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Robert L. Barbieri, MD

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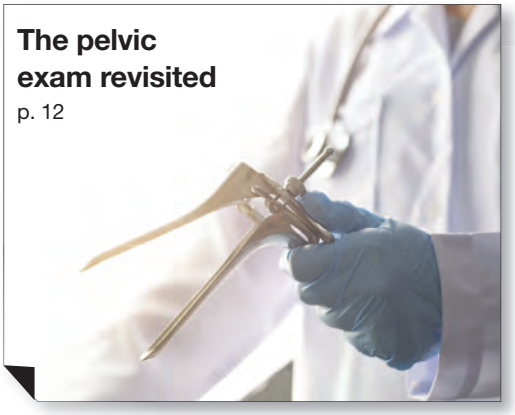

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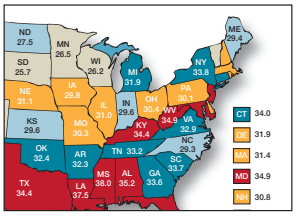

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FROM ENDOMETRIOSIS JOURNEY

Pathogenesis

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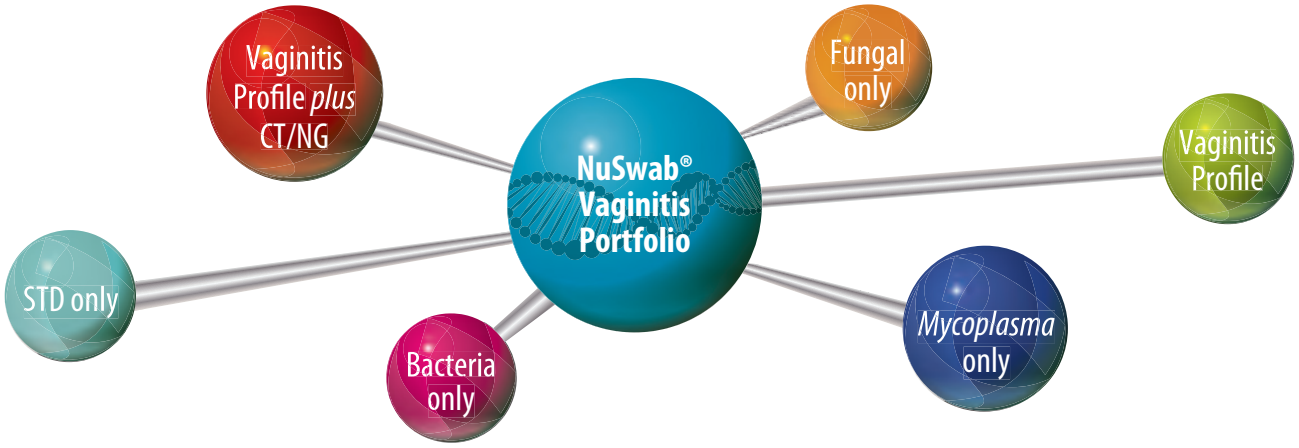

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- shown to be more sensitive than culture, microscopy, and Affirm™ VPIII[7]
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For the management of labor, patience is a virtue

Start using the ACOG/SMFM labor management guidelines in your practice

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During the past 45 years, the cesarean delivery (CD) rate in the United States has increased from 5.5% in 1970 to 33% from 2009 to 2013, followed by a small decrease to 32% in 2014 and 2015.[1] Many clinical problems cause clinicians and patients to decide that CD is an optimal birth route, including: abnormal labor progress, abnormal or indeterminate fetal heart rate pattern, breech presentation, multiple gestation, macrosomia, placental and cord abnormalities, preeclampsia, prior uterine surgery, and prior CD.[2] Recent secular trends that contribute to the current rate of CD include an adversarial liability environment,[3,4] increasing rates of maternal obesity,[5] and widespread use of continuous fetal-heart monitoring during labor.[6]

Wide variation in CD rate has been reported among countries, states, and hospitals. The variation is due, in part, to different perspectives about balancing the harms and benefits of vaginal delivery versus CD. In Europe, in 2010 the CD rates in Sweden and Italy were 17.1% and 38%, respectively.[7] In 2010, among the states, Alaska had the lowest rate of CD at 22% and Kentucky had the highest rate at 40%.[8] In 2015, the highest rate was 38%, in Mississippi (**FIGURE**).[9] In 2014, among Massachusetts hospitals with more than 2,500 births, the CD rate ranged from a low of 22% to a high of 37%.[10]

Clinicians, patients, policy experts, and the media are perplexed and troubled by the "high" US CD rate and the major variation in rate among countries, states, and hospitals. Labor management practices likely influence the rate of CD and diverse approaches to labor management likely account for the wide variation in CD rates.

A nationwide effort to standardize and continuously improve labor management might result in a decrease in the CD rate. Building on this opportunity, the American College of Obstetricians and Gynecologists (ACOG) and the Society of Maternal-Fetal Medicine (SMFM) have jointly recommended new labor management guidelines that may reduce the primary CD rate.[8]

The ACOG/SMFM guidelines encourage obstetricians to extend the time for labor progress in both the 1st and 2nd stages prior to recommending a CD.[8] These new guidelines emphasize that for a modern obstetrician, **patience is a virtue**. There are 2 important caveats to this statement: to safely extend the length of time of labor requires both (1) a reassuring fetal heart rate tracing and (2) stable maternal health. If the fetus demonstrates a persistent worrisome Category II or a Category III heart-rate tracing, decisive intervention is necessary and permitting an extended labor would not be optimal. Similarly, if the mother has rapidly worsening preeclampsia it may not be wise to extend an induction of labor (IOL) over many days.

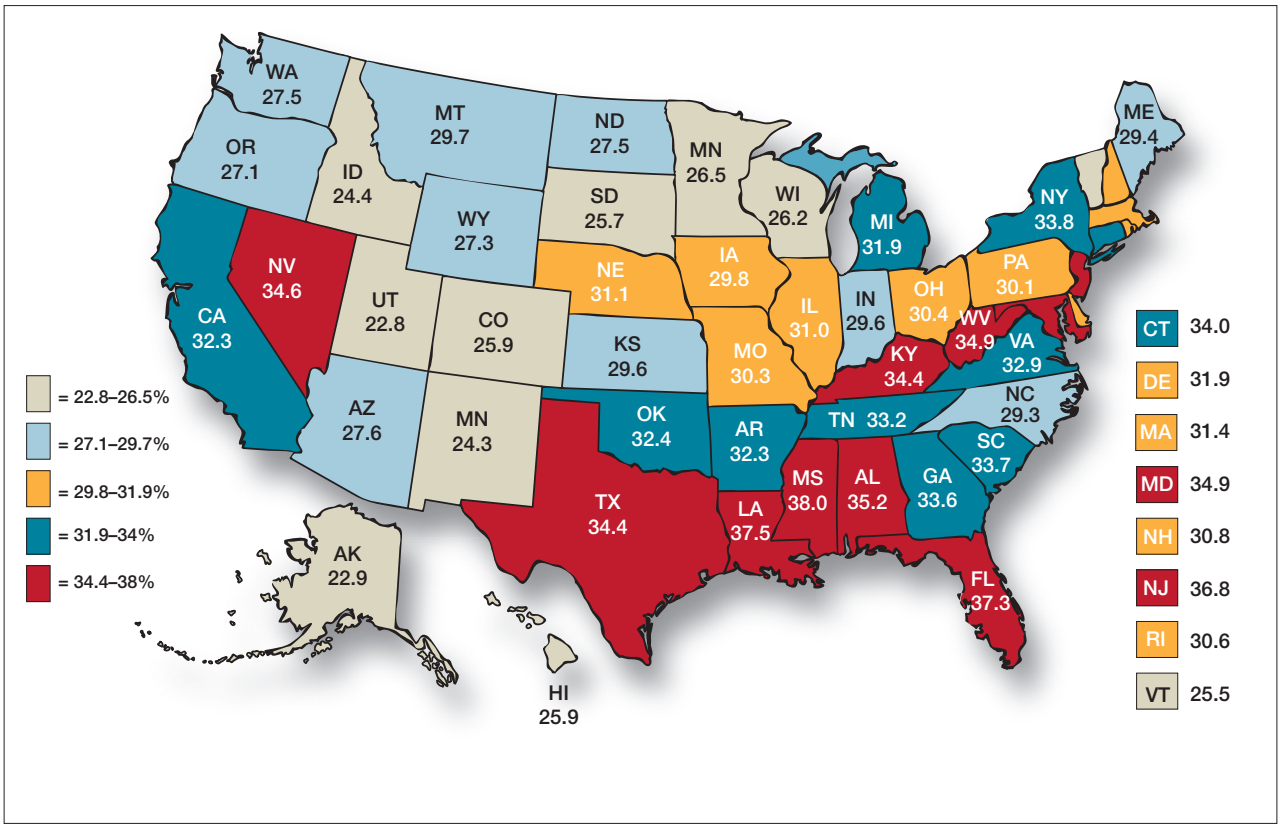
There are risks with extending the length of labor. An extended duration of the 1st stage of labor is associated with an increased rate of maternal

Instant Poll

Will you begin using the ACOG/SMFM labor management guidelines in your practice?

Tell us at **rbarbieri@frontlinemedcom.com** Please include your name and city and state.

FIGURE **US total cesarean delivery rates by state, 2015**[9]



chorioamnionitis and shoulder dystocia at birth.[11] An extended duration of the 2nd stage of labor is associated with an increase in the rate of maternal chorioamnionitis, anal sphincter injury, uterine atony, and neonatal admission to an intensive care unit.[12] Clinicians who adopt practices that permit an extended length of labor must weigh the benefits of avoiding a CD against these maternal and fetal complications.

Active phase redefined

Central to the ACOG/SMFM guidelines is a new definition of the active phase of labor. The research of Dr. Emmanuel Friedman indicated that at approximately 4 cm of cervical dilation many women in labor transition from the latent phase, a time of slow change in cervical dilation, to the active phase, a time of more rapid change in cervical dilation.[13,14] However, more recent research indicates that the transition between the latent and active phase is difficult to precisely define, but more often occurs at about 6 cm of cervical dilation and not 4 cm of dilation.[15] Adopting these new norms means that laboring women will spend much more time in the latent phase, a phase of labor in which patience is a virtue.

The ACOG/SMFM guidelines

Main takeaways from the ACOG/SMFM guidelines are summarized below. Interventions that address common obstetric issues and labor abnormalities are outlined in the box on page 9.

Do not perform CD for a prolonged latent phase of labor, defined as regular contractions of >20 hours duration in nulliparous women and >14 hours duration in multiparous women. Patience with a prolonged latent phase will be rewarded by the majority of women entering the active phase of labor. Alternatively, if appropriate, cervical ripening followed by oxytocin IOL and amniotomy will help the patient with a prolonged latent phase to enter the active phase of labor.[16]

For women with an unfavorable cervix as assessed by the Bishop score, cervical ripening should be performed prior to IOL. Use of cervical ripening prior to IOL increases the chance of achieving vaginal delivery within 24 hours and

may result in a modest decrease in the rate of CD.[17,18]

Failed IOL in the latent phase should only be diagnosed following 12 to 18 hours of both ruptured membranes and adequate contractions stimulated with oxytocin. The key ingredients for the successful management of the latent phase of labor are patience, oxytocin, and amniotomy.[16]

CD for the indication of active phase arrest requires cervical dilation ≥6 cm with ruptured membranes and no change in cervical dilation for ≥4 hours of adequate uterine activity. In the past, most obstetricians defined active phase arrest, a potential indication for CD, as the absence of cervical change for 2 or more hours in the presence of adequate uterine contractions and cervical dilation of at least 4 cm. Given the new definition of active phase arrest, slow but progressive progress in the 1st stage of labor is not an indication for CD.[11,19]

"A specific absolute maximum length of time spent in the 2nd stage beyond which all women should be offered an operative delivery has not been identified."[8] Diagnosis of arrest of labor in the 2nd stage may be considered after at least 2 hours of pushing in multiparous women and 3 hours of pushing in nulliparous women, especially if no fetal descent is occurring. The guidelines also state "longer durations may be appropriate on an individualized basis (eg, with use of epidural analgesia or with fetal malposition)" as long as fetal descent is observed.

Patience is a virtue, especially in the management of the 2nd stage of labor. Extending the 2nd stage up to 4 hours appears to be reasonably safe if the fetal status is reassuring and the mother is physiologically stable. In a study from San Francisco of 42,268 births with **normal newborn outcomes**, the 95th percentile for the length of the 2nd stage of labor for nulliparous women was 3.3 hours without an epidural and 5.6 hours with an epidural.[20]

In a study of 53,285 births, longer duration of pushing was associated with a small increase in the rate of neonatal adverse outcomes. In nulliparous women the rate of adverse neonatal outcomes increased from 1.3% with less than 60 minutes of pushing to 2.4% with greater than 240 minutes of pushing. Remarkably, even after 4 hours of pushing, 78% of nulliparous women who continued to push had a vaginal delivery.[21] In this study, among nulliparous women the rate of anal sphincter injury increased from 5% with less than 60 minutes of pushing to 16% with greater than 240 minutes of pushing, and the rate of postpartum hemorrhage increased from 1% with less than 60 minutes of pushing to 3.3% with greater than 240 minutes of pushing.

I am not enthusiastic about patiently watching a labor extend into the 5th hour of the 2nd stage, especially if the fetus is at +2 station or lower. In a nulliparous woman, after 4 hours of managing the 2nd stage of labor, my patience is exhausted and I am inclined to identify a clear plan for delivery, either by enhanced labor coaching, operative vaginal delivery, or CD.

Operative vaginal delivery in the 2nd stage of labor is an acceptable alternative to CD. The rate of operative vaginal delivery in the United States has declined over the past 2 decades (**TABLE**). In Sweden in 2010 the operative vaginal delivery rate was 7.6% with a CD rate of 17.1%.[7] In the United States in 2010 the operative delivery rate was 3.6%, and the CD rate was 33%.[1] A renewed focus on operative vaginal delivery with ongoing training and team simulation for the procedure would increase our use of operative delivery and decrease the overall rate of CD.

TABLE Percent of live births delivered by forceps or vacuum in the United States in 2015[1]

Year	Forceps	Vacuum
1995	3.48%	5.90%
2000	2.07%	4.85%
2005	0.93%	3.87%
2010	0.66%	2.96%
2015	0.56%	2.58%

Encourage the detection of persistent fetal occiput posterior position by physical examination and/or ultrasound and consider manual rotation of the fetal occiput from the posterior to anterior position in the 2nd stage. Persistent occiput posterior is the most common fetal malposition.[22] This malposition is associated with an increased rate of CD.[23] There are few randomized trials of manual rotation of the fetal occiput from posterior to anterior position in the 2nd stage of labor, and the evidence is insufficient to determine the efficacy of manual rotation.[24] Small nonrandomized studies report that manual rotation of the occiput from posterior to anterior position may reduce the CD rate.[25–27]

For persistent 2nd stage fetal occiput posterior position in a woman with an adequate pelvis,

Interventions to reduce the cesarean delivery rate

Labor is often associated with clinical conditions that increase the risk of cesarean delivery. Potential interventions that may reduce the cesarean delivery rate are summarized below.

Obstetric condition	Potential interventions to reduce the cesarean delivery rate
Abnormal labor progress- **Prolonged latent phase**	• Supportive counseling and patience[1] • Therapeutic rest with morphine[2,3] • Induction of labor[4]
Abnormal labor progress- **Active phase and second stage abnormalities**	• Patience with labor progress in the 1st and 2nd stage[4] • Expertise with operative vaginal delivery to complete the 2nd stage of labor[4] • Manual rotation of the occiput for the fetus with a persistent occiput posterior position in the 2nd stage[4]
Abnormal or indeterminate fetal heart-rate (FHR) pattern	• Fetal scalp stimulation as an adjunctive measure to assess fetal status[5] • Interventions to resolve abnormal or indeterminate FHR patterns: discontinue oxytocin infusion, change maternal position, amnioinfusion for recurrent variable decelerations[a] and/or administration of a tocolytic for uterine tachysystole[4]
Fetal breech presentation	• External cephalic version[6,a]
Multiple gestation	• Recommend fertility treatments that reduce the rate of multiple gestation, including single embryo transfer in in vitro fertilization[7,a] • Encourage vaginal delivery for twin pregnancies when the presenting twin is vertex[8,9,a]
Gestational age ≥41 weeks	• Induction of labor at 41 weeks' gestation compared with expectant management increases the rate of vaginal delivery[10,a]
Trial of labor after cesarean (TOLAC)	• Develop maternity care systems that encourage the use of TOLAC.[11] TOLAC may increase rate of vaginal delivery with a small increase in neonatal morbidity.

[a]Recommendation based, in part, on data from randomized clinical trials.

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where manual rotation was not successful and the fetus is at +2 station or below, operative vaginal delivery is an option. "Vacuum or forceps?" and "If forceps, to rotate or not to rotate?" those are the clinical questions. Forceps delivery is more likely to be successful than vacuum delivery.[28] Direct forceps delivery of the occiput posterior fetus is associated with more anal sphincter injuries than forceps delivery after successful rotation, but few clinicians regularly perform rotational forceps.[29] In a study of 2,351 women in the 2nd stage of labor with the fetus at +2 station or below, compared with either forceps or vacuum delivery, CD was associated with more maternal infections and fewer perineal lacerations. Neonatal composite morbidity was not significantly different among the 3 routes of operative delivery.[30]

Amnioinfusion for repetitive variable decelerations of the fetal heart rate may reduce the risk of CD for an indeterminate fetal heart-rate pattern.[31]

IOL in a well-dated pregnancy at 41 weeks will reduce the risk of CD. In a large clinical trial, 3,407 women at 41 weeks of gestation were randomly assigned to IOL or expectant management. The rate of CD was significantly lower in the women assigned to IOL compared with expectant management (21% vs 25%, respectively; $P = .03$).[32] The rate of neonatal morbidity was similar in the 2 groups.

