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- No reader required
- No speculum required

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The CDC recommends TB testing for pregnant women who are at increased risk for infection and disease progression (1).

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- Single patient visit
- Unaffected by the BCG vaccine
- No PPD injection required

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References:

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Endometrial polyps
Management and removal
Anthony N. Imudia, MD, and Erika P. New, MD, MPH

Biomarker testing for ovarian cancer
What’s new

HIV: Treatment as prevention

SMFM CONSULT
Sepsis

Get ready for ACOG

TEST YOUR KNOWLEDGE
Vulvar conditions

Intrauterine view of an inpatient polyp removal procedure.
First of its kind: Introducing the only FDA-approved bio-identical combination hormone therapy for the treatment of moderate to severe vasomotor symptoms (VMS) due to menopause in women with a uterus.

**INDICATION**

BIJUVA™ is a combination of estradiol and progesterone indicated in a woman with a uterus for the treatment of moderate to severe vasomotor symptoms due to menopause.

**IMPORTANT SAFETY INFORMATION**

**WARNING: CARDIOVASCULAR DISORDERS, BREAST CANCER, ENDOMETRIAL CANCER, AND PROBABLE DEMENTIA**

See full prescribing information for complete boxed warning.

**Estrogen Plus Progestin Therapy**

- Estrogen plus progestin therapy should not be used for the prevention of cardiovascular disease or dementia
- The Women’s Health Initiative (WHI) estrogen plus progestin substudy reported increased risks of stroke, deep vein thrombosis (DVT), pulmonary embolism (PE), and myocardial infarction (MI)
- The WHI estrogen plus progestin substudy reported increased risks of invasive breast cancer
- The WHI Memory Study (WHIMS) estrogen plus progestin ancillary study of WHI reported an increased risk of probable dementia in postmenopausal women 65 years of age or older

**Estrogen-Alone Therapy**

- There is an increased risk of endometrial cancer in a woman with a uterus who uses unopposed estrogens
- Estrogen-alone therapy should not be used for the prevention of cardiovascular disease or dementia
- The WHI estrogen-alone substudy reported increased risks of stroke and DVT
- The WHIMS estrogen-alone ancillary study of WHI reported an increased risk of probable dementia in postmenopausal women 65 years of age or older
CONTRAINDICATIONS
• BIJUVA is contraindicated in women with any of the following conditions: undiagnosed abnormal genital bleeding; known, suspected, or history of cancer of the breast; known or suspected estrogen-dependent neoplasia; active DVT, PE, or history of these conditions; active arterial thromboembolic disease (for example, stroke, MI), or a history of these conditions; known anaphylactic reaction, angioedema, or hypersensitivity to BIJUVA or any of its ingredients; known liver impairment or disease; known protein C, protein S, or antithrombin deficiency, or other known thrombophilic disorders.

WARNINGS AND PRECAUTIONS
• An increased risk of PE, DVT, stroke, and MI has been reported with estrogen plus progestin therapy. Should these occur or be suspected, therapy should be discontinued immediately. Risk factors for arterial vascular disease and/or venous thromboembolism (VTE) should be managed appropriately.
• The WHI substudy of daily estrogen plus progestin after a mean follow-up of 5.6 years reported an increased risk of invasive breast cancer. Observational studies have also reported an increased risk of breast cancer for estrogen plus progestin therapy after several years of use. The risk increased with duration of use and appeared to return to baseline over about 5 years after stopping treatment (only the observational studies have substantial data on risk after stopping). The use of estrogen plus progestin therapy has been reported to result in an increase in abnormal mammograms requiring further evaluation.
• Endometrial hyperplasia (a possible precursor to endometrial cancer) has been reported to occur at a rate of approximately less than one percent with BIJUVA. Clinical surveillance of all women using estrogen plus progestin therapy is important. Adequate diagnostic measures should be undertaken to rule out malignancy in postmenopausal women with undiagnosed persistent or recurring abnormal genital bleeding.
• The WHI estrogen plus progestin substudy reported a statistically non-significant increased risk of ovarian cancer. A meta-analysis of 17 prospective and 35 retrospective epidemiology studies found that women who used hormonal therapy for menopausal symptoms had an increased risk for ovarian cancer. The exact duration of hormone therapy use associated with an increased risk of ovarian cancer, however, is unknown.
• In the WHIMS ancillary studies of postmenopausal women 65 to 79 years of age, there was an increased risk of developing probable dementia in women receiving estrogen plus progestin when compared to placebo. It is unknown whether these findings apply to younger postmenopausal women.
• Estrogens increase the risk of gallbladder disease.
• Discontinue estrogen if severe hypercalcemia, loss of vision, severe hypertriglyceridemia, or cholestatic jaundice occurs.
• Monitor thyroid function in women on thyroid replacement hormone therapy.

ADVERSE REACTIONS
The most common adverse reactions (≥3%) for BIJUVA are breast tenderness (10.4%), headache (3.4%), vaginal bleeding (3.4%), vaginal discharge (3.4%) and pelvic pain (3.1%).

Please note that this information is not comprehensive. Please see Brief Summary of the Full Prescribing Information, including the BOXED WARNING, on the following pages.

Bijuva™ (estradiol and progesterone) capsules, for oral use

BRIEF SUMMARY OF PRESCRIBING INFORMATION
This Brief Summary does not include all the information needed to use Bijuva safely and effectively. See package insert for full prescribing information.

WARNING: ENDOMETRIAL CANCER, CARDIOVASCULAR DISORDERS, BREAST CANCER
and PROBABLE DEMENTIA

Estrogen Plus Progestin Therapy
Cardiovascular Disorders and Probable Dementia
Estrogen plus progestin therapy should not be used for the prevention of cardiovascular disease or dementia [see Warnings and Precautions (5.1, 5.3), and Clinical Studies (14.4, 14.5) in full prescribing information].

The Women’s Health Initiative (WHI) estrogen plus progestin substudy reported increased risks of deep vein thrombosis (DVT), pulmonary embolism (PE), stroke, and myocardial infarction (MI) in postmenopausal women 50 to 79 years of age after 6 years of treatment with daily oral conjugated estrogens (CE) [0.625 mg] combined with medroxyprogesterone acetate (MPA) [2.5 mg], relative to placebo [see Warnings and Precautions (5.1), and Clinical Studies (14.4) in full prescribing information].

The WHIMS Memory Study (WHIMS) estrogen plus progestin ancillary study of WHI reported an increased risk of dementia in postmenopausal women 65 years of age or older during 7.1 years of treatment with daily CE (0.625 mg) combined with MPA (2.5 mg), relative to placebo. It is unknown whether this finding applies to younger postmenopausal women [see Warnings and Precautions (5.3), Use in Specific Populations (8.5), and Clinical Studies (14.5) in full prescribing information].

Breast Cancer
The WHI estrogen plus progestin substudy demonstrated an increased risk of invasive breast cancer [see Warnings and Precautions (5.2), and Clinical Studies (14.4) in full prescribing information]. In the absence of individual women, these risks should be assumed to be similar for other doses of CE and MPA, and other combinations and dosage forms of estrogens and progestins.

Estrogens with or without progestins should be prescribed at the lowest effective doses and for the shortest duration consistent with treatment goals and risks for the individual woman.

Estrogen-Alone Therapy
Endometrial Cancer
There is an increased risk of endometrial cancer in a woman with a uterus who uses unopposed estrogens. Adding a progestin to estrogen therapy has been shown to reduce the risk of endometrial hyperplasia, which may be a precursor to endometrial cancer. Adequate diagnostic measures, including directed or random endometrial sampling when indicated, should be undertaken to rule out malignancy in postmenopausal women with undiagnosed persistent or recurring abnormal genital bleeding [see Warnings and Precautions (5.2) in full prescribing information].

Cardiovascular Disorders and Probable Dementia
Estrogen-alone therapy should not be used for the prevention of cardiovascular disease or dementia [see Warnings and Precautions (5.1, 5.3), and Clinical Studies (14.4, 14.5) in full prescribing information]. The WHI estrogen-alone substudy reported increased risks of stroke and DVT in postmenopausal women 50 to 79 years of age after 7.1 years of treatment with daily oral CE [0.625 mg]-alone, relative to placebo [see Warnings and Precautions (5.1), and Clinical Studies (14.4) in full prescribing information].

In the WHI estrogen-alone substudy, there was a statistically non-significant increased risk of coronary heart disease (CHD) events (defined as fatal MI, silent MI, or CHD death) reported in women receiving daily CE (0.625 mg) plus placebo versus those receiving placebo (18 versus 21 per 10,000 women-years).[1]

Coronary Heart Disease
In the WHI estrogen plus progestin substudy, there was a statistically non-significant increased risk of coronary heart disease (CHD) events (defined as fatal MI, silent MI, or CHD death) reported in women receiving daily CE (0.625 mg) plus placebo (2.5 mg) compared to women receiving placebo (41 versus 34 per 10,000 women-years). An increase in relative risk was demonstrated in year 1, and a trend toward a relative risk was reported in years 2 through 5 [see Clinical Studies (14.4) in full prescribing information].

In the WHI estrogen-alone substudy, no overall effect on CHD events was reported in women receiving estrogen-alone compared to placebo [see Clinical Studies (14.4)]. Subgroup analysis of women 50 to 59 years of age at study entry reported a statistically non-significant reduction in CHD events (CE [0.625 mg]-alone compared to placebo) in women with less than 10 years since menopause (8 versus 16 per 10,000 women-years).[1]

In postmenopausal women with documented heart disease (n = 2,763), average 66.7 years of age, in a controlled clinical trial of secondary prevention of cardiovascular disease (Heart and Estrogen/Progestin Replacement Study [HERS]), treatment with daily CE (0.625 mg) plus placebo (2.5 mg) demonstrated no cardiovascular benefit. During an average follow-up of 4.1 years, treatment with CE plus MPA did not reduce the overall rate of CHD events in postmenopausal women with established coronary heart disease. There were more CHD events in the CE plus MPA-treated group than in the placebo group in year 1, but not during the subsequent years. Two thousand, three hundred and twenty and (2,321) women from the original HERS trial agreed to participate in an open label extension of the original HERS, HERS II. Average follow-up in HERS II was an additional 2.7 years, for a total of 6.8 years overall. Rates of CHD events were comparable among women in the CE plus MPA group and the placebo group in HERS, HERS II, and overall.

Venous Thromboembolism
In the WHI estrogen plus progestin substudy, a statistically significant 2-fold greater rate of VTE (DVT and PE) was reported in women receiving daily CE (0.625 mg) plus MPA (2.5 mg) compared to placebo (35 versus 17 per 10,000 women-years). Statistically significant increases in risk for both DVT (26 versus 13 per 10,000 women-years) and PE (18 versus 8 per 10,000 women-years) were also demonstrated. The increase in risk of VTE was demonstrated during the first year and persisted [see Clinical Studies (14.4) in full prescribing information]. Should a VTE occur or be suspected, estrogen plus progestin therapy should be discontinued immediately. In the WHI estrogen-alone substudy, the risk of VTE was increased for women receiving daily CE (0.625 mg) compared to placebo (30 versus 22 per 10,000 women-years), although only the increased risk of DVT reached statistical significance (23 versus 15 per 10,000 women-years). The increase in VTE was demonstrated during the first 2 years [see Clinical Studies (14.4)]. Should a VTE occur or be suspected, estrogen-alone therapy should be discontinued immediately.

In feasibility, feasible dosages should be discontinued in 6 to 12 weeks because of the risk of venous thromboembolism, or during periods of prolonged immobilization.

Malignant Neoplasms
Breast Cancer
The most important randomized clinical trial providing information about breast cancer in estrogen plus progestin users is the WHI substudy of daily CE (0.625 mg)-alone plus MPA (2.5 mg). After a mean follow-up of 5.6 years, the estrogen plus progestin substudy reported an increased risk of invasive breast cancer in women who took daily CE plus MPA. In this substudy, prior use of estrogen-alone or estrogen plus progestin therapy was reported by 26% of the women. The relative risk of invasive breast cancer was 1.24, and the absolute risk was 41 versus 33 cases per 10,000 women-years, for CE plus MPA compared with placebo. Among women who reported prior use of hormone therapy, the relative risk of invasive breast cancer was 1.86, and the absolute risk was 46 versus 25 cases per 10,000 women-years, for CE plus MPA compared with placebo.

Among women who reported no prior use of hormone therapy, the relative risk of invasive breast cancer was 1.59, and the absolute risk was 40 versus 36 cases per 10,000 women-years for CE plus MPA compared with placebo. In this same substudy, invasive breast cancers were larger, were more likely to be node positive, and were diagnosed at a more advanced stage in the CE (0.625 mg) plus MPA (2.5 mg) group compared with the placebo group. Metastatic disease was rare, with no apparent difference between the two groups. Other studies, including one that used histologic grade and hormone receptor status did not offer different between the groups [see Clinical Studies (14.4) in full prescribing information].

The most important randomized clinical trial providing information about breast cancer in estrogen-alone users is the WHI substudy of daily CE (0.625 mg)-alone. In the WHI estrogen-alone substudy, after an average follow-up of 7.1 years, daily CE alone was not associated with an increased risk of breast cancer. [relative risk (RR) 0.80] [see Clinical Studies (14.4)]. Consistent with the WHI clinical trial, observational studies have also reported an increased risk of breast cancer for estrogen plus progestin therapy, and a smaller increased risk for estrogen-alone therapy, after several years of use. The risk increased with duration of use, and appeared to return to baseline over about 5 years after stopping treatment (only the observational studies have substantial data on risk after stopping). Observational studies also suggest that the risk of breast cancer was greater, and became apparent earlier, with estrogen plus progestin therapy than prior use of estrogen-alone therapy as compared to estrogen-alone therapy. However, these studies have not generally found significant variation in the risk of breast cancer among different estrogen plus progestin combinations, doses, routes of administration. The use of estrogen-alone and estrogen plus progestin therapy has been reported to result in an increase in benign mammarygrams requiring further evaluation.

In a one-year trial, among 1684 women who received a combination of estradiol plus progesterone (1 mg estradiol plus 100 mg progesterone or 0.5 mg estradiol plus 100 mg progesterone or 0.5 mg estradiol plus 50 mg progesterone or 0.25 mg estradiol plus 50 mg progesterone) (placebo=151), six cases of breast cancer were diagnosed, two of which were invasive (one group receiving estradiol and progesterone, one group receiving estradiol and placebo) capsules, 1 mg/100 mg. No new cases of breast cancer were diagnosed in the group of 151 women treated with placebo.

All women should receive yearly breast examinations by a healthcare provider and perform monthly breast self-examinations. In addition, mammography should be performed on postmenopausal women, risk factors, and prior mammogram results.

Endometrial Cancer
Endometrial hyperplasia (a possible precursor of endometrial cancer) has been reported to occur at a rate of approximately 1 to 2 percent or less in oral estrogen therapy and progestin therapy alone or in combination.

An increased risk of endometrial cancer has been reported with the use of unopposed estrogen therapy in a woman with a uterus. The reported endometrial cancer risk among unopposed estrogen users is about 2- to 12-fold greater than in non-users, and appears dependent on duration of treatment and estrogen.
1.19 to 2.60). Since both ancillary studies were conducted in women 65 to 79 years of age, it is unknown whether the two populations in the WHIMS estrogen-alone and estrogen plus progestin ancillary studies were pooled.

Estrogens and progestins may cause some degree of fluid retention. Women with conditions that might be exacerbated by fluid retention should have their thyroid function monitored in order to maintain their free thyroid hormone T4 and T3 serum concentrations in the normal range. Women dependent on thyroid hormone replacement therapy who are induced by estrogen treatment alone should have their thyroid function monitored. In the case of recurrence, medication should be discontinued.

Hypothyroidism
Women with pre-existing hypertriglyceridemia, estrogen therapy may be associated with elevations of serum triglycerides. Women with pre-existing hypertriglyceridemia should avoid釈服s of estrogen therapy and should be monitored for hypertriglyceridemia.

Hypertension
The WHI estrogen plus progestin substudy reported a statistically nonsignificant increased risk of coronary heart disease. A meta-analysis of 17 prospective and 35 retrospective epidemiology studies found that women who used hormonal therapy for menopausal symptoms had an increased risk for coronary heart disease. The primary analysis, using case-control comparisons, included 12,110 cancer cases from the 17 prospective studies. The relative risks associated with current use of hormonal therapy was 1.41 (95% CI, 1.32 to 1.50); there was no difference in the risk estimates by duration of the exposure (less than 5 years [median of 5 years] vs. greater than 5 years [median of 10 years] of use before the cancer diagnosis). The relative risk associated with combined current and recent use (discontinued use within 5 years before cancer diagnosis) was 1.37 (95% CI, 1.27 to 1.48), and the elevated risk was significant for both estrogen-alone and estrogen plus progestin products. The exact duration of hormone therapy use associated with an increased risk of ovarian cancer, however, is unknown.

Probable Dementia
In the WHI estrogen plus progestin ancillary study of WHI, a population of 4,532 postmenopausal women 65 to 79 years of age was randomized to daily CE (0.625 mg) plus MPA (2.5 mg) or placebo. After an average follow-up of 4.4 years, 40 women in the CE plus MPA group and 21 women in the placebo group were diagnosed with probable dementia. The relative risk of probable dementia for CE plus MPA versus placebo was 1.49 (95% CI, 1.05 to 2.10). The absolute risk of probable dementia for CE plus MPA versus placebo was 2.05% (95% CI, 1.21 to 3.48). The absolute risk of probable dementia for CE plus MPA versus placebo was 45 versus 22 cases per 10,000 women-years [see Use in Specific Populations (8.5), and Clinical Studies (14.5) in full prescribing information].

In the WHIMS estrogen-alone ancillary study of WHI, a population of 2,847 hysterectomized women 65 to 79 years of age was randomized to daily 0.625 mg CE alone or placebo. After an average follow-up of 5.2 years, 28 women in the estrogen-alone group and 19 women in the placebo group were diagnosed with probable dementia. The relative risk of probable dementia for CE-alone versus placebo was 1.49 (95% CI, 0.83 to 2.66). The absolute risk of probable dementia for CE-alone versus placebo was 37 versus 25 cases per 10,000 women-years [see Use in Specific Populations (8.5), and Clinical Studies (14.5)]. When data from the female population in the WHIMS estrogen-alone and estrogen plus progesterone ancillary studies were pooled as planned in the WHIMS protocol, the reported overall relative risk for probable dementia was 1.76 (95% CI, 1.19 to 2.60). Since both ancillary studies were conducted in women 65 to 79 years of age, it is unknown whether these findings apply to younger postmenopausal women [see Use in Specific Populations (8.5), and Clinical Studies (14.5) in full prescribing information].

