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OBG MANAGEMENT

Highlights from Society of Gynecologic Surgeons Annual Meeting, Part 2

Universal cervical length screening is saving babies' lives

Laparoscopic vs abdominal hysterectomy for endometrial cancer

Your role in caring for the transgender patient

Cecile A. Unger, MD, MPH

Pregnancy test missed before IUD placement? Your liability.

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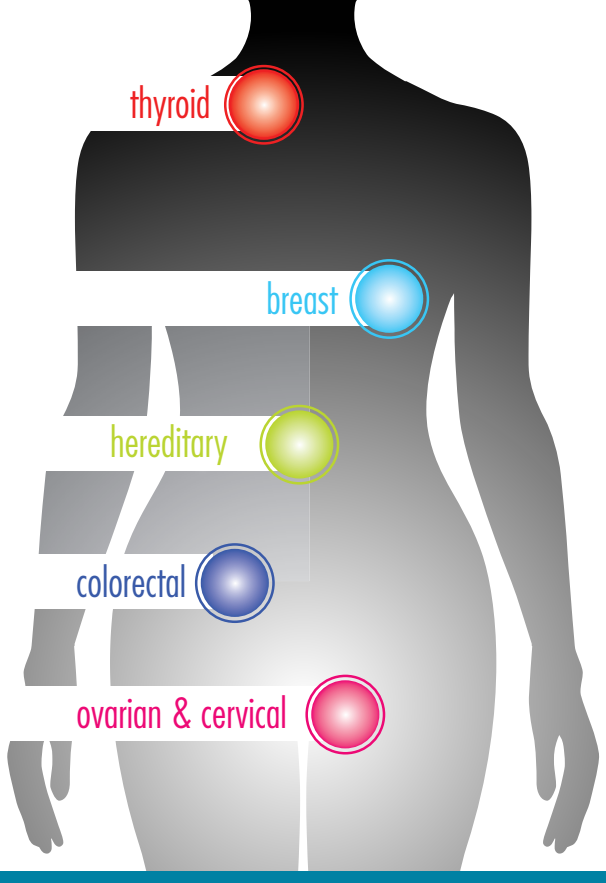

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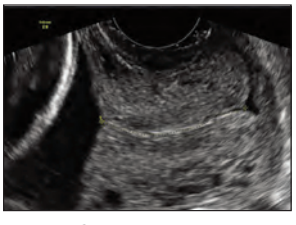

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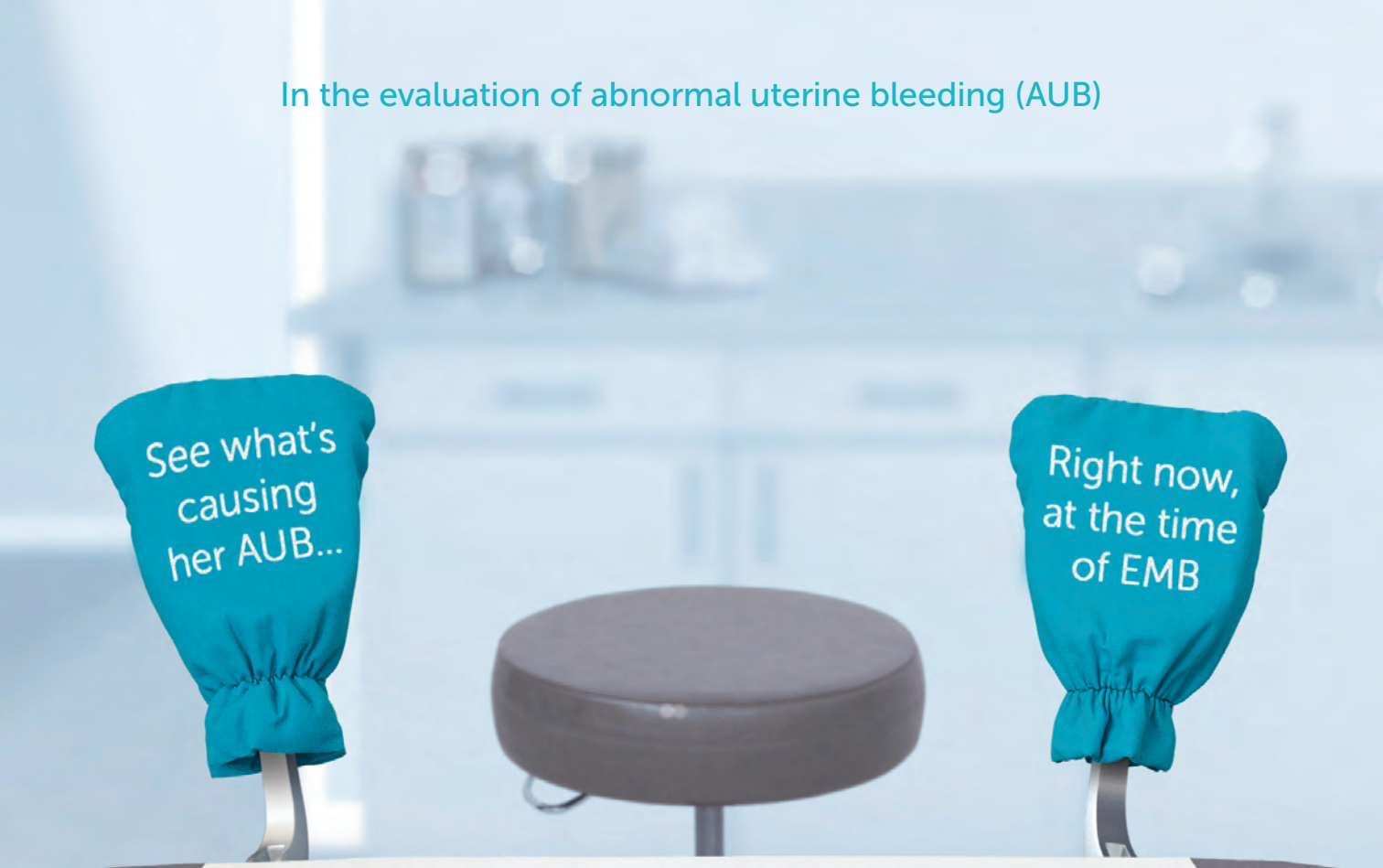
In the evaluation of abnormal uterine bleeding (AUB)



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References: 1. Garcia, A. *OBG Manage.* 2013;25:44-48.
2. Grimbizis GF, Tsolakidis D, Mikos T, et al. *Fertil Steril.* 2010;94:2721-2725.

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GYN Imaging Quiz: A woman with heavy noncyclical bleeding 6 weeks after abortion
DEVARAJU KANMANIRAJA, MD, AND ANDREW M. KAUNITZ, MD

Intra-amniotic sludge: Cerclage or no cerclage?
MARY C. TOLCHER, MD, AND ALEX C. VIDAEFF, MD

Educate patients about dense breasts and cancer risk

Los Angeles County encourages LARC use to decrease Zika cases

Letters to the Editor: Delayed diagnosis of endometriosis

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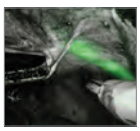

Near-infrared imaging in robotically-assisted urogynecologic surgery
LIOUDMILA LIPETSKAIA, MD; PAULA JAYE DOYLE, MD; AND RONALD WOOD, PHD

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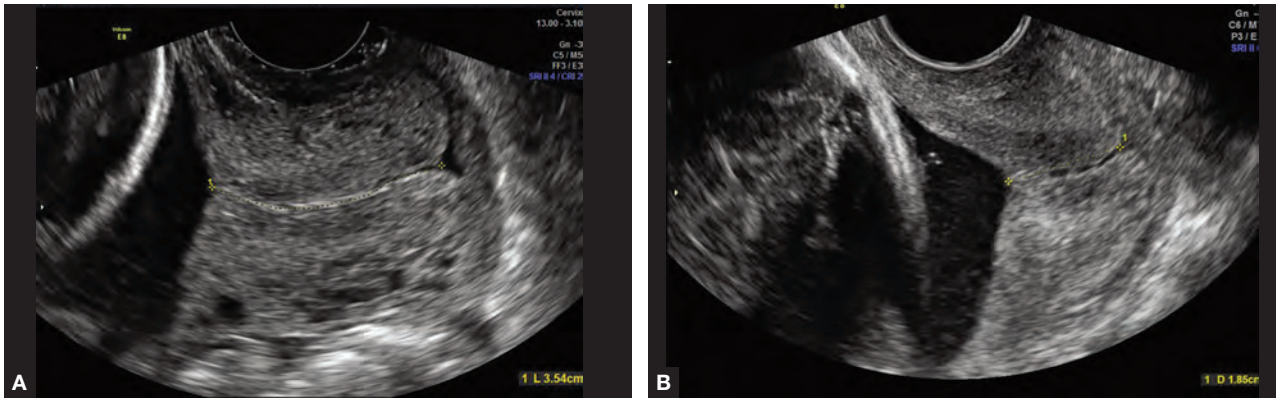
Universal cervical length screening–saving babies lives

Universal second-trimester transvaginal ultrasound cervical length screening of both singleton and twin gestations should be seriously considered by obstetric practitioners to successfully decrease the grave burden of spontaneous preterm birth

Vincenzo Berghella, MD
Dr. Berghella is Director, Division of Maternal-Fetal Medicine, and Professor, Department of Obstetrics and Gynecology, Thomas Jefferson University, Philadelphia, Pennsylvania

Rupsa C. Boelig, MD
Dr. Boelig is Fellow, Division of Maternal-Fetal Medicine, Department of Obstetrics and Gynecology, Thomas Jefferson University



Transvaginal ultrasound image of normal cervical length (A) and short cervical length (B).

IMAGES: COURTESY OF PERINATAL QUALITY FOUNDATION

Transvaginal ultrasound (TVU) cervical length (CL) screening for prediction and prevention of spontaneous preterm birth (SPTB) is among the most transformative clinical changes in obstetrics in the last decades. TVU CL screening should now be offered to all pregnant women: hence the appellative 'universal CL screening.'

TVU CL screening is an excellent screening test for several reasons. It screens for SPTB, which is a clinically important, well-defined disease whose prevalence and natural history is known, and has an early recognizable asymptomatic phase in CL shortening detected by TVU. TVU CL screening is a well-described technique, safe and acceptable, with a reasonable cutoff (25 mm) now identified for all populations, and results are reproducible and accurate. There are hundreds of studies proving these facts. In the last 10 years, TVU measurement of CL as a screening test has been accepted[1,2]: it identifies women at risk for SPTB, and an early intervention (progesterone or cerclage depending on the clinical situation) is effective in preventing SPTB. Screening and treatment of short cervix is cost-effective and readily available as an early intervention (progesterone or cerclage depending on the clinical situation), is effective in preventing the outcome (SPTB), treating abnormal results is cost-effective, and facilities for screening are available and treatments are readily available.[3–5] It is also important to emphasize that CL screening for prevention of SPTB should be done by TVU, and not by transabdominal ultrasound.[6]

It is best to review TVU CL screening by populations: singletons

The authors report no financial relationships relevant to this article.

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TABLE Recommendations for TVU CL screening[2,10,11,17,18]

Population	Frequency of TVU CL screening	GA for TVU CL screening	TVU CL cutoff for intervention	Incidence of short TVU CL	Intervention for short TVU CL
Singletons without a prior SPTB	Once	20 weeks (range, 18–23 6/7 weeks)	≤25 mm	2%–3%	Vaginal progesterone
Singletons with prior SPTB	Every 2 weeks; increase to weekly if TVU CL 25–29.9 mm	16–23 6/7 weeks	<25 mm	30%–40%	Cerclage
Twins	At least once	20 weeks (range, 18–23 6/7 weeks)	≤25 mm	15%–20%	Vaginal progesterone

Abbreviations: CL, cervical length; GA, gestational age; SPTB, spontaneous preterm birth; TVU, transvaginal ultrasound.

without prior SPTB, singletons with prior SPTB, and twins (**TABLE**).

Singletons without prior SPTB

Women with no previous SPTB who are carrying a singleton pregnancy is the population in which TVU CL could have the greatest impact on decreasing SPTB, for several reasons:

1. Up to 60% to 90% of SPTB occur in this population.
2. More than 90% of these women have risk factors for SPTB.[7,8]
3. Vaginal progesterone has been associated with a significant 39% decrease in PTB at <33 weeks of gestation and a significant 38% decrease in perinatal morbidity and mortality in a meta-analysis of randomized controlled trials (RCTs) including 606 women without prior PTB.[9,10]
4. Cost-effectiveness studies have shown that TVU CL screening in this specific population prevents thousands of preterm births, saves or improves from death or major morbidity 350 babies' lives annually, and saves approximately $320,000 per year in the US alone.[3] These numbers may be even higher now as the TVU CL cutoff for offering vaginal progesterone has moved in many centers from ≤20 mm to ≤25 mm, including more women (from about 0.8% to about 2% to 3%, respectively[11]) who benefit from screening.
5. Real-world implementation studies have indeed shown significant decreases in SPTB when a policy of universal TVU CL screening in this specific population is implemented.[12,13]

Universal TVU CL screening recently called into question

In a recent article published in the *Journal of the American Medical Association*,[14] TVU CL screening in this population, in particular for nulliparous women, has come under interrogation. The authors found only an 8% sensitivity of TVU CL screening for SPTB using a cutoff of ≤25 mm at 16 0/7 to 22 6/7 weeks of gestation in 9,410 nulliparous women. This result is different compared with other previous cohort studies in this area, however, and is likely related to a number of issues in the methodology.

First, TVU CL screening was done in many women at too early a gestational age. The earlier the CL screening, the lower the sensitivity of the procedure. Data at 16 and 17 weeks of gestation should have been excluded, as almost all RCTs and other studies on universal TVU CL screening in this population recommended doing screening at about 18 0/7 to 23 6/7 weeks.

Second, women with TVU CL <15 mm received vaginal progesterone. This would decrease the incidence of PTB and, therefore, sensitivity.

Third, outcomes data were not available for 469 women and, compared with women analyzed, these women were at higher risk for SPTB as they were more likely to be aged 21 years or younger, black, with less than a high school education, and single, all significant risk factors for SPTB. (Not all risk factors for SPTB were reported in this study.)

Fourth, pregnancy losses before 20 weeks were excluded, and these could have been early SPTB; therefore, the sensitivity could have been decreased if women with this outcome were excluded.

Fifth, prior studies have shown that TVU CL screening in singletons without prior SPTB has a sensitivity of about 30% to 40%.[15,16] In nulliparas, the sensitivity of TVU CL ≤20 mm had been reported previously to be 20%.[16] Additional data from 2012–2014 at our institution demonstrate that the incidence

of CL ≤25 mm is about 2.8% in nulliparous women, with a sensitivity of 19.5% for SPTB <37 weeks. These numbers show again that 8% sensitivity was low in the *JAMA* study[14] due the shortcomings we just highlighted. Furthermore, the reported sensitivity of TVU CL ≤25 mm for PTB <32 weeks was 24% in Esplin and colleagues' study,[14] while 60% in our data. Given that early preterm births are the most significant source of neonatal morbidity and mortality, women with a singleton gestation and no prior SPTB but with a short TVU CL are perhaps the most important subgroup to identify.

Sixth, a low sensitivity in and of itself is not reflective of a poor screening test. We have known for a long time that SPTB has many etiologies. No one screening test, and no one intervention, would independently prevent all SPTBs. In a population that accounts for more than half of PTBs and for whom no other screening test has been found to be effective, much less cost effective, it is important not to cast aside the dramatic potential clinical benefit to TVU CL screening.

Singletons with a prior SPTB

This is the first population in which TVU CL screening was first proven beneficial for prevention of SPTB. These women all should receive progesterone starting at 16 weeks because of the prior SPTB. In these women, TVU CL screening should be initiated at 16 weeks, and repeated every 2 weeks (weekly if TVU CL is found to be 25 mm to 29 mm) until 23 6/7 weeks. If the TVU CL is identified to be <25 mm before 24 weeks, cerclage should be recommended.[1,2,17]

Twins

Twins are the most recent population in which an intervention based on TVU CL screening has been shown to be beneficial. Vaginal progesterone has been associated with a significant decrease in SPTB as well as in some neonatal outcomes in twin gestations found to have a TVU CL <25 mm in the midtrimester in a meta-analysis of RCTs.[18] Based on these results, we at our institution recently have started offering TVU CL screening at the time of the anatomy scan (about 20 weeks) to twin gestations.

Bottom line

In summary, universal second trimester TVU CL screening of both singletons and twin gestations should be considered seriously by obstetric practitioners to successfully decrease the grave burden of SPTB.

