FETAL HYDROPS
THE SMFM GUIDELINES

Society for Maternal-Fetal Medicine with the assistance of Mary Norton, MD; Suneet P. Chauhan, MD; and Jodi Dashe, MD
Women with hypertriglyceridemia, or a family history thereof, may be dyslipidemias. A small proportion of women will have adverse lipid Carefully monitor prediabetic and diabetic women who are taking 5.6 Carbohydrate and Lipid Metabolic Effects increasing concentrations of progestin. duration of use. The incidence of hypertension increases with COCs, and this increase is more likely in older women with extended An increase in blood pressure has been reported in women taking with uncontrolled hypertension or hypertension with vascular disease should not use COCs. with a history of pregnancy-related cholestasis. Women with a history Oral contraceptive-related cholestasis may occur in women with per million users. Acute or chronic disturbances of liver function may necessitate the Discontinue Lo Loestrin Fe if jaundice develops. Steroid hormones differences in sexual behavior and other factors. is controversy about the extent to which these findings may be due to the risk of cervical cancer or intraepithelial neoplasia. However, there Some studies suggest that COCs are associated with an increase in 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 at the time of the first missed period and take If the patient has not adhered to the possibility of pregnancy. If the patient has adhered to the scheduled (withdrawal) bleeding and/or spotting remained fairly Spotting (which may be prodromal of a cerebrovascular event) may be a An increase in frequency or severity of migraine during COC use Lo Loestrin Fe if indicated. If a woman taking Lo Loestrin Fe develops new headaches that are 5.7 Headache 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/m² 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. Please see Important Safety Information and Brief Summary of Full Prescribing Information for Lo Loestrin Fe, including Boxed Warning, on adjacent pages and also available at www.loloestrin.com.
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/m² 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 an 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
- 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
Information

BRIEF SUMMARY: Consult the Package Insert for Complete Prescribing

Lo Loestrin® Fe (norethindrone acetate and ethinyl estradiol tablets, following conditions:

- Do not prescribe Lo Loestrin Fe to women who are known to have the
  - Have headaches with focal neurological symptoms or have
  - Have diabetes mellitus with vascular disease
  - Have uncontrolled hypertension
  - Have inherited or acquired hypercoagulopathies
  - Have cerebrovascular disease
  - Smoke, if over age 35

Now or in the past [see Warnings and Precautions (5.2)]

valvular

[see Boxed Warning and Warnings and Precautions]

COCs might increase the incidence of breast cancer, more recent 

Women who currently have or have had breast cancer should not use

5.2 Carcinoma of the Breast and Cervix

risks of cerebrovascular events (thrombotic and hemorrhagic strokes),

Women with a history of depression should be carefully observed and

Lo Loestrin Fe discontinued if depression recurs to a serious degree.

Women with a history of depression should be carefully observed and

Studies also do not suggest a teratogenic effect,

Extensive epidemiologic studies have revealed no increased risk

6.1 Clinical Trial Experience

A multicenter phase 3 clinical trial evaluated the safety and efficacy

A total of 1,660

1 percent of subjects

8.3 Nursing Mothers

Women who do not breastfeeding mothers. This is less likely to occur once breastfeeding is well-established; however,

8.8 Body Mass Index

The safety and efficacy of Lo Loestrin Fe in women with a body mass index (BMI) > 35 kg/m² has not been evaluated.

10 OVERDOSE

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

17 PATIENT COUNSELING INFORMATION

See FDA-approved patient labeling.
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/m² has not been evaluated.

SELECTED SAFETY INFORMATION about Lo Loestrin Fe, including Boxed Warning

<table>
<thead>
<tr>
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<tbody>
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</tr>
</tbody>
</table>

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.


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- NO GESTATIONAL AGE LIMITATION
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- MOST WIDELY USED ROM IMMUNOASSAY


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24 Fetal hydrops
SOCIETY FOR MATERNAL-FETAL MEDICINE WITH
THE ASSISTANCE OF MARY NORTON, MD;
SUNEET P. CHAUHAN, MD; AND JODI DASHE, MD
A summary of the evidence-based SMFM guidelines for the evaluation and management of nonimmune hydrops fetalis (NIHF).

POINT/COUNTERPOINT
18 Emergency contraception: Are we getting the word out?
FRANCES CASEY, MD
CHRISTINE ISAACS, MD
One writer feels that we’ve come a long way in increasing awareness; the other argues that we still have a long way to go.

PRACTICE MATTERS
21 Getting paid: New strategies
CHERYL BISERA
In an age of high deductables, a clear financial policy is essential.

CLINICIAN TO CLINICIAN
28 The importance of an AGC Pap
STEVEN R. GOLSTEIN, MD, CCD NCMP, FACOG, FRCOG(H), AND RACHEL C. CARROLL, MD, MPH
Should a finding of atypical glandular cells (AGC) merit the same concern as postmenopausal bleeding?

34 Reproductive coercion: Counseling strategies
ELIZABETH MILLER, MD, PHD, AND JUDY CHANG, MD, MPH
A guide for the clinician faced with IPV.

EDITORIAL
6 CHARLES J. LOCKWOOD, MD, MHCM
The new FDA categories for drugs used in pregnancy are a big improvement.

WOMEN'S HEALTH UPDATE
8

LETTERS TO THE EDITOR
11

OB/GYN STAT BITE: CONTRACEPTION
46

CAREERS/AD INDEX
52

LEGALLY SPEAKING
56
Koh-Effi cient Helps to Create a “Margin of Safety” by Displacing the Ureters during Colpotomy Incision

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New FDA pregnancy drug categories: a significant improvement

In a welcome change, the old letter-based system will be replaced by 3 narrative subsections.

For decades obstetricians have complained about the Food and Drug Administration (FDA) system for labeling prescription drugs and newer biological agents. The letter categories (i.e., A, B, C, D, X) are confusing, at times counter-intuitive and, from a counseling perspective, often useless.

Fortunately, the FDA recently announced a completely new approach to labeling which represents a vast improvement over the old paradigm and should make counseling patients more efficient, effective, and accurate.

The old labeling system

For decades the FDA employed a simple classification scheme to rate the relative safety of a given pharmacological agent in pregnancy. This letter system can be summarized as follows:

A: Controlled human studies show no fetal risk—this category is straightforward.

B: Either animal studies have not demonstrated a fetal risk but there are no controlled studies in pregnant women, or animal studies have demonstrated a fetal risk not confirmed by studies in pregnant women—in other words, the drug probably is safe.

C: Either animal studies demonstrate adverse fetal effects (e.g., pregnancy loss or teratogenesis) and there are no controlled studies in women, or studies in women and animals are not available. In either case, such drugs should be given only if the potential benefits justify potential risks to the fetus—but of course we can’t be sure what those risks actually are!

D: While there is evidence of human fetal risk, maternal benefits render such therapy acceptable—except that, in my experience, many women are willing to sacrifice the clear benefit to their health of a drug to lower even an abstract theoretical risk to their fetus!

X: Contraindicated in pregnancy—Also a straightforward category.

Of course, manufacturers generally provide more detail about available studies in pregnancy, and they usually note whether a drug can be found in breast milk and attempt to address breastfeeding implications. However, such data are highly variable in detail, quality, and utility.

The new labeling system

The new drug use in pregnancy information system is contained in a “final rule” published on December 3, 2014 as “Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements for Pregnancy and Lactation Labeling.”

This new approach to labeling represents a vast improvement over the old paradigm.

It is referred to more succinctly as the “Pregnancy and Lactation Labeling Rule” (PLLR) and will formally take effect on June 30. The rule will apply to all drugs approved, or that are in the process of approval, after June 30, 2001. Manufacturers of drugs approved before that time will be required to remove their drug’s pregnancy category from their labeling in 3 years and, although exempt from
The “Pregnancy and Lactation Labeling Rule” (PLLR) will formally take effect on June 30.

The PLLR, are encouraged to follow the new guidelines. The old letter-based system will be replaced by 3 narrative subsections: pregnancy (including labor and delivery), lactation, and females and males of reproductive potential. Each subsection is designed to provide evidenced-based information that can be used by providers to more effectively counsel patients and help them make more informed choices.

Subsection 8.1, Pregnancy
Information in this subsection includes 4 subheadings addressing the availability of pregnancy exposure registries, a risk summary statement, other pertinent clinical considerations, and details on how relevant data were gathered. Pregnancy registries can be found by either medical condition (eg, asthma, epilepsy, transplants) or specific prescription drug or biological agent (eg, Actemra-tocilizumab, Zyprexa-olanzapine).

This emphasis on pregnancy registries is, in part, informational but also designed to encourage participation in registries to enhance their usefulness.

The Risk Summary subheading is designed to provide a description of a drug’s risk of adverse developmental outcome based on relevant human studies, animal data and/or the agent’s pharmacology. Adverse developmental outcomes include structural abnormalities, embryonic or perinatal mortality, functional impairment, and aberrant growth patterns. Acceptable human studies include clinical trials, the aforementioned registries, large-scale epidemiological studies, and well-documented case studies describing the common occurrence of an otherwise rare adverse outcome in exposed pregnancies.

In conformance with teratological principles, the incidence of an abnormality should be presented in exposed and unexposed pregnancies, as should the relationship between a given abnormality and drug dosage, duration, and gestational age of exposure. Animal studies should describe the number and types of species studied. Such studies should also provide data on timing of exposure, and doses should be expressed in terms of human exposure.

The FDA has made it clear that it is dubious about animal studies unless multiple species are affected, a consistent teratogenic effect is observed across species, and there is biological plausibility for an alleged teratogenic effect. Use of pharmacological data alone to assign relative risk may be acceptable if an agent’s mechanism of action is unambiguously known to result in an adverse developmental effect (eg, cytotoxic chemotherapy agents or sex hormone antagonists).

The Data subheading provides details on the quality of available evidence. For human studies, this might include study type/data source, number of subjects, details on exposure, and potential biases. For animal studies, types of studies performed, species evaluated, and dose, duration, and gestational timing of exposures should all be noted, as well as the presence or absence of toxicity.

Subsection 8.2, Lactation
The Lactation subsection also includes a Risk Summary subheading that notes the presence or absence of an agent in breast milk and the limits of detection of available assays. If present, the PLLR will formally take effect on June 30.
Use of ICSI on rise, but are outcomes better?

Results of a retrospective cohort study by investigators from the Centers for Disease Control and Prevention (CDC) and Emory University show that use of intracytoplasmic sperm injection (ICSI) is on the rise but cast doubt on whether the technology is improving reproductive outcomes.

The findings, which were most striking in cases without male-factor infertility, reflect national trends with fresh cycles of in vitro fertilization (IVF) and have sparked significant discussion in the ob/gyn community.

Nearly 1.4 million fresh IVF cycles from 1996 through 2012 were represented in the study, based on data on fresh IVF and ICSI cycles reported to the US National Assisted Reproductive Technology Surveillance System (NASS) from 1996 to 2012. Using linear regression, the authors looked at trends in ICSI use during that period for ICSI in all fresh cycles and those with male-factor infertility, unexplained infertility, maternal age 38 years of older, low oocyte yield, and two or more prior assisted reproductive technology (ART) cycles.

Reproductive outcomes for conventional IVF and ICSI from 2008 to 2012 were assessed and the data were stratified by the presence or absence of male-factor infertility.

From 1996 through 2012, ICSI was used in 65.1% of the 1,395,634 fresh IVF cycles and male-factor infertility was reported in 35.8% (499,135 cycles). Among cycles with male-factor infertility, ICSI use increased from 76.3% to 93.3% (P<.001), compared with an increase from 15.4% to 66.9% (P<.001) during that time period. Among the 35.7% of fresh cycles from 2008 to 2012 for which male-factor infertility was reported, the rate of multiple birth was lower than with conventional IVF (30.9% vs 34.2%; adjusted relative risk [RR], 0.87; 95% CI, 0.83-0.91). Among cycles without male-factor infertility, ICSI use was associated with lower rates of implantation (23.0% vs 25.2%; adjusted RR, 0.93; 95% CI, 0.91-0.95), live birth (36.5% vs 39.2%; adjusted RR, 0.95; 95% CI, 0.93-0.97), and multiple live birth (30.1% vs 31.0%; adjusted RR, 0.93; 95% CI, 0.95-0.95) versus conventional IVF.