Women with twin gestations and the first twin in a cephalic presentation may elect vaginal delivery. In a large clinical trial, 1,398 women with a twin gestation and the first twin in a cephalic presentation were randomly assigned to planned vaginal delivery (with cesarean only if necessary) or planned CD.[33] The rate of CD was 44% and 91% for the women in the planned-vaginal and planned-cesarean groups, respectively. There was no significant difference in composite fetal or neonatal death or serious morbidity. The authors concluded that, for twin pregnancy with the presenting twin in the cephalic presentation, there were no demonstrated benefits of planned CD.

Develop maternity care systems that encourage the use of trial of labor after cesarean (TOLAC). The ACOG/SMFM guidelines focus on interventions to reduce the rate of primary CD and do not address the role of TOLAC in reducing CD rates. There are little data from clinical trials to assess the benefits and harms from TOLAC versus scheduled repeat CD.[34] However, our experience with TOLAC in the 1990s strongly suggests that encouraging TOLAC will decrease the rate of CD. In 1996 the US rate of vaginal birth after cesarean (VBAC) peaked at 28%, and the rate of CD achieved a recent historic nadir of 21%. Growing concerns that TOLAC occasionally results in fetal harm was followed by a decrease in the VBAC rate to 12% in 2015.[1] A recent study of obstetric practices in countries with high and low VBAC rates concluded that patient and clinician commitment and comfort with prioritizing TOLAC over scheduled repeat CD greatly influenced the VBAC rate.[35]

Labor management is an art

During labor obstetricians must balance the unique needs of mother and fetus, which requires great clinical skill and patience. Evolving concepts of normal labor progress necessitate that we change our expectations concerning the acceptable rate of progress in the 1st and 2nd stage of labor. Consistent application of these new labor guidelines may help to reduce the rate of CD.

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The pelvic exam revisited

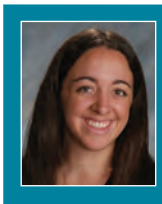
The USPSTF says there is not enough evidence to assess the benefits and harms of the routine screening pelvic exam. These experts say that ObGyns should renew their commitment to individualized well-woman care and shared decision making.

Erin Higgins, MD, and Cheryl B. Iglesia, MD

IN THIS ARTICLE

More than 44 million pelvic examinations are performed annually in the United States.[1] In March 2017, the United States Preventive Services Task Force (USPSTF) published an updated recommendation statement regarding the need for routine screening pelvic examinations in asymptomatic adult women (18 years and older) receiving primary care: "The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of performing screening pelvic examinations in asymptomatic, nonpregnant adult women."[2]

That statement, however, was assigned a grade of I, which means that evidence is lacking, of poor quality, or conflicting, and that the balance of benefits and harms cannot be determined. This USPSTF recommendation statement thus will not change practice for ObGyn providers but likely will renew our commitment to provide individualized well-woman care. There was inadequate or poor quality evidence for benefits related to all-cause mortality, disease-specific morbidity, and quality of life, as well as inadequate evidence on harms related to false-positive findings and anxiety stemming from screening pelvic exams.



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Interpreting the new USPSTF statement

We understand the USPSTF statement to mean that pelvic exams should *not* be abandoned, but rather should be individualized to each patient for her specific visit. We agree that for visits focused on counseling and routine screening in asymptomatic, nonpregnant women, pelvic exams likely will not increase the early detection and treatment of disease and more benefit likely would be derived by performing and discussing evidence-based and age-appropriate health services. A classic example would be for initiation or maintenance of oral contraception in an 18-year-old patient for whom an exam could cause unnecessary trauma, pain, or psychological distress leading to future avoidance or barriers to seeking health care. For long-acting

The pelvic examination and insurance coverage

Melanie Witt, RN, MA

Coding and billing for the care provided at a well-woman visit can be uncomplicated if you know the right codes for the right program. The information presented here concerns straightforward preventive care and assumes that the patient also has not presented with a significant problem at the same visit.

First, a patient who is not Medicare-eligible might have insurance coverage for an annual preventive care examination every year. Normally, this service would be billed using the *Current Procedural Terminology* (CPT) preventive medicine codes, but some insurers require the use of special codes for an annual gynecologic exam. These special codes are:

- **S0610**, *Annual gynecological examination, new patient*
- **S0612**, *Annual gynecological examination, established patient*
- **S0613**, *Annual gynecological examination; clinical breast examination without pelvic evaluation.*

Notably, Aetna, Cigna, and UnitedHealthcare require these codes to signify that a pelvic examination has been performed (except for code **S0613**), but many Blue Cross Blue Shield programs, for whom these codes were originally created, are now reverting to the CPT preventive medicine codes for all preventive care.

CPT outlines the requirements for use of the preventive medicine codes as: an initial or periodic comprehensive preventive medicine evaluation or reevaluation and management (E/M) service, which includes an age- and gender-appropriate history, examination, counseling/anticipatory guidance/risk factor reduction interventions, and the ordering of laboratory/diagnostic procedures. The codes are divided into new or established patient categories by age range as follows:

New patient	
CPT code	**Age range, years**
99385	18–39
99386	40–64
99387	65 or older
Established patient	
99395	18–39
99396	40–64
99397	65 or older

The Medicare E/M documentation guidelines do not apply to preventive services, and a head-to-toe examination also is not required. CPT recognizes the American College of Obstetricians and Gynecologists (ACOG) as an authoritative body to make recommendations for the expected preventive service for women, and if such a service is provided and documented, the preventive care codes are to be reported. The payers who use the S codes for a gynecologic exam will require that a pelvic examination has been performed, but such an examination would not be required when using the CPT codes or ACOG's guidelines if the physician and patient agreed that such an exam was not warranted every year. The other components of a preventive service applicable to the female patient's age, however, should be documented in order to report the CPT codes for preventive medicine services.

If a pelvic examination is not performed, say because the patient is young and not sexually active, but an examination of other areas is carried out, the diagnosis code would change from **Z01.411**, *Encounter for gynecological examination (general) (routine) with abnormal findings,* or **Z01.419**, *Encounter for gynecological examination (general) (routine) without abnormal findings, to a general health exam:* **Z00.00**, *Encounter for general adult medical examination without abnormal findings,* or **Z00.01**, *Encounter for general adult medical examination with abnormal findings.*

What about Medicare?

Medicare requirements are somewhat different. First, Medicare covers only a small portion of the preventive care service; that is, it covers a physical examination of the genital organs and breasts and the collection and conveyance of a Pap specimen to the laboratory every 2 years for a low-risk patient. Second, the codes required to get reimbursed for the examination are:

- **G0101**, *Cervical or vaginal cancer screening; pelvic and clinical breast examination*
- **Q0091**, *Screening Papanicolaou smear; obtaining, preparing, and conveyance of cervical or vaginal smear to laboratory.*

It is not necessary to perform both of these services every 2 years (for instance, the patient may not need a Pap smear every 2 years based on her age and history), but the benefit is available if the service is performed. If the woman is at high risk for developing cervical or vaginal cancer, Medicare will cover this portion of the encounter every year so long as the Medicare-defined criteria for high risk have been documented at the time of the exam.

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The author reports no financial relationships relevant to this article.

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The pediatric and adolescent gynecologist perspective

Roshanak Mansouri Zinn, MD, and Rebekah L. Williams, MD, MS

No literature addresses the utility of screening pelvic examination in the pediatric and adolescent population. According to the American College of Obstetricians and Gynecologists Committee on Adolescent Health Care opinion on the initial reproductive health visit for screening and preventive reproductive health care (reaffirmed in 2016), a screening internal exam is not necessary, but an external genital exam may be indicated and may vary depending on the patient's concerns and prior clinical encounters.[1] The American Academy of Pediatrics promotes annual screening external genital examination for all female patients as part of routine primary care, with internal examinations only as indicated.[2]

Age-appropriate pelvic examination for girls and nonsexually active adolescents usually is limited to an external genital exam to evaluate the anatomy and note the sexual maturity rating (Tanner stage), an important indicator of normal pubertal development. As in adults, the potential benefits of screening examination in this population include detection of benign gynecologic conditions (including vulvar skin conditions and abnormalities of hymenal or vaginal development). Additionally, early reproductive health visits are an important time for clinicians to build rapport with younger patients and to provide anticipatory education on menstruation, hygiene, and anatomy. These visits can destigmatize and demystify the pelvic examination and help young women seek care more appropriately and more comfortably if problems do arise.

Even when a pelvic exam is indicated, a patient's young age can give providers pause as to what type of exam to perform. Patients with vulvovaginal symptoms, abnormal vaginal bleeding, vaginal discharge, or pelvic or abdominal pain should receive complete evaluation with external genital examination. If external vaginal examination does not allow for complete assessment of the problem, the patient and provider can assess the likelihood of her tolerating an internal exam in the clinic versus undergoing vaginoscopy under sedation. Limited laboratory evaluation and transabdominal pelvic ultrasonography may provide sufficient information for appropriate clinical decision making and management without internal examination. If symptoms persist or do not respond to first-line treatment, an internal exam should be performed.

Patients of any age may experience anxiety or physical discomfort or may even delay or avoid seeking care because of fear of a pelvic exam. However, providers of reproductive health care for children and adolescents can offer early education, reassurance, and a more comfortable experience when pelvic examination is necessary in this population.

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reversible contraception placement, however, a pelvic exam clearly would be necessary for insertion of an intrauterine device.

Indications for pelvic examination

Remember that the pelvic examination has 3 distinct parts (and that not all parts need to be routinely conducted)[3]:

- general inspection of the external genitalia and vulva
- speculum examination and evaluation of the vagina and cervix
- bimanual examination with possible recto-vaginal examination in age-appropriate or symptomatic women.

According to the Well-Woman Task Force

of the American College of Obstetricians and Gynecologists (ACOG), "For women 21 years and older, external exam may be performed annually and that inclusion of speculum examination, bimanual examination, or both in otherwise healthy women should be a shared, informed decision between patient and provider."[4]

Indications for performing certain parts of the pelvic exam include[4]:

- routine screening for cervical cancer (Pap test)
- routine screening for gonorrhea, chlamydia infection, and other sexually transmitted infections
- evaluation of abnormal vaginal discharge
- evaluation of abnormal bleeding, pelvic pain, and pelvic floor disorders, such as prolapse, urinary incontinence, and accidental bowel leakage
- evaluation of menopausal symptoms, such as dryness, dyspareunia, and the genitourinary syndrome of menopause
- evaluation of women at increased risk for gynecologic malignancy, such as women with known hereditary breast–ovarian cancer syndromes.

In 2016, ACOG launched the Women's Preventive Services Initiative (WPSI) in conjunction with the Health Resources and Services Administration (HRSA) of the US Department of Health and Human Services. In this 5-year collaboration, the agencies are endeavoring to review and update the recommendations for women's preventive health care services, including well-woman visits, human papillomavirus testing, and contraception, among many others.[5] Once the HRSA adopts these recommendations, women will be able to access comprehensive preventive health services without incurring any out-of-pocket expenses.

How will the USPSTF statement affect practice?

In an editorial in the *Journal of the American Medical Association* commenting on the

USPSTF statement, McNicholas and Peipert stated, "Based on the recommendation from the task force, clinicians may ask whether the pelvic examination should be abandoned. The answer is not found in this recommendation statement, but instead in a renewed commitment to shared decision making."[6] We wholeheartedly agree with this statement. The health care provider and the patient should make the decision, taking into consideration the patient's risk factors for gynecologic cancers and other conditions, her personal preferences, and her overall values.

This new USPSTF recommendation statement will not change how we currently practice, and the statement's grade I rating should not impact insurance coverage for pelvic exams. Additionally, further research is needed to better elucidate the role of the pelvic exam at well-woman visits, with hopes of obtaining more precise guidelines from the USPSTF and ACOG.

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CONTRACEPTION

Adopting the "opportunistic salpingectomy philosophy" for benign hysterectomies has been fairly easy for ObGyns, but what about for permanent contraception? Is it time to advocate for this global practice?

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According to the most recent data (2011–2013), 62% of women of childbearing age (15–44 years) use some method of contraception. Of these "contracepting" women, about 25% reported relying on permanent contraception, making it one of the most common methods of contraception used by women in the United States (**FIGURE 1,** page 18).[1,2] Women either can choose to have a permanent contraception procedure performed immediately postpartum, which occurs after approximately 9% of all hospital deliveries in the United States,[3] or at a time separate from pregnancy.

The most common methods of permanent contraception include partial salpingectomy at the time of cesarean delivery or within 24 hours after vaginal delivery and laparoscopic occlusive procedures at a time unrelated to the postpartum period.[3] Hysteroscopic occlusion of the tubal ostia is a newer option, introduced in 2002; its worldwide use is concentrated in the United States, which accounts for 80% of sales based on revenue.[4]

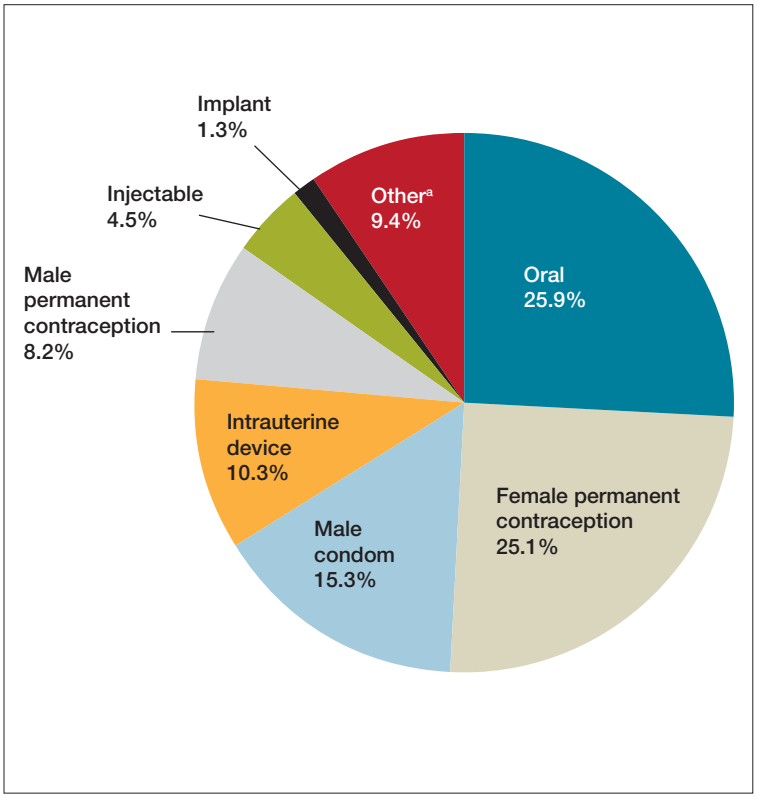
Historically, for procedures remote from pregnancy, the laparoscopic approach evolved with less sophisticated laparoscopic equipment and limited visualization, which resulted in efficiency and safety being the primary goals of the procedure.[5] Accordingly, rapid occlusive procedures were commonplace. However, advancement of laparoscopic technology related to insufflation systems, surgical equipment, and video capabilities did not change this practice.

Recent literature has suggested that complete fallopian tube removal provides additional benefits. With increasing knowledge about the origin of ovarian cancer, as well as increasing data to support the hypothesis that complete tubal excision results in increased ovarian cancer protection when compared with occlusive or partial salpingectomies, both the American College of Obstetricians and Gynecologists (ACOG)[6] and the Society of Gynecologic Oncology (SGO)[7] recommend discussing bilateral total salpingectomy with patients desiring permanent contraception. Although occlusive procedures decrease a woman's lifetime risk of ovarian cancer by 24% to 34%,[8,9] total salpingectomy likely reduces this risk by 49% to 65%.[10,11]

With this new evidence, McAlpine and colleagues initiated an educational campaign, targeting all ObGyns in British Columbia, which outlined the role of the fallopian tube in ovarian cancer and urged the consideration of total salpingectomy for permanent

IN THIS ARTICLE

FIGURE 1 **Percent distribution of contracepting women by type of method: United States, 2011–2013**[1,2]



[a]Other includes withdrawal (4.8%), hormonal ring or patch (2.6%), and "other" (2.0%).

contraception in place of occlusive or partial salpingectomy procedures. They found that this one-time targeted education increased the use of total salpingectomy for permanent contraception from 0.5% at 2 years before the intervention to 33.3% by 2 years afterwards.[12] On average, laparoscopic bilateral salpingectomy took 10 minutes longer to complete than occlusive procedures. Most importantly, they found no significant differences in complication rates, including hospital readmissions or blood transfusions.

Although our community can be applauded for the rapid uptake of concomitant bilateral salpingectomy at the time of benign hysterectomy,[12,13] offering total salpingectomy for permanent contraception is far from common practice. Similarly, while multiple studies have been published to support the practice of opportunistic salpingectomy at the time of hysterectomy, little has been published about the use of bilateral salpingectomy for permanent contraception until this past year.

In this article, we review some of the first publications to focus specifically on the feasibility and safety profile of performing either immediate postpartum total salpingectomy or interval total salpingectomy in women desiring permanent contraception.

Stop using the term "sterilization"

Family Planning experts are now strongly discouraging the use of terms like "sterilization," "permanent sterilization," and "tubal ligation" due to sterilization abuses that affected vulnerable and marginalized populations in the United States during the early- to mid-20th century.

In 1907, Indiana was the first state to enact a eugenics-based permanent sterilization law, which initiated an aggressive eugenics movement across the United States. This movement lasted for approximately 70 years and resulted in the sterilization of more than 60,000 women, men, and children against their will or without their knowledge. One of the major contributors to this movement was the state of California, which sterilized more than 20,000 women, men, and children.

They defined sterilization as a prophylactic measure that could simultaneously defend public health, preserve precious fiscal resources, and mitigate menace of the "unfit and feebleminded." The US eugenics movement even inspired Hitler and the Nazi eugenics movement in Germany.

