterial vaginosis**—Requires a vaginal sample. Endocervical specimens from a Pap vial are not acceptable specimens or collection devices.

Note: A single collection device is not appropriate for processing a combination of tests that fall into multiple categories, such as genetic, bacterial, and molecular infectious disease.



To learn more about the test options, visit **www.LabCorp.com.**

1. Centers for Disease Control and Prevention. Recommendations for the laboratory-based detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae*- 2014. *MMWR.* 2014 Mar 14;63(2):1-19.
2. Centers for Disease Control and Prevention. Prevention of perinatal Group B Streptococcal disease. *MMWR.* 2010 Nov 19;(59)RR-10:1-33.

BY **CHARLES J. LOCKWOOD, MD, MHCM**

Professional liability reform

Is it time to double down or change direction?

Driving through Tampa, you can't help being struck by the inordinate number of billboards advertising the services of personal injury attorneys. These ads also festoon newspapers and fill the air waves and television channels. Of course, the millions of dollars generated by media companies come at a high cost to the economy.

Beyond the actual costs of litigation, and of excess professional liability insurance premiums, defensive medicine adds billions to US healthcare costs. Baicker and associates noted that professional liability premium increases during the height of the last malpractice insurance crisis were associated with a staggering $15 billion increase in Medicare spending.[1] Every 10% increase in malpractice payments was associated with a nearly 1% increase in physician-directed healthcare spending.

While most rational observers accept that defensive medicine contributes to excessive healthcare costs, it has been difficult to establish a precise correlation between tort reform efforts and reductions in such medical practices or their costs. Trial lawyers and their apologists argue that tort reform has no economic impact, but objective analysis suggests otherwise. Detailed economic modeling data presented by Kessler and McClellan indicate that federal caps on noneconomic damages and other measures could reduce healthcare costs by nearly 10%.[2]

So after two decades of internecine conflict in state legislatures and in Congress between lobbyists and various advocates of trial lawyers and organized medicine over tort reform, where do we stand?

Trial lawyers and their apologists argue that tort reform has no economic impact, **but objective analysis suggests otherwise.**

Fewer malpractice claims, cheaper premiums

Mello and her associates merged payment data from the National Practitioner Database (NPDB) with the American Medical Association's master file and carried out a Poisson regression of numbers of claims per 1000 physicians over time in five representative markets.[3] These included Southern California, Long Island, New York, and select counties in Illinois and the states of Tennessee and Colorado. They also studied professional liability premium costs over time extracted from the Medical Liability Monitor's Annual Rate Survey.

They reported that the annual rate of paid claims per 1000 physicians had fallen markedly, from 18.6 to 9.9, between 2002 and 2013.

During that same period, the annual average rate of claims paid per 1000 physicians decreased by 6.3% (95% CI: 6.2% to 6.5%) for MDs and 5.3% (95% CI: 4.8% to 5.9%) for DOs. Moreover, since 2007, the median indemnity paid decreased from $218,400 to $195,000 and high-end award values have plateaued. Interestingly, only 3.4% of payments made from 1994 to 2013 resulted from jury verdicts. And while there is regional variability, in general, professional liability insurance premiums have dropped, with the largest decreases in states where the toughest tort reform measures have been enacted.

Thus, between 2004 and 2013, California, Illinois, and Tennessee have seen a 36% drop in premiums for internists and ob/gyns and a 30% drop for general surgeons, while Long Island, New York, witnessed increases of 12% for ob/gyns, 16% for internists, and 35% for general surgeons.

WE WANT TO HEAR FROM YOU

Send your feedback to:
DrLockwood@advanstar.com.

There was more than a five-fold difference in premiums paid by ob/gyns in Tennessee (about $40,000) versus Miami-Dade County (about $190,000).

Now, I seriously doubt that South Florida ob/gyns are five-fold less safe or, indeed, any less safe, than their brethren in Tennessee!

Why these generally favorable professional liability trends?

Medical liability tort reforms have traditionally focused on creating barriers to lawsuits and limiting payments.[3] Primary contrivances for the former are screening panels and certificate-of-merit requirements. Payment limits typically take the form of caps on potential capricious non-economic awards, collateral source rule reforms, and joint and several liability reform.

Mello and her associates are largely dismissive, and I would argue prematurely so, of the notion that tort reform has played a significant role in the recent, albeit inconsistent, reduction in professional liability insurance premiums. They contend that these reductions are better ascribed to the mysterious cycle of the malpractice insurance market.

I would counter that recent drops in premiums are of a greater magnitude than accompanied resolution of prior crises, disproportionately favor states with the strictest reforms and are, in general, too temporally coupled with broad successes in state professional liability reforms accompanying recent Republican domination of state house, senate, and gubernatorial races not to be ascribable, at least in part, to tort reform. For example, there are now more than 30 states with caps on non-economic damages. Moreover, why would fluctuations in the insurance market alone trigger falling claims and payments?

Alternatives to traditional tort reform

Mello and her associates do make a compelling case that the current professional liability system has largely failed to achieve its two fundamental purposes: compensating victims and deterring errors. They propose a laundry list of common-sense, ethically unassailable, though largely unproven measures to further drive down costs and increase fairness.

First on the list are so-called communication and resolution programs. These take the general form of candid discussions between patients and/or their families and providers about the cause(s) of unexpected outcomes, disclosure of root cause analyses, and acceptance of responsibility appropriate to the circumstance. Immediate compensation is offered if appropriate. This approach has been pioneered by the University of Michigan and certain large VA hospitals, with apparent reductions in their malpractice-related expenses.

The applicability in smaller community settings, however, is unproven. "Apology laws" have been adopted by most states but, while well-intentioned, they have not been shown to decrease costs and, in certain states selectively advantage plaintiff attorneys. Similarly, cooling-off periods to allow time for mediation have now been mandated by 11 states, but with as yet unrealized benefits.

Likely more effective are state-facilitated dispute resolution laws, such as have recently been enacted in Oregon. The theory is that confidential "early discussions" between patients and providers concerning an unexpected untoward event will achieve prompt dispute resolution. If that initial effort fails, a mediator may be engaged. Patients and their families retain the ability to file a lawsuit prior to any settlement. However, all settlements must be reported to the NPDB, which likely will diminish physician participation. Nonetheless, it will be interesting to track healthcare costs in Oregon over time.

'Apology laws' have been adopted by most states but **have not been shown to decrease costs** and may selectively advantage plaintiff attorneys.

Benefits of tort reform and increased dialogue may be complementary

I contend that traditional tort reform initiatives and efforts to improve the transparency of error notification are not mutually exclusive and are probably complementary, if not synergistic, since both providers and patients are far more likely to engage in real dialogue if the system is perceived to be fairer and payments are tightly linked to actual otherwise uncompensated costs and apportioned fairly among those responsible.

Thus, we should double down on federal tort reform efforts and expand state programs to locales where basic reforms have been stymied by the trial lawyer lobby. Simultaneously, we should study non-traditional approaches, which I suspect will best take root in the fertile soil of tort reform.

Take-home message

Regardless of whether insurance cycles, tort reform, or increased transparency in patent-provider dialogue have contributed to reduced malpractice claims and payments, I am absolutely convinced that the very best way to reduce professional liability claims, payments, and premiums—and ultimately the cost of defensive medicine—is by simply not making errors.

My colleagues and I have demonstrated that patient safety programs work in obstetrics, and that they reduce adverse outcomes and cost while improving both patient and caregiver satisfaction.[4,5] Thus, I have a strong hunch that the findings of Mello and associates are in no small measure also the result of the growing patient safety movement. COG

READ A LETTER TO THE EDITOR REGARDING 'PREVENTING URETERAL INJURY AT HYSTERECTOMY: AN EXPERT APPROACH' ON PAGE 39.

DR LOCKWOOD, Editor-in-Chief, is Dean of the Morsani College of Medicine and Senior Vice President of USF Health, University of South Florida, Tampa. He can be reached at DrLockwood@advanstar.com.

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BY **BRIAN A. LEVINE, MD, MS,**
AND **DAN GOLDSCHLAG, MD, FACOG**

Top 5 apps for ob/gyns and their patients in 2015

No more excuses for not reaching your health and fitness goals: These apps do (almost) everything for you.

We are witnessing an interesting trend in the mobile phone market. During the late 1990s and early 2000s, mobile phone manufacturers focused on making phones as small and unobtrusive as possible.

In the intervening decade, phones have gotten larger, and in the past 18 months, we have seen mainstream smartphones of record size, including the iPhone 6 4.7" display, iPhone 6 Plus 5.5" display, Galaxy S5 5.1" display, and Galaxy Note 5.3" display. Given these dramatic increases in screen real estate, the onus is on app developers not only to create visually pleasing apps that capitalize on increased screen resolution, but also to take advantage of a device's ability to present large amounts of information on a single screen.

Here are our top apps for women's health practitioners and their patients in 2015.

1 iOS Health

www.apple.com/ios/whats-new/health/

Not only did Apple's newest operating system, iOS, come with a bevy of improvements to the strength, power, and capability of iPhones, but it also came with a preloaded healthcare-focused app named Health. With this unified metric-based wellness consolidation app, users can track a wide array of health and wellness information via statistics on the dashboard.

Think of Health as an easy-to-use and easy-to-navigate repository of health information. Samsung and other Android manufacturers have fragmented the Android health data storage market with their individual iterations, while Apple aims for a single app on a single secure platform.

Information can be automatically synced between Health and other wellness apps, such as those that track weight, heart rate, blood pressure, steps, and sleep. In fact, iOS Health has a built-in pedometer that tracks your steps.

Apple prohibits the app from connecting with third-party developers that might trade sensitive information, such as "advertising platforms, data brokers, or information resellers," without user permission. In fact, Apple encrypts the information with the security used to lock their phones, which has been cited by the FBI as being almost too secure.

> Apple encrypts the information with the security used to lock their phones, which has been cited by the FBI as **being almost too secure**.

Health users can enter almost any piece of health information, such as blood test results, or they can sync their Health app with other electronic health record manufacturers' apps. For example, Epic, the electronic medi-

cal records incumbent, has updated their app, called MyChart, to allow seamless syncing with Health. This allows Apple Health users who are patients at Epic-compliant institutions to track their health and wellness while reporting their performance to their physicians.

Even in this early version, Health is impressive: For example, diabetic users can track and chart blood glucose values and never have to worry about forgetting to bring their logs to a doctor appointment.

Another great feature in Health is the ability to enter critical health and contact information. For example, in the event of an emergency, if someone were to find your phone, you now have the ability to have a *Medical ID icon on your homescreen/locked screen. You have to activate this feature and enter the key information, but this information could save your life. Even if your phone is locked, a first responder has only to click the *Medical ID to find out your name, birthdate, medical conditions, medical notes, allergies, medications, and emergency contact, as well as blood type and organ donation status.

This app may prove to be Apple's greatest achievement in mobile health. The app is free and preloaded on all updates to iOS 8.

2 MyFitnessPal

www.myfitnesspal.com

While we all would agree that the best way to lose weight is to burn more calories than consumed, actually counting those edible calories can be the toughest part of the weight-loss challenge. In an attempt to help us count our calories, MyFitnessPal was developed around tracking diet habits and food intake. So how does it work? According to the MyFitnessPal website, it is very simple.

After you set up a basic fitness profile, MyFitnessPal will recommend a daily net calorie target for your weight loss (or gain) goals. As you eat and exercise throughout the day, you log your snacks, drinks, meals, and exercise in the Food and Exercise diaries. This can be done on the app or with your own synced MyFitnessPal webpage. As the data are logged, MyFitnessPal will calculate the number of calories you've consumed and burned and let you know how many calories you have left for the day.

MyFitnessPal will **calculate the number of calories you've consumed and burned** and let you know how many calories you have left for the day.

If you stay within your calorie limits, you should achieve the weight loss (or gain) you're looking for. One of the best features of the program is the relatively simple food logging interface: MyFitnessPal remembers the foods and exercises you like most and makes it easy for you to add those items to your diary. Periodically the app will remind you to use the Check-In feature (or "Progress" page in the app) to track your weight/progress over time and also adjust your calorie goals vis a vis your new weight.

MyFitnessPal syncs to Apple Health and a number of other third-party apps. It is available for free on Android and Windows Phone 8, and as a stand-alone website.

3 Yummly Recipes & Grocery Shopping List

www.yummly.com

One of the most popular apps that is dedicated to helping people buy and eat high-quality food, Yummly uses high-tech solutions to solve the rather simple problem of deciding what's best to eat. Yummly is one of the fastest-growing food websites, with more than 1 million recipes logged and nearly 15 million monthly visitors.

According to its website, Yummly "utilizes its proprietary food genome and technology to understand recipes, ingredients and products creating 'Big Data for Food.'" This translates into nearly 100,000 classifications for food. Users can search for recipes by holiday, cuisine, taste, diet, nutrition, allergy, cook time, technique, ingredients, and more, on either the downloadable app or website.

Favorite recipes can be saved to a "personalized digital recipe box" and you can even create shopping lists with ingredients for the meals that you plan to make, or you can get recipe suggestions based on a customized list you create. Users can also scan items to add them to a shopping list or get recipe inspiration.

Yummly is available for free on Android, iOS, and as a stand-alone website.

4 CARROT Fit

www.meetcarrot.com/fit/

There is no fitness app quite like CARROT Fit. CARROT Fit is a talking, tongue-in-cheek fitness coaching app with one goal: "To transform your flabby carcass into a Grade A specimen of the human race." CAR-

ROT Fit actively threatens, inspires, ridicules, and bribes you based on the data it aggregates. It makes looking at the data fun because you have no idea what it is going to say. The app works best when synced with Apple's Health app. It is able to sync weight and workout data with Health-compatible apps even when you're not actively using CARROT Fit.

Included in the app is a native step pedometer/step-counter and a "7 Minutes in Hell" workout during which CARROT may have you, on a given day, "traveling through time, escaping from an elite squad of attack ostriches, and punching Justin Bieber in his pretty face." Each exercise is fully narrated and contains training tips, vignettes, and pop culture references to energize you.

CARROT Fit is available for iOS for $2.99.

5 iHealth

www.ihealthlabs.com

iHealth is close to a one-stop shop for health and wellness data acquisition. Not only does the company manufacture wireless blood pressure monitors, blood glucose meters, wireless scales, wireless pulse oximeters, and activity trackers; it also develops apps that sync with many of these devices.

The MyVitals app tracks exactly what it says: your vital health information. What sets it apart from all the competitors is that it aggregates data from the iHealth Blood Pressure monitors, iHealth Scales, iHealth Pulse Oximeters, and iHealth Activity and Sleep Trackers, as well as allowing users to manually enter data.

iHealth Gluco-Smart syncs with the company's Wireless Smart Gluco-Monitoring System to allow users to measure and record their glucose levels using a portable testing kit and Bluetooth-enabled mobile device. The glucometer is small, wireless (of course!) and delivers results in approximately 5 seconds on an easy-to-read LED display.

The iHealth SpO2 mobile app works with the wireless pulse oximeter to help athletes and those with respiratory issues track blood oxygen saturation (SpO2), pulse rate (BPM), and perfusion index.

iHealth has the ability to collect, store, and display almost any user-defined piece of health information that you can think of. iHealth integrates seamlessly with Apple iOS Health, letting users populate all their favorite Health-compatible apps with oodles of data points.

iHealth MyVitals is available for free on Android and iOS.

iHealth Gluco-Smart is available for free on Android and iOS.

iHealth SpO2 is available for free on iOS.

Devices pairing with each of these apps range from less than $20 to approximately $100 and are available at the iHealth web store: https://store.ihealthlabs.com. COG

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COG COMING IN THE MARCH ISSUE OF *CONTEMPORARY OB/GYN*: DRS. LEVINE AND GOLDSCHLAG REVIEW 5 MORE APPS YOU'LL WANT TO TRY IN 2015

HEART HEALTH APPS FOR YOUR PATIENTS

Healthy Heart 2 (Free)

Help your patients who are at risk of heart disease monitor their high blood pressure and high cholesterol with this app. It tracks blood pressure, pulse, cholesterol, blood glucose, and potassium. It also monitors medication, which may be beneficial to a patient's caregivers. The app's news articles can be easily shared on Facebook.

Smart Blood Pressure (Free)

SmartBP allows patients to track their blood pressure, analyze the results, and share the information with their physicians in a variety of formats. The app will calculate pulse pressure, body mass index and mean arterial pressure. Patients can set reminders to take their medication or to measure their blood pressure.

Blood Pressure Companion ($0.99)

This app allows patients to monitor their blood pressure, heart rate, and weight, while also comparing it to their previous entries. Users can generate comprehensive reports to email to their physicians, and the app's passcode function will help to keep a patient's information private.

Heart Health Mobile (Free)

From the Marshfield Clinic Research Foundation, this app provides an assessment to determine those at risk of cardiovascular disease. It also provides directions to pharmacies that offer blood pressure and cholesterol screenings.