The authors concluded that compared with conventional IVF, ICSI use was not associated with improved post-fertilization reproductive outcomes, irrespective of male-factor infertility diagnosis. They acknowledged that the study was limited, in that NASS does not collect information on fertilization rates, nor on outcomes for ICSI vs IVF for cryopreserved oocytes.

**REFERENCE**


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then gently inject it into the egg. This selection process allows the operator to inject what may appear to be the best sperm into the eggs. Some may feel that this is “unnatural,” but embryologists and ICSI operators strive to identify the best gametes, which may ultimately make the best embryos, furthering what everyone would agree is the goal of IVF: creation of the healthiest pregnancy possible for both mother and baby. Discussing “natural selection” in the context of ART, thus, is awkward.

Boulet and colleagues do not address the relative importance of egg freezing in the armamentarium of tools that reproductive endocrinologists can offer their patients. With the advent and adoption of oocyte cryopreservation, many women are choosing to freeze their eggs for a multitude of reasons. That being said, cryopreserved eggs that are subsequently thawed must undergo ICSI for efficient fertilization because of the steps involved for proper freezing/thawing. Therefore, as more women thaw and fertilize their eggs, use of ICSI is likely to increase.

Similarly, trophectoderm (Day 5) biopsies for preimplantation genetic diagnosis (PGD) can only be done on an embryo that has been fertilized by ICSI because excess sperm surrounding the embryo would skew the genetic results, potentially generating a false diagnosis. Increased use of ICSI in patients undergoing PGD—a population that is growing—is an indicator that practitioners are offering better genetic testing modalities (Day 5 instead of Day 3) to these women.

The authors of this article incorrectly focus on post-fertilization outcomes: specifically, rates of implantation, live birth, and multiple live births. It is possible that ICSI was associated with lower post-fertilization metrics in couples for whom male-factor infertility was not considered a primary diagnosis and instead, the male may have been subfertile but did not meet the threshold for being called infertile.

As such, some of the non-male-factor cases in which ICSI was used may, in fact, be some of the most complicated cases in the series and not cases “without any indication,” as the authors describe them. For example, the etiology of infertility may not have been labeled as male factor for a patient with a history of recurrent miscarriage and low ovarian reserve whose partner had low sperm motility.

Taking all of this information together, it is important to understand that, while this article has academic merit, it does not address the emergence of new technologies and the effects of market pressures and technological development on increased access to care. It is “good” that the cycles using ICSI had more Day 5 transfers and more embryos cryopreserved because we should try to avoid multiple gestations whenever possible.

This paper indirectly shows that IVF is becoming potentially safer and more available. However, given that this is a large retrospective study, all of the findings are worth discussing, but it is also important to understand that it suffers from the limitations of analyzing large registry-derived data. The hardest task would be designing and implementing a prospective study to address the authors’ concerns about the current state of IVF in America.

Dr. Levine is Clinical Fellow, Reproductive Endocrinology & Infertility, Ronald O. Perelman and Claudia Cohen Center for Reproductive Medicine, Weill Cornell Medical College, New York.

Dr. Goldschlag is Assistant Professor of Clinical Obstetrics and Gynecology and Assistant Professor of Clinical Reproductive Medicine, Ronald O. Perelman and Claudia Cohen Center for Reproductive Medicine, Weill Cornell Medical College, New York.

Online Poll: PAs and NPs

A recent poll on ContemporaryOBGYN.net asked the question “What concerns you most about delegating responsibility to a PA or NP?”

- **27%** Patient dissatisfaction
- **10%** Substandard care
- **2%** State scope of practice restriction
- **2%** Low reimbursement
- **1%** Other
- **47%** Increased liability risk
- **11%** I have none of these concerns

Dr. Levine is Clinical Fellow, Reproductive Endocrinology & Infertility, Ronald O. Perelman and Claudia Cohen Center for Reproductive Medicine, Weill Cornell Medical College, New York.

Dr. Goldschlag is Assistant Professor of Clinical Obstetrics and Gynecology and Assistant Professor of Clinical Reproductive Medicine, Ronald O. Perelman and Claudia Cohen Center for Reproductive Medicine, Weill Cornell Medical College, New York.
TO THE EDITOR:

[Regarding “Is there a future for the independent ob/gyn?” January 2015 Contemporary OB/GYN]: After [being in] private practice for 24 years I can only say that being one’s own boss is far superior to being an employee. Being told I could not do infertility (by Kaiser) and [being forbidden by a hospital] to do any ob or gyn ultrasound on patients in the women’s clinic are 2 egregious dictates that burned my brain.

As a hospital employee I supervised 9 certified nurse practitioners. Based on that experience, and having a real grasp about what is coming for ob/gyns, if I were starting over I would limit my practice to either gyn or ob right from the start.

If I chose ob, I would hire 3 to 5 CNMs over the first year and have them do most of the work. Their volume would have to be unlimited for patients to be economically stable. That means a medical practice in a city of over a million residents, preferably in the Midwest. I believe that ob and gyn will have to be divided into 2 specialties for many good reasons. If I chose gyn, I would aim at advanced laparoscopic surgery and outpatient surgery.

Economic restrictions on fees, high education debt, dropping incomes, and [the expense of] starting private practice is forcing all doctors into indentured servitude. Concierge practice will be the only medical practice method for the future.

The primary cause of doctors becoming employed, quitting medicine, and becoming severely disappointed with their careers is that they cannot make enough money today to meet their financial obligations. And that is because they have never been taught anything about business and marketing that would provide them with the tools to succeed financially. Doctors have no idea how to get out of financial trouble, or to prevent it from happening, because they are business ignorant.

Curt Graham, MD, FACOG, FACS
Las Vegas, Nevada

IN REPLY:

Thank you for your commentary. We regret that employment has brought you so many personal and professional challenges. Unfortunately, many of our colleagues have had similar experiences. When queried, most articulate concerns with leadership, approaches to patient care and operations, and organizational values; hence our focus on the importance of corporate culture and creating alignment between your values and cultural expectations, and those of the people and organizations who are hiring you, or purchasing your practice. As we emphasize, while an opportunity may appear to have all the features of a great “deal,” in the absence of a cultural match, the relationship will ultimately dissolve into mutual dissatisfaction.

Robert Wolfson, MD, PhD
Steven Furman, MBA

TO THE EDITOR:

[Regarding “Meaningful use 2? Just say no,” December 2014 Contemporary OB/GYN]: Finally! Somebody writes the truth! I have said from day one this EMR farce being forced on the medical profession is nothing more than a way for Big Brother to watch over what we do and use it as an excuse to pay us less. It has never been about improving patient care. Now it is coming home to roost.

We need not even bother to do stage 2 as it too much effort and too
dependent on factors we cannot control (patient input). Take your pay cut and be glad that is all it cost you.

Our experience with stage 1 was even worse. We did what we thought was the correct process: spent hundreds of thousands of dollars to implement the EMR system (we got miserable education and training but did our best regardless), worked harder and longer than ever to make less money, and spent most days in frustration. Our reward was, 3 years after the fact, all 5 physicians were randomly audited by CMS and have been demanded to pay back roughly $90,000, plus penalties and interest, at the proverbial point of the spear.

Use the system to practice your craft, if you must, but other than that, it is nothing but EFMR: electronic fraudulent medical records. Probably not what some might think the F was for.

Scott Peters, MD
Oak Ridge, Tennessee

IN REPLY:
Thanks for responding to my article on meaningful use, stage 2.

It is clear you are one of the many providers who are passionate in their dislike of electronic healthcare records (EHRs). In my view EHRs improve care just by producing legible office notes, and keeping medication and problem lists current. Let’s not complicate EHR adoption and use by generating meaningless data for the Centers for Medicare and Medicaid Services (CMS).

I agree that many EHRs are over-priced, too complicated, and require too much button clicking and data entry just to document a straightforward patient visit. As is too often the case, following EHR adoption, office productivity declines and with it, office revenue. Also, if you and your EHR don’t get along well, [you may] spend unnecessary time after hours to finish charting. If you add meaningful use 1 and 2 documentation requirements then EHRs can become overwhelming!

There are solutions to most EHR-associated dilemmas. Scribes are a cost-effective alternative solution to doing your own charts. You can switch to an EHR that is more user-friendly, and make the time to learn how to use it correctly. It is very important to fine-tune your templates, as by doing so you can speed chart completion. I personally have found that using voice dictation software cuts the time required to complete my EHR charts nearly in half.

Many physicians don’t adequately document office visits to justify the level of service being billed, and this happens whether they use paper charts or an EHR. When documentation is inadequate, practices risk being subject to paybacks and penalties when audited. It is well worth your time to take a coding course so you always document your level of service correctly. Many such courses are available online. Also have your coders regularly audit your documentation of the level of service provided and you are likely to avoid needing to pay back funds.

Andrew J. Schuman, MD

TO THE EDITOR:

[Regarding “Professional liability reform,” January 2015 Contemporary OB/GYN]: The states have long been a source of “demonstration projects” for various governmental attempts to change things. Seeing what works in one state helps other states to either replicate success or not waste efforts on governmental duds. I am somewhat surprised that Mississippi’s experience with tort reform has not been examined more by national media and researchers.

In 2003 Mississippi was in a full-blown medical liability insurance crisis. Access to care was being impaired significantly because of this. Previous efforts at tort reform legislation had been weak and ineffective. Haley Barbour was elected governor that year using tort reform as a major part of his platform. After a long hard political fight almost all of the reforms that Gov. Barbour, the medical community, and business interests wanted were enacted. Since that time frivolous suits have become almost non-existent, liability insurance rates have dropped by half, and the number of medical malpractice cases filed has dropped dramatically. The major
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LETTERS TO THE EDITOR

parts of the reform package that led to this were venue reform and a cap on non-economic damages. Mississippi should be looked at as a tort reform success and a model for other states.

Sidney W. Bondurant, MD
Madison, Mississippi

IN REPLY:

I heartily agree that states should be the “laboratories of democracy” and that we have much to learn from one another. I only wish my new home state of Florida (I say “new” though my grandfather lived here for 40 years and my father was a Gator alumnus) would copy Mississippi’s approach to tort reform, which may well be among the most strict in the nation.

Charles J. Lockwood, MD, MHCM

EDITORIAL

the bioavailability of an agent should be noted (eg, some agents cannot be absorbed via or are destroyed in an infant’s gastrointestinal tract).

If available, data should also be presented on the effect of the drug on the breastfed child and the effect of an agent on milk production. A clear risk-benefit statement should also be included in this subheading.

A Clinical Consideration subheading is also included in the Lactation subsection. Pertinent information should include how to minimize exposure in milk or via maternal skin. For example, pharmacokinetic data can be used to optimally time treatment relative to feedings or to better monitor an infant or a child for adverse reactions.

Again, a Data subheading is required to allow providers to judge the quality of evidence presented.

Males of Reproductive Potential

This subsection addresses the need for pregnancy testing and/or contraception if an agent (eg, warfarin, methotrexate) exerts clear adverse developmental effects.

In addition, any relevant data regarding potential drug effects on fertility or preimplantation viability should be provided.

Take-home message

The FDA has taken an important step to improve communication about the potential reproductive effect(s) of prescription drugs and newer biological agents.

The new labeling format will facilitate the choice of agents to be prescribed by providers and permit more informed and meaningful counseling of patients. It should also help clinicians to better utilize medications during pregnancy and reduce both the potential for error and underutilization of needed therapies.

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.

REFERENCES


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A New Year’s awakening: Life lessons from residency

I’ve never been a New Year’s resolution kind of girl. But there is something attractive about the idea that you can tell yourself you will “ctrl + alt + delete” to refresh...

Christina Saad Asaad
Incredibly well written and outlines my sentiments exactly, except I wouldn’t have been able to verbalize them so eloquently. Great job, Dr. Yalda Afshar! You make me so proud to know you as a colleague and as a friend!