Because of these reproductive rights atrocities, a large counter movement to protect the rights of women, men, and children resulted in the creation of the Medicaid permanent sterilization consents that we still use today. Although some experts question whether the current Medicaid protective policy should be reevaluated, many are focused on the use of less offensive language when discussing the topic.

Current recommendations are to use the phrase "permanent contraception" or simply refer to the procedure name (salpingectomy, vasectomy, tubal occlusion, etc.) to move away from the connection to the eugenics movement.

Total salpingectomy: A viable option for permanent contraception after vaginal or at cesarean delivery

Shinar S, Blecher Y, Alpern S, et al. Total bilateral salpingectomy versus partial bilateral salpingectomy for permanent sterilization during cesarean delivery. Arch Gynecol Obstet. 2017;295(5):1185–1189.

Danis RB, Della Badia CR, Richard SD. Postpartum permanent sterilization: could bilateral salpingectomy replace bilateral tubal ligation? J Minim Invasive Gynecol. 2016;23(6):928–932.

Shinar and colleagues presented a retrospective case series that included women undergoing permanent contraception procedures during cesarean delivery at a single tertiary medical center. The authors evaluated outcomes before and after a global hospital policy changed the preferred permanent contraception procedure from partial to total salpingectomy.

Details of the Shinar technique and outcomes

Of the 149 women included, 99 underwent partial salpingectomy via the modified Pomeroy technique and 50 underwent total salpingectomy using an electrothermal bipolar tissue-sealing instrument (Ligasure). The authors found no difference in operative times and similar rates of complications. Composite adverse outcomes, defined as surgery duration greater than 45 minutes, hemoglobin decline greater than 1.2 g/dL, need for blood transfusion, prolonged hospitalization, ICU admission, or re-laparotomy, were comparable and were reported as 30.3% and 36.0% in the partial and total salpingectomy groups, respectively, (P = .57). One major complication occurred in the total salpingectomy cohort; postoperatively the patient had hemodynamic instability and was found to have hemoperitoneum requiring exploratory laparotomy. Significant bleeding from the bilateral mesosalpinges was discovered, presumably directly related to the total salpingectomy.

Details of Danis et al

Intuitively, performing salpingectomy at the time of cesarean delivery does not seem as significant a change in practice as would performing salpingectomy through a small periumbilical incision after vaginal delivery. However, Danis and colleagues did just that; they published a retrospective case series of total salpingectomy performed within 24 hours after a vaginal delivery at an urban, academic institution. They included all women admitted for full-term vaginal deliveries who desired permanent contraception, with no exclusion criteria related to body mass index (BMI). The authors reported on 80 women, including 64 (80%) who underwent partial salpingectomy via the modified Pomeroy or Parkland technique and 16 (20%) who underwent total salpingectomy. Most women had a BMI of less than 30 kg/m^2; less than 15% of the women in each group had a BMI greater than 40 kg/m^2.

The technique for total salpingectomy involved a 2- to 3-cm vertical incision at the level of the umbilicus, elevation of the entire fallopian tube with 2 Babcock clamps, followed by the development of 2 to 3 windows with monopolar electrocautery in the mesosalpinx and subsequent suture ligation with polyglactin 910 (Vicryl, Ethicon).

Major findings included slightly longer operative time in the total salpingectomy compared with the partial salpingectomy group (a finding consistent with other

FAST TRACK

Minimal operative time differences between total and partial salpingectomy were found in both case series

studies[12,14,15]) and no difference in complication rates. The average (SD) surgical time in the partial salpingectomy group was 59 (16) minutes, compared with 71 (6) minutes in the total salpingectomy group (P = .003). The authors reported 4 (6.3%) complications in the partial salpingectomy group—ileus, excessive bleeding from mesosalpinx, and incisional site hematoma—and no complications in the total salpingectomy group (P = .58).

WHAT THIS EVIDENCE MEANS FOR PRACTICE

These 2 studies, although small retrospective case series, demonstrate the feasibility of performing total salpingectomies with minimal operative time differences when compared with more traditional partial salpingectomy procedures. The re-laparotomy complication noted in the Shinar series cannot be dismissed, as this is a major morbidity, but it also should not dictate the conversation.

Overall, the need for blood transfusion or unintended major surgery after permanent contraception procedures is rare. In the U.S. Collaborative Review of Sterilization study, none of the 282 women who had a permanent contraception procedure performed via laparotomy experienced either of these outcomes.[16] Only 1 of the 9,475 women (0.01%) having a laparoscopic procedure in this study required blood transfusion and 14 (0.15%) required reoperation secondary to a procedure complication.[17] The complication reported in the Shinar study reminds us that the technique for salpingectomy in the postpartum period, whether partial or total, should be considered carefully, being mindful of the anatomical changes that occur in pregnancy.

While larger studies should be performed to confirm these initial findings, these 2 articles provide the reassurance that many providers may need before beginning to offer total salpingectomy procedures in the immediate postpartum period.

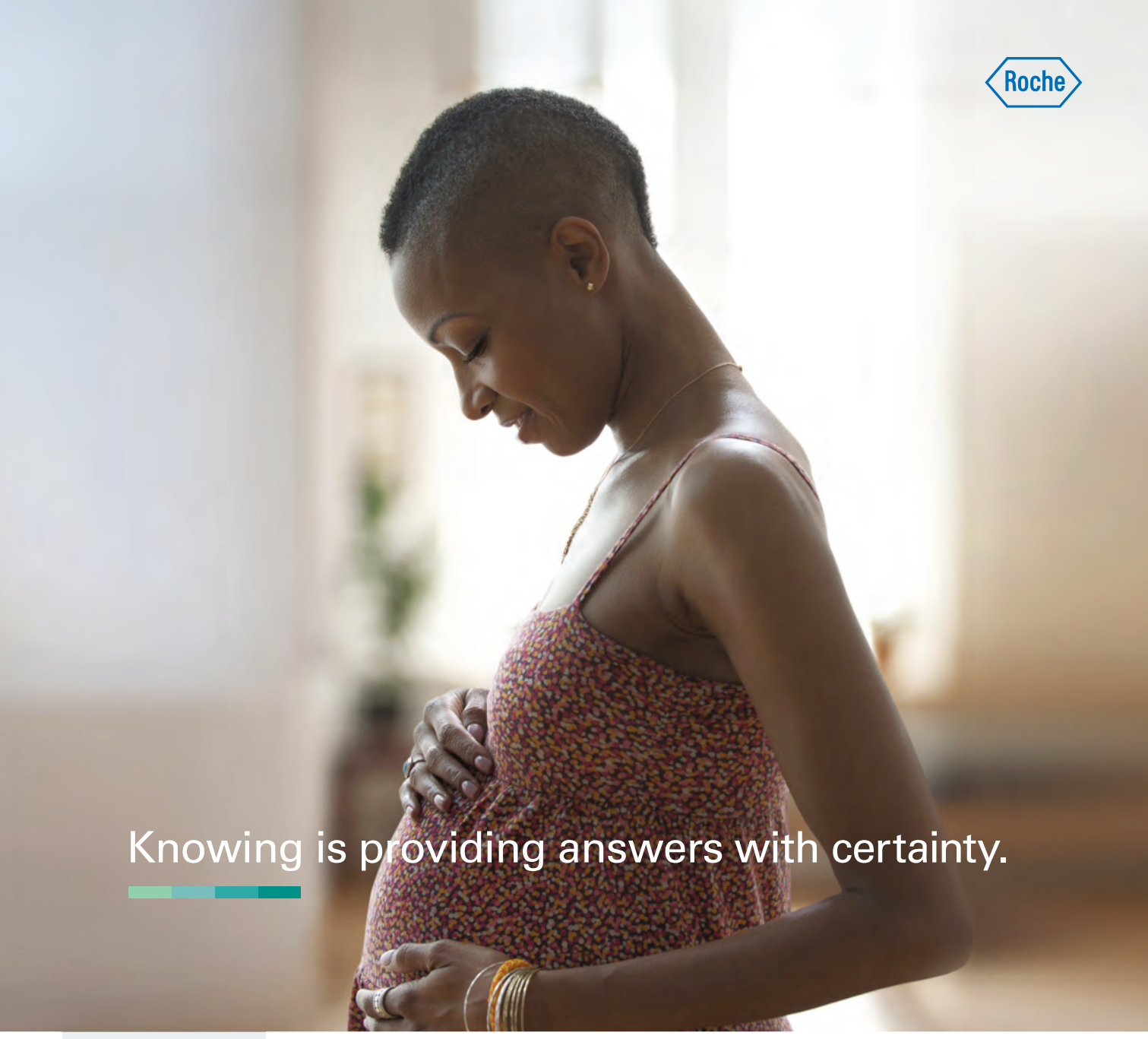
Feasibility of interval laparoscopic permanent contraception via bilateral salpingectomy

Westberg J, Scott F, Creinin MD. Safety outcomes of female sterilization by salpingectomy and tubal occlusion. Contraception. 2017;95(5):505–508.

In this retrospective study, authors used billing data to identify women undergoing interval laparoscopic permanent contraception at a single academic medical center. They educated physicians and patients about the potential benefits to ovarian cancer risk with total salpingectomy (similar to the educational initiative done in British Columbia) and discussed the requirement for the extra incision and more time for the surgery. From 2013 to 2015 use of salpingectomy for permanent contraception changed from 45% of the procedures to 85%, a fairly dramatic trend.[18] With these data, the authors compared outcomes between the women receiving tubal occlusive procedures and women receiving bilateral salpingectomy.

Details of surgical time and complications

Tubal occlusion procedures were performed through 2 abdominal ports, and device placement was at the discretion of the provider. Bilateral salpingectomies were



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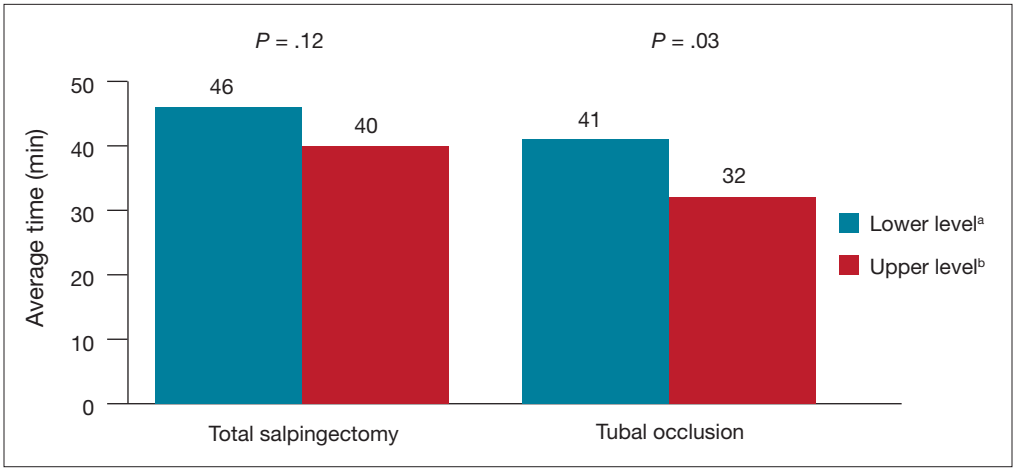
*The combined false positive rate is for trisomies 21, 18 and 13.

[1]Stokowski R. et al. (2015). Prenatal Diagnosis: Clinical performance of non-invasive prenatal testing (NIPT) using targeted cell-free DNA analysis in maternal plasma with microarrays or next generation sequencing (NGS) is consistent across multiple controlled clinical studies.

The Harmony Prenatal Test was developed by Ariosa Diagnostics, a CLIA-certified laboratory. As with other lab-developed tests, it has not been cleared or approved by the FDA and is not available for sale as an IVD in the US. Noninvasive prenatal testing (NIPT) based on cell-free DNA analysis is not diagnostic; results should be confirmed by diagnostic testing.

FIGURE 2 Surgical times for total salpingectomy and tubal occlusion procedures based on gynecology resident year[15]



[a]Years 1 and 2 of residency.
[b]Years 3 and 4 of residency.

FAST TRACK

Tubal occlusion procedure length averaged only 6 minutes less than bilateral salpingectomies, and more experienced residents had shorter surgical times

performed through 3 abdominal port sites with an electrothermal bipolar tissue-sealing instrument. A total of 149 procedures were identified, 68 tubal occlusions (19% Falope rings, 32% bipolar cautery, and 47% Filshie clips) and 81 bilateral salpingectomies.

The surgical time average (SD) was 6 minutes longer for the salpingectomies (44 [13] minutes vs 38 [15] minutes; $P = .018$). As would be expected, more experienced residents had shorter surgical times when compared with less experienced residents for both procedures (**FIGURE 2**).[15] Similar rates of both immediate and short-term surgical complications were noted. One immediate complication was reported in each group, both of which were secondary to anesthesia issues.

Interestingly, short-term complications were lower in the salpingectomy group (4.9%) versus the tubal occlusion group (14.7%), although this difference was barely not statistically significant ($P = .051$). These complications included 1 incisional site infection requiring oral antibiotics and 3 cases of increased pain in the salpingectomy group and 4 incisional site infections with 6 patients reporting increased pain in the tubal occlusion group.

WHAT THIS EVIDENCE MEANS FOR PRACTICE

This retrospective analysis provides further reassurance regarding the safety of offering bilateral salpingectomy to patients desiring permanent contraception. This study again consistently demonstrates that bilateral salpingectomy increases the operative time, but only minimally, which is unlikely clinically significant, especially when considering the potential benefits from total salpingectomy (increased ovarian cancer protection, higher contraceptive efficacy, decreased ectopic pregnancy rates, reduced risk of future surgeries for such tubal pathology as hydrosalpinx, etc). The study also shows that educational initiatives targeted at providers likely will increase acceptability as well as uptake of this practice for permanent contraception.

Our contraceptive counseling philosophy: The shared decision-making model

When women present for permanent contraception counseling, we must remember that our patients' needs are often far too diverse and dynamic to allow a universal counseling technique. Every provider likely has a counseling style, with a structure and language that has been altered and changed through years of practice, patient experiences, and new scientific technologies and data. Unfortunately, provider biases and past coercive practices also influence contraceptive counseling.

Historically, some providers used formulas related to a woman's age and parity to decide if she could have a permanent contraception procedure, possibly based on fears of patient regret. Such practices are an embarrassment to the principles of patient autonomy and empowerment, which should serve as the foundation for any contraceptive conversation. Studies of regret after permanent contraception procedures are often misinterpreted; although younger women experience higher rates of regret, the absolute rate still favors performing the procedure.[1,2] When comparing women aged 30 or younger to those older than 30 years at the time of procedure, the vast majority (about 80%) of those 30 and younger do not express regret.[1] Less than 5% of women who express regret access a reversal procedure.[2,3] Our job as providers is to educate and allow women to understand the options—and with permanent contraception that also means explaining the potential for regret; however, empowering women does not mean limiting an opportunity for the majority to potentially impact the minority.

Our contraceptive counseling philosophy follows the shared decision-making model. This model informs the patient, tailors the conversation toward her priorities, and maintains patient autonomy, while empowering the patient to take control of her reproductive health and future. When a patient expresses the desire for permanent contraception, we ensure she understands the permanence of the procedure and offer information about other Tier 1 contraceptive options, including long-acting reversible methods and vasectomy. We use the evidence-based World Health Organization counseling table[4,5] to assist with the discussion and provide vasectomy referral and further information about specific intrauterine devices or the contraceptive implant based on the woman's interests.

For women who desire a female permanent contraception procedure, we also provide information tables comparing laparoscopic tubal occlusion procedures, laparoscopic bilateral salpingectomy, and hysteroscopic tubal occlusion. These tables review how each procedure is performed; risks and benefits, including failure rates over time; and ovarian cancer protection estimates. Our office also has devised tables to inform women seeking permanent contraception immediately after delivery and unrelated to pregnancy. Ultimately, the woman can choose what makes the most sense for her at that specific time in her life, and as providers we must support and uphold that decision.

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FAST TRACK

Offering patients comparative information on permanent contraception options, risks, benefits, failure rates, and ovarian cancer prevention can aid the decision-making process

WATCH FOR...

›› Update on femal sexual dysfunction
from Barbara Levy, MD

CONTINUED ON PAGE 44

How to sell your ObGyn practice

Your retirement may be a long way off, but the planning pointers presented here can help smooth the transition of your practice when you decide to sell

Randy Bauman and Neil H. Baum, MD

IN THIS ARTICLE

›› Have you read "ObGyns' choice of practice environment is a big deal" on page 39?

For ObGyns, 2 intensely stressful career milestones are the day you start your practice and the day you decide to put it up for sale.

One of us, Dr. Baum, started a practice in 1976. At that time, many clinicians seemed to work right up until the day they died—in mid-examination or with scalpel in hand! Today, clinicians seriously contemplate leaving an active practice at age 55, 60, or, more traditionally, 65.

ObGyns in group practice, even those with only 1 or 2 partners, presumably have in place a well-thought-out and properly drafted contract with buyout and phase-down provisions. For members of a group practice, it is imperative to critically review and discuss contractual arrangements periodically and decide if they make sense as much now as they did at the start. ObGyns who continually revisit their contracts probably have an exit strategy that is fairly self-executing and effective and that will provide the seller with a seamless transition to retirement.

A solo ObGyn who is selling a practice has 3 basic options: find a successor physician, sell to a hospital or to a larger group, or close the practice.

Mr. Bauman is a practice management consultant and CEO of Delta Health Care, Brentwood, Tennessee.

Dr. Baum is a Professor of Clinical Urology at Tulane Medical School, New Orleans, Louisiana, and is the author of The Complete Business Guide for a Successful Medical Practice (Springer, 2016). He is an OBG MANAGEMENT Contributing Editor.

The authors report no financial relationships relevant to this article.