Galbladder Disease
A 2- to 4-fold increase in the risk of galbladder disease requiring surgery in postmenopausal women receiving estrogens has been reported.

Hypercalcemia
Estrogen administration may lead to severe hypercalcemia in women with breast cancer and bone metastases. Estrogen-related effects of hypercalcemia include anorexia, nausea, vomiting, constipation, and weakness. Patients who have hypercalcemia should be monitored for signs of dehydration, hypovolemia, and renal dysfunction.

Hypotensive
In a large, randomized, placebo-controlled clinical trial, a generalized effect of estrogens on blood pressure was not seen.

Hypoglycemia
Women with pre-existing hypertension or diabetes mellitus may experience hypoglycemia and should avoid use of estrogens. Women with diabetes mellitus and a history of hypoglycemia should be monitored for worsening of their disease.

Hypervolemia
Estrogens and progestins may cause some degree of fluid retention. Women with conditions that might be exacerbated by fluid retention should have their thyroid function monitored in order to maintain their free thyroid hormone T4 and T3 serum concentrations in the normal range. Women dependent on thyroid hormone replacement therapy who are induced by estrogen treatment alone should have their thyroid function monitored. In the case of recurrence, medication should be discontinued.

Hypertension
Estrogen administration leads to increased thyroid-binding globulin (TBG) levels. Women with normal thyroid function can compensate for the increased TBG by making more thyroid hormone, thus maintaining free T4 and T3 serum concentrations in the normal range. Women dependent on thyroid hormone replacement therapy who are induced by estrogen treatment alone should have their thyroid function monitored. Women with hypoparathyroidism as measured by protein-bound iodine (PBI), T4 levels (by column or by radioimmunoassay) or T3 levels by radioimmunoassay. T3 resin uptake is decreased, reflecting the elevated TBG. Free T4 and free T3 concentrations are unaltered. Women on thyroid replacement therapy may require higher doses of thyroid hormone. Other binding proteins may be elevated in serum, for example, corticosteroid binding globulin (CBG), sex hormone-binding globulin (SHBG), leading to increased total circulating corticosteroids and sex steroids, respectively. Free hormone concentrations, such as testosterone and estradiol, may be decreased. Other plasma proteins may be increased (angiotensinogen/renin substrate, alpha-1-antitrypsin, ceruloplasmin). Increased plasma high-density lipoprotein (HDL) and low-density lipoprotein (LDL) cholesterol concentrations, increased triglyceride levels. Increased glucose tolerance.

ADVERSE REACTIONS
In a single, prospective, randomized, placebo-controlled, double-blind trial, the most common adverse reactions with BUJVA 10/0.5 (incidence >3% of women and greater than placebo) were breast tenderness (10.4%), headache (3.4%), vaginal bleeding (3.4%), vaginal discharge (3.4%) and pelvic pain (3.1%).

DIURETIC INTERACTIONS
Inducers and inhibitors of CYP3A4 may affect estrogen drug metabolism and decrease or increase the estrogen plasma concentration.

USE IN SPECIFIC POPULATIONS
Pregnancy
BUJVA is not indicated for use in pregnancy. There are no data with the use of BUJVA in pregnant women, however, epidemiologic studies and meta-analyses have not found an increased risk of genital or non-genital birth defects (including cardiac anomalies and limb reduction defects) following exposure to combined hormonal contraceptives (estrogens plus progestins) before conception or during early pregnancy.

Lactation
BUJVA is not indicated for use in females of reproductive potential. Estrogen are present in human milk and decrease milk production in breast-feeding females. This reduction can occur at any time but is less likely to occur once breast-feeding is well-established.

Pediatric Use
BUJVA is not indicated in children. Clinical studies have not been conducted in the pediatric population.

Geriatric Use
There have been sufficient numbers of geriatric women involved in clinical studies utilizing BUJVA to determine whether those over 65 years of age differ from younger women in their response to BUJVA. An increased risk of probable dementia in women over 65 years of age was reported in the Women's Health Initiative Memory ancillary studies of the Women's Health Initiative.

OVERDOSAGE
Overdosage of estrogen plus progestogen may cause nausea, vomiting, breast tenderness, abdominal pain, drowsiness and fatigue, and withdrawal bleeding may occur in women. Treatment of overdose consists of discontinuation of BUJVA therapy with institution of appropriate symptomatic care.

PATIENT COUNSELING INFORMATION
Advise the patient to read the FDA-approved patient labeling (Patient Information).

Abnormal Vaginal Bleeding
Inform postmenopausal women of the importance of reporting abnormal vaginal bleeding to their healthcare provider as soon as possible. [see Warnings and Precautions (5.2) in full prescribing information].

Possible Serious Adverse Reactions with Estrogen Plus Progestrone Therapy
Inform postmenopausal women of possible serious adverse reactions of estrogen plus progestrone therapy including cardiovascular disorders, malignant neoplasms, and probable dementia [see Warnings and Precautions (5.1, 5.2, 5.3) in full prescribing information].

Possible Less Serious but Common Adverse Reactions with Estrogen Plus Progestrone Therapy
Inform postmenopausal women of possible less serious but common adverse reactions of estrogen plus progestrone therapy such as breast tenderness, headache, vaginal discharge, and pelvic pain [see Adverse Reactions (6.1) in full prescribing information].

Missed Evening Dose of BUJVA
Advise the patient that if she misses her evening dose, she should take the dose with food as soon as she can, unless it is within two hours of the next evening dose.

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*Psychiatric Times*
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What is pediatric and adolescent gynecology?

Talking with patients about their daughters is one way to build a practice focused on caring for girls, adolescents, and young adults.

I know you’ve been there. Someone, somewhere, wanting to make conversation, asks you what type of work you do. Typically, I’ll answer that I’m a physician, and we all know that reply can trigger a long story from the questioner about their own latest encounter with the medical profession. Sometimes, if they are curious and ask for more information, “what type of doctor?”, I’ll respond that I’m a gynecologist. Before volunteering even this limited information, I’ll try to gauge their interest. If my questioner is a man, the conversation may quickly turn another subject. This is certainly not always the case, and a man may choose to pursue a discussion, just as the subject may change when I am speaking with a woman. But more often than not, when speaking with a woman, the topic of gynecology or obstetrics leads to further discussion.

The conversation may then evolve to a discussion of my gynecology practice that no longer includes adult women, but which focuses on pediatric and adolescent gynecology (PAG).

Here’s where I often see a puzzled look, and some variation on the question, “What on earth is pediatric and adolescent gynecology?” Many people are surprised that PAG is a “thing.” I may describe some of what I do as “preventive obstetrics,” which typically brings a smile or a chuckle, albeit often with a bit of lag time.

Once you earn their trust with honest answers and sincerity, teens will confide a lot— including their hopes, dreams, fears, and foibles. Preventing unintended pregnancies in adolescents is indeed a major focus of my practice, but my practice is much broader than just contraception. I see girls, adolescents, and young adult women in my practice at the Lucile Packard Stanford Children’s Hospital in Palo Alto, California. My patients come from all around the San Francisco bay area, as well as from much further afield in California and other parts of the western United States. I care for these individuals with problems ranging from abnormal menstrual bleeding, abnormal puberty (too early, or too late), vulvar and vaginal symptoms, pelvic/ovarian masses, pelvic pain, differences of sex development, concerns about sexually transmitted infections, congenital utero-vaginal variants, and much more.

I regularly provide preventive guidance to teens (and their parents), address anxieties about fertility and future reproductive health, encourage preventive services including human papillomavirus vaccinations, and talk about the benefits and risks of hormone therapies including oral contraceptives and hormonal intrauterine devices not only for contraception, but also for managing menstrual pain, irregular bleeding, or heavy menstrual bleeding. I talk about condoms, safe sex, responsible sex, abstinence, self-esteem, bullying, and uncover never-before-disclosed sexual abuse. I answer questions about normal anatomy—breasts of different sizes, or labia that may not look like the idealized images of porn stars on the Internet. Once you earn their trust with honest answers and
sincerity, teens will confide a lot—including their hopes, dreams, fears, and foibles. And if I’m lucky and have the privilege of seeing an individual weather her teen years into young adulthood, I’m often witness to the amazing transformation of adolescent development.

If you practice general obstetrics and gynecology, and if you enjoy taking care of teens, you likely do some or all of these things in your ob/gyn practice. I just do them every day. If you don’t like taking care of adolescents (and if you’re the parent of a teen, you’ll understand that they can be prickly at times, and that eye-rolling is par for the course), then you probably shouldn’t do much of it. Most teens are pretty discerning, and it’s hard to fake sincerity. But if you remember how hard it was to BE a teen, and how much you would have appreciated a caring physician who addressed your concerns about growing up (including menstrual concerns, if you identify as female), you may want to learn more about PAG and include more adolescents in your practice. I have no doubt that if you want to do this, and you start to ask your adult patients about their adolescent daughters, you will begin to build a practice that includes adolescents.

The American College of Obstetricians and Gynecologists recommends that the initial visit for screening and provision of preventative health care services should take place between ages 13 and 15.

The CREOG educational objectives include topics on pediatric and adolescent gynecology, and more and more residency training programs have faculty with expertise and experience in dealing with girls and adolescent young women, so that current residents are better prepared than ever before to care for this underserved population. For residency programs without PAG-trained faculty, or for individuals in practice who want to learn more PAG, two publications (dubbed the Short and the Long curriculum) provide a standard curriculum with resources and guidance for self-learning. The American Board of Obstetrics and Gynecology (ABOG) includes articles on PAG among the lifelong learning papers for Maintenance of Certification (MOC). For the first time, in 2018, ABOG offered an examination and focused practice designation in PAG. The North American Society for Pediatric and Adolescent Gynecology (NASPAG) website offers resources for clinicians, patient handouts, and the annual clinical and research meeting each May is a wonderful Continuing Medical Education (CME) opportunity for learning more about caring for young girls’ and teens’ gynecologic needs. The next NASPAG meeting will be held in New Orleans on April 11-13, 2019.

I’ve been on the editorial board of Contemporary OB/GYN since 1992, and I am passionate about the clinically relevant articles that you and I read on a regular basis. Contemporary OB/GYN has published a number of excellent reviews of PAG topics, including eating disorders, heavy menstrual bleeding in adolescents, and pelvic pain in the adolescent. These reviews are great places to start reading if you want to become more familiar with care of adolescents and young girls. I thank Charly Lockwood for his leadership as Editor-in-Chief of Contemporary OB/GYN, as well as my fellow editorial board members for their dedication to this publication. I’m grateful that they have allowed me this forum to be an evangelist for Pediatric and Adolescent Gynecology. My PAG practice is never boring. I would encourage you to add care for more adolescents and young girls to your practice of general obstetrics and gynecology. It is gratifying, and much appreciated by the girls and their mothers.

Dr. Hillard is professor, Department of Obstetrics and Gynecology, Chief Division of Gynecologic Specialties, Stanford University School of Medicine, and Director of Gynecology, Lucile Packard Children’s Hospital, Stanford, Calif. She is also a member of the Contemporary OB/GYN editorial board.

Disclosures The author reports no potential conflicts of interest with regard to this editorial.

For references visit contemporaryobgyn.net/PediatricGynecology
Mifepristone and misoprostol
Medical management of missed abortion

Hello,

I respectfully disagree that one study of 300 patients with improved results of 84% to 67% constitutes a new standard of care for medical treatment for missed ab. This protocol may be better and, if future studies confirm that it is, then it may become the standard of care, but I don’t believe that can be said yet. I agree that a medication shouldn’t be classified as dangerous just because it could be used for elective abortion and that is a different discussion. Because states have various laws as to access and consent issues with elective abortion, allowing it to be distributed by pharmacies has caused concern, and I feel that is up to our lawmakers to address.

Sincerely,
Melissa Reisinger MD
NEWBURGH, INDIANA

IN REPLY:
We thank the reader for her comments. It is worth noting that the American College of Obstetricians and Gynecologists (ACOG) supports use of mifepristone in medical management of early pregnancy loss.1 But perhaps more importantly, ACOG also affirms that physicians and medical evidence — not lawmakers — should provide the basis for health policy.2

Nancy L. Stanwood, MD, MPH,
and Abigail S. Cutler, MD

2. https://www.acog.org/About-ACOG/ACOG-Departments/State-Legislative-Activities/Political-Interference

Unplanned out-of-hospital birth and risk of perinatal death


Nancy Draznin, LM, CPM
GENESEE, IDAHO
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Severe maternal morbidity indicators and racial disparities
Bobby Lazzara, MD
Brought to you by Medical News Minute

LARC ‘Quick Start’ in adolescents embraced by many providers
Bob Kronemeyer

CONTRACEPTION
DMPA, OCs, and risk of STIs
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MENTAL HEALTH
Pregnancy, infection, and childhood psychiatric issues
Judith M. Orvos

OBSTETRICS
Blood samples used to examine prenatal nicotine exposure and offspring ADHD
Ben Schwartz

ContemporaryOBGYN @ContempOBGYN
How to minimize vaginal #birth #complications https://buff.ly/2XLpeVV

Cor de Kroon @cordekoorn
And what happened to #onall4s? In my opinion one of the first manoeuvres to be performed!

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drmollyjoseph @drmollyjoseph
Great information #womenshealth

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Bar’s Heart NPO @BarsHeartNPO

ContemporaryOBGYN @ContempOBGYN Are you persuaded by data about gum-chewing and ileus prevention?

Cecille T Stgo I have been telling patients to chew gum after surgery for over 10 years!

61%
244 said
Yes

The existing data convinced me.

39%
156 said
No

The jury is still out and better-quality evidence is needed.

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Help HIV-positive women reach reproductive goals

Strong findings suggest that HIV-positive women have safe options for achieving pregnancy without use of assisted reproduction.

by MEGAN J. HUCHKO, MD, MPH

As primary care providers for a significant proportion of women in their practices, ob/gyns need to be holistic in their approach to patient care. This includes a comprehensive assessment of risk factors for different diseases, including HIV. This article underscores the importance of keeping up to date on the latest evidence and recommendations on HIV prevention. The focus is on the Undetectable=Untransmittable (U=U) advocacy campaign, which has been essential in disseminating key science to both the healthcare community and the general public.

Ob/gyns must provide the highest quality, most effective care for patients who may be at risk for acquiring HIV, and for women living with HIV (WL-HIV). Prevention has always been a cornerstone of high-quality and cost-effective medical care, but the growing understanding of how to effectively prevent HIV transmission makes this even more imperative. Ob/gyns also must consider how best to help women achieve their reproductive health goals while preventing HIV acquisition or transmission to their partner.

Current guidelines and HIV prevention

The most recent American College of Obstetricians and Gynecologists (ACOG) guidelines to address gynecologic care for WLHIV are Practice Bulletin (PB) 167 and Committee Opinion 595. PB 167 integrates the 2016 Department of Health and Human Services (DHHS) recommendation that antiretroviral therapy with a triple drug regimen be initiated in all adults and adolescents diagnosed with HIV, regardless of their current clinical symptoms or CD4+ count. This update replaced previous recommendations for therapy based on a threshold CD4+ count, pregnancy or...
Indication
EXPAREL is indicated for single-dose infiltration in adults to produce postsurgical local analgesia and as an interscalene brachial plexus nerve block to produce postsurgical regional analgesia. Safety and efficacy have not been established in other nerve blocks.

Important Safety Information
EXPAREL is contraindicated in obstetrical paracervical block anesthesia. Adverse reactions reported with an incidence greater than or equal to 10% following EXPAREL administration via infiltration were nausea, constipation, and vomiting; adverse reactions reported with an incidence greater than or equal to 10% following EXPAREL administration via interscalene brachial plexus nerve block were nausea, pyrexia, and constipation.

If EXPAREL and other non-bupivacaine local anesthetics, including lidocaine, are administered at the same site, there may be an immediate release of bupivacaine from EXPAREL. Therefore, EXPAREL may be administered to the same site 20 minutes after injecting lidocaine.

EXPAREL is not recommended to be used in the following patient population: patients <18 years old and/or pregnant patients. Because amide-type local anesthetics, such as bupivacaine, are metabolized by the liver, EXPAREL should be used cautiously in patients with hepatic disease.

Warnings and Precautions Specific to EXPAREL
Avoid additional use of local anesthetics within 96 hours following administration of EXPAREL.

EXPAREL is not recommended for the following types or routes of administration: epidural, intrathecal, regional nerve blocks other than interscalene brachial plexus nerve block, or intravascular or intra-articular use.

The potential sensory and/or motor loss with EXPAREL is temporary and varies in degree and duration depending on the site of injection and dosage administered and may last for up to 5 days, as seen in clinical trials.

Warnings and Precautions for Bupivacaine-Containing Products Central Nervous System (CNS) Reactions: There have been reports of adverse neurologic reactions with the use of local anesthetics. These include persistent anesthesia and paresthesia. CNS reactions are characterized by excitation and/or depression.

Cardiovascular System Reactions: Toxic blood concentrations depress cardiac conductivity and excitability which may lead to dysrhythmias, sometimes leading to death.

Allergic Reactions: Allergic-type reactions (eg, anaphylaxis and angioedema) are rare and may occur as a result of hypersensitivity to the local anesthetic or to other formulation ingredients.

Chondrolysis: There have been reports of chondrolysis (mostly in the shoulder joint) following intra-articular infusion of local anesthetics, which is an unapproved use.

Methemoglobinemia: Cases of methemoglobinemia have been reported with local anesthetic use.

Please refer to brief summary of Prescribing Information on adjacent page. For more information, please visit www.EXPAREL.com or call 1-855-RX-EXPAREL (793-9727).

Other than bupivacaine as noted above, EXPAREL should not be admixed with other drugs prior to administration.

Local and Intravenous Use

Non-bupivacaine Local Anesthetics

Examples of Drugs Associated with Methemoglobinemia:

- Local anesthetics: articaine, benzocaine, bupivacaine, lidocaine, mepivacaine, ropivacaine, prilocaine, procaine, tetracaine

Anticonvulsants: Phenobarbital, phenytoin, sodium valproate

Antimalarials: chloroquine, primaquine

Methemoglobinemia can result from the administration of drugs that interact with nitric oxide, leading to the formation of organic nitrites. These drugs include:

- Nitric oxide donors and analogues
- Nitroprusside
- Nitrates (e.g., isosorbide dinitrate, isosorbide mononitrate)

Phenobarbital may increase the likelihood of methemoglobinemia, particularly in individuals with a genetic defect in the heme oxygenase-1 enzyme.