No better way to reduce risk of birth defects: folic acid works. @mysmfm @contempobgyn
http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6401a1.htm?s_cid=mm6401a1_e#.VLgG0sZAHSt.twitter …

SMFM and Yalda Afshar retweeted a Tweet you were mentioned in:
No better way to reduce risk of birth defects: folic acid works. @mysmfm @contempobgyn
http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6401a1.htm?s_cid=mm6401a1_e#.VLgG0sZAHSt.twitter …
Rosacea: The physical and emotional toll

By Scott Kober, MBA, CCMEP

Rosacea is a chronic cutaneous disorder that primarily affects the central face, including the cheeks, eyes, nose, chin, and forehead. It is important to note that there is not a specific characteristic or set of characteristics that define rosacea. Rather, there are specific features that vary in presentation and magnitude among patients (Table 1).^1^

Although the pathophysiology of rosacea is not yet completely understood, it is believed to involve both the innate and adaptive immune systems. Patients with rosacea often have abnormal regulation of the neurovascular system, Vascular abnormalities, microbial activity, and pilosebaceous gland abnormalities may also exacerbate the condition. Clinical studies have shown that patients with rosacea have a high concentration of cathelicidin-derived peptide (LL-37), which can contribute to inflammation. Recent research has also focused on the possible influence of Demodex mites on the pathophysiology of rosacea, showing that Demodex density is almost 6 times higher in patients with rosacea than it is in the normal population.^

Rosacea affects up to 10% of the general population, with the greatest prevalence in individuals aged 30 to 50 years. Although most common in light-skinned individuals of Northern European descent, rosacea is not exclusive to Caucasians and can be seen, albeit with less frequency, in Asians, Hispanics, African-Americans, and other demographic groups. There is certainly a physical burden associated with rosacea, but the emotional impact of the condition is often even more substantial. Whereas acne is often considered almost a rite of passage for teenagers, many adult rosacea patients avoid going out in public due to psychological factors. A recent National Rosacea Society (NRS) survey of more than 400 rosacea sufferers showed that 75% had low self-esteem, 70% were “embarrassed” by their condition, and 56% felt robbed of pleasure/happiness.^

In 2002, the NRS identified 4 distinct subgroups of rosacea. Although there may be some overlapping characteristics of these subtypes, the classifications have helped with diagnosis and initial treatment plans:^

- **Erythematotelangiectatic rosacea:** Mainly characterized by flushing and persistent central facial erythema. Telangiectases are common, but not essential for diagnosis. Most common rosacea subtype.
- **Papulopustular rosacea:** Characterized by persistent central facial erythema with transient papules or pustules (or both) in a central facial distribution. Papules and pustules may also occur periodically. Resembles acne, except for the presence of comedones.
- **Phymatous rosacea:** Characterized by thickening skin, irregular surface nodularities, and enlargement. Predominantly present in male patients.
- **Ocular rosacea:** Characterized by watery or bloodshot eyes, foreign body sensation, burning/stinging, dryness, itching, light sensitivity, blurred vision, telangiectases of the conjunctiva and lid margin, or lid and periorcular erythema.

In addition to rosacea classifications, the NRS also developed a standard grading system to provide a common reference for diagnosis, treatment, and assessment of results in clinical practice. This grading system is commonly used in clinical trials to allow for comparability of results. A modified version of an available grading scorecard is included in Table 2. It gives a general overview of the delineation between severity ratings.

The determination of rosacea severity is helpful, but it is important for clinicians to do more than simply perform a visual assessment of a patient’s condition as they consider initial steps of treatment. For example, a patient may present with symptoms consistent with mild rosacea, but if they report significant issues with social and/or professional embarrassment due to their appearance, more-aggressive therapy may be warranted. It is also important to keep in mind that despite the general condition of many clinicians to expect more psychological strain in women with rosacea, many men with rosacea also report a significant emotional burden.

**Determining initial treatment options**

Many patients with rosacea will try over-the-counter medications indicated for the treatment of acne prior to seeking a clinician’s evaluation. Unfortunately, many of these medications will exacerbate rather than ameliorate a rosacea patient’s inflammation. Patients with rosacea have very sensitive skin that results in a prickly or painful feeling with use of certain agents. It is important for clinicians seeing a patient for the first time to gather a thorough medication history that will help determine initial therapeutic steps.

At baseline, a gentle skin care and photoprotective regimen should be recommended for all rosacea patients with centrofacial erythema, regardless of the presence of papulopustular lesions. Generally, a sunscreen with an SPF of at least 30 is recommended for protecting against incidental sun exposure. Patients who present with centrofacial erythema but without papules or pustules can often be managed with use of a once-daily alpha agonist, which will demonstrate an initial effect within 30 to 60 minutes of application and peak after 3 to 4 hours. Intense pulsed light or laser therapy may also be incorporated into the treatment plan.

### ROSECA TYPES AND TREATMENTS

<table>
<thead>
<tr>
<th>SUBTYPES:</th>
<th>1: Erythematotelangiectatic Rosacea (Facial Redness)</th>
<th>2: Papulopustular Rosacea (Bumps and Pimples)</th>
<th>3: Phymatous Rosacea (Skin Thickening)</th>
<th>4: Ocular Rosacea (Eye Irritation)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SYMPTOMS:</td>
<td>Flushing and persistent redness, may include visible blood vessels, stinging, burning, and swelling</td>
<td>Bumps (papules) or pimples (pustules) that come and go, includes red patches</td>
<td>Excess tissue often results in enlargement of the nose and irregular surface nodules (bump-like lesions)</td>
<td>Watery or bloodshot eyes, tearing and burning, swollen eyelids, recurrent styes</td>
</tr>
</tbody>
</table>

**Examples:**

![Image 1](https://example.com/image1)

![Image 2](https://example.com/image2)

![Image 3](https://example.com/image3)

**Courtesy of: National Rosacea Society**
The majority of research in rosacea has focused on the treatment of inflammatory papules and pustules, which can be more difficult to manage. There are currently 2 topical agents approved by FDA for the treatment of inflammatory lesions of rosacea: metronidazole (MTZ; twice-daily 0.75% gel, cream, or lotion, and once-daily 1% gel or cream) and azelaic acid (AZA; twice-daily 15% gel). Also available is modified-release doxycycline 40 mg once daily, a systemic therapy.5,10

MTZ and AZA are most commonly used initially in patients with mild or moderate disease, whereas doxycycline is often initiated in patients with more severe rosacea. Use of a combination regimen of a topical agent with doxycycline is a popular option for some patients. Recent survey data of 300 dermatologists showed that this combination approach is used as initial therapy in 83.7% of patients with moderate-to-severe papulopustular rosacea.11

The overall safety and tolerability profiles of MTZ and AZA are favorable, with the most common adverse events related to local reactions. AZA may cause neurosensory symptoms after application, but these are usually transient and remit within 1 to 2 weeks after initiating a regimen.9

The submicrobial dose of doxycycline was designed to provide anti-inflammatory effects with no antibiotic activity, even with prolonged duration of use for several months. It has been shown to be equally efficacious regardless of a patient’s rosacea severity at baseline. Common side effects include headache, nausea, and vomiting. These side effects have been shown to appear less frequently in the anti-inflammatory 40-mg dose compared to the antimicrobial 100-mg dose.12

Setting treatment goals

Television advertisements often serve as false idols for patients with rosacea, promising “Results within 24 hours!” or “Skin as clear as you could ever imagine!” Unfortunately, this often creates a wildly inflated sense of expectations among patients that can be difficult to temper. It is vital for rosacea patients to understand that, with anything prescribed for them, improvements are not going to occur overnight.

In the majority of phase 2 and 3 clinical trials for agents approved by FDA or in late-stage clinical trials, patients are treated for 12 to 16 weeks.9,10,13,14 Although patients can expect to see some improvement in their symptoms within a few weeks of therapy (assuming adherence to the prescribed regimen), it may take 6 to 8 weeks for significant improvement to occur. Even then, there may not be complete resolution of background erythema or inflammatory lesions.

Some patients will develop an immediate skin reaction to topical medications, but for those who can tolerate them, a 6- to 8-week trial at minimum should be prescribed to gauge efficacy.9 This can be difficult for some patients who want a more-immediate panacea, which is why a frank, upfront discussion is vital to calm overzealous expectations.

Because rosacea is a lifelong condition that may wax and wane over the course of a patient’s lifetime, it is also important to discuss long-term maintenance for patients who do get relief from the use of 1 or more medications. Unfortunately, there are few long-term studies in the published literature that address maintenance of disease control beyond 6 months, so it is often up to clinician judgment and patient tolerance to determine the best course of action for lifelong maintenance of rosacea symptoms.8 Many clinicians will see the same patients multiple times during the course of their lifetime to deal with rosacea flares. These flares can sometimes be managed with a short course of antibiotics but in other instances may require additional topical or systemic therapies.

Coming up next

In part 2 of this series, we’ll take a closer look at the newest treatment option for the inflammatory component of rosacea—ivermectin—and discuss how it may fit into the overall treatment armamentarium.

References

10. Del Rosso JQ, Patterns of use of topical and oral therapies in the treatment of different subtypes of rosacea. Presented at the 11th Annual South Beach Symposium; April 11–15, 2013; Miami Beach, FL.

Table 1
Features of rosacea

<table>
<thead>
<tr>
<th>Primary features</th>
<th>Secondary features</th>
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</thead>
<tbody>
<tr>
<td>Flushing (transient erythema)</td>
<td>Burning or stinging</td>
</tr>
<tr>
<td>Nontransient erythema</td>
<td>Phymatous changes</td>
</tr>
<tr>
<td>Papules and pustules</td>
<td>Plaque</td>
</tr>
<tr>
<td>Telangiectasia</td>
<td>Dry appearance</td>
</tr>
<tr>
<td>Edema</td>
<td>Ocular manifestations</td>
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<tr>
<td>Peripheral location</td>
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Table 2
Severity grading of rosacea papules and pustules

<table>
<thead>
<tr>
<th>Rosacea severity</th>
<th>Papules/pustules</th>
<th>Plaques</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild</td>
<td>Few</td>
<td>None</td>
</tr>
<tr>
<td>Moderate</td>
<td>Several</td>
<td>None</td>
</tr>
<tr>
<td>Severe</td>
<td>Many</td>
<td>Present</td>
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Are we getting the word out about emergency contraception?

Two experts debate whether unrestricted access to emergency contraception has really translated into awareness about how it works and how to get it.

PRO

Yes. We’ve made great strides in educating the public.

Frances Casey, MD

The rates of unintended pregnancy in the United States have changed very little in the past decade. Unrestricted access to over-the-counter (OTC) emergency contraception (EC) grants couples the autonomy to make their own reproductive decisions. This access provides a rich opportunity for healthcare professionals to engage in discussions with their patients regarding reproductive life plans.

Whether this discussion is occurring as often as it should is debatable, but recent events have at least increased awareness among the public.

In 2013, debate concerning age restrictions on the sale of EC prompted vigorous discussion among health professionals, politicians, and parents alike. Studies assessing label comprehension demonstrated that adolescents younger than 17 could obtain adequate information for safe and effective use of EC without clinician supervision.1,2

The decision by the US Department of Justice to reverse its appeal of a US District Court ruling expanding access without age restrictions was applauded by the American Academy of Pediatrics (AAP), the American College of Obstetricians and Gynecologists (ACOG), and the Society for Adolescent Health and Medicine (SAHM).

Increasing access to online information has improved patients’ ability for Adolescent Health and Medicine (SAHM).

Any improvement in availability/awareness of contraceptive methods is a step in the right direction.
to learn about and potentially utilize EC. A simple search on “emergency contraception” results in at least 5 evidence-based sites detailing how it works, how much it costs, and where to purchase it. Websites such as Bedsider (www.bedsider.org) have performed extensive studies to create age-appropriate and easy-to-use materials.

Widespread availability of EC and acknowledgement that couples should have autonomy to plan their families are steps toward reaching our common goal of reducing unintended pregnancies. We should encourage and promote healthcare professionals to educate themselves and their patients about the benefits and limitations of EC, and also acknowledge that any improvement in availability/awareness of contraceptive methods is a step in the right direction.