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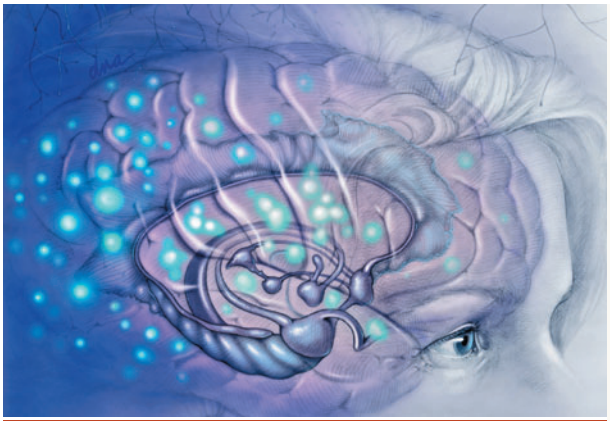

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Many women complain of changes in their cognitive function during the menopausal transition. Here's how to tell what's normal and what's not—and how to treat appropriately.

on twitter

A few recent tweets and retweets from and about ContempOBGYN

March of Dimes
@modhealthtalk

Almost half of all babies with whooping cough actually get it from their parents. Have you gotten your adult booster shot yet?

Suzan
@periodwise

@modhealthtalk @ContempOBGYN Adults should get a booster shot for Whooping Cough? I didn't know! What if they had WC as a child?

ContemporaryOBGYN
@ContempOBGYN

@periodwise @modhealthtalk According to the CDC, adults should get a booster every 10 years. See this site: http://www.cdc.gov/pertussis/about/prevention/index.html …

Joshua Copel
@jacopel

For those who think ACA doesn't work: improved coverage of #pregnant women always a good thing. @contempobgyn http://t.usnews.com/Z4q7om

Jessica Shepherd, MD
@JShepherd_MD

Sexual and intimate partner violence is more prevalent than you think. A chilling infographic via @ContempOBGYN pic.twitter.com/68Y1ZBMn0i

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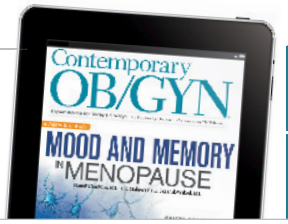

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Contemporary OB/GYN
December

Now available only on our website: Commentary from Dr. Charles Lockwood on The American Congress of Obstetricians and Gynecologists (ACOG National) Practice Bulletin Number 146.

ACOG Guidelines: Management of Late-Term and Postterm Pregnancies

Committee on Practice Bulletins—Obstetrics ACOG Practice Bulletin Number 146: Management of Late-Term and Postterm Pregnancies, August 2014. Obstet Gynecol. 2014;124:390-39

Contemporary OB/GYN
December

Myometrial contractions are theorized to be necessary to achieve fertilization and this is the first study to look at the association between uterine contractility post-IUI and cycle

Are uterine contractions linked with IUI success?

Unlike with in vitro fertilization, it appears that uterine contractions may increase the chance of a successful intrauterine insemination (IUI), according to a new study in Fertility and Sterility.

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A highly sensitive and accurate detection method for group B streptococcal colonization of pregnant women, Xpert® GBS LB.

Now available from LabCorp

Ellen Jo Baron, PhD, D(ABMM)
Professor Emerita, Stanford University, Department of Pathology
Executive Director, Technical Support, Cepheid

Epidemiology and pathogenesis of neonatal early-onset Group B *Streptococcus* disease

Although the rates of early-onset group B streptococcal (EOGBS) disease have dropped dramatically with the broad acceptance of both risk-based and colonization status-based interventions, as recommended by the Centers for Disease Control and Prevention, the American Academy of Pediatrics, and the American College of Obstetricians and Gynecologists, many neonates still suffer from EOGBS disease annually in the US.

Figure 1

Incidence of early- and late-onset invasive group B streptococcal (GBS) disease: Active Bacterial Core surveillance areas, 1990-2008, and activities for prevention of GBS disease

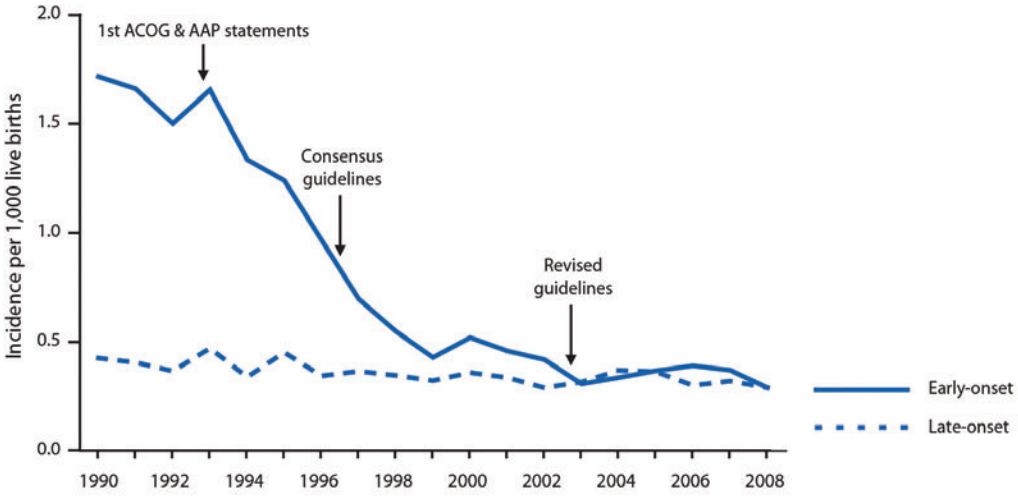


Figure 1: Adapted from Verani, J. R., L. McGee, and S. J. Schrag. 2010. Prevention of perinatal group B streptococcal disease--revised guidelines from CDC, 2010. MMWR Recomm Rep 59:1-36.
Adapted from Jordan HT, Farley MM, Craig A, et al. Revisiting the need for vaccine prevention of late-onset neonatal group B streptococcal disease. Pediatr Infect Dis J 2008;27:1057-1064.

Content and funding provided by Cepheid® *and* LabCorp Laboratory Corporation of America

Acquisition of group B *Streptococcus* (GBS; also known as *Streptococcus agalactiae*) by the newborn can occur either *in utero* or during birth.[1] To initiate infection in the uterus, the organisms traverse the membranes of the chorioamnion and begin to multiply in the amniotic fluid; the baby aspirates this infected fluid, spreading the organisms systemically to cause pneumonia, sepsis, and meningitis.[2] In other cases, the infant encounters the streptococci during passage through the mother's colonized vaginal canal. The organisms adhere to neonatal tissues, evade host antibodies and phagocytes, and initiate the disease process.

Even with currently available evidence-based recommendations, the babies of 1% to 2% of women colonized with GBS will develop EOGBS disease.[1] According to one study, intrapartum colonization of the neonate occurs in approximately 9% of the 14.8% of women who carry GBS organisms.[3]

Unfortunately, strategies to decolonize mothers who carry GBS without harming the normal microbiota of their intestinal tracts are not available. In lieu of decolonization, beginning in the 1980s, it was shown that delivering effective antibiotics to the baby's bloodstream via the maternal circulation across the placenta can effectively prevent the sepsis and meningitis syndromes that signify EOGBS disease in the majority of cases.[1,4] The incidence of EOGBS has dropped significantly — since introduction of national prevention guidelines in 1994 — from almost 2 cases per 1000 live births to below 0.5 cases per 1000 live births, where it has remained for the last 12 years. CDC's 2002 revised guidelines have been successful in decreasing the incidence of EOGBS.[2] The CDC's 2002 guidelines also discussed the detection of colonized women using enriched culture methods of vaginal/anal specimens taken at 35 to 37 weeks of gestation and intrapartum antibiotic prophylaxis for GBS colonized women as well as a risk-based approach for women who present in labor with an unknown colonization status.[5] The enriched culture, usually performed in Lim broth (LB), controls overgrowth of non-GBS vaginal bacteria with antibiotics, while encouraging multiplication of GBS with special nutrients. After overnight incubation, the LB culture is subcultured to solid agar to facilitate identification of GBS colonies. The bacteria on the agar plate are also used for antimicrobial susceptibility testing with clindamycin, the agent used for intrapartum treatment of women (and thus their babies) who are allergic to penicillins. Although effective, the recommendations have resulted in approximately 26% to 38% of all women receiving intravenous antibiotics during labor and delivery, although, according to one study, as many as half of these women have negative GBS cultures at time of delivery and are at low risk of delivering infants with EOGBS disease.[4,6]

More disturbing are the cases of EOGBS disease that still occur: more than 3,000 cases per year in the US. Stoll et al have shown that 80% of infants with early-onset disease were born to mothers who had been screened and tested negative.[7]

Given these interventions, why do so many neonates still develop EOGBS disease? One reason is that many infants are born prematurely before their mothers are tested for GBS colonization.[6] Even when screening cultures are performed, a number of the results are not available at the time or place when the women present for delivery.[8] The other issue is that a number of women who had negative GBS cultures at 35 to 37 weeks have GBS in the vaginal vault at the time of delivery, leading to infection of the newborn.[9,10] Although it is possible that the antenatal culture method was not sensitive enough to detect colonization, it is also possible that the women acquired GBS in the interim between culture and delivery. As methods for detection of GBS become more sensitive, including the use of novel molecular techniques, it may be possible to reduce the number of EOGBS infections even further.

A closer look at the new real-time PCR test for GBS colonization

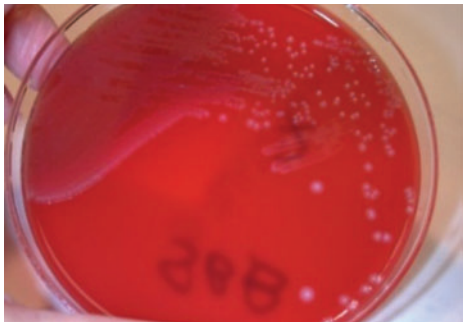
The Xpert® GBS LB test has a sensitivity of detecting GBS in Lim broth samples of 99%, with a specificity of approximately 92%, based on clinical trials with more than 825 patients.[11] The Xpert GBS LB test, performed on the GeneXpert® or Infinity System, represents an enhancement in molecular diagnostics with regard to speed, simplicity, quality control, and automated control of processes. The method starts with placement of the vaginal/anal swab samples in Lim broth and incubating the broth overnight to amplify the number of GBS organisms that are present. The Xpert GBS LB test concentrates the organisms from the enrichment broth on a filter, washes away any inhibitory substances, then lyses the bacteria to release bacterial DNA. The bacterial DNA is amplified by polymerase chain reaction (PCR), a process that is both highly sensitive and specific. Organism lysis, amplification of specific GBS DNA sequences, and detection of the amplified target all occur in a closed system within a plastic cartridge, which is the size of a salt shaker. Traditional molecular detection methods may fail to detect the GBS in the subculture due to overgrowth by other organisms or atypical colony morphology.[12]

Molecular detection of GBS using Xpert GBS LB reduces the problems associated with traditional bacterial cultures, especially cultures in which low amounts of GBS are overgrown by other bacterial species, or are missed because they produce non-β-hemolytic colonies.

Using PCR in conjunction with broth enrichment culture provides improved sensitivity over a standard overnight broth culture, which was the previous gold standard for GBS detection.[11,13] Xpert GBS LB also reduces the risk of cross-contamination of specimens, which can occur with other molecular tests when large numbers of GBS specimens are handled in open areas. The Xpert cartridge is a closed system, and each test is totally independent with no interaction

Figure 2

Photo of GBS on blood agar plate by the author.



of sample and the instrument, minimizing the risk of false-positive results. The FDA has cleared the Xpert GBS LB test and the Clinical Laboratory Improvement Amendments (CLIA) deemed the test moderate in complexity, which allows the test to be performed by technical staff without advanced molecular training.

Proper sample collection is critical to optimal performance

The accuracy of test results is dependent on the integrity of specimens. Collecting the appropriate sample types as directed helps to enable the laboratory to detect the maximum number of GBS-colonized pregnant women. Because GBS organisms reside in the gastrointestinal tract and migrate to the vagina across the perineum, it is critical that both rectal/anal and vaginal swabs are collected for detection. Vaginal swabs alone may miss 52% of colonized women, and rectal or anal swabs alone may miss another 11%.[14] Also, GBS in the vagina adheres to the lower vaginal squamous epithelial cells, not the endocervical os, where *Chlamydia trachomatis* and *Neisseria gonorrhoeae* preferentially colonize. Consequently, vaginal swabs need to be collected from the walls of the lower vagina, and not from higher up near the cervix. *(Figure 3)*

Susceptibility testing to manage penicillin-allergic patients

LabCorp offers susceptibility testing for patients with a penicillin allergy who need an alternative regimen. GBS isolates recovered from the LB liquid culture, after the Xpert GBS LB identifies the broth as positive for GBS, are tested for susceptibility to certain drugs. LabCorp follows CDC guidelines for susceptibility tests, performing susceptibility testing for GBS with both erythromycin and clindamycin in a D-zone test to detect inducible clindamycin resistance.[1]

Figure 3

Collect from vaginal walls and rectum, not from cervical os. Photo by Cepheid.

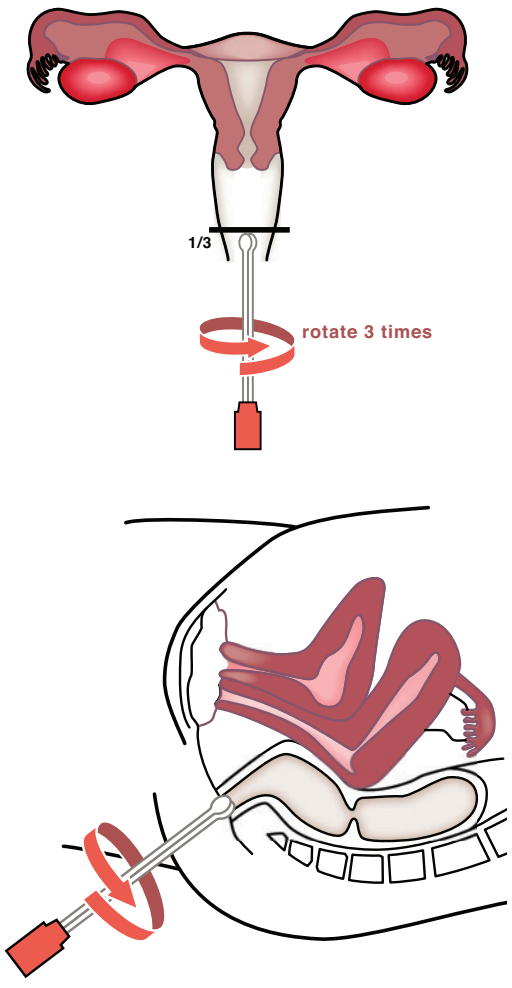
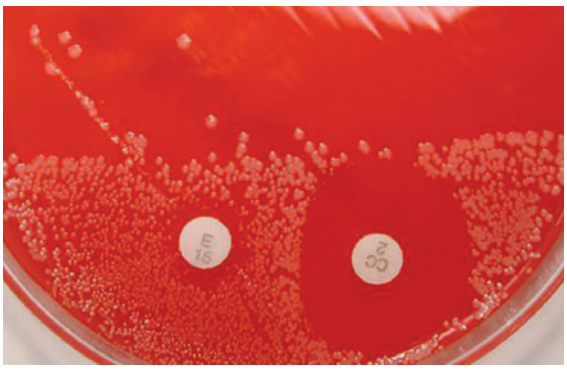


Figure 4

Example of D-zone test showing induction of clindamycin (CC disk) resistance by erythromycin (E-disk) in Staphylococcus aureus, the same procedure as used for GBS susceptibility testing. Photo by the author.



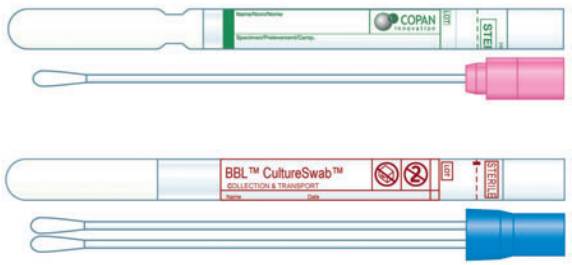
Accessibility through a national reference laboratory – LabCorp laboratory network

Xpert GBS LB is available to physicians and their patients through LabCorp, one of the first national reference laboratories to offer this highly-sensitive method for identifying GBS colonization in pregnant women. Following the enrichment process (18 to 24 hours), the approximate turnaround time for this test is 24 to 48 hours after receipt of the specimen in the laboratory. LabCorp also offers susceptibility test options. The turnaround time combined with sensitivity of Xpert GBS LB provides clinicians with the information needed to help safeguard the health of patient and baby from EOGBS disease.

For more information, visit www.labcorp.com, or ask your local sales representative.

Swab or Double Swab in Amies Agar Gel

Use for Group B Streptococcus colonization detection from vaginal/rectal specimens. Transport at room temperature after collection.



(Other non-nutritive transport medium is available for specimen collection.) ©2014 Nucleus Medical Media

LabCorp Test Options

188132 Group B *Streptococcus* Colonization Detection, NAA

188139 Group B *Streptococcus* Colonization Detection, NAA With Reflex to Susceptibilities

For specimen requirements and additional information, please see the LabCorp Test Menu at www.LabCorp.com.