Bupivacaine is known to be substantially excreted by the kidney, and the risk of toxic effects in subjects with moderate to severe hepatic disease is uncertain.

The toxic effects of these drugs are additive and their administration should be used with caution including monitoring for neuroaxis and cardiovascular effects related to local anesthetic systemic toxicity. The use of a single local anesthetic for a limited duration from EXPAREL or its use as the underlying material is not reported.

Hematologic Impairment

Amide-type local anesthetics, such as bupivacaine, are metabolized by the liver. Patients with severe hepatic dysfunction may have difficulty metabolizing local anesthetic normally, and are at a greater risk of developing toxic plasma concentrations, and potentially local anesthetic systemic toxicity. Therefore, consider monitored management for local anesthetic systemic toxicity in subjects with compromised liver function.

Reversal of Neuroaxis

Bupivacaine-Associated Toxicity can be reversed by the use of benzodiazepines, such as diazepam. However, in the event of acute bupivacaine toxicity, symptoms of toxic levels are reported to be as low as 800 ng/mL, and 600 ng/mL in cardiac function.

Increased pup survival was noted at 1.5 times the MIN in a rat pre- and post-natal development study when pregnant animals were administered subcutaneous dosages of 4, 13.4, and 40 mg/kg of bupivacaine hydrochloride (equivalent to 5.2, 16.3 and 51.5 times the MIN, respectively, based on the BSA comparisons and a 60 kg human weight); histological effects were observed in the rat at the 1.5 times the MIN and in fetal toxicity. The increase in neonatal death was observed in rabbits at the high dose in the absence of maternal toxicity.

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clinical signs of immunosuppression. In addition, the DHHS guidelines suggest that male partners of WLHIV may take a daily antiretroviral pill (tenofovir/emtricitabine or PrEP) to reduce risk of HIV acquisition.

Consistent use of antiretroviral therapy reduces risk of short and long-term complications of HIV, including risks related to immunosuppression and development of drug resistance. Use of effective antiretroviral therapy that induces HIV viral suppression, which is the reduction of HIV viral load in the blood to undetectable levels, is a powerful HIV prevention mechanism, also known as Treatment as Prevention (TasP). In addition to several smaller studies, three large, randomized studies that included over 3300 couples in which the infected partner was virally suppressed on antiretroviral therapy for at least 6 months showed no HIV transmissions to the HIV-negative partner. 4-8 That protection has been shown to be durable for over 10 years in Switzerland, which has seen an overall decrease in HIV incidence despite an increase in condomless sex over the past decade, and reports no documented HIV transmission in the setting of suppression. 9 Since these studies were published, researchers, advocates and patients have sought clarity on the practical implications for serodiscordant couples. What about condoms? PrEP? A combination of TasP + PrEP? These nuanced questions are especially relevant for serodiscordant couples seeking pregnancy, who for a long time have been treated as a high-risk group, and still have recommendations that fall outside of this list of evidence-based options.

**U=U Campaign**

Despite strong evidence from clinical trials, the value of TasP had not reached people living with HIV (PLWH). To remedy inadequate dissemination of research findings and recommendations, Prevention Access Campaign spearheaded the Undetectable=Untransmittable, or U=U, campaign. In the past 3 years, the U=U campaign has become a popular global movement endorsed by over 400 organizations from 60 countries. Although the evidence for treatment as prevention has been around for almost 20 years, U=U has played a key role in simplifying and amplifying the message. Ob/gyns should understand the implications of the message, and how the science and tools for HIV prevention translate to their patients. The strong, consistent evidence that virally suppressed individuals on antiretroviral therapy do not transmit HIV has the potential to transform the lives of people and couples living with HIV, removing barriers of stigma and allowing PLWH to imagine lives in which they are not risking their intimate partners with infection. The U=U movement scored major victories in 2017 when the director of the National Institute of Allergy and Infectious Diseases (NIAID), Dr. Anthony Fauci, declared that the evidence now shows that no HIV transmission has been documented when viral suppression treatment has been implemented. In October 2017, the Centers for Disease Control and Prevention (CDC) made a definitive statement supporting U=U, specifically affirming that "when ART results in viral suppression, defined as less than 200 copies/mL or undetectable levels, it prevents transmission." 10

How does this now widely accepted understanding of the lack of HIV-transmission risk among virally suppressed individuals align with the 2016 ACOG PB? 1 ACOG does not directly address U=U, and it recommends that women with HIV use condoms to prevent transmission of HIV, citing level A evidence. Published before the NIH and CDC statements of 2017, the ACOG PB states that "women infected with HIV with undetectable plasma loads should be counseled that they can still transmit HIV." 1 While the recommendation for universal treatment is important, ob/gyns should rely on DHHS and CDC recommendations when counseling serodiscordant couples.

**Preconception counseling**

Another key area where guidance from an ob/gyn may impact decision-making and health behaviors is preconception counseling. While ACOG recognizes that WLHIV and HIV-uninfected women have similar reproductive health desires, the PB states that the safest way for serodiscordant couples to conceive is through artificial insemination. 1 Unfortunately, a CDC update on conception among serodiscordant couples released in August 2017 echoed this recommendation, which was not reflective of the strong evidence on TasP. Many experts in the field would argue that the evidence for TasP does not support the contin-
ued need for assisted reproductive technology in women who are virally suppressed. I support the opinion expressed in the consensus statement that recommendations to use assisted reproductive technology in spite of evidence supporting TasP and PrEP as options for safe conception do a disservice to women and couples. These recommendations continue to “other” and stigmatize serodiscordant couples, and putting the achievement of a desired pregnancy out of financial reach for many of them. This is compounded by continued evidence that many laboratories that provide assisted reproductive technology discriminate against and do not provide services for serodiscordant couples. In the face of strong and consistent evidence supporting the effectiveness of both TasP and PrEP, WLHIV should know that they have the option to achieve pregnancy safely and effectively without assisted reproductive technology. ACOG and the Society and Maternal and Fetal Medicine are the bodies that provide guidelines for identifying who, beyond women in serodiscordant relationships, would benefit from PrEP. In alignment with CDC guidelines, risk factors include sexual activity within a high HIV-prevalence area or high-risk sexual network along with one or more of the following: inconsistent or no condom use; diagnosis of sexually transmitted infections (STIs); exchange of sex for commodities (such as money, shelter, food, or drugs); use of intravenous drugs or alcohol dependence or both; or incarceration. Importantly, providers should ask patients about potential partner(s) whose HIV status may be unknown and who may share any of the characteristics listed above. Counseling around family planning, STI and abortion services may be an ideal time to identify and discuss risks and benefits of PrEP with patients, although ob/gyns should do a risk and pregnancy desires assessment at each well-woman visit.

Beyond HIV risk reduction and preconception counseling, the increased number of women living longer, healthier lives on antiretroviral therapy means that ob/gyns should become familiar with gynecologic care of WLHIV, including cytology screening guidelines, potential complications of antiretroviral therapy, and factors that may change their transmission risk and medication adherence. Most importantly, ob/gyns should reinforce the importance of adherence to antiretroviral therapy, both for women’s own health and to reduce the risk for HIV and partner with a primary HIV-care provider or seek expert advice when complex issues arise. The National Clinician Consultation Center through the University of California, San Francisco, is an excellent source of up-to-date guidelines for care of WLHIV and HIV-exposed women and free real-time clinician support for HIV-related questions (http://nccc.ucsf.edu/clinical-resources/hiv-aids-resources/womens-health/).

Conclusion
The U=U movement has helped to inform the greater public that PLWH who are virally suppressed cannot transmit the virus through sexual activity. Their message, which has been instrumental in reducing stigma and discrimination among PLWH, is built on a strong foundation of scientific evidence. As ob/gyns, we owe it to our patients to understand the evidence and provide the information and potentially life-saving HIV-prevention strategies to our patients.

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

FOR REFERENCES VISIT contemporaryobgyn.net/HIVwomen

Ob/gyns should reinforce the importance of adherence to antiretroviral therapy.
Chronic vulvar lesions in a woman in her 30s

What’s your diagnosis in a patient with lesions that are sometimes painful and do not respond to antibiotics?

by ROSALYN E. MABEN-FEASTER, MD, MPH, JOHN O. DELANCEY, MD, AND HOPE K. HAEFNER, MD

PRESEN TATION
A 34-year-old G3P2 is referred to your clinic for evaluation due to chronic vulvar lesions that intermittently become painful with purulent discharge despite antibiotics.

YOUR DIAGNOSIS IS:
A. Acne vulgaris
B. Folliculitis
C. Hidradenitis suppurativa

TREATMENT FOR THIS CONDITION IS:
A. General care (avoid vulvar irritants and tight clothing, lose weight, cease smoking)
B. Systemic antibiotics—doxycycline 100 mg po BID for 12 weeks
C. Yasmin
D. Deroofing of sinus tracts
E. All of the above

For the diagnosis, treatment plan, and discussion turn to page 38.
Endometrial polyps are common structural and epithelial abnormalities of the endometrium that are often encountered by gynecologists in office-based practice. These endometrial growths may be found incidentally in as many as 10% to 15% of asymptomatic women, and between 20% to 30% of women with abnormal uterine bleeding (AUB).\(^1,2\) Given their prevalence in patients presenting with AUB, polyps are considered as part of the FIGO classification for causes of abnormal uterine bleeding - PALM-COEIN.\(^3\) They may cause a variety of abnormal bleeding patterns, likely due to small muscular arteries found within the growths,\(^4\) but they can also be completely asymptomatic. Structural uterine pathologies often cause menstruation that is heavy or prolonged, albeit monthly,\(^5\) but polyps can also cause intermenstrual or postmenopausal bleeding.\(^1\) Endometrial polyps are usually benign but in 0.5% to 3% of cases, they are malignant.\(^1\)

Endometrial polyps are thought to impact fertility, and removal is recommended prior to initiating treatment, especially before proceeding with in vitro fertilization (IVF). Some proposed mechanisms by which polyps are thought to impact fertility include inhibition of implantation, endometrial inflammation, mechanical blockage of sperm from fertilization, or changes in endometrial receptivity.\(^6\) In the infertile population, prevalence of polyps is thought to be between 11% and 45%, which is higher than in the general population.\(^6,7\) Hysteroscopic removal of endometrial polyps found incidentally during fertility evaluation is recommended, with one study showing post-polypectomy implantation rates during IVF to be similar to those in women who do not have endometrial polyps.\(^7\)

True to their name, polyps may grow on a thin stalk from anywhere.

Office hysteroscopy … is the preferred method for management of endometrial polyps.

Practical tips on what to look for to spot these common growths on ultrasound and how to remove them.

by ANTHONY N. IMUDIA, MD, AND ERIKA P. NEW, MD, MPH
within the uterine cavity, or they may appear sessile: smooth and flat with a broad base. They typically measure up to about 3 cm. Histopathologically, polyps appear as cystic dilation of glands with mononuclear cells, often filled with mucous. They may contain vascular pedicles, connective tissue, and even glandular tissue. Their prevalence makes them an important pathology to study, so that proper diagnosis and treatment can be undertaken, with the gold standard being hysteroscopy.

Making the diagnosis
Because AUB triggers further evaluation of potential etiologies, endometrial polyps are often diagnosed on ultrasound, as seen in Figure 1. The sonographic finding suggestive of an endometrial polyp is a bright, hyperechoic area visualized within the endometrium (Table 1). Using power doppler sonography may reveal a single-vessel pattern of blood flow to the polyp (sensitivity 81.2%, positive predictive value [PPV] 92.9%) compared to fibroids, which more often show an enhancing rim of vessels.

If further characterization is needed, office hysteroscopy is considered the gold standard for further evaluation, however, saline infusion sonography (SIS) is another excellent diagnostic study with a sensitivity of 93% and specificity of 81% in diagnosing endometrial polyps. Hysteroscopy and SIS are best performed during the proliferative phase of the menstrual cycle shortly after cessation of menses. Hysteroscopy allows for direct visualization of the polyps while SIS with a skillful operator can also provide specific details, such as where the polyp is attached and its size. If there is uncertainty about presence of a polyp on transvaginal ultrasound, SIS can be used as the next step for better visualization, with a PPV of 88.5%, compared to only 65.2% with ultrasound alone.

Polyp management
Because endometrial polyps are often the culprit in AUB, treatment is warranted to decrease a patient’s symptoms and confirm the diagnosis, especially because benign and malignant polyps cannot be reliably distinguished with imaging alone. Hysteroscopy with polypectomy is the treatment of choice, serving both as a diagnostic and therapeutic procedure. With office hysteroscopy now widely available, it is much easier to address polyps than in the past. Narrow-caliber hysteroscopes with diameters ranging from 2 to 3 mm and flexible hysteroscopes allow for these office procedures to be performed with minimal pain for patients. Office hysteroscopy can be used for both diagnosis and treatment and it has the ability to immediately confirm successful polyp removal; therefore, it serves as the gold standard for management of endometrial polyps (Figures 2a and 2b). When a polyp is visualized during office hysteroscopy, directed removal or biopsy should be performed, even if it is suspected to be benign.

Office hysteroscopy as opposed to hysteroscopy performed in the operating room is the preferred method for management of endometrial polyps for a variety of reasons. Benefits for patients include reduced cost of medical services and time off from work.
greater convenience, and more flexibility in scheduling the surgery. A recent study evaluating the effectiveness of office hysteroscopic removal of endometrial polyps showed that office hysteroscopy was successful in removing endometrial polyps 95.7% of the time, and while hysteroscopy in the operating room resulted in fewer residual polyps (98.1% successful), office hysteroscopy is still preferred due to the aforementioned benefits.

Because of the convenience and cost savings associated with office hysteroscopy, many women are amenable to it, but special consideration has to be paid to patients’ pain and comfort during the procedure. Patients’ reported pain has been shown to be reasonable and tolerable, with an average reported pain score of 5 on the visual analogue scale, the classic pain scale ranging from 0 to 10. When selecting candidates for office hysteroscopy, individual patient self-assessment of pain tolerance and anxiety can help determine who would benefit most from an office-based procedure as opposed to an operating room procedure (Table 2).

Determinants of successful office-based hysteroscopy for polyp removal are polyp number, size, and location; patient characteristics such as body mass index (BMI) and other comorbidities; availability of an appropriate hysteroscopic system; and physician experience and comfort level with the procedure.

Traditional mechanical instruments such as polyp scissors or grasping forceps introduced down the operative channel of a hysteroscopy as well as more modern tissue-extracting devices are both excellent ways of resecting polyps under direct visualization. The appeal of modern tissue removal systems such as TRUCLEAR, MyoSure, and the Integrated Bigatti Shaver is

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**TABLE 2**

<table>
<thead>
<tr>
<th>STEPS</th>
<th>Steps for successful diagnostic and operative office hysteroscopy</th>
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| 1. Patient selection | Counsel and educate the patient about the planned procedure  
Discuss the patient’s perceived pain tolerance and anxiety about the procedure |
| 2. Patient preparation | Administer NSAIDs such as Ibuprofen 800 mg PO 1 hour pre-procedure.  
Administer low-dose vaginal misoprostol (50 mcg) the night prior to the procedure if operative hysteroscopy  
Administer an anxiolytic (Valium 5-10 mg) 1 hour prior to procedure if operative hysteroscopy |
| 3. Procedural techniques | Apply topical 20% benzocaine gel to the external cervical os with a cytology brush for further pain control.  
Use a tenaculum only if you are unable to enter the cavity  
Ensure that the physician has adequate training and prior experience performing office hysteroscopy. |
| 4. Hysteroscopy | For diagnostic hysteroscopy, a flexible hysteroscope is recommended  
For operative hysteroscopy for polypectomy,  
• small-caliber rigid hysteroscope (< 5 mm) is recommended to prevent cervical dilation  
• Adhere to Steps 2 and 3 |

Source: USF Center for Fibroid and Endometriosis Research and Treatment Center (CFERT) protocol
Not all Pap tests are created equal

The BD SurePath™ Liquid-based Pap Test has the only approved specimen collection method that ensures 100% of collected cells arrive in the laboratory. Specimen collection using 2 to 10 rinsing rotations may lose 47.8% to 26.6% of collected cells, respectively.1 The unique BD cell enrichment process separates and removes blood, mucus and interfering materials from the sample, meaning the most diagnostically relevant material is transferred to the slide, with reduced obstructions for easier screening.2,3 Specimens collected in BD SurePath™ Preservative Fluid are FDA approved for HPV testing4,5 and FDA cleared for CT6 and GC7 testing.

All of this means greater assurance in detection, fewer callbacks and unsats, and most importantly, improved patient management.

4. BD Oncolary™ HPV Assay Package Insert. US label no.: 8089894(01) 2018-02
6. BD ProbeTec™ Chlamydia trachomatis (CT) Qx Amplified DNA Assay Package Insert. US label no.: 8081408 2017-03
7. BD ProbeTec™ Neisseria gonorrhoeae (GC) Qx Amplified DNA Assay Package Insert. US label no.: 8081409 2018-06
One study show(s) post-polypectomy implantation rates during IVF to be similar to those in women who do not have endometrial polyps.

that they allow for mechanical cutting of tissue and suction extraction, ensuring full removal of the polyp and easy collection of tissue for further histopathologic evaluation and diagnosis.\(^1\) Blind, sharp dilation and curettage previously may have been performed for polypectomy, but it is no longer recommended because of its lack of targeted effect.\(^1\)

Treatment of all visible endometrial polyps is recommended, but some patients decline removal, perhaps because they are asymptomatic. In those cases, data on the natural history of polyps may help guide clinical management. One retrospective study estimated that 6.3% of polyps may spontaneously resolve after 6 months in premenopausal women, however, 15% of these patients may develop AUB in that same time period.\(^15\) Hysteroscopic polypectomy should be recommended and advocated, especially in patients with higher risk factors for malignant transformation.