REFERENCES


DR. CASEY is Director of Family Planning Services, Department of Obstetrics and Gynecology, Virginia Commonwealth University Medical Center, Richmond.

CON

No. We assume that patients know more than they actually do.

Christine Isaacs, MD

After many tumultuous turns in the road to unrestricted access to OTC EC, the US Food and Drug Administration finally allowed OTC sales of Plan B One Step with no age restrictions in June 2013. This expanded access to EC was a substantial victory for women and for reproductive rights. It also holds great promise for the effort to reduce the rates of unintended pregnancy and abortion in the United States.

Unintended pregnancy rates are highest among poor, low-income, and minority women. The Guttmacher Institute reports that at least half of all American women will experience an unintended pregnancy by age 45. In addition, (at 2008 rates) 1 in 10 women will have an abortion by age 20, and 1 in 4 women will have an abortion by age 30.1 Of nearly 2 million publicly funded births, 53% resulted from unintended pregnancies, accounting for $12.5 billion in costs.1

Unrestricted legal access to OTC EC holds great promise for changing some of these statistics. But do we really have the word out—both within our profession and in the public sector? Are we really reaching the women who are most vulnerable to experiencing unintended pregnancies or are we missing an opportunity to empower these women with information?

One might think that such a profound policy change—allowing unrestricted access to one of the forms of EC—would prompt robust investigation and study on resulting behavior patterns, and clinical outcomes. One might also assume that such a “hot topic” in the medical literature would heighten the level of awareness of today’s busy clinicians. Sadly, a PubMed search from 2013 (the year of the FDA unrestricted approval) to the present day using “emergency contraception pill” and “United States” produces only 6 citations. Out of sight, out of mind.

It would be terribly unfortunate if OTC availability created an accidental assumed knowledge of EC’s purpose, mechanism of action, and accessibility.
to receive little formal training about barrier and OTC contraceptive options (condoms, spermicides, sponges, etc.) and as a result, they want more education because of perceived inadequate knowledge. It would be terribly unfortunate if OTC availability of Plan B One-Step created an accidental assumed knowledge of its purpose, mechanism of action, and unrestricted accessibility.

How many of us feel comfortable and confident counseling patients on the pros and cons of the various methods of EC? How many of us counsel our patients that yes, even men can purchase OTC Plan B One-Step without restriction?

We cannot afford to have such an important victory in women’s reproductive health lessen our enthusiasm for public education, physician education, research, and family planning advocacy.

We must stay steadfast in our commitment to women’s reproductive health issues and not assume that FDA approval of the unrestricted sale of Plan B One-Step (and the associated “sound bites” referencing it on the evening news) are synonymous with true patient education and physician awareness.

REFERENCES


Getting paid in an age of high deductibles
It takes a new strategy

Develop a patient financial policy and educate staff and patients about it to boost revenue, improve patient relations, and protect yourself.

BY CHERYL BISERA

Perhaps you’ve noticed certain patients not coming in as often as they used to or a rising accounts receivable (A/R) that’s increasing in age and amount. The shift by third-party payers and government entities to have patients shoulder more of the cost of healthcare is creating a need for hospitals, clinics, and private practices to change how they communicate about and collect patient payments.

As healthcare costs continue to rise, frustrations are also rising for both patients and practices. To fully understand and address this challenge, it’s important to put it all in perspective by understanding where we’ve come from and how we got to where we are now.

Between 2003 and 2013, healthcare premiums in the United States rose 80%; from an average of $9,068 for a single worker to $16,351. The increase in premiums translated to an increase to the employee’s contribution toward insurance of 89%—from an average of $2,412 per single worker in 2003 to $4,565 in 2013—as employers began shifting more of the cost of healthcare coverage to workers. This means that before a patient has even seen a single doctor in a new year, her healthcare is now already costing her nearly double what it cost her only 10 years ago. These numbers are expected to rise with healthcare reform and the shared costs of covering the previously uninsured.

Onus on patients
On top of premiums nearly doubling for many of our patients, more employers are choosing to shift offerings to high-deductible plans to keep their premiums more affordable. Patients are also pushing for these shifts in hopes that putting the onus on patients for a larger...
portion of their visits will discourage frivolous use of healthcare coverage and reduce costs.

One statistic that illustrates this particularly well is that in 2006 only 16% of small firms (companies with 3 to 199 workers) had their employees enrolled in high-deductible plans requiring employees to pay the first $1,000 or higher of their care, on top of premium charges. That number increased consistently over the next 6 years and by 2012 about 50% of small firms had their workers on these types of plans. It is expected that once the numbers come in for 2013 and 2014 a significant increase will be seen.

What does this all mean to you and your patients? It means that patients are finding themselves responsible for their entire bill until they’ve met their deductibles. Practices and patients are not accustomed to this radical change after many years of paying or collecting nominal copays of $10 to $25 per visit or billing the 20% due after the payer paid their 80%. This affects your A/R radically because traditionally, practices have written off an average of nearly half of patient portion when it goes uncollected. Patient portion might not have been detrimental, but today failing to collect from patients can mean a loss of 15% or more of revenue, weighing down A/R and increasing costs to collect as time goes on.

Not only are practice employees and patients unaccustomed to these changes, practices are often ill-prepared to communicate with patients and collect from them in ways that increase their time-of-service payments and give patients realistic expectations.

Your practice works hard to provide patient care day in and day out—you deserve to be paid! By equipping your practice you can boost revenue, improve patient relations, and protect yourself.

**Develop a policy for success**

With high-deductible health plans on the rise, patients are expected to shoulder more of the cost of healthcare, yet practices are finding it difficult to collect. Many patients aren’t prepared to pay their portion because they don’t understand how their high-deductible plan works and may be accustomed to paying small copays at the time of visit. On the other hand, staff members are often unprepared to collect high-deductible patient portion.

**Self-pay increases**

The percentage of practice revenue that should come from patients has grown dramatically. In 2007, patients’ self-pay was an average of just 12% of practice revenue, but by 2012 that number had nearly tripled to 30%. This could double as the Affordable Care Act contributes to an increase in high deductible plans. This means your practice can no longer afford to look the other way when it comes to patient portion. Historically, 50% of patient responsibility goes uncollected. In the past, writing off half of patient portion might not have been detrimental, but today failing to collect from patients can mean a loss of 15% or more of revenue, weighing down A/R and increasing costs to collect as time goes on.

Not only are practice employees and patients unaccustomed to these changes, practices are often ill-prepared to communicate with patients and collect from them in ways that increase their time-of-service payments and give patients realistic expectations.

Your practice works hard to provide patient care day in and day out—you deserve to be paid! By equipping your practice you can boost revenue, improve patient relations, and protect yourself.

**Steps in creating a policy**

- Document your patient financial policy within your broader existing financial policy. A detailed policy for internal staff members’ eyes only should guide them on steps to take and what exceptions to make. A summary policy — the patient financial policy — should be crafted for patients to view and sign, outlining their responsibility in regard to any services not paid for by their carrier.
- Use patient-friendly terminology to reduce confusion. A lack of understanding of what they owe is cited as one of the top 4 reasons for nonpayment. That means you may need to explain that they could pay for “covered” services if they haven’t met their deductible.
- Include all the basics, such as when payment is required, how payment is accepted, when they can expect to be billed, if you will bill secondary insurance, late payment penalties, cancellation or missed appointment fees, and payment.
- Payment plans are often used to help patients pay for medical bills in a reasonably timely manner that they can manage. How payment plans are laid out should be addressed in your larger financial policy. Offer them to those who indicate they cannot pay in full at that time.
- Create a payment safety net by having patients on the new healthcare exchanges sign a waiver that specifies their responsibility to pay for uncovered services and have a credit card on file in that case. This will offset your risk should they fail to pay their premiums and become retroactively uninsured.
- Always consult with your legal advisor regarding all aspects of both your internal and public self-pay policies to be sure you are complying with the law and operating within the boundaries of your payer contracts.
- Once you have a strong, patient-friendly and defined self-pay financial policy, it’s important that you communicate it clearly to patients as well as educate and support your entire staff to enforce it.
tions and may have no policy in place to guide and support their efforts.

Practices and clinics must change how they communicate about and collect patient payments in order to curtail the rising age and amount in their A/R due to the increase in patient responsibility. One of the first steps is to prepare a clear, strong patient financial policy.

By educating and preparing patients about what your practice and their insurer expects from them financially, you improve the odds of collecting in full for what you’ve already earned and contracted for. But before you can support your staff in enforcing the policy and educating your patients, you must create the policy!

Most patients want to stay in good financial standing with their physicians. Your practice can help them feel good about doing so by encouraging clear communication by friendly, helpful practice staff. Begin with your policy, then educate patients by communicating it in several ways (eg, on the website and when signing in at first visit) and lastly, get practice leaders and staff on board to support the goal of getting paid all that you’re owed, sooner and faster!

**Tools to help you collect from patients**

Practices that are unable to successfully collect from or make payment agreements with patients at the time of service will see increased bad debt and be at significant financial risk. If you want to increase practice profitability and haven’t mastered patient collections, consider how you might employ technology to help you succeed in the new high-deductible landscape. Doing so will support and expedite the staff collection efforts and patient payment efforts.

It’s time that healthcare providers catch up with other industries in their consumer-focused strategies. After all, no one thinks twice about handing over their credit card to pay their mechanic, paying in full at the grocery store, or paying at the time of ordering purchases online—it’s expected that we will pay at time of service and it’s expected that these businesses will accept our preferred payment methods.

Patient collection efforts need to be consistent. Humans simply aren’t as reliably consistent as automated systems. It’s important to consider taking advantage of anything your practice management vendor offers to relieve your staff’s administrative burden.

Technology will never replace the personal touch that a properly trained and naturally suited staff member can bring to this process. All members of your practice team should understand your financial policy and their part in reinforcing it with patient-friendly language. However, utilizing technological tools to support your staff’s efforts to communicate to patients before, during, and after visits will significantly increase your chances of getting full payment from your patients before they even leave your office.

**REFERENCES**

3. Woodcock E. Seven Steps to Improve Your Practice’s Revenue Cycle Management; Navicure. 2014
What is the definition and frequency of hydrops fetalis?

Hydrops fetalis is a Greek term that describes pathological accumulation of fluid (‘ὕδωρ’ meaning water) in fetal soft tissues and serous cavities. The features are detected by ultrasound, and are defined as the presence of 2 or more abnormal fluid collections in the fetus. These include ascites, pleural effusions, pericardial effusion, and generalized skin edema (defined as skin thickness >5 mm). Other frequent sonographic findings include placental thickening (typically defined as a placental thickness >4 cm in the second trimester or >6 cm in the third trimester) and polyhydramnios (Figure 1). NIHF refers specifically to cases not caused by red cell alloimmunization.

With the development and widespread use of Rh (D) immune globulin, the prevalence of Rh (D) alloimmunization and associated hydrops has dramatically decreased. As a result, NIHF now accounts for almost 90% of cases of hydrops, with the prevalence in published series reported as 1 in 1700–3000 pregnancies.

What are the risks factors for and causes of NIHF?

NIHF can result from a large number of underlying conditions. The differential diagnosis is extensive, and success in identifying a cause partially depends on the thoroughness of efforts to establish a diagnosis. In 85% of cases of NIHF overall, a cause is identified; in 60% of cases, the determination is made prenatally.

What is the work-up for NIHF?

Figure 2 describes one proposed algorithm for the work-up and evaluation of NIHF.

This is a summary of the evidence-based SMFM guidelines for the evaluation and management of nonimmune hydrops fetalis (NIHF). The guidelines review the epidemiology, risk factors, work-up, prognosis, and treatment of pregnancies complicated by NIHF.
What are the risks and frequency of complications of NIHF?

Polyhydramnios and preterm birth occur frequently with NIHF, with reported incidences as high as 29% and 66%, respectively. Women with NIHF may develop mirror syndrome, an uncommon complication in which the mother develops edema that “mirrors” that of her hydropic fetus. Mirror syndrome may represent a form of preeclampsia, and is characterized by edema in approximately 90%, hypertension in 60%, and proteinuria in 40% of cases. Because it is uncommon and likely underdiagnosed, the incidence is unclear. Resolution occurs with either treatment of the hydrops or delivery.