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BY **ANDREW I KAPLAN, ESQ**

Did surgeon inexperience result in iatrogenic injury?

Facts

On July 29, 2010, a 46-year-old obese primarily Spanish-speaking patient was admitted to a hospital by her private ob/gyn Dr. A for a total laparoscopic hysterectomy (TLH) and/or laparoscopically assisted vaginal hysterectomy (LAVH) that day. Dr. A was new to the facility, not yet board-eligible, and had never performed the procedure as primary surgeon.

The patient and Dr. A. signed a consent (in English) for the TLH and/or LAVH with removal of tubes and ovaries bilaterally, possible vaginal assistance, possible laparotomy and all related procedures. According to the pre-procedure history and physical examination authored by Dr. A, the patient was seeking surgical management of her fibroid uterus and menometrorrhagia after failed medical treatment with birth control pills. The risks, benefits, and alternatives of LAVH, TAH, and total vaginal hysterectomy (TVH) were discussed with the patient.

Dr. A believed that a laparoscopic approach was the best option because of the patient's obesity, but she documented the possibility that the procedure might not be totally accomplished laparoscopically, and a vaginal approach or conversion to an open abdominal procedure was also possible.

The patient's surgery was originally scheduled for 1:45 PM but did not start until 6:42 PM because of operating room (OR) back-ups; it ended at 3 AM.

Dr. B, a fellow attending, observed the procedure at Dr. A's request but did not scrub in. Dr. A and the chief resident were operating the equipment and Dr. B was watching on the screen. Dr. A had difficulty visualizing the right uterine artery because of the patient's body habitus, which required them to tilt the patient back further in Trendelenburg to lift her bowels and omentum out of the area. When they did so, however, the anesthesiologist had difficulty adequately ventilating her in that position; therefore, the decision was made to attempt a vaginal approach.

> There was a burst of urine and Dr. A said she could feel the tubing of the Foley catheter **within the bladder.**

Because multiple hands would be needed, Dr. B scrubbed in and held the retractor to improve visualization of the anatomy. While Dr. B was doing so, Dr. A clamped one pedicle of the uterus and "with the first bite" of her Mayo scissors inadvertently entered the bladder. The injury was immediately apparent (there was a burst of urine and Dr. A said she could feel the tubing of the Foley catheter within the bladder). Urology was called for a consult; the chief resident responded and, after consulting with his attending, decided that an abdominal incision was needed to fully evaluate the injury. Accordingly, the hysterectomy and BSO were completed by Dr. A via the abdomen, which she accomplished with the ob/gyn residents without further incident.

Dr. B did not participate in the open procedure; she later stated she believed she left the OR when the urology team arrived for their portion of the surgery.

According to the anesthesia record, the bladder injury occurred at 8:26 and the conversion to an exploratory laparotomy/abdominal hysterectomy commenced at 8:51. The anesthesia record indicates that the urology team began repairing the bladder at 9:32.

There is a brief, incomplete but electronically signed ob/gyn operative report that indicates that the LAVH was converted to an explor-

atory laparotomy, abdominal hysterectomy, bilateral salpingo-oophorectomy (BSO) with left ureteral reimplantation, and cystotomy repair. According to this incomplete operative report, the attending surgeons were Drs. A and B, assisted by ob/gyn residents Drs. C and D.

According to the urology operative report, the primary gyn surgical team noted that a cystotomy occurred during the anterior vaginal wall dissection. The gyn doctors immediately contacted the urologist on call and asked for an "intraoperative consultation." By the time they scrubbed in, conversion to an exploratory laparotomy and dissection to the level of the uterus and posterior bladder had already been accomplished. After the gyn team completed the BSO and hysterectomy, the vaginal cuff was closed. At that point, the urology team took over and evaluation revealed a defect in the posterior wall of the bladder. The ureters were dissected and identified. The dome of the bladder was tented and opened.

The injury to the trigone of the bladder was apparent and an additional vaginal defect—described as very large with some ragged edges—could be palpated through the opening. The urology report noted that the gyn service used both electrocautery (endoshears) and sharp dissection in the area and that the defect was "quite substantial."

The urology operative report goes on to state that the gyn surgeons repaired the anterior vaginal defect and completed the closure of the vaginal cuff. The urology team then began repair of the left ureter "as it was never identified originally." The left ureteral orifice was likely involved in the defect, and it was never identified in the surgery. Therefore, a ureteral reimplant was necessary and accomplished."

According to the 3:10 AM brief ob/gyn operative note written by ob/gyn resident Dr. C, Drs. A and B were assisted by Drs. D and C. The estimated blood loss was 800 cc and the patient received 4800 cc of Lactated Ringer's solution.

The findings included a 12-week size fibroid uterus, a right ovarian cyst, and a normal left ovary. The patient was sent to the recovery room in stable condition and the operative report was to be "dictated by Dr. A."

The pathology report indicates the uterus was noted to be 10 x 8 x 7 cm (440 g) and was deformed by "multiple nodules measuring from 1 cm to 3 cm in diameter." The cervix had mild parakeratosis; there was proliferated endometrium, leiomyomata, and cystic ovaries noted.

The discharge summary written by chief ob/gyn resident Dr. D describes a 19- to 20-week sized uterus. On August 3, the patient was discharged with a Foley catheter in place and instructions to follow up with urology and gynecology.

On August 18, the patient was admitted to the hospital for a cystogram. According to the operative/cystoscopy report, the patient was aware that because of the anatomic location of her injury, vascular blood supply to the area might be compromised and the risk of vesicovaginal fistula was significant. Examination revealed a significant defect consistent with a vesicovaginal fistula.

The urologist documented an extended conversation with the patient, her husband, and daughter over the etiology and prognosis that further operative repair would be required. In addition, the ureteral stent would need to be removed approximately 3 weeks later. The plan was for the patient to follow up in the urology clinic.

The gyn doctors **immediately contacted the urologist on call** and asked for an intraoperative consultation.

On September 14, the patient was again admitted to the hospital for removal of the ureteral stent. During the procedure, a left retrograde pyelogram revealed good drainage into the bladder. The vesicovaginal fistula was not visualized; however, repeat cystogram dye test demonstrated leakage into the vagina.

On October 18, the patient was admitted to the hospital for vaginal repair of the vesicovaginal fistula. According to the operative report, the patient was told she would need at least 3 weeks of postoperative suprapubic tube drainage as well as a Foley catheter.

The next day the patient was discharged with the suprapubic tube in place and instructions to follow up with urology. On November 3 the patient was seen by urology. She reported pain at the suprapubic tube site and mild leakage through the urethra was reported with bowel movements. On pelvic exam, the fistula site was visualized without evidence of leakage.

Lo Loestrin® Fe

The *only* available ultra–low-dose oral contraceptive with just 10 mcg of daily ethinyl estradiol. Its unique 24/2/2 regimen may provide women with short, lighter periods.[1,2]

FDA draft guidance on labeling states that women taking combined oral contraceptives should take those with the least amount of estrogen and progestin to remain effective and fit the medical needs of the patient.[3]

Most eligible insured patients **PAY NO MORE THAN $25*** for **Lo Loestrin Fe** prescriptions!

*This offer is valid only for patients with commercial prescription drug insurance and applies to prescriptions for Lo Loestrin Fe. Most eligible insured patients will pay $25 per 28-day supply for each of up to 12 prescription fills. Other eligible insured patients should check with their pharmacist for their copay discount. Maximum reimbursement limits apply; patient out-of-pocket expense may vary. Please see full terms and conditions at **actavisocsavings.com**.

Lo Loestrin® Fe

(norethindrone acetate and ethinyl estradiol tablets, ethinyl estradiol tablets and ferrous fumarate tablets)
1 mg/10 mcg and 10 mcg

INDICATION AND USAGE for Lo Loestrin® Fe

Lo Loestrin Fe is an estrogen/progestin combination oral contraceptive (COC) indicated for use by women to prevent pregnancy. The efficacy of Lo Loestrin Fe in women with a body mass index (BMI) of >35 kg/m^2 has not been evaluated.

SELECTED SAFETY INFORMATION about Lo Loestrin Fe, including Boxed Warning

WARNING: CIGARETTE SMOKING AND SERIOUS CARDIOVASCULAR EVENTS

Cigarette smoking increases the risk of serious cardiovascular events from combination oral contraceptive (COC) use. This risk increases with age, particularly in women over 35 years of age, and with the number of cigarettes smoked. For this reason, Lo Loestrin Fe should not be used by women who are over 35 years of age and smoke.

Lo Loestrin Fe is contraindicated in pregnant patients, and those with a high risk of arterial or venous thrombotic diseases, liver tumors (benign or malignant) or liver disease, undiagnosed abnormal uterine bleeding, or breast cancer or other estrogen- or progestin-sensitive cancer, now or in the past.

Discontinue Lo Loestrin Fe if a thrombotic event occurs, and at least 4 weeks before and through 2 weeks after major surgery. Lo Loestrin Fe should not be started any earlier than 4 weeks after delivery, in women who are not breastfeeding. If jaundice occurs, treatment should be discontinued.

Lo Loestrin Fe should not be prescribed for women with uncontrolled hypertension or hypertension with vascular disease. Women who are pre-diabetic or diabetic, should be monitored while using Lo Loestrin Fe.

Alternate contraceptive methods should be considered for women with uncontrolled dyslipidemia. Patients using Lo Loestrin Fe who have a significant change in headaches or irregular bleeding or amenorrhea should be evaluated.

In the clinical trial for Lo Loestrin Fe, serious adverse reactions included deep vein thrombosis, ovarian vein thrombosis, and cholecystitis. The most common adverse reactions (incidence ≥2%) were nausea/vomiting, headache, bleeding irregularities, dysmenorrhea, weight fluctuation, breast tenderness, acne, abdominal pain, anxiety, and depression.

Patients should be counseled that COCs do not protect against HIV infection (AIDS) and other sexually transmitted diseases.

To report a Suspected Adverse Reaction from one of our products, please contact Actavis Drug Safety Department at 1-800-272-5525.

Please see Brief Summary of Full Prescribing Information for Lo Loestrin Fe, including Boxed Warning, on adjacent pages.

Please see Full Prescribing Information for Lo Loestrin Fe, including Boxed Warning, available at www.loloestrin.com.

References: 1. Lo Loestrin® Fe prescribing information. Rockaway, NJ: Warner Chilcott (US), LLC; 2012. **2.** Data on file. Rockaway, NJ: Warner Chilcott (US), LLC. **3.** US Food and Drug Administration. Guidance for industry: labeling for combined oral contraceptives. http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm075075.pdf. Published March 2004. Accessed May 21, 2014.

Lo Loestrin® Fe (norethindrone acetate and ethinyl estradiol tablets, ethinyl estradiol tablets and ferrous fumarate tablets)

BRIEF SUMMARY: Consult the Package Insert for Complete Prescribing Information

WARNING: CIGARETTE SMOKING AND SERIOUS CARDIOVASCULAR EVENTS

Cigarette smoking increases the risk of serious cardiovascular events from combination oral contraceptive (COC) use. This risk increases with age, particularly in women over 35 years of age, and with the number of cigarettes smoked. For this reason, COCs should not be used by women who are over 35 years of age and smoke *[see Contraindications (4)]*.

1 INDICATIONS AND USAGE

Lo Loestrin® Fe is indicated for use by women to prevent pregnancy.

The efficacy of Lo Loestrin Fe in women with a body mass index (BMI) of > 35 kg/m^2 has not been evaluated.

4 CONTRAINDICATIONS

Do not prescribe Lo Loestrin Fe to women who are known to have the following conditions:

- A high risk of arterial or venous thrombotic diseases. Examples include women who are known to:
  - Smoke, if over age 35 *[see Boxed Warning* and *Warnings and Precautions (5.1)]*
  - Have deep vein thrombosis or pulmonary embolism, now or in the past *[see Warnings and Precautions (5.1)]*
  - Have cerebrovascular disease *[see Warnings and Precautions (5.1)]*
  - Have coronary artery disease *[see Warnings and Precautions (5.1)]*
  - Have thrombogenic valvular or thrombogenic rhythm diseases of the heart (for example, subacute bacterial endocarditis with valvular disease, or atrial fibrillation) *[see Warnings and Precautions (5.1)]*
  - Have inherited or acquired hypercoagulopathies *[see Warnings and Precautions (5.1)]*
  - Have uncontrolled hypertension *[see Warnings and Precautions (5.4)]*
  - Have diabetes mellitus with vascular disease *[see Warnings and Precautions (5.6)]*
  - Have headaches with focal neurological symptoms or have migraine headaches with or without aura if over age 35 *[see Warnings and Precautions (5.7)]*
- Breast cancer or other estrogen- or progestin-sensitive cancer, now or in the past *[see Warnings and Precautions (5.2)]*
- Liver tumors, benign or malignant, or liver disease *[see Warnings and Precautions (5.3)]*
- Undiagnosed abnormal uterine bleeding *[see Warnings and Precautions (5.8)]*
- Pregnancy, because there is no reason to use COCs during pregnancy *[see Warnings and Precautions (5.9)* and *Use in Specific Populations (8.1)]*

5 WARNINGS AND PRECAUTIONS

5.1 Thrombotic and Other Vascular Events

Stop Lo Loestrin Fe if an arterial or deep venous thrombotic event occurs. Although use of COCs increases the risk of venous thromboembolism, pregnancy increases the risk of venous thromboembolism as much or more than the use of COCs. The risk of venous thromboembolism in women using COCs is 3 to 9 per 10,000 woman-years. The risk is highest during the first year of use of a COC. Use of COCs also increases the risk of arterial thromboses such as strokes and myocardial infarctions, especially in women with other risk factors for these events. The risk of thromboembolic disease due to oral contraceptives gradually disappears after COC use is discontinued.

If feasible, stop Lo Loestrin Fe at least 4 weeks before and through 2 weeks after major surgery or other surgeries known to have an elevated risk of thromboembolism.

Start Lo Loestrin Fe no earlier than 4 weeks after delivery, in women who are not breastfeeding. The risk of postpartum thromboembolism decreases after the third postpartum week, whereas the risk of ovulation increases after the third postpartum week.

COCs have been shown to increase both the relative and attributable risks of cerebrovascular events (thrombotic and hemorrhagic strokes), although, in general, the risk is greatest in older (> 35 years of age), hypertensive women who also smoke. COCs also increase the risk for stroke in women with underlying risk factors.

Oral contraceptives must be used with caution in women with cardiovascular disease risk factors.

Stop Lo Loestrin Fe if there is unexplained loss of vision, proptosis, diplopia, papilledema, or retinal vascular lesions. Evaluate for retinal vein thrombosis immediately.

5.2 Carcinoma of the Breast and Cervix

Women who currently have or have had breast cancer should not use Lo Loestrin Fe because breast cancer is a hormonally-sensitive tumor.

There is substantial evidence that COCs do not increase the incidence of breast cancer. Although some past studies have suggested that COCs might increase the incidence of breast cancer, more recent studies have not confirmed such findings.

Some studies suggest that COCs are associated with an increase in the risk of cervical cancer or intraepithelial neoplasia. However, there is controversy about the extent to which these findings may be due to differences in sexual behavior and other factors.

5.3 Liver Disease

Discontinue Lo Loestrin Fe if jaundice develops. Steroid hormones may be poorly metabolized in patients with impaired liver function. Acute or chronic disturbances of liver function may necessitate the discontinuation of COC use until markers of liver function return to normal and COC causation has been excluded.

Hepatic adenomas are associated with COC use. An estimate of the attributable risk is 3.3 cases per 100,000 COC users. Rupture of hepatic adenomas may cause death through intra-abdominal hemorrhage.

Studies have shown an increased risk of developing hepatocellular carcinoma in long-term (>8 years) COC users. However, the attributable risk of liver cancers in COC users is less than one case per million users.

Oral contraceptive-related cholestasis may occur in women with a history of pregnancy-related cholestasis. Women with a history of COC-related cholestasis may have the condition recur with subsequent COC use.

5.4 High Blood Pressure

For women with well-controlled hypertension, monitor blood pressure and stop Lo Loestrin Fe if blood pressure rises significantly. Women with uncontrolled hypertension or hypertension with vascular disease should not use COCs.

An increase in blood pressure has been reported in women taking COCs, and this increase is more likely in older women with extended duration of use. The incidence of hypertension increases with increasing concentrations of progestin.

5.5 Gallbladder Disease

Studies suggest a small increased relative risk of developing gallbladder disease among COC users.

5.6 Carbohydrate and Lipid Metabolic Effects

Carefully monitor prediabetic and diabetic women who are taking Lo Loestrin Fe. COCs may decrease glucose tolerance in a dose-related fashion.

Consider alternative contraception for women with uncontrolled dyslipidemias. A small proportion of women will have adverse lipid changes while on COCs.

Women with hypertriglyceridemia, or a family history thereof, may be at an increased risk of pancreatitis when using COCs.

5.7 Headache

If a woman taking Lo Loestrin Fe develops new headaches that are recurrent, persistent, or severe, evaluate the cause and discontinue Lo Loestrin Fe if indicated.