Although in polyps, risk of underlying malignancy is not very high, careful clinical evaluation to rule it out is critical.\(^16\) In postmenopausal women who have AUB, risk of finding precancerous pathology in polyps may be as high as 6%.\(^17\) Risk factors that increase concerns about cancer include: postmenopausal status (OR 8.274), obesity, AUB, polyp size, and even diabetes and hypertension.\(^2,8\) One study suggests that BMI > 32 or endometrial thickness > 10 mm increases risk of hyperplasia or malignancy.\(^11\) Use of tamoxifen, a common maintenance medication taken by women with a history of estrogen receptor-positive breast cancer or who are at risk of breast cancer, has been shown to increase risk not only of endometrial polyps, but of endometrial hyperplasia and cancer. It is thought that while tamoxifen has an anti-estrogenic effect on breast tissue, it may selectively promote proliferation in the endometrium (Table 3).\(^16\)

**Conclusion**

Endometrial polyps, whether found on ultrasound during a workup for AUB or suspected to be the etiology of a patient’s infertility, are commonly encountered and easily managed with office-based hysteroscopic procedures. Given the underlying risk of malignancy in endometrial polyps, which may be as low as 0.5% to 3% in all women diagnosed with polyps\(^1\) or up to 6% in postmenopausal women presenting with bleeding,\(^17\) removal is strongly recommended with hysteroscopic polypectomy for eventual histopathologic diagnosis.

<table>
<thead>
<tr>
<th>TABLE 3</th>
<th>Risk factors for malignancy in endometrial polyps</th>
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<tr>
<td></td>
<td>Abnormal uterine bleeding</td>
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<td></td>
<td>Postmenopausal status</td>
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<td></td>
<td>Obesity</td>
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<td>Larger polyp size, or endometrial thickness &gt; 10 mm</td>
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<td></td>
<td>Diabetes</td>
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<td>Hypertension</td>
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<td>Tamoxifen use</td>
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**DISCLOSURES** The authors report no potential conflicts of interest with regard to this article.

**FOR REFERENCES VISIT** contemporaryobgyn.net/EndometrialPolyps

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**Need help explaining endometrial polyps to your patients?**
Download a patient education handout at [CONTEMPORARYOBGYN.NET/ENDOMETRIALPOLYPHANDOUT](CONTEMPORARYOBGYN.NET/ENDOMETRIALPOLYPHANDOUT)
PROLONG trial fails to meet co-primary endpoints

by JUDITH M. ORVOS, ELS

The much-anticipated top-line results of a clinical trial of injectable progesterone for prevention for preterm birth (PTB) in women with a history of the complication showed that treatment was no better than placebo. The findings, which have not yet been published, were announced by AMAG Pharmaceuticals, Inc., manufacturers of Makena, the drug that was tested.

The US Food and Drug Administration (FDA) granted approval for 17 alpha-hydroxyprogesterone caproate (17P) in February 2011 and the drug had orphan drug exclusivity through February 3, 2018. The PROLONG (Progestin’s Role in Optimizing Neonatal Gestation) trial was part of an approval commitment under the FDA’s “Subpart H” accelerated approval process.

The randomized, double-blinded, placebo-controlled trial was designed to assess the safety and efficacy of 17P injection, 250 mg/mL, in reducing risk of PTB and neonatal morbidity/mortality in women pregnant with a singleton gestation who had a previous singleton spontaneous PTB. For the multicenter, multinational research, the investigators chose a sample size of 1707 with the goal of achieving 95% power and a 35% reduction in neonatal reduction in neonatal morbidity and mortality.

The trial had two coprimary outcomes: PTB < 35 weeks and a composite neonatal morbidity and mortality index. Secondary outcomes included 2-year follow-up of infants.

According to press release from the drug’s manufacturer, PROLONG top-line results showed an 11.0% incidence of PTB at < 35 weeks in the treatment group vs. 11.5% for the placebo group ($P = .72$) and 5.4% vs. 5.2%, respectively ($P = .84$) for the neonatal morbidity and mortality composite index. Adverse events of special interest, including miscarriage and stillbirth, were described as “infrequent” and “similar” between the two arms.

Commenting in the release, principal investigator and chair of the PROLONG Publications Committee Sean Blackwell, MD, of UTHHealth at Houston said, “Our committee will be reviewing the trial data in detail and we will be actively involved in the analysis and interpretation of the findings. It is clear that the overall study population of PROLONG is significantly different than those who participated in the NICHD MFMU trial with respect to race, socioeconomic status, and severity of disease. Thus, we need sufficient time to thoughtfully interpret these findings in the context of the prior clinical trials.”

Results of the previous trial, conducted by investigators from the National Institute of Child Health and Human Development Maternal-Fetal Medicine Units Network, showed that weekly injections of 17P, 250 mg/mL, resulted in a substantial reduction in the rate of recurrent PTB in women at particularly high risk for the condi-
Evidence is conflicting on whether prenatal use of folic acid reduces risk of autism spectrum disorder (ASD) in offspring. A new study in *JAMA Psychiatry* has looked at that purported connection from a different angle, examining whether maternal folic acid intake is associated with rates of ASD in younger siblings of children with this condition.

The participants were mothers in Northern California who had a child with confirmed ASD and were planning a pregnancy or were pregnant with another child. Information on the vitamins and supplements they took (brand, frequency, dose and timing of maternal intake) was obtained through telephone interviews. The younger siblings’ development was assessed at age 3, and they were classified into 1 of 3 outcome groups: ASD, typical development (TD) or non-typical development (non-TD).

A total of 241 siblings were included—58.1% male and 41.9% female. Fifty-five children (22.8%) were diagnosed with ASD, 60 (24.9%) children were diagnosed as non-TD, and 126 (52.3%) were confirmed with TD. Children with ASD were more likely to be male.

Prevalence of ASD among children whose mothers took folic acid in the first month of pregnancy was 14.1% (18) compared with 32.7% (37) in children whose mothers did not take folic acid during that time. After adjusting for maternal education, children whose mothers took folic acid in the first month of pregnancy were half as likely to receive an ASD diagnosis (adjusted RR, 0.50; 95% CI 0.30-0.81) or a non-TD outcome (adjusted RR, 1.14; 95% CI 0.75-1.75).

The authors found that the highest tertile (805–4800μg) of total mean folic acid supplemental intake during the first month of pregnancy was associated with the greatest reduction in estimated ASD risk (RR, 0.36; 95% CI 0.15-0.84; *P* = .02).

The researchers say their findings suggest that maternal intake of folic acid during the first month of pregnancy may reduce incidence of ASD recurrence in younger siblings of children with this condition. However, they urge that more studies be done to see if their results can be replicated. Future studies, they said, should focus on the impact of specific nutrients from vitamin supplements and food sources, diet quality, dose thresholds, interactions with genetic variants, and potential mechanisms of action.

**EXPERT PERSPECTIVE**

More research needs to be done to fully understand whether this association is causal, and if so, what is driving it and how it is working, so we can then figure out the best way to lower autism risk in affected families.

Rebecca J. Schmidt, PhD
Assistant Professor, Department of Public Health Sciences and the MIND Institute, University of California Davis School of Medicine
FDA gives nod to first drug for postpartum depression

by JUDITH M. ORVOS, ELS

Brexanolone, an analog of an endogenous human hormone, has been approved by the US Food and Drug Administration (FDA) for postpartum depression. Sixty-hour infusions of the drug—the first with such an indication—will cost upwards of $30,000, according to a report by the Associated Press.

In a press release, manufacturer Sage Therapeutics said it expects brexanolone, under the trade name Zulresso, to be on the market in June. Its use, on an inpatient basis, is restricted to providers in health care facilities that have been certified under an FDA Risk Evaluation and Mitigation Strategy (REMS) program. The REMS program ensures careful monitoring of patients for potential side effects such as sudden loss of consciousness and excessive sedation and with continuous use of pulse oximetry.

Approval of brexanolone was based on results of three multicenter, randomized, double-blind, parallel-group, placebo-controlled trials in women aged 18 to 45 with moderate and severe postpartum depression. Outcomes with continuous intravenous infusion for 60 hours were assessed using the 17-item Hamilton Rating Scale for Depression (HAM-D).

Thirty clinical research centers and specialized psychiatric units in the United States were involved in two phase 3 trials. In the first study, brexanolone 90 μg/kg/hour and 60 μg/kg/hour were tested versus placebo. In the second study, brexanolone 90 μg/kg/hour was tested against placebo. In the first study, the lower dosage and the higher dosage of the drug were associated with 19.5-point (P = 0.0013) and 17.7-point (P=0.0252) reductions in the HAM-D score, versus a 14.0-point reduction the placebo group. The mean reduction in HAM-D scores in study two were 14.6 points for brexanolone versus 12.1 points for placebo (P= 0.0160).

According to Dr. Kimberly Yonkers, Professor of Psychiatry, of Epidemiology (Chronic Diseases) and of Obstetrics, Gynecology, and Reproductive Sciences; and Director, Center for Wellbeing of Women and Mothers at Yale School of Public Health, the difference in magnitude of effect seen in the two studies may have been due to the population assayed or variability in response. In both trials, the rate of response was pronounced and it was sustained for 30 days, she said, while noting that the drug is expensive and whether its benefits persist beyond 30 days is unknown.

Headache, dizziness, and somnolence were the most common treatment-emergent adverse events seen in the two studies. In the first trial, one patient treated with the 60-μg dosage had suicidal ideation and an intentional overdose attempt during follow-up. In the second trial, one patient had what were considered to be treatment-related altered state of consciousness and syncope.

Basic research leading to the development of brexanolone was done in the 1980s by scientists from the National Institute of Mental Health. They found that levels of allopregnanolone, a neuroactive metabolite of progesterone, increase during pregnancy but decrease after delivery. In some women, that postpartum drop leads to development of depression and anxiety. Brexanolone has also been studied as a treatment for a life-threatening form of epilepsy.

Judith M. Orvos, ELS, is an editorial consultant for Contemporary OB/GYN.

SOURCE

...the drug is expensive and whether its benefits persist beyond 30 days is unknown.
What’s new in biomarker testing for ovarian cancer

Three tests are now FDA-approved for triaging pelvic masses in asymptomatic women.

by ANDREW JOHN LI, MD

Management of an adnexal mass is a common clinical scenario for obstetricians, gynecologists, and other providers in women’s health. Masses may be identified upon routine annual examinations, incidentally during imaging for other conditions, or when women present with pelvic and/or abdominal symptomatology. Many masses are ultimately found to be benign at time of surgery. Others, however, are malignant, and appropriate preoperative referral to a gynecologic oncologist for surgical management, staging, and determination of potential adjuvant therapy is critical to the outcome in these patients.

Epithelial ovarian cancer remains an aggressive disease. The American Cancer Society estimates that in 2019, 22,530 women will be diagnosed with ovarian cancer and 13,980 of them will die, ranking this malignancy the fifth most lethal behind lung, breast, colon and pancreas. Unfortunately, fewer than half of all women with ovarian cancer are cared for by a gynecologic oncologist, despite data supporting improved outcomes when a specialist is managing their care. These findings underscore the importance of appropriate and early referral.

Determining which women with adnexal masses will ultimately have cancer at time of surgery remains a clinical challenge. To assist in this risk stratification, initial evaluation of women with a pelvic mass has typically included ultrasound imaging and serum biomarker testing. To best care for patients most at risk, the American College of Obstetricians and Gynecologists (ACOG) recommends referral to a gynecologic oncologist for women who have a pelvic mass combined with elevated serum CA125, ascites, and/or evidence of metastatic disease. For women who have a mass but no ascites or imaging suggestive of metastatic disease, the accuracy of biomarkers for identification of those at highest risk of cancer is crucial to determine whether they would benefit from specialty referral. This review updates our current knowledge of preoperative biomarker utilization to optimize outcomes for women with a pelvic mass.
CA125 testing

The serum biomarker CA125 has long been considered one of the primary evaluation tools in preoperative assessment of women with pelvic or adnexal masses. CA125 is a protein expressed in epithelial tissues, including the mesothelial lining of the pleura and peritoneum, and the Müllerian cells of the fallopian tube, endometrium, and endocervix.5

Surprisingly, CA125 is not typically expressed by the surface epithelium of benign ovaries. However, 90% of women with metastatic epithelial ovarian cancer have elevated serum levels, which has led to widespread adoption of this test in evaluation of potential malignancy. Unfortunately, the sensitivity and specificity of CA125 in predicting ovarian cancer remains low. Fifty percent of women with stage I ovarian cancers, where disease is confined to the ovaries, will have a normal preoperative CA125 level. In addition, several conditions will lead to serum elevations in CA125. These include both benign gynecologic processes, such as uterine fibroids, ovulation, menstruation, and endometriosis, and malignancies of other abdominal organs, such as gastric, colon, and pancreatic cancers.5

For these reasons, the US Food and

| TABLE 1 | ROMA score calculation |
|-----------------------------------------------|
| **Premenopausal women** | \[PI = -12.0 + 2.38 \times \ln[\text{HE4}] + 0.0626 \times \ln[\text{CA125}]\] |
| **Postmenopausal women** | \[PI = -8.09 + 1.04 \times \ln[\text{HE4}] + 0.432 \times \ln[\text{CA125}]\] |

\text{Predicted probability} = \frac{\exp(PI)}{1 + \exp(PI)} \times 100

Abbreviations: exp, exponential; LN, natural logarithm; PI, predictive index; ROMA, Risk of Ovarian Malignancy Algorithm

* A score > 12.5% is considered high risk in premenopausal women.

** A score > 14.4% is considered high risk in postmenopausal women.
Drug Administration (FDA) has not approved CA125 for preoperative use, but only for cancer surveillance after a diagnosis of ovarian cancer.

**Novel biomarkers**

Over recent decades, limitations in the ability of CA125 to detect ovarian cancer have led investigators to evaluate additional serum proteins as potential candidates for biomarker utility, given the relative ease and reliable reproducibility of serum testing. Several initial studies in the early 2000s suggested combinations of serum markers, in contrast to CA125 alone, as a diagnostic tool in women with adnexal masses. These include the OvaSure serum test, which incorporated serum levels of leptin, prolactin, osteopontin, insulin-like growth factor II, macrophage inhibitory factor, and CA125 into a diagnostic algorithm. The OvaCheck test similarly expanded this scale into proteomic profile analyses of thousands of serum proteins.6-8 Unfortunately, the lack of validation studies undermined the effectiveness of these modalities in clinical care.

**HE4 and risk of malignancy algorithm**

New data identified additional markers, which have led to development and validation of diagnostic tests in clinical care of women with a pelvic mass. Human epididymis protein 4, or HE4, is a protease inhibitor expressed by malignant epithelial ovarian cells that can be identified in the sera of women with ovarian cancer.9 In 2008, data on HE4 led to FDA approval of it as a monitoring tool for women who have a history of ovarian cancer.

Subsequent research examining HE4 in combination with CA125, in the context of menopausal status, led to development of a logistic regression model as a diagnostic tool in women with a pelvic mass. This Risk of Malignancy Algorithm (ROMA) classifies patients into high risk or low risk for ovarian cancer based upon a score, which is a predictive index calculated with equations that differ based on the patient’s menopausal status (Table 1). Calculators are available online (http://romatools.he4test.com/calculator_row_en.html) that can generate the risk assessment based upon CA125 and HE4 assay results, along with menopausal status.

Validation studies that led to FDA approval of ROMA were detailed in a prior review in this journal.10 In brief, the initial prospective study in a high-risk population (women recruited after seeing a gynecologic oncologist) identified sensitivities of 92% and 76% (for postmenopausal and premenopausal women, respectively), with a specificity of 75%.11 A subsequent study in a low-risk population (women with an adnexal mass recruited into the study after seeing a gynecologist, family practitioner, internist, or general surgeon) reported sensitivities of 100% and 92% and specificities of 76% and 74% (in postmenopausal and premenopausal women, respectively).12 These data led to the 2011 FDA approval of ROMA to determine risk of ovarian cancer in women with a pelvic mass.

**OVA1**

In parallel studies, other investigators examined additional biomarkers in a multivariate index assay as a diagnostic tool in women with suspected ovarian malignancies. This assay, now known as OVA1, incorporates serum levels of five serum proteins (transferrin, apolipoprotein A-1, b2-microglobulin, transferrin, and CA125) in a proprietary software calculation to generate a high or low probability for malignancy score (Table 2). As with ROMA, menopausal status affects interpretation of the score; 5.0 or higher is considered high probability of ovarian cancer in premenopausal women, whereas a score of 4.4 or higher is high probability in postmenopausal women.

Validation studies that led to FDA approval of OVA1 were detailed in a prior review in this journal.13 In brief, the sensitivity of OVA1 was found to be 100% for stages II, III, and IV ovarian cancer, and 90% for stage I ovarian cancer.

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<thead>
<tr>
<th>TABLE 2</th>
<th>Comparison of OVA1 and Overa</th>
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<tr>
<td><strong>OVA1</strong></td>
<td><strong>Overa</strong></td>
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<tr>
<td>Apolipoprotein A-1</td>
<td>Apolipoprotein A-1</td>
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<tr>
<td>Transthyretin</td>
<td>Human epididymis protein 4 (HE4)</td>
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<tr>
<td>Beta-2-microglobulin</td>
<td>Follicle-stimulating hormone (FSH)</td>
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<td>Transferrin</td>
<td>Transferrin</td>
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<tr>
<td>CA125</td>
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The Secret to Incorporating Aesthetic Services? Technology.

If you’re already treating patients who have expressed interest in aesthetic gynecological services, how do you market your practice as their first choice for specialty procedures? With the right variety of energy-based technology at your fingertips.

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cancer. The specificity in this cohort, however, was 43% for OVA1 alone, and 35% for OVA1 combined with physician assessment. The investigators of this study further evaluated their cohort in the context of the ACOG referral guidelines; when substituting OVA1 for CA125, they found improved sensitivity (94% with OVA1 versus 77% with CA125) but decreased specificity (35% versus 68%). These studies led to FDA approval of this assay in 2009 as a tool for use by a patient’s primary physician to decide whether a patient with an ovarian mass should be referred to a gynecologist or a gynecologic oncologist. It is not approved for use to screen or to determine whether a patient should proceed to surgery.

**Overa**

The relatively low specificity of OVA1 led to valid concerns by many obstetricians and gynecologists about a larger proportion of patients with benign disease being referred to specialists outside their practices. As such, additional biomarker breakthroughs have led to a second-generation OVA1 test. Initially known as OVA2, this novel assay is now trademarked as Overa. Overa replaces transthyretin and beta-2-microglobulin from OVA1 with HE4 and follicle-stimulating hormone (FSH) (Table 2). The goals of this new assay are to improve the specificity and positive predictive value (PPV) of OVA1 while maintaining high sensitivity and negative predictive value; in addition, inclusion of FSH abrogated the need for clinicians to determine menopausal status when interpreting the results. Overa stratifies patients with an adnexal mass into high- or low-risk categories based upon a scale of 0 to 10, and uses a single cutoff of 5. Clinical validity was determined using banked serum samples from a prospective cohort of 493 women undergoing surgery for an adnexal mass, with an observed cancer prevalence of 18.7%. The sensitivity of Overa remained high at 91%; combining Overa score with physician assessment demonstrated a sensitivity of 94%. Specificity of Overa was significantly higher at 69%, compared to 54% seen in the same cohort with OVA1. The PPV of Overa was also superior (40% versus 31%). Inclusion of Overa with physician assessment identified 75% of the malignancies missed by physician assessment alone. These data led to FDA approval in 2016 to market this second-generation assay in conjunction with independent clinical and imaging assessment prior to planned surgery for women with a pelvic mass.