What is the antenatal and delivery management for NIHF?

Management is guided by the presence or absence of additional anomalies. Sonographic evaluation should include a detailed survey for anomalies of the fetus, umbilical cord, and placenta, and estimation of amniotic fluid volume. A fetal echocardiogram should be performed, because fetal cardiac anomalies are among the most common causes of NIHF.

Recommended treatment depends on the underlying etiology and gestational age; preterm delivery is recommended only for obstetric indications, including development of mirror syndrome. Corticosteroids and antepartum surveillance may be an option for NIHF with an idiopathic etiology, an etiology amenable to prenatal or postnatal treatment, and when intervention is planned. Should fetal deterioration occur, antepartum surveillance is generally used in the setting of maternal or pregnancy complications associated with an increased risk of fetal demise, and when findings from surveillance will assist with delivery decisions.

In the absence of clinical deterioration or other indication for earlier intervention, delivery by 37 to 38 weeks should be considered. We recommend delivery in most cases if mirror syndrome develops.

If the parents and their physician have decided not to intervene for fetal indications (ie, to provide only comfort care upon delivery) vaginal delivery is preferred un-
What is the prognosis of NIHF?

The prognosis depends on etiology, response to therapy if treatable, and the gestational age at detection and delivery. Aneuploidy confers a poor prognosis, and even in the absence of aneuploidy, neonatal survival is often less than 50%. In one recent prenatal series, survival was approximately 50%, and survival without major morbidities was only 25%. Hydrops that develops from treatable causes, such as fetal arrhythmia or infection with parvovirus B19, has a better prognosis.

Reference


Detailed ultrasound including fetal echocardiogram
Maternal history including family history, medications, exposures

Structurally normal, no arrhythmia

MCA Doppler

Normal

Amniocentesis

• Karyotype and/or CMA
• AFAFP
• PCR for CMV, toxoplasmosis
• Lysosomal enzyme testing

Anemic (PSV >1.5 MoM)

Amniocentesis or fetal blood sampling (FBS)
If concomitant intrauterine transfusion is planned

Structurally abnormal

Invasive Prenatal Testing

Karyotype and/or CMA
• PCR for CMV, toxoplasmosis
DNA testing for specific anomalies as indicated


If you have a question on high-risk pregnancy, we’d like to hear from you. Those of interest to a wide audience will be answered in future installments of SMFM Consult. Send your question to solmstead@advanstar.com.


Assuming negative antibody screen and normal indirect Coombs to rule out alloimmunization; CMV/toxo testing if fetal anomalies suggestive of infection; available in some laboratories.

Abbreviations: CMA, chromosomal microarray; CMV, cytomegalovirus; G6PD, glucose-6-phosphate dehydrogenase deficiency; PCR, polymerase chain reaction; PSV, peak systolic velocity; MCV, mean corpuscular volume.
Change the conversation

The Aptima® HPV test makes it easier.

Detecting HPV DNA identifies the presence of a high-risk HPV infection. HPV is a common transient infection and very few infections will lead to cervical cancer. Looking for the presence of high-risk HPV DNA can lead to unnecessary difficult patient conversations.

The Aptima HPV test targets high-risk HPV mRNA. Studies have shown HPV mRNA identifies the presence and activity of a high-risk HPV infection.1

The Aptima HPV test has shown:

- **Excellent sensitivity** — demonstrating equivalent sensitivity to DNA-based HPV tests in multiple clinical studies involving over 50,000 women worldwide2
- **Improved specificity** to DNA-based HPV tests — reducing false-positives by 24% in the clinical trial3

The combination of excellent sensitivity and improved specificity with the Aptima HPV test may help change patient conversations and may minimize the potential for over-treatment.

Interested in learning more about mRNA and the Aptima HPV test difference? Contact us.
It’s time to rethink atypical glandular cells on Pap smear

An AGC Pap smear should prompt suspicion of malignancy and merits thorough evaluation and close follow-up, especially among high-risk women older than age 50.

BY STEVEN R. GOLDSTEIN, MD, CCD NCMP, FACOG, FRCOG(H), AND RACHEL C. CARROLL, MD, MPH

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DR. CARROLL is Senior Resident, Department of Obstetrics, Gynecology and Reproductive Science, Mount Sinai Medical Center, New York, New York.

"P"ostmenopausal bleeding should be considered endometrial cancer until proven otherwise." This is one of the clinical truisms that every medical student learns to recite and that every ob/gyn resident and attending physician incorporates into clinical practice without question. Studies indicate that between 1% and 14% of women who present with postmenopausal bleeding will, on further evaluation, be found to have endometrial cancer, although most large studies suggest a range of 3% to 7%. This percentage is significant enough to warrant treating any postmenopausal bleeding episode with a high index of suspicion for malignancy and ensuring adequate management and follow-up.

When we perform a routine Pap test on a patient and it reveals atypical glandular cells (AGC), do we treat it with the same level of care as we do postmenopausal bleeding? Although clear guidelines exist for dealing with AGC, multiple studies indicate that it is largely undermanaged or mismanaged by clinicians, with fewer than 30% of women undergoing an appropriate and comprehensive workup. However, 10% to 38% of women with AGC on cytology will be shown to have a malignant or premalignant lesion, the majority of them endometrial or cervical lesions.

Thus, shouldn’t an AGC Pap smear prompt the same index of suspicion for malignancy and merit thorough evaluation and close follow-up, especially among
Which key nutrients are in your patients’ OTC prenatal vitamin?*

One A Day® Women’s Prenatal 1 contains folic acid, calcium, iron, and has omega-3 DHA — all recommended by ACOG during pregnancy1

- Provides key nutrients for women before, during, and after pregnancy
- Ensure your patients aren’t missing key nutrients they may need

Learn more at oneadaypro.com.

*Among leading brands.
†20 nutrients per One A Day Women’s Prenatal 1 label. Serving size is 1 softgel daily, with food.
‡12 nutrients per vitafusion PreNatal label. Serving size is 2 gummy vitamins daily.


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A BRAND WOMEN TRUST

One complete softgel
women older than age 50 who are at high risk? Our answer is an emphatic yes.

Although AGC is a relatively uncommon finding, accounting for just 0.2% to 0.4% of all cervical cytology results, it holds great significance when detected.5 AGC is diagnosed when abnormal glandular epithelial cells are present. They can originate from the endocervix or endometrium. When present, they display features of atypia greater than expected from benign reactive changes, but that fall short of meeting diagnostic criteria for invasive adenocarcinoma (Table 1).

Endocervical, endometrial, or not otherwise specified (NOS) is noted as a subcategory. This replaces the previous term “atypical glandular cells of undetermined significance (AGUS).” This term should not be confused with terminology for squamous cell abnormalities, which includes atypical squamous cells of undetermined significance (ASCUS).

Benign lesions are most frequently the etiology responsible for AGC, as is the case with postmenopausal bleeding, but on further evaluation, up to 38% of cases will prove to be malignant or premalignant. As noted above, endometrial and endocervical disease are the most common malignant etiologies, but a finding of AGC also occasionally indicates the presence of other malignancies, including cancer of the ovaries, vagina, Fallopian tubes, breast, and even colon.6 Some suggest a transvaginal ultrasound is a useful adjunct in the management of an AGC Pap smear when all tissue samples are negative for pathology to exclude any obvious adnexal source.

In a 2006 meta-analysis of 24 studies in which more than 2.3 million Pap tests were evaluated, the prevalence of AGC was reported to be 0.29%. Of those AGC Pap results, 5.2% represented malignancy, nearly 60% of them endometrial and 24% cervical adenocarcinomas.4 Individual risk factors for cancer include older age, concurrent squamous abnormality, and cytology classified as AGC-favor neoplasia.

In a retrospective study performed in 2009, age was shown to be directly correlated with malignancy rate. While women younger than age 40 had only a 2.0% malignancy rate with AGC, women ages 40 to 49 had a rate of malignancy of 2.8%, and women aged 50 or older had a 15% malignancy rate.7 It could be argued that an AGC Pap result in women older than 50 has at least the same and perhaps a greater predictive value for a malignancy than does postmenopausal bleeding.

Another consideration is that cervical cytology generally has lower sensitivity for detection of endocervical glandular dysplasia and malignancy than for squamous malignancy. This should mean that when we do detect AGC, there is a higher likelihood that the patient has true pathology.

Unlike cytology showing ASCUS, which can be differentially managed based on HPV testing, AGC is associated with a much greater risk of cervical and endometrial neoplasia, and physicians cannot afford to manage AGC conservatively by repeat Pap or colposcopy alone. Rather, the finding of AGC should be regarded with the same caution as postmenopausal bleeding, and appropriate comprehensive evaluation should be performed. Modifying guidelines from the American Society for Colposcopy and Cervical Pathology (ASCCP) (Table 2), the workup for all subcategories except “atypical endometrial cells” should involve colposcopy with biopsies and endocervical curettage

<table>
<thead>
<tr>
<th>TABLE 1</th>
<th>Epithelial cell abnormalities</th>
</tr>
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<tbody>
<tr>
<td><strong>Glandular abnormalities</strong></td>
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<tr>
<td><strong>Atypical</strong></td>
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<td>• Endocervical cells</td>
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<td>• Endometrial cells</td>
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<td><strong>Atypical, favor neoplastic</strong></td>
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<td>• Endocervical cells</td>
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<td>• Not otherwise specified</td>
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<tr>
<td><strong>Adenocarcinoma in situ (AIS)</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Adenocarcinoma</strong></td>
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</tbody>
</table>
What would you call a breakthrough technology that detects 41% more invasive breast cancers?

If you’re a woman whose breast cancer might have been missed, you’d call it genius.

Genius 3D mammography™ is the first and only FDA approved 3D mammography clinically proven to be superior to 2D.

It is a major breakthrough in the early detection of breast cancer and the best mammogram for all breast densities. What’s more, it reduces false positives by up to 40%.1,2

Talk to your patients about the benefits of Genius 3D mammography™ and the importance of having an annual mammogram.

What woman wouldn’t want a more accurate mammogram?


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This modification of ASCCP guidelines (changing “endometrial sampling” to “endometrial evaluation”), in our opinion, reflects revised guidelines from the American College of Obstetricians and Gynecologists for AUB (abnormal uterine bleeding), which state that if endometrial biopsy is performed as a first step it can only be considered an endpoint if it is positive for malignancy or atypical complex hyperplasia.

This is based on the reduced reliability of blind endometrial sampling when complex hyperplasia or malignancy occupies less than 50% of the endometrial surface area. These guidelines were not developed for AGC on Pap smear, but in light of the high rate of potential endometrial malignancy (similar to postmenopausal bleeding), we believe practitioners should be alert to the shortcomings of blind endometrial sampling, especially since serious pathologies are often not global.

In fact, in Guido et al, cancer occupied less than 50% of the surface area in 16% of cases. What that number might be with complex atypical hyperplasia is unknown but it probably is as high or higher. Thus, techniques that can distinguish between global and focal pathologies (saline infusion sonohysterography or office hysteroscopy) should be employed. Why do we continue to allow AGC to slip through the cracks and lead to delayed diagnosis and increased morbidity and mortality? Possible explanations include lack of understanding by providers of the significance of the AGC Pap smear and the high underlying rate of coexisting or associated cervical and endometrial pathology and confusion about the difference between ASCUS and AGC Pap smear results.

When we look at the evidence, we find that AGC should be taken just as seriously as or perhaps even more seriously than postmenopausal bleeding in order to truly care for our patients to the best of our ability. Timely and thorough evaluation of postmenopausal bleeding will improve the detection of endometrial cancer and decrease associated mortality and morbidity. An AGC Pap smear mandates similar clinical vigilance and evaluation, especially in postmenopausal women.

We must follow appropriate treatment algorithms to evaluate the cervix and uterus and exclude concurrent malignancy to improve health outcomes for our patients. 

DR. GOLDSTEIN reports receiving honoraria from Pfizer and Shionogi, consulting fees from Cook ObGyn and Smith & Nephew, and fees for services from JDS Therapeutics, Noven, Pfizer, and Shionogi.