An increase in frequency or severity of migraine during COC use (which may be prodromal of a cerebrovascular event) may be a reason for immediate discontinuation of the COC.

5.8 Bleeding Irregularities and Amenorrhea

Unscheduled (breakthrough or intracyclic) bleeding and spotting sometimes occur in patients on COCs, especially during the first three months of use. If bleeding persists or occurs after previously regular cycles, check for causes such as pregnancy or malignancy. If pathology and pregnancy are excluded, bleeding irregularities may resolve over time or with a change to a different COC.

The clinical trial that evaluated the efficacy of Lo Loestrin Fe also assessed unscheduled bleeding and/or spotting. The participants in this 12-month clinical trial (N = 1,582 who had at least one post-treatment evaluation) completed over 15,000 cycles of exposure.

A total of 1,257 women (85.9 percent) experienced unscheduled bleeding and/or spotting at some time during Cycles 2 to 13 of this study. The incidence of unscheduled bleeding and/or spotting was highest during Cycle 2 (53 percent) and lowest at Cycle 13 (36 percent). Among these women, the mean number of days of unscheduled bleeding and/or spotting during a 28-day cycle ranged from 1.8 to 3.2 days.

Scheduled (withdrawal) bleeding and/or spotting remained fairly constant over the one year study, with an average of less than 2 days per cycle.

Women who are not pregnant and use Lo Loestrin Fe may experience amenorrhea (absence of scheduled and unscheduled bleeding/spotting). In the clinical trial with Lo Loestrin Fe, the incidence of amenorrhea increased from 32 percent in Cycle 1 to 49 percent by Cycle 13. If scheduled (withdrawal) bleeding does not occur, consider the possibility of pregnancy. If the patient has not adhered to the prescribed dosing schedule (missed one or more active tablets or started taking them on a day later than she should have), consider the possibility of pregnancy at the time of the first missed period and take appropriate diagnostic measures. If the patient has adhered to the prescribed regimen and misses two consecutive periods, rule out pregnancy.

Some women may experience amenorrhea or oligomenorrhea after stopping COCs, especially when such a condition was preexistent.

5.9 COC Use Before or During Early Pregnancy

Extensive epidemiologic studies have revealed no increased risk of birth defects in women who have used oral contraceptives prior to pregnancy. Studies also do not suggest a teratogenic effect, particularly in so far as cardiac anomalies and limb reduction defects are concerned, when oral contraceptives are taken inadvertently during early pregnancy. Lo Loestrin Fe use should be discontinued if pregnancy is confirmed.

Administration of oral contraceptives to induce withdrawal bleeding should not be used as a test for pregnancy *[see Use in Specific Populations (8.1)]*.

5.10 Depression

Women with a history of depression should be carefully observed and Lo Loestrin Fe discontinued if depression recurs to a serious degree.

5.11 Interference with Laboratory Tests

The use of COCs may change the results of some laboratory tests, such as coagulation factors, lipids, glucose tolerance, and binding proteins. Women on thyroid hormone replacement therapy may need increased doses of thyroid hormone because serum concentrations of thyroid binding globulin increase with use of COCs.

5.12 Monitoring

A woman who is taking COCs should have a yearly visit with her healthcare provider for a blood pressure check and for other indicated healthcare.

5.13 Other Conditions

In women with hereditary angioedema, exogenous estrogens may induce or exacerbate symptoms of angioedema. Chloasma may occasionally occur, especially in women with a history of chloasma gravidarum. Women with a tendency to chloasma should avoid exposure to the sun or ultraviolet radiation while taking COCs.

6 ADVERSE REACTIONS

The following serious adverse reactions with the use of COCs are discussed elsewhere in the labeling:

- Serious cardiovascular events and smoking *[see Boxed Warning* and *Warnings and Precautions (5.1)]*
- Vascular events *[see Warnings and Precautions (5.1)]*
- Liver disease *[see Warnings and Precautions (5.3)]*

Adverse reactions commonly reported by COC users are:

- Irregular uterine bleeding
- Nausea
- Breast tenderness
- Headache

6.1 Clinical Trial Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to the rates in the clinical trials of another drug and may not reflect the rates observed in practice.

A multicenter phase 3 clinical trial evaluated the safety and efficacy of Lo Loestrin Fe for pregnancy prevention. The study was a one year, open-label, single-arm, uncontrolled study. A total of 1,660 women aged 18 to 45 were enrolled and took at least one dose of Lo Loestrin Fe.

Common Adverse Reactions (≥ 2 percent of all Treated Subjects): The most common adverse reactions reported by at least 2 percent of the 1,660 women using Lo Loestrin Fe were the following in order of decreasing incidence: nausea/vomiting (7 percent), headache (7 percent), bleeding irregularities (including metrorrhagia, irregular menstruation, menorrhagia, vaginal hemorrhage and dysfunctional uterine bleeding) (5 percent), dysmenorrhea (4 percent), weight fluctuation (4 percent), breast tenderness (4 percent), acne (3 percent), abdominal pain (3 percent), anxiety (2 percent), and depression (2 percent).

Adverse Reactions Leading to Study Discontinuation: 10.7 percent of the women discontinued from the clinical trial due to an adverse reaction. Adverse reactions occurring in ≥1 percent of subjects leading to discontinuation of treatment were in decreasing order: menstrual irregularities (including metrorrhagia, irregular menstruation, menorrhagia and vaginal hemorrhage) (4 percent), headache/migraine (1 percent), mood disorder (including mood swings, depression, anxiety) (1 percent), and weight fluctuation (1 percent).

Serious Adverse Reactions: deep vein thrombosis, ovarian vein thrombosis, cholecystitis.

7 DRUG INTERACTIONS

No drug-drug interaction studies were conducted with Lo Loestrin Fe.

7.1 Changes in Contraceptive Effectiveness Associated with Co-Administration of Other Products

If a woman on hormonal contraceptives takes a drug or herbal product that induces enzymes, including CYP3A4, that metabolize contraceptive hormones, counsel her to use additional contraception or a different method of contraception. Drugs or herbal products that induce such enzymes may decrease the plasma concentrations of contraceptive hormones, and may decrease the effectiveness of hormonal contraceptives or increase breakthrough bleeding. Some drugs or herbal products that may decrease the effectiveness of hormonal contraceptives include:

- barbiturates
- bosentan
- carbamazepine
- felbamate
- griseofulvin
- oxcarbazepine
- phenytoin
- rifampin
- St. John's wort
- topiramate

HIV protease inhibitors and non-nucleoside reverse transcriptase inhibitors: Significant changes (increase or decrease) in the plasma levels of the estrogen and progestin have been noted in some cases of co-administration of HIV protease inhibitors or of non-nucleoside reverse transcriptase inhibitors.

Antibiotics: There have been reports of pregnancy while taking hormonal contraceptives and antibiotics, but clinical pharmacokinetic studies have not shown consistent effects of antibiotics on plasma concentrations of synthetic steroids.

Consult the labeling of all concurrently-used drugs to obtain further information about interactions with hormonal contraceptives or the potential for enzyme alterations.

7.2 Increase in Plasma Levels of Ethinyl Estradiol Associated with Co-Administered Drugs

Co-administration of atorvastatin and certain COCs containing ethinyl estradiol increase AUC values for ethinyl estradiol by approximately 20 percent. Ascorbic acid and acetaminophen may increase plasma ethinyl estradiol levels, possibly by inhibition of conjugation. CYP3A4 inhibitors such as itraconazole or ketoconazole may increase plasma hormone levels.

7.3 Changes in Plasma Levels of Co-Administered Drugs

COCs containing some synthetic estrogens (for example, ethinyl estradiol) may inhibit the metabolism of other compounds. COCs have been shown to significantly decrease plasma concentrations of lamotrigine, likely due to induction of lamotrigine glucuronidation. This may reduce seizure control; therefore, dosage adjustments of lamotrigine may be necessary. Consult the labeling of the concurrently-used drug to obtain further information about interactions with COCs or the potential for enzyme alterations.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

There is little or no increased risk of birth defects in women who inadvertently use COCs during early pregnancy. Epidemiologic studies and meta-analyses have not found an increased risk of genital or non-genital birth defects (including cardiac anomalies and limb reduction defects) following exposure to low dose COCs prior to conception or during early pregnancy.

The administration of COCs to induce withdrawal bleeding should not be used as a test for pregnancy. COCs should not be used during pregnancy to treat threatened or habitual abortion.

Women who do not breastfeed should not start COCs earlier than 4 weeks postpartum.

8.3 Nursing Mothers
When possible, advise the nursing mother to use other forms of contraception until she has weaned her child. Estrogen-containing OCs can reduce milk production in breastfeeding mothers. This is less likely to occur once breastfeeding is well-established; however, it can occur at any time in some women. Small amounts of oral contraceptive steroids and/or metabolites are present in breast milk.

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

8.5 Geriatric Use
Lo Loestrin Fe has not been studied in postmenopausal women and are not indicated in this population.

8.6 Renal Impairment
The pharmacokinetics of Lo Loestrin Fe has not been studied in subjects with renal impairment.

8.7 Hepatic Impairment
No studies have been conducted to evaluate the effect of hepatic impairment on the disposition of Lo Loestrin Fe. However, steroid hormones may be poorly metabolized in patients with impaired liver function. Acute or chronic disturbances of liver function may necessitate the discontinuation of COC use until markers of liver function return to normal and COC causation has been excluded *[see Contraindications (4)* and *Warnings and Precautions (5.3)]*.

8.8 Body Mass Index
The safety and efficacy of Lo Loestrin Fe in women with a body mass index (BMI) > 35 kg/m^2 has not been evaluated.

10 OVERDOSAGE
There have been no reports of serious ill effects from overdose of oral contraceptives, including ingestion by children. Overdosage may cause withdrawal bleeding in females and nausea.

17 PATIENT COUNSELING INFORMATION
See FDA-approved patient labeling.

Based on Lo Loestrin Fe Prescribing information dated 06/2012.

Manufactured By:
Warner Chilcott Company, LLC
Fajardo, PR 00738

Distributed By:
Actavis Pharma, Inc.
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The patient was diagnosed with **PTSD and adjustment disorder** as a result of being nervous and anxious about her surgical course and incontinence.

The patient was instructed in how to clamp the suprapubic tube. If no leakage was apparent, the suprapubic tube would be removed the following week.

On November 10 the patient was seen in the urology clinic. She reported being unable to tolerate suprapubic tube clamping due to bladder spasms, so the tube was not removed as planned. The fistula site revealed no evidence of leakage. Medications were ordered for a superficial wound infection and the reported bladder spasms. The patient was told to try to clamp the tube 48 hours before the next urology visit.

On January 5, 2011, the patient underwent cystoscopy with video dynamics. She reported that following the fistula repair, she remained dry after the suprapubic tube was clamped, but that she later developed urinary incontinence/stress incontinence. She reported that she had to wear diapers, but her symptoms could not be reproduced on exam in the office. Cystoscopy was done and the vaginal fistula was noted through the old suture line. The plan was to attempt to manage the condition conservatively with diversion of urine via indwelling Foley for 2 more weeks.

On January 21 the patient returned to the hospital for another cystoscopy, examination under anesthesia, and possible fistulogram. Per the history, she had sustained a complicated bladder and ureteral injury during hysterectomy and underwent primary repair at time of injury, but then developed a urethrovaginal fistula. Urethrovaginal repair was initially successful, but she began leaking from her vagina. Pelvic exam suggested recurrence of fistula without leakage per urethral meatus. Surgery was suggested to repair it.

On February 11 the patient was admitted to the defendant hospital and underwent a repeat fistula repair. She was discharged on February 15 to follow up at an incontinence clinic. On April 22 another cystoscopy was performed and stress incontinence was confirmed.

On June 13 the patient was admitted to the hospital to undergo a mid-urethral sling procedure to treat her for incontinence. On July 11, she had a follow-up cystoscopy for complaints of incontinence and urinary frequency. On cystoscopy, however, there was no evidence of mesh erosion, leak, or fistula.

In 2011 the patient was diagnosed with post-traumatic stress disorder and adjustment disorder; she reported being nervous and anxious about her surgical course and incontinence.

Allegations

The plaintiff alleged that through Dr. A's inexperience and surgical negligence, she was caused to suffer bladder laceration; trigonal injury and left ureteral injury requiring emergent surgical repair and left ureteral reimplantation; ureteral stenting; vaginal wall tears; urethrovaginal and vesicovaginal fistula requiring repeated surgical repair; urinary incontinence; bladder overactivity; recurrent vesicovaginal/urethrovaginal fistula; pain and suffering; post-traumatic stress/adjustment disorder for which she takes antianxiety medications; prolonged disability; scarring hip to hip; and inability to engage in social, sexual, and work activities.

The plaintiff also alleged that Dr. A failed to write a complete operative report or brief op note and that the urologists involved botched the primary repair and the subsequent fistula repairs.

Discovery

The plaintiff testified that despite the fact that the conversations were all conducted in English, she understood what Dr. A was explaining to her, and had the opportunity to ask questions. In addition, she and Dr. A discussed the option of removing only her uterus and not her ovaries, but she was aware that the ovarian cysts could return and she opted to have both the ovaries and the uterus removed during the same procedure.

The plaintiff described her uri-

nary complaints as causing lower abdominal pain, urinary urgency when sitting, poor bladder control when standing, and the need to use the bathroom 3 to 4 times per hour. She used incontinence pads and needed to change them frequently. She was unable to sleep, and needed to get up to urinate 6 or 7 times during the night. She conceded incontinence prior to her procedure but described it as urinary leakage while coughing, laughing, or sneezing, but not more than twice an hour.

Dr. A had testified she had included the risk of bladder injury in her discussion with the patient. She recommended a laparoscopic approach because of the patient's obesity; there was a concern about wound separation. Additionally, time was a consideration and the patient wanted a shorter recovery period. She also wanted the surgery sooner rather than later, despite Dr. A's advice that there was no urgency.

Going into the surgery, the intent was to use a laparoscopic approach, converting to a vaginal approach if necessary. Dr. A had difficulty visualizing the uterine artery and asked for the patient to be put in steeper Trendelenburg. However, Trendelenburg could not be maintained secondary to the patient's respiratory status. The surgical team tried this a few times but each time the respiratory status deteriorated when the patient was placed in Trendelenburg and improved when she was brought down.

When the patient was lying flat, Dr. A could not visualize the uterine artery secondary to the bowel and omentum. The new plan was then to enter the peritoneal cavity through the vagina. Suddenly Dr. A felt the bulb in the bladder with her finger. There had been an inadvertent entry into the bladder with the Mayo scissors. Dr. A immediately removed the instrumentation and called urology.

Dr. A testified that she was a new attending and requested the assistance of Dr. B, who was a more senior surgeon, familiar with customary surgical practice at the hospital, and who had performed many laparoscopic and vaginal hysterectomies.

Our expert ob/gyn felt this surgery was too complicated for Dr. A's level of expertise and she should have requested that a more seasoned senior attending surgeon review the case well in advance, evaluate the patient and the sonograms, and be present at the surgery for advice and assistance. He believed that a more experienced surgeon should have evaluated the patient's ultrasounds and determined the actual size of the fibroid uterus before deciding if a LAVH was an option.

A 12-week fibroid uterus can be removed laparoscopically without problem but morcellating and removing a 19– to 20-week fibroid uterus laparoscopically is difficult, even in the most skilled hands. In addition, the expert ob/gyn witness believed that the patient's complaints of stress incontinence needed to be worked up by a urologist before the hysterectomy, so that if warranted, a sling procedure could have been performed simultaneous with the hysterectomy.

In this case, he believed that the extent of this bladder, trigone, ureter, and vaginal wall injury spoke to Dr. A's inexperience and that the extent and location of the injuries made blood supply and healing an issue, prolonged the time needed for Foley catheterization and ureteral stenting, and made fistula formation far more likely.

Verdict

The case settled on the eve of trial as to Dr. A.

Analysis

This was a case that ultimately had to settle not only because of the documented persistent injuries suffered by the patient, but also because of the many pitfalls of attempting trial by jury, including but not limited to the surgeon's inexperience, the partially dictated operative report signed 2 months after the surgery, and the urologist's hypercritical note regarding the defects initially encountered intraoperatively and the cause thereof.

Although the patient had recently undergone additional surgery to address her urinary incontinence and recurring vesicovaginal fistula, her problems continued, and according to her surgeon, further surgery will need to be considered.

At the time of the settlement, the patient still required a diaper when she went out and still had incontinence when she engaged in any physical activity. She and her husband had not had sexual intercourse since the hysterectomy. COG

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Caring for patients with chronic pelvic pain

The right combination of medication, physical therapy, and lifestyle changes may help patients with this sometimes stubborn condition.

BY **ERIN T. CAREY, MD, MSCR,** AND **AUSTIN FINDLEY, MD**

DR. CAREY is Assistant Professor, University of Kansas Medical Center Department of Obstetrics and Gynecology Center for Pelvic Pain and Sexual Health, Kansas City.