Overa has been further examined in an independent cohort to assess the combination of a symptom index with this assay to predict risk of malignancy in a prospective cohort of 216 women with a documented adnexal mass planned for surgery. In this cohort where 64 patients (21%) were found to have epithelial ovarian or fallopian tube cancers, self-reported symptoms (pelvic and/or abdominal pain, increased abdominal size and/or bloating, and difficulty eating and/or feeling full) and Overa independently demonstrated high sensitivities (87% and 92%, respectively). However, the combination of both a positive symptom index and a positive Overa test led to a significant improvement in sensitivity (96%). Taken together, these data suggest that physician assessment, including evaluation of patient self-reported symptoms, combined with Overa are powerful and accurate tools to determine which patients are at highest risk of malignancy.

**Conclusion**

Advances in biomarker discovery have led to several FDA-approved tests superior to CA125 in preoperative evaluation of women with a pelvic mass. While OVA1 has higher sensitivity for determining malignancy than CA125, its decreased specificity may generate referrals of benign disease to gynecologic oncologists. Both Overa and ROMA have comparable higher sensitivities, and their improved specificities can more accurately determine which subgroups of patients would most benefit from consultation with a gynecologic oncologist. While none of these three tests can be or should be used for screening asymptomatic women with unremarkable imaging, Overa and ROMA represent the culmination of significant efforts that can improve risk stratification in women with a pelvic mass to triage their care to the appropriate provider.

**DISCLOSURE:** The author reports no potential conflicts of interest with regard to this article.

**FOR REFERENCES VISIT** [contemporaryobgyn.net/BiomarkerTesting](http://contemporaryobgyn.net/BiomarkerTesting)
Contemporary OB/GYN contributors at ACOG

Contemporary OB/GYN is proud of our board members and our authors, and we never want to miss an opportunity to applaud their contributions to our pages each month. The following board members — both past and current — authors and collaborators will be appearing in Nashville at the ACOG Annual Clinical and Scientific Meeting in May. Here is a rundown on where you can find them and the programs they will be participating in. Don’t miss this opportunity to hear their presentations and talk to these great folks in person.

FRIDAY MAY 3

CLINICAL SEMINARS

10:30-11:15 am Contraception: What you need to know in 2019 – Eve Espey, MD, MPH

1:30-2:15 pm Fourth Trimester Care: When to initiate care postpartum – Haywood L. Brown, MD

Contemporary OB/GYN past editorial board member

4:15-5 pm The Use and Benefit of Cervical Length Screening – Vincenzo Berghella, MD

SUBSPECIALTY COLLABORATIVE SESSIONS

1:30-4:30 pm Guidance on Common Difficult Obstetric Scenarios – A Joint ACOG/SMFM Session – Brian K. Iriye, MD, et al

COLLOQUIA

4:15-5 pm Are You Smarter Than a Junior Fellow – Sharon Phelan, MD

Contemporary OB/GYN editorial board member

SATURDAY MAY 4

CLINICAL SEMINARS

8-8:45 am Anomalies that should not be missed by ultrasound – Stephen Chasen, MD

8:10-9 am The John I Brewer Memorial Lecture – Tubes out forever! Should everyone have a salpingectomy at the time of tubal ligation – Ilana Cass, MD

Contemporary OB/GYN editorial board member

9:15-10 am Perils and pitfalls of expanded carrier screening – Mary E. Norton, MD

9:15-10 am Timing of Induction of Labor and Cesarean Epidemic – Aaron Caughey, MD

1:30-2:15 pm Pregnancy in the opioid crisis – Mishka Terplan, MD
**LUNCH CONVERSATIONS**

12-1:15 pm **Why does it hurt? A differential diagnosis for breastfeeding associated pain** – Alison M. Stuebe, MD, MSc

**EDTALKS**

3:15-4 pm **Salpingectomy – It’s not just for sterilization anymore** – Ilana Cass, MD

*Contemporary OB/GYN* editorial board member

**The agony and ecstasy of immediate postpartum LARC** – Eve Espey, MD

**COLLOQUIA PANEL**

10:50-11:40 am **Mental Health, Suicide and Substance Abuse Disorder** – Kimberly Yonkers, MD

**SUNDAY MAY 5**

**CLINICAL SEMINARS**

1:30-2:15 pm **Hereditary cancers in gynecology: What ob-gyns should know about genetic testing, screening, and risk reduction** – Susan C. Modesitt, MD

**ACOG COLLABORATIVE SESSIONS WITH SUBSPECIALTY SOCIETIES**

130-4:30 pm **Advancing your surgical skills to the next level: Evidence based updates for the gynecologic surgeon – a joint ACOG/SGS session** – Peter L. Rosenblatt, MD

**4:40-5:30 pm The ABOG Educational Foundation Lectureship on Patient Safety – Obstetric care redesign – “One size does not fit all”** – Nathaniel DeNicola, MD, MSHP

**MONDAY, MAY 6**

**HANDS-ON COURSE**

8 am-3 pm **Emergencies in clinical obstetrics** – Shad Deering, MD

**POSTGRADUATE COURSE**

8:30-11:30 am **Best Practice in High-Risk OB** – Catherine Y. Spong, MD

*Contemporary OB/GYN* former editorial board member

**Colloquia**

3-4:30 pm **Gerald and Barbara Holzman Stump the Professors** – John O. Delancey, MD; Beth Karlen, MD; Charles J. Lockwood, MD, MHCM; Mary E. Norton, MD; Hugh S. Taylor, MD

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Sepsis during pregnancy and the puerperium

Maternal sepsis is a significant cause of maternal morbidity and mortality. Recent US data report that maternal sepsis complicates 4 to 10 per 10,000 live births. Incidence of maternal sepsis appears to be increasing; in the United States between 1998 and 2008, rates of severe maternal sepsis and sepsis-related deaths increased 10% per year. Nulliparity, black race, and public or no insurance have been identified as risk factors for pregnancy-associated sepsis. Obstetric risk factors include cesarean delivery, use of assisted reproductive technologies, and multiple gestation. More than 50% of the women who die from sepsis have one or more chronic comorbid conditions, including chronic renal disease, chronic liver disease, and congestive heart failure.

How is sepsis defined and what are the clinical features?

In 2016, The Third Internal Consensus Definitions for Sepsis and Septic Shock task force defined sepsis as “life-threatening organ dysfunction caused by a dysregulated host response to infection.” Organ dysfunction may be objectively defined as an acute increase of two or more points in the Sequential Organ Failure Assessment (SOFA) score. Septic shock can be identified within a clinical construct of sepsis with persistent hypotension requiring vasopressors to maintain mean arterial pressure (MAP) ≥ 65 mm Hg and a serum lactate level > 2 mmol/L despite adequate volume resuscitation.

A brief bedside assessment tool known as the quick SOFA score (qSOFA) can be used to assist in evaluation of suspected sepsis. The qSOFA score evaluates presence of three clinical criteria: systolic blood pressure ≤ 100 mm Hg, respiratory rate ≥ 22/min, and altered mental status. If two or more of these criteria are present, the patient is at increased risk for poor-sepsis related outcomes. These signs should prompt the physician to look carefully for organ dysfunction, start or escalate therapy, increase the acuity of monitoring, and consider transfer to an intensive care unit. Importantly, fever is neither necessary nor sufficient to determine whether sepsis is present.

What is the pathophysiology of sepsis?

Sepsis results from a dysregulated host response to infection resulting in organ damage, and virtually any organ system can be affected. The excessive inflammatory response that occurs with sepsis includes extravasation of albumin and fluid, with resultant intravascular hypovolemia. Cytokine release leads to decreased systemic vascular resistance and increased cardiac output, although up to 60% of patients with sepsis have an ejection fraction below 45% (systolic dysfunction). Septic cardiomyopathy may also manifest with diastolic dysfunction due to cardiac edema and diminished compli-
The noncompliant left ventricle will result in decreased diastolic filling and less stroke volume, increasing risk of pulmonary edema with excessive fluid resuscitation. Tissue ischemia (and dysfunction) results not only from hypotension but also secondary to microvasculature occlusion from microthrombi due to disseminated intravascular coagulation.

How do clinical features of sepsis differ in pregnancy?

Normal human pregnancy is a state of expanded plasma volume, increased cardiac output, and peripheral vasodilation. None of the existing definitions of sepsis account for physiologic alterations of normal pregnancy. When nonpregnant norms are used, either overdiagnosis or underdiagnosis of sepsis may occur. Of the SOFA criteria, those most affected by pregnancy are creatinine and MAP. An obstetric-modified qSOFA has been proposed by the Society of Obstetric Medicine Australia and New Zealand (SOMANZ) and includes systolic blood pressure ≤ 90 mm Hg, respiratory rate > 25/min, and altered mental status. The SOMANZ guidelines also include modifications to laboratory components when applying the SOFA score to pregnancy, including a point value above zero for a creatinine > 90 μmol/L (1.02 mg/dL).

Most important in optimizing outcomes is early recognition of organ dysfunction in the septic patient. In addition to the SOMANZ guidelines described above, there have been other attempts to devise a pregnancy-specific scoring system for sepsis. Evaluation of the “Sepsis in Obstetrics Score,” a combination of maternal temperature, blood pressure, heart rate, respiratory rate, peripheral oxygen saturation, white blood cell count, and lactic acid level as predictors of intensive care unit (ICU) admission for sepsis and modified to account for normal physiologic changes of pregnancy reported a positive predictive value (PPV) of only 16.7% for ICU admission. A prospective validation study of the Sepsis in Obstetrics Score found that a score of 6 or greater had a sensitivity of 64%, specificity of 88%, PPV of 15%, and negative predictive value of 98.6%.

What are the most common infectious etiologies of sepsis?

The source of infection in puerperal sepsis can be either pelvic or nonpelvic. Antepartum cases of sepsis are most commonly nonpelvic in origin, while intrapartum and postpartum cases are more likely to have a pelvic source. In 30% of cases, no source is identified. In the UK Obstetric Surveillance System, clinical laboratory testing was only able to identify the causative microorganism in 64% of maternal sepsis cases, and the clinician could identify the source in only 74%. In 16%, neither the inciting organism nor the source of sepsis was identified.

The most frequently isolated organisms in maternal sepsis are Escherichia coli and group A and group B Streptococcus, although staphylococci, gram-negative and anaerobic bacteria, and many other organisms have been reported. Mixed infections are also possible; in 15% of maternal sepsis deaths in which organisms could be identified, the infection was polymicrobial. Empiric antibiotic choices will be driven by the presumed source, likely microorganisms, and local patterns of antibiotic resistance and should include coverage of anaerobic and aerobic gram-positive and gram-negative bacteria. Hospitals may have specific recommendations in place or guidance may be sought from a consultant in infectious disease or from specialty society guidelines. Antibiotic coverage should be narrowed and focused once culture results are available.

Molecular techniques, such as polymerase chain reaction (PCR)-based systems, can identify inciting organisms not detected by culture-based methods and can provide pathogen identification from blood samples before cultures become positive. PCR testing results are positive in approximately 11% of patients with a clinical suspicion of bacteremia but negative blood cultures.

What is initial management of sepsis?

Imaging is often required when searching for a source of infection. If a specific focus is identified, appropriate steps should be undertaken, such as curettage for retained products of conception or drainage of an abscess. The intervention with the least potential for physiologic derange-
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Passive leg raising may not be useful during the third trimester due to uterine compression of the inferior vena cava and should not be used to guide therapy.

What is the role of fluid therapy in sepsis management?
Fluid resuscitation should be part of the initial intervention if hypotension or hypoperfusion is present. Fever, venodilation, and capillary leakage all lead to inadequate preload in the patient with sepsis. The Surviving Sepsis Campaign’s recommendation of an initial bolus of 30 mL/kg of crystalloid may be overly aggressive in pregnancy, where colloid oncotic pressure is lower and risk of pulmonary edema is higher. Patients who are fluid responsive should be identified before further fluid administration (especially after the initial 1 to 2 liters, or 30 mL/kg, have been administered) by dynamic measures of preload. For pregnant women, these include analysis of pulse-pressure variation in the waveform of an arterial line and passive leg raising. The former method is only reliable in sedated individuals receiving positive-pressure, controlled mechanical ventilation and who are in sinus rhythm. A pulse-pressure variation of more than 13% with the respiratory cycle identifies the patient as volume responsive.

For patients who are breathing spontaneously and in sinus rhythm, passively raising the legs 30 to 45 degrees causes an autotransfusion of close to 300 mL of blood from the legs into the chest. After 2 to 3 minutes of passive leg raising, fluid responders will have an increase in cardiac output (utilizing noninvasive cardiac output monitors), while those who do not improve are probably better treated with vasopressors. Passive leg raising may not be useful during the third trimester due to uterine compression of the inferior vena cava and should not be used to guide therapy. In such cases, an increase in cardiac output may be identified by administering a small bolus of fluid (250-500 cc); if cardiac output increases after such an intervention, further fluid administration is likely indicated. Determination of fluid responsiveness using point-of-care ultrasound measurements of the diameter of the inferior vena cava with respiration is most commonly used in patients receiving mechanical ventilation and has not been validated in pregnancy.

When are vasopressors and inotropes indicated?
In hypotensive patients who are not fluid responsive or who are not candidates for further fluid resuscitation (e.g., women who are in pulmonary edema), vasopressors should be utilized to increase blood pressure. The purpose of vasopressors is to constrict the pathologically dilated systemic circulation and maintain adequate perfusion. Current guidelines recommend norepinephrine as the first-line agent with a target MAP above 65 mm Hg, although the latter threshold has not been studied in pregnant women. Determining the target MAP in a septic pregnant patient must be individualized, with consideration of overall organ perfusion. Lower blood pressures may be acceptable during pregnancy provided no signs of hypoperfusion are present (such as altered mental status, oliguria, elevated serum lactate, cold extremities, or evidence of fetal compromise). Early goal-directed therapy is no longer recommended in management of sepsis.

Norepinephrine has been studied in human pregnancy and is often used to maintain blood pressure with regional anesthesia at time of cesarean delivery. Norepinephrine appears to be safe for the fetus, especially at low doses.

When is delivery indicated in pregnant women with sepsis?
Presence of sepsis alone is not an immediate indication for delivery (except in cases of chorioamnionitis). Delivery should be reserved for the usual obstetric indications after stabilization of the woman; there is no evidence that delivery improves maternal outcomes. The primary objective should be hemodynamic supportive therapy for maternal benefit and antimicrobial treatment with appropriate source control of the infection. Corticosteroids for fetal lung maturity are not contraindicated and may be used in sepsis if indicated (regardless of use...
of hydrocortisone for refractory septic shock). Norepinephrine has been studied in human pregnancy and is often used to maintain blood pressure with regional anesthesia at time of cesarean delivery. Norepinephrine appears to be safe for the fetus, especially at low doses.

**Q** What are the maternal and perinatal outcomes associated with sepsis?

The mortality rate for sepsis in pregnant women is difficult to quantify. The few existing studies have reported rates from 1% to 4.6%. Because incidence of and mortality from sepsis are dependent on age, comparisons to the general population depend on finding a similar group of reproductive-age women. In 2012, an analysis from New Zealand and Australia found the mortality rate in young adults aged 44 years and younger to be 8% in the absence of comorbidities.

Preterm delivery is common after critical maternal illness, including sepsis, even when the source is not uterine. An Irish study found that in women with antepartum bacteremia, 69% either miscarried or delivered preterm. The outcome was worse for women with antepartum bacteremia of uterine origin; all delivered within 24 hours of onset. Among women with a nonpelvic source of bacteremia in the antepartum period, 12% miscarried, 33% delivered soon after onset, and the remainder delivered between 1 week and 7 months after onset.

**Q** How can deaths from sepsis be prevented?

Among women who died from sepsis, a majority had a delay in care and a delay in escalation of care. Most were afebrile, possibly delaying recognition of presence of sepsis. Even after diagnosis, 73% of women were started on antibiotics that provided inadequate coverage. Implementation of an early warning system may decrease maternal risk. In addition, with publication of the Surviving Sepsis guidelines, early involvement of consultants with expertise in infectious disease may expedite treatment of sepsis and help improve outcomes.

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>GRADE</th>
</tr>
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<tbody>
<tr>
<td>1 We recommend that sepsis and septic shock be considered medical emergencies and that treatment and resuscitation for sepsis begin immediately.</td>
<td>1B Strong recommendation, moderate-quality evidence</td>
</tr>
<tr>
<td>2 We recommend that providers consider the diagnosis of sepsis in pregnant patients with otherwise unexplained end-organ damage in the presence of an infectious process, regardless of the presence of fever.</td>
<td>1B Strong recommendation, moderate-quality evidence</td>
</tr>
<tr>
<td>3 We recommend that empiric broad-spectrum antibiotics be administered as soon as possible, ideally within 1 hour, in any pregnant woman in whom sepsis is suspected.</td>
<td>1B Strong recommendation, moderate-quality evidence</td>
</tr>
<tr>
<td>4 We recommend obtaining cultures (blood, urine, respiratory, and others as indicated) and serum lactate levels in pregnant or postpartum women in whom sepsis is suspected or identified. Early source control should be completed as soon as possible.</td>
<td>1C Strong recommendation, low-quality evidence</td>
</tr>
<tr>
<td>5 We recommend early administration of 1 to 2 L of crystalloid solutions in sepsis complicated by hypotension or organ hypoperfusion.</td>
<td>1C Strong recommendation, low-quality evidence</td>
</tr>
<tr>
<td>6 We recommend use of norepinephrine as the first-line vasopressor during pregnancy and the postpartum period in sepsis with persistent hypotension and/or hypoperfusion despite fluid resuscitation.</td>
<td>1C Strong recommendation, low-quality evidence</td>
</tr>
<tr>
<td>7 We recommend against immediate delivery due to the sole indication of sepsis and that delivery should be dictated by obstetric indications.</td>
<td>1B Strong recommendation, moderate-quality evidence</td>
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**Discussion**

The most likely diagnosis in this patient is hidradenitis suppurativa (HS) (Hurley stage 2) and you could use all of the listed treatments to address this condition. HS is a chronic inflammatory skin condition that involves skin in areas where apocrine glands are found.\(^1,2\) The lesions of HS can mimic other conditions such as acne, carbuncles or Crohn’s disease but they are distinct in their pattern of distribution.