DR. CARROLL has no conflict of interest to report with respect to the content of this article.

**TABLE 2**

Workup of women with atypical glandular cells (AGC)

<table>
<thead>
<tr>
<th>All Subcategories (except atypical endometrial cells)</th>
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</thead>
<tbody>
<tr>
<td>Colposcopy (with endocervical sampling) and endometrial evaluation (if ≥ 35 yrs or at risk for endometrial neoplasia*)</td>
</tr>
<tr>
<td>*Includes unexplained vaginal bleeding or conditions suggesting chronic anovulation</td>
</tr>
<tr>
<td>Atypical Endometrial Cells</td>
</tr>
<tr>
<td>Endometrial and endocervical evaluation</td>
</tr>
<tr>
<td>No endometrial pathology</td>
</tr>
<tr>
<td>Colposcopy</td>
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</tbody>
</table>


RECENT REFERENCES

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.
Reproductive and sexual coercion: Counseling strategies

Patients who have experienced intimate partner violence have reported that positive, supportive encounters with healthcare providers have helped them to improve their situations.

A.

n estimated 42.4 million US women, or more than 1 in 3, will experience rape, physical violence, or stalking by an intimate partner during their lives, according to the Centers for Disease Control and Prevention (CDC) 2011 National Intimate Partner and Sexual Violence Survey (NISVS).

Intimate partner violence (IPV) is the use of physical, sexual, emotional, or verbal threats or violence between married or unmarried partners, homosexual or heterosexual. The behaviors—such as stalking, cyber threats, and control of finances or movement—are intended to control or demean.

IPV disproportionately affects younger women, as underscored by the CDC survey, which showed that 69% of those who had experienced IPV reported the first occurrence before age 25. Such victimization is associated with unintended pregnancy, sexually transmitted infection (STI), condom non-use, inconsistent condom use, and fear of condom negotiation. Coerced sexual experiences are also common, with 28% to 42% of women in college samples reporting at least one such experience.

Among women who reported ever being raped, 80% reported that the first assault occurred before age 25 and almost half experienced their first rape before age 18 (30% between age 11 and 17 and 12% at or before age 10).

IPV is connected to poor reproductive health when male partners control women’s reproduction by attempting to impregnate a partner against her wishes (pregnancy pressure), controlling outcomes of a pregnancy (pregnancy coercion), coercing a partner to have unprotected sex (sexual coercion), or interfering with her attempts to use birth control (birth control sabotage).
The prevalence of RC was approximately 10% among women surveyed by the CDC. RC can occur in the absence of physical and sexual violence, and is independently associated with unintended pregnancy.17

Because of the association with a variety of reproductive and sexual health concerns, it is not surprising that IPV and RC have been experienced by many women who seek care confidentially in reproductive health and adolescent care settings.18-20

In one study of female family planning clients ages 16–29 in California, 53% reported IPV and 25% had experienced RC.21 Among women reporting RC, 79% had also experienced IPV.21 Similar studies among patients seeking ob/gyn care have found a 16% prevalence of RC with significant overlap with IPV.22

In another study from Pennsylvania, 5% of patients reported experiencing RC in the past 3 months, which is associated with an 80% increase in past-year unintended pregnancy compared to women not experiencing RC, and a 2-fold increase in IPV and recent RC combined.17

Thus, addressing IPV and RC in the reproductive health setting may reach significant numbers of women at risk of violence and unintended pregnancy.15 Health providers are also in a position to offer contraception that a partner is less likely to be able to influence (such as IUDs) as a harm-reduction strategy.15

A woman may not recognize her own experience of violence, domination, intimidation, or control as IPV, nor see herself as a victim.

Healthcare providers can make a difference

Repeatedly, surveys of women—both with and without a history of IPV—show that women want their healthcare providers to bring up the topic of IPV.23-27 Discussions about IPV/RC are associated with cognitive and behavioral changes for women that promote their safety and reduce risk of poor health outcomes. In several qualitative studies, women with IPV histories described how positive encounters with healthcare providers led to changes that ultimately improved their situations.28,29 In one study, women who were offered information about IPV and RC in a palm-sized brochure were more likely to leave a relationship that felt unhealthy or unsafe.30

Another study found increased safety behaviors—eg, hiding money, removing weapons from the home, and establishing a coded method of calling for help from friends and family—among pregnant victims of IPV who underwent a brief informational intervention.31 In another study, women who talked to a healthcare provider about their abuse were almost 4 times as likely to use an IPV intervention as women who did not. Those who used an IPV intervention were 2.6 times more likely to leave their abusive relationship, and those who left reported improved physical health.32

Research shows that the key components associated with an IPV victim’s increased willingness to consider changes in her situation are an increased awareness of IPV and options for addressing it, a sense of external support, and improved sense of self-efficacy or perceived power.33

The Readiness Model for IPV victims developed by Cluss and colleagues provides a framework for addressing IPV and RC: Integration of IPV assessment with education and resources, use of validating, empathetic, and supportive communication to increase women’s sense of external support, and use of open-ended questions and patient-centered communication to improve patient autonomy and empowerment.34

Office-based IPV/RC assessment can be the first step in recognizing abuse. However, a woman may define IPV narrowly and thus not recognize her own experience of violence, domination, intimidation, or control as IPV or “domestic violence,” nor may she see herself as a victim.35,36 IPV/RC assessment should thus include a definition.

The American College of Obstetricians and Gynecologists (ACOG)
INTIMATE PARTNER VIOLENCE

SAMPLE SIGNS OF ABUSE CHECKLIST FOR PATIENTS

Some of these are illegal. All of them are wrong. You may be abused if your partner:

- Monitors what you’re doing all the time
- Unfairly accuses you of being unfaithful all the time
- Prevents or discourages you from seeing friends or family
- Prevents or discourages you from going to work or school
- Gets very angry during and after drinking alcohol or using drugs
- Controls how you spend your money
- Controls your use of needed medicines
- Decides things for you that you should be allowed to decide (like what to wear or eat)
- Humiliates you in front of others
- Destroys your property or things that you care about
- Threatens to hurt you, the children, or pets
- Hurts you (by hitting, beating, pushing, shoving, punching, slapping, kicking, or biting)
- Uses (or threatens to use) a weapon against you
- Forces you to have sex against your will
- Controls your birth control or insists that you get pregnant
- Blames you for his or her violent outbursts
- Threatens to harm himself or herself when upset with you
- Says things like, “If I can’t have you then no one can.”

Source: Women's Health.gov
http://www.womenshealth.gov/violence-against-women/am-i-being-abused/#a

Raising the topic of IPV/RC

Any discussion of IPV/RC should occur in private, without accompanying individuals (including partners) in the room. For minors, as well as in states where domestic violence may require a mandatory report, always disclose the limits of confidentiality before beginning the discussion.

The National Center for Youth Law offers guidance on minor consent and confidentiality at www.teenhealthlaw.org/resources_for_other_us_states. Depending on such reporting requirements, an introductory script may be:

“As we talk about a range of topics during your visit, we want to make sure you understand that everything is private and confidential here, unless the person sitting in front of me says they are planning to hurt themselves or someone is actively hurting them. Then we may need to get other authorities involved to help keep that individual safe. What questions do you have for me?”

IPV/RC should be introduced as a topic during all types of clinical visits and a discussion can be initiated by trained medical assistants and nurses. ACOG suggests starting with the following statement: “Because violence is so common in many women’s lives and because there is help available for women being abused, I now ask every patient about domestic violence.”

The use of a palm-sized brochure (see www.healthcaresaboutipv.org/tools) is one strategy to facilitate the discussion while ensuring that all women know that the clinical staff care about IPV/RC and that the office is a safe place to discuss concerns about relationships and to be connected to helpful services.

Universal education approach

In one qualitative study, women with IPV histories advised health providers to consider offering IPV resources regardless of disclosure. They explained that while they may be too afraid or not ready to share their experience of IPV with their provider, they would still be willing to read or consider any information, resources, or support and possibly act on this information later.

Another study supporting the idea of universal education showed that women who received routine IPV education, both with and without a history of IPV, benefitted from increased awareness. Overall, the intervention group was 60% more likely to end “unhealthy” relationships than those in the control group—regardless of IPV history.

Thus, education for all women seeking reproductive health services can support informed decision-making, use of advocacy services, harm-reduction strategies, and safety planning.

recommendsthat physicians screen all patients for IPV. In particular, ACOG highlights routine ob/gyn visits, contraceptive counseling visits, and preconception visits and the first prenatal visit, trimester check-ups, and the postpartum visit.

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Thus, education for all women seeking reproductive health services can support informed decision-making, use of advocacy services, harm-reduction strategies, and safety planning.
A validating statement from an ob/gyn such as “You deserve to be treated with respect” can be life-changing for a patient.

The information can be introduced using normalizing language such as:

“We are learning more about how relationships affect women’s health and want all the women who we care for to have this information. If it’s safe to take with you, please take this card and some extra to share with friends or family members.”

**Targeted assessment in the context of reproductive health visits**

IPV and RC have profound consequences for women’s reproductive health, including unintended pregnancy and STIs. Frequent requests for pregnancy or STI testing and for emergency contraception (EC) are red flags that should prompt further assessment.

Other signs of RC may include a patient not using any contraception although she does not desire a pregnancy, missing appointments for depot medroxyprogesterone acetate injections, and “losing” birth control pills, the patch, or ring. Targeted assessment involves addressing the specific reproductive health concern:

“I see you are here for a pregnancy test, and you’ve told me that you don’t want to be pregnant right now. We are hearing from women that their male partners pressure them to get pregnant, mess with their birth control, and refuse to use condoms. Is this something that could be going on for you?”

**Harm-reduction strategies in the reproductive health setting**

In the clinical setting, healthcare providers can offer additional harm-reduction strategies. These may include placement of an IUD (which is less likely to be sabotaged), use of injectable or implantable contraceptives, and access to EC. Providers also can discuss how to negotiate condom use.

Notably, for women whose partners are monitoring their menstrual cycles, the copper IUD is the most discreet and least vulnerable to partner influence. To reduce the chance of removal by a partner, offer the option of cutting the strings in the endocervical canal at the time of placement.

Implants and depot medroxyprogesterone injections are less likely to be influenced by partners than are oral contraceptives, the vaginal ring, patch, or condoms, but assess whether a partner is also monitoring a woman’s menstrual cycle before offering these options.

Specific harm-reduction strategies include:

- Offering a copper IUD and cutting strings so the partner cannot feel or remove the device
- Recommending that the patient keep EC hidden in a small envelope (rather than the large product box)
- Offering to notify a partner anonymously about an STI diagnosis and need for treatment
- Discussing LARCs as methods less vulnerable to partner influence
- Offering use of the office phone to place a call to a victim service advocate so the call doesn’t show up on a woman’s cell phone

**Responding to disclosures and making warm referrals**

The goals of integrating IPV/RC assessment are to support women experiencing such abuse, validate their experiences, reduce their sense of shame and isolation, and provide information about advocacy services. Pushing a woman to disclose abuse is not the goal of assessing for IPV and RC. Rather, the message should be that she is not alone, that she can get support and help, and that the clinical office is a caring, safe space.

Because abuse is profoundly demoralizing and isolating, a validating statement from a healthcare provider such as “You deserve to be treated with respect” or “No one deserves to be hurt or afraid of the people who...”

**POWER POINTS**

IPV/RC should be introduced as a topic during all types of clinical visits.

Discussion can be initiated by trained medical assistants and nurses.
are supposed to love them” can be life-changing. Women whose healthcare providers discuss IPV during the visit are more likely to use victim services.

When disclosures happen, providers can offer supportive statements like “I know it took a great deal of courage to share that with me. Thank you for sharing your story.”

Even after an IPV/RC disclosure, it is crucial to respect the patient’s autonomy. Women have said that an unintended negative consequence of disclosing IPV was losing their ability to choose what happened next or having yet another person tell them what they needed to do. After a validation statement, a provider may then inquire, “What can I do to help you?” or “What would be most helpful to you?”

If a woman says that she is uncertain about the provider’s ability to help, the provider can then ask permission to offer suggestions: “May I offer some thoughts about how I might be helpful?” or “Can I share some ideas that other women have found useful?”