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Chronic pelvic pain is defined as noncyclic pelvic pain with a duration of > 6 months, localized below the umbilicus to the anatomic pelvis, and resulting in decreased quality of life and the need for medical treatment.[1] Chronic pelvic pain affects approximately 15% of women in the United States ever year. It is associated with significant costs to the health care system, estimated at nearly $2 billion per year.[2]

The multifactorial nature of chronic pelvic pain makes it difficult to evaluate and treat. In fact, 70% of cases of chronic pelvic pain are estimated to be from non-gynecologic etiologies.[3] Despite the cause (and even following definitive treatment; eg, hysterectomy) chronic pain may result in central sensitization, maintaining chronic pain pathways between the periphery and the brain, altering the central processing of pain. This leading theory supports the use of multimodal therapy and centrally acting medications to treat chronic pain.[4]

Chronic pelvic pain affects approximately **15% of women** in the U.S.

Medications

Analgesics

Many patients with chronic pain have developed some level of centralized pain sensitization and will benefit most from medications that act on the central nervous system. However, traditional analgesics still have a role in management of chronic pelvic pain. Nonsteroidal anti-inflammatory drugs (NSAIDs), acetaminophen, and opioids can be used, alone or in combination, for patients with chronic pain who experience acute pain "flares" (Table 1).

NSAIDs work by non-selectively inhibiting the cyclooxygenase (COX) enzyme, which in turn inhibits formation of prostaglandins and thromboxane. The most commonly prescribed NSAIDs are aspirin, ibuprofen, and naproxen. Potential adverse effects of NSAIDs include gastrointestinal upset, ulcers, or bleeding, as well as renal failure, hypertension, heart attack, and stroke.

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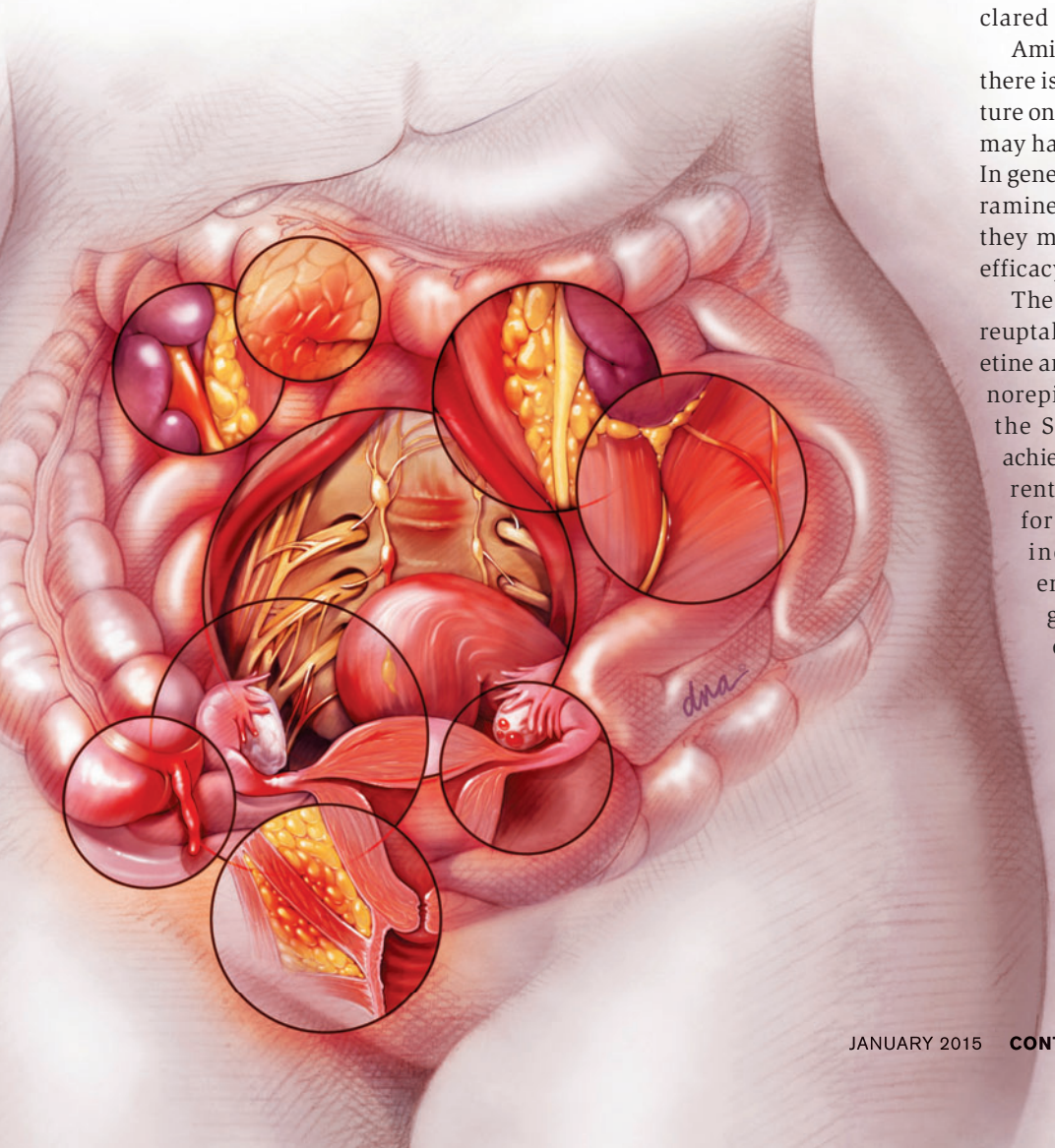
The exact mechanism of action of acetaminophen is unknown, but it is believed to work by inhibiting cyclooxygenase, specifically COX-2. Adverse effects include liver damage, skin reactions, and potential for overdose.

Many opioid medications, both synthetic and natural derivatives of the opium poppy, are used to treat chronic pain,. Opioids work by binding to opioid receptors in the central and peripheral nervous system. They are highly effective for acute pain and chronic malignant pain but, their use in treatment of chronic noncancer pain remains controversial. Patients who require long-term opioid use are at risk of developing tolerance, physical dependence, and addiction.

In addition to common short-term adverse effects such as nausea and vomiting, itching, constipation, and drowsiness, many long-term negative health consequences are associated with opioid use (Table 2).[5] Many patients are not familiar with the risks of long-term opioid use and have not been offered other alternatives for pain management.

Most patients with chronic pain do not want to be maintained on opioids and are agreeable to alternative therapies when given a choice. In general, we advise against routine use of opioids for management of chronic pelvic pain.



Antidepressants

Tricyclic antidepressants (TCAs) are a mainstay of treatment for chronic pain. While their effectiveness in pain management is well established, the anticholinergic adverse effect profile can limit use. Generally, the rule "start low and go slow" should be applied to centrally acting medications. This approach will reduce early discontinuation and improve compliance, as most centrally acting medications need to be given at a moderate dose for 6 to 8 weeks before they are declared ineffective.

Amitriptyline is the TCA for which there is the most evidence in literature on gynecologic pain, but it also may have the most adverse effects. In general, nortriptyline and desipramine may be better tolerated but they may have slightly decreased efficacy in pain management.

The selective neurotransmitter reuptake inhibitors (SNRIs) duloxetine and venlafaxine also increase norepinephrine. Pain relief from the SNRIs is most likely to be achieved at the higher doses. Currently, duloxetine is indicated for certain pain syndromes, including diabetic peripheral neuropathy, fibromyalgia, and chronic musculoskeletal pain such as chronic low back pain and osteoarthritis. Serotonin syndrome is a risk and if it occurs, a prolonged taper may be required.

Neuroleptics

Gabapentin and pregabalin can be effective centrally

continued on **PAGE 27**

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TABLE 1 Medications for chronic pelvic pain

Class/Medication	Dosing	Side effects	Considerations
Tricyclic antidepressants (TCAs)		Sedation, dry mouth, constipation, weight gain, tachycardia, hyperglycemia	Urinary retention
↳ **Amitriptyline**	• 10-25 mg qhs • Titrate 10–25 mg/week to 75–150 mg qhs	Pelvic exam/Pelvic U/S/Pelvic MRI to evaluate anatomy	
↳ **Nortriptyline**	• 10 mg qhs • Titrate 10 mg/week to 50–100 mg qhs		
↳ **Desipramine**	• 25 mg daily • Titrate 10–25 mg/week to 75–100 mg daily		
Selective norepineprhine reuptake inhibitors (SNRIs)		Sedation, headache, dizziness	Hepatic dysfunction, caution with serotonergic drugs (risk for serotonin syndrome), rapid-cycling bipolar. Taper off required.
↳ **Duloxetine**	• 20 mg daily • Titrate 20 mg/week to 60–90 mg daily		
↳ **Desvenlofaxine**	• 37.5 mg twice daily • Titrate 37.5 mg/week until maximum dose of 150–225 mg daily		
Gamma-aminobutyric acid analogues		Sedation, dizziness, anxiety	Taper off required
↳ **Gabapentin**	**1st month:** • 100 mg qhs x 1 week • 200 mg qhs x 1 week • 300 mg qhs x 1 week • 100 mg q am/300 mg qhs **2nd month:** • 300 mg tid • If some relief, can continue to increase incrementally to 600 mg po tid Max dose 3600 mg/24 hrs		
↳ **Pregabalin**	**1st month:** • 25 mg qhs x 1 week • 25 mg bid x 1 week • 25 mg q am, 50 mg qhs x 1 week • 50 mg bid x 1 week **2nd month:** • 50 mg tid • If some relief, can continue to increase to 150 mg tid. Max dose 600 mg daily		
Anxiolytics		Sedation	Dependency. Taper off required. Do not use with additional benzodiazepines.
↳ **Clonazepam**	0.5 mg qhs		
Muscle relaxants		Sedation	Avoid in patients with myasthenia gravis, liver disease, narrow-angle glaucoma, sleep apnea.
↳ **Flexeril**	10 mg q 8 hours prn for spasm		
↳ **Valium**	10 mg per vagina q 8 hrs prn for pain		

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TABLE 2 Long-term risks of opioid use

- Dependence
- Depression
- Opioid-induced hyperalgesia
- Immunosuppression
- Narcotic bowel syndrome
- Decreased quality of sleep
- Decreased sexual function

acting medications despite the expectation that they are only effective for neuropathic pain. These drugs are generally well tolerated and have few interactions with other medications, but consideration should be given to consulting a psychiatric provider if the patient has underlying mood disorders.

Anxiolytics

Despite the indicated use for anxiety, some anxiolytics provide an analgesic effect. Also, the management of anxiety and depression can decrease pain perception. Unfortunately, the risk of misuse is high due to the fast-acting euphoria associated with some anxiolytics. We recommend treating anxiety with antidepressants and using anxiolytics as short-term treatment for night pain and for temporary improvement in insomnia patterns.

Muscle relaxants

Cyclobenzaprine is effective for treatment of the myofascial pain seen in patients with fibromyalgia. The diazepam oral tablet or compounded suppository can be placed in the vagina to relieve pelvic floor muscle spasm. Both of these medications should be used as needed; we do not recommended scheduled use.[6]

Physical therapy

The role of the pelvic floor as a contributing factor in chronic pelvic pain has been well described.[7,8] In prospective evaluations, up to 73% of women with self-reported pelvic pain demonstrate pelvic floor muscle tenderness or hypertonicity.[9]

Despite this fact, many practitioners do not routinely include a thorough examination of the pelvic floor in their evaluation of patients with chronic pelvic pain (Table 3). In many patients with pelvic floor myofascial pain, it may be difficult to distinguish whether the pelvic floor is the primary cause of the pain or a reaction to another etiology.

Regardless of the initial etiology of pain, in women with chronic pelvic pain who demonstrate pelvic floor tenderness or hypertonicity, treatment with physical therapy of the pelvis has proven to be effective.

In one study examining the effectiveness of pelvic floor physical therapy in the treatment of pelvic pain, 63% of women reported significant improvement or resolution of pain, and pain scores improved in proportion to the number of physical therapy sessions completed.[10] In addition to the improvements in pain provided by the therapy itself, there are other benefits to having patients work with a skilled pelvic floor physical therapist. It provides a great deal of education and individualized attention, and empowers them to become active participants in their care.

TABLE 3 Pelvic pain exam

1. **External exam**
2. **Q-tip exam of the vestibule and hymen**
3. **Single-digit exam:**

A. **Evaluate the general tone of the pelvic floor.**

B. **Assess control of the pelvic floor muscles by asking the patient to perform a Kegel.**

C. **Apply moderate pressure (approximately 2 kg) to the:**

1. levator ani muscles (5 and 7 o'clock position just beyond the hymen)
2. obturator internus muscles (Hook index finger past pubic rami laterally and have patient abduct thigh. This will "pop" the muscle into the digit.)
3. piriformis muscles (high posterior vagina, lateral to the rectum on either side)

D. **With each palpation, ask the patient if she experiences pain or pressure. This should be a non-painful exam. If pain is evoked, consider a referral to physical therapy.**

4. **Palpation of the urethra and bladder base**
5. **Bimanual exam**
6. **Rectovaginal exam**

Other approaches

Lifestyle modifications

In addition to medical and therapeutic modalities for management of chronic pelvic pain, it is also important to address lifestyle modifications that can provide benefit to patients. These include diet modifications, exercise, sleep hygiene, and the use of complementary and alternative medicine techniques.

No randomized, controlled trials have examined the effects of diet on chronic pelvic pain. However, we do know that chronic pain results in altered adrenal secretion of cortisol, which can make serum glucose levels unstable. Over time, that can lead to severe weight loss or gain, muscle wasting, fatigue, and poor mentation.[11]

Although the effects of diet on pain may not be known, encouraging a healthy, balanced diet in patients with long-standing pain seems to make intuitive sense as a principal component of good health. Many patients who suffer from chronic pelvic pain may have food sensitivities. Having patients maintain a food journal and eliminate items that seem to correlate with pain flares may also be beneficial.[12] For patients with chronic pain who struggle to maintain a healthy diet, referral to a dietician may be helpful.

While it may seem counterintuitive to patients, exercise plays a very important role in management of chronic pelvic pain. A large body of evidence demonstrates benefit from regular exercise for numerous chronic pain conditions.[13] Exercise has been shown to reduce the amount of pain medications required, reduce stress, improve symptoms of depression, improve muscle strength, increase energy, improve quality of sleep, and increase overall sense of well-being and ability to cope with pain.[14]

No specific exercise regimen has been proven beneficial over another, but it makes sense to recommend a routine that consists of aerobic and strength training exercises. We have found that yoga provides a good combination of aerobic and muscle-building activity, and is well tolerated by most women with chronic pelvic pain.

Patients with chronic pain conditions frequently suffer from poor sleep quality, and the prevalence of sleep disturbance in chronic pain patients is much higher than in the general population. Poor sleep quality has been reported in up to 80% of patients with chronic pelvic pain.[15] These patients also often develop poor pain coping behaviors, such as spending excessive time in bed, frequent napping, opioid use, and overuse of caffeine, all of which further contribute to poor sleep quality.[16]

Lack of restful sleep can result in a host of behavioral and physical impairments, including changes in the nervous, metabolic, endocrine, and immune systems and decreased mood and cognitive capacity. Improving sleep habits can greatly improve the quality of life off patients living with chronic pain. Patients with chronic pain are also more likely to engage in spontaneous physical activity following a better night of sleep.[17] The National Sleep Foundation has established a set of recommendations on good sleep hygiene that can be shared with patients (Table 4).[18]

TABLE 4 Sleep hygiene tips

1. Stick to the same bedtime and wake-up time, even on the weekends.
2. Practice a relaxing bedtime ritual.
3. Avoid naps, especially in the afternoon.
4. Exercise daily.
5. Keep the bedroom cool, quiet, and dark.
6. Sleep on a comfortable mattress and pillows.
7. Use bright light in the morning to help manage your circadian rhythms.
8. Avoid alcohol, cigarettes, and heavy meals in the evening.
9. Wind down by avoiding electronics 60 minutes before bed.
10. If you can't sleep, go into another room and do something relaxing until you feel tired.

Source: National Sleep Foundation

While it may seem counterintuitive to patients, **exercise plays a very important role** in management of chronic pelvic pain.

Psychotherapy

Psychotherapy remains an important component in multimodal treatment of chronic pain. In addition to optimizing the treatment of baseline mental health abnormalities (anxiety, depression, etc.), introducing skills to cope with chronic pain can improve overall care. Coping tech-

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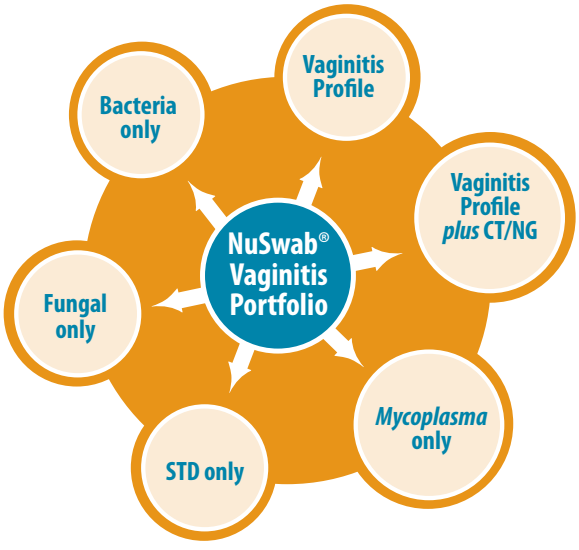

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THE TOP 5 CHALLENGES Physicians Face in 2015

Spending sufficient time with patients will be more of a challenge this year as coding changes, insurance demands, and certification requirements will need even more of your attention.