You should suspect HS if the following three criteria are met:

1. Lesions are nodules, abscesses, tunnels or scars;
2. Location is axillae, inframammary folds, groin, perigenital, or perineal area; and
3. Lesions progress (two recurrences within 6 months or chronic or persistent lesions for \(\geq 3\) months).\(^1,3\)

It has been suggested that HS develops due to a defect in the folliculopilosebaceous unit.\(^3,4\) This results in weak-walled follicles that when occluded ultimately rupture, resulting in release of multiple inflammatory factors.\(^3,4\) In turn, an acute inflammatory response develops in the surrounding tissue. As the body attempts to heal, chronic inflammation occurs, creating chronic tissue damage and resultant scarring.\(^1,3-5\) HS also is thought to have a genetic component, with multiple genes likely to be involved.\(^6\) Infection appears to be a secondary reaction.\(^1,3\) Androgens also play a role likely secondary to an increased end-organ sensitivity of androgen receptors mediated by insulin and insulin-like growth factor.\(^7\)

HS is seen primarily after puberty and before menopause, with women affected more commonly than men.\(^3,5\) Estimated prevalence is 0.5% to 4%.\(^1,8,9\) Mean time to diagnosis is 7.2 years, which is unfortunate as the disease can be progressive and debilitating.\(^1,10\)

HS is staged by Hurley’s criteria.\(^1\) Stage 1 is characterized by transient abscess formation without scarring and sinus tracts.\(^1\) Stage 2 is characterized by recurrent abscesses (single or multiple) with sinus tracts or scarring.\(^1\) If multiple lesions are present, they are separated by normal skin.\(^1\) Finally the most severe stage is stage 3, consisting of diffuse disease with multiple connected tracts, tunnels, and significant scarring.\(^1\) (Figure 2)

The therapeutic goals of treatment are to treat active disease and prevent disease progression. Most therapies target suspected underlying mechanisms. For stage 1 disease, patients are treated with general care measures, including avoiding vulvar irritants and tight clothing.\(^1,3\) Behavioral and dietary changes such as weight loss, smoking cessation, and elimination of dairy products are encouraged as well.\(^1,3\)

For the initial flare, amoxicillin/clavulanic acid (875 mg po every 12
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hours for 7 to 10 days) helps to treat the inflammation and secondary infection. Other antibiotics that can be considered include doxycycline (100 mg po twice daily) or clindamycin (300 mg po twice daily) for 7 to 10 days. Patients are also advised to take zinc picolinate (30 mg) with copper gluconate (2 mg). This is available in a single pill to be taken twice a day. Other therapies offered include topical clindamycin lotion 1% twice daily. Intraloesional triamcinolone injections are used at times. Antiandrogens such as drospirenone-containing oral contraceptives, spironolactone (50-100 mg po daily), or finasteride (5 mg po daily) may be helpful to control disease. For stage 2 disease, other oral agents can be considered (sulfamethoxazole-trimethoprim, dapsone, or a combination of rifampin, moxifloxacin, and metronidazole), with maintenance on doxycycline or minocycline for approximately 3 months. Local surgical treatments such as unroofing tracts, wide local excision of lesions, skin tissue-sparing excision with electrosurgical peeling (STEEP) surgery and carbon dioxide laser evaporation of diseased tissue may be used for stage 2 HS.

For stage 3 or severe HS, radical wide excision with skin grafting is recommended for definitive treatment (Figure 3). This is an extensive process requiring resection of HS and wound vac placement, wound vac changes, and skin grafting 1 week later, if the tissue is granulating well. A wound vac is applied over the skin graft for 5 days.

**FIGURE 3** Healed vulva and abdomen in a patient with a history of stage 3 HS, 1 year out from surgery (vulvectomy, abdomen and buttock resection with skin grafting).
For stage 3 HS, you can also consider medical therapy with clindamycin 300 mg BID with rifampin 300 mg BID and a TNFα inhibitor such as adalimumab or infliximab. This is typically done in consultation with a dermatologist. Unfortunately, medical management is generally not a cure for patients with stage 3 HS. Surgical management of stage 3 HS has been found to have good results. Finally, psychosocial support is critical for patients with HS as the condition can be isolating due to its nature.

Acne vulgaris
Acne vulgaris is a chronic inflammatory skin disease that affects the pilosebaceous unit and is typically seen in adolescents and young adults. The skin changes can be described as open or closed comedones or as inflammatory nodules, pustules or papules. Inflammatory lesions look most similar to HS lesions but the topographical distribution differs. In general, acne tends to be found on the face, neck, and back. The two disorders also share some similarities with regards to treatment goals and minimizing comorbid conditions such as depression.

As with HS, treatment for acne vulgaris is designed based on disease severity. First-line treatment for mild disease is primarily treated with topical medications (e.g. benzoyl peroxide, retinoids or combinations of these with or without antibiotics). Moderate disease is treated with topical combination therapy or topical therapy with oral antibiotics. Severe disease is treated with an oral antibiotic along with a topical combination regimen or with oral isotretinoin.

Folliculitis
Folliculitis is a bacterial infection of the hair follicles. It can occur in any hair-bearing area and is a common skin condition. Tissue trauma (e.g. shaving, excess heat (tight clothing) and immunosuppression (chronic steroid use) can predispose to development of these lesions. On vulvar examination, one would see papules and pustules. Diagnosis of folliculitis can be confirmed with a culture, in contrast to HS. Typically, Staphylococcus aureus is the offending microbe. Therapy usually is short-term and can include topical cleansers or medications such as chlorhexidine, benzoyl peroxide, clindamycin, fusidic acid or mupirocin. Oral antibiotics such as dicloxacillin, clindamycin or a macrolide can be used for cases that do not respond to topical therapy. Good vulvar care hygiene is key to avoid recurrence.

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

For references visit contemporaryobgyn.net/HidradenitisSuppurativa

Psychosocial support is critical for patients with HS as the condition can be isolating due to its nature.

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Patients not always truthful when dealing with clinicians

by LINDA MARIE WETZEL, RN

A recent study shows that patients fail to disclose pertinent information to their physicians, which can undermine patient care or even cause unexpected harm.

Scientists at University of Utah Health and Middlesex Community College led the study in collaboration with colleagues at University of Michigan and University of Iowa. The research was conducted to determine if a conventional belief that patients lie to physicians has merit. Previous studies that attempted to examine this hypothesis were limited in scope, usually examining a single issue. This study attempted to focus on the types of behavior deemed basic and essential to health care and the characteristics of the nondisclosure.

“If patients are withholding information about what they’re eating, or whether they are taking their medication, it can have significant implications for their health. Especially if they have a chronic illness,” said the study’s first author, Andrea Gurmankin Levy, PhD, MBe, an associate professor in social sciences at Middlesex Community College in Middletown, Connecticut.

The study used two separate surveys. The first sample was recruited from internet users who participate in surveys and other tasks in exchange for financial compensation. These participants were age 18 and older. The second sample group, aged 50 and older, was obtained from Survey Sampling International (SSI) and received reward points for their participation. Both online surveys were self-administered.

Of 4510 total respondents, 2011 (mean age of 36 years, range 18-79) completed a MTurk survey, and 2685 participants (mean age 61 years, range 50-91), completed an SSI survey. In both groups, approximately 80% of participants were white. Of the MTurk and SSI participants, 60.7% and 51.5%, respectively, were female. Nearly 80% of the respondents reported their health as good, very good, or excellent. Chronic illness was reported by 22.5% of those in the MTurk group and 39.2% in the SSI group.

Medically relevant information was divided into types with reasons for avoiding the truth regarding that information. The information included disagreeing with the clinician’s recommendation, not understanding instructions, an unhealthy diet, not taking prescription medication as instructed, not exercising, taking a certain medication/not mentioning the medication, and taking someone else’s medication.

Of the MTurk participants, 81.1% reported being untruthful with their physicians about any of seven types of relevant information. The same was true of 61.4% of those in the SSI group.

The most common reasons for avoiding the truth included not wanting to be judged or lectured on behaviors, not wanting to hear something is bad, being embarrassed, not wanting to be seen as difficult or stupid, not wanting to take up the provider’s time, and not wanting information recorded in the medical record.

“I’m surprised that such a substantial number of people chose to withhold relatively benign information, and that they would admit to it,” said Levy.

“We also have to consider the interesting limitation that survey participants might have withheld information about what they withheld, which would mean that our study has underestimated how prevalent this phenomenon is.”

SOURCE
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Minilaparoscopic Instruments from KARL STORZ
A not-so-minor matter I have advised clients on is how medical practices should care for patients seen as minors who continue to be in their care after they turn 18. Many practices, especially those with long-term relationships for chronic medical conditions, often forget the legal formalities when their patients become adults.

Here are some issues for ob/gyns to consider:

1. Make sure the practice has a way of monitoring when patients turn 18 so that it can be sure to comply with HIPAA. Violations can be avoided by having a formal process in place.

2. HIPAA dictates that once patients turn 18, parents or legal guardians can no longer have access to their child’s medical records or information. While parents are likely to still call, make appointments, and accompany their child to appointments, medical information can no longer freely be shared.

3. Since parents may cover their child well past age 18 on their health insurance, this can often lead to the incorrect belief that HIPAA does not apply. Practices need to be careful not to disclose protected health information improperly when answering insurance questions.

Patients over 18 who wish to share health information with their parents must complete a HIPAA authorization form and such other documentation that state law and the provider may require, depending on the information to be shared. The authorization may restrict what information can be shared, so parents will not necessarily have access to all information.

I generally advise my clients to share information in advance with patients and parents about what happens at age 18. In the event of a medical emergency, parents will not easily be able to make decisions or receive information about their child’s condition without having appropriate documentation in place. Failure to have documentation in place can create significant distress for all parties involved.

In addition to a HIPAA authorization, a medical power of attorney allows a child to appoint his/her parents as a medical decision-maker. A lawyer can provide both parties a form that complies with state laws. If patients will be attending college out of state, it’s wise to advise them to review that state’s legal requirements as well.

For ob/gyns that provide services to both minor and adult patients, it’s important to be prepared when patients turn 18. Education of parents and patients, as well as completing proper documentation, will protect all parties involved and ensure continuity of care in a legally compliant way.

Ericka L. Adler, JD, has practiced in the area of regulatory and transactional healthcare law for more than 20 years. She represents physicians and other healthcare providers across the country in their day-to-day legal needs.

Ob/gyns can take steps to limit confusion among patients and parents about the privacy laws that apply once a child turns 18.

by ERICKA L. ADLER
Talk to the Expert!

In Nashville for ACOG 2019? Come to booth #2135 and meet our editor-in-chief! Share your suggestions or concerns about clinical, practice management, or technology issues facing today’s ob/gyns.

Charles J. Lockwood, MD, MHCM
Saturday, May 4th
12:00 to 2:00 PM
Mistakes
Residency growing pains should eventually lead to confidence, but sometimes they just result in more growing pains.

by Luke Burns, MD

When I first became a physician, I felt like I was lying to patients I saw in clinic. I would introduce myself as their doctor, but as I waited for my clinical knowledge to catch up to my new title, I realized I barely knew the basics. I barely knew where the bathrooms were.

Every day I danced carefully around the questions I knew I could answer and the ones I would have to defer awkwardly to a more senior physician. In the latter cases, when I would stumble clumsily, the patient’s eyes would invariably flick toward my ID badge just long enough to make sure she really saw an “MD” after my name.

Now, after almost a year as a physician, there are some days when I can manage to convince everybody, even myself, that I am competent. While the big things need to be run by my attendings, there are a thousand small decisions I make every day on my own. How much Tylenol should I send this patient home with? Does this lady’s postoperative pain warrant another oxycodone? Do I have time to wolf down a lunch before I go to this consult in the ED? I never had a lecture on these questions in medical school. I can’t run every single one of these problems by one of the higher-ups. I have to learn to find answers on my own, to rely on my developing medical intuition and some common sense.

I have to learn to find answers on my own, to rely on my developing medical intuition and some common sense. With every tiny decision, and every patient who leaves my care unscathed, I develop a little more confidence.

But I still make mistakes all the time. A few months ago, I spent a day in the outpatient surgery center, running my own OR. I did five cases in a row with a single attending, who was quite kind as I slowly prepared each patient for the case. When it was time to make our first incision, she handed me the scalpel and gestured for me to go ahead. But when it came time to place the Veress needle, she gently took the instrument from my hands. A resident had once pushed too far in one of his operations, she said, puncturing the aorta and nearly killing the patient on the operating table. Since then, this attending inserted every Veress herself.

The day progressed, and after a few surgeries together, the attending began to trust me more and more. We were laughing with the scrub nurses, bonding over a shared taste in the music that was blasting from the OR speakers. I began to anticipate the attending’s requests before she made them, learning exactly how to turn the camera or my wrist to give her the angle she needed on a tricky cut. In the last case of the day, the patient draped and prepped, she handed me the Veress needle, saying quietly, “It’s been a long time since I’ve let a resident do one of these. Don’t mess it up.”

I took a deep breath, acknowledging the gravity of this decision. I grasped the needle and drove it slowly through the layers of fascia,
Since that surgery, I have made dozens of mistakes...But of course, now is the time for me to be making them. Residency is a constant cycle of hubris and humiliation.

hearing the satisfying double pop that told me we were in the right place. The gas flowed in easily and a quick scan with the camera inserted moments later showed no damage. The attending smiled and we turned the OR music up a little bit.

Near the end of the case, the attending moved away from the table to check on some of the instruments, leaving me to sew shut the three incision sites we had left on the patient’s abdomen: two on each side and one in the umbilicus. We let the anesthesia team know we were ready for the patient to start waking up and began removing the various drapes from the operation. As I was clearing up, I suddenly heard the attending shout out. She looked up at me in horror. “You didn’t close one of the incision sites.”

And then I realized what had happened. In every laparoscopic case I had done so far, the attending physician had been the one to sew shut the tricky umbilical incision. Growing more and more confident, I had overlooked this task, completely forgetting to do what I had been asked. I had been about to send this patient back to the recovery room with a 10-mm hole in her umbilicus, leading directly into her abdominal cavity.

I was dumbstruck. Before I could even grab a needle and thread, the attending silently sewed the incision herself. I felt mortified. How could I make such a simple, potentially dangerous mistake? I imagined the attending telling future trainees, “I never let residents close the umbilical incision. One time one of them nearly sent a patient home with a hole in her belly...”

Since that surgery, I have made dozens of mistakes, and probably hundreds that I will never know about. But of course, now is the time for me to be making them. Residency is a constant cycle of hubris and humiliation. I am surrounded by patient educators and educators with patience. As I navigate the space between the emotional peaks and troughs, I do my best to focus on the senior residents and attendings around me who I respect the most. If they can all survive this constant assault on the ego and come out the other side as knowledgeable, humanistic, confident physicians, there’s a chance I may be able to also.

Read more resident’s articles including Night call siren song from the March issue at CONTEMPORARYOBGYN.NET/RESIDENTS-BLOG/NIGHT-CALL-SIREN-SONG

Legally Speaking

Not-so-‘routine’ prenatal visit

Continued from page 53

Ultimately the patient was diagnosed with disseminated intravascular coagulation.

ean followed by virtually uncontrolled vaginal bleeding. Ultimately, the patient was diagnosed with disseminated intravascular coagulation (DIC) with suspected sepsis. The patient’s hematocrit dropped from 36.8% on admission to 12.7%. In the surgical ICU following the cesarean, she received 8 units of packed red blood cells, 8 units of fresh frozen plasma, 2 bags of crystalloids, and 1 unit of platelets. She was also receiving triple antibiotics. Nonetheless, the patient continued to actively bleed vaginally. Hypogastric artery embolization was performed with a note that the uterine arteries had been vasoconstricted previously.

The next note was from gynecology...
pale, and upon entering the uterus there were clots and frank blood, “likely placental abruption” and the baby was delivered with poor Apgars. The next obstetrical attending note stated that “my review of the case at the time of my arrival, patient had an uncomplicated pregnancy, but presented to hospital for two days of diarrhea and abdominal pain, noted to have fetal bradycardia and triaged.” Initial labs were suspicious for abruption, and the patient essentially arrived with DIC.

On May 7 at 1 p.m. the attending was called to the Intensive Care Unit (ICU) by the obstetrical team because the patient “started” to develop severe vaginal bleeding due to uterine atony, requiring vasopressors. Given failure of conservative measures, she was now believed to have a life-threatening hemorrhage. The decision was made to go forward with a lifesaving salvage hysterectomy. The procedure was discussed with the patient’s sister and family and it was explained that, absent surgical intervention, the woman would not survive owing to the bleeding.

By May 9, the notes reflected that the patient had apparently developed compartment syndrome of her right hand. On that date, the patient underwent a right-hand fasciotomy with a carpal tunnel release. Fasciotomies of the right volar, forearm, and dorsal hand also were performed.

Also on May 9, the patient developed acute compartment syndrome in her right leg. That led to a right thigh compartment fasciotomy and right calf compartment fasciotomy. While in surgical ICU, the woman also developed streptococcal toxic shock syndrome (STSS).

Allegations
Plaintiff alleged that at the last prenatal visit to defendant obstetrician, an appropriate history was not taken. The claim was that the doctor failed to learn the length of time plaintiff was exhibiting complaints of lower abdominal pain with fatigue, which would have required immediate delivery. It was also alleged that the attending failed to appropriately evaluate the mother’s abdomen during the visit and did not appreciate that there was fetal tachycardia. A fetal biophysical profile allegedly should have been performed, given the woman’s complaint of fatigue and lower abdominal pain with fetal tachycardia.

On June 30, as a result of bilateral ischemic gluteal ulcers, a flapping procedure was performed. On July 22, owing to right index finger gangrene, the patient’s right index finger was amputated through the midline phalanx. On July 27, owing to right foot gangrene, the patient underwent a right below-the-knee amputation. On August 10, owing to left foot gangrene, the patient underwent a left below-the-knee amputation.