Preparing your practice for sale

Regardless of who will take over your practice, you need to prepare for its transition.

The most important aspect of selling your practice is knowing its finances and ensuring that they are in order. Any serious buyer will ask to examine your books, see how you are running the business, and assess its vitality and potential growth. Simply, a buyer will want to know where your revenue comes from and where it goes.

Your practice will be attractive to a buyer if it shows a stable or growing revenue base, an attractive payer mix, reasonable overhead, and personal income that is steady if not increasing. If your earning capacity is low or declining, you will need to explain why.

Timing is key

We strongly recommend beginning the process 3 to 5 years before your intended exit.

By starting early, up to 5 years in advance, you can maximize the likelihood that your practice will retain all or most of

its value. Moreover, you can use the long lead time to thoroughly explore all available options and find a committed buyer.

Selling a practice can be a complicated affair, and many ObGyns do not have the requisite skills. So much of the success in selling depends on the specifics of the practice, the physician, and the market (the hospital and physician environment).

Identifying potential buyers

Other ObGyns. Recruiting an ObGyn to take over your practice seems to be the best option but can prove very difficult in today's environment. Many younger clinicians are either joining large groups or becoming hospital employees.

Other physician groups. While working your way down your list of potential buyers, you should also be quietly, subtly, and tactfully assessing other practices, even your competitors, to see if any are candidates for merging with and/or acquiring yours and all your charts, records, and referring physicians.

Hospitals. In today's health care environment, in which more than half of clinicians are becoming hospital employees, selling to your associated hospital may be a viable option.

Your practice is probably contributing millions of dollars in income to that hospital each year, and of course the hospital would like to maintain this revenue stream. You should consider talking to the hospital's CEO or medical director.

Hospitals also know that, if you leave and the market cannot absorb the resulting increase in demand for care, patients may go elsewhere, to a competing hospital or outside the community. Rather than lose your market share, a hospital may consider the obvious solution: recruit a replacement ObGyn for your practice.

Your goal here is to negotiate an agreement in which your hospital will recruit a replacement ObGyn, provide financial support, and transition your practice to that ObGyn over a specified period.

The hospital could acquire your practice and either employ you during the transition or provide recruiting support and an income guarantee to help your practice pay the new physician's salary. Whether to sell or remain independent is often driven by the needs and desires of the recruit. As the vast majority of clinicians coming out of training are seeking employment, in most cases the agreement will require a sale.

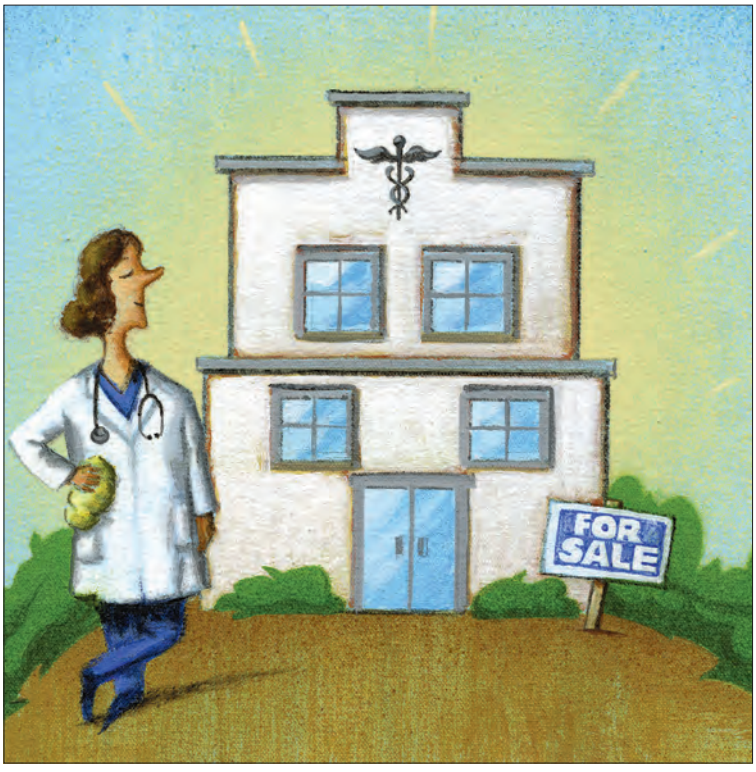

ILLUSTRATION: PAUL ZWOLAK FOR OBG MANAGEMENT

Selling to a hospital a few years before your retirement can be a plus. You might find employment a welcome respite from the daunting responsibility of managing your own practice. Life can become much less stressful as you introduce and transition your patients to the new ObGyn. You will be working less, taking fewer calls, and maintaining or even increasing your income, all without the burden of managing the practice.

Putting a monetary value on your practice

After deciding to sell your practice, you need to determine its value. Buying a practice may be the largest financial transaction a young ObGyn will ever make. For a retiring

FAST TRACK

We strongly recommend beginning the selling process 3 to 5 years before your intended exit

Factors to consider in calculating practice value

The formulas and calculations presented here should give you a good overview of the value potential of your practice, but note that they yield estimates only. You may wish to consult a certified public accountant or your practice advisor when using these formulas and calculations to make your own estimates.

1. Accounts receivable estimated value
   —take total accounts receivable balance outstanding less than 90 days
   —multiply by gross collection percentage (cash collections for previous year divided by gross charges)
2. Furniture and equipment estimated value
   —conduct physical inventory of all furniture and equipment
   —determine current new cost for items of similar utility
   —multiply quantities of each item by new cost
   —sum total cost
   —multiply by 40%
3. Medical records
   —determine number of individual patients (not visits) seen in past 12 months
   —multiply by either $15 (electronic health records) or $10 (paper charts)
4. Trained workforce
   —determine total annual salaries and benefit costs of full-time staff
   —exclude anyone working less than 30 hours per week
   —exclude physician owners
   —include employed physicians and nonphysician providers
   —multiply by either 20% (little turnover) or 15% (active turnover)

TOTAL: Sum items 1 to 4 to obtain estimated practice value

FAST TRACK

A hospital may be willing to pay fair market value for your practice, but it cannot legally pay more than fair market value as determined by an independent appraiser

physician, valuation of a practice may reflect a career's worth of "sweat equity."

What is your practice worth?

All ObGyns believe their practice is worth far more than any young ObGyn or hospital is willing to pay for it. After all, you have spent a medical lifetime creating, building, and nurturing your practice. You have cared for several thousand patients, who have been loyal and may want to stay with the practice under its new ObGyn. So, how does a retiring physician put a value on his or her practice and then "cast the net" to the marketplace? How do you find a buyer who will pay the asking price and then help the practice make the transition from seller to buyer and continue to serve their patients?

The buyer's perspective on value. In a pure sense, the value of any asset is what a potential buyer is willing to pay. From a value standpoint, the price that potential buyers are willing to pay varies by the specifics of the situation, regardless of what a valuation or practice appraisal might indicate.

For example, once your plan to retire becomes known, why would a young ObGyn agree to pay X dollars for all your medical records? After all, the potential buyer knows that your existing patients and your referral base will need to seek care from another ObGyn after you leave, and they will likely stay with the practice if they feel they will be treated well by the new clinician.

A hospital may take a similar tack but more often will be willing to pay fair market value for your practice. Hospitals, however, cannot legally pay more than fair market value as determined by an independent appraiser.

Valuation methods

The valuation of any business generally is approached in terms of market, assets, and income.

CONTINUED ON PAGE 28

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The **market approach** usually is taken only with regard to office real estate. Given the lack of reliable and comparable sales information, this approach is seldom used in the valuation of medical practices. If you own your office real estate, a real estate appraiser will establish its fair market value.

In the **assets approach,** the individual assets of a medical practice are valued on the basis of their current market values. These assets are either tangible or intangible.

Tangible assets can be seen and touched. Furniture, equipment, and office real estate are examples.

The fair market value of used furniture and equipment is most often determined by replacement cost. The value of these items is limited. Usually it starts at 50% of the cost of buying new furniture or equipment of the same utility. From there, the value is lowered on the basis of the age and condition of the items.

Often, the market value of major ObGyn office equipment, such as a DXA (dual-energy x-ray absorptiometry) scanner, is based on similar items for sale or recently sold in the used secondary equipment market.

Tangible assets may include accounts receivable (A/R). A/R represents uncollected payment for work performed. Most buyers want to avoid paying for A/R and assuming the risk of collections. Generally, you should expect to retain your A/R and pay a small or nominal fee to have the buyer handle the collections after you have retired.

Intangible assets are not physical. Examples include the physician's name, phone number, reputation, referral base, trained staff, and medical records—in other words, what gets patients to keep coming back. Most physicians value these goodwill or "blue-sky" assets highly. Today, unfortunately, most sellers are unable to reap any financial benefit from their intangible assets.

The **income approach** is based on the premise that the value of any business is in the income it generates for its owner. In simple terms, value in the income approach is a multiple of the cash the business generates after expenses.

FAST TRACK

Specify in your contract agreement an overlap period, when both the exiting ObGyn and the new ObGyn are at the practice. We suggest a minimum of 6 months and a maximum of 1 year.

Transitioning the practice: Role of the seller and the buyer

First and very important is the contract agreement regarding the overlap period, when both the exiting ObGyn and the new ObGyn are at the practice. We suggest making the overlap a minimum of 6 months and a maximum of 1 year. During this period, the exiting physician can introduce the incoming physician to the patients. A face-to-face introduction can amount to an endorsement, which can ease a patient's mind and help her decide to take on the new ObGyn and philosophy rather than search elsewhere for obstetric and gynecologic care. The new ObGyn also can use the overlap period to become familiar and comfortable with the staff and learn the process for physician and staff management of case flow, from scheduling and examination to insurance and patient follow-up.

We suggest that the exiting ObGyn send a farewell/welcome letter to patients and referring physicians. The letter should state the exiting ObGyn's intention to leave (or retire from) the practice and should introduce the ObGyn who will be taking over.

The exiting ObGyn should also take the new ObGyn to meet the physicians who have been providing referrals over the years. We suggest visiting each referring physician's office to make the introduction. Another good way to introduce a new ObGyn to referring physicians and other professionals—endocrinologists, cardiologists, nurses, pharmaceutical representatives—is to host an open house at your practice. Invite the staff members of the referring physicians as well, since they can be invaluable in making referrals.

We recommend that the exiting ObGyn spend the money to update all the practice's stationery, brochures, and print materials and ensure they look professional. Note that it is not acceptable to place the new ObGyn's name under the exiting ObGyn's name. If the practice has a website, introduce the new physician there and make any necessary updates regarding office hours and accepted insurance plans.

If the exiting ObGyn's practice lacks a robust Internet and social media presence, the new ObGyn should establish one. We recommend setting up an interactive website that patients can use to make appointments and pay bills. The website should have an email component that can be used to ask questions, raise concerns, and get answers. We also recommend opening Facebook, YouTube, and Twitter accounts for the practice and being active on these social media.

In our experience, smoothly transitioning practices can achieve patient retention rates as high as 90% to 95%. For practices without a plan, however, these rates may be as low as 50%, or worse. Therefore, work out a plan in advance, and include the steps described here, so that on arrival the new ObGyn can hit the ground running.

Acquiring a successful medical practice is doable and offers many advantages, such as autonomy and the ability to make business decisions affecting the practice. Despite all the changes happening in health care, we still think this is the best way to go.

Bottom line

Selling an ObGyn practice can be a daunting process. However, deciding to sell your practice, performing the valuation, and ensuring a smooth transition are part and parcel of making the transfer a success, equitable for both the buyer and the seller.

Managing psychiatric illness during pregnancy and breastfeeding: Tools for decision making

Changing drug safety ratings and conflicting information can make maintaining the mental health of the mother and the well-being of the fetus and infant complex. Here, a pharmacologic framework that allows for consistency of care.

Lucy J. Puryear, MD; Nicole R. Hall, MD; Manju Monga, MD; and Susan M. Ramin, MD

IN THIS ARTICLE

Increasingly, women with psychiatric illness are undergoing pharmacologic treatment during pregnancy. In the United States, an estimated 8% of pregnant women are prescribed antidepressants, and the number of such cases has risen over the past 15 years.[1] Women with a psychiatric diagnosis were once instructed either to discontinue all medication immediately on learning they were pregnant, or to forgo motherhood because their illness might have a negative effect on a child or because avoiding medication during pregnancy might lead to a relapse.

Fortunately, women with depression, anxiety, bipolar disorder, or schizophrenia no longer are being told that they cannot become mothers. For many women, however, stopping medication is not an option. Furthermore, psychiatric illness sometimes is diagnosed initially during pregnancy and requires treatment.

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Dr. Monga is Professor and Vice Chair (Clinical), Department of Obstetrics and Gynecology, Baylor College of Medicine, Texas Children's Hospital–Pavilion for Women.

At the time of this writing, Dr. Hall was Assistant Professor, Baylor College of Medicine, Texas Children's Hospital–Pavilion for Women, and is currently an obstetrician-gynecologist with Georgia Perinatal Consultants, Atlanta.

Dr. Ramin is Henry and Emma Meyer Chair in Obstetrics and Gynecology, and Professor and Vice Chair for Education, Department of Obstetrics and Gynecology, Baylor College of Medicine, Texas Children's Hospital–Pavilion for Women.

Dr. Puryear reports that she is a consultant to Sage Therapeutics. The other authors report no financial relationships relevant to this article.

Many women with psychiatric illness no longer have to choose between mental health and starting a family.

Pregnant women and their physicians need accurate information about when to taper off medication, when to start or continue, and which medications are safest. Even for clinicians with a solid knowledge base, counseling a woman who needs or may need psychotropic medication during pregnancy and breastfeeding is a daunting task. Some clinicians still recommend no drug treatment as the safest and best option, given the potential risks to the fetus.

In this review we offer a methodologic approach for decision making about pharmacologic treatment during pregnancy. As the scientific literature is constantly being updated, it is imperative to have the most current information on psychotropics and to know how to individualize that information when counseling a pregnant woman and her family. Using this framework for analyzing the risks and benefits for both mother and fetus, clinicians can avoid the unanswerable question of which medication is the "safest."

A patient's mental health care provider is a useful resource for information about a woman's mental health history and current stability, but he or she may not be expert or comfortable in recommending treatment for a pregnant patient. During pregnancy, a woman's obstetrician often becomes the "expert" for all treatment decisions.

Analyze risks and benefits of medication versus no medication

The US Food and Drug Administration (FDA) has not approved any psychotropic medication for use during pregnancy. While a clinical study would provide more scientifically rigorous safety data, conducting a double-blinded, placebo-controlled trial in pregnant women with a psychiatric disorder is unethical. Thus, the literature consists mostly of reports on case series, retrospective chart reviews, prospective naturalistic studies, and analyses of large registry databases. Each has benefits and limitations. It is important to understand the limitations when making treatment decisions.

FAST TRACK

Use a methodologic approach for decision making as a framework for analyzing the risks and benefits of pharmacologic treatment for mother and fetus

CONTINUED ON PAGE 32

ILLUSTRATION: KIMBERLY MARTENS FOR OBG MANAGEMENT

CONTINUED FROM PAGE 31

Psychotropic use during pregnancy: Certain risks in offspring lower than thought, recent data show

Antidepressants. Previous studies may have overestimated the association between prenatal use of antidepressants and attention deficit/hyperactivity disorder (ADHD) in children because they did not control for shared family factors, according to investigators who say that their recent study findings raise the possibility that "confounding by indication" might partially explain the observed association.[1]

In a population-based cohort study in Hong Kong, Man and colleagues analyzed the records of 190,618 maternal-child pairs.[1] A total of 1,252 children were exposed to maternal antidepressant use during pregnancy. Medications included selective serotonin reuptake inhibitors (SSRIs), non-SSRIs, and antipsychotics as monotherapy or in various combination regimens. Overall, 5,659 of the cohort children (3%) were diagnosed with or received treatment for ADHD.

When gestational medication users were compared with nongestational users, the crude hazard ratio (HR) of antidepressant use during pregnancy and ADHD was 2.26 ($P<.01$). After adjusting for potential confounding factors (such as maternal psychiatric disorders and use of other psychotropic drugs), this reduced to 1.39 (95% confidence interval [CI], 1.07–1.82; $P = .01$). Children of mothers with psychiatric disorders had a higher risk of ADHD than did children of mothers without psychiatric disorders (HR, 1.84; 95% CI, 1.54–2.18; $P<.01$), even if the mothers had never used antidepressants.

While acknowledging the potential for type 2 error in the study analysis, the investigators proposed that the results "further strengthen our hypothesis that confounding by indication may play a major role in the observed positive association between gestational use of antidepressants and ADHD in offspring."

Lithium. Similarly, investigators of another recently published study found that the magnitude of the association between prenatal lithium use and increased risk of cardiac malformations in infants was smaller than previously shown.[2] This finding may be important clinically because lithium is a first-line treatment for many US women of reproductive age with bipolar disorder.

Most earlier data were derived from a database registry, case reports, and small studies that often had conflicting results. However, Patorno and colleagues conducted a large retrospective cohort study that involved data on 1,325,563 pregnancies in women enrolled in Medicaid.[2] Exposure to lithium was defined as at least 1 filled prescription during the first trimester, and the primary reference group included women with no lithium or lamotrigine (another mood stabilizer not associated with congenital malformations) dispensing during the 3 months before the start of pregnancy or during the first trimester.

A total of 663 pregnancies (0.05%) were exposed to lithium and 1,945 (0.15%) were exposed to lamotrigine during the first trimester. The adjusted risk ratios for cardiac malformations among infants exposed to lithium were 1.65 (95% CI, 1.02–2.68) as compared with nonexposed infants and 2.25 (95% CI, 1.17–4.34) as compared with lamotrigine-exposed infants. Notably, all right ventricular outflow tract obstruction defects identified in the infants exposed to lithium occurred with a daily dose of more than 600 mg.