References

1. Berghella V. Progesterone and preterm birth prevention: Translating clinical trials data into clinical practice. Am J Obstet Gynecol. 2012;206(5):376–386.
2. Committee on Practice Bulletins—Obstetrics, The American College of Obstetricians and Gynecologists. Practice Bulletin No. 130: Prediction and prevention of preterm birth. Obstet Gynecol. 2012;120(4):964–973.
3. Werner EF, Hamel MS, Orzechowski K, Berghella V, Thung SF. Cost-effectiveness of transvaginal ultrasound cervical length screening in singletons without a prior preterm birth: an update. Am J Obstet Gynecol. 2015;213(4):554.e1–e6.
4. Einerson BD, Grobman WA, Miller ES. Cost-effectiveness of risk-based screening for cervical length to prevent preterm birth. Am J Obstet Gynecol. 2016;215(1):100.e1–e7.
5. McIntosh J, Feltovich H, Berghella V, Manuck T; Society for Maternal-Fetal medicine. The role of routine cervical length screening in selected high- and low-risk women for preterm birth prevention. Am J Obstet Gynecol. 2016;215(3):B2–B7.
6. Khalifeh A, Quist-Nelson J. Current implementation of universal cervical length screening for preterm birth prevention in the United States. Obstet Gynecol. 2016;127(suppl 1):7S.
7. Mella MT, Mackeen AD, Gache D, Baxter JK, Berghella V. The utility of screening for historical risk factors for preterm birth in women with known second trimester cervical length. J Matern Fetal Neonatal Med. 2013;26(7):710–715.
8. Saccone G, Perriera L, Berghella V. Prior uterine evacuation of pregnancy as independent risk factor for preterm birth: a systematic review and metaanalysis. Am J Obstet Gynecol. 2016;214(5):572–591.
9. Romero R, Nicolaides K, Conde-Agudelo A, et al. Vaginal progesterone in women with an asymptomatic sonographic short cervix in the midtrimester decreases preterm delivery and neonatal morbidity: A systematic review and metaanalysis of individual patient data. Am J Obstet Gynecol. 2012;206(2):124.e1–e19.
10. Romero R, Nicolaides KH, Conde-Agudelo A, et al. Vaginal progesterone decreases preterm birth ≤34 weeks of gestation in women with a singleton pregnancy and a short cervix: an updated meta-analysis including data from the OPPTIMUM study. Ultrasound Obstet Gynecol. 2016;48(3):308–317.
11. Orzechoski KM, Boelig RC, Baxter JK, Berghella V. A universal transvaginal cervical length screening program for preterm birth prevention. Obstet Gynecol. 2014;124(3):520–525.
12. Son M, Grobman WA, Ayala NK, Miller ES. A universal mid-trimester transvaginal cervical length screening program and its associated reduced preterm birth rate. Am J Obstet Gynecol. 2016;214(3):365.e1–e5.
13. Temming LA, Durst JK, Tuuli MG, et al. Universal cervical length screening: implementation and outcomes. Am J Obstet Gynecol. 2016;214(4):523.e1–e8.
14. Esplin MS, Elovitz MA, Iams JD, et al; njMoM2b Network. Predictive accuracy of serial ttransvaginal cervical lengths and quantitative vaginal fetal fibronectin levels for spontaneous preterm birth among nulliparous women. JAMA. 2017;317(10):1047–1056.
15. Iams JD, Goldenberg RL, Meis PJ, et al. The length of the cervix and the risk of spontaneous premature delivery. National Institute of Child Health and Human Development Maternal Fetal Medicine Unit Network. N Engl J Med. 1996;334(9):567–572.
16. Orzechowski KM, Boelig R, Nicholas SS, Baxter J, Berghella V. Is universal cervical length screening indicated in women with prior term birth? Am J Obstet Gynecol. 2015;212(2):234.e1–e5.
17. Preterm labour and birth. National Institute for Health and Care Excellence website. https://www.nice.org.uk/guidance/ng25?unlid=92910360720162132012 57. Published November 2015. Accessed May 18, 2017.
18. Romero R, Conde-Agudelo A, El-Refaie W, et al. Vaginal progesterone decreases preterm birth and neonatal morbidity and mortality in women with a twin gestation and a short cervix: an updated meta-analysis of individual patient data. Ultrasound Obstet Gynecol. 2017;49(3):303–314.

"TREATING POLYCYSTIC OVARY SYNDROME: START USING DUAL MEDICAL THERAPY"
ROBERT L. BARBIERI, MD
(EDITORIAL; APRIL 2017)

Weight loss and dietary management for PCOS

I enjoyed Dr. Barbieri's editorial on polycystic ovary syndrome (PCOS), but I feel that first-line management for PCOS should be weight loss and diet modifications that include instructions on decreasing carbohydrates and insulin spikes. A 5% to 10% weight loss should produce a return of cycles. Of course, metformin and spironolactone have a place for added treatment/prevention of acne and diabetes.

Luis Linan, MD
El Paso, Texas

Metformin and progesterone for PCOS-related infertility

I have been using Beyaz and Yaz for several years in my PCOS patients for the lower androgenic activity of the drospirenone based on the same assumption and its similarity to spironolactone. I have gotten great results with metformin 1,500 mg daily and, for those who desire fertility, cycling once a month for 10 days with progesterone. My own daughter was able to conceive in just 3 months of therapy. PCOS is extremely common in our region, probably due to the high obesity rate. I saw many more cases here than I ever thought I would when I was training.

Lisa Gowan, CNM, WHNP-BC
Albany, Georgia

Check insulin levels in PCOS patients before giving metformin?

Thank you for the very nice article regarding PCOS treatment. Does Dr. Barbieri routinely check insulin levels on patients before treating with metformin and does he require abnormal insulin levels to be present before initiating treatment? The article suggested that using the listed risk factors is sufficient. Additionally, does he perform glucose-insulin testing? If so, what is the protocol used? I have used fasting levels and 2-hour post 75-g glucose-drink testing as well. What is the best approach?

Scott A. Beckman, MD
Jasper, Indiana

Contraception and spironolactone

As usual, Dr. Barbieri has provided a thorough, concise, and practical overview on the medical management of PCOS. I would add just one small point. Another reason for using an oral estrogen-progestin pill concomitantly with spironolactone is due to the potential teratogenicity of this medication.

Bryan R. Hecht, MD
Cleveland, Ohio

Low-carb diet helps mitigate metformin side effects

Thank you for the article on PCOS. I have been treating PCOS this way for about 15 years and have been following lipids and seen dramatic improvements with that as well. I wish we as a medical community would focus on the low carbohydrate diet to help avert metformin side effects as well as treat the metabolic issues. You can get many people back on metformin by just adjusting their diet. I hope you can spread this word.

Steven Foley, MD
Lamar, Colorado

Appreciates Dr. Barbieri's editorials

G'Day from Australia. I am a big fan of your editorials and opinions and enjoy reading OBG Management. Please keep it up.

Kanapathippillai Sivanesan, MD
Brisbane, Australia

›› Dr. Barbieri responds

I thank Dr. Linan, Dr. Foley, and Ms. Gowan for sharing their important insights with our readers. I agree with Dr. Linan that I should have highlighted the important guidance that women with PCOS and a body mass index (BMI) above the normal range should be encouraged to reduce their weight by 5% to 10% with diet and exercise. Dr. Foley offers a clinical pearl that a low carbohydrate diet will reduce the gastrointestinal symptoms that may occur with metformin therapy. Ms. Gowan notes that the combination of metformin plus cyclic progesterone may help to initiate more frequent ovulatory cycles in women with PCOS, thereby improving fertility. Dr. Hecht reminds us that spironolactone is a teratogen and using effective contraception can help reduce the risk of exposing a pregnancy to the medication.

Dr. Beckman raises the important clinical issue of whether it is helpful to measure insulin concentration. Measuring insulin and glucose is especially helpful in understanding the causes of hypoglycemia. An elevated insulin level at the time of an abnormally low glucose level is very worrisome. However, for women with PCOS, in whom insulin resistance is common, measuring insulin is of minimal clinical value. A normal or elevated insulin level is consistent with the diagnosis of PCOS. Assessing BMI, waist circumference, HDL-cholesterol, fasting triglyceride level, and blood pressure—components of the metabolic syndrome—are much more useful clinically. The dermatologic skin lesion

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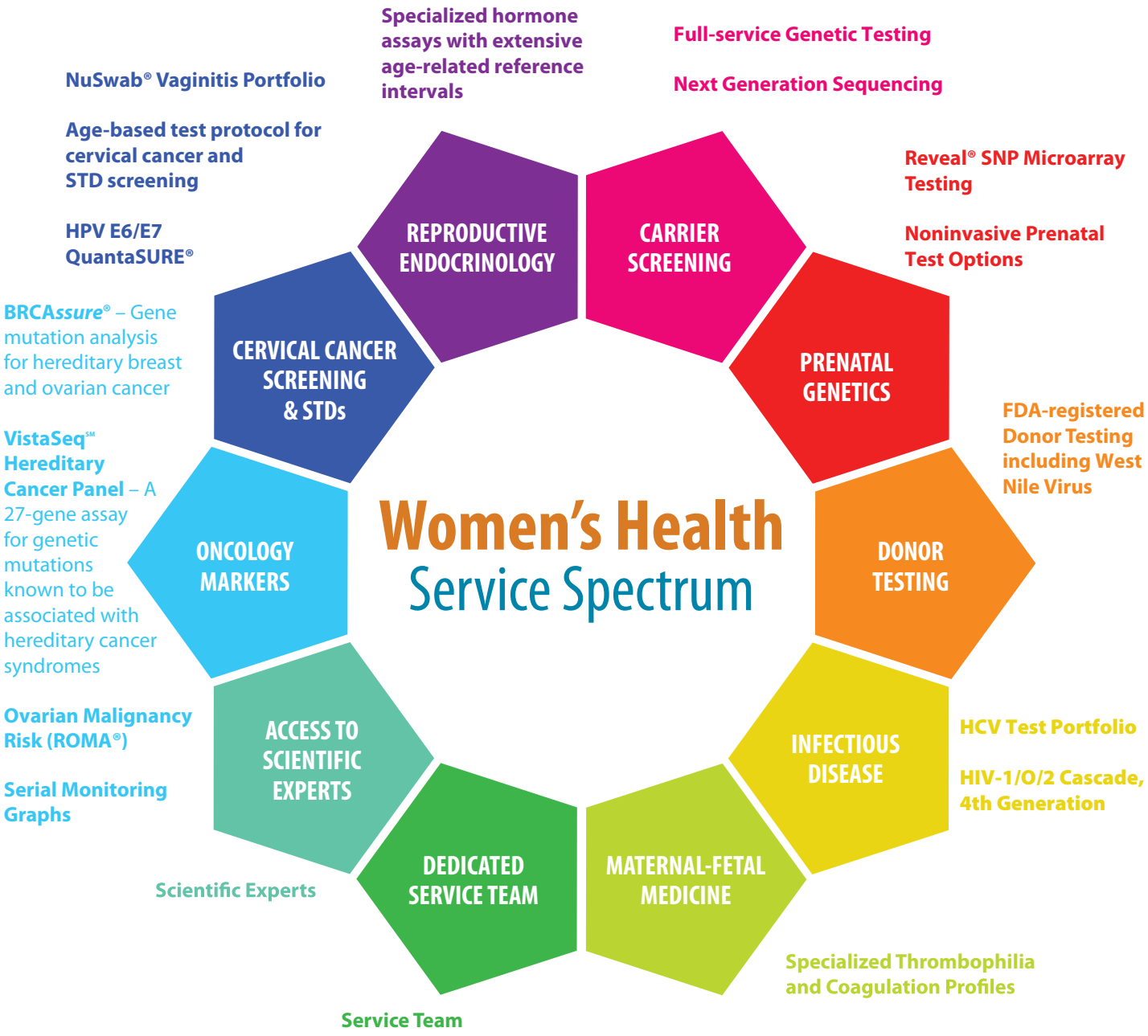

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acanthosis nigricans is also a sign consistent with insulin resistance. I do not measure insulin levels in my patients with PCOS. Metformin is a useful agent in the treatment of PCOS whether or not insulin resistance is present. Metformin may have direct actions on the ovary to reduce androgen production, in addition to its beneficial effects in the liver.

"MORE THAN ONE-THIRD OF TUMORS FOUND ON BREAST CANCER SCREENING REPRESENT OVERDIAGNOSIS"
ANDREW M. KAUNITZ, MD (MARCH 2017)

Refutes concept of overdiagnosis of breast cancer

I read with interest and serious concern the commentary and conclusions of "overdiagnosed" breast cancer. Let us revisit a few time-honored principles. Are we throwing away the valued concept of the early diagnosis of node-negative breast cancer? Is it still true that 5-year and long-term survivals are markedly better for stage I and II disease as opposed to stage III and IV disease? Is it still true that treatments designed for cure are substantially less involved, more successful, and more likely to conserve the breast and require less chemotherapy in early stage disease? Is it still true that the majority of women diagnosed with breast cancer are in the lowest risk category, ie, no family history and negative for the *BRCA* gene? If so, then who can explain the statement that "an invasive breast cancer detected by any means is overdiagnosis"? Would this imply that screening and the biopsy required to make the diagnosis was time poorly spent, the breast cancer should not be treated, and/or we should simply wait for a lump to be found by the patient deep in a large breast most likely at that point representing advanced disease?

The last paragraph notes the current US Preventive Services Task Force (USPSTF) guidance: wait until 50 years of age to start biennial screening. If so, what do we say to women in their 40s who, through screening with mammography and/or ultrasound, were diagnosed with early node-negative invasive breast cancer? That all of that was unnecessary and would not have led to symptoms? Would extreme morbidity from advanced or recurrent disease and the horrors of treatment just to extend a few months of life qualify as a symptom to these investigators? Lax protocols are not for me, my colleagues, or patients that I know. One of the most common reasons for a lawsuit to be brought against a primary care or ObGyn provider is failure to diagnose breast cancer!

John T. Armstrong, MD
Napa, California

›› Dr. Kaunitz responds

I thank Dr. Armstrong for his interest in my commentary on screening mammography and overdiagnosis. As I indicated in my commentary, I continue to recommend screening mammography for my patients, encouraging average-risk women to begin biennial screens at age 50 (consistent with USPSTF guidance), when the likelihood that tumors found with mammograms representing overdiagnosis is lower. I also indicated that I recognize that some patients prefer to begin screening at a younger age and to be screened more frequently. Dr. Armstrong's letter refers to the "horrors of treatment" of breast cancer. From my perspective, the most "horrible" treatment is that which is administered to a woman diagnosed with a tumor destined to not cause clinical problems during her lifetime (overdiagnosis). You also refer to a statement, "an invasive breast cancer detected by any means is overdiagnosis." That statement does not appear in my commentary.

My commentary's point is that overdiagnosis is common among tumors diagnosed by screening mammography, and likely explains why, in contrast with cervical cancer screening, screening mammography has failed to reduce the incidence of breast cancers presenting as advanced (metastatic) disease. Although this represents a confusing and disquieting reality for our patients, and for us their clinicians, I agree with Dr. Otis Brawley, Chief Medical and Scientific Officer of the American Cancer Society, that we must acknowledge to our patients that overdiagnosis is common, the benefits of screening have been overstated, and that some patients considered as "cured" from breast cancer have in fact been harmed by unneeded treatment.[1]

Reference

1. Brawley OW. Accepting the existence of breast cancer overdiagnosis [published online ahead of print January 10, 2017]. Ann Intern Med. doi:10.7326/M16-2850.