Analysis
This was a case of significantly high exposure given the injuries, the favorable plaintiff’s venue and the obvious jury appeal. Sometimes, early analysis and resolution of high-exposure claims such as these is the best option, particularly when there is nothing to be gained by proceeding with formal discovery and depositions, and risk of disclosure of additional damaging evidence or testimony is high. We often harp on the necessity of thorough, accurate, contemporaneous documentation in this column. This case is no different, but here there was also a “failure” by the defendant obstetrician to take time in a busy practice to recognize the potential for danger to mother and fetus and investigate pertinent findings before discharging her home. More often than not, it is those seemingly minor oversights that lead to bigger issues later on and, eventually, litigation.
Failure to appreciate the abruption, the plaintiff claimed, caused uncontrollable hemorrhage, uterine atony, DIC, and STSS, ultimately leading to ischemic limbs and the need for a hysterectomy and significant amputations. All of this led to the death of the child, multi-organ failure in the mother leading to a hysterectomy, limb ischemia, amputation of the left index finger, and below-the-knee amputations of both her legs. This, in turn, led to the need for prosthetics and use of a wheelchair. The plaintiff claimed a loss of earning capacity and the emotional components of all of these damages.

As to the defendant Hospital, the plaintiff alleged it was improper to close the incision following the cesarean when the patient was still bleeding; a delay in transfusing the patient; and failure to appropriately monitor the patient after the procedure, resulting in DIC. In the face of uterine atony, they alleged there was a failure to timely perform a hysterectomy in an attempt to control the bleeding.

**Discovery**

Early discussion with defendant OB revealed that he recalled the May 6 visit as a routine scheduled visit not occasioned by any complaints. If the patient had abdominal pain consistent with placental abruption, he did not believe she would have been able to withstand the ultrasound performed by him that day. Pursuant to that ultrasound, however, was a FHR of 194 bpm, which the defendant conceded he should have rechecked prior to sending the patient home. If the FHR did not come down to 160 bpm or below, he would have done a non-stress test to verify the finding and, potentially, would have sent the patient to the hospital for fluids and concern about maternal infection.

Our expert obstetrician wasn’t certain what prompted an ultrasound at 37 weeks but opined that a FHR of 194 bpm is quite abnormal and required immediate attention, i.e., sending the patient to the hospital immediately. A FHR that climbs over 180 bpm, to her mind, should be presumed to be a significant maternal infection, usually chorioamnionitis, and a reading like that is a red flag for maternal sepsis, and defendant OB should have checked the patient’s temperature as well.

She also had critiques for the Hospital co-defendant. She posited they were not having trouble finding the FHR; this was not a case of fetal bradycardia but rather there was fetal demise by the time the patient arrived. In the face of a raging infection, a cesarean would be contraindicated, especially in the face of fetal demise. She believed the proper course of care would have been to start the patient on medications to advance vaginal delivery and deliver the stillborn. Performing a cesarean in the face of a significant ascending infection would allow new entry portals for more organisms and rapidly spread the infection. She posited that ultimately caused the septic shock.

Placental pathology showed 4+ group A Streptococcus infection, and a similar finding was made and confirmed based upon blood cultures. By performing a cesarean rather than controlling the infection with proper antibiotics, the Hospital staff exacerbated the infection. The fact that the patient progressed to sepsis not only affected the woman’s respiratory ability, but more importantly, affected and caused a drop in platelets, which impaired her clotting ability. This led to DIC, which was the precursor to the salvage hysterectomy that the patient underwent 1 day later. However, she progressed to necrotizing fasciitis, which ultimately led to limb loss.

The patient had been fitted with bilateral lower limb prostheses. Those records reflected a history of undiagnosed group A Streptococcus infection during pregnancy leading to STSS.

Performing a cesarean in the face of a significant ascending infection would allow new entry portals for more organisms and rapidly spread the infection.
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When a routine prenatal visit is not-so-‘routine’

Failure to recognize the warning signs led to poor outcomes for mother and child.

**Facts**

A pregnant primigravida had her last menstrual period on August 28, 2014, an assigned due date of June 4, 2015. Her key prenatal visit took place on May 6, 2015. With a gestational age of 36 weeks, the fundal height was listed at 35 cm or 38 cm, as it was difficult to read the doctor’s handwriting. The presentation was vertex and fetal heart rate (FHR) and fetal movement were present. There was no indication of preterm labor and the mother’s cervix was intact. She weighed 119 lb, reflecting a 21-lb gain. Urinalysis was noted as negative. A note initialed by the defendant obstetrician indicated that the woman’s next appointment was scheduled in 1 week but there was no entry in the comment section, which reflected a routine visit with no complaints. The patient’s blood pressure was 91/77 mmHg, inconsistent with all blood pressures checked on past visits, which ranged anywhere from 97/64 mmHg to 126/80 mmHg.

Shortly after midnight on May 7, the patient arrived at the hospital, and according to a note, had been “referred for emergency delivery.” The notes stated that the woman had come in complaining of abdominal pain, diarrhea, and fever since May 5, 2015 with suspected premature contractions. The initial nursing history note at roughly 2:00 a.m. stated that the patient’s chief complaint was “fatigue, feverish, as per family, with abdominal pain, vaginal bleeding.”

The resident’s assessment noted that the patient came into labor triage at 36 weeks, feeling contractions, and the “team was called” to evaluate bradycardia upon placing the external monitor. The external FHR monitor showed a rate of 75 and the mother was given oxygen by face mask and an intravenous bolus of fluid. The Neonatal Intensive Care Unit and Anesthesia were notified. An obstetrical ultrasound performed shortly after midnight showed that the fetal heart was visible with cardiac activity, but the rate was bradycardic. The patient was taken to the operating room for a STAT cesarean. Verbal consent was obtained because of the emergency situation.

The attending’s first note suggested that when the patient presented to triage, she had complaints of abdominal pain and diarrhea, “since the morning.” On external monitor, the FHR was 130 bpm and the maternal heart rate was also 130 bpm, prompting a sonogram. Because the FHR could not be “determined” a STAT cesarean was initiated.

A male fetus was delivered via cesarean with a birth weight of 2625 g, and Apgar scores of 0 and 0. The hospital’s obstetrical notes reflected that the emergent delivery was performed for fetal bradycardia, with an estimated blood loss of 1000 mL. during cesarean.

**CORRECTION:** Last month’s Legally Speaking column “**Vesicovaginal fistula after laparoscopic hysterectomy**” was written by James M. Shwayder, MD, JD. The editors regret the attribution error.

Contemporaryobgyn.net/VesicovaginalFistula
fFN testing can help rule out
~80% of patients
with symptoms of preterm labor.

~80% Patients receive a negative result

~20% Patients receive a positive result

Benefits of a Negative Result
A negative fFN result means the patient has a <1% chance of delivery in the next 14 days.

High NPV:
NPV for delivery within:

<table>
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<th>7 days</th>
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Useful PPV:
PPV for delivery within:

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<th>7 days</th>
<th>14 days</th>
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<td>12.7%</td>
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Benefits of a Positive Result
A positive result can help clinicians identify patients that may benefit from interventions, such as steroids or maternal transfer.


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**Technology Matters:**
How the Pap Test Protects Your Patients

**Author:**
Darren Wheeler, MD
Regional Medical Director, Anatomic Pathology, West Region
Quest Diagnostics and AmeriPath
Las Vegas, NV

The Pap test is arguably the most significant technological advancement contributing to the decrease in the incidence of cervical cancer in the United States over the past 30 years. But despite its role in reducing this incidence rate, the Pap test does have its limitations. For instance, while Pap screening is very specific, it’s not very sensitive, with reported sensitivities ranging from 20% to 80% depending on the method used.\(^1\)\(^-\)\(^4\) With these drawbacks in mind, improving cervical cancer screening methods has been a main focus so that the progress already achieved in combating one of the leading causes of death among women can continue.

**Improvements in Cervical Cancer Screening and Current Guidelines**

In order to enhance the diagnostic capabilities of the Pap test, new technologies have been developed since its implementation, including the ability to test for human papillomavirus (HPV) and the improvement of the Pap test with the introduction of liquid based cytology and imaging technologies.\(^2\) High-risk HPV testing, which is more sensitive and less specific than cytology at detecting dysplasia or malignancy, has proven to be a useful adjunct to perform with the Pap in certain age groups.\(^5\) Liquid-based cytology has also improved sensitivity of the Pap itself.\(^1\)

As diagnostic accuracy has improved due to these new technologies, so too have cervical cancer screening guidelines undergone numerous revisions to reflect these advancements.

While many screening options are acceptable for women aged 30 to 65, ACOG and other organizations prefer co-testing every 5 years.\(^5\) Cytology alone via Pap testing every 3 years is also acceptable, but co-testing is preferred\(^5\)-\(^7\) since women with a negative cytological screening test and a negative high-risk HPV test are at an extremely low risk of developing CIN2, CIN3, or cancer over the next several years.\(^5\)-\(^7\) Additionally the United States Preventive Services Task Force (USPSTF) recently included HPV screening alone at a 5-year interval as an acceptable option for women aged 30 and above, and societies including SGO, ASCCP, and ACOG have provided interim guidance on the use of HPV screening alone.\(^8\)

**Liquid-Based Cytology: A Key Advancement in Cervical Cancer Screening**

Although both liquid-based and conventional methods of Pap testing are acceptable to use for cervical cancer screening, they are not equal. In response to the poor sensitivities observed with the conventional Pap, the liquid-based collection method was developed.\(^1\) Current liquid-based techniques boast improved sensitivity for the detection of HSIL and LSIL, improved detection of adenocarcinomas, and have the ability to perform out-of-the vial testing, such as co-testing for HPV or sexually transmitted infections without obtaining an additional specimen.\(^1\)
Due to the benefits of this technology, over 90% of Pap tests in the United States are performed using liquid-based cytology over conventional cytology. For both liquid-based and conventional methods, the initial collection is similar. In each case, exfoliated cells are collected from the transformation zone of the cervix using a brush or spatula collection device. In the liquid-based technique, these cells are transferred to a vial of liquid preservative for later processing in a laboratory. In the conventional technique, the cells are transferred directly to a slide and fixed. The poor sensitivities observed with conventional Paps have been largely attributed to sampling errors or inadequate slide preparation. Only a small portion of the sample is actually evaluated, as the majority is discarded with the sampling device. In fact, the amount transferred with conventional cytology varies widely, from just 6.5 up to 62.5%.

To address these shortcomings, the first liquid-based cytology assay, the ThinPrep® Pap test, was approved by the FDA in 1996, and the second liquid-based test, SurePath™, was approved by the FDA in 1999.

Liquid-based cytology represents an improvement over conventional Pap tests in part because it results in homogenous cell sampling during transfer, which can reduce sampling errors and improve specimen quality. This also aids in making slide interpretation easier, whether by a trained pathologist or computer-assisted technology. Additional benefits of liquid-based cytology include immediate fixation, an accurate representation of the entire specimen, decreased obscuring elements, and the ability to produce multiple reproducible slides. This improvement in sensitivity allowed by liquid-based cytology has contributed to extensions of the screening interval from 1 to 3-5 years.

**The Clinical Benefits of the ThinPrep® Pap Test**

ThinPrep®, the first FDA-approved, liquid-based cytology, is the preferred method of testing in the United States, accounting for over 80% of Pap tests performed and over 650 million tests completed globally and is used in over 90% of the Top 50 U.S. Best Hospitals for Gynecology. This technology has been extensively studied in over 170 different clinical trials and has consistently been shown to improve outcomes for women as compared to use of conventional cytology. As reported by the College of American Pathologists, ThinPrep® has resulted in increased HSIL detection, increased LSIL detection, and improved sensitivity for cervical adenocarcinoma when compared to conventional testing methods. This test is also approved for use with several FDA-approved HPV testing methods and numerous sexually transmitted infection tests (Table 1).

ThinPrep® is performed by first obtaining a sample of cells from the patient’s cervix using a broma-type or endocervical brush/plastic spatula combination device. The sampling device is immersed and rinsed in a liquid solution. This sample is then placed into a ThinPrep® cytology processor, which serves to break up mucus, blood, and other debris. The fluid currents are strong in lieu of lubricant, as this has the least risk to the quality of the Pap.

**Tips for Collecting ThinPrep® Samples**

Although ThinPrep® is the superior choice for Pap tests, boasting optimal sensitivity and specificity for the detection of dysplasia and cancer, test accuracy depends on following proper instructions for use. Sampling errors, or false-negative Pap tests that are free of abnormal cells, can occur due to inadequate patient preparation or sampling technique errors. Understanding how to avoid these errors can maximize accuracy and minimize the number of insufficient Pap tests collected.

First, prepare the patient. Patients can be educated over the phone during appointment scheduling or by online alerts when scheduling online. Women should be told the following:

- Abstain from intercourse, douching, tampons, or intravaginal medication for at least 48 hours prior to the examination.
- Do not schedule the Pap during heavy menstrual bleeding.
- Ideally, schedule approximately 2 weeks after the first day of her last menstrual period.

Clinicians need to ensure the specimen is labeled properly so that the specimen is matched with the correct patient. Other relevant history should be obtained and provided to the pathologist, such as prior abnormal Pap tests, previous cervical treatment, current pregnancy, or current hormone use.

When sampling, the clinician should use the approved sampling device provided. ThinPrep® uses a broma-type or endocervical brush/plastic spatula combination collection devices. When inserting the speculum, lukewarm water should be considered

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In the initial collection is similar. In each case, exfoliated cells are collected from the transformation zone of the cervix using a brush or spatula collection device. In the liquid-based technique, these cells are transferred to a vial of liquid preservative for later processing in a laboratory. In the conventional technique, the cells are transferred directly to a slide and fixed. The poor sensitivities observed with conventional Paps have been largely attributed to sampling errors or inadequate slide preparation. Only a small portion of the sample is actually evaluated, as the majority is discarded with the sampling device. In fact, the amount transferred with conventional cytology varies widely, from just 6.5 up to 62.5%.

To address these shortcomings, the first liquid-based cytology assay, the ThinPrep® Pap test, was approved by the FDA in 1996, and the second liquid-based test, SurePath™, was approved by the FDA in 1999.

Liquid-based cytology represents an improvement over conventional Pap tests in part because it results in homogenous cell sampling during transfer, which can reduce sampling errors and improve specimen quality. This also aids in making slide interpretation easier, whether by a trained pathologist or computer-assisted technology. Additional benefits of liquid-based cytology include immediate fixation, an accurate representation of the entire specimen, decreased obscuring elements, and the ability to produce multiple reproducible slides. This improvement in sensitivity allowed by liquid-based cytology has contributed to extensions of the screening interval from 1 to 3-5 years.

**The Clinical Benefits of the ThinPrep® Pap Test**

ThinPrep®, the first FDA-approved, liquid-based cytology, is the preferred method of testing in the United States, accounting for over 80% of Pap tests performed and over 650 million tests completed globally and is used in over 90% of the Top 50 U.S. Best Hospitals for Gynecology. This technology has been extensively studied in over 170 different clinical trials and has consistently been shown to improve outcomes for women as compared to use of conventional cytology. As reported by the College of American Pathologists, ThinPrep® has resulted in increased HSIL detection, increased LSIL detection, and improved sensitivity for cervical adenocarcinoma when compared to conventional testing methods. This test is also approved for use with several FDA-approved HPV testing methods and numerous sexually transmitted infection tests (Table 1).

ThinPrep® is performed by first obtaining a sample of cells from the patient’s cervix using a broma-type or endocervical brush/plastic spatula combination device. The sampling device is immersed and rinsed in a liquid solution. This sample is then placed into a ThinPrep® cytology processor, which serves to break up mucus, blood, and other debris. The fluid currents are strong in lieu of lubricant, as this has the least risk to the quality of the Pap. For this same reason, it’s also recommended that the Pap be performed prior to bimanual examination.

If lubricant is used, the following tips are recommended:

- Lubricant should be using sparingly, using a dime-sized amount, and applied only to the exterior sides of the speculum, avoiding the tip.
- Lubricants containing thickening agents, such as carbomer or Carbopol® polymers, are most likely to interfere with the ThinPrep® Pap and should be avoided.
- Water-based lubrication is preferable.

Prior to obtaining the sample, excessive blood, mucus, or discharge should be blotted from the cervix. The removal should be performed with a folded gauze pad on a ring forceps. The cervix should not be cleaned with saline as this could result in an acellular specimen. If significant inflammation or infection is present, the physician should consider rescheduling the Pap after treatment of the infection. The specimen should be immersed in the liquid medium immediately after sampling.

The liquid medium (PreservCyt Solution) should be stored between 15°C (59°F) and 30°C (86°F). After sampling, the PreservCyt Solution can be stored up to 6 weeks. The clinician should also ensure that the liquid is not expired.

Finally, providers need to remember that HPV testing and sexually transmitted infection screening can be performed using the same vial, with any of the FDA-approved HPV or gonorrhea and chlamydia assays.
enough to separate out the debris, but gentle enough to protect the integrity of the cells. The cells are then collected on a ThinPrep® Pap test filter, which prevents the cells from becoming too scant or too dense. The resulting optimal layer of cells are then transferred to a glass slide, which is then placed into a fixative solution. The slide is then evaluated by a pathologist appropriately trained in the interpretation of ThinPrep® prepared slides.

Compared to SurePath™, the alternate liquid-based cytology method, the use of ThinPrep ensures that virtually 100% of the cervical cellular sample is preserved. With ThinPrep®, the slide is created directly from the PreservCyt solution, with minimal transfer. SurePath™, on the other hand, must be transferred from the initial vial to a separate tube prior to slide preparation. The transfer can result in a loss of up to 33% of epithelial cells, potentially compromising the accuracy of the Pap.

**Improved Detection of Cervical Dysplasia**

When compared to other Pap techniques, the most significant benefit of the ThinPrep® method is the improved detection of cervical dysplasia and malignancy. A prospective, multicenter clinical trial of over 7,000 patients encompassing three screening centers and three hospitals was conducted to compare the ThinPrep® 2000 to the conventional Pap smear. In this trial, the conventional Pap was performed first for each patient and the remaining sample was used for ThinPrep® liquid-based cytology. An independent pathologist then reviewed slides for any discrepant cases. ThinPrep® was found to be just as accurate or more accurate than conventional cytology among all participating sites.

Another multi-site clinical study evaluated ThinPrep® versus conventional Pap for the detection of HSIL and greater sensitivity. Conventional Pap had a detection rate of 511 out of 20,917 compared to 399 out of 10,226 for ThinPrep®, achieving a 59.7% increase in HSIL detection with ThinPrep®. A statistically significant increase in LSIL detection was also achieved.

A New England study revealed that ThinPrep® led to a 71.65% increased detection rate of LSIL and a 102.54% increased detection rate of HSIL when compared to conventional cytology.

Other trials have replicated these findings with liquid-based cytology, achieving improvements of up to 200% or greater in the detection of LSIL and HSIL when compared to conventional cytology. Among 679 laboratories using a combination of conventional and liquid preparations, Eversole et al. observed that the detection rate of both LSIL and HSIL was higher for not only liquid-based cytology in general, but was highest with the ThinPrep® system.