BY **KEN TERRY, ALISON RITCHIE, DONNA MARBURY, LISA SMITH,** AND **ELAINE POFELDT**

From the pages of Medical Economics
SMARTER BUSINESS. BETTER PATIENT CARE.

Physicians will need to navigate some tough obstacles in the coming year. These include the increased costs of operating a practice, time-consuming regulatory burdens, and hassles related to getting paid by insurance companies.

The pressures are not likely to abate any time soon, thanks to three upcoming regulatory changes. Starting January 1, 2015, physicians' payments are increasingly tied to providing higher-value care under the Affordable Care Act (ACA). In February, financial penalties kick in for practices that do not attest to meaningful use. Then in October, the ICD-10 transition deadline finally arrives.

Perhaps it shouldn't be surprising that more practices are struggling.

"It used to be that physicians made enough money that they could let a lot of things slide," says Cindy Ackrill, a non-practicing physician based in Alexandria, Virginia, who coaches physicians in areas such as leadership and stress management. "The margin is so much thinner now. You do have to micromanage the money. No one taught us to do that."

That's the bad news. The good is that it's possible to maintain a viable, even thriving practice if you confront challenges and identify fixes.

CHALLENGE 1

ICD-10 implementation

Even with an extra year to prepare, will doctors be ready to go live with ICD-10 in October 2015?

"I guarantee there will be one large payer or a few small payers, or both, that won't be ready to process ICD-10 claims on October 1,

2015," says Joshua Berman, director of business analytics and ICD-10 lead at Relay Health Financial.

The ICD-10 delay either helped or hurt practitioners, depending on who you ask. According to a Medical Group Management Association survey in February 2014, 79% of practices had not yet started implementation or were only somewhat ready. A survey by Part B News says that the delay will cost practices more money in training, and that 34% of practitioners would have been ready for the October 2014 deadline.

No matter where practices are in their preparation for ICD-10, the new coding system will cost a considerable amount of money. The American Medical Association (AMA) estimates that small practices could spend between $56,639 and $226,015 to implement the coding system.

Pam Jodock, senior director of health business solutions for Healthcare Information and Management Systems Society (HIMSS), suggests that practitioners allot time for testing to ensure coding is working properly. HIMSS has an "ICD-10 playbook" on its website. Jodock suggests that practices take advantage of this and of the Centers for Medicare and Medicaid Services (CMS) ICD-10 testing in March and June of 2015.

Berman says that practices will have to be ready to send both ICD-9 and ICD-10 claims during a period of transition to ensure payment. "The dual coding process . . . will prove to be very time-consuming, resource-intensive [and] difficult to do via current health information systems and/or practice management systems."

Having extra cash on hand during ICD-10 implementation will help in the event of increased denials and delayed payments. "Denials from miscoding or other process glitches could significantly slow down payment," says Berman.

CHALLENGE 2

HIPAA

Though the chances your practice will be audited for Health Insurance Portability and Accountability Act (HIPAA) violations are slim, keeping patient information secure is growing more complicated. Since 2009, there have been more than 800 patient data breeches and 29 million patient records affected by HIPAA violations, according to the 2013 Redspin Breach Report.

The Office of Civil Rights began its second phase of HIPAA audits in October 2014, and will continue until June 2015. Of the 350 healthcare organizations that will be asked to submit information on patient health data security, approximately 150 will be audited. Fines for HIPAA violations start at $100 and can go as high as $50,000, capping at $1.5 million annually, depending on the scale of the breach. Fines aren't the only consequence practitioners face—a HIPAA violation can also violate patient trust.

HIPAA violations may seem to be a large-organization problem, but considering that many breaches are a result of employee theft and carelessness, smaller practices are at risk. For instance, it becomes harder to keep track of electronic communication within the practice when patients and staff often have mobile devices and may be unaware of how easily HIPAA rules can be violated.

Practices must consider mobile technology as a threat to patient security. Be aware of smartphones and other portable devices with audio and video capabilities.

Both HIPAA and meaningful use require practices to complete and keep updated a security risk analysis. Many physicians are not aware of this requirement, and it is a primary reason why practices fail meaningful use audits, says Mark Norris, a consultant who specializes in privacy, security, and meaningful use attestation.

CHALLENGE 3

Meaningful use 2

Meaningful use 2 (MU2), which has been a challenge for physicians, is unlikely to get easier in 2015, according to Bethany Jones and Naomi Levinthal, health IT consultants for The Advisory Board Company. Starting in 2015, eligible professionals (EPs) will see a 1% decrease in Medicare reimbursements for each year they don't meet meaningful use requirements. The penalty will change by 1% each year to a maximum of 5%. EPs have until the end of February 2015 to attest to MU2. As of November 1, 2014, 11,478 EPs, or 2%, had attested to MU2.

CMS has not made things any easier with its frequent rule changes. To start with, Levinthal notes, some electronic health record (EHR) vendors have not obtained 2014 certification, which is required for use in MU2. Other vendors have elected not to pursue this certification at all. That means that their customers will have to switch to other EHRs to show they have met the MU2 requirements.

In August 2014, CMS finalized a "flexibility rule" that allows EPs to use 2011- or 2014-certified EHRs or a combination of them if their vendors have been slow in delivering upgrades to the 2014 edition. But in 2015, vendors will have to use 2014-certified EHRs, and EPs who are scheduled

to attest to MU2 will have to do so.

The AMA has requested a stop to MU2 penalties due to interoperability challenges. "The whole point of the meaningful use incentive program was to allow for the secure exchange of information across settings and providers, and right now that type of sharing and coordination is not happening on a wide scale for reasons outside physicians' control," says AMA President-elect Steven J. Stack, MD.

In the MU2 attestation data that CMS has released, Levinthal says, 70% of attesting EPs have qualified for exclusions from the transitions-of-care requirements. CMS allows EPs to exclude these criteria if they have referred fewer than 100 patients to another physician or have ordered them to be transferred to another care setting, such as home care or a skilled nursing facility, during the reporting period.

Jones doesn't expect most EPs to abandon meaningful use and accept the Medicare penalties for failing to attest. As of July, CMS had received more than 44,000 hardship applications from practitioners requesting an extension for MU2 attestation. CMS stopped accepting hardship applications in November.

CHALLENGE 4

Getting paid

Increasingly, payment challenges will be tied to the ACA and the shift from the fee-for-service model to a value-based payment model.

The challenges are likely to grow in 2015 for some of those who work with Medicare patients. Under the ACA, physicians who don't participate in the Physician Quality Reporting System (PQRS) or aren't deemed successful participants for the 2013 program year will face a 1.5% penalty in Medicare payments in 2015 and 2% thereafter. In 2014, Medicare proposed that physicians not participating in PQRS that year would face penalties in 2016.

Private insurers are also increasingly adopting value-based payment models. An October 2014 study by the Analysis Group showed that private insurers are quickly shifting to value-based payments and risk-sharing. In 2011, 46% of respondents' beneficiaries were involved in such payment programs. That figure rose to 62% in 2014 and was projected to increase to 75% by 2017.

While claim denials have been decreasing in the past few years, some experts believe the ACA will usher in an era of more denied claims, so physicians are taking steps to avoid losing money this way.

Some physicians have opted out of accepting insurance altogether to avoid the hassles and changes resulting from healthcare reform. Mary Ann Block, MD, a general practitioner in the Dallas-Fort Worth, Texas, area, accepted insurance during her first year in private practice but didn't like having a third party making decisions that affected her patients. So 21 years ago she stopped accepting insurance. She doesn't work with Medicare and Medicaid patients, but says not all of her patients are wealthy. Her patients often have insurance and submit claims on their own. She says the decision has helped her avoid the insurance hassles with which many of her peers contend.

CHALLENGE 5

MOC

The controversy surrounding the American Board of Internal Medicine's (ABIM) Maintenance of Certification (MOC) program is extensive, and it's a challenge that will certainly follow physicians into 2015.

ABIM has faced backlash from physicians and advocacy groups over MOC's cost and time requirements. Depending on a physician's specialty, the application fee alone can range from $1,300 to $1,500.

The ABIM and other MOC proponents say that the program is necessary to ensure that physicians maintain their medical knowledge. However, some physicians argue that the test material often is not applicable to their specialties.

The ABIM released changes to the accreditation process at the beginning of 2014, and nearly 20,000 physicians signed a petition calling for those changes to be rescinded.

"Board certification is intended to serve both the public and our diplomates. Physicians rightly have expectations for a credential that recognizes their ongoing efforts to keep up in the specialty, but they also want it to be relevant and reflect what they do in practice," said Richard J. Baron, MD, ABIM president and chief executive officer. "We are listening to the feedback we have received from the community about changes to our program, but at the same time the public is seeking a way to know that their doctor is 'keeping up in their field.'"

Another point of contention is that the ABIM publishes physician certification statuses on its website as either "meeting" or "not meeting" MOC requirements. The ABIM said it would revisit this policy.

In June, the AMA's House of Delegates voted to assess the feasibility of conducting a study on MOC's impact on the medical profession and patient outcomes. COG

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NAVIGATING THE WATERS: BALANCING PATIENT CARE AND COSTS IN A COMMON OBSTETRICAL DILEMMA

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Case for consideration:[1]
A woman at 40 weeks' gestation presented to her Ob/Gyn due to suspected amniotic fluid leakage. After examining the patient (pooling, nitrazine and ferning), the physician determined no amniotic fluid was present and discharged the patient.

The following day, the woman once again presented with suspected premature rupture of membranes (PROM). Upon examination, a second Ob/Gyn observed green mucus, prompting the doctor to admit her for induction.

The child was infected at birth and suffered from cerebral palsy and developmental delay.

What would you do? Of course given hindsight, this outcome never would have happened on your watch. But are you really that confident in your traditional PROM diagnostics when the patient presents without that obvious gush or that convincing story? I am not, nor am I alone. This critical diagnosis continues to be one of the most challenging in Obstetrics. A landmark study by Neil and Wallace demonstrated that when patients presented with suspicion of PROM, in about 50% of cases the attending physician was uncertain about the diagnosis based upon history and physical examination alone.[2] Accurately diagnosing PROM at initial presentation, regardless of gestational age, is key to optimizing management decisions for these patients. The "gold standard" for diagnosing PROM, intra-amniotic infusion of indigo carmine dye, is highly invasive and not readily accessible. And traditional diagnostics have proven unreliable in cases of uncertain PROM.[3,4] Clinician uncertainty often leads to both unnecessary intervention and added costs for risk management reasons. So what are we as clinicians to do?

TECHNOLOGICAL ADVANCEMENTS

Objective evaluation of traditional testing methods (pooling, nitrazine, ferning and AFI) has shown each to be easy to use but relatively inaccurate.[5-8] This issue led to the investigation of numerous biomarkers with the goal of identifying an effective biomarker for PROM. The AmniSure® ROM Test detects placental alpha microglobulin-1 (PAMG-1) and has been an FDA-cleared diagnostic option since 2004. AmniSure is 99% accurate[3] and superior to standard clinical assessment.[9] Further, since October 2013, biomarker tests have been included in ACOG's PROM guidelines with specific reference to the PAMG-1 test (AmniSure).[10] Subsequent to the most recent publication of ACOG's PROM guidelines, a published multi-center study of 140 patients comparing the AmniSure ROM Test with intra-amniotic infusion of indigo carmine dye demonstrated 99% correlation.[11] The solution to our "PROM dilemma" is easily accessible now, so why is it not a universally used test?

THE COST OF CARE EQUATION

As a medical community, we often have trouble dealing with the higher cost of advanced diagnostics, even as we celebrate their increased effectiveness in practice. Not surprisingly, a rapid immunoassay costs more than a fern slide or nitrazine paper. However, the clinical utility of the AmniSure test really lies in its accuracy and how it is used in practice. Traditional diagnostic methods used alone or in combination are associated with increased cost as result of their poor accuracy, especially in non-obvious cases.[12] As is evident from our opening case, failure to diagnose PROM puts the patient at risk and eliminates the opportunity to implement timely and salutary obstetric measures. Conversely, a false positive PROM diagnosis can lead to unnecessary hospital admissions and inductions. Both of these situations can result in profound medical and financial implications for all involved.

Recently published evidence has investigated the costs of diagnosing PROM using AmniSure as compared to standard clinical assessment (SCA). Eleje et al found that, despite the higher material costs of the AmniSure test, the overall cost of SCA was 45% greater than that of the AmniSure test due to the longer time taken to perform SCA and the added costs of managing false-positive and false-negative cases.[13] This echoes the conclusions from Birkenmaier and colleagues' 2012 study comparing SCA to the AmniSure test. The study found that, when compared to clinical evaluation, an overall cost reduction of 58.8% could be realized by using only the AmniSure test.[4]

Further, Echebiri et al conducted an extensive theoretical analysis to compare the cost-benefit of AmniSure versus SCA in patients at 34 to <37 weeks presenting with suspicion of PROM. AmniSure was found to be the most cost-beneficial diagnostic method, especially when the probability of rupture was <38%. Additionally, the model demonstrated through probabilistic sensitivity analysis with Monte Carlo simulations that using the AmniSure test leads to an optimal strategy with a frequency of 89% regardless of rupture probability.[14]

Given the increased material cost of the AmniSure test, it makes economic sense that it should not be used in all cases when patients present with signs and symptoms of rupture. If the patient is obviously ruptured, there is no need for such an advanced diagnostic. However, in those non-obvious cases, clinical practice can benefit from the accuracy and the cost effectiveness of the AmniSure test. Bottom line, the AmniSure test is the most accurate non-invasive method of PROM diagnosis available today, and when used appropriately, the AmniSure test will provide optimal clinical utility.

NOT ALL PROM BIOMARKERS ARE EQUAL

Of note, not all biomarkers for PROM yield the diagnostic accuracy of the AmniSure test. The ROM Plus® Test is based on a combination of biomarkers (AFP and IGFBP-1) and demonstrates a poor specificity (75%) as noted in the warning on its FDA clearance.[15] False positive ROM Plus test results may lead to unnecessary and costly patient admissions, transfers or inductions. Further, there is no reference to the ROM Plus Test or its specific biomarker technology in ACOG's Guidelines for Management of PROM,[10] and clinical evidence has demonstrated diagnostic performance comparable to SCA.[16] From a clinical utility standpoint, it does not make sense to use a more costly biomarker test in lieu of SCA unless the biomarker test's performance is far superior to SCA.

The highly accurate and consistent clinical performance of the AmniSure ROM Test and its cost efficacy have been well demonstrated. In the words of Dr. Federico Mariona, "we must remain alert and responsive to useful changes and innovations in our field of practice."[17] As technology evolves, we as clinicians must evolve with it. Do not let your practice and your patient care linger in the 1940s with SCA. With the AmniSure ROM Test, we now have a better and more cost effective option to better guide our clinical decisions for optimal patient care.

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Is there a future for the independent ob/gyn?

BY **ROBERT WOLFSON, MD, PHD, FACOG, FAIUM,** AND **STEVEN FURMAN, MBA**

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Healthcare reform has left no provider untouched. Every day, physicians are faced with a daunting question: Do I remain independent, or do I sell my practice and become an employee?

As the main providers of primary and specialty care to women, ob/gyns are finding themselves at the forefront of this quandary. The Patient Protection and Affordable Care Act (ACA) is forcing practitioners to create an integrated system centered on the patient, clinical outcomes, and value (called the Triple Aim Objective).[1] In response to this pressure, healthcare is consolidating and moving toward hospital or healthcare system employment for practicing physicians and new residency graduates.

Although a 2012 survey of physicians by the American Medical Association showed that 53.2% of physicians were self-employed and 60% of physicians worked in practices that were wholly physician-owned,[2] physician hiring suggests a trend toward the employed physician. The American Hospital Association describes a 32% increase in hospital-employed physicians since 2000;[3] HealthLeaders Media's annual *Physician Alignment Survey* showed that 71% of their membership anticipated an increase in physician employment through 2015;[4] Merritt Hawkins reported that in 2012/2013, 64% of their physician searches featured hospital employment compared to 11% in 2004;[5] and Accenture, using data from Medical Group Management Association surveys, reported a decline in the "truly independent" physician from 57% in 2000 to approximately 33% in 2013.[6]

Challenges ob/gyns face

Ob/gyns face many challenges as healthcare is transformed from a fee-for-service, independent-based practice model to a global-payment, outcome-based employed model. **Our research, which included interviews with practice leaders,[7] identified 7 major challenges faced by most practitioners:**

1 ***Reimbursements.*** The shift in payment models from fee-for-service to pay-for-performance; increased access to healthcare via Medicaid expansion; coordination of

TABLE 1 Employed versus independent practice

	Hospital, Healthcare System, Group	Hospitalist	Boutique	Coalescence
Key attributes	• Employee of a large organization or hospital	• Practice as an obstetrical hospitalist	• Singularly independent	• Network of independent practices
Benefits	• Sophisticated support & administrative systems • Salaried • Focus on clinical care	• Salaried • Defined hours • High work-life balance	• Personalized care • Retainer fee • Complete practice autonomy • Equity ownership	• Economies of scale • Maintain autonomy & control • Equity ownership
Concerns	• Lack of cultural alignment • External leadership • Loss of control	• Must practice in alignment with hospital expectations	• Small, limited application • Population and geography dependent	• Different values & operating cultures • Multiple IT systems – lack of integration

care following discharge from the hospital; increasing risk and cost management shifted to the practice and the patient; and incentives to improve quality and efficiency of healthcare delivery all demand more personnel, IT, and financial resources to maintain current reimbursements.