"HOW AND WHEN UMBILICAL CORD GAS ANALYSIS CAN JUSTIFY YOUR OBSTETRIC MANAGEMENT"
MICHAEL G. ROSS, MD, MPH (MARCH 2017)

Cord gas analysis can be beneficial but has drawbacks

In his article, Dr. Ross makes a few statements I would like to challenge. He gives a list of indications for cord gas analysis, even with a vigorous newborn. I would suggest that doing so is not only unnecessary, but could get the delivering provider in trouble. Normal gases with a vigorous infant are not actionable, and neither are abnormal gases with a vigorous

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December 13-16, 2017

OPTIONAL PRE-CONFERENCE WORKSHOPS
December 13, 2017

SCIENTIFIC SESSIONS
December 14-16, 2017

THE COSMOPOLITAN of Las Vegas

COURSE CHAIRS

Tommaso Falcone, MD
Cleveland Clinic

Mickey M. Karram, MD
The Christ Hospital

SPECIAL KEYNOTE SPEAKER

Bahaeddine M. Sibai, MD
University of Texas Medical School

Faculty

Michael S. Baggish, MD
St. Helena Hospital

Linda D. Bradley, MD
Cleveland Clinic

Andrew I. Brill, MD
California Pacific Medical Center

Amanda Nickles Fader, MD
Johns Hopkins Hospital

John Gebhart, MD
Mayo Clinic

Rosanne M. Kho, MD
Cleveland Clinic

Javier F. Magrina, MD
Mayo Clinic Phoenix

Mark D. Walters, MD
Cleveland Clinic

OPTIONAL PRE-CONFERENCE HANDS-ON WORKSHOPS

- Tissue Extraction Techniques *NEW!*
- Laparoscopic Suturing - The "Vertical Zone" (Simulation Lab)
- Hysteroscopy
- Ultrasound
- Technical Aspects of Vaginal Hysterectomy & Cystourethroscopy for the Gynecologist

SPECIAL KEYNOTES

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

PLUS

- Hysterectomy Techniques
  Vaginal • Single Port • Robotic • Total Laparoscopic • Morcellation • Preserving Level 1 Support • Which Approach is Best?
- Incontinence and Prolapse Surgery
- Avoiding and Managing Complications
- Gynecologic Oncology for the Generalist
- Medical Legal Cases
- Fibroid Management & Principles of Electrosurgery
- Surgical Tips for Successful Pelvic Surgery Video Session

PLUS Optional Post-Conference
P.E.P. Practice Management Workshop

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

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: Roseanne 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**

7:30 AM **Course Overview**
Mickey Karram, MD

Pelvic Anatomy

7:35 AM **Pelvic and Abdominal Anatomy from the Laparoscopic Surgeon's View**
Tommaso Falcone, MD

8:15 AM **Anatomic Considerations: Facilitating Vaginal Procedures Safely and Effectively**
Mickey Karram, MD

Incontinence and Prolapse Surgery

8:45 AM **Case Discussions: How Best to Evaluate a Variety of Female Pelvic Floor Disorders**
John Gebhart, MD
Mickey Karram, MD

9:30 AM **Question and Answer Session**

10:00 AM **Break/Exhibits**

10:45 AM **Surgery for Stress Incontinence: Does One Sling Fit All?**
Mark D. Walters, MD

11:15 AM **Surgery for Pelvic Organ Prolapse: Getting Back to Basics - Native Tissue Suture Repairs**
John Gebhart, MD

11:45 AM **Mesh Augmented Prolapse Repair; Vaginal Mesh vs. Sacrocolpopexy**
Roseanne M. Kho, MD

12:15 PM **Question and Answer Session**

12:45 PM **Luncheon Symposium**

1:45 PM **Dessert Break/ Exhibits**

Thursday's Keynote Lecture

2:15 PM **Avoiding and Managing Postpartum Perineal Disorders**
Bahaeddine M.Sibai, MD

Fibroid Management & Principles of Electrosurgery

3:00 PM **Myomectomy: Open to Robotic Approaches**
Tommaso Falcone, MD

3:30PM **The Hysteroscopic Treatment of Submucosal Fibroids and Polyps**
Linda D. Bradley, MD

4:00 PM **Break/Exhibits**

4:30 PM **Safe Use of Electrosurgical Devices for Gynecologic Surgery**
Andrew I. Brill, MD

5:00 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**
Roseanne 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
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**

(Optional. Separate fee required)
3.25 CME Credits Available

P.E.P. PRACTICE MANAGEMENT WORKSHOP AGENDA

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

PAGS Scientific Faculty

Course Chairs

Tommaso Falcone, MD
Professor and Chair
Department of Obstetrics-Gynecology
Cleveland Clinic
Cleveland, Ohio

Mickey M. Karram, MD
Director of Fellowship Program
Female Pelvic Medicine and Reconstructive Surgery
The Christ Hospital
Professor of Ob/Gyn & Urology
University of Cincinnati
Cincinnati, Ohio

Special Keynote Speaker

Bahaeddine M. Sibai, MD
Professor
Department of Obstetrics, Gynecology and Reproductive Sciences
University of Texas Health Science Center
Houston, Texas

Faculty

Michael S. Baggish, MD
Professor of Obstetrics and Gynecology
University of California San Francisco
St. Helena Hospital
St. Helena, California

Linda D. Bradley, MD
Vice Chair Obstetrics, Gynecology, and Women's Health Institute
Director, Fibroid and Menstrual Disorders Center
Director, Hysteroscopic Services
Cleveland Clinic
Cleveland, Ohio

Andrew I. Brill, MD
Director, Minimally Invasive Gynecology
California Pacific Medical Center
Mill Valley, California

Amanda Nickles Fader, MD
Associate Professor and Director
Kelly Gynecologic Oncology Service
Director of Minimally Invasive Surgery
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Javier F. Magrina, MD
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Co-Director Minimally Invasive Fellowship in Gynecologic Surgery
Director, Gynecologic Oncology
Department of Gynecologic Surgery
Mayo Clinic
Phoenix, Arizona

Mark D. Walters, MD
Professor and Vice Chair of Gynecology
Center for Urogynecology and Reconstructive Pelvic Surgery
Department of Obstetrics-Gynecology
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
8:00 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.

PAGS ACCREDITATION

This activity has been planned and implemented in accordance with the accreditation requirements and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint providership of the University of Cincinnati and Global Academy for Medical Education, Inc. The University of Cincinnati is accredited by the ACCME to provide continuing medical education for physicians.

The University of Cincinnati Continuing Medical Education Office has reviewed this activity and has approved it for 20 *AMA PRA CME Category 1 credits*™ for the conference scientific program, the pre-conference workshops at 4.0 *AMA PRA CME Category 1 credits*™ each, and the post workshop at 3.25 *AMA PRA CME Category 1 credits*™.

2017

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The Premier Meeting for all Facets of Gynecologic Surgery

THE **COSMOPOLITAN** of Las Vegas

- *Optional* **Pre-Conference Hands-on Workshops***
  - Tissue Extraction Techniques Workshop NEW!
  - Laparoscopic Suturing
  - Hysteroscopy
  - Ultrasound
  - Technical Aspects of Vaginal Hysterectomy & Cystourethroscopy for the Gynecologist
- **Incontinence and Prolapse Surgery**
- **Gynecologic Oncology for the Generalist**
- **Hysterectomy Techniques**
  - Vaginal
  - Single-port
  - Total Lap
  - Robotic
  - Morcellation
  - Preserving Level 1 Support
  - 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**

Plus! "PEP" Practice Management Workshop*

*(*Optional, separate fee required)*

SCIENTIFIC SESSIONS 20 CME Credits Available
December 14-16, 2017

Optional **PRE-CONFERENCE WORKSHOPS**
8 CME Credits Available
December 13, 2017

Optional **"PEP" PRACTICE MANAGEMENT PROGRAM**
3.25 CME Credits Available
December 16, 2017

About Our Venue
Cosmopolitan of Las Vegas

The 2017 Pelvic Anatomy and Gynecologic Surgery Symposium will take place at the ultra-modern Cosmopolitan of Las Vegas, where we have arranged for a discount room rate of just $179* a night for PAGS participants. To make your reservation call-855.435.0005 (domestic toll free) or 855.455.1055 (international toll free) and reference the code SGAME7.

The discount rate expires November 14, but we urge you to make your arrangements now, as our room block will sell out.

*Plus $25 amenity fee.

How to Register for PAGS

Online: www.PAGS-CME.org

Mail: PAGS 2017
c/o Global Academy for Medical Education
7 Century Drive, Suite 301
Parsippany, NJ 07054

Inquiries: PAGS@globalacademycme.com

Group discounts of two or more available! See website.

	Until Aug. 4	Aug 4 – Sept 29	Sept 30 – Nov 3	After Nov 3
PAGS Scientific Program				
■ Physicians	$775	$795	$895	$995
■ Residents, Fellows, Allied Health	$695	$750	$750	$795
■ **P.E.P. Program only**	$275	$295	$395	$495
■ **Best Buy!** PAGS + P.E.P. Discount Combination Package	$975	$995	$1,195	$1,395
■ **Hands on Workshop (each)**	$195	$205	$255	$350

Cancellation Policy: 2017 PAGS will offer a full refund less a $50 administrative fee as follows: requests for refunds must be made in writing, postmarked, e-mailed, or faxed prior to November 14, 2017. After November 14, 2017, no refunds will be granted. Substitutions are welcomed in lieu of cancellations.
Refunds will not be issued to no-shows.

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

CONTINUED FROM PAGE 12

infant. The latter situation could, however, lower the bar for a lawsuit if any neurologic pathology is diagnosed in the child.

At our hospital, blood gas assessments generate charges of $90 for each arterial and venous sample. The author states that gases are helpful for staff education. If that is the purpose of measuring the gases when Apgar scores are normal, then the bill for the gases should be sent to the staff, not the patient or insurance company.

The precise reason for doing cord gases is to prove you are a good doctor. If the Apgar scores are low, a healthy set of gases shows that your interventions were timely and appropriate. Normal gases prevent lawsuits in this situation.

Joe Walsh, MD
Philadelphia, Pennsylvania

›› Dr. Ross responds

I appreciate the comments of Dr. Walsh, who suggests that we should not obtain cord gases in vigorous infants due, in part, to the hospital charges. There are several reasons for the indications detailed in the article. Although normal Apgar scores would appear to negate the potential for severe metabolic acidosis, Apgar scoring accuracy has been challenged in medical legal cases. Furthermore, there may be newborn complications (eg, pre-existing hypoxic injury, intraventricular bleed) that may not be recognized immediately, yet hypoxemia and acidosis may be alleged to have contributed to the outcome. The actual cost of running a blood gas sample is far less than the $90 hospital charges. Nevertheless, if hospital charge is a concern, I recommend that the physician obtain a cord gas sample immediately following the delivery and determine whether to run the sample after the 5-minute Apgar score is obtained.

›› Readers periodically send in questions for our coding specialist Melanie Witt, RN, MA. Ms. Witt is an independent coding and documentation consultant and former program manager, department of coding and nomenclature, American Congress of Obstetricians and Gynecologists.

Reader inquires about coding for McCall culdoplasty

It is difficult to know what CPT code to use for billing when my practice's physicians do a McCall culdoplasty during a vaginal or laparoscopic hysterectomy. They often do a McCall procedure when a rectocele is present. One provider said it is CPT 57283. But I read an article that said a McCall repairs an "enterocele" and code 58263 would be used if doing one during a vaginal hysterectomy. Do you have a recommendation?

Sonia Pap, CPC, COBGC
Linville/Boone, North Carolina

›› Melanie Witt responds

Preventing vaginal vault prolapse by supporting the vaginal cuff is an essential part of hysterectomy, whether abdominal or vaginal. The McCall culdoplasty procedure is performed to support the vaginal cuff at the time of a vaginal hysterectomy by attaching the uterosacral and cardinal ligaments to the peritoneal surface with suture material such that, when tied, it draws toward the midline, helping to close off the cul-de-sac. This procedure not only supports the vaginal cuff but also closes off the cul-de-sac, thus preventing the formation of an enterocele.

As such it would be considered integral to the normal vaginal hysterectomy procedure and is not separately billable. However, in some cases where the patient has stage 1 to stage 4 uterovaginal prolapse, adjunct vaginal apex support is necessary. If the patient has this documented prior to the surgery, she will likely need more than the included uterosacral-cardinal ligament attachment to the vaginal membrane. This is where a colpopexy comes into play, and traditionally, sacrospinous fixation has been performed to accomplish this. In recent years, the uterosacral ligaments have been used instead, which is why we now have 2 codes for vaginal approach colpopexy: 57283 (uterosacral) and 57282 (sacrospinous). Both of these procedures will eliminate an existing enterocele and therefore could potentially be billed with a vaginal hysterectomy unless a more comprehensive code exits that describes the total surgery.

If the purpose of the colpopexy is to repair an existing enterocele, you would not itemize, but rather would report a vaginal hysterectomy with enterocele repair code (58263, 58270, 58292, or 58294) for that complete surgery. The codes do not specify the type of enterocele repair performed and so by definition would include "any method" including a colpopexy. You will note that the colpopexy codes 57283 and 57282 are bundled into all vaginal hysterectomy codes, and although you can use a modifier -59 to bypass this edit, you must meet the criteria for doing so. But especially, 57283 and 57282 are permanently bundled with the vaginal hysterectomy codes that include enterocele repair. Since there already exists a code that describes a vaginal hysterectomy with enterocele repair, you cannot report the modifier -59 for a separate colpopexy if the reason for doing it was to repair an enterocele. You could, however, use it if the sole reason was to do an adjunct vaginal vault repair due to documented uterovaginal prolapse.

Does laparoscopic versus open abdominal surgery for stage I endometrial cancer affect oncologic outcomes?

No. There were no significant differences in disease-free survival, recurrence and location of recurrence, or overall survival in 760 patients treated by total laparoscopic hysterectomy or total abdominal hysterectomy.

Janda M, Gebski V, Davies LC, et al. Effect of total laparoscopic hysterectomy vs total abdominal hysterectomy on disease-free survival among women with Stage 1 endometrial cancer: a randomized clinical trial. JAMA. 2017;317(12):1224–1233.

FAST TRACK

Disease-free survival at 4.5 years was 81.3% in the TAH group and 81.6% in the TLH group—a 0.3% difference

EXPERT COMMENTARY

›› **Kathryn A. Mills, MD,** is gynecologic oncology fellow in the Division of Gynecologic Oncology, Department of Obstetrics and Gynecology, Washington University School of Medicine, St. Louis, Missouri.

›› **David G. Mutch, MD,** is the Ira C. and Judith Gall Professor of Obstetrics and Gynecology and Vice Chair of Gynecology in the Department of Obstetrics and Gynecology, Division of Gynecologic Oncology, Washington University School of Medicine, St. Louis, Missouri. He serves on the OBG MANAGEMENT Board of Editors.

The objective of the study by Janda and colleagues (known as the "LACE" trial) was to evaluate the equivalency of total laparoscopic hysterectomy (TLH) with staging versus the standard procedure, which is total abdominal hysterectomy (TAH) with staging, for surgical management of women with presumed low-risk, early-stage endometrial cancer.

Details of the study

This nonblinded, randomized controlled multicenter equivalency trial included 760 women from Australia, New Zealand, and Hong Kong undergoing surgical management of presumed stage I uterine endometrioid adenocarcinoma. All surgeries were performed or supervised by trained gynecologic oncologists. Pelvic lymph node sampling was required but omission was permitted for: morbid obesity, low risk of metastasis based on frozen section results, medically unfit status, or institutional guidelines prohibiting the procedure. Patients were excluded for preoperative nonendometrioid histology, suspected ultimate FIGO stage II–IV based on preoperative imaging, or uterine size greater than 10 weeks' gestation.

The primary outcome was disease-free survival, defined as the time from surgery to the date of first recurrence, which included disease progression, development of a new primary malignancy, or death. Secondary outcomes included disease recurrence, patterns of recurrence, and overall survival. A 7% difference in disease-free survival at 4.5 years postoperatively was prespecified and determined based on previously published literature.[1–4]

By Kaplan-Meier estimates, disease-free survival at 4.5 years was 81.3% in the TAH group and 81.6% in the TLH group, a 0.3% difference. In addition, there were no differences noted in secondary outcomes, further supporting equivalency of the surgical

CONTINUED ON PAGE 16

The authors report no financial relationships relevant to this article.

Introducing
The Advincula Delineator™

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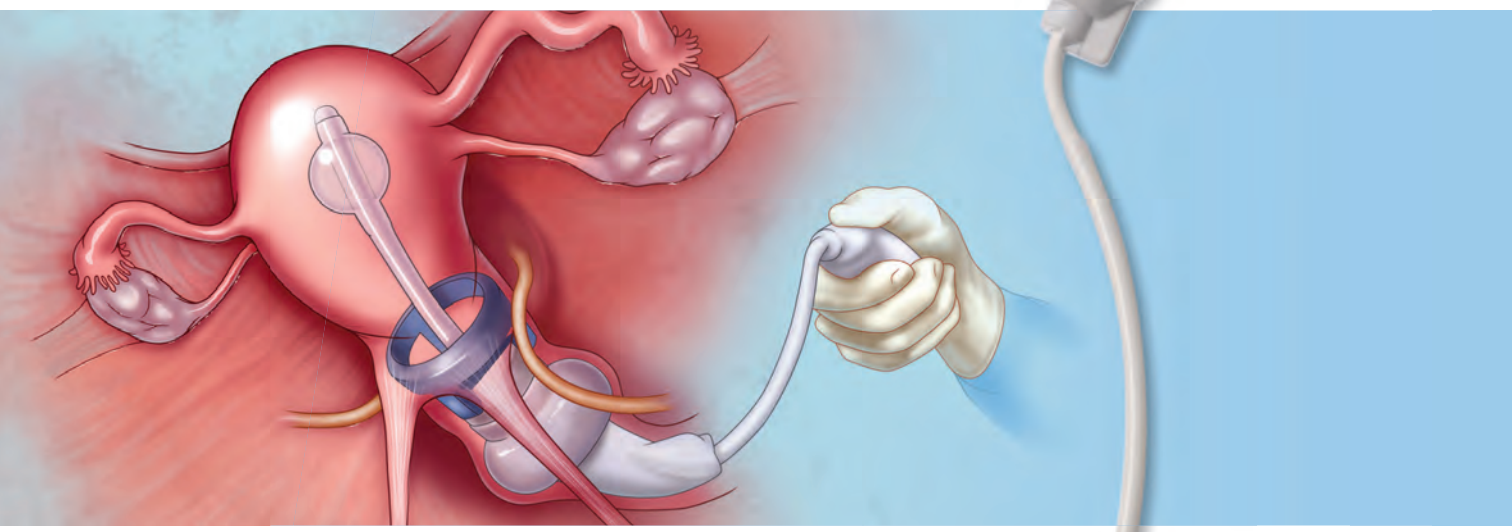

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CONTINUED FROM PAGE 14

WHAT THIS EVIDENCE MEANS FOR PRACTICE

This level I evidence should strongly encourage physicians to offer laparoscopic hysterectomy to patients with clinically suspected low-risk histologic types of stage I uterine endometrioid adenocarcinoma whenever technically feasible, as oncologic outcomes are equivalent up to nearly 5 years.

›› KATHRYN A. MILLS, MD, AND DAVID G. MUTCH, MD

modalities. The only significantly different surgical findings included decreased operative time in the TAH group and decreased lymph node dissection completion in the TLH group.