Although it was not a direct comparison, a study of the ProPath database confirmed the superiority of ThinPrep® compared to SurePath™ in the detection of cervical cancer precursors. A 2014 review of over 100,000 Pap specimens in the ProPath database evaluated clients that had switched from SurePath™ testing to ThinPrep®, comparing 2 years of SurePath™ results to 2 years of ThinPrep® results. ThinPrep® testing resulted in a significantly higher rate of HSIL, ASC-HG, and LSIL detection in 16 out of 18 clients. Although no head-to-head comparison was done, both cohorts exhibited similar demographics, and over 90% of specimens were evaluated by the same pathologists.

**Better Adenocarcinoma Detection**

Another area improved by the ThinPrep® technology is that of adenocarcinoma detection. While cervical cancer incidence as a whole has been decreasing since the arrival of the Pap smear, adenocarcinoma has remained a significant concern. Over the past 35 years, the rate of new adenocarcinoma diagnoses has risen by 32.2% in the United States. Traditionally, the conventional Pap was better at diagnosing squamous cell carcinomas due to the ease of sampling the ectocervix compared to the endocervix, but liquid-based cytology—in addition to its superior performance at detecting squamous cell carcinomas and its precursors—is better at identifying glandular abnormalities. ThinPrep® in particular, has been recognized by the FDA for this indication.

Numerous clinical trials have also shown that liquid-based cytology is better at diagnosing adenocarcinoma of the cervix. In 2002, Hecht et al showed that the positive predictive value of AGUS with a ThinPrep® Pap was 22%, compared to just 15% with conventional Pap testing. And Schorge et al showed that the ThinPrep® achieved a 65.2% sensitivity at detecting adenocarcinoma of the cervix, while the sensitivity of conventional Pap reached only 41.5%.
Currently, ThinPrep® is the only Pap test that is FDA-approved for the improved ability to detect cervical glandular disease, compared to conventional Pap methods. ThinPrep® is also endorsed by the Society of Gynecologic Oncology for this indication and is deemed to produce “more reliable results” when it comes to glandular abnormalities.

Fewer Insufficient or Unsatisfactory Results

In addition to improving diagnostic accuracy of cervical dysplasia and malignancy, liquid-based cytology methods such as ThinPrep® offer a decreased number of unsatisfactory Pap results compared to conventional cytology. Aside from the inconvenience of repeating a Pap test, for both patient and provider, insufficient Pap tests worsen clinical outcomes. Unsatisfactory results are associated with up to a 4-fold higher risk for CIN2 or greater when compared to normal Pap test results. Other trials have found that over a quarter of unsatisfactory Pap tests were from patients with a history of previous cervical epithelial abnormalities. Since it has been shown that over 30% of women do not follow up after an insufficient Pap, this has potentially devastating consequences.

The use of ThinPrep® and other liquid cytology methods can reduce the likelihood of unsatisfactory Pap tests. A 2018 study showed that unsatisfactory results occurred with 7.1% of conventional Pap smears, compared with just 1.61% of liquid-based methods. The most common reason for unsatisfactory tests is too few squamous cells. According to Bethesda guidelines, adequate squamous cellularity for conventional smears requires at least 8,000 to 12,000 well-preserved and well-visualized squamous epithelial cells, while for liquid-based tests, that number is only 5,000 cells. Other reasons for unsatisfactory results include an air-drying artifact, which does not occur with liquid-based methods, as well as inadequate patient preparation, sampling technique errors, intermittent shedding of abnormal cells, inflammation, blood, or foreign materials such as lubricant. Improvements in the ease of collection and interpretation of slides with liquid-based cytology result in less sample reprocessing and, by extension, fewer rescheduled patients, which greatly improves patient care.

Enhanced Accuracy with ThinPrep® Digital Imaging

Digital imaging technologies have further advanced the sensitivity and specificity of liquid-based cytology, improving the detection of cervical dysplasia and malignancy. Both ThinPrep® and SurePath™ have developed digital imaging technologies. The ThinPrep Imaging System was approved by the FDA in 2003. Trials have shown that digital imaging modalities can improve the detection of HSIL by up to 38% and LSIL by up to 46% compared to manual screening. A trial of over 50,000 ThinPrep® Pap tests showed that the ThinPrep® Imaging System achieved a significant increase in detecting HSIL and greater lesions when compared to manual screening. After implementation of the ThinPrep® Imaging System, one institution found they achieved a 37% increase in LSIL detection, 42% increase in HSIL detection, and cut their false-negative rate in half. The ThinPrep® Imaging System has also been found to decrease the number of ASCUS results, further decreasing unnecessary follow-up procedures.

Figure 3: ThinPrep® Imaging System Improves LSIL and HSIL Detection
The ThinPrep Pap® imaging system improves detection of both LSIL and HSIL when compared to manual review of specimens, as evidenced by multiple trials.

Figure 4: ThinPrep Pap® Imaging System Reduces Unsatisfactory Paps

Figure 5: ThinPrep Pap® Imaging System Decreases ASCUS results

A 2018 study
Researchers compared over 300,000 co-testing results and found that 76.3% were preceded by a positive HPV result while 83.3% were preceded by a positive cytology result.46

Convenience of ThinPrep®: One Vial Testing for HPV and STIs

In addition to the benefits of improved cervical dysplasia and cervical cancer detection, ThinPrep® has the distinct advantage of being able to use a single specimen for HPV testing and sexually transmitted screening in addition to cytology.5 One sample can be used to test for HPV, using any of the FDA-approved HPV tests, as well as to test for gonorrhea, chlamydia, and trichomonas.5 Not only does this option enable providers to cut supply costs, but it can also help decrease the number of repeat appointments for add-on tests, making it more convenient for both providers and patients.

Conclusion

While the Pap has been instrumental in decreasing the incidence of cervical cancer and its precursors for women around the world, not all Pap testing is created equal. Liquid-based cytology has led to improved detection of dysplasia and cervical malignancy and fewer unsatisfactory or insufficient results. ThinPrep®, the first FDA-approved and most widely used liquid-based cytological testing method, has the additional benefit of being compatible with most approved HPV testing devices and many different STI screening devices. This makes it an optimal cytological choice when performing co-testing for women aged 30 years and above. Even more importantly, the ThinPrep® technology will continue to contribute to the decrease in the incidence of cervical cancer.

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Author Biography
Dr. Darren Wheeler

Dr. Wheeler received his medical degree and completed his residency in Anatomic Pathology at the University of Washington in Seattle and completed a fellowship in Gynecologic Pathology at the Johns Hopkins Hospital in Baltimore, Maryland. Before joining Quest Diagnostics in Las Vegas, he served two years as a consultant for the Gynecologic and Breast Pathology Department at the Armed Forces Institute of Pathology (AFIP) in Washington, D.C. Based on his work there, Dr. Wheeler was the recipient of the Young Investigator Award in 2006 by the International Society of Gynecological Pathologists. He currently serves on multiple speaker bureaus for women’s health pathology-related topics including cervical cancer screening. He continues to perform subspecialty consultation for Quest Diagnostics in Gynecologic and Breast Pathology in Las Vegas and serves as the Regional Medical Director of Anatomic Pathology, overseeing multiple practices for Quest Diagnostics and AmeriPath throughout the Western U.S.

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Integrating Aesthetic Services INTO THE Ob/Gyn Practice
Integrating Aesthetic Services into the Ob/Gyn Practice

The use of radiofrequency or laser energy-based devices is becoming increasingly common in Ob/Gyn practices for a variety of FDA-cleared indications. Some practices, however, are expanding their use of these energy-based devices and providing aesthetic services to their patients as a part of a holistic approach in patient care.

In this supplement, our physician experts talk about how their practices have evolved through the introduction of energy-based devices and why they continue to expand the services they provide.

Contemporary OB/GYN: How would you describe the makeup of your current practice? How has it evolved over the years?

Anne Lord-Tomas, DO, FACOOG: I’m currently owner of a private practice and surgical center along with my husband. Although I am Ob/Gyn certified, I do not practice obstetrics anymore, which seems to be a growing trend for many of us who trained in this specialty. My current practice is a direct patient care model—we are not insurance-based. It’s a much more peaceful, low stress, highly educational way to practice, and we have had success with this business model.

Nancy Carlson, MD, FACOOG: I started my privately-owned gynecology practice in 2003. My gynecology services are insurance-based, and I provide comprehensive women’s health care and outpatient surgery. I began adding medical aesthetic services to my practice in 2004, and my business has evolved into a combination of insurance-based and cash-based services.

Contemporary OB/GYN: When did you initially start exploring the introduction of energy-based aesthetic devices into your practice? What initially drove that decision?

Dr. Lord-Tomas: We started looking into our initial energy-based device about 7 or 8 years ago as we moved into integrating a med-spa to complement our specialty practice. It took a bit of time to get a good feel for what technologies we would need. It’s almost like going to the convenience store to buy a health supplement. There are 50,000 different items on the shelf to choose from, and they all could be good for me, but it’s very confusing and overwhelming to figure out which ones are going to be best. Similarly, when a practitioner is looking into adding a med spa or just broadening their array of services, the options can be overwhelming.

I started by talking to colleagues I knew who had already made the investment in these technologies and observed that they spent time and money training their staff. I started going to different conferences beyond those focused on Ob/Gyn clinical topics—for instance, ones that focused on wellness practices, age management, and cosmetology. Going to those types of conferences allows you not only to think more about what services you may want to integrate but it also allows you to get hands-on exposure to technologies from companies that may not necessarily exhibit at traditional medical conferences. I also did a lot of due diligence in researching which companies seemed to have the soundest foundations, reputation, and stability.

I have been fortunate enough to forge a relationship with the team at Candela as manufacturer of a lot of the technology I’ve acquired. They have been extremely diligent and patient.

PANELISTS

ANNE LORD-TOMAS, DO, FACOOG, is a partner and cofounder of U First Health & Rejuvenation in Fort Myers, FL. She received her medical degree as a Doctor of Osteopathic Medicine from Nova Southeastern University and completed a medical internship and residency in Ob/Gyn at Michigan State University. Dr. Anne is Board Certified in her specialty, and also offers services in Cosmetogynecology, energy-based devices, hormonal restoration and a passion for women’s & couple’s wellness.

NANCY CARLSON, MD, FACOOG, is a board-certified Ob/Gyn and owner of Lumina Med Spa in South Burlington, VT, and Estero, FL. She earned her MD at SUNY Upstate in Syracuse, New York, and completed her residency training at what is now UVM Medical Center in Burlington, Vermont. Dr. Carlson added aesthetic services to her private practice of gynecology in 2004. Both aspects of her practice continue to grow and offer the most current options for women in healthcare and aesthetics.

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with training of everyone on my team, and their representatives have made themselves available to answer any questions we have had. Because of the growth of the aesthetic industry in Ob/Gyn circles, the Candela team has been able to hone their expertise in the field and are able to provide us with better feedback and more in-depth training about the potential use of their technologies.

**Dr. Carlson:** While attending a national meeting of the American College of Obstetricians and Gynecologists meeting in 2004, I met a female physician from New York City who had recently purchased a 1064-nm long-pulsed neodymium-YAG laser for hair removal services in her practice. She encouraged me to explore acquiring a laser for my practice. That’s when I started to consider broadening services for my patients and to incorporate some of these technologies into my practice. I followed her suggestion and attended seminars offered by the manufacturer of her laser. I initiated laser-based services with this company, but have since expanded my equipment and now primarily use Candela technology. I was named a Candela Center of Excellence in October 2018, the third location in the United States to earn this designation.

**Contemporary OB/GYN:** How did you determine that your gynecology patients would be interested in aesthetic services that utilize laser technology?

**Dr. Carlson:** My main practice is located in Vermont, and when I started looking into the acquisition of a laser in 2004, laser hair removal had already become popular among women living in metropolitan areas such as New York and Boston. In my community, there were two providers offering that service, both men. I just took a leap of faith and believed that aesthetic services offered by a female physician would be in demand. I didn’t do any formal surveying of my patients, but I knew through conversations with them that a lot of them were complaining of issues that I would be able to treat with the laser, specifically hair and spider vein removal. It was immediately popular. I almost couldn’t keep up with the initial demand.

**Contemporary OB/GYN:** When you first started providing aesthetic services, how did you build awareness within your practice and the broader community?

**Dr. Lord-Tomas:** That’s a key question because it is not something that comes naturally for a lot of us. The first thing is that you need to be passionate about the technology and truly believe in its ability to change lives. If you are going to be wishy-washy about it, it will be much harder to talk convincingly about the benefits with your patients. Once we found a technology we believed in, our first step was to create a short survey for our current patients. Many companies will help you with that to make sure you are asking the right questions and getting the information you need. So, whenever patients came in for their gynecology exam and were filling out an initial intake form or sitting in the waiting room, we asked them to complete this survey to gauge whether they would be interested in our practice’s new services. This not only built awareness but it also identified those specific patients who would be viable candidates for follow-up.

In my opinion, starting with your in-house patient population is the smartest way to begin because these are people who are already confident in you. You are already taking care of them. Another important step is to use your staff as early beneficiaries of the technology. Not only can these free cosmetic procedures be a fringe benefit of their employment but they will also be able to serve as ambassadors to your patients, telling them, “Hey, I already did this, the results were great, and the recovery was simple.” Again, your patients know and trust your staff, so getting them excited about new technologies can provide an initial boost. None of these efforts cost much, if anything.

When the time comes to try to market your services outside of your current patient population, that’s when you have to do some research into your potential demographic and decide how aggressive you want to be. We have run some newspaper advertisements, renovated our web site, and done some commercials on the Latin Network because of the large Latino population near my practice. Something else that I found helpful was going around to other local physician practices and offering free educational seminars. We even had a couple of seminars at our office after normal working hours, and we served hors d’oeuvres. Doctors, their staff, and motivated patients love to be educated. These seminars have provided a great return on investment for our practice through direct referrals.

**Dr. Carlson:** Physicians typically feel uncomfortable advertising themselves, which is slowly changing, but at the time I acquired my first laser and began offering more aesthetic services, I was cautious about being too visible to the general public. I relied instead on subtle techniques like brochures in the waiting room, along with a few open houses and educational seminars, but the growth was really driven by word of mouth. That may not have worked in a larger metropolitan area, but because my main practice is located in a smaller geographic area, I was able to rely on my current gynecology patients to spread the word. I also surveyed the initial patients who came to my practice for aesthetic laser services to find out how they heard about it. The majority of them came via referral from a friend or other physician.

**Contemporary OB/GYN:** How has the use of laser technologies in your practice evolved over time?

**Dr. Carlson:** It has been a slow build. I didn’t rush out and spend a lot of money on new equipment all at once. Many gynecology patients have asked me to add specific services over the years with questions such as “Can you remove this brown spot?” or “Can you take care of my large pores?” So, I have listened to their requests, considered the overall need, and then added technologies and services accordingly. What has perhaps been a little unique in my practice is that initially
I was personally the one who provided all new services. I think that helped build trust, because it was frequently my regular gynecology patients who were coming in for these additional procedures and they could see that I believed in these services. I think that legitimized services more than if I had delegated these procedures to other staff from the beginning.

What also helped is that the initial platform I selected was a versatile laser system to which I could add different forms of energy therefore expanding my services. Consequently, it didn’t require a purchase of additional equipment every time I wanted to introduce a new service to my patients. As demand for some of these procedures grew and I added additional services, I was able to hire and train staff to ease the demand and allow me to continue to see and treat my gynecology patients.

Currently, in addition to a team of fulltime aestheticians, I have a nurse practitioner who is also a certified nurse midwife and provides gynecology services to patients. I employ two medical assistants, a wellness counselor, and a massage therapist. Importantly, everyone on my team provides 360-degree support to the practice. Everyone is knowledgeable about all of the procedures we offer, can talk intelligently about them to patients and schedule efficiently. Despite the shift in the overall focus of the practice, my professional time is still spent primarily on gynecologic services.

**Key Takeaways**

Integrating the first energy-based device into your Ob/Gyn practice:

- Thoroughly research services offered by other providers in your area
- Choose a device and a company that have been strong reputation and successful track record
- Choose a device that is FDA cleared for a variety of indications
- Ensure that the device manufacturer provides robust customer support that is included as part of the device purchase
- Start small by offering 1 or 2 basic procedures that fit with the overall demographic of your practice
- Educate your entire staff about any new services being offered so they can speak knowledgeably to patients
- Develop a comprehensive marketing campaign to reach potential customers outside of your current patient roster
- Believe in the device and the procedures you are offering
- Be the expert in what you offer

which devices offer the best safety profile, will be easiest for you and your staff to use, and offer the best customer support. Don’t underestimate the value of the manufacturer’s company representatives and their availability and consistency. When you are considering your first purchase of an energy-based device, I recommend looking for a technology and a company that has demonstrated success over time and offers a multitude of services and devices. For me, Candela has been that company, and their support of my practice has enabled me to remain current and successful.

**Contemporary OB/GYN: What advice would you offer to peers who are thinking about integrating an energy-based device into their practice but remain reticent about making that leap?**

**Dr. Lord-Tomas:** The time for lasers has come. The predictability of the results has really improved over the last few years. This is no longer new technology, and the applications and indications keep increasing and results keep improving. There should no longer be anything scary or intimidating about the technology. It’s just a matter of deciding which applications you should focus on based on the needs of your practice.

As Ob/Gyns, we’re already treating patients who want these services. By acquiring an energy-based device and expanding your practice, you are going to fill a need and prevent possible leakage of your patients to other nearby practices that already offer these services. Incorporating one or more energy-based devices isn’t as intimidating as it used to be perhaps 10 years ago. The technology and manufacturer support is so strong, and recouping the initial investment often takes only a few months.

There is a lot of talk at medical conferences about “physician burnout.” With the stress related to insurance battles and administrative paperwork, providing aesthetic services can ease those burdens and provide a predictable and reliable additional revenue stream that can also energize your staff and revitalize your practice.

**Dr. Carlson:** When I first investigated acquiring an energy-based device for my practice, the marketplace was diverse with several companies from which to choose. Currently, post-consolidation of smaller companies, there are a handful of leaders that each offer an array of reliable devices. It is a matter of doing research and evaluating...

**Contemporary OB/GYN: This has been a terrific discussion, and we want to thank both of you for your insights. I hope that our audience is able to take away some helpful information from our discussion as they consider the future evolution of their professional practice in regard to providing aesthetic services.**

**REFERENCE**