Providers should be prepared to make a “warm referral” to an advocate. This means assisting the patient in making contact with an advocate immediately. Some larger clinical sites have on-site victim service advocates. For most offices, advocates are off site and may be willing to come to an office to meet with a client (it may be easier for a woman to say to a partner that she is going to the clinical site for a health concern and meet with an advocate there than to go to a domestic violence agency).

If the client is willing, allowing her to use an office phone to talk to a victim service advocate during her visit can help. If the client is unwilling, providing hotline numbers, particularly the easy-to-memorize National Domestic Violence Hotline number (1-800-799-SAFE) allows her to use resources when or if she feels ready.

Frequent requests for pregnancy or STI testing and for emergency contraception are red flags that should prompt further assessment.

An advocate can also assist the client in making a safety plan, particularly if she is not yet ready to make any changes in her situation. Safety plans are strategies to prepare for another episode of violence. The National Coalition Against Domestic Violence has an example of a safety plan at www.ncadv.org/protectyourself/SafetyPlan.php.

To reinforce that a patient is not alone and that she has support regardless of what she is ready or able to do, providers should offer follow-up and schedule a return visit.

Assessing safety around pregnancy diagnosis

Providers also have an obligation to ask about a woman’s safety once a pregnancy is diagnosed. A question such as “How might the person who got you pregnant react if he were to know about your positive pregnancy test?” can reveal conflict around pregnancy intentions and can be helpful in guiding pregnancy counseling.

In some situations, a positive pregnancy test could lead to escalation of violence, forced continuation of the pregnancy, or threats to kill her if she doesn’t do what a partner expects regarding the pregnancy.

Summary

Healthcare providers are in a unique position to educate all women about IPV and RC, to offer harm-reduction strategies, and to build a link to victim advocates in a supportive and empowering way.

Providers should nurture close collaborations with on-site social workers (where available) and advocates to connect women to violence victimization-related resources. 

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REFERENCES


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- Clinical evidence supports offering expanded CF carrier screening to all patients who are pregnant or are planning a pregnancy
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References

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INTIMATE PARTNER VIOLENCE

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 guidelines²)
- **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.

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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Antepartum Fetal Surveillance

The goal of antepartum fetal surveillance is to prevent fetal death. Antepartum fetal surveillance techniques based on assessment of fetal heart rate (FHR) patterns have been in clinical use for almost four decades and are used along with real-time ultrasonography and umbilical artery Doppler velocimetry to evaluate fetal well-being. Antepartum fetal surveillance techniques are routinely used to assess the risk of fetal death in pregnancies complicated by preexisting maternal conditions (eg, diabetes mellitus) as well as those in which complications have developed (eg, fetal growth restriction). The purpose of this document is to provide a review of the current indications for and techniques of antepartum fetal surveillance and outline management guidelines for antepartum fetal surveillance that are consistent with the best scientific evidence.

COMMENTARY

Balancing cost and benefit in antepartum fetal surveillance

By Haywood L. Brown, MD

Dr. Brown is F. Bayard Carter Professor and Chair, Division of Maternal Fetal Medicine, Department of Obstetrics and Gynecology, Duke University School of Medicine, Durham, North Carolina.

For nearly 4 decades, fetal heart monitoring (FHR) has been used to assess antenatal and intrapartum fetal well-being. While both antenatal and intrapartum monitoring have come under criticism, antepartum fetal heart rate surveillance to assess the risk of fetal death and stillbirth is less controversial for the purpose for which it was intended when it was introduced in the 1970s.

This Practice Bulletin provides a review of the indications and techniques for antepartum fetal surveillance with FHR being the consistent parameter used in the assessment of fetal well-being.

Abnormal fetal surveillance is based on physiologic changes that alter fetal heart rate and fetal activity. Fetal heart rate, fetal movement, and tone in particular are impacted by uteroplacental fetal blood flow alterations and are thereby sensitive to fetal hypoxemia and acidemia. While nonreassuring fetal surveillance is associated with fetal hypoxemia and acidemia based on these physiologic adjustments, these indicators can neither predict the degree or duration of the fetal acid base disturbance nor precisely predict neonatal outcome.

Antepartum surveillance techniques

A warning sign that a fetus may be at risk of compromise is maternal perception of decrease in fetal movement. If “kick counting” is used by the patient, a nonreassuring count provides the alert for further assessment. Many approaches to counting kicks have been used over the past decades, but the perception of 10 distinct movements in a period of up to 2 continuous or interrupted hours is considered reassuring. A nonreassuring count should prompt notification for further fetal assessment.

The non-stress test (NST) and the ultrasound biophysical profile (BPP) are the primary antenatal fetal surveillance methods now used. The NST is based on the principle that the fetal heart will accelerate with movement in a fetus with normal autonomic function. Accelerations of 15 beats per minute above baseline and for 15 seconds from the baseline in a 20- to 40-minute period are considered reactive and are a measure that has stood the test of time as a predictor of fetal well-being at that point in time.
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A normal BPP score along with a reactive NST is an indication of fetal well-being. The BPP provides 2 points each for fetal breathing, movement, and fetal tone in 30 minutes and 2 points for normal amniotic fluid volume. There has been debate regarding the ultrasound definition of oligohydramnios and whether a single deepest vertical pocket of fluid of ≤2 cm, as recommended in the Practice Bulletin, is more acceptable as a predictor than an amniotic fluid index (AFI) of <5 cm. Oligohydramnios suggests renal under-perfusion and decreased fetal urination and should prompt further evaluation or delivery, especially if other biophysical parameters are altered. A total biophysical score of <4 is abnormal and suggestive of fetal compromise and increased risk of adverse outcome.

With the addition of umbilical artery Doppler velocimetry, particularly in the surveillance of fetal growth restriction (FGR), the contraction stress test (CST) is now rarely used to assess for fetal compromise or potential hypoxemia. There is no evidence that inclusion of umbilical artery Doppler interrogation in antenatal surveillance provides additional benefit in the assessment of a normally growing fetus.

**Timing of reactive testing**

Current clinical practice calls for performing a NST once or twice weekly after 32 0/7 gestational weeks, depending on the indication for testing. If the indication for testing is not persistent, the NST need not be repeated. If the maternal condition is stable and testing is reassuring, the NST is typically repeated weekly.

The negative predictive value of NST alone for predicting stillbirth within 1 week of a normal test is 99.8%; for BPP, modified BPP, and CST, it is greater than 99.9%.

**Indications for antenatal surveillance and management**

Antenatal testing is used for pregnancies considered at risk of antepartum stillbirth, such as those complicated by pre-gestational diabetes, poorly controlled gestational diabetes, maternal vascular disease (chronic hypertension), and FGR. (See Box 1 of the Practice Bulletin).²

Initiation of testing at 32 0/7 weeks is appropriate for most women at risk with the exception of patients with FGR recognized prior to 32 weeks’ gestation. The challenge for the clinician is acting on an abnormal (false-positive) test result, which has the potential for iatrogenic premature delivery with resultant complications of prematurity. In one large single-center review, 60% of fetuses with an abnormal antepartum test result had no evidence of short-term or long-term fetal compromise.¹ While statistically these are “false positives,” the clinician has to take into consideration the clinical indications for testing in the first place and the goal of the test in preventing stillbirth.

Management depends on gestational age, maternal condition, and which antenatal testing or combination thereof is abnormal. Abnormal results of an NST (nonreactive) should be followed by a BPP, modified BPP, or a CST.

A BPP of 6 is considered equivocal and prompts consideration for delivery, especially beyond 37 0/7 weeks, or repeat testing in 24 hours if <37 weeks. A BPP score <4 is an indication for delivery in most circumstances with a viable fetus. If the gestational age is <32 0/7 weeks, maternal steroid administration and extended monitoring is appropriate but such management should be individualized, especially in cases of FGR. The FGR guidelines from the Society for Maternal-Fetal Medicine suggest delivery if there is absent end-diastolic flow or at beyond 34 0/7 weeks and with reverse end-diastolic flow delivery if gestational age is ≥32 0/7 weeks.³

Management decisions are more challenging in cases with oligohydramnios as the only abnormality in antenatal surveillance. Most experts agree that the best course of action with a finding of isolated and uncomplicated oligohydramnios is expectant management if gestational age is <36 0/7 weeks and delivery if gestational age is >36 completed weeks.

**Summary**

Antenatal fetal surveillance has stood the test of time with regard to the goal of preventing stillbirth in the fetus at risk based on indications for testing. As such, the additional cost for testing in the appropriate setting appears to have benefit. However, clinicians should be reminded that the least costly antenatal surveillance modality is maternal fetal movement assessment as a test for well-being in low- and high-risk women, even if its effectiveness in preventing stillbirth is uncertain.

Fetal kick counting in current antenatal clinical care appears to be underutilized and clinicians should be reminded to educate women about this modality in antenatal care.²²

**References**

USE OF CONTRACEPTION IN WOMEN

A data snapshot by the Centers for Disease Control and Prevention (CDC) for 2011 to 2013 shows that during that period, 62% of US women ages 15 to 44 were using contraception. Age, Hispanic origin and race, and educational attainment all impacted use and choice of contraception. Understanding how social and demographic characteristics impact contraception can influence the incidence of unintended pregnancy.

Most common methods of contraception

- The pill: 16%
- Female sterilization: 15.5%
- Male condoms: 9.4%
- Long-acting reversible contraceptives: 7.2%

Percentage of all women aged 22-44 using contraception by educational attainment

- No high school diploma
- High school diploma or GED
- Some college, no bachelor’s degree
- Bachelor’s degree or higher

Overall contraceptive use

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ages 15-24</td>
<td>47.4%</td>
</tr>
<tr>
<td>Ages 25-34</td>
<td>67.4%</td>
</tr>
<tr>
<td>Ages 35-44</td>
<td>70%</td>
</tr>
</tbody>
</table>

Most popular form of contraception

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ages 15-24</td>
<td>The pill: 22.4%</td>
</tr>
<tr>
<td>Ages 25-34</td>
<td>The pill: 16.9%</td>
</tr>
<tr>
<td>Ages 35-44</td>
<td>Female sterilization: 31%</td>
</tr>
</tbody>
</table>

In case you missed this must-read promotional supplement in the January 2015 issue of Contemporary OB/GYN—

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

Ellen Jo Baron, PhD, D(ABMM)
Professor Emerita, Stanford University, Department of Pathology
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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


Loss of triplet pregnancy

AN ALABAMA WOMAN who had difficulty becoming pregnant underwent in vitro fertilization in 2010 and became pregnant with triplets. She was followed by obstetricians at a university hospital. At 17 ½ weeks’ gestation she came to the hospital with vaginal bleeding. Her obstetrician examined her and concluded that she was in labor with the first fetus and that its amniotic sac was in the vagina. The patient was admitted to the hospital on complete bed rest in Trendelenburg position and started on antibiotics. On the day of admission, the obstetrician spoke to the patient and explained that it might be possible to save the other 2 fetuses even if the first fetus delivered. He also stated, however, that he believed that the likelihood of maintaining the pregnancy with fetuses 2 and 3 until viability was remote.

After a week the patient developed a high fever and exhibited signs of impending shock. An examination by a second-year obstetrical resident revealed a suspicion of chorioamnionitis, and the patient was transferred to labor and delivery, where an obstetrician delivered all 3 fetuses. The first was stillborn, and the other 2 died shortly after birth from severe prematurity.

The patient sued those involved with her delivery, claiming that the physicians failed to make proper efforts to save the second and third fetuses. She alleged that allowing the amniotic sac to remain in the vagina allowed the infection to progress.

The case went to trial against the second-year resident and the delivering obstetrician. Both denied any negligence in the patient’s management. They stated that the patient developed a life-threatening infection that necessitated emptying the uterus and that the infants were just previable.

The verdict
A trial resulted in a defense verdict for the resident and a mistrial for the delivering obstetrician. During a second trial, however, a defense verdict was returned.