Study strengths and weaknesses

The largest previous trial of more than 2,000 patients examining the method of surgical management was the Gynecologic Oncology Group's (GOG) noninferiority LAP2 trial.[3] This trial has been used widely to promote a minimally invasive approach, but did not actually reach the prespecified statistical goals. The LACE trial, however, successfully reached its statistical targets and is now the largest randomized trial supporting an equivalence in oncologic outcomes.

It is important to recognize the limitations of the LACE trial in the current medical environment. The study population was a very specific group of low-risk women without high-risk histologic subtypes or even moderately enlarged uteri; many institutions would consider offering a minimally invasive approach to these women. In addition, this study did not include robotic minimally invasive surgery, which in many regions of the country is rapidly becoming accepted as the first choice procedure over traditional laparoscopy.[5] Furthermore, the FIRES trial and others[6–8] have demonstrated that utilizing a minimally invasive approach that includes sentinel lymph node identification and removal may be as diagnostic as a full dissection, adding considerations to surgical modality selection.

FAST TRACK

Offer laparoscopic hysterectomy to patients with clinically suspected low-risk types of stage 1 uterine endometroid adenocarcinoma whenever technically feasible

References

1. Fleshman J, Branda M, Sargent DJ, et al. Effect of laparoscopic-assisted resection vs open resection of stage II or III rectal cancer on pathologic outcomes: the ACOSOG Z6051 randomized clinical trial. JAMA. 2015;314(13):1346–1355.
2. Stevenson AR, Solomon MJ, Lumley JW, et al; ALaCaRT Investigators. Effect of laparoscopic-assisted resection vs open resection on pathological outcomes in rectal cancer: the ALaCaRT randomized clinical trial. JAMA. 2015;314(13):1356–1363.
3. Walker JL, Piedmonte MR, Spirtos NM, et al. Recurrence and survival after random assignment to laparoscopy versus laparotomy for comprehensive surgical staging of uterine cancer: Gynecologic Oncology Group LAP2 Study. J Clin Oncol. 2012;30(7):695–700.
4. Creutzberg CL, van Putten WL, Koper PC, et al; Post Operative Radiation Therapy in Endometrial Carcinoma. Surgery and postoperative radiotherapy versus surgery alone for patients with stage-1 endometrial carcinoma: multicentre randomised trial. PORTEC Study Group. Lancet. 2000;355(9213):1404–1411.
5. Wright JD, Burke WM, Tergas AI, et al. Comparative effectiveness of minimally invasive hysterectomy for endometrial cancer. J Clin Oncol. 2016;34(10):1087–1096.
6. Rossi EC, Kowalski LD, Scalici JS, et al. A comparison of sentinel lymph node biopsy to lymphadenectomy for endometrial cancer staging (FIRES trial): a multicentre, prospective, cohort study. Lancet Oncol. 2017;18(3):384–392.
7. Barlin JN, Khoury-Collado F, Kim CH, et al. The importance of applying a sentinel lymph node mapping algorithm in endometrial cancer staging: beyond removal of blue nodes. Gynecol Oncol. 2012;12(3):531–535.
8. Darai E, Dubernard G, Bats AS, et al. Sentinel node biopsy for the management of early stage endometrial cancer: long-term results of the SENTI-ENDO study. Gynecol Oncol. 2015;136(1):54–59.

COMING SOON...

›› **Update on Infectious Disease**
Patrick Duff, MD

OBG MANAGEMENT

SPECIAL SECTION

HIGHLIGHTS FROM THE 2017 SOCIETY OF GYNECOLOGIC SURGEONS SCIENTIFIC MEETING

PART 2

Geoffrey W. Cundiff, MD
Dr. Victor Gomel Professor and Head
Department of Obstetrics and Gynaecology
University of British Columbia
Vancouver, British Columbia

Kimberly Kenton, MD, MS
Professor, Obstetrics and Gynecology and Urology
Division Chief and Fellowship Program Director
Female Pelvic Medicine and Reconstructive Surgery
Medical Director, Women's Integrated Pelvic Health Program
Northwestern Medicine/Northwestern University Feinberg School of Medicine
Chicago, Illinois

Denise M. Elser, MD
Urogynecologist
Women's Health Institute of Illinois
Oak Lawn, Illinois

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Obstetrics and gynecology: A marriage of inconvenience?

For better or for worse, obstetrics and gynecology are united as a single specialty. Exploring the clinical implications of a separation allows for a thoughtful consideration of how the practice could evolve to best meet the needs of patients and providers.

Geoffrey W. Cundiff, MD

Calls to separate obstetrics and gynecology into 2 specialties are not new and may emanate from the relatively recent marriage of these specialties. It was not until 1903 that the American Medical Association held the first combined Section Meeting on Obstetrics and Diseases of Women. Many medical schools had separate departments for gynecology and obstetrics. Even the American College of Obstetricians and Gynecologists (ACOG) was not formed until 1951. While the combined specialty is relatively young, the appeals for separation have grown louder of late. Contemplating the factors behind the increased appeals is a pragmatic place to start a thoughtful consideration of the proposed separation.

Factors compelling separation

Perhaps the most convincing factor is the increasing segregation of providers into focused practices. This includes the emergence of office-based practice, due in part to the rebranding of a surgical specialty, obstetrics and gynecology, as primary care during the 1990s.[1] Transforming obstetrics and gynecology into primary care coincided with increased primary maternity care by obstetricians, a trend accelerated by the paucity of family physicians and midwives to meet the primary maternity needs of the population.[2] Primary maternity care is time-consuming, leaving little time to pursue a surgical practice. The latest evolution of the primary care obstetrician is the laborist, who provides maternity care as a full-time shift worker.[3] The laborist's dedication to a maternity ward fits nicely into modern concepts of team-based maternity care, and studies suggest better maternity outcomes with this model.[4,5] This highlights another important driver of separation: modern health care's focus on enhancing the quality of care.

The literature provides ample evidence that higher clinical volume translates to better outcomes for both gynecology and obstetrics.[6,7] This is a compelling argument for focusing clinical care and has been a major driver of the subspecialization of gynecologic surgery. The introduction of new technologies and minimally invasive surgical approaches has drastically enlarged the surgical repertoire within gynecology. Developing and maintaining competence across the entire field may be unrealistic and increasingly is pursued through subspecialty training following residency.

As training programs, practice patterns, and the focus on quality outcomes increasingly push providers away from the provision of general obstetrics and gynecology, it is not surprising that members of the specialty identify less with a combined specialty. However, before filing for a

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divorce, it is important to consider the implications of such a decision, which include repercussions for clinical care, medical education, and women's health care in general.

Implications of separation

Clinical care

Obstetrics is a surgical specialty, and eliminating gynecologic competencies from obstetricians' skill sets would negatively influence obstetric care. The loss of surgical skills would have the most serious consequences for difficult perineal repairs and cesarean deliveries, including cesarean hysterectomy. This is worrisome given the increased prevalence of placenta previa, placenta accreta, and postpartum hemorrhage.

At the same time, many gynecologic conditions are tied to or result from childbirth, and eliminating obstetric competencies from gynecologists' skill sets would also negatively influence gynecologic care. For example, infertility specialists would lose the obstetric context of infertility interventions and urogynecologists would lose the knowledge of how pregnancy and labor influence pelvic floor function and injury. Given the benefits of combined training, it is difficult to conceptualize the benefits that would be realized from training in the vestigial field. Urogynecologists are perhaps best equipped to recognize this value through contrasting themselves with urologists pursuing female pelvic medicine and reconstructive surgery (FPMRS). Urologists pursuing FPMRS come to fellowship training with excellent surgical skills but a significantly more limited understanding of female pelvic floor function.

Medical education

Obstetrics and gynecology are presently considered core subjects in medical education, enabling all medical students to be intimately introduced to the specialty. This serves as a principal driver in many graduates' decisions to pursue postgraduate training in the field.[8] Losing that prominent position in medical education would significantly decrease the pool of candidates drawn to the specialty. The ability to pursue many different paths after training in the spectrum of obstetrics and gynecology is another attractive feature that would be lost should the specialty be dismantled.

Additionally, postgraduate education must be tied to population needs or trainees will not have positions to fill. While the development of a postgraduate program in obstetrics could succeed due to the demand for primary care maternity care, a program in general gynecology would be less viable. ACOG projects a shortfall of 9,000 to 14,000 obstetricians in the next 20 years, and more than 20 states already have "red alerts" due to insufficient maternity providers to meet patients' needs.[5] The same workforce gap does not exist in gynecology, with the exception of surgical subspecialties like gynecologic oncology and female pelvic medicine and reconstructive surgery.

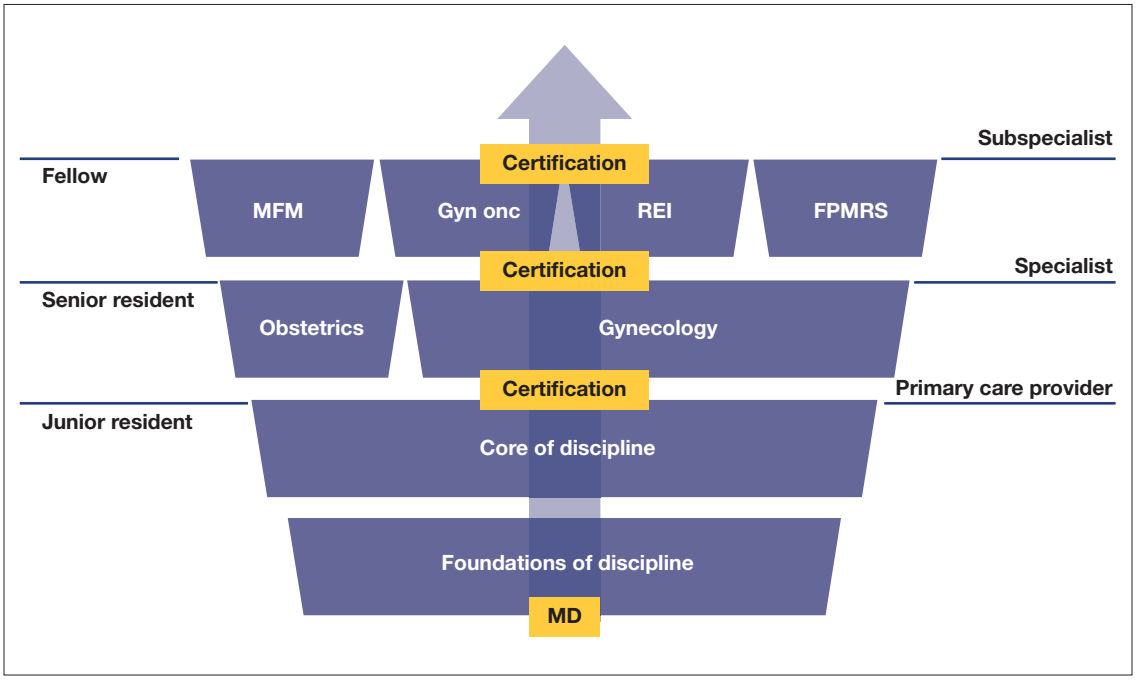
This mismatch between the needs of a gynecologic residency and subsequent subspecialty training goes further than population demand. Increasingly, general gynecology is office based, while subspecialists provide for gynecologic surgical needs. This creates a disparity between postgraduate gynecology training, which needs a curriculum strong in nonsurgical care, and postgraduate training in surgical subspecialties. Can a gynecology residency prepare physicians to pursue subspecialty surgical training?

We need gynecologists to perform surgery—we just do not need as many of them given that general gynecology surgical volumes are dropping.[9] Moreover, a significant proportion of basic surgical volume for current residents comes from cesarean deliveries. Eliminating this from the curriculum would significantly decrease the surgical volume of gynecologic residents. For a residency program focused on gynecology, the only means to address this would be by decreasing the number of resident spots, which would result in an insufficient number of candidates to meet the increasing volumes in subspecialty gynecologic surgical training.

Women's health care

Women's health care is a broad term, but such an all-encompassing concept is necessary to fully recognize the impact separating obstetrics and gynecology would have. In addition to the previously described deterioration in the quality and capacity of women's health care providers, the segregation of obstetrics from gynecology would also diminish the position of women's health in competing for health care resources. Much like undergraduate

FIGURE Competency-based medical education paradigm



Abbreviations: FPMRS, female pelvic medicine and reconstructive surgery; Gyn onc, gynecologic oncology; MFM, maternal-fetal medicine; REI, reproductive endocrinology and infertility.

education, where separating the O from the G surrenders clout in determining medical school curricula, it would also diminish political power in other important jurisdictions, including hospitals, health authorities, government regulation, and insurance and government reimbursements.

Several Canadian jurisdictions have applied this model, resulting in the department of obstetrics and gynecology being rendered the division of gynecology within the department of surgery, and the division of obstetrics within the department of maternity. As a result, obstetrics and gynecology leaders no longer sit on hospital or health authority committees that determine resource allocation or planning priorities. In effect, the separation erased women's health care from the agenda entirely. It also silenced ObGyns, who have historically been the most vocal and effective advocates for women's health.

Alternative models

If the consequences of separating obstetrics and gynecology seem prohibitive, then it is incumbent upon us to propose an alternative that addresses the public's demand for quality care and providers' tendency to focus their practices. The solution is "streaming."

Streaming is not a new idea. Calls for a shorter core curriculum and earlier entry into subspecialties date back to 1985.[10] In the early 1990s, as ACOG began rebranding obstetrics and gynecology as primary care, the Institute of Medicine recommended that the American Board of Obstetrics and Gynecology consider a shorter training period in core competencies, and the board expressed support for early tracking for future subspecialties.[10] By 1995, the idea of a shorter training program in core obstetrics and gynecology with subsequent optional subspecialty training was a national discussion.[11] The logic of streaming was widely recognized but rarely has been implemented. Happily, the environment has changed recently with the embrace of competency-based medical education (CBME).

This paradigm shift is founded on the concept of preparing physicians for practice based on developing graduate skills or competencies that are founded on societal (patient) needs.[12] It recognizes the inherent differences in learners and provides a

learner-centered approach, with greater flexibility and accountability through de-emphasizing time-based training. Moreover, it supports the move toward focused individual practices.

As a concept, CBME has received worldwide endorsement, although it has yet to be widely implemented. The US Accreditation Council for Graduate Medical Education (ACGME) recognized the value of CBME as far back as 1978.[13] In Canada, the Royal College of Physicians and Surgeons of Canada (RCPSC) developed CanMEDS in 1996, a framework for CBME that is not only for residency education but also for the maintenance of certification of licensed specialists.[14] The ACGME Milestones are also designed for a CBME curriculum and offer a framework for streaming.[15]

The ACGME Milestones were designed to assess key dimensions of competency in specific categories (see the **TABLE** in the online version of this article). Resident physicians' performance in each category is assessed based on 5 levels of competency, with Level 4 being the expected (but not required) competency for graduating residents. Many graduating residents do not achieve Level 4 competencies, particularly in gynecologic technical skills. There also is significant redundancy between the milestones for residency and fellowships in the categories of systems-based practice, practice-based learning and improvement, professionalism, and interpersonal and communications skills.

Because CBME is structured to assess sequential competencies, it lends itself to defining different levels of training (**FIGURE**). Initially, a core set of competencies that would prepare a resident to provide primary care, including primary maternity and ambulatory gynecology, is offered. For learners seeking more specialized skills in either obstetrics or gynecology, training could continue to achieve Level 4 competency in either one or both areas, depending on their practice plans. These specialty skills would also prepare residents for further subspecialty learning—maternal-fetal medicine after obstetrics and gynecologic surgical subspecialties following gynecology. While the Cleveland Clinic has begun a partial streaming class, wide adoption will require a national commitment to CBME by the ACGME residency review committee.

In summary, we cannot ignore the forces affecting our specialty. Our training and certification system no longer reflects the nature of evolving practice within obstetrics and gynecology. However, separating the constituent parts is an oversimplified solution that serves neither us nor the women we care for. We must be bold and evolve how we teach and certify physicians. This demands a system that accommodates the spectrum of practice, from primary care to specialty care to subspecialty care. Streaming is the solution and CBME is the mechanism to achieve it. ■

References

1. American College of Obstetricians and Gynecologists. Retreat on education in obstetrics and gynecology, final report. Washington, DC: American College of Obstetricians and Gynecologists; 1991:1–32.
2. American College of Obstetricians and Gynecologists. The Obstetrician-Gynecologist Workforce in the United States: facts, figures, and implications. Washington, DC: American College of Obstetricians and Gynecologists; 2011.
3. Weinstein L. The laborist: a new focus of practice for the obstetrician. Am J Obstet Gynecol. 2003;188(2):310–312.
4. Olson R, Garite TJ, Fishman A, Andress IF. Obstetrician/gynecologist hospitalists: can we improve safety and outcomes for patients and hospitals and improve lifestyle for physicians? Am J Obstet Gynecol. 2012;207(2):81–86.
5. Srinivas SK, Small DS, Macheras M, Hsu JY, Caldwell D, Lorch S. Evaluating the impact of the laborist model of obstetrical care on maternal and neonatal outcomes. Am J Obstet Gynecol. 2016;215(6):770.e1–e9.
6. Drukker L, Hants Y, Farkash R, et al. Impact of surgeon annual volume on short-term maternal outcome in cesarean delivery. Am J Obstet Gynecol. 2016;215(1):85.e1–e8.
7. Mowat A, Maher C, Ballard E. Surgical outcomes for low-volume vs high-volume surgeons in gynecology surgery: a systematic review and meta-analysis. Am J Obstet Gynecol. 2016;(1):21–33.
8. Hammoud MM, Stansfield RB, Katz NT, Dugoff L, McCarthy J, White CB. The effect of the obstetrics and gynecology clerkship on student's interest in a career in obstetrics and gynecology. Am J Obstet Gynecol. 2006;195(5):1422–1426.
9. Vree FE, Cohen SL, Chavan N, Einarsson JI. The impact of surgeon volume on perioperative outcomes in hysterectomy. JSLS. 2014;18(2):174–181.
10. Bissonette JM, Gabbe SG, Hammond CB, MacDonald PC, Polan ML, Roberts JM. Restructuring residency training in obstetrics and gynecology. Am J Obstet Gynecol. 1999;180(3 pt 1):516–518.
11. Hammond CB. Future directions for academic obstetrics and gynecology— "… through a glass, darkly…." Am J Obstet Gynecol. 1995;172(4 pt 1):1073–1079.
12. Frank JR, Mungroo R, Ahmad Y, Wang M, De Rossi S, Horsley T. Toward a definition of competency-based education in medicine: a systematic review of published definitions. Med Teach. 2010;32(8):631–637.
13. McGaghie WC, Miller GE, Sajid AW, Telder TV. Competency-based curriculum development on medical education: an introduction. Public Health Pap. 1978;(68):11–91.
14. Frank JR, Snell L, Sherbino J, eds. CanMEDS 2015 Physician Competency Framework. Ottawa, Canada: Royal College of Physicians and Surgeons of Canada; 2015.
15. Accreditation Council for Graduate Medical Education, American Board of Obstetrics and Gynecology, American College of Obstetrics and Gynecology. The obstetrics and gynecology milestones project. http://www.acgme.org/Portals/0/PDFs/Milestones/ObstetricsandGynecologyMilestones.pdf. Published September 2015. Accessed March 15, 2017.

The need for change in gynecologic surgery: Separating gynecology from obstetrics

Within the context of modern medicine and health care, is obstetrics and gynecology still maximizing health care for women? An expert explores the evolving challenges facing the field and alternative models for training that may help clinicians keep pace.

Kimberly Kenton, MD, MS

PHOTO: SHUTTERSTOCK

While obstetrics and gynecology has a long history of synergy and advocacy for women's health care, data are compelling that the field must evolve to continue to advocate for women's health. As a surgical field, we must acknowledge that declining major gynecologic surgical volume among both trainees and practicing surgeons impacts our patients' outcomes.

The debate over how to optimize health care for women dates back to the late 1800s when Howard Atwood Kelly identified many of the issues regarding gynecologic surgery and surgical training that our current discussions still focus on.

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Dr. Kelly, along with William Halsted, William Osler, and William Welch, was a founding chairman at Johns Hopkins Medical School. Dr. Kelly believed that the barrier between gynecology and surgery was artificial, and he negotiated to divide the department of obstetrics and gynecology into 2 separate departments. In 1899, Dr. Kelly became the first chairman of the department of gynecology, and J. Whitridge Williams became the first chairman of the department of obstetrics.[1] Dr. Kelly touted goals for gynecologic surgical education similar to ours today. He advocated for wide surgical training and experience and that each year residents should be given increasing responsibility in the care of patients and procedures in the operating room (OR). His words echo those of the Accreditation Council of Graduate Medical

Education (ACGME), which sets minimum standards for surgical training and requires that "graded and progressive responsibility" be the core tenet of surgical training.

How we got here

The American Board of Obstetrics and Gynecology (ABOG) was established as one of the 4 founder boards of the American Board of Medical Specialties (ABMS) in 1930. In contrast to the traditional division of medicine and surgery, in 1951 ABOG and the American College of Obstetricians and Gynecologists' (ACOG) vision was based on the comprehensive care of women rather than a discrete skill set. This unification of gynecologic surgery and obstetrics, with women's health care at the center, has unquestionably led to huge advancements in legislation and standard setting for women's health.

Our current challenge, however, is to decide how well the system—designed nearly 100 years ago—is working within the context of modern medicine and health care and, more importantly, if the system is still maximizing health care for women. Perhaps, if we are to achieve our primary mission and goal of optimizing health care for US women, we need to be nimble enough to adapt to changing needs and times.

While the aims of surgical training today are similar to those Dr. Kelly promoted in the late 1800s, we must acknowledge new challenges to the practice of obstetrics and gynecology in the current system. We are faced not only with decreasing surgical volume but also with increasing complexity of surgical procedures, subspecialization of care, emphasis on and accountability for quality and safety, decentralization of care (surgery is no longer done at a single academic site), and duty hour limitations. All these factors impact both resident surgical training and practice patterns of board-certified ObGyns.

Shifts in gynecologic surgery and training

Some argue that skill mastery requires 10,000 hours, or 20 hours per week for a decade, of deliberate practice.[2] This is far more time than most gynecologic residents or practicing surgeons spend in the OR each week. However, a recent study of ABOG–accredited fellowship directors from female pelvic medicine and reconstructive surgery (FPMRS), gynecologic oncology, maternal-fetal medicine (MFM), and reproductive endocrinology and infertility (REI) showed that fellowship directors were concerned about their incoming fellows' preparedness.[3]

> Residents are required to perform 360 deliveries (200 vaginal, 145 cesarean, and 15 operative) compared with only 70 hysterectomies (35 abdominal, 20 laparoscopic, and 15 vaginal).

Responses from gynecologic surgery fellowship directors (FPMRS and gynecologic oncology) showed that less than 20% of surgical fellows could independently perform a vaginal hysterectomy, just 27% were able to repair a cystotomy, and barely half could perform an abdominal hysterectomy, adequately retract and pack the bowel, recognize surgical complications, or take general gynecologic call independently. By contrast, the majority of MFM program directors thought that their incoming fellows could perform basic obstetric procedures. Approximately three-quarters thought that fellows could independently perform a vacuum extraction, repair a 3rd-degree laceration, take obstetrics call, and recognize obstetric complications.[3]

Program directors' perceptions parallel the minimum case volumes for each resident set by the ACGME for common gynecologic and obstetric procedures. These minimum requirements are largely based on the resident-reported number of each procedure performed during residency. They reflect workload rather than competency or proficiency. Residents are required to perform fivefold more deliveries than hysterectomies. Specifically, residents are required to perform 360 deliveries (200 vaginal, 145 cesarean, and 15 operative) compared with only 70 hysterectomies (35 abdominal, 20 laparoscopic, and 15 vaginal). It is therefore not surprising that graduates seem more proficient at obstetric than gynecologic surgical procedures. Arguably, we are training residents to meet women's obstetric needs but not their gynecologic surgical needs. According to the National Residency Match

Program data from 2017, there were 1,288 obstetrics and gynecology residency positions, which is a 12% increase from 2006 (134 spots) and a 31% increase from 1980 (307 spots).

Yet numerous studies demonstrate a decline in hysterectomy volumes in the United States, which translates to fewer procedures per surgeon or resident.[4] According to the New York State Department of Health Database from 2001 to 2006, the mean number of hysterectomies per ObGyn per year was 6.8; the median was only 3.[5] Similarly, estimates of the mean number of hysterectomies done per graduating resident have decreased markedly over the last 40 years, with approximately 175 to 180 per resident in the 1980s, 120 in 1990, and 90 in 2015. Further complicating decreasing hysterectomy volumes is the advent of laparoscopic and robotic routes of access. In 1980, residents had to master 2 routes of hysterectomy (vaginal and abdominal), but they now need to develop competency in 4 routes of access (vaginal, abdominal, laparoscopic, and robotic).

While the number of residency slots has increased by 31% over the last 35 to 40 years, residents are performing approximately 48% fewer hysterectomies.

Procedures and proficiency: How many is too few?

The pressing question is: How many surgical procedures or hysterectomies does one need to perform to develop and maintain proficiency? Mounting data across surgical specialties show a strong association between surgeon volumes and operative morbidity and mortality. A recent systematic review explored the impact of gynecologic surgeon volumes on patient outcomes.[6] Investigators defined low-volume surgeons as those who perform ≤10 of a particular procedure per year; they discovered that gynecologists performing ≤1 procedure a month had higher rates of adverse outcomes. Low-volume surgeons had increased rates of total, intraoperative, and postoperative complications. High-volume surgeons were more likely to perform hysterectomies by the vaginal or minimally invasive routes and at lower costs.[5,7]

Decreased surgical experience may impact obstetrics outcomes as well. A study investigating unlabored primary cesarean deliveries at a single academic center from 2003 to 2010 found that total cesarean delivery time increased by 16 minutes over the study period, although time to deliver the baby out was unchanged. In other words, only the surgical portion of the case increased significantly. The cesarean delivery case volume per resident was unchanged during the study period, with a mean of 213 in 2003 and 227 in 2010. The mean number of abdominal hysterectomies per resident, however, decreased by 54% (from 114 to 52).[8]

Where do we go from here?

Fortunately, our major specialty organizations remain committed to ensuring the best quality of care for women. They recognize the need to re-evaluate optimal training schema and scope of practice for ObGyns and are launching important new initiatives to determine what the field must do to adapt to the changing health care and training environments to continue providing exceptional obstetric and gynecologic care.

Undeniable changes are occurring in health care, and they may adversely impact gynecologic care for women. While the number of residency slots has increased by 31% over the last 35 to 40 years, residents are performing approximately 48% fewer hysterectomies. This likely reflects ongoing demands to provide low-risk obstetric care, which carries over to independent practice.

Other health care models. We need to consider other models, including how other health systems administer obstetric care. In the United Kingdom, all pregnant women are cared for by midwives. There, as in many other European countries, midwives act as primary providers for healthy, low-risk obstetric patients, and ObGyns are reserved for women and fetuses at high risk or those undergoing medical procedures.

Residency pathways. Alternatively, many advocate for differentiating residents into tracks that allow them to focus on obstetrics, gynecology, or subspecialty training. Some large US health care systems have already adopted this model. Acknowledging that outcomes are better when high-volume physicians provide care, ObGyns are

required to focus their scope of practice to ensure that hysterectomies are not being done by surgeons who perform only 3 to 6 per year.

As health care changes, the field of obstetrics and gynecology must evolve to keep pace and to ensure that we do not lose sight of our mission. Our mission remains constant: to provide the highest quality of obstetric and gynecologic care for women. Does our current model of training prepare our residents to meet that mission? If not, then we must change our training model to meet these standards. ■

References

1. Bent AE. Howard Atwood Kelly (1858–1943). Int Urogynecol J Pelvic Floor Dysfunc. 1996;7(1):48–61.
2. Gladwell M. Outliers: the story of success. New York, NY: Little, Brown and Company; 2008.
3. Guntupalli SR, Doo DW, Guy M, et al. Preparedness of obstetrics and gynecology residents for fellowship training. Obstet Gynecol. 2015;126(5):559–568.
4. Wright JD, Herzog TJ, Tsui J, et al. Nationwide trends in the performance of inpatient hysterectomy in the United States. Obstet Gynecol. 2013;122(2 pt 1):233–241.
5. Boyd LR, Novetsky AP, Curtin JP. Effect of surgical volume on route of hysterectomy and short-term morbidity. Obstet Gynecol. 2010;116(4):909–915.
6. Mowat A, Maher C, Ballard E. Surgical outcomes for low-volume vs high-volume surgeons in gynecology surgery: a systematic review and meta-analysis. Am J Obstet Gynecol. 2016;215(1):21–33.
7. Rogo-Gupta LJ, Lewin SN, Kim JH, et al. The effect of surgeon volume on outcomes and resource use for vaginal hysterectomy. Obstet Gynecol. 2010;116(6):1341–1347.
8. Smrtka MP, Gunatilake RP, Harris B, et al. Increase in cesarean operative time following institution of the 80-hour workweek. J Grad Med Educ. 2015;7(3):369–375.

Top reasons why you should be a mentor to your ObGyn colleagues

Serving as a mentor to a new ObGyn benefits the young physician, the institution, and you

Denise M. Elser, MD

As ObGyns or gynecologic surgeons, most of us can identify a role model who profoundly influenced our education, career, and success. That mentor may have been an excellent surgeon, a compassionate caregiver, or a brilliant researcher. Some of us may have sought out a program or joined a department because we wanted to work under or alongside a specific seasoned veteran with a great reputation from whom we hoped to learn or seek advice. Yet, the fact is that finding a mentor in medicine is largely a matter of luck. Most of us formed informal mentoring relationships with a colleague whose path we just happened to cross at our hospital, in our department, or at a conference.

What exactly is a mentor?

A *mentor* can refer to anyone who is a trusted guiding influence in another (usually younger) person's life.[1]

A mentor is different from a coach. A coach's job is task driven—usually short term—and is judged on performance. A mentor's job, on the other hand, is relationship driven, relatively long term, and development driven. While the initiation of the mentor-mentee relationship may be based on accomplishing a specific goal or task, it may extend into areas such as work-life balance, self-confidence, and self-perception.[2]

Do I have what it takes to be a mentor?

The short answer is, of course you do. If you are a successful ObGyn or gynecologic surgeon, you have many desirable skills and experiences that you have honed along your career pathway and that have led you to your current position. Younger, less-experienced physicians or students can benefit from your wisdom and guidance.

PHOTO: SHUTTERSTOCK

A few common themes are found in the literature on mentoring[3–5]:

- **Listen.** To understand your mentee's situation, concerns, skills, barriers, and so on, you need to listen to the individual's story. Imagine being a therapist. At times, sit back, nod, say "uh-huh," and just listen.
- **Be compassionate.** To provide valuable guidance, you need to empathize with your mentee's situation and challenges.
- **Have patience.** Like a parent-child relationship, the relationship with a mentee may be frustrating if he or she does not follow the path you would have followed, does not heed your advice, or does not act as quickly as you would like. Let your mentee make mistakes; mistakes are a necessary part of learning.
- **Care about the relationship.** While coaching may involve caring about the result, mentoring involves much more. You need to care about your mentee as a person and not just as a project. When describing his or her goals and life situation, for example, your mentee may talk about his or her family life, love life, and even financial concerns.

The author reports no financial relationships relevant to this article.

Mentorship can be an antidote to burnout

The benefits for a protégé working with a mentor may seem obvious, but mentors also benefit from such relationships. If an organization involves high-stress jobs (for example, employees experience work overload and a lack of social support and feel incapable of completing tasks—a bit like practicing medicine), a formal mentorship program results in less emotional cognitive fatigue, greater confidence and efficacy, lower absentee rates, and less tendency to leave the organization—improvements that lead to a better work environment for all involved.

Mentors, however, realize benefits beyond helping a younger colleague or the department or practice they share. Serving as a mentor builds confidence, self-esteem, and a sense of accomplishment. Further, mentors are perceived by their peers and their supervisors to be more credible and competent. Being a mentor requires self-reflection. You will likely find that you have come farther than you realized. Give yourself a pat on the back. Finally, mentors are more visible in the organization in a positive way. They are more connected, interact with other leaders, and are believed to add value to the department.

- **Maintain confidentiality.** As a trusted confidante, you may hear intimate details you never expected. Protect your mentee's personal information as you would guard a patient's medical information.
- **Push to action.** Your goal is not only to provide wisdom and advice but also to motivate your mentee to take action. For example, although I know perfectly well how to exercise, spending an hour with my personal trainer at the health club helps me achieve a more vigorous workout than exercising solo.
- **Be a role model.** As the saying goes, actions speak louder than words. Keep growing. Question your own goals and the path you are taking to achieve them. What have you not achieved that you would like to? What are the barriers to your goals, and what can you do to get around or through them? How have your goals changed over the years?

Strongly consider becoming a mentee. Who would you choose as a mentor? If you have not partnered up with a mentor, why not?

What's in it for me?

Being a mentor has many potential benefits.

Personal benefits

Mentoring encourages lifelong learning. We may learn something from our mentee, such as computer or social media skills. The emotional attachment we develop with a mentee can stave off loneliness at a time when many of us are becoming empty nesters. Psychologist Erik Erikson identified 8 stages of life from infancy to adulthood. When we reach our 40s through our mid-60s, we are faced with "generativity versus stagnation." Mentoring another person can help us remain productive at work. It helps us to give back to the community, recognize that we are part of the big picture, and thus helps us avoid stagnation. Helping a younger colleague provides us with a chance to pay back what we received from someone who helped us early in our career. Perhaps you will see mentoring as an opportunity to "pay it forward."[3,6]

Organization benefits

Mentoring helps organizations. Formal mentoring programs help develop a talent pool and may save on recruitment costs. Offering mentoring as part of an organization helps recruitment efforts. If you practice academic medicine or work in a large organization, the institution may reward these endeavors, as mentoring employees can provide an edge in recruiting, shorten learning curves, increase job satisfaction and loyalty, and improve productivity and quality.[6,7]

Mentoring for ObGyns

In about 2010, 2 physicians in District VI of the American College of Obstetricians and Gynecologists (ACOG)—Dr. Thomas Arnold and Dr. Tamara Helfer—were champions of mentoring. Recognizing that organizations such as the American College of Surgeons and the Association of Healthcare Executives offered formal mentoring programs, they researched the topic and developed a pilot program for the District. Based on the success of the pilot, in 2016 ACOG decided to adopt the mentorship endeavor at a national level.

Every ACOG Fellow and Junior Fellow is welcome and encouraged to join the program. To join, log in to the ACOG website (http://www.acog

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.org), go to http://www.acog.org/About-ACOG/Careers/ACOG-Mentorship-Program/Join-Now and hit the "join now" button. You can fill out the short survey, including whether you want to be paired as a mentee or a mentor, or both. Besides providing the matching service, the program sends monthly hints, highlights, and suggested video clips or readings for both mentors and mentees.

The Society of Gynecologic Surgeons (SGS) mentorship program is an affiliate of the ACOG formal mentorship program. This program uses MentorCity software to match mentors and mentees across the country. The questionnaire includes an open-ended question on what type of mentor a mentee is seeking, such as an SGS member, an ObGyn department chair, an SGS committee chair, or a National Institute of Health–funded researcher, or what topics a mentor is comfortable with, such as how to succeed in academic medicine, how to obtain a fellowship, running a private practice, or work-life–balance, to name just a few.

The "mentorship mingle" event was introduced at the 2017 SGS annual meeting in San Antonio. The 1-hour event featured 5 roundtables, each featuring 1 to 2 distinguished mentors and 7 to 8 younger physicians (fellows, residents, and attending physicians). Discussion topics assigned to the tables included the changing face of gynecologic surgery, cultivating an academic career, how to stay relevant, and incorporating research into private practice. The mentors rotated to a different table every 10 minutes, giving each attendee a chance to meet a senior and well-respected SGS member up close and personal. The event was sold out and an expanded version is planned for 2018.

Two examples of why ObGyns need mentors

Mentee #1. A young ObGyn who finished residency about 2 years ago joined a 2-person private practice in a small town. She soon discovered that because of her in-depth exposure to urogynecologic procedures in residency and the town's lack of subspecialists, local physicians were referring women with urinary incontinence and pelvic organ prolapse to her. She was seeking a mentor with whom to discuss interesting or difficult cases as well as to brainstorm about workplace interactions.

Mentee #2. An ObGyn worked for about 10 years in an underserved area, paying back his National Health Service debt. After the debt was repaid, he faced a personal health challenge and thought it was important to relocate to live near family. He was seeking a "situational" mentor—someone with whom he could discuss his potential new private practice and who could provide advice on the contract negotiation.

Do I have time to be a good mentor?

Yes, you do. You can decide at the start of a mentoring relationship how much time you are willing to commit. Each mentoring pair has different needs, expectations, and agreements—a weekly cup of coffee or a quarterly phone call may work for some. You establish how much time and effort you are willing to put into the relationship.

You have learned an incredible amount throughout your career and have conquered many challenges to get where you are today. By sharing your knowledge and wisdom, you will help a young physician. And you will be glad that you did. ■

References

1. Merriam-Webster. Mentor. https://www.merriam-webster.com/dictionary/mentor. Accessed March 15, 2017.
2. The differences between coaching & mentoring. Management Mentors website. http://www.management-mentors.com/resources/coaching-mentoring-differences. Accessed March 15, 2017.
3. Phillips-Jones L. Reasons to be a mentor. https://www.mentoringgroup.com/html/articles/mentor_1.html. Accessed March 15, 2017.
4. Holmes DR Jr, Hodgson PK, Simari RD, Nishimura RA. Mentoring: making the transition from mentee to mentor. Circulation. 2010;121(2):336–340.
5. Marusic A. Evidence base for mentoring women in academic medicine. J Grad Med Educ. 2012;4(3):389–390.
6. Ramaswami A, Dreher GF. The benefits associated with workplace mentoring relationships. In: Allen TD, Eby LT, eds. The Blackwell handbook of mentoring: a multiple perspectives approach. San Francisco, CA: Wiley-Blackwell; 2007:211–232.
7. Lockwood AL, Evans SC, Eby LT. Reflections on the benefits of mentoring. In: Allen TD, Eby LT, eds. The Blackwell handbook of mentoring: a multiple perspectives approach. San Francisco, CA: Wiley-Blackwell; 2007:232–236.

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MENOPAUSE

The North American Menopause Society has updated hormone therapy guidelines; herein, what you need to know. Plus, a continued call for the boxed warning to be removed from low-dose vaginal estrogen.

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Since publication of initial findings of the Women's Health Initiative (WHI) in 2002, use of systemic menopausal hormone therapy (HT) has declined by some 80% among US women.[1] Against this backdrop, this year's Menopause Update highlights the "hot off the press" updated position statement on menopausal HT from The North American Menopause Society (NAMS), summarized by Dr. JoAnn V. Pinkerton. Although this guidance is chock full of practical, evidence-based guidance, the take-home message that Dr. Pinkerton and I would like to leave readers of OBG MANAGEMENT with is that for women with bothersome menopausal symptoms aged in their 50s or within 10 years of the onset of menopause who are free of contraindications, use of systemic HT is appropriate.

Although menopausal vasomotor and related symptoms improve as women age, in untreated women, vulvovaginal atrophy (VVA, also known as genitourinary syndrome of menopause, or GSM) tends to progress, causing vaginal dryness and sexual dysfunction, among other symptoms. When symptomatic GSM represents the

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1. Norton ME, Jacobsson B, Swamy GK, et al. *N Engl J Med.* 2015;372(17):1589-1597. 2. ACOG Committee on Practice Bulletin No. 640. September 2015. 3. Stokowski et al. Prenat Diagn. 2015 35:1243-1246.

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CONTINUED FROM PAGE 18

only indication for treatment, low-dose local vaginal estrogen, ospemifene, or dehydroepiandrosterone (DHEA; prasterone) is safe and effective. However, as with systemic HT, specific treatments for GSM are substantially underutilized.[2] The current package labeling for low-dose vaginal estrogen deters many appropriate candidates from using this safe, effective treatment. In this Update, Dr. JoAnn E. Manson reviews the rationale for updating this labeling as well as recent efforts to accomplish the task.

Guidelines on HT have been updated by The North American Menopause Society

The 2017 hormone therapy position statement of The North American Menopause Society [published online ahead of print June 2017]. Menopause.

FAST TRACK

NAMS recommends individual decision making and using the most appropriate type, dose, duration, and formulation of HT

The North American Menopause Society Hormone Therapy (HT) Position Statement Advisory Panel, composed of more than 20 experts in menopausal women's HT, including clinicians, researchers, and epidemiologists, reviewed the 2012 HT Position Statement, evaluated prior and new literature and used levels of evidence to identify the quality of the evidence and strength of the recommendations and to find consensus for the guidelines. The following information comes from the NAMS 2017 Hormone Therapy Position Statement.[3]

What are the major findings?

HT is the most effective treatment for vasomotor symptoms (VMS) and GSM and has been shown to prevent bone loss and fracture. Risks of HT may differ for women depending on type, dose, duration, route of administration, and timing of initiation and whether or not a progestogen is needed. Treatment should be individualized using the best available evidence to maximize benefits and minimize risks, with periodic reevaluation about benefits and risks of continuing or discontinuing HT.

For women who are younger than age 60 or within 10 years of menopause and have no contraindication, the clearest benefit of HT is for the treatment of VMS and prevention of bone loss in those at elevated risk.

The clinical guidelines were presented to NAMS audience at the 2016 annual clinical meeting, where NAMS recommended "determining the most appropriate type, dose, formulation, and duration of HT."[4]

When to initiate HT and duration of use

In its soon-to-be-published 2017 guidelines on HT, NAMS affirms the safety and efficacy of HT for symptomatic menopausal women or those at high risk for bone loss who are under age 60 or within 10 years of menopause. NAMS encourages practitioners to employ shared decision making with their patients to find the appropriate type, dose, formulation, and duration of HT, making individualized decisions based on evidence-based information, the unique health risks of women, and with periodic reassessment.

In the clinical guidelines presented in the 2016 NAMS annual meeting,[4] key recommendations taken from the 2017 Hormone Therapy Position Statement[3] include the following: For women who are aged younger than 60 years or within 10 years of menopause and have no contraindications, the benefit/risk ratio appears favorable for treatment of bothersome VMS and in those at elevated risk for bone loss or fracture.

For women who initiate HT more than

10 years from menopause or after age 60, this benefit/risk ratio appears less favorable because of greater absolute risks of coronary heart disease, stroke, venous thromboembolism, and dementia.

What about extended use of hormone therapy? There is no evidence to support routine discontinuation of HT after age 65. Decisions about longer durations of HT should be individualized and considered for indications such as persistent VMS or bone loss, with shared decision making, documentation, and periodic reevaluation. Longer duration is more favorable for estrogen therapy than for estrogen-progestin therapy, based on the Women's Health Initiative (WHI) randomized controlled trials.[5]

What about only vaginal symptoms? For bothersome GSM not relieved with over-the-counter therapies and without indications for use of systemic HT, low-dose vaginal estrogen therapy or other therapies are recommended and can be continued as long as indicated since there is minimal systemic absorption of estrogen, with serum levels remaining within the normal postmenopausal range.[6,7] For women with estrogen sensitive cancer, oncologists should be included in decision making, particularly for women on aromatase inhibitors.

Considerations for special populations

Early menopause. For women with hypoestrogenism, primary ovarian insufficiency, or premature surgical menopause without contraindications, HT is recommended until at least the median age of menopause (52 years), as studies suggest that benefits outweigh the risks for effects on bone, heart, cognition, GSM, sexual function, and mood.[8]

Family history of breast cancer. Observational evidence suggests that use of HT does not further alter the risk for breast cancer in women with a family history of breast cancer. Family history is one risk, among others, that should be assessed when counseling women regarding HT.

Women who are *BRCA*-positive without breast cancer. For women who are *BRCA*-positive (higher genetic risk of breast cancer, primarily estrogen-receptor–negative), and have undergone surgical menopause (bilateral salpingo-oophorectomy), the benefits of estrogen to decrease health risks caused by premature loss of estrogen need to be considered on an individual basis.[9] On the basis of limited observational studies, consider offering systemic HT until the median age of menopause (52 years) with longer use individualized.[10-12]

Survivors of endometrial and breast cancer with bothersome VMS. For women with prior estrogen-sensitive cancers, non-HTs should be considered first, particularly those agents studied through randomized controlled trials in this population and found to be effective. If systemic estrogen is considered for persistent symptoms after non-HT or complementary options have been unsuccessful, decisions should be made for compelling reasons and after detailed counseling, with shared decision making and in conjunction with their oncologist.

Bothersome GSM. On the basis of limited observational data, there appears to be minimal to no demonstrated elevation in risk for recurrence of endometrial or breast cancer using low-dose vaginal estrogen,[13] but decisions should be made in conjunction with an oncologist.

The importance of relaying the new guidelines to patients

It is important for clinicians to talk to women about their menopausal symptoms and their options for relief of symptoms or prevention of bone loss. Discussion should take into account age and time from menopause, include evidence-based information about benefits and risks of different types of therapy, and employ shared decision making to choose the most appropriate therapy to maximize benefits and minimize risks for the individual woman.

Following the WHI initial release in 2002, both women and providers became fearful of HT and believed media hype and celebrities that compounded bioidentical HT was safer than FDA-approved HTs. However, compounded products lack safety and

FAST TRACK

For women who are *BRCA*-positive with no breast cancer, consider offering systemic HT until approximately age 52, with longer use individualized

efficacy data, are not monitored or regulated by the FDA, and have unique risks associated with compounding, including concerns about sterility, impurities, and overdosing or underdosing, which could increase cancer risk.[3]

WHAT THIS EVIDENCE MEANS FOR PRACTICE

The bottom-line takeaways for clinicians are:

- Hormone therapy for symptomatic menopausal women is safe and effective for those under age 60 or within 10 years of menopause.
- Identify the most appropriate type, dose, formulation, and duration of hormone therapy for an individual woman based on evidence.
- We want to remove the fear of using hormone therapy for healthy symptomatic women who are under age 60 or within 10 years of menopause.
- Age at initiation of hormone therapy matters.
- NAMS endorses use of FDA-approved hormone therapy over compounded therapies.

Physicians continue to underwhelmingly prescribe low-dose vaginal estrogen for GSM

FAST TRACK

Half of the surveyed 1,858 US women aged 45 and older never used any treatment for their reported GSM

Kingsberg SA, Krychman M, Graham S, Bernick B, Mirkin S. The Women's EMPOWER survey: identifying women's perceptions on vulvar and vaginal atrophy and its treatment. J Sex Med. 2017;14(3):413–424.

GSM is seriously underrecognized and undertreated.[2,8,14] It has a major impact on women's lives—a silent epidemic affecting women's quality of life, sexual health, interpersonal relationships, and even physical health in terms of increased risk of urinary tract infections and urinary symptoms. Unfortunately, patients are reluctant to mention the problem to their clinicians, and they do not clearly recognize it as a medical condition that has available treatment options. Clinicians also rarely receive adequate training in the management of this condition and how to discuss it with their patients. Given busy schedules and time constraints, addressing this topic often falls through the cracks, representing a missed opportunity for helping our patients with safe and effective treatments. In a recent study by Kingsberg and colleagues, an astoundingly low percentage of women with GSM symptoms received treatment.

Details of the study

The study authors evaluated women's perceptions of GSM and available treatment options. US women aged 45 and older who reported GSM symptoms were surveyed. Of 1,858 women with a median age of 58 (range, 45–90), the study authors found that 50% had never used any treatment; 25% used over-the-counter medications; 18% were former users of GSM treatments; and 7% currently used prescribed GSM therapies.

When GSM was discussed, women were more likely than their clinicians to initiate the conversation. The main reason for women not mentioning their symptoms was the perception that GSM symptoms were a natural and inevitable part of aging. Hormonal products were perceived by women as having several downsides, including risk of systemic absorption, messiness of local creams, and the need to reuse an applicator. Overall, clinicians recommended vaginal estrogen

therapy to only 23% and oral HTs to 18% of women.

The results of the study are consistent with results of earlier surveys of menopausal women. Although the survey included nearly 2,000 women, it has the potential for selection biases inherent to most Internet-based surveys. In addition, the respondents tended to be white and have higher socieconomic status, with limited representation from other groups.

Calls for the current boxed warning to be revised

GSM is highly prevalent among postmenopausal women; the condition has adverse effects on quality of life and sexual health.[2,8,14] Safe and effective treatments are available but are underutilized.[1,8,15,16] A current boxed warning appears on low-dose vaginal estrogen—class labeling that appears on all medications in the class of estrogen or HT, regardless of dose or route of administration. These warnings are based on findings from the WHI and other studies of systemic estrogen or estrogen plus progestin, which demonstrated a complex pattern of risks and benefits of HT (including increased risk of venous thrombosis or pulmonary embolism, stroke, and breast cancer [with estrogen plus progestin]).

These findings, however, do not appear to be relevant to low-dose vaginal estrogen, given minimal if any systemic absorption and much lower blood levels of hormones than found with systemic HT. Blood levels of estradiol with low-dose vaginal estrogen remain in the normal postmenopausal range, compared to several-fold elevations in hormone levels with systemic HT.[8,15,16] Additionally, observational studies of low-dose vaginal estrogen, as well as short-term randomized clinical trials, show no evidence of an increased risk of venous thromboembolic events, heart disease, stroke, breast cancer, or dementia—the listed possible adverse effects in the boxed warning. The current warning is based on extrapolating findings from systemic HT, which is inappropriate and not evidence-based for low-dose vaginal estrogen.[15]

The inappropriate boxed warning contributes to the problem of undertreatment of GSM in women by discouraging clinicians from prescribing the medication and dissuading patients from taking it even after purchase. Testimonials from many clinicians caring for these women have underscored that women will fill their prescription, but after seeing the boxed warning will often become alarmed and decide not to take the medication. Clinicians reported that patients often say at their next appointment: "No, I never took it. I got very scared when I saw the boxed warning." As a result, clinicians often have to spend a great deal of time explaining the limitations of, and lack of evidence for, the boxed warning on low-dose vaginal estrogen.

Recommended label revisions

A modified label, without a boxed warning, would be safer for women because the key messages would not be obscured by the large amount of irrelevant information. Our Working Group recommended that the label explain that the listed risks were found in studies of systemic HT and their relevance to low-dose vaginal estrogen is unknown. The Group also recommended that warning text should be added in bold font to advise patients to seek medical attention if they have vaginal bleeding or spotting while taking the medication. In addition, patients who have a history of breast cancer or other hormone-sensitive cancer should discuss the use of the medication with their oncologist.

Status update on efforts to revise label. A citizen's petition was filed in the Spring of 2016, with signatures from more than

FAST TRACK

Unlike systemic HT, low-dose vaginal estrogen results in estradiol blood levels in the normal postmenopausal range

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WHAT THIS EVIDENCE MEANS FOR PRACTICE

GSM continues to be underrecognized and undertreated, despite recent educational initiatives. Suboptimal communication between clinicians and patients, reluctance to prescribe available treatments, and product labeling that is not evidence based contribute to this problem. Ultimately, we hope that a modified label that better reflects the safety profile of treatment will facilitate the safe and effective treatment of GSM.

Pregnancy test missed before IUD placement? Your liability.

A patient is pregnant at intrauterine device placement, physician fails to administer pregnancy test. What is the outcome of this case?

Joseph S. Sanfilippo, MD, MBA, and Steven R. Smith, JD

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CASE Gynecologist accused of placing an IUD without performing a pregnancy test

A 34-year-old woman (G4 P3013) presents to her gynecologist for planned placement of the Mirena Intrauterine System (Bayer HealthCare). She was divorced 2 months ago and is interested in birth control. She smokes 1.5 packs per day, and her history includes irregular menses, an earlier Pap smear result of atypical squamous cells of undetermined significance (ASCUS) with negative colposcopy results, polycystic ovary syndrome, obesity, migraine headaches with aura, bilateral carpel tunnel surgery, and a herniated L4.5 disc treated conservatively. She has no history of any psychiatric problems.

One week before intrauterine device (IUD) placement, she discussed the options with her gynecologist and received a Mirena patient brochure. At the office visit for IUD placement, the patient stated she had a negative home pregnancy test 1 week earlier. She did not tell the gynecologist that she had taken Plan B One-Step (levonorgestrel, 1.5 mg) emergency contraception 2 weeks prior to presenting to her gynecologist after receiving it from a Planned Parenthood office following condom breakage during coitus. IUD placement was uncomplicated.

After noting spotting several weeks later, she contacted her gynecologist's office. Results of an office urine pregnancy test were positive; the serum human chorionic gonadotropin (hCG) level was reported at 65,000 mIU/mL. The results of a pelvic sonogram showed a 12 5/7-week intrauterine gestation. The gynecologist unsuccessfully tried to remove the IUD. Options for termination or continuation of the pregnancy were discussed. The patient felt the gynecologist strongly encouraged, "almost

In this quarterly column, these medical and legal experts and educators present a case-based discussion and provide clear teaching points and takeaways for your practice.

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The authors report no financial relationships relevant to this article.

The facts are not from a single case, but rather a composite of a number of incidents.

insisting on," termination. Termination could not be performed locally as her state laws did not allow second trimester abortion; the gynecologist provided out-of-state clinic options.

The patient aborted the pregnancy in a neighboring state. She was opposed to the termination but decided it was not a good time for her to have a baby. She felt the staff at the facility were "cold" and had a "we got to get this done attitude." As she left the clinic, she saw people picketing outside and found the whole process "psychologically traumatic." When bleeding persisted, she sought care from another gynecologist. Pelvic sonography results showed retained products of conception (POC). The new gynecologist performed operative hysteroscopy to remove the POC. The patient became depressed and felt as if she was a victim of pain and suffering.

The patient's attorney filed a medical malpractice claim against the gynecologist who inserted the IUD, accusing her of negligence for not performing a pregnancy test immediately before IUD insertion.

In a deposition, the patient stated she bought the home pregnancy test in a "dollar store" and was worried about its accuracy, but never told the gynecologist. Conception probably occurred 2 weeks prior to IUD insertion, correlating with the broken condom and taking of Plan B. She did not think the gynecologist needed to know this as it "would not have made any difference in her care."

The gynecologist confirmed that the patient's record included "Patient stated 'pregnancy test negative within 1 week of IUD placement.'" The gynecologist did not feel that obtaining the date of the patient's last menstrual period (LMP) was required since she asked if the patient had protected coitus since her LMP and the patient answered yes. The gynecologist thought that if a pregnancy were in utero, Mirena placement would prevent implantation. She believed that she had obtained proper informed consent and that the patient acknowledged receiving and reading the Mirena patient information prior to placement. The gynecologist stated she also provided other birth control options.

The patient's expert witness testified that the gynecologist fell below the standard of care by not obtaining a pregnancy test prior to IUD insertion.

The gynecologist's expert witness argued that the patient told the gynecologist that she did not have unprotected coitus. The patient herself withheld information from the gynecologist that she had taken Plan B due to condom breakage. The physician's attorney also noted that the pelvic exam at time of IUD placement was normal.

WHAT'S THE VERDICT?

The patient has a fairly good case. The gynecologist may not have been sufficiently careful, given all of the facts in this case, to ensure that the patient was not pregnant. An expert is testifying that this fell below the acceptable level of care in the profession. At the same time, the failure of the patient to reveal some information may result in reduced damages through "comparative negligence." Because there will be several questions of fact for a jury to decide, as well as some emotional elements in this case, the outcome of a trial is uncertain. This suggests that a negotiated settlement before trial should be considered.

Medical considerations

First, some background information on Mirena.

Indications for Mirena

Here are indications for Mirena[1]:

- intrauterine contraception for up to 5 years
- treatment of heavy menstrual bleeding for women who choose to use intrauterine contraception as their method of contraception.

Prior to insertion, the following are recommended[2]:

- a complete medical and social history should be obtained to determine conditions that might influence the selection of a levonorgestrel-releasing intrauterine system (LNG IUS) for contraception
- if indicated, perform a physical examination, and appropriate tests for any forms

FAST TRACK

Prior to insertion, perform a physical exam and appropriate tests for STDs and pregnancy

of genital or other sexually transmitted infections
- there is no requirement for prepregnancy test.

Contraindications for Mirena

Contraindications for Mirena include[2]:
- pregnancy or suspicion of pregnancy; cannot be used for postcoital contraception
- congenital or acquired uterine anomaly including fibroids if they distort the uterine cavity
- acute pelvic inflammatory disease or a history of pelvic inflammatory disease unless there has been a subsequent intrauterine pregnancy
- postpartum endometritis or infected abortion in the past 3 months
- known or suspected uterine or cervical neoplasia
- known or suspected breast cancer or other progestin-sensitive cancer, now or in the past
- uterine bleeding of unknown etiology
- untreated acute cervicitis or vaginitis, including bacterial vaginosis or other lower genital tract infections until infection is controlled
- acute liver disease or liver tumor (benign or malignant)
- conditions associated with increased susceptibility to pelvic infections
- a previously inserted IUD that has not been removed
- hypersensitivity to any component of this product.

FAST TRACK

Per ACOG, Mirena has not been studied for emergency contraception

Is Mirena a postcoital contraceptive?

The American College of Obstetricians and Gynecologists (ACOG) bulletin on long-acting reversible contraception states "the levonorgestrel intrauterine system has not been studied for emergency contraception."[3] Ongoing studies are comparing the levonorgestrel IUD to the copper IUD for emergency contraception.[4]

Accuracy of home pregnancy tests

Although the first home pregnancy test was introduced in 1976,[5] there are now several home pregnancy tests available over the counter, most designed to detect urinary levels of hCG at ≥25 mIU/mL. The tests identify hCG, hyperglycosylated hCG, and free Betasubunit hCG in urine. When Cole and colleagues evaluated the validity of urinary tests including assessment of 18 brands, results noted that sensitivity of 12.4 mIU/mL of hCG detected 95% of pregnancies at time of missed menses.[6] Some brands required 100 mIU/mL levels of hCG for positive results. The authors concluded "the utility of home pregnancy tests is questioned."[6] For urinary levels of hCG, see **TABLE**.

TABLE Days of pregnancy and corresponding median urinary hCG levels[4]

Day	Level
9	4 mIU/mL
11	25 mIU/mL
14	100 mIU/mL

Pregnancy with an IUD

The gynecologist's concern about pregnancy when an IUD is inserted was valid.

With regard to pregnancy with Mirena in place, the full prescribing information states[2]:

> Intrauterine Pregnancy: If pregnancy occurs while using Mirena, remove Mirena because leaving it in place may increase the risk of spontaneous abortion and preterm labor. Removal of Mirena or probing of the uterus may also result in spontaneous abortion. In the event of an intrauterine pregnancy with Mirena, consider the following:
>
> *Septic abortion*
>
> In patients becoming pregnant with an IUD in place, septic abortion - with septicemia, septic shock, and death may occur.
>
> *Continuation of pregnancy*
>
> If a woman becomes pregnant with Mirena in place and if Mirena cannot be removed or the woman chooses not to have it removed, warn her that failure to remove Mirena increases the risk of

miscarriage, sepsis, premature labor and premature delivery. Follow her pregnancy closely and advise her to report immediately any symptom that suggests complications of the pregnancy.

Concern for microbial invasion of the amniotic cavity must be considered. Kim and colleagues addressed pregnancy prognosis with an IUD in situ in a retrospective study of 12,297 pregnancies; 196 had an IUD with singleton gestation.[7] The study revealed a higher incidence of histologic chorioamnionitis and/or funisitis when compared with those without an IUD (54.2% vs 14.7%, respectively; $P<.001$). The authors concluded that pregnant women with an IUD in utero are at very high risk for adverse pregnancy outcomes. Brahmi and colleagues[8] reported similar risks with higher incidence of spontaneous abortion, preterm delivery, and septic abortion.

Efficacy and safety concerns with emergency contraception

The efficacy and safety of emergency contraception using levonorgestrel oral tablets (Plan B One-Step; Duramed Pharmaceuticals) is another concern. Plan B One-Step should be taken orally as soon as possible within 72 hours after unprotected intercourse or a known or suspected contraceptive failure. Efficacy is better if Plan B is taken as soon as possible after unprotected intercourse. There are 2 dosages: 1 tablet of levonorgestrel 1.5 mg or 2 tablets of levonorgestrel 0.75 mg. The second 0.75-mg tablet should be taken 12 hours after the first dose.[9]

Plan B can be used at any time during the menstrual cycle. In a series of 2,445 women aged 15 to 48 years who took levonorgestrel tablets for emergency contraception (Phase IV clinical trial), 5 pregnancies occurred (0.2%).[10]

ACOG advises that emergency contraception using a pill or the copper IUD should be initiated as soon as possible (up to 5 days) after unprotected coitus or inadequately protected coitus.[9]

Retained products of contraception

ACOG Practice Bulletin No. 135 on complications associated with second trimester abortion discusses retained POC.[11] The approach to second trimester abortion includes dilation and evacuation (D&E) as well as medical therapy with mifepristone and misoprostol. D&E, a safe and effective approach with advantages over medical abortion, is associated with fewer complications (up to 4%) versus medical abortion (29%); the primary complication is retained POC (placenta).[11]

Legal considerations

The malpractice lawsuit filed in this case claims that the gynecologist failed to exercise the level of care of a reasonably prudent practitioner under the circumstances and was therefore negligent or in breach of a duty to the patient.

First, a lawyer would look for a medical error that was related to some harm. Keep in mind that *not* all medical errors are negligent or subject to liability. Many medical errors occur even though the physician has exercised all reasonable care and engaged in sound practice, given today's medical knowledge and facilities. When harm is caused through medical error that was careless or otherwise does not meet the standard of care, financial recovery is possible for the patient through a malpractice claim.[12]

In this case, the expert witnesses' statements focus on the issue of conducting a pregnancy test prior to IUD insertion. The patient's expert testified that failure to perform a pregnancy test was below an acceptable standard of care. That opinion may have been based on the typical practice of gynecologists, widely accepted medical text books, and formal practice standards of professional organizations.[13]

Cost-benefit analysis. Additional support for the claim that not performing the pregnancy test is negligent comes from applying a cost-benefit analysis. In this analysis, the risks and costs of performing a pregnancy test are compared with the benefits of doing the test.

In this case, the cost of conducting the pregnancy test is very low: essentially risk-free

FAST TRACK

The cost of conducting a pregnancy test is very low. The harm that could be avoided would be significant.

and relatively inexpensive. On the other hand, the harm that could be avoided would be significant. Kim and colleagues suggest that pregnant women with an IUD in utero are at very high risk for adverse pregnancy outcomes.[7] Given that women receiving IUDs are candidates for pregnancy (and perhaps do not know they are pregnant), a simple, risk-free pregnancy test would seem to be an efficient way to avoid a nontrivial harm.[14]

Did she have unprotected sex? The gynecologist's expert notes that the patient told the gynecologist that she did not have unprotected coitus. Furthermore, the patient withheld from the gynecologist the information that she had taken Plan B because of a broken condom. Is this a defense against the malpractice claim? The answer is "possibly no," or "possibly somewhat."

As for unprotected coitus, the patient could easily have misunderstood the question. Technically, the answer "no" was correct. She had not had unprotected sex—it is just that the protection (condom) failed. It does not appear from the facts that she disclosed or was asked about Plan B or other information related to possible failed contraception. As to whether the patient's failure to provide that information could be a defense for the physician, the best answer is "possibly" and "somewhat." (See below.)[15]

Withholding information. Patients, of course, have a responsibility to inform their physicians of information they know is relevant. Many patients, however, will not know what is relevant (or why), or will not be fully disclosing.

Professionals cannot ignore the fact that their patients and clients are often confused, do not understand what is important and relevant, and cannot always be relied upon. For that very reason, professionals generally are obliged to start with the proposition that they may not have all of the relevant information. In this case, this lack of information makes the cost-calculation of performing a pregnancy test that much more important. The risk of not knowing whether a patient is pregnant includes the fact that many patients just will not know or cannot say with assurance.[16]

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Patients have a responsibility to inform their physicians of information they know is relevant. However, many patients will not know what is relevant or not be fully disclosing.

A "somewhat" defense and comparative negligence

Earlier we referred to a "somewhat" defense. Almost all states now have some form of "comparative negligence," meaning that the patient's recovery is reduced by the proportion of the blame (negligence) that is attributed to the patient. The most common form of comparative negligence works this way: If there are damages of $100,000, and the jury finds that the fault is 20% the patient's and 80% the physician's, the patient would receive $80,000 recovery. (In the past, the concept of "contributory negligence" could result in the plaintiff being precluded from any recovery if the plaintiff was partially negligent—those days are mostly gone.)

Statement of risks, informed consent, and liability

The gynecologist must provide an adequate description of the IUD risks. The case facts indicate that appropriate risks were discussed and literature provided, so it appears there was probably appropriate informed consent in this case. If not true, this would provide another basis for recovery.

Two other aspects of this case could be the basis for liability. We can assume that the attempted removal of the IUD was performed competently.[16] In addition, if the IUD was defective in terms of design, manufacture, or warnings, the manufacturer of the device could be subject to liability.[17]

Final verdict: Out of court settlement

Why would the gynecologist and the insurance company settle this case? After all, they have some arguments on their side, and physicians win the majority of malpractice cases that go to trial.[18] On the other hand, the patient's expert witness' testimony and the cost-benefit analysis of the pregnancy test are strong, contrary claims.

Cases are settled for a variety of reasons. Litigation is inherently risky. In this case, we assume that the court denied a motion to dismiss the case before trial because there is a

legitimate question of fact concerning what a reasonably prudent gynecologist would have done under the circumstances. That means a jury would probably decide the issue of medical judgment, which is generally disconcerting. Furthermore, the comparative negligence defense that the patient did not tell the gynecologist about the failed condom/Plan B would most likely reduce the amount of damages, but not eliminate liability. The questions regarding the pressure to terminate a second trimester pregnancy might well complicate a jury's view.

Other considerations include the high costs in time, money, uncertainty, and disruption associated with litigation. The settlement amount was not stated, but the process of negotiating a settlement would allow factoring in the comparative negligence aspect of the case. It would be reasonable for this case to settle before trial.

Should the physician have apologized before trial? The gynecologist could have sent a statement of regret or apology to the patient before a lawsuit was filed. Most states now have statutes that preclude such statements of regret or apology from being used against the physician. Many experts now favor apology statements as a way to reduce the risk of malpractice suits being filed.[19]

Defensive medicine. There has been much discussion of "defensive medicine" in recent years.[20] It is appropriately criticized when additional testing is solely used to protect the physician from liability. However, much of defensive medicine is not only to protect the physician but also to protect the patient from potential physical and mental harm. In this case, it would have been "careful medicine" in addition to "defensive medicine."

References

1. Heikinheimo O, Gemell-Danielsson K. Emerging indications for the levonorgestrel-releasing intrauterine system. ACTA Obstet Gynecol Scand. 2012;91(1):3–9.
2. Mirena [prescribing information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc; 2000.
3. American College of Obstetricians and Gynecologists. Practice Bulletin No. 121: Long-acting reversible contraception: Implants and intrauterine devices. Obstet Gynecol. 2011;118(1):184–196.
4. Rapid EC–Random clinical trial assessing pregnancy with intrauterine devices for emergency contraception. Clinical Trials Identifier: NCT02175030. https://www.clinicaltrials.gov/ct2/show/NCT02175030?term=NCT02175030&rank=1. Updated May 1, 2017. Accessed May 11, 2017.
5. Gnoth C, Johnson S. Strips of hope: Accuracy of home pregnancy tests and new developments. Gerburtshilfe Frauenheilkd. 2014;74(7):661–669.
6. Cole LA, Khanlian SA, Sutton JM, Davies S, Rayburn WF. Accuracy of home pregnancy tests at the time of missed menses. Am J Obstet Gynecol. 2004;190(1):100–105.
7. Kim S, Romero R, Kusanovic J, et al. The prognosis of pregnancy conceived despite the presence of an intrauterine device (IUD). J Perinatal Med. 2010;38(1):45–53.
8. Brahmi D, Steenland M, Renner R, Gaffield M, Curtis K. Pregnancy outcomes with an IUD in situ: a systematic review. Contraception. 2012;85(2):131–139.
9. American College of Obstetricians and Gynecologists. Practice Bulletin No. 152: Emergency contraception. Obstet Gynecol. 2015;126(3):685–686.
10. Chen Q, Xiang W, Zhang D, et al. Efficacy and safety of a levonorgestrel enteric-coated tablet as an over-the-counter drug for emergency contraception: a Phase IV clinical trial. Hum Reprod. 2011;26(9):2316–2321.
11. American College of Obstetricians and Gynecologists. Practice Bulletin No. 135: Second-trimester abortion. Obstet Gynecol. 2013;121(6):1395–1406.
12. White A, Pichert J, Bledsoe S, Irwin C, Entman S. Cause and effect analysis of closed claims in obstetrics and gynecology. Obstet Gynecol. 2005;105(5 pt1):1031–1038.
13. Mehlman M. Professional power and the standard of care in medicine. Case Western Reserve University Scholarly Commons. 2012: Paper 574. http://scholarlycommons.law.case.edu/cgi/viewcontent.cgi?article=1576&context=faculty_publications. Accessed May 11, 2017.
14. Klein D, Arnold J, Reese E. Provision of contraception: key recommendations from the CDC. Am Fam Physician. 2015;91(9);625–633.
15. Reyes J, Reyes R. The effects of malpractice liability on obstetrics and gynecology: taking the measure of a crisis. N England Law Rev. 2012;47;315–348. https://www.scribd.com/document/136514285/Reyes-Reyes-The-Effect-of-Malpractice-Liability-on-Obstetrics-and-Gynecology#fullscreen&from_embed. Accessed May 11, 2017.
16. Peckham C. Medscape Malpractice Report 2015: Why Ob/Gyns get sued. http://www.medscape.com/features/slideshow/malpractice-report-2015/obgyn#page=1. Published January 22, 2016. Accessed May 11. 2017.
17. Rheingold P, Paris D. Contraceptives. In: Vargo JJ, ed. Products Liability Practice Guide New York, New York: Matthew Bender & Company; 2017;C:62.
18. Jena AB, Chandra A, Lakdawalla D, Seabury S. Outcomes of medical malpractice litigation against US physicians. Arch Intern Med. 2012;172(11):892–894.
19. Helmreich JS. Does sorry incriminate? Evidence, harm and the protection of apology. Cornell J Law Public Policy. 2012;21(3);567–609. http://scholarship.law.cornell.edu/cgi/viewcontent.cgi?article=1363&context=cjlpp.
20. Baicker K, Wright B, Olson N. Reevaluating reports of defensive medicine. J Health Polit Policy Law. 2015;40(6);1157–1177.

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Most states now have statutes that preclude statements of regret or apology from being used against the physician

The transgender man—a female-assigned person who self-identifies as male—has unique health care needs that can be addressed only by a gynecologist. It is important to become comfortable with and educated about these health needs and their subtleties, starting with understanding the patient's gender dysphoria associated with the gynecologic visit and examination.

ILLUSTRATION: KIMBERLY MARTENS FOR OBG MANAGEMENT

Caring for the transgender patient: The role of the gynecologist

Gynecologists must become comfortable with and educated about transgender men's unique health care needs and issues, starting with the gender dysphoria associated with the gynecologic visit and examination

Cecile A. Unger, MD, MPH

CASE Transgender man consults gynecologist for fertility options

A 36-year-old transgender man considering the possibility of having his own biological children presents to the gynecology office to discuss hysterectomy as gender dysphoria treatment as well as his fertility preservation options. He has never had a gynecologic examination. Since age 24, he has been on testosterone therapy. Although his menses initially ceased, each month over the past 2 years he has had breakthrough spotting lasting 2 to 4 days, sometimes accompanied by pelvic pain and cramping. These symptoms have caused him distress and anxiety, which have led to his missing work 1 to 3 days each month. On presentation, he appears anxious and makes little eye contact. His girlfriend of 6 years has come in with him and is very supportive.

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Over the past decade, transgender health care has moved to the forefront of the medical conversation. At many prominent medical centers across the United States, clinicians are forming multidisciplinary teams to help improve the health care of this patient population. Outcomes are being studied, and the literature is becoming more robust.

People tend to think of transgender women—male-assigned persons who self-identify as female—as the typical prototype for transgender people, but this focus is skewed in both society and the medical community. Transgender men—female-assigned persons who self-identify as male—remain underrepresented, mostly because they want to stay "under the radar," especially with respect to medical care and, more specifically, routine gynecologic care.

Although the transgender woman has unique health needs and may present to a gynecologist for care after gender-affirmation surgery, the transgender man's many health care needs and their subtleties can be addressed only by a gynecologist. In this article, I review these intricacies of care to help increase clinician comfort in treating these patients.

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Making transgender patients feel comfortable in the office

Taking small steps to create an inclusive office environment will help transgender men feel less anxious, discriminated against, and threatened when seeking gynecologic services—resulting in a stronger patient–physician relationship.

Clinicians can take steps to:

- ensure all patients have the correct identifiers in their medical records
- provide staff with the proper education and diversity training
- instruct staff in proper use of pronouns
- set up unisex or gender-nonbinary restrooms with appropriate signage
- make the decor gender nonspecific.

Beth Cronin, MD, a practicing general gynecologist in Providence, Rhode Island, says that you also should consider a general sign, placed in a highly visible area, that represents your nondiscrimination policy. The AMA offers this wording: "This office appreciates the diversity of human beings and does not discriminate based on race, age, religion, ability, marital status, sexual orientation, sex or gender identity." She also recommends having education and marketing materials with affirmative imagery and content and providing educational brochures on transgender health topics.

Why transgender patients may delay seeking health care

Transgender patients remain underserved because of the health care barriers they encounter. Factors contributing to poor access include lack of health insurance, inability to pay for services, clinician insensitivity and hostility, and fear of exposure of transgender status during health care encounters.[1] In a recent large survey study, 30% of transgender respondents indicated that they delayed or did not seek medical care as a result of discrimination, and those who had needed to teach their clinicians about transgenderism were 4 times more likely to postpone or not seek care.[2]

In a 2015 survey of ObGyns' current knowledge and practice regarding LGBT (lesbian, gay, bisexual, transgender) care, only one-third of respondents indicated they were comfortable caring for transgender patients.[3] In addition, only one-third indicated being knowledgeable about the steps transgender patients must take to transition to their self-identified gender, and less than half were familiar with the recommendations for the routine health maintenance and screening of these patients.

Much of this discomfort derives from the lack of incorporation of LGBT-specific topics in medical curricula. In 2011, Obedin-Maliver and colleagues found that, at 176 US and Canadian allopathic and osteopathic medical schools, the median time dedicated to LGBT health care needs and related topics was unsatisfactory.[4] This deficiency is slowly being reduced with changes in the curricula of many health care specialties. In ObGyn residency programs, for example, transgender-specific questions have been added to annual in-service examinations. The hope is that, as education initiatives improve, clinicians will become more comfortable caring for gender-minority patients, who with improved access to care will no longer need to seek subspecialists in transgender services.

Considerations for the gynecologic visit and examination

Transgender men visit the gynecology office for many reasons, including routine gynecologic care and health maintenance, care for acute and chronic gynecologic conditions (abnormal bleeding, pelvic pain, vaginitis), evaluation and management of pelvic floor disorders, consultation on hysterectomy for gender transition, and fertility counseling.

However, transgender men who reach their third, fourth, or fifth decade without having had a pelvic examination cite many reasons for avoiding the gynecology office. Most commonly, gynecologic visits and genital examination can severely exacerbate these patients' gender dysphoria. In addition, many patients who do not engage in penetrative vaginal sex think their health risks are so low that they can forgo or delay pelvic exams. Patients who have stopped menstruating while on testosterone therapy may think there is no need for routine gynecologic care. Other reasons for avoiding pelvic exams are pain and traumatic sexual memories.[5]

Transgender men need to receive the regular guideline-recommended pelvic exams and screenings used for cisgender women. (*Cisgender* refers to a person whose sense of gender identity corresponds with their birth sex.) We need to educate patients in this regard and to discuss several issues before performing an examination. First, take a thorough history and avoid making assumptions about sexual orientation and sex practices. Some patients have penetrative vaginal intercourse with either men or women. For some patients, the exam may cause dysphoria symptoms, and we need to validate patients' fears. Discussing these issues ahead of time helps patients get used to the idea of undergoing an exam and assures them that the clinician is experienced in performing these exams for transgender men. In my practice, we explain the exam's purpose (screening or diagnosis) and importance. We also counsel patients that they may experience some normal, and temporary, spotting after the exam. For those who experience severe dysphoria with vaginal bleeding of any kind, we acknowledge that postexam spotting may cause some anxiety. Patients with severe anxiety before the exam may be premedicated with an anxiolytic agent as long as someone can transport them to and from the office.

The bimanual exam should be performed with care and efficiency and with the patient given as much control as possible. In most cases, we ask patients to undress only from the waist down, and their genitals stay covered. Patients uncomfortable in stirrups are asked to show us the position that suits them best, and we try to accommodate them. Although speed is a goal, remember that many patients are nulliparous, have had limited or no vaginal penetration, or are on testosterone and have significant vaginal dryness. Use the smallest speculum possible, a pediatric or long and narrow adult speculum, and apply lubricant copiously. Preexam application of topical lidocaine jelly to the introitus can help reduce pain. To help a patient relax the pelvic floor muscles and habituate to the presence of a foreign object in the vagina, start the exam by inserting a single digit. In addition, ask the patient about speculum placement inside the vagina: Does he want to place the speculum himself or guide the clinician's hand? Open the speculum only as much as needed to adequately visualize the cervix and then remove it with care.

Managing benign gynecologic disorders

The same algorithms are used to evaluate abnormal bleeding in all patients, but the differential diagnosis expands for those on testosterone therapy. Testosterone may no longer be suppressing their cycles, and abnormal bleeding could simply be the return of menses, which would present as regular cyclic bleeding. Increasing the testosterone dosing or changing the testosterone formulation may help, and the gynecologist should discuss these options with the patient's prescribing clinician. In addition, progesterone in any form (for example, medroxyprogesterone acetate 5 to 30 mg daily) can be added to testosterone regimens to help suppress menses. The levonorgestrel-releasing intrauterine device (LNG-IUD) can be very effective, but placement can induce anxiety, and some patients decline this treatment option.

In patients with intermenstrual spotting, assess the vagina for atrophy. Both over-the-counter vaginal moisturizers and DHEA (dehydroepiandrosterone) suppositories (1% compounded) can help treat atrophy, but not all patients are comfortable using them. Most patients decline vaginal estrogen products for symptomatic vaginal atrophy even though the systemic effects are minimal.

The historic literature suggests that female-to-male patients' long-term exposure to androgens leads to atrophic changes in the endometrium and myometrium, and clinical studies of menopausal women who take exogenous androgens have confirmed this effect.[6] However, new data point to a different histologic scenario. A recent study found a possible association between long-term testosterone use in transgender men

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For transgender patients taking testosterone, over-the-counter vaginal moisturizers and DHEA suppositories can help treat intermenstrual spotting due to vaginal atrophy, but not all patients are comfortable using these treatments

of reproductive age and a low proliferative active endometrium, as well as hypertrophic changes in the myometrium.[7] The causes may be peripheral aromatization of androgens and expression and up-regulation of androgen receptors within the endometrial stroma and myometrial cells.[8] Given these emerging data and anecdotal cases reported by clinicians who perform hysterectomies for transgender men, imaging and tissue sampling should be used to evaluate abnormal uterine bleeding, particularly in patients previously amenorrheic on testosterone. Be aware that transvaginal ultrasound or endometrial biopsy are challenging procedures for these patients. Counsel patients to ensure that they adhere to follow-up.

The ongoing need for cervical cancer screening

The concept of "original gender surveillance" was presented in a 2-case series of transgender men with uterine and cervical cancer that might have been detected earlier with better screening and routine care.[9] There is no evidence, however, that long-term high-dose androgen therapy causes endometrial or cervical cancer,[10] and the data on endometrial cancer in patients on cross-sex hormone therapy are limited such that a causal relationship between testosterone and these malignancies cannot be established.[9,11–14]

The rate of unsatisfactory Pap smears is higher in transgender men than in cisgender women. The difference was anecdotally noted by clinicians who routinely cared for transgender patients over time and was confirmed with a retrospective chart review.[15]

Peitzmeier and colleagues reviewed the records of 233 transgender men and 3,625 cisgender women with Pap tests performed at an urban community health center over 6 years.[15] The transgender cohort, with its prevalence rate of 10%, was 10 times more likely to have an unsatisfactory or inadequate Pap smear. Moreover, the transgender patients were more likely to have longer latency to follow-up for a repeat Pap test. In addition, testosterone therapy was more likely associated with inadequate Pap smears, and time on testosterone therapy was associated with higher odds of Pap smear inadequacy. Besides the exogenous hormone therapy, clinician comfort level and experience may have contributed to the high prevalence of inadequate Pap smears.

As mentioned earlier, it is important to become comfortable performing pelvic exams for transgender men and to prepare patients for the possibility that a Pap smear might be inadequate, making a follow-up visit and repeat Pap test necessary.[16]

Consultation for hysterectomy: Perioperative considerations

Transgender men may undergo hysterectomy, oophorectomy, and/or vaginectomy. The **TABLE** summarizes the indications and perioperative considerations for each procedure.

Some transgender men undergo hysterectomy for benign gynecologic disease. Counseling and perioperative planning are the same for these patients as for cisgender women, although some of the considerations discussed here remain important.

Other patients undergo hysterectomy as part of transitioning to their self-affirmed gender. The World Professional Association for Transgender Health (WPATH) Standards of Care should be used to guide counseling and treatment.[17] These guidelines were designed as a framework for performing hysterectomy and other gender-affirming procedures. According to the WPATH standards, the criteria for hysterectomy and oophorectomy are:

- 2 referral letters from qualified mental health professionals
- well-documented persistent gender dysphoria
- capacity to make fully informed decisions and to consent to treatment
- age of majority in given country
- good control of any concurrent medical or mental health concerns, and
- hormone therapy for 12 continuous months, as appropriate to gender goals, unless the patient has a medical contrain-

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The WPATH Standards of Care, a framework for performing hysterectomy and other gender-affirming procedures, should be used to guide counseling and treatment for patients transitioning to their self-affirmed gender

TABLE Surgical treatment options: Indications and perioperative considerations

Treatment option	Indication	Perioperative considerations
Hysterectomy	Benign gynecologic disease	Counseling and perioperative planning same as for cisgender women
	Transition to self-affirmed gender	• WPATH Standards of Care criteria (not applicable to indications other than gender dysphoria): — 2 referral letters from qualified mental health professionals — well-documented persistent gender dysphoria — capacity to make fully informed decisions and to consent to treatment — age of majority in given country — good control of any concurrent medical or mental health concerns — hormone therapy for 12 continuous months, as appropriate to gender goals, unless patient has medical contraindication or is otherwise unable or unwilling to take hormones • Most are performed laparoscopically, although ACOG recommends vaginal hysterectomy for limiting complications and morbidity and maximizing cost-effectiveness • Can be performed concurrently with oophorectomy or vaginectomy
Oophorectomy	Transition to self-affirmed gender	• WPATH Standards of Care criteria as described for hysterectomy • Concurrent with hysterectomy is a topic of debate • Effect on fertility is a concern; candidates are as follows: — hysterectomy: patients want to become parent but do not want to carry child (current or future partner or surrogate will carry) — oophorectomy: patients do not want genetic child — oophorectomy concurrent with hysterectomy: patients do not want to preserve fertility (or have already ended it) and meet WPATH criteria for surgery — undecided: isolated hysterectomy with subsequent staged oophorectomy
	Pain caused by ovarian cysts	• Concurrent oophorectomy and hysterectomy • Thorough counseling on risks and benefits
Vaginectomy	Severe gender dysphoria	• No standard of care • Transvaginal or abdominal (open, laparoscopic, robotic) • Surgeons must be experienced in the procedure • Genital reconstruction considerations
Vaginal cuff closure	Vaginal cuff evisceration	• Close vaginal cuff in 2 layers using at least 1 layer of delayed absorbable suture • No guidance on stopping or continuing testosterone therapy perioperatively • Counsel patients that severe mood swings and malaise may occur after testosterone therapy is stopped

Abbreviations: ACOG, American College of Obstetricians and Gynecologists; WPATH, World Professional Association for Transgender Health.

dication or is otherwise unable or unwilling to take hormones.

As the guidelines emphasize, these criteria do not apply to patients undergoing either procedure for medical indications other than gender dysphoria.

Hysterectomy approach. Most surgeons perform gender-affirming hysterectomies laparoscopically. Many clinicians hesitate to perform these hysterectomies vaginally, as the patients are often nulliparous. In general, the best operative route is the one the surgeon feels most comfortable performing safely and efficiently. For a nulliparous

patient with minimal pelvic organ descensus and a narrow pelvis, the laparoscopic approach is reasonable. A recent study in a small cohort of transgender men found that vaginal hysterectomy was successful in only 1 in 4 patients.[18] Nevertheless, the American College of Obstetricians and Gynecologists (ACOG) recommends vaginal hysterectomy, when appropriate, for limiting complications and morbidity while maximizing cost-effectiveness.[19] Although data are limited, vaginal hysterectomy seems feasible and should be considered in a subset of patients who present for gender-affirming hysterectomy.

The oophorectomy debate

Oophorectomy concurrent with hysterectomy remains a topic of debate among gynecologists who perform hysterectomy for gender transition. Some clinicians think gonadectomy poses a significant risk for bone