2 ***Federal mandate compliance.*** Programs implemented by the Centers for Medicare and Medicaid Services (CMS) are mandated to meet the Triple Aim Objective and include Meaningful Use, Value-Based Payment Modifier, and Physician-Quality Reporting System. Compliance with these already demands greater resources in personnel and practice expense.

3 ***Increased practice expenses.*** Beyond the demands of federal compliance programs, practices face increasing direct and indirect costs of operation, increased investment in practice infrastructure (including EMR and IT systems), greater complexity in practice management, and increasing liability coverage costs.

4 ***Lifestyle.*** Ob/gyns new to practice tend to place a greater emphasis on life balance, a flexible or part-time schedule, and financial stability in the face of substantial personal educational debt.

5 ***A dichotomy within the physician community.*** Balancing the needs of physicians and the demands of care objectives seems to be translating into a division between practice within and exclusively outside of the hospital.

6 ***Physician shortage.*** Fewer ob/gyns are anticipated to practice as the baby boomer population retires.

7 ***Aging population.*** Every day, about 10,000 baby boomers retire. That trend may lead to increased demand for outpatient gynecologic services complicated by a declining number of ob/gyns.

Operating models

Given these challenges, we believe most practices will find themselves in one of 4 major operating models; 2 are employed-practice models and 2 are independent-practice models, as described in Table 1.

Employed

Outright sale of the practice. You sell your practice to a hospital or healthcare system, or multispecialty or single-specialty group. You relinquish ownership and delegate management tasks.

Exit the ob/gyn practice office. You commit to practicing full time in the hospital as an obstetric hospitalist—either as an employee of the hospital or under the auspices of a network of ob/gyn practices. The practice has defined hours. Full time may be working 3 out of 7 days.

Independent

Boutique practice. You remain fully independent in a small practice, but contract with patients for unique access and personalized care in return for an annual retainer fee that is above and beyond payer reimbursement. This creates a more stable revenue stream. However, to be viable, this

configuration depends on population features and geography beyond the control of the practice.

Boutique practice also implies a cash-only operation, because most current payer contracts preclude additional patient fees.

Coalescence. You form an independent practice association or network of independent ob/gyn practices under one entity that can take advantage of economies of scale and retain leverage in reimbursement negotiations while maintaining autonomy and control. There are also opportunities to be independent and an exclusive provider of ob/gyn services under an Exclusive Provider Organization or Accountable Care Organization. You are not selling your practice; rather, you are joining like-minded practices and colleagues. You retain equity ownership.

Why you should consider selling your practice

Should you sell your practice or remain independent? **Our interviews with practice leaders suggest you should consider selling your practice for these reasons:**

Reimbursement. Independent practice leaders shared with us that the scale provided by a hospital or healthcare system implies better reimbursement negotiating power. As a result, reimbursement from payer can be greater for the same care. This tends to give hospitals and healthcare systems a competitive advantage.

Management support. Management of the practice by others means more time for providers to focus on providing healthcare. Professionally managed independent practices may not realize this benefit.

A more stable work environment. Clinical care can come in defined shifts, simplifying being on-call. Full time may be no more than 3 shifts per week as an obstetrical hospitalist. Flexible schedules and part-time practice are possible.

More back-office resources and support. Larger organizations are more competitive in providing resources beyond just IT and HR, such as creating marketing, Web and social media presence.

Financial stability. Compensation is commonly a salary with productivity bonus based on RVUs per patient encounter.

Federal mandate compliance. Programs implemented by CMS, including MU, VBPM and the PQRS, will shift from incentives to penalties as early as 2015. Intended to enhance the value of healthcare, these federal programs will require substantial resources to achieve compliance—resources that are more easily had in a larger organization.

Risks to operating under an employed model

Financial stability. Compensation is a salary with a productivity bonus, but the value is not guaranteed and may fluctuate. Formulas used to calculate compensation and productivity may change.

Management support. On-call schedules and clinic schedules may change to meet the operational and financial needs of the organization. Choices may not take into account the needs of patients and staff.

Back-office resources and support. The way the cost of these services is allocated to physicians or their area of practice impacts salary and bonuses can change.

Federal mandate compliance. Program goals may be met and benchmarks may be achieved, but at what cost? Will this translate into laying off (rather than training) physicians who do not meet benchmarks? Will patient encounter times be shorter? Will the doctor-patient relationship matter?

How independent practices can succeed

There will always be a place for ob/gyns in independent practice. They play a unique role in the healthcare delivery system. They are typically very connected to their communities and patients; physicians in these practices have often trained in their communities; they tend to live in the communities where they practice; and they may have treated many generations of a family.

Among the successful independent practitioners we interviewed, 3 characteristics stand out:

1 ***They have autonomy and control.*** Independent practices value their autonomy and independence. They believe that independence enables them to create their own practice style and operating environment, and to adapt to the needs of their patients. They do not want another entity to dictate how they practice medicine and affect patient care and their personal happiness. They also fear loss of internal leadership.

2 ***They prioritize what is best for their patients.*** Independent practices strive to preserve the long-standing physician-patient relationship. Because they have a connection with

TABLE 2 Questions to ask about leadership style before selling your practice

INDEPENDENCE: To what degree will you be given leadership independence?

OPPORTUNITIES: What role will you have in creating and positively influencing your future?

INPUT: To what degree will you be included in the strategic decision-making process?

ALIGNMENT: In what areas does the acquirer's approach to leadership align with yours, and where do you differ?

their patients and have earned their respect and trust over time, their patients believe they are always acting in their best interest. This increases patients' willingness to share sensitive information and enables physicians to deliver high-quality care.

3 ***They have a strong practice culture predicated on shared values.*** The foundation of a practice is its culture. It determines how its members act. Culture directly affects physician productivity, happiness, passion, engagement, and performance. Practices with a strong organizational culture tend to have better clinical, operational, and financial outcomes. Successful independent practices reflect a culture that prioritizes the happiness of their providers. As one clinician we interviewed stated: ". . . we prioritize the happiness and fulfillment of our teammates. This is a value we hold dear."

Beyond the money: what to consider when selling your practice

Due diligence typically uncovers the financial, operational, and (to some extent) clinical benefits and risk factors associated with a particular deal. Once those details have been articulated, most owners and practice managers believe they have the information necessary to ascertain whether to proceed with the sale or merger. Unfortunately, they have underestimated the importance of culture. Robert W. Holthausen, who teaches merger and acquisition strategy at the Wharton School of the University of Pennsylvania, notes that mergers and acquisitions have failure rates of between 50% and 80%.[8] While startling, this statistic is understandable when you realize that most deals derail not because of financial reasons, but because of cultural differences.

Physicians should assess their practice's culture and whether it aligns with the culture of a potential acquirer. Cultural alignment is the key to a successful and sustainable merger or acquisition. If the 2 cultures align, it is highly probable that the merger will prove sustainable. Lack of cultural alignment is a strong indicator that this is a high-risk deal with a high probability of failure.

Consider 5 components of organizational culture when making the decision to sell your practice. They will enable you to determine the degree of alignment between your practice and the person or entity that is acquiring it.[9] **These components are:**

1 ***Purpose and values.*** What is the practice's reason for being? Values are a practice's enduring tenets—the way the practice pursues its purpose. It is what the practice stands for and defines how the practice treats its team members and patients. A practice's values are manifest in specific behaviors.

This is the area that creates the most dissonance between entities. Lack of value alignment typically leads to decreased morale; unhappy clinical providers; disengaged providers; diminished trust; suboptimal clinical, operational, and financial outcomes; and ultimate failure of the merger.

2 ***Leadership.*** Leadership is about creating a compelling vision and strategic influence. It entails encouraging, inspiring, and motivating people. Leadership resides within an independent practice. Once you agree to sell your practice, you also agree to relinquish leadership and decision-making authority, and must now rely on the leadership expertise of others. Answers to the questions in Table 2 will help avoid surprises, provide insight and enable you to understand how you will be led after the acquisition.

3 ***Teams.*** Successful independent practices typically have a team-oriented culture. They understand that there is a direct correlation between having dedicated, committed, passionate, and satisfied caregivers and providing high-quality care. Team members are included in strategic, clinical, operational, and financial decisions. They trust and respect one another. Ideas and concerns are shared freely. Most importantly, team members feel valued.

TABLE 3 Steps to take before practice sale or merger

Component	Action	Considerations
I. Assess existing practice culture and values	• Understanding, assessing and quantifying the 5 cultural factors	• Degree of alignment between potential buyer or merger partner
II. Review self-knowledge	• Self-awareness/self-understanding	• Personal values; practice culture; lifestyle; risk tolerance
III. Consider practice models or retirement		
*Practice network	• Coalescence of practices—optimal strategy for staying indepe ndent	
* Obstetrical hospitalist	• Becoming a hospital or healthcare system employee	• Lifestyle and career advantages and satisfaction
* Boutique practice	• Practicing medicine under boutique model	• Lacks viability except in unique settings
* Retirement	• Developing exit strategy	• Action required in the near term – less than 5 years

4 ***Support mechanisms.*** One of the benefits to merging with a larger entity is the increased breadth and quality of its support mechanisms for reimbursement, revenue cycle, EMR, IT, scheduling, reporting, and performance-tracking. Having someone else provide administrative/back office support is liberating and enticing.

5 ***Performance improvement strategies.*** Focusing on strategies to improve performance enables a practice to deliver high-quality care while achieving superior clinical, operational, and financial outcomes. Practice networks, hospitals, and healthcare systems understand the need to optimize their administrative/back office systems; they accept the challenges of ACA and strive to improve their performance.

In contrast, an independent practice's desire to maintain its autonomy may diminish its perceived need to adapt and change in response to ACA.[2] For example, many independent practices are struggling with meaningful use compliance. They cling to outdated record systems and processes. But ACA is here to stay.

Before being acquired by a larger entity or acquiring a practice, understand your potential partner's approach to performance improvement and how efficiency and productivity are prioritized.

Recommendations

For many physicians, deciding what to do in the face of healthcare reform is very taxing. They put their heart and soul into building their practice and creating long-standing relationships with their patients. There is no ideal solution or optimal course of action that meets the needs and expectations of every practice and physician.

Before selling or merging your practice, objectively assess yourself, your team, your practice, and your potential partner/employer in the areas in Table 3. This will enable you to make an informed decision and minimize risk. COG

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Regarding 'Preventing ureteral injury at hysterectomy: an expert approach'

TO THE EDITOR:

Dr. Magrina's article on ureteral injuries during hysterectomy [Preventing ureteral injury at hysterectomy: an expert approach, October 2014 *Contemporary OB/GYN*] was very informative. However, I think stating that the risk of ureteral injury is higher for vaginal hysterectomy (VH) was misleading.

The reference for this information was a report from Mayo Clinic in Rochester, Minnesota.[1] The population of this study was highly skewed for pelvic floor disorders and included women who had already undergone hysterectomy. It was actually a descriptive analysis of all ureteral injuries during all major pelvic operations for benign conditions over 6 years. They identified 18 such cases and reported a 0.33% ureteral injury rate.[1] An overwhelming 16 of these occurred during vaginal reconstructive procedures (13 cases included VH) but exclusively in cases performed for correction of pelvic organ prolapse (POP) and urinary incontinence as a result of placement of uterosacral suspension sutures for a high McCall procedure or elevation of the bladder neck.

High uterosacral suspension, which is known to cause intraoperative ureteral occlusion in up to 11% of the cases,[2] is not indicated during a simple vaginal hysterectomy if there is no POP. One must bear in mind that only a small fraction of all hysterectomies are performed for prolapse.

According to the most recent meta-analysis by the Cochrane Library on all hysterectomy routes, no statistically significant differences in bladder, ureter, or urinary tract injuries were noted between VH and abdominal hysterectomy (AH).[3] There was a greater than 2-fold increased risk of urinary tract injury (bladder and ureter injuries were pooled together, as the combined sample size was too small to detect a statistical difference) for laparoscopic hysterectomy (LH) versus AH but no difference between LH and VH.

Among different types of LH techniques such as laparoscopic total (TLH), supracervical and laparoscopically assisted vaginal hysterectomy, specifically TLH was found to increase the risk of urinary tract injuries over 3-fold when compared to VH.

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Oz Harmanli, MD
Springfield, MA

IN REPLY:

Dr. Harmanli indicates in his letter that in my article, "Prevention of ureteral injury at hysterectomy: an expert approach," I misquoted Dr. Stanhope's results of ureteral obstruction[1] in saying that the rate of ureteral obstruction after vaginal hysterectomy is higher than abdominal hysterectomy, and he finds this misleading.

Dr. Harmanli is incorrect in his letter. Dr. Stanhope reported a rate of ureteral obstruction of 0.07% for 2833 abdominal hysterectomies, while the rate of ureteral obstruction after vaginal hysterectomy was 9 times higher: 0.63% for 2546 vaginal hysterectomies.[1] While the rate may be higher, lower, or similar in other reports, this was not the case in that study.

Javier F. Magrina, MD

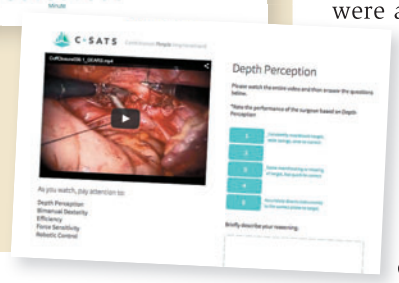
REFERENCE

1. Stanhope CR, Wilson TO, Utz WJ, Smith LH, O'Brien PC. Suture entrapment and secondary ureteral obstruction. *Am J Obstet Gynecol.* 1991;164:1513–1517.

Product doubleheader

Our reviewer took two products for gynecologic surgeons for a test drive. Here's what he found.

PRODUCT: C-SATS



COMPANY: C-SATS
(SEATTLE, WA)

WEBSITE: WWW.CSATS.COM

LIST PRICE: $100 PER ASSESSMENT

Background

According to the Greek writer Pausanias, "γνῶθι σεαυτόν" ("know thyself") was inscribed in the forecourt of the Temple of Apollo at Delphi. Without getting overly spiritual, this ancient dictum can be an excellent starting point for surgeons who want (or need) to improve their technique. But how do surgeons gain insight into their technical failings to best understand where they need improvement? One simple way is to ask colleagues for constructive criticism. While this approach is easy enough in theory, the perils and pitfalls when seeking meaningful change are obvious.

Recording videos of cases and personally reviewing them with a critical eye is another option that is practical and has many benefits (I do it regularly and highly recommend it). However, it does introduce a huge element of observer bias; specifically, techniques that each of us may consider adequate may be viewed by others as suboptimal. Finally, a combination method might be to record cases anonymously and ask skilled observers to review elements of the procedures and offer their collective opinions as feedback to the operating surgeon. Nice idea but it seems sort of a "pie-in-the-sky" solution. Well, it may be that the pie has landed in the form of "Crowd-Sourced Assessment of Technical Skills," or C-SATS.

Design/Functionality

Based on technology developed at the University of Washington by a team of physicians, software engineers, and biostatisticians, researchers in 2013 demonstrated that, using specific criteria, a group a 500 Internet reviewers were able to score a surgeon's technique as accurately as 10 expert surgeons.[1] C-SATS uses the power of the Internet to rapidly and reproducibly have surgical videos analyzed by a wide range of reviewers with a focus on a defined sets of skills, such as tissue handling, efficiency of movement, and bimanual dexterity.

Reduced to simple terms, surgeons submit videos of procedures to C-SATS, which the company edits to highlight specific areas in which specific skills are demonstrated. Next, the clips are sent to online experts and reviewers worldwide, who anonymously evaluate them using defined and accepted assessment tools, such as GOALS and GEARS. The results are then tabulated and quantified and qualified feedback is provided to the submitting surgeon within hours.

Feedback is provided to the submitting surgeon within hours.

I submitted 4 separate videos of vaginal cuff closures at laparoscopic and/or robotic total hysterectomy to C-SATS. Within 12 hours, their analyses of all 4 procedures came back. I then reviewed my videos again against my performance summary from C-SATS to see what I thought of their analysis of my skills. I was impressed (with their analysis, not my techniques). I mostly agreed with their conclusions and thought the whole exercise was an outstanding, confidential self-assessment tool that will help me im-

prove my technique so that I can offer better care to my patients.