Bowel injury following elective cesarean delivery

AN OBSTETRICIAN PERFORMED an elective cesarean delivery on a Texas woman in her mid-thirties in 2010. The patient was seen by that doctor the day after surgery, and by a partner on the second and third postoperative days. She was discharged on day 3 and, within 36 hours, developed a fever and became ill while at the pediatrician’s office with her daughter. The pediatrician’s staff placed the patient in a wheelchair and took her to the adjacent hospital’s emergency room. She was worked up for a pulmonary embolism, but tests were negative. A CT scan showed free air in the abdomen and emergency laparotomy was performed by a general surgeon with the obstetrician observing. An area of the cecum was inflamed and a small amount of bowel contents was found to be leaking. A primary anastomosis was performed to repair the bowel with no colostomy required.

The woman sued the original obstetrician, alleging negligence in injuring the cecum during the cesarean. She claimed that pressure from a retractor pinched and injured the bowel during the cesarean and the perforation developed over the next several days. She also alleged that the hospital staff was negligent in failing to properly document her condition and complications prior to discharge, claiming she had fever, tachycardia, and irregular bowel movements that indicated a cecum injury.

The hospital settled for a confidential amount early in the litigation. The obstetrician denied that the cecum was injured in the cesarean and claimed that the perforation was caused by Ogilvie’s syndrome. The physician also pointed to lack of contamination of the abdominal viscera at the time of laparotomy to support the claim that the perforation was acute and did not occur during the cesarean. In addition, the obstetrician noted that the retractor was not located anywhere near the cecum.

The verdict
A defense verdict was returned.

Failure to follow up fundal height discrepancy

A 37-YEAR-OLD MASSACHUSETTS WOMAN was pregnant with her second child and received prenatal care from her obstetrician. At 37 weeks’ gestation, it was noted that the fundal height was lagging gestational age of the fetus greater than 2 cm. At 39 ½ weeks she called the office to report decreased fetal movement. Because her treating
physician was on vacation, the woman was evaluated by another physician in the group. A fetal heart rate (FHR) monitor showed a non-reactive tracing and the doctor advised her to drive herself to the hospital for evaluation. At the hospital the lack of variability in the FHR was confirmed and an emergency cesarean delivery was performed. The infant had no respirations initially and was treated by the pediatric team before transfer to the transitional care unit, subsequent intubation, and transfer to the neonatal intensive care unit (NICU). Cord blood gases confirmed metabolic acidosis. The child was ultimately diagnosed with dystonic cerebral palsy. He is unable to speak, walk, eat, or care for himself in any way.

In the lawsuit that followed, the patient alleged negligence in the failure to order any fetal testing after the fundal height discrepancy was found, claiming that testing at that time would have led to an earlier delivery and avoided the profound brain damage. She also alleged negligence by the pediatrician in failing to ensure adequate oxygenation after delivery by promptly transferring him to the NICU and immediately intubating him.

The physicians claimed that the fundal height discrepancy was explained by the position of the fetus in utero and that the pediatrician had acted heroically in saving the baby’s life after delivery.

The verdict
A $3.5 million settlement was reached.

Compartiment syndrome in lower leg following delivery

A 45-YEAR-OLD WASHINGTON WOMAN was 42 weeks pregnant in 2010 when she was admitted to the hospital in labor after a failed attempt at a home birth. The baby was delivered about 4 1/2 hours after her arrival. The next day the patient complained of shin and leg pain, but was able to ambulate and dorsiflex her foot. On the morning of discharge, the patient was offered the choice to stay in the hospital for evaluation by a neurologist or discharge with outpatient follow up if her symptoms continued. The patient left the hospital. After she got home, her symptoms worsened, with increased swelling in her leg and foot, followed by inability to ambulate or dorsiflex her foot with color changes in the leg. She returned to the hospital and was evaluated in the emergency room and diagnosed with compartment syndrome of the right leg. That day, she underwent a fasciotomy. She continues to suffer foot drop, irregular gait, and right hip pain.

The verdict
A $3,500 settlement was reached.

Hemorrhage after cesarean results in maternal death

A VIRGINIA WOMAN went to a hospital in 2007 for delivery at 42 weeks’ gestation with ruptured membranes. Her obstetrician ordered oxytocin and labor continued through the day. A decision was made that night to deliver her by emergency cesarean; the patient was noted to have increased bleeding at that time. The bleeding continued and worsened after the cesarean. The patient went into hemorrhagic shock and died the next day.

A lawsuit was filed, claiming that the patient had uterine atony caused by the use of oxytocin, and that the obstetrician failed to appreciate the severity of the bleeding until too late. The suit also alleged that a hysterectomy should have been performed or blood products used in a more timely manner.

The case went to the jury against the obstetrician only, who maintained there had been a prompt response to the patient’s bleeding. He claimed that the death was due to an unpredictable, unpreventable, and irreversible amniotic fluid embolism, which triggered a global vascular coagulation problem.

The verdict
A defense verdict was returned. An appeal is pending.

Retained foreign bodies after alleged robot malfunction

AN OREGON WOMAN had worsening chronic pelvic pain when she went to a gynecologist in 2007 for a sterilization procedure. Five months later she consented to the surgical removal of her right ovary and Fallopian tube, as well as her appendix. The gynecologist performed
the surgery using a robotic device. After the procedure, the pathology report stated that the ovary and tube were intact, functioning, and normal. The patient moved to Montana and continued to have pain and sought care there. A CT scan more than 3 years after the robotic procedure revealed that something plastic had been left in the patient’s body. An operation was performed and one full Essure coil, a non-fired coil, a second partial Essure coil, and a laparoscopy sheath were removed. According to the old records, the robotic device had malfunctioned during the original robotic surgery.

The patient sued the gynecologist who performed the robotic procedure.

**The verdict**
A $110,513 verdict was returned.

**Urosepsis in early pregnancy results in death**

A 27-YEAR-OLD KENTUCKY WOMAN was pregnant with her second child in 2010. She received prenatal care from the obstetrician who had delivered her son a year earlier. She had pyelonephritis earlier in the pregnancy but it was otherwise uncomplicated until 19 weeks’ gestation, when she felt ill and complained of abdominal pain. She was taken to a hospital emergency room (ER). The nurses believed she was suffering a urinary tract infection and consulted with her obstetrician, who concurred with the diagnosis without seeing the patient. She was given antibiotic and pain medication before being discharged.

The patient was worse the next day and was taken back to the hospital. Urosepsis was diagnosed and a surgeon took over her care and performed emergency surgery. The fetus died during the operation and the patient coded at the end of the procedure. She was resuscitated, but suffered significant brain damage and died 4 days later when life support was removed.

In the lawsuit that followed, negligence was alleged against the obstetrician in failing to see the patient during the initial ER visit, given the woman’s history of pyelonephritis. The contention was that the patient should not have been discharged and that intravenous antibiotics would have allowed both mother and fetus to survive.

The obstetrician claimed that there was no negligence and that admission at the time of the first ER visit was not warranted, based on the reports from the hospital nurses. He also claimed that the 19-week fetus was non-viable and made a motion for summary judgment to drop claims related to the fetus, which was denied.

**The verdict**
Claims against the hospital resulted in a confidential settlement prior to trial. At trial the claims included those for the death of the mother and the fetus. The jury found the hospital 60% at fault and the obstetrician 40% at fault. A verdict awarding $7,440,000 was returned, although no damages for the fetus’ death were awarded. The net amount against the physician was $2,976,000.
Contemporary OB/GYN welcomes new board members

Iana Cass, MD, is a faculty physician for the Division of Gynecologic Oncology within the Department of Obstetrics and Gynecology at Cedars-Sinai Medical Center, Los Angeles, California. Board-certified in obstetrics and gynecology and in gynecologic oncology, Dr. Cass has been awarded investigative grants from the Ovarian Cancer Research Fund, the American Cancer Society, the Gynecologic Cancer Foundation and pharmaceutical companies. Her primary area of research interest involves genetic alterations as prognostic markers in ovarian cancer.

Dr. Cass received her bachelor’s degree from Brown University in Providence, Rhode Island, and her medical degree from Mount Sinai School of Medicine in New York City. She completed a residency in obstetrics and gynecology at Yale/New Haven Hospital in Connecticut and a fellowship in gynecologic oncology at Albert Einstein College of Medicine/Montefiore Medical Center in the Bronx.

She is the first candidate from Cedars-Sinai to be nominated and the first accepted to the year-long Hedwig van Ameringen Executive Leadership in Academic Medicine fellowship.

Christian Pettker, MD, graduated from Princeton University (Princeton, New Jersey) and subsequently gained experience in teaching at Eton College in England under an Annenberg Fellowship. He received his medical degree from the Columbia University College of Physicians and Surgeons and completed his obstetrics/gynecology residency at New York–Presbyterian Hospital (Columbia University).

Following this, he joined Yale University (New Haven, Connecticut) as a fellow in Maternal–Fetal Medicine and is now on the faculty as an Associate Professor.

Dr. Pettker’s special areas of interest are labor and delivery and healthcare quality and safety. His work in these areas was featured in an October 2014 New York Times blog, “When doctors and nurses work together” (http://well.blogs.nytimes.com/2014/10/16/when-doctors-and-nurses-work-together/?smid=pl-share).

It discussed the findings of the study “A comprehensive obstetric patient safety program reduces liability claims and payments,” which was published online by the American Journal of Obstetrics and Gynecology in June 2014 and which was led by Dr. Pettker. His team found that an obstetric safety initiative can improve liability claims exposure and reduce liability payments.
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For more information, please contact
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A 39-YEAR-OLD ILLINOIS WOMAN went to her gynecologist in 2008 for a tubal ligation. One of her 3 children had sickle cell disease and she did not want to have another child with the disease. She had experienced complications from other forms of birth control.

The patient’s history included 2 cesarean deliveries and, according to her statement, she had had a left salpingo-oophorectomy at a young age. An ultrasound done in 2004, however, indicated that the woman’s right ovary had been surgically removed and that a cystic interface had been identified on the left ovary at that time.

The patient had been scheduled for a tubal ligation 3 years earlier, but it was not performed because she could not be intubated. Her gynecologist then recommended and performed a mini-laparotomy and tubal ligation under spinal anesthesia. During the operation the gynecologist identified a Fallopian tube and ovary on the right side, but because of a large amount of adhesions on the left side, he could not visualize a left Fallopian tube or ovary. A tubal ligation was performed on the right side, but the physician did not remove all the adhesions on the left side because of the patient’s representation that she had a left salpingo-oophorectomy.

Six months later, the woman had a positive pregnancy test and she later gave birth by cesarean to a child who was diagnosed with sickle cell disease. The physician who performed the cesarean did not find an ovary on the right side, but did find a tube that was shortened and wrapped around itself. He also took down the adhesions on the left side and found an intact left Fallopian tube and ovary. He ligated both tubes.

The patient had postoperative complications including a lung infection with surgical drainage, development of shingles, and post-herpetic neuralgia. She sued the gynecologist who performed the mini-laparotomy and alleged negligence in failing to properly evaluate her prior to the procedure, failing to actually perform a ligation on the right side, and failing to remove the left-side adhesions and discover the intact tube and ovary, resulting in the pregnancy.

The physician claimed that further evaluation would not have provided any new information and that the risks of taking down the adhesions outweighed the potential benefits.

Analysis

In a malpractice case claiming wrongful pregnancy, the suit is brought by the parent(s) and claims a physician’s negligence in performing a sterilization procedure resulted in pregnancy. The usual damages sought are the costs and any pain and suffering from the negligent procedure, and the costs, both economical and emotional, from the pregnancy and delivery. The parents can seek damages for the costs of rearing a child, but this issue is problematic for jurors as they weigh those “costs” against the joy or emotional benefit of having a child. In this case, the parents also claimed extraordinary expenses of raising a child with sickle cell disease—the exact condition they were trying to avoid with the tubal ligation—and although the physician sought dismissal of that claim, the trial court denied his motion. This decision was upheld on appeal, so those damages would have been allowed if the jury had found negligence by the physician. FOR MORE LEGALLY SPEAKING TURN TO PAGE 48

The verdict

A defense verdict was returned.
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  - 19% incidence of adhesion formation¹
  - Up to 32% incidence of adhesion formation after multiple procedures.⁶

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Hologic.com | MyoSure.com | NovaSure.com