Although the study results suggest an increased risk of cardiac malformations—of approximately 1 additional case per 100 live births—associated with lithium use in early pregnancy, the magnitude of risk is much lower than originally proposed based on early lithium registry data.

—KATHY CHRISTIE, SENIOR EDITOR

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2. Patorno E, Huybrechts KR, Bateman BT, et al. Lithium use in pregnancy and risk of cardiac malformations. N Engl J Med. 2017;376(23):2245–2254.

In 1979, the FDA developed a 5-letter system (A, B, C, D, X) for classifying the relative safety of medications used during pregnancy.[2] Many clinicians and pregnant women relied on this system to decide which medications were safe. Unfortunately, the information in the system was inadequate for making informed decisions. For example, although a class B medication might have appeared safer than one in class C, the studies of risk in humans might not have been adequate to permit comparisons. Drug safety classifications were seldom changed, despite the availability of additional data.

In June 2015, the FDA changed the requirements for the Pregnancy and Lactation subsections of the labeling for human prescription drugs and biologic products. Drug manufacturers must now include in each subsection a risk summary, clinical considerations supporting patient care decisions and counseling, and detailed data. These

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PAGS SCIENTIFIC PROGRAM AGENDA

Agenda and faculty is subject to change. Please see website for updates.

WEDNESDAY, DECEMBER 13, 2017

Pre-Conference Workshops
(Optional, Separate fee required)

8:30 AM **Hands-On Tissue Extraction Techniques** (New workshop)
Led by: Rosanne M. Kho, MD

8:30 AM **Hands-On Laparoscopic Suturing - The "Vertical Zone"** (Simulation Lab)
Led by: Charles H. Koh, MD

1:30 PM **Hands-On Hysteroscopy Workshop**
Led by: Andrew I. Brill, MD

1:30 PM **Hands-On Ultrasound Workshop**
Led by: James M. Shwayder, MD, JD

1:30 PM **Technical Aspects of Vaginal Hysterectomy & Cystourethroscopy for the Gynecologist**
Led by: Mickey Karram, MD

THURSDAY, DECEMBER 14, 2017

6:30 AM **Registration/Breakfast/Exhibits**

7:10 AM **Breakfast Symposium**

7:55 AM **Course Overview**
Mickey Karram, MD

Pelvic Anatomy

8:00 AM **Pelvic and Abdominal Anatomy from the Laparoscopic Surgeon's View**
Tommaso Falcone, MD

8:40 AM **Anatomic Considerations: Facilitating Vaginal Procedures Safely and Effectively**
Mickey Karram, MD

Incontinence and Prolapse Surgery

9:10 AM **Case Discussions: How Best to Evaluate a Variety of Female Pelvic Floor Disorders**
John Gebhart, MD, MS
Mickey Karram, MD

9:55 AM **Question and Answer Session**

10:25 AM **Break/Exhibits**

11:10 AM **Surgery for Stress Incontinence: Does One Sling Fit All?**
Mark D. Walters, MD

11:40 AM **Surgery for Pelvic Organ Prolapse: Getting Back to Basics - Native Tissue Suture Repairs**
John Gebhart, MD, MS

12:00 PM **Mesh Augmented Prolapse Repair; Vaginal Mesh vs. Sacrocolpopexy**
Mark D. Walters, MD

12:40 PM **Question and Answer Session**

1:10 PM **Luncheon Symposium**

2:10 PM **Dessert Break/ Exhibits**

Thursday's Keynote Lecture

2:40 PM **Avoiding and Managing Postpartum Perineal Disorders**
Bahaeddine M.Sibai, MD

Fibroid Management & Principles of Electrosurgery

3:25 PM **Myomectomy: Open to Robotic Approaches**
Tommaso Falcone, MD

3:55 PM **The Hysteroscopic Treatment of Submucosal Fibroids and Polyps**
Linda D. Bradley, MD

4:25 PM **Break/Exhibits**

4:40 PM **Safe Use of Electrosurgical Devices for Gynecologic Surgery**
Andrew I. Brill, MD

5:10 PM **Question and Answer Session**

FRIDAY, DECEMBER 15, 2017

7:00 AM **Breakfast/Exhibits**

7:10 AM **Breakfast Symposium**

Hysterectomy - Technique

8:15 AM **The Difficult Vaginal Hysterectomy**
Rosanne M. Kho, MD

8:50 AM **Single Port Approaches to Hysterectomy**
Amanda Nickles Fader, MD

9:25 AM **Total Laparoscopic Hysterectomy**
Andrew I. Brill, MD

10:00 AM **Break /Exhibits**

10:45 AM **Robotic Hysterectomy**
Javier F. Magrina, MD

11:15 AM **Tissue Extraction Techniques (Morcellation)**
Tommaso Falcone, MD

11:45 AM **Techniques to Preserve Level 1 Support at the Time of Vaginal Laparoscopic and Robotic Hysterectomy**
Mark D. Walters, MD

12:15 PM **Which Hysterectomy Approach is Best?** Case Presentation and Audience Participation

12:45 PM **Question and Answer Session**

1:00 PM **Luncheon Symposium**

2:00 PM **Dessert Break/Exhibits**

Friday's Keynote Lecture

2:30 PM **Management of Obstetric Hemorrhage**
Bahaeddine M. Sibai, MD

Oncology For The Generalist

3:15 PM **Surgical Management of Pre-Cancer Vulvovaginal Lesions**
Amanda Nickles Fader, MD

4:00 PM **Laparoscopic and Robotic Management of the Adnexal Mass**
Javier F. Magrina, MD

4:45 PM **Spectrum of Vulvovaginal Disorders**
Michael S. Baggish, MD

5:30 PM **Question and Answer Session**

SATURDAY, DECEMBER 16, 2017

6:30 AM **Breakfast**

7:30 AM **Management of Endometriosis**
Tommaso Falcone, MD

8:30 AM **Avoiding and Managing Urogynecologic Complications**
John Gebhart, MD, MS
Mickey Karram, MD

9:30 AM **Avoiding and Managing Laparoscopic Complications**
Tommaso Falcone, MD

10:30 AM **Break**

10:45 AM **Medical Legal Cases**
Michael S. Baggish, MD
Tommaso Falcone, MD

11:30 AM **Surgical Tips for Successful Pelvic Surgery: Video Session**
Surgical Management of Cornual Ectopic & Dermoid Cysts
Tommaso Falcone, MD
Techniques to Suspend the Apex at the Time of Vaginal Surgery
Mickey Karram, MD

1:00 PM **PAGS Scientific Program Adjournment**

P.E.P. PRACTICE ENHANCEMENT PROGRAM AGENDA

(Optional. Separate fee required)

Open to Non-Attendees so bring your staff!

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Director
Neil H. Baum, MD
Associate Clinical Professor of Urology
Tulane Medical School and Louisiana State University
New Orleans, Louisiana

Dr. Neil Baum is the author of
The Complete Business Guide to a Successful Medical Practice and *3-Stages of a Physician's Career*

SATURDAY, DECEMBER 16, 2017

2:00 PM **Course Overview**

2:10-3:00 PM
Looking at the 4 Pillars of a Successful Practice in the Current Healthcare Environment
- Keeping patients already in your practice
- Attracting new patients to your practice (social media techniques to add 3-5 new patients a day to your practice)
- Communicating with your professional colleagues
- Enhancing staff morale

3:00-3:30 PM
Moving from Volume to Value-The New Metric of Healthcare
- Fee for Service and volume of work performed will no longer be the method of reimbursement in the near future
- Will define quality (outcomes\costs)
- Provide the 7 steps to measure cost-of-care

3:30-3:45 PM **Break**

3:45-4:15 PM
Online Reputation Management
- The importance of a physician's reputation
- How it can be ruined with the click of a mouse
- How to obtain positive reviews
- Management of negative reviews

4:15-4:45 PM
Patient Satisfaction
- Discuss why patient satisfaction is important
- What are the needs and wants of today's primary care patient
- How we measure patient satisfaction
- Practical suggestions for enhancing patient satisfaction

4:45-5:00 PM
Numbers you Need to Know
- Obstetricians and gynecologists need to know and monitor just a few numbers
- Without understanding these concepts, you will not understand the value of the services that you provide
- Will review 5 numbers that need to be monitored (charges\receipts, RVUs, ARs\days in AR, charge lag, denials)

5:00-5:15 PM **Q and A**

5:15-5:30 PM
The Future of Medical Practice and Conclusion
- What is the current situation
- What happens if ACA is repealed
- What can primary care providers do pro-actively to enhance their practices in the near future

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Special Keynote Speaker

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Cleveland Clinic
Cleveland, Ohio

Pre-Conference Workshops

(Optional. Separate fee required)
Please note: PAGS workshops have limited space available and do sell out. First come. First served!

Wednesday, December 13, 2017 The Cosmopolitan of Las Vegas

HANDS-ON TISSUE EXTRACTION TECHNIQUES WORKSHOP NEW!
4 CME Credits Available
8:30 AM - 12:30 PM
Director: Rosanne M. Kho, MD
Faculty: Andrew I. Brill, MD; Tommaso Falcone, MD; Keith B. Isaacson, MD

HANDS-ON LAPAROSCOPIC SUTURING - THE "VERTICAL ZONE" (SIMULATION LAB)
4 CME Credits Available
8:30 AM - 12:30 PM
Led by: Charles H. Koh, MD

HANDS-ON HYSTEROSCOPY WORKSHOP
4 CME Credits Available
1:30-PM - 5:30 PM
Led by: Andrew I. Brill, MD
Faculty: Linda D. Bradley, MD; Tommaso Falcone, MD; Keith B. Isaacson, MD

HANDS-ON ULTRASOUND WORKSHOP
4 CME Credits Available
1:30 PM - 5:30 PM
Led by: James M. Shwayder, MD, JD
Faculty: William W. Brown, III, MD, FACOG, FAIUM; Todd Deutch, MD; Tommaso Falcone, MD

HANDS-ON TECHNICAL ASPECTS OF VAGINAL HYSTERECTOMY & CYSTOURETHROSCOPY FOR THE GYNECOLOGIST
4 CME Credits Available
1:30 PM - 5:30 PM
Led by: Mickey Karram, MD
Faculty: Rosanne M. Kho, MD and Douglas Miyazaki, MD

Who Should Attend?

The PAGS conference is designed for obstetricians/gynecologists, second, third and fourth-year residents in OB/GYN, as well as sub-specialty fellows and advanced practice clinicians. Residents and advanced practice health clinicians are welcome at reduced rates.

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About Our Venue
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  - Ultrasound
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- **Gynecologic Oncology for the Generalist**
- **Hysterectomy Techniques**
  - Vaginal • Single-port • Total Lap • Robotic
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  - Which Approach is Best?
- **Avoiding and Managing Complications**
- **Fibroid Management & Principles of Electrosurgery**
- **Surgical Tips for Successful Pelvic Surgery**

SPECIAL KEYNOTES: Bahaeddine M. Sibai, MD

- **Avoiding and Managing Postpartum Perineal Disorders**
- **Management of Obstetric Hemorrhage**

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Cancellation Policy: Full refund less a $50 administrative fee as follows: Cancellations can be made using our online registration system until November 14, 2017. After November 14, 2017 no refunds will be granted. After the refund date, you have two options: you can send someone in your place, or we can mark a credit in the amount you paid minus $50 administration fee (plus additional $35 administration fee per workshop) to be applied to your registration for next year's conference. Refunds will not be issued to no-shows.

To register and for complete information please see our website: PAGS-cme.org.

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TABLE 1 When to taper off, or start or continue, psychotropic medication during pregnancy and the postpartum period

Taper off	Start or continue
• First episode of illness	• Chronic psychiatric illness
• Symptom stability for 6 months to 1 year with medication	• Relapse of illness within weeks to months after medication is stopped
• History of symptom stability for 1 year or more after medication is stopped	• History of severe symptoms without medication: inability to function (activities of daily living), suicidal, psychotic, manic
• Mild symptoms	• History of psychiatric hospitalization
• Patient preference	• Diagnosis of psychotic disorder: bipolar disorder or schizophrenia
	• Several medication trials with difficulty stabilizing symptoms

subsections provide information on available human and animal studies, known or potential maternal or fetal adverse reactions, and dose adjustments needed during pregnancy and the postpartum period. In addition, the FDA added a subsection: Females and Males of Reproductive Potential.[3]

These changes acknowledge there is no list of "safe" medications. The safest medication generally is the one that works for a particular patient at the lowest effective dose. As each woman's history of illness and effective treatment is different, the best medication may differ as well, even among women with the same illness. Therefore, medication should be individualized to the patient. A risk–benefit analysis comparing psychotropic medication treatment with no medication treatment must be performed for each patient according to her personal history and the best available data.

What is the risk of untreated illness during pregnancy?

During pregnancy, women are treated for many medical disorders, including psychiatric illness. One general guideline is that, if a pregnant woman does not need a medication—whether it be for an allergy, hypertension, or another disorder—she should not take it. Conversely, if a medication is required for a patient's well-being, her physician should continue it or switch to a safer one. This general guideline is the same for women with depression, anxiety, or a psychotic disorder.

Managing hypertension during pregnancy is an example of choosing treatment when the risk of the illness to the mother and the infant outweighs the likely small risk associated with taking a medication. Blood pressure is monitored, and, when it reaches a threshold, an antihypertensive is started promptly to avoid morbidity and mortality.

Psychiatric illness carries risks for both mother and fetus as well, but no data show a clear threshold for initiating pharmacologic treatment. Therefore, in prescribing medication the most important steps are to take a complete history and perform a thorough evaluation. Important information includes the number and severity of previous episodes, prior history of hospitalization or suicidal thoughts or attempts, and any history of psychotic or manic status.

Whether to continue or discontinue medication is often decided after inquiring about other times a medication was discontinued. A patient who in the past stayed well for several years after stopping a medication may be able to taper off a medication and conceive during a window of wellness. Some women who have experienced only one episode of illness and have been stable for at least a year may be able to taper off a medication before conceiving (**TABLE 1**).

In the risk–benefit analysis, assess the need for pharmacologic treatment by considering the risk that untreated illness poses for both mother and fetus, the benefits of treatment for both, and the risk of medication exposure for the fetus.[4]

FAST TRACK

Assess the need for pharmacologic treatment by considering the risk of untreated illness for mother and fetus, benefits of treatment for both, and risk of drug exposure for the fetus

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FAST TRACK

Women with functional impairment—inability to work, perform activities of daily living, take care of other children—likely require treatment

Mother: Risk of untreated illness versus benefit of treatment

A complete history and a current symptom evaluation are needed to assess the risk that nonpharmacologic treatment poses for the mother. Women with functional impairment, including inability to work, to perform activities of daily living, or to take care of other children, likely require treatment. Studies have found that women who discontinue treatment for a psychiatric illness around the time of conception are likely to experience a recurrence of illness during pregnancy, often in the first trimester, and must restart medication.[5,6] For some diagnoses, particularly bipolar disorder, symptoms during a relapse can be more severe and more difficult to treat, and they carry a risk for both mother and fetus.[7] A longitudinal study of pregnant women who stopped medication for bipolar disorder found a 71% rate of relapse.[7] In cases in which there is a history of hospitalization, suicide attempt, or psychosis, discontinuing treatment is not an option; instead, the physician must determine which medication is safest for the particular patient.

Fetus: Risk of untreated illness versus benefit of treatment

Mothers with untreated psychiatric illness are at higher risk for poor prenatal care, substance abuse, and inadequate nutrition, all of which increase the risk of negative obstetric and neonatal outcomes.[8] Evidence indicates that untreated maternal depression increases the risk of preterm delivery and low birth weight.[9] Children born to mothers with depression have more behavioral problems, more psychiatric illness, more visits to pediatricians, lower IQ scores, and attachment issues.[10] Some of the long-term negative effects of intrauterine stress, which include hypertension, coronary heart disease, and autoimmune disorders, persist into adulthood.[11]

Fetus: Risk of medication exposure

With any pharmacologic treatment, the timing of fetal exposure affects resultant risks and therefore must be considered in the management plan.

Before conception. Is there any effect on ovulation or fertilization?

Implantation. Does the exposure impair the blastocyst's ability to implant in the uterine lining?

First trimester. This is the period of organogenesis. Regardless of drug exposure, there is a 2% to 4% baseline risk of a major malformation during any pregnancy. The risk of a particular malformation must be weighed against this baseline risk.

According to limited data, selective serotonin reuptake inhibitors (SSRIs) may increase the risk of early miscarriage.[12] SSRIs also have been implicated in increasing the risk of cardiovascular malformations, although the data are conflicting.[13,14]

Antiepileptics such as valproate and carbamazepine are used as mood stabilizers in the treatment of bipolar disorder.[15] Extensive data have shown an association with teratogenicity. Pregnant women who require either of these medications also should be prescribed folic acid 4 or 5 mg/day. Given the high risk of birth defects and cognitive delay, valproate no longer is recommended for women of reproductive potential.[16]

Lithium, one of the safest medications used in the treatment of bipolar disorder, is associated with a very small risk of Ebstein anomaly.[17]

Lamotrigine is used to treat bipolar depression and appears to have a good safety profile, along with a possible small increased risk of oral clefts.[18,19]

Atypical antipsychotics (such as aripiprazole, olanzapine, quetiapine, and risperidone) are often used first-line in the treatment of psychotic disorders and bipolar disorder in women who are not pregnant. Although the safety data on use of these drugs during pregnancy are limited, a recent analysis of pregnant Medicaid enrollees found no increased risk of birth defects after controlling for potential confounding factors.[20] Common practice is to avoid these newer agents, given their limited data and the time needed for rare malformations to emerge (adequate numbers require many exposures during pregnancy).

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Second trimester. This is a period of growth and neural development. A 2006 study suggested that SSRI exposure after pregnancy week 20 increases the risk of persistent pulmonary hypertension of the newborn (PPHN).[21] In 2011, however, the FDA removed the PPHN warning label for SSRIs, citing inconsistent data. Whether the PPHN risk is increased with SSRI use is unclear, but the risk is presumed to be smaller than previously suggested.[22] Stopping SSRIs before week 20 puts the mother at risk for relapse during pregnancy and increases her risk of developing postpartum depression. If we follow the recommendation to prescribe medication only for women who need it most, then stopping the medication at any time during pregnancy is not an option.

Third trimester. This is a period of continued growth and lung maturation.

Delivery. Is there a potential for impairment in parturition?

Neonatal adaptation. Newborns are active mainly in adapting to extrauterine life: They regulate their temperature and muscle tone and learn to coordinate sucking, swallowing, and breathing. Does medication exposure impair adaptation, or are signs or symptoms of withdrawal or toxicity present? The evidence that in utero SSRI exposure increases the risk of neonatal adaptation syndrome is consistent, but symptoms are mild and self-limited.[23] Tapering off SSRIs before delivery currently is not recommended, as doing so increases the mother's risk for postpartum depression and, according to one study, does not prevent symptoms of neonatal adaptation syndrome from developing.[24]

Behavioral teratogenicity. What are the long-term developmental outcomes for the child? Are there any differences in IQ, speech and language, or psychiatric illness? One study found an increased risk of autism with in utero exposure to sertraline, but the study had many methodologic flaws and its findings have not been replicated.[25] Most studies have not found consistent differences in speech, IQ, or behavior between infants exposed and infants not exposed to antidepressants.[26,27] By contrast, in utero exposure to anticonvulsants, particularly valproate, has led to significant developmental problems in children.[28] The data on atypical antipsychotics are limited.

None of the medications used to treat depression, bipolar disorder, anxiety, or schizophrenia is considered first-line or safest therapy for the pregnant woman. For any woman who is doing well on a certain medication, but particularly for a pregnant woman, there is no compelling, data-supported reason to switch to another agent. For depression, options include all of the SSRIs, with the possible exception of paroxetine (**TABLE 2**). In conflicting studies, paroxetine was no different from any other SSRI in not being associated with cardiovascular defects.[29]

One goal in treatment is to use a medication that previously was effective in the remission of symptoms and to use it at the lowest dose possible. Treating simply to maintain a low dose of drug, however, and not to effect symptom remission, exposes the fetus to both the drug and the illness. Again, the lowest *effective* dose is the best choice.

FAST TRACK

One goal in treatment is to use a medication that previously was effective in symptom remission at the lowest dose possible

Treatment during breastfeeding

Women are encouraged to breastfeed for physical and psychological health benefits, for both themselves and their babies. Many medications are compatible with breastfeeding.[30] The amount of drug an infant receives through breast milk is considerably less than the amount received during the mother's pregnancy. Breastfeeding generally is allowed if the calculated infant dose is less than 10% of the weight-adjusted maternal dose.[31]

The amount of drug transferred from maternal plasma into milk is highest for drugs with low protein binding and high lipid solubility.[32] Drug clearance in infants must be considered as well. Renal clearance is decreased in newborns and does not reach adult levels until 5 or 6 months of age. In addition, liver metabolism is impaired in neonates and even more so in premature infants.[33] Drugs that require extensive first-pass metabolism may have higher bioavailability, and this factor should be considered.

Some clinicians recommend pumping and discarding breast milk when the drug in it is at its peak level; although the drug is not eliminated, the infant ingests less of it.[34] Most women who are anxious about breastfeeding while on medication "pump and dump" until they are more comfortable nursing and the infants are doing well. Except in cases of mother preference, most physicians with expertise in reproductive mental health generally recommend against pumping and discarding milk.

Through breast milk, infants ingest drugs in varying amounts. The amount depends on the qualities of the medication, the timing and

TABLE 2 Oral antidepressants commonly used during pregnancy and breastfeeding, with dose ranges

Class	Medication	When to use	Dose range
SSRI	Sertraline	• Often first choice for depression and anxiety • Well tolerated • Abundant data on safety during pregnancy and breastfeeding • Higher doses for obsessive-compulsive disorder	• Start at 25 mg for 1 week • Increase to 50 to 200 mg • Monitor clinical response every 2 to 3 weeks, before increasing dose
	Citalopram	• Good choice for depression and anxiety • Abundant data on safety during pregnancy and breastfeeding • Higher doses associated with prolonged QT interval	• Start at 5 to 10 mg for 1 week • Increase to 20 to 40 mg
	Escitalopram	• Compared with citalopram, this S enantiomer of citalopram has fewer data on safety during pregnancy and breastfeeding • May have fewer adverse effects	• Start at 5 mg for 1 week • Increase to 10 mg • Dose range: 10–20 mg
	Fluoxetine	• Of SSRIs, has most data available • Possible small increased risk of cardiac defect • Conflicting data • Useful for depression and anxiety • Long half-life • No withdrawal effects in adults	• Start at 10 mg for 1 week • Increase to 20 mg (usually effective) • Dose range: 20–80 mg • Higher doses for obsessive-compulsive disorder
	Paroxetine	• Possible small increased risk of cardiac defect • Missed doses lead to significant withdrawal symptoms • Compared with other SSRIs, may be more effective for anxiety	• Start at 10 mg for 1 week • Increase to 20 mg • Dose range: 20–40 mg
NDRI	Bupropion	• Not useful for anxiety symptoms, may exacerbate anxiety • Compared with SSRIs, has fewer safety data • Good antidepressant for complaints related to attention and focus • No weight gain or sexual dysfunction	• Start at 150 mg for 1 week • Increase to 300 mg • Dose range: 150–450 mg
SNRI	Venlafaxine	• May be related to hypertension during pregnancy • In many patients, missed doses lead to significant withdrawal symptoms • Limited data on safety during pregnancy • Useful for treatment-resistant depression	• Start at 37.5 mg • Increase every week to 150 mg • Dose range: 75–300 mg

Abbreviations: NDRI, norepinephrine-dopamine reuptake inhibitor; SNRI, serotonin-norepinephrine reuptake inhibitor; SSRI, selective serotonin reuptake inhibitor.

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duration of breastfeeding, and the characteristics of the infant. Few psychotropic drugs have significant effects on breastfed infants. Even lithium, previously contraindicated, is successfully used, with infant monitoring, during breastfeeding.[35] Given breastfeeding's benefits for both mother and child, many more women on psychotropic medications are choosing to breastfeed.

Balance the pros and cons

Deciding to use medication during pregnancy and breastfeeding involves considering the risk of untreated illness versus the benefit of treatment for both mother and fetus, and the risk of medication exposure for the fetus. Mother and fetus are inseparable, and neither can be isolated from the other in treatment decisions. Avoiding psychotropic medication during pregnancy is not always the safest option for mother or fetus. The patient and her clinician and support system must make an informed decision that is based on the best available data and that takes into account the mother's history of illness and effective treatment. Many women with psychiatric illness no longer have to choose between mental health and starting a family, and their babies will be healthy.

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ObGyns' choice of practice environment is a big deal

ObGyns are moving from private practice to employment to reduce stress and burnout and increase their quality of life

Deborah Reale, Managing Editor

ObGyns are mindfully choosing their practice environments. The trend, as reported by the American College of Obstetricians and Gynecologists (ACOG),[1] shows movement from private practice to employment: an increasing number of ObGyns have joined large practices and are employed. Overall, fewer than half of US physicians owned their medical practice in 2016, reported the American Medical Association (AMA).[2] This is the first time that the majority of physicians are not practice owners.

Although employed ObGyns earn 9% less than self-employed ObGyns, ($276,000 vs $300,000, respectively), trading a higher salary for less time spent on administrative tasks seems to be worth the pay cut, reports Medscape. Employed ObGyns reported receiving additional benefits that might not have been available to self-employed ObGyns: professional liability coverage, employer-subsidized health and dental insurance, paid time off, and a retirement plan with employer match.[3]

What matters to ObGyns when choosing a practice setting?

Several decisions about practice setting need to be made at the beginning and throughout a career, among them the type of practice, desired salary, work-life balance, (the latter 2 may be influenced by practice type), and location.

Type of practice

"Patients benefit when physicians practice in settings they find professionally and personally rewarding," said AMA President Andrew W. Gurman, MD. "The AMA is committed to helping physicians navigate their practice options and offers innovative strategies and resources to ensure physicians in all practice sizes and setting can thrive in the changing health environment."[2]

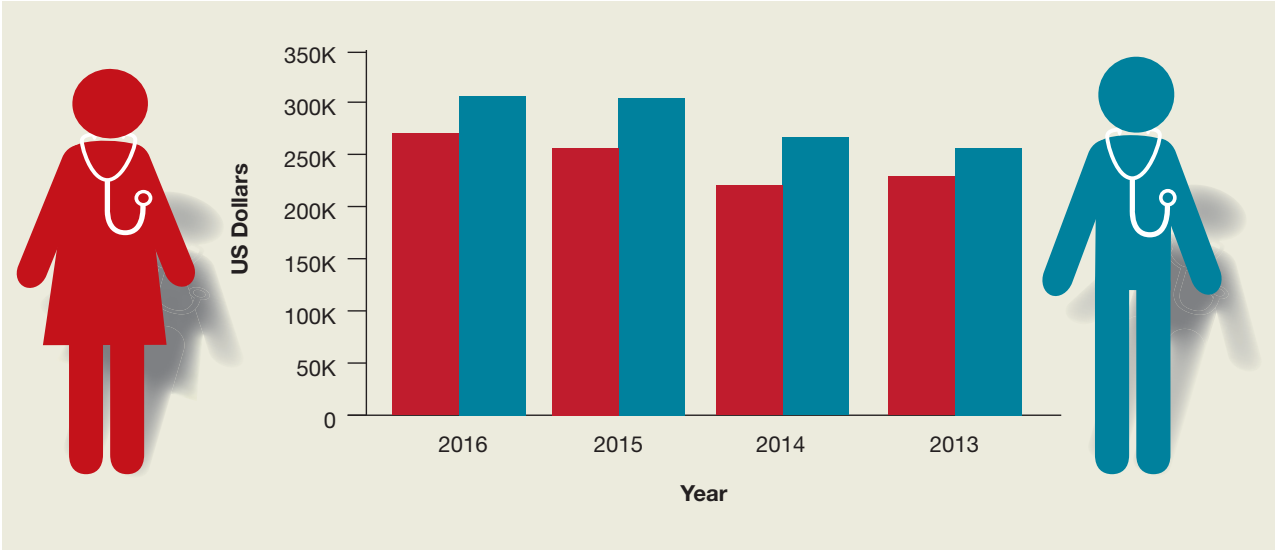
More and more, that environment is a practice wholly owned by physicians. The AMA reports that in 2016, 55.8% of physicians worked in such a practice (including physicians who have an ownership stake in the practice, those who are employed by the practice, and those who are independent contractors).[2] An approximate 13.8% of physicians worked at practices with more than 50 physicians in 2016. The majority (57.8%), however, practiced in groups with 10 or fewer physicians. The most common practice type was the single-specialty group (42.8%), followed by the multispecialty group practice (24.6%).[2]

Paying physicians a salary instead of compensating them based on volume may

IN THIS ARTICLE

›› Have you read "How to sell your ObGyn practice" on page 24?

FIGURE 1 **ObGyns: Which gender earns more?**[3,5,7,8]



FAST TRACK

Fewer than half of ObGyns who completed the Medscape survey felt they were fairly compensated in 2016

improve physician satisfaction—it removes the need to deal with complex fee-for-service systems, say Ian Larkin, PhD, and George Loewenstein, PhD. In fee-for-service payment arrangements, physicians may be encouraged to order more tests and procedures because doing so may increase income. A better strategy, say Larkin and Loewenstein, is to switch to a straight salary system. Known for their quality of care and comparatively low costs, the Mayo Clinic, Cleveland Clinic, and Kaiser Permanente have successfully implemented this payment system.[4]

Desired salary

The mean income for ObGyns rose by 3% in 2016 over 2015 ($286,000 compared with $277,000), according to Medscape.[5] This jump follows a gradual increase over the last few years ($249,000 in 2014; $243,000 in 2013; $242,000 in 2012; $220,000 in 2011).[1,5,6]

The highest earnings among all physicians were orthopedists ($489,000), plastic surgeons ($440,000), and cardiologists ($410,000). Pediatricians were the lowest paid physicians at $202,000.[3]

Fair compensation. Fewer than half (48%) of ObGyns who completed the Medscape survey felt they were fairly compensated in 2016, and 41% of those who were dissatisfied with their compensation believed they deserved to be earning between 11% and 25% more. When asked if they would still choose medicine, 72% of ObGyns answered affirmatively. Of those who would choose medicine again, 76% would choose obstetrics and gynecology once more.[3]

Gender differences. As in years past, full-time male ObGyns reported higher earnings (13%) than female ObGyns ($306,000 vs $270,000, respectively; (**FIGURE 1**).[3,5,7,8]

Among ObGyns who responded to the 2017 Medscape survey, 14% of women and 10% of men indicated that they work part-time.[3] Last year, 13% of female ObGyns reported part-time employment versus 16% of male ObGyns.[6]

Among the ObGyns who answered the 2017 survey, there was a gender gap in participation related to race. Although more men than women responded to the survey, more women than men ObGyns among black/African American (women, 78%), Asian (women, 69%), and white/Caucasian (women, 53%) groups responded. Men outweighed women only among Hispanic/Latino ObGyns (60%) who answered the survey.[3]

Work-life balance

ACOG predicts that mid-career and younger ObGyns will focus on work-life balance issues. Practice sites (ambulatory, hospital,

or a combination) that offer part-time schedules or extra time for nonprofessional matters are becoming the most desirable to these practitioners.[1]

What satisfies and dissatisfies ObGyns? ObGyns reported to Medscape that their relationships with patients (41% of respondents) was the most rewarding part of their job (**FIGURE 2**).[3]

There are many job aspects that dissatisfy ObGyns, including[1,3,9]:

- too many bureaucratic tasks
- the short time allotted for each patient office visit
- electronic health records (EHR) and increased computerization
- not feeling appreciated or properly compensated
- spending too many hours at work
- the impact of regulatory changes on clinical practice.

Bureaucratic tasks remain a primary cause for burnout among all physicians.[10] This year, 56% of all physicians reported spending

FIGURE 2 What did ObGyns find as the most rewarding part of their job in 2016?[3]

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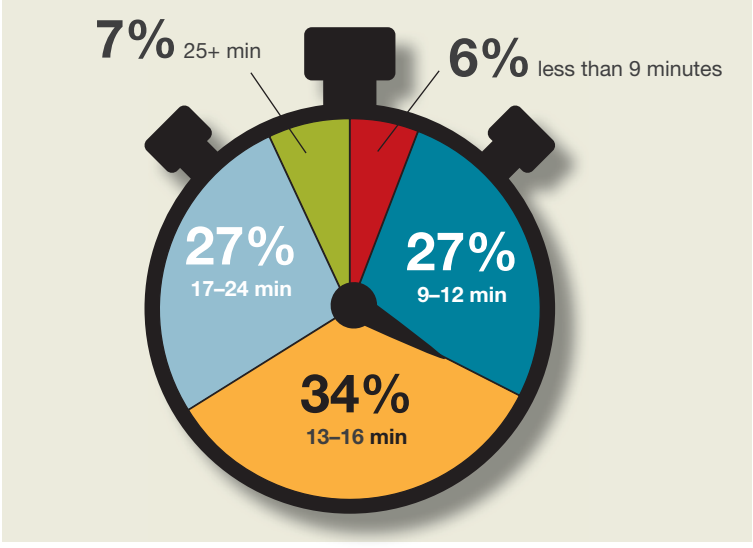
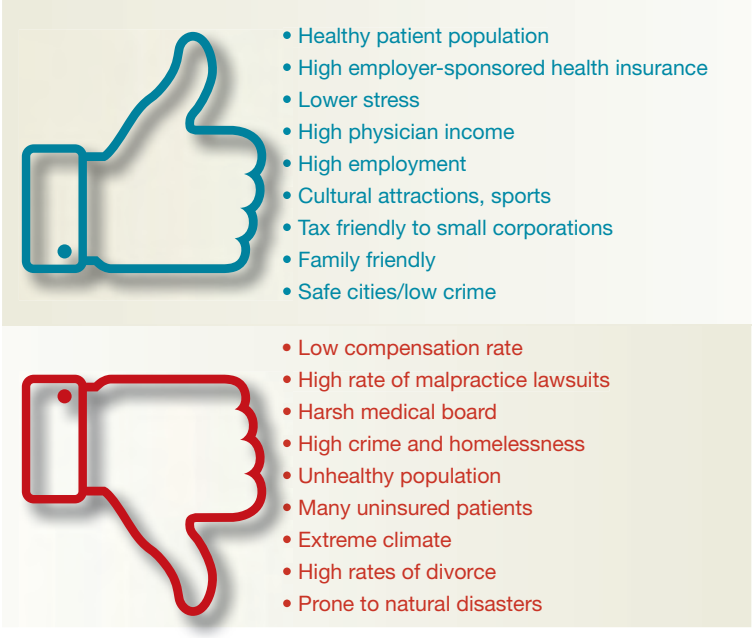
FIGURE 3 How much time did ObGyns spend with patients in 2016?[3]



10 hours or more per week on paperwork and administrative tasks, up from 35% in the 2014 report. More than half (54%) of ObGyns reported spending 10 hours or more on paperwork.[3] For every hour of face-to-face patient time, physicians spent nearly 2 additional hours on their EHR and administration tasks.[9]

FIGURE 4 What factors attract/do not attract physicians to states?[12]



Time with patients. Medscape reported that 38% of ObGyns spent more than 45 hours per week with patients (**FIGURE 3**).

ACOG notes that ObGyns are increasingly referring patients to subspecialists, which frustrates patients and increases their costs.[1]

ObGyns rank high in burnout rates. Burnout rates for physicians are twice that of other working adults.[1] ObGyns rank second (56%) in burn out (Emergency Medicine, 59%).[10] When Medscape survey respondents were asked to grade their burnout level from 1 to 7 (1 = "It does not interfere with my life;" 7 = "It is so severe that I am thinking of leaving medicine altogether"), ObGyns ranked their burnout level at 4.3.[10] Female physicians reported a higher percentage of burnout than their male colleagues (55% vs 45%, respectively).[10] An estimated 40% to 75% of ObGyns experienced some level of burnout.[1]

According to ACOG, the specialty is included among the "noncontrollable" lifestyle specialties, especially for those aged 50 years or younger. Many Millennials (born 1980 to 2000) do not view their work and professional achievement as central to their lives; ObGyns aged younger than 35 years want to work fewer hours per week compared with their older colleagues, says ACOG. However, when this option is unavailable, an increasing number of Millennials report lowered job satisfaction.[1]

Mindfulness about quality of life. The relationship of burnout to quality of life issues is gaining in awareness. In a recent OBG MANAGEMENT article, Lucia DiVenere, MA, noted that, "Being mindful of wellness strategies and practice efficiencies can help ObGyns avoid burnout's deleterious effects—and thrive both personally and professionally."[11]

"We need to stop blaming individuals and treat physician burnout as a system issue…If it affects half our physicians, it is indirectly affecting half our patients," notes Tait Shanafelt, MD, a hematologist and physician-burnout researcher at the Mayo Clinic.[9] He says that burnout relates to a physician's "professional spirit of life, and it primarily affects individuals whose work involves an intense interaction with people."[9]

The Mayo Clinic in Minneapolis, Minnesota, has taken a lead in developing a space for their physicians to "reset" by offering a room where health professionals can retreat if they need a moment to recover from a traumatic event.[9]

Location, location, location

Specific areas of the country are more attractive for their higher compensation rates. The highest average compensation was reported by ObGyns in the North Central area ($339,000), West ($301,000), and Great Lakes ($297,000) regions, while the lowest compensation rates were found in the Northwest ($260,000), Southwest ($268,000), and South Central ($275,000) areas.[3]

Key factors, such as healthy patient populations, higher rates of health insurance coverage, and lower stress levels attract physicians (**FIGURE 4**). Minnesota ranked the #1 best place to practice because it has the 4th healthiest population, 2nd highest rate of employer-sponsored health insurance, the 17th lowest number of malpractice lawsuits, and a medical board that is the 3rd least harsh in the nation.[12] Unfortunate situations such as the highest malpractice rates per capita, least healthy population, 8th lowest rate of employer-sponsored health insurance, and the 9th lowest compensation rate for physicians make Louisiana the worst place to practice in 2017.[12]

Supply and demand creates substantial geographic imbalances in the number of ObGyns in the United States. ACOG projects that the need for ObGyns will increase nationally by 6% in the next 10 years, although demand will vary geographically from a 27% increase in Nevada to an 11% decrease in West Virginia.[1] Especially vulnerable states (Arizona, Washington, Utah, Idaho) currently have an insufficient supply of ObGyns and are projected to see an increased future demand. Florida, Texas, North Carolina, and Nevada will be at risk, according to ACOG, because the adult female population is expected to increase.[1]

2017 Medscape survey demographics

The Medscape Compensation Report 2017 is a based on the responses of 19,270 physicians across 27+ specialties, 5% of whom were ObGyns. Data were collected in an online survey conducted from December 20, 2016, to March 7, 2017.[3]

FAST TRACK

ACOG projects that the need for ObGyns will increase nationally by 6% in the next 10 years

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Does total removal of the tubes affect ovarian reserve?

Ganer Herman H, Gluck O, Keidar R, et al. Ovarian reserve following cesarean section with salpingectomy vs tubal ligation: a randomized trial. Am J Obstet Gynecol. 2017;doi: 10.1016/j.ajog.2017.04.028.

FAST TRACK

Preoperative and postoperative anti-Müllerian hormone levels were similar for women undergoing partial or total salpingectomy at elective cesarean delivery

As acceptability of total salpingectomy for permanent contraception increases, one concern is that complete removal may alter blood supply to the ovary, resulting in decreased ovarian reserve and, subsequently, earlier menopause. Several studies have addressed the potential effect of salpingectomy on ovarian function when performed at the time of hysterectomy, most of which have noted no difference in anti-Müllerian hormone (AMH) levels and sonographic parameters following surgery.[19] However, very little has been published to assess this same question when the salpingectomy is performed for the purpose of permanent contraception.

Ganer Herman and colleagues aimed to assess short-term ovarian reserve by measuring AMH levels preoperatively and 6 to 8 weeks postoperatively in patients undergoing partial or total salpingectomy at the time of elective cesarean delivery.

Details of the study

The study included women aged 18 to 45 who presented for elective cesarean delivery and who requested permanent contraception. Exclusion criteria included previous tubal surgery, emergent cesarean delivery, personal history of breast carcinoma, familial history of ovarian carcinoma, and *BRCA* carriage.

Women were randomly assigned at a 1:1 ratio to bilateral total salpingectomy or bilateral partial salpingectomy. A complete blood count and AMH level were drawn the night prior to surgery. Intraoperatively, after delivery and hysterotomy closure, partial salpingectomy, via the Parkland technique, or total salpingectomy, using a suture ligation technique, was performed.

Of the 46 women enrolled, follow-up was completed by 16 of 22 women (72%) in the total salpingectomy group and 18 of 24 women (75%) in the partial salpingectomy group. Patients in the total salpingectomy group were slightly older (mean age, 37 vs 34 years; $P = .02$), but otherwise all demographic and obstetric characteristics were comparable.

No differences were noted in preoperative and postoperative AMH levels between groups, with an average (SD) increase of 0.58 (0.98) ng/mL versus 0.39 (0.41) ng/mL in the total salpingectomy and partial salpingectomy groups, respectively ($P = .45$), consistent with known postpartum AMH level trends.

Other findings included an average 13-minute increase in operative time in the total salpingectomy cases, similar safety profile of the 2 methods as there were no postoperative complications during the study period, and no differences in postoperative hemoglobin levels.

Conclusion

The studies reviewed in this article are some of the first to evaluate the feasibility and safety of opportunistic, or total, salpingectomy for permanent contraception since the ACOG and SGO recommendations were published. Just as our community has adopted the common practice of opportunistic salpingectomy at the time of hysterectomy, we should continue to advocate for a similar practice when discussing permanent contraception. Additionally, the Westberg study provides good evidence that educational initiatives can influence provider practices, which upholds the data published by McAlpine and colleagues in British Columbia. This information is promising and valuable.

Our universal goal as ObGyns is to provide the best reproductive health care possible based on the most recent evidence available. Continuing to advocate for opportunistic salpingectomy for permanent contraception purposes meets this goal and potentially provides significant noncontraceptive benefits.

WHAT THIS EVIDENCE MEANS FOR PRACTICE

This study was designed as a pilot trial to assess feasibility of enrollment, safety, and short-term ovarian reserve after salpingectomy for permanent contraception. Although the study is small and does not assess long-term effects, the findings are reassuring, especially in conjunction with other data.

A meta-analysis demonstrated no effect on ovarian reserve up to 18 months after salpingectomy based on AMH changes.[19] A 5-year follow-up evaluation of 71 women undergoing total laparoscopic hysterectomy with bilateral salpingectomy also showed no effect on ovarian reserve as measured by multiple hormone levels including AMH and ultrasonographic findings.[20] Thus, it is highly unlikely that a permanent contraception procedure that does not include removal of the uterus will have long-term ovarian reserve effects.

Additionally, consistent with other trials, Ganer Herman and colleagues demonstrate a slightly increased operative time and no increased complications. The surgical technique used in the study reflects the concern for postoperative bleeding from the mesosalpinx, and methods that ensure excellent hemostasis with suture ligation were used.

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Delay in delivery—mother and child die: $1.4M settlement

RESULTS OF ULTRASONOGRAPHY on January 8 identified placenta accreta and placenta previa in a woman at 36 weeks of gestation. On January 14, she was referred to a university medical center for treatment. Instead of scheduling a prompt delivery, the ObGyns sent her home with a plan to deliver her at 39 weeks. Nine days later, the mother collapsed at home. She was taken to a nearby hospital, where an emergency cesarean delivery was performed. She died after delivery. The baby was profoundly acidotic and asphyxiated and died 10 months later.

ESTATE'S CLAIM: The standard of care for placenta accreta requires delivery between 34 and 36 weeks of gestation. The mother died from a placental abruption and amniotic fluid embolism. Placenta accreta increases the risk of catastrophic hemorrhage. If delivery had occurred on January 14, both the mother and child would be alive.

DEFENDANTS' DEFENSE: The case settled before trial.

VERDICT: A $1.425 million Georgia settlement was reached. The settlement amount was limited by a damages cap unique to the defendant hospital.

Woman dies after robotic hysterectomy: $5M verdict

WHEN A 36-YEAR-OLD WOMAN underwent robotic hysterectomy, the gynecologist inserted a plastic trocar and sleeve through the patient's umbilicus to access the abdominal cavity at 7:30 AM.

The certified registered nurse anesthetist (CRNA) noted a significant abnormality in the patient's vital signs at 8:07 AM and administered medication and fluids to treat a suspected blood loss. When the patient's heart rate became extremely elevated at 8:25 AM, the CRNA administered another drug, which failed to bring the patient's heart rate down. At 8:37 AM, the monitoring machine could not record the patient's blood pressure. The CRNA informed the surgeon of the patient's condition. The supervising anesthesiologist was called; he arrived at 8:45 AM and determined that the patient was bleeding internally. He asked the surgeon if he could visualize any bleeding; the surgeon could not.

The patient's condition continued to deteriorate. At 9:05 AM, her blood pressure was still undetectable on the monitor. A Code Blue was called at 9:30 AM. Exploratory surgery and blood transfusions begun at 9:43 AM were not able to counteract the patient's massive blood loss. After cardiac arrest, she was pronounced dead at 11:18 AM.

ESTATE'S CLAIM: The surgeon was negligent in lacerating the left common iliac artery when inserting the trocar, and in not detecting the injury intraoperatively.

The anesthesia staff was negligent. The CRNA did not inform the surgeon until the situation was dire. A simple procedure could have been performed at any time to check the patient's hematocrit and hemoglobin levels, but that was not done until 9:30 AM. If the severity of the patient's condition had been determined earlier, blood transfusions and further treatment could have saved her life.

DEFENDANTS' DEFENSE: There was no negligence on the part of the surgeon or anesthesia team. The standard of care was met. Arterial laceration is a known risk of the surgery.

VERDICT: A $5,008,922 Illinois verdict was returned against all defendants except the CRNA.

Placental abruption not detected: $6.2M settlement

AT 24 WEEKS OF GESTATION, a mother presented to the hospital with premature contractions that subsided after her arrival. She was discharged from the hospital. The woman gave birth in her bathtub several hours later. The baby was 10 weeks premature. He suffered profound brain damage and has significant physical defects.

PARENT'S CLAIM: Neither the ObGyn nor the hospital staff appreciated that the mother was experiencing placental abruption. If diagnosed, treatment could have prevented fetal injury.

These cases were selected by the editors of OBG MANAGEMENT *from* Medical Malpractice Verdicts, Settlements, & Experts, *with permission of the editor, Lewis Laska (www.verdictslaska.com). The information available to the editors about the cases presented here is sometimes incomplete. Moreover, the cases may or may not have merit. Nevertheless, these cases represent the types of clinical situations that typically result in litigation and are meant to illustrate nationwide variation in jury verdicts and awards.*

CONTINUED ON PAGE 46

PHOTO: SHUTTERSTOCK

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DEFENDANTS' DEFENSE: The case was settled prior to trial.

VERDICT: A $6.2 million New York settlement was reached.

A woman with MS becomes incontinent after surgery

A 43-YEAR-OLD WOMAN with multiple sclerosis (MS) underwent a hysterectomy performed by a gynecologic surgeon. During surgery, the patient's ureter was injured, requiring additional surgery. The patient is now permanently incontinent.

PATIENT'S CLAIM: During surgery, the surgeon constricted the ureter with stitches. A second surgery was needed to remove the stitches and reimplant the ureter. The second surgery left her permanently incontinent. Although incontinence is a known complication of the second surgery, the second surgery would not have been necessary if the surgeon had not injured the ureter during the first surgery. Incontinence was not a result of her MS as she was not incontinent before the second surgery.

DEFENDANTS' DEFENSE: There was no deviation from the standard of care. There was no stitching around the ureter. The ureter was damaged by kinking, which was addressed during the second surgery. Incontinence was a result of her MS.

VERDICT: A $700,000 South Carolina verdict was returned.

Child has brachial plexus injury: $2M award

A WOMAN WAS ADMITTED to the hospital for elective induction of labor. She gained a significant amount of weight while pregnant. During delivery, her family practitioner (FP) determined that vacuum extraction was needed but he was not qualified to use the device. An in-house ObGyn was called in to use the vacuum extractor. The FP delivered the baby's shoulders. The infant was born with a floppy right arm and later diagnosed with rupture injuries to the C-5 and C-6 vertebrae and permanent brachial plexus damage. She has limited range of motion in her right arm and shoulder.

PARENTS' CLAIM: The FP was relatively inexperienced in labor and delivery. He should not have ordered vacuum extraction because of risk factors including the mother's small stature, her significant weight gain during pregnancy, the use of epidural anesthesia, and induction of labor. Using vacuum extraction increases the risk of shoulder dystocia.

The FP improperly applied excessive downward traction on the fetus causing the infant to sustain a brachial plexus injury.

The FP did not notify the parents of the child's injury immediately after birth; he told them about the injury just before discharge.

DEFENDANTS' DEFENSE: There is no evidence in the medical records of a shoulder dystocia; "no shoulder dystocia" was charted shortly after delivery. No one in the delivery room testified to a delay in delivering the infant's shoulders. The mother's internal contractions caused the injury. The baby was not injured to the extent claimed.

VERDICT: The ObGyn who used the vacuum extractor settled before the trial for $300,000. A $2 million Illinois verdict was returned against the FP.

Bowel injury during robotic procedure: $6.25M settlement

A WOMAN IN HER LATE 60S reported minor urinary incontinence to her gynecologist. She underwent robot-assisted laparoscopic hysterectomy with a sling procedure for pelvic prolapse. During the sling procedure, the transverse colon was injured. The patient developed sepsis, requiring multiple attempts at surgical repair, including colostomy. The patient requires a permanent colostomy. She has a malabsorption disorder and needs frequent intravenous treatment for dehydration.

PATIENT'S CLAIM: The surgeon failed to properly control the robotic device, causing injury to the patient's bowel. The surgeon deviated from the standard of care by failing to convert from the robot-assisted laparoscopic procedure to an open procedure when complications arose. The injury was not properly treated before the surgeon closed the initial surgery, causing the patient to develop sepsis.

PHYSICIAN'S DEFENSE: The surgeon claimed that the injuries and resulting sepsis were the fault of other physicians and hospital staff. The case settled during trial.

VERDICT: A $6.25 million New Jersey settlement was reached.

Delay in treating infant in respiratory distress: $7.27M settlement

A CHILD WAS DELIVERED by a certified nurse midwife at a birthing center. At birth, the baby had a heart rate of 60 bpm and was in respiratory distress but there was no one at the

clinic qualified to intubate the infant. Emergency personnel were called but the infant remained in respiratory distress for 8 minutes. The baby experienced birth asphyxia with hypoxic ischemic encephalopathy resulting in severe cerebral palsy.

PARENTS' CLAIM: The birthing center was poorly staffed and unprepared to treat an emergency situation.

DEFENDANTS' DEFENSE: The defendants denied all allegations of negligence. The case was settled during trial.

VERDICT: A $7.27 million Pennsylvania settlement was reached.

Hydrothermal ablation led to genital burns

A WOMAN SAW AN OBGYN on October 2 to report menorrhagia. She had been treated for uterine fibroids with a Mirena intrauterine device and hydrothermal ablation. Another physician had suggested hysterectomy, which she declined.

When the ObGyn found that the patient had an enlarged uterus, he ordered ultrasonography and an endometrial biopsy. On follow-up, the ObGyn provided options of robotic hysterectomy or operative hysteroscopy with hydrothermal ablation. The patient chose hysteroscopy and the procedure was scheduled for December 28.

During surgery, an improper seal to the cervix around the hydrothermal ablation sheath was detected before heating the fluid. A tenaculum and 2 sponges were placed on the cervix to help form a seal and the fluid was heated for 4 minutes. The procedure was aborted when fluid was seen to be leaking again. Instruments were removed after a cooling period. The patient was discharged from the surgery center the same day with a prescription for oral hydrocodone bitartrate and acetaminophen for pain.

On January 4, the patient reported severe vulvar pain. The ObGyn found thermal burns on both labia with possible cellulitis. He prescribed silver sulfadiazine cream twice daily, levofloxacin 500 mg for 7 days, and warm-water soaks. When the patient called to report continued pain on January 7, the hydrocodone and acetaminophen prescription was renewed. On January 8, the ObGyn found continued evidence of labia and introitus burns with no signs of infection. The patient was told to continue taking the oral pain medication and to apply topical lidocaine gel and silver sulfadiazine cream.

Examinations on January 11, 17, 24, and 31 showed continued evidence of active healing. When new evidence of vulvar ulceration with inflammation and infection appeared, supportive care and antibiotics were given. On February 7, granulation tissue had developed at the introitus with continued healing.

On March 27, she saw a gynecologist for dyspareunia. The skin was healed but a tender band of scar tissue was noted at the burn site. She was referred for physical therapy and given estradiol vaginal cream.

On December 11, the patient reported dyspareunia and depression to the gynecologist, who prescribed medication for depression and referred her to counseling.

PATIENT'S CLAIM: The ObGyn was negligent in failing to maintain a proper seal around the hydrothermal ablation shield. The patient sustained second-degree burns to her genital area from the hot saline solution that leaked from the uterus. The injury caused lasting dyspareunia and depression.

PHYSICIAN'S DEFENSE: There was no negligence. Once the ObGyn realized that the seal was incomplete, the procedure was stopped and the fluid cooled before being released. Burns were treated within the standard of care.

VERDICT: A Texas defense verdict was returned based on a no-evidence partial summary judgment: neither the patient nor the expert witness supplied evidence to support the claims of gross negligence or exemplary damages against the ObGyn.

Was the spinal block given at wrong level?

A MOTHER WENT TO THE HOSPITAL in labor. Prior to cesarean delivery, she underwent an anesthetic spinal block administered by a CRNA. Initially, the patient reported pain shortly after the injection was performed until the block worked. The baby's delivery was uneventful.

In recovery a few hours later, the patient reported intense and uncontrollable pain in her legs. Magnetic resonance imaging revealed a fluid pocket on her spinal cord at the L1-L2 level. The patient has permanent pain, numbness, and tingling in in both legs.

PATIENT'S CLAIM: The CRNA failed to insert the spinal block needle in the proper location.

DEFENDANT'S DEFENSE: The CRNA contended that he complied with the standard of care. He claimed that the patient had an unusual spinal cord anatomy: it was tethered down to the L3-L4 level.

VERDICT: A $509,152 Kentucky verdict was returned.

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Vaginal salpingo-oophorectomy: Tips and tricks

JENNIFER J. SCHMITT, DO; JENIFER N. BYRNES, DO;
ERIK D. HOKENSTAD, MD; AND JOHN B. GEBHART, MD, MS

The authors of this video discuss the trends and feasibility of successful transvaginal salpingo-oophorectomy at the time of vaginal hysterectomy, emphasizing that adequate lighting and exposure are key. They review 5 surgical techniques including a round ligament technique with or without isolated transection of the ligament, and the use of a pre-tied surgical suture loop, a surgical stapler, and a bipolar vessel-sealing device. Surgical options are discussed when an unexpected adnexal mass is encountered.

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SCREEN FOR HERPES SIMPLEX VIRUS

Hologic now offers the **Aptima Herpes Simplex Virus (HSV) 1 & 2 molecular assay.** This nucleic acid amplification test detects and differentiates between HSV-1 and HSV-2 strains in anal and genital lesions. Specimens are collected using the **Aptima Multitest Swab Specimen Collection Kit** or commercially available viral transport media. The Centers for Disease Control and Prevention (CDC) recommends that all patients with first-episode genital herpes be tested for strain type. According to Hologic, studies show that HSV molecular diagnostics like the **Aptima HSV assay** are 3 to 5 times more sensitive than live culture samples.

According to the CDC, infections with HSV-2 affect more than 24 million Americans. Patients with HSV-2 strain are at increased risk for contracting and transmitting HIV. Pregnant women infected with HSV-2 are at risk of transmitting the virus to their babies, with increased risk for neurologic complications in the child.

FOR MORE INFORMATION, VISIT:
http://www.hologic.com/search/site/aptima%20hsv

PRECISELY TARGET TISSUE DURING BREAST LUMPECTOMY OR BIOPSY

Cianna Medical designed the **SAVI SCOUT Radar Localization System** using radar instead of wires or radiation to help surgeons target tissue during breast lumpectomy or surgical biopsy. According to **Cianna Medical**, a reflector smaller than a grain of rice is placed into the breast up to 30 days before surgery. During the procedure, the **SCOUT** guide detects the reflector, allowing surgeons to precisely focus on the affected tissue. **SCOUT**'s detection range is 1 mm to 50 mm. **Cianna Medical** says that this localization level allows for better surgical planning that may improve cosmetic results as less tissue may need to be removed.

Cianna Medical reported recent data showing that, when compared with wire localization, the **SCOUT** reduces breast surgery operating room (OR) delay times by 72.5%, resulted in an average 29-minute reduction in OR waiting time, and significantly improved workflow efficiency.

FOR MORE INFORMATION, VISIT:
https://www.ciannamedical.com/savi-scout/

PLASMA HYSTEROSCOPIC RESECTION

The 8.5-mm **Hystero-Resectoscope** and others in the **Olympus plasma hysteroscopic resection and vaporization** product portfolio have recently received US Food and Drug Administration clearance. **Olympus** asserts that bipolar electrosurgery featured in the plasma hysteroscopic resection and vaporization system has lower risks of electrolyte imbalance (hyponatremia) compared with monopolar electrosurgery. In addition to improved patient outcomes, Olympus says that its system benefits include cutting precision, better visibility, and cost-savings potential by using a variety of plasma-enabled electrodes in multiple hysteroscopic procedures.

During gynecologic procedures, the **Olympus 8.5-mm hystero-resectoscope** uses a combination of radio frequency, energy, and saline to create plasma, an electrically conductive gas cloud of vapor and charged particles. Due to its conductivity, plasma allows energy to cross into targeted tissue at lower energy levels than with more traditional approaches. This effect leads to lower operating temperatures and therefore less thermal spread.

FOR MORE INFORMATION, VISIT:
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APP-BASED HANDHELD ULTRASOUND

Clarius Mobile Health is offering **Point-and-Shoot Ultrasound Scanners** that operate with any iOS or Android smart device using an app. **Clarius** says its wireless, handheld ultrasound scanners help ObGyns perform quick scans or are used to guide short procedures at bedside without having to rely on the availability of a cart-based ultrasound system. The **Clarius C3 Scanner** is designed for scanning all parts of the patient's torso, including the heart. The **Clarius L7 Linear Array Ultrasound Scanner** is ideal for guiding procedures. Both scanners have automated gain and frequency settings.

High-resolution images can be saved, reviewed, and managed on the secure **Clarius Cloud**. Built with a durable magnesium shell, each device has an IPX7 immersion rating so it can be sterilized. Power is obtained from a rechargeable battery that will last for more than 45 minutes of scanning; 2 batteries come with each **Clarius** device.

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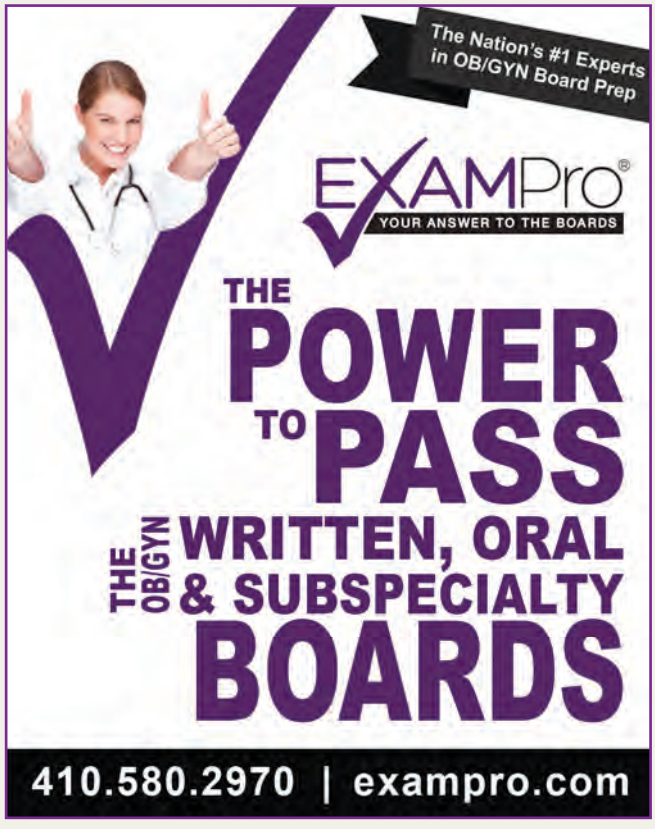

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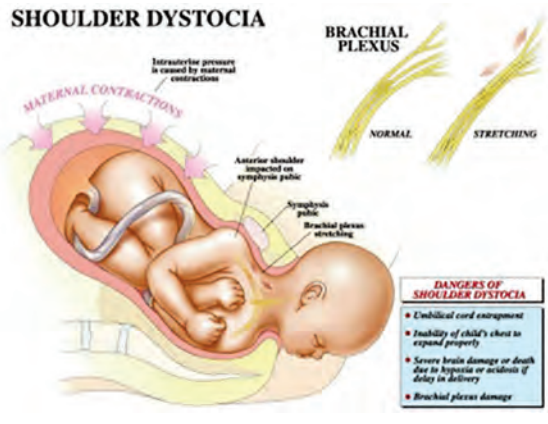

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ages 45 to 49 and ≥50 years for the composite and for morbidities with high incidence. Logistic regression and sensitivity analyses were used to control for demographic and prepregnancy characteristics, underlying medical conditions, assisted conception, and delivery characteristics.

Severe maternal morbidities demonstrated a J-shaped association with age: the lowest rates of morbidity were observed in women 20 to 34 years of age, and steeply increasing rates of morbidity were observed for women aged 40 and older. One notable exception was the rate of sepsis, which was increased in teen mothers compared with all other groups.

The unadjusted rate of the composite outcome of severe maternal morbidity and mortality was 2.1% in teenagers, 1.5% among women 25 to 29 years, 2.3% among those aged 40 to 44, and 3.6% among women aged 45 and older.

Although rates were somewhat attenuated after adjustment for demographic and prepregnancy characteristics, chronic medical conditions, assisted conception, and delivery characteristics, most morbidities remained significantly increased among women aged 39 years and older, including the composite outcome. Among the individual morbidities considered, increased risk was highest for renal failure, amniotic fluid embolism, cardiac morbidity, and shock, with adjusted odds ratios of 2.0 or greater for women older than 39 years.

Study strengths and weaknesses

This study contributes substantially to the existing literature that demonstrates higher rates of pregnancy-associated morbidities in women of increasing maternal age.[1,2] Prior studies in this area focused on perinatal morbidity and mortality and on obstetric outcomes such as cesarean delivery.[3–5] This large-scale study examined the association between advancing maternal age and a variety of serious *maternal* morbidities. In another study, Callaghan and Berg found a similar pattern among mortalities, with high rates of mortality attributable to hemorrhage, embolism, and cardiomyopathy in women aged 40 years and older.[1]

Exclusion of multiple gestations. As in any study, we must consider the methodology, and it is notable that Lisonkova and colleagues' study excluded multiple gestations. Given the association with advanced maternal age, assisted reproductive technology, and the incidence of multiple gestations, a high rate of multiple gestations would be expected among women of advanced maternal age. (Generally, maternal age of at least 35 years is considered "advanced," with greater than 40 years "very advanced.") Since multiple gestations tend to be associated with increases in morbidity, excluding these pregnancies would likely bias the study results toward the null. If multiple gestations had been included, the rates of serious maternal morbidities in older women might be even higher than those demonstrated, potentially strengthening the associations reported here.

WHAT THIS EVIDENCE MEANS FOR PRACTICE

This large, retrospective study (level II evidence) suggests that women of advancing age are at significantly increased risk of severe maternal morbidities, even after controlling for preexisting medical conditions. We therefore recommend that clinicians inform and counsel women who are considering pregnancy at an advanced age, and those considering oocyte cryopreservation as a means of extending their reproductive life span, about the increased maternal morbidities associated with pregnancy at age 40 and older.

›› AMY E. JUDY, MD, MPH, AND YASSER Y. EL-SAYED, MD

FAST TRACK

Severe maternal morbidities showed a J-shaped association with age. The lowest morbidity rates were seen in 20- to 34-year-olds, with steeply rising morbidity rates observed in women aged 40 and older.

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Are women of advanced maternal age at increased risk for severe maternal morbidity?

Yes. Severe maternal morbidities, including renal failure, shock, amniotic fluid embolism, and cardiac morbidity, **were significantly increased for women older than 39 years,** according to results of a study that included more than 800,000 singleton births over 10 years. The observed increases in maternal morbidity persisted after controlling for assisted conception and comorbid medical conditions.

FAST TRACK

The primary study objective, in 828,269 pregnancies in women aged 15 to 60 years, was to examine the association between age and severe maternal morbidities

Lisonkova S, Potts J, Muraca GM, et al. Maternal age and severe maternal morbidity: a population-based retrospective cohort study. PLoS Med. 2017;14(5):e1002307.

EXPERT COMMENTARY

Amy E. Judy, MD, MPH, is Clinical Assistant Professor, Division of Maternal-Fetal Medicine and Obstetrics, Department of Obstetrics and Gynecology, Stanford University School of Medicine, Stanford, California.

Yasser Y. El-Sayed, MD, is the Charles B. and Ann L. Johnson Professor and the Division Director of Maternal-Fetal Medicine and Obstetrics, Department of Obstetrics and Gynecology, Stanford University School of Medicine.

While numerous studies have investigated the risk of perinatal outcomes with advancing maternal age, the primary objective of a recent study by Lisonkova and colleagues was to examine the association between advancing maternal age and severe maternal morbidities and mortality.

Details of the study

The population-based retrospective cohort study compared age-specific rates of severe maternal morbidities and mortality among 828,269 pregnancies in Washington state between 2003 and 2013. Singleton births to women 15 to 60 years of age were included; out-of-hospital births were excluded. Information was obtained by linking the Birth Events Record Database (which includes information on maternal, pregnancy, and labor and delivery characteristics and birth outcomes), and the Comprehensive Hospital Abstract Reporting System database (which includes diagnostic and procedural codes for all hospitalizations in Washington state).

The primary objective was to examine the association between age and severe maternal morbidities. Maternal morbidities were divided into categories: antepartum hemorrhage, respiratory morbidity, thromboembolism, cerebrovascular morbidity, acute cardiac morbidity, severe postpartum hemorrhage, maternal sepsis, renal failure, obstetric shock, complications of anesthesia and obstetric interventions, and need for life-saving procedures. A composite outcome, comprised of severe maternal morbidities, intensive care unit admission, and maternal mortality, was also created.

Rates of severe morbidities were compared for age groups 15 to 19, 20 to 24, 25 to 29, 30 to 34, 35 to 39, 40 to 44, and ≥45 years to the referent category (25 to 29 years). Additional comparisons were also performed for

The authors report no financial relationships relevant to this article.

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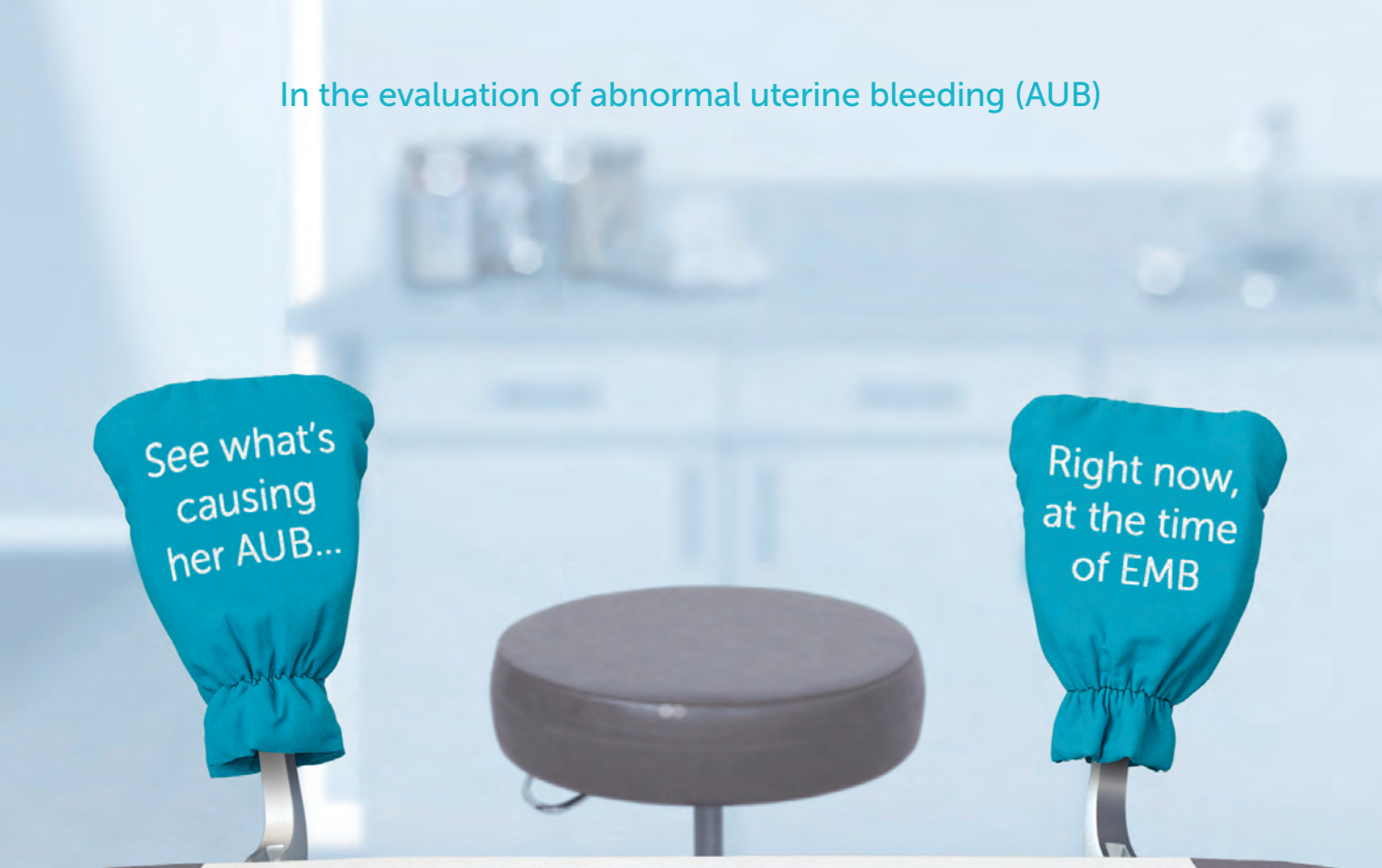

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