DESIGN/FUNCTIONALITY: ★★★★

Innovation

In his 1951 sci-fi classic, *Foundation*, Isaac Asimov introduced us to Hari Seldon and the "psychohistorians" who use mathematics and the psychology of populations to predict the future. As the Web increasingly connects our world of individuals into a crowd in the cloud, innovators are daily introducing technologies to harness our collective energy to efficiently offer solutions to challenges that previously were unattainable. I have never seen a similar product in this space but I have little doubt there will soon be many. C-SATS is innovation gone wild.

INNOVATION SCORE: ★★★★★

Clinical Transformative Potential

Crowd-sourced assessment of technical skills as a technology is new—very new—and, in theory, offers tremendous potential for helping surgeons perfect their technique. As excited as I was to try this product, the cynic in me cautions that the technology will be only as good as an individual's willingness to accept the results and those results will be only as good as the assessment tools that are employed.

CLINICAL TRANSFORMATIVE POTENTIAL: ★★★★½

Summary

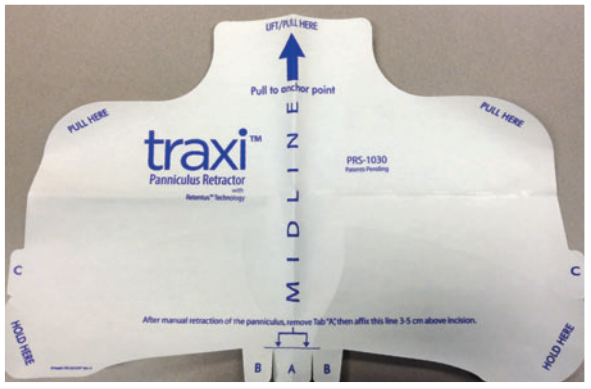
Submitting oneself to the judgment of others can be a threatening endeavor but, more often than not, improving necessitates some external analysis and feedback. In that regard, the technology introduced by C-SATS is beautiful in its efficiency and cold anonymity. It is not a panacea for inadequately trained surgeons or a perfectly validated method of assessing surgical competence but it is a really exciting start. Physicians who are not interested in improving their professional skills need to get different jobs. As I have long maintained, to expect perfection is unrealistic; to not seek perfection is unacceptable.

OVERALL SCORE: ★★★★½

REFERENCE

1. Kowalewski TM, White LW, Lendvay TS, et al. Beyond task time: automated measurement augments fundamentals of laparoscopic skills methodology. *J Surg Res*. 2014;192 (2): 329–338.

PRODUCT: **TRAXI PANNICULUS RETRACTOR WITH RETENTUS TECHNOLOGY**



COMPANY: CLINICAL INNOVATIONS *(MURRAY, UT)*
WEBSITE: WWW.CLINICALINNOVATIONS.COM
LIST PRICE: $599.95 (BOX OF 10)

Background

Obesity is a big problem in the United States that seems to be growing. According to a recent study published in JAMA, more than one third of American adults (34.9%) qualify as obese (BMI ≥30) with 7.7% of women in their peak reproductive years (ages 20–39) categorized as obese grade 3 (BMI ≥40).[1] While this issue has a myriad of health and healthcare implications, in operative obstetrics, it often presents the practical challenge of how to safely and comfortably perform a cesarean delivery with a massive pannus overhanging the intended surgical site.

With experience, many hospitals, L&D nurses, and obstetricians have developed their own MacGyver-style solutions with some combination of pads, tape, sheets, straps, and gravity. All too often, though, the final plan has relied on good old-fashioned elbow grease from the lowest person on the totem pole. For those of us unlucky enough to have sweated through this extreme retracting opportunity, Clinical Innova-

tions now comes to the rescue with the Traxi Panniculus Retractor.

Design/Functionality

The Traxi Panniculus Retractor is a 25" x 16" latex-free, hypoallergenic sheet of adhesive-backed film. It is FDA-approved as a Class I device and sterilely packaged as a single-use product. In a nutshell, it looks like a giant piece of Telfa. According to the company, "application is quick and easy." The idea is to manually retract the pannus, apply the lower portion of the Traxi 5 cm above the incision line, lift the pannus cephalad and secure the upper portion of the device to the upper abdomen/lower thorax and the level of the xiphoid process.

A common-sense, straightforward solution.

I used the Traxi for cesarean delivery on a patient with a BMI of 45 and a serious overhanging pannus. WOW! This thing really worked! Easy to apply; fully retracted the pannus. I see no obvious areas for improvement from my perspective.

DESIGN/FUNCTIONALITY: ★★★★★

Innovation

As much as I love this product, I cannot give the folks at Clinical Innovations too many innovation stars because the Traxi is really just the best iteration of similar things many of us have been doing for years. That said, they did it, they got it right, and nobody else put all the pieces together in such a common-sense, straightforward fashion. So, kudos to the Traxi.

INNOVATION SCORE: ★★★

Clinical Transformative Potential

Performing safe cesarean deliveries on significantly obese patients is not to be taken lightly. These cases can be very difficult and present a variety of added dangers to both mother and baby. Having a simple, reliable, and reproducible way to mitigate some of the unique challenges a large pannus presents is essential. I think Traxi is that answer in a package.

CLINICAL TRANSFORMATIVE POTENTIAL: ★★★★

Summary

I really, really, really hate holding back the pannus when doing cesarean deliveries. I am old and weak and invariably come away with a sore shoulder and sweat-soaked scrubs.

The Traxi Panniculus Retractor with Retentus Technology is as perfect a solution to the pannus problem as I have ever tried. This product is a winner . . . a big-time winner.

OVERALL SCORE: ★★★★★

DR. GREENBERG is Chief, Division of Gynecology, Brigham & Women's Faulkner Hospital, and Associate Professor, Harvard Medical School, Boston, Massachusetts.

The views of the author are personal opinions and do not necessarily represent the views of *Contemporary OB/GYN*. Dr. Greenberg personally tests all of the products he reviews. He has no conflicts of interest with these products or the companies that produce them.

REFERENCE

1. Ogden CL, Carroll MD, Kit BK, Flegal KM. Prevalence of childhood and adult obesity in the United States, 2011-2012. *JAMA*. 2014;311(8):806–814.

IN CASE YOU MISSED IT

Have you read these product reviews by Dr. Greenberg?

The NeoClose
http://bit.ly/1A0MCzq

T'Lift
http://bit.ly/1vC3WTR

PKS BiLL
http://bit.ly/1tym8y2

Tools for laparoscopic contained tissue extraction
http://bit.ly/1xCVLe8

continued from **PAGE 28**

niques can be introduced through traditional pathways such as cognitive behavioral therapy or with mindfulness-based stress reduction. Both techniques have been shown to diminish emotional distress and reported pain intensity, and may contribute to an overall improvement in a patient's perceived ability to recover.[19]

Identify local psychologists with a focus on pain management and pain coping to ensure that your patients receive exposure to these successful practices. They can also provide an opioid risk assessment for patients for whom you are considering long-term opioid therapy.

Complementary and alternative medicines

While limited evidence exists regarding complementary medicine practices and chronic pelvic pain, anecdotal experience is mainstream.[20] Dietary changes, supplement use, yoga, and acupuncture are popular pain management practices in patients with nonmalignant pain. However, clinical data are lacking. Referral to an academic-based integrative medicine program may not be covered by insurance but can provide guidance for patients interested in alternative practices for pain management.

Summary

Caring for patients with functional chronic pelvic pain without an obvious etiology can be very challenging. It is important to review realistic expectations with your patients in regard to tolerable daily pain levels and have an action plan to manage pain "flares" to reduce phone calls and emergency room visits. Regular scheduled visits to review the action plan can be effective. COG

DR. CAREY reports receiving honoraria from Teleflex.

DR. FINDLEY has no conflict of interest to resport with respect to the content of this article.

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COG

Find resources for chronic pain patients at the National Center for Complementary and Alternative Medicine of the National Institutes of Health:

- **Complementary Health Approaches for Chronic Pain: What the Science Says**
  http://nccam.nih.gov/health/providers/digest/chronic-pain-science
- **Chronic Pain and Complementary Health Approaches: What You Need To Know**
  http://nccam.nih.gov/health/pain/chronic.htm

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FEBRUARY 2015

2–7: The Society for Maternal-Fetal Medicine 35th Annual Pregnancy Meeting
San Diego, California
https://www.smfm.org/the-pregnancy-meeting

28: Advances in Obsteterics and Gynecology Conference
San Diego, California
http://www.sharp.com/health-classes/advances-in-obstetrics-and-gynecology-conference-1530?utm_source=Advertising&utm_medium=Vanity&utm_campaign=CME

MARCH

4–7: Council on Resident Education in Obstetrics and Gynecology and Association of Professors of Gynecology and Obstetrics
San Antonio, Texas
https://www.apgo.org/meetings/creog-a-apgo-annual-meeting.html

22–25: Society of Gynecologic Surgeons 41st Annual Scientific Meeting
Orlando, Florida
http://www.sgsonline.org/scientific-meeting

25–28: Society for Reproductive Investigation Annual Meeting
San Francisco, California
http://www.sgionline.org/sri-meetings

28–31: Society of Gynecologic Oncology Annual Meeting on Women's Cancer
Chicago, Illinois
https://www.sgo.org/education/annual-meeting-on-womens-cancer/

MAY

2–6: American College of Obstetricians and Gynecologists Annual Clinical Meeting
San Francisco, California
http://www.acog.org/About-ACOG/ACOG-Departments/Annual-Meeting

14–16: Update on Fetal Diagnosis and Treatment
Philadelphia, Pennsylvania
http://www.chop.edu/events/update-fetal-diagnosis-and-treatment#.VHOLHBb6ZhN

JUNE

6-10: American Medical Association Annual Meeting
Chicago, Illinois
http://www.ama-assn.org/ama/pub/about-ama/our-people/house-delegates/meeting-dates.page?

9-12: The Society of Obstetricians and Gynaecologists of Canada Annual Clinical and Scientific Conference
Quebec City, Quebec, Canada
http://sogc.org/events/annual-clinical-scientific-conference/

SEPTEMBER

2-5: Society of Laparoendoscopic Surgeons Minimally Invasive Surgery Week / Annual Meeting and Endo Expo
New York City, New York
http://sls.org/mis2015/

17-19: American Gynecological and Obstetrical Society Annual Meeting
Half Moon Bay, California
http://agosonline.org/event-2015-annual-meeting.html

30- OCT 3: North American Menopause Society Annual Meeting
Las Vegas, Nevada
http://www.menopause.org/annual-meetings

OCTOBER

4-9: International Federation of Gynecology and Obstetrics World Congress
Vancouver, British Columbia, Canada
http://figo2015.org/

10-15: International Society of Ultrasound in Obstetrics and Gynecology World Congress
Montreal, Quebec, Canada
http://www.isuog.org/WorldCongress/2015/

13-17: American Urogynecologic Society Annual Scientific Meeting
Seattle, Washington
http://www.augs.org/p/cm/ld/fid=52

17-21: American Society for Reproductive Medicine Annual Meeting
Baltimore, Maryland
http://www.asrm.org/awards/detail.aspx?id=5802

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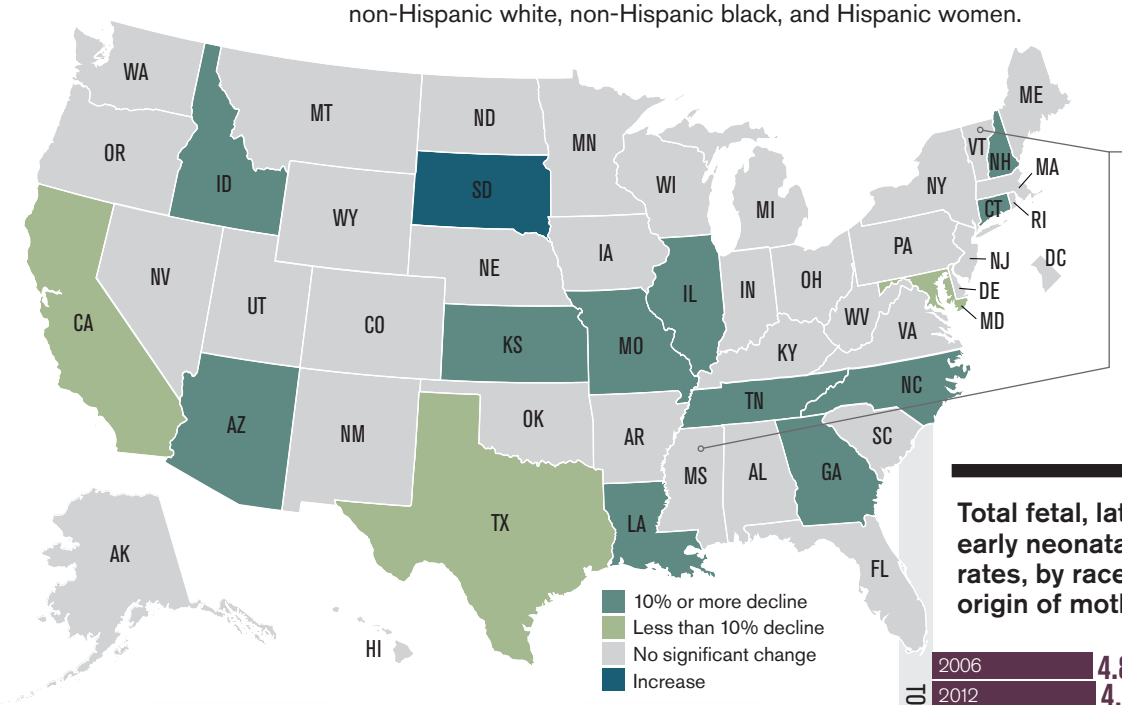
PAULA J. ADAMS HILLARD, MD
SECTION EDITOR

TRENDS IN FETAL AND PERINATAL MORTALITY

A new CDC report shows that while perinatal mortality rates are continuing to decline—down 10% since 2000—the US fetal mortality rate for the latest study period (2006–2012) did not improve. Rates of total, early, and late fetal mortality were flat for the most recent years and essentially unchanged among non-Hispanic white, non-Hispanic black, and Hispanic women.



Perinatal mortality rates in the US ranged from **3.65 per 1,000 in Vermont** to a high of **8.91 in Mississippi** in 2010-2011.

4%

decline in overall perinatal mortality rate

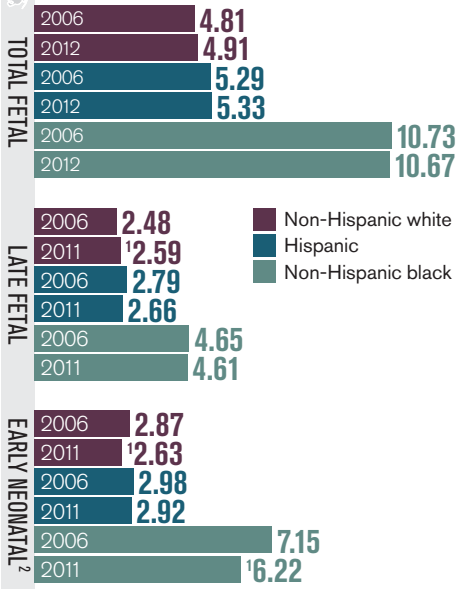
From 6.51 per 1,000 in 2006 to 6.26 in 2011

8%

decline in overall early neonatal mortality rate

From 3.55 per 1,000 in 2006 to 3.28 in 2011

Total fetal, late fetal, and early neonatal mortality rates, by race and Hispanic origin of mother



1. Change is significant at 0.05.
2. 2011 is the most recent year for which neonatal death data are available.

Early fetal morality rate is the number of fetal deaths at 20-27 weeks' gestation per 1,000 live births and fetal deaths at 20-27 weeks' gestation.

Early neonatal mortality rate is the number of infant deaths under age 7 days per 1,000 live births.

Perinatal mortality rate is the number of infant deaths under age 7 days and fetal deaths at ≥28 weeks' gestation per 1,000 live births and fetal deaths at ≥28 weeks' gestation.

Source: Gregory ECW, MacDorman MF, Martin JA. Trends in fetal and perinatal mortality in the United States, 2006–2012. NCHS data brief, no 169. Hyattsville, MD: National Center for Health Statistics. 2014.

BEST HOSPITALS
U.S.News & WORLD REPORT
NATIONAL
GYNECOLOGY
2014-15

WE'RE CHANGING THE WAY

OVARIAN CANCER PATIENTS FEEL ABOUT THE FUTURE

Intraperitoneal (IP) chemotherapy was introduced as a way to treat ovarian cancer by administering chemotherapy directly to the abdomen rather than through a vein. While this treatment extended median survival for women, the side effects were harsh and many women were unable to complete treatment. Our faculty at **Magee-Womens Hospital of UPMC** and **UPMC CancerCenter** played a major role in the adaptation of IP to a modern outpatient regimen, reducing side effects and improving outcomes by adjusting dosing and anticipating and controlling symptoms. Oncologists at Magee and throughout UPMC were also among the first to use hyperthermic IP chemotherapy for the treatment of ovarian cancer. Learn more at **UPMCPhysicianResources.com/OvarianCancer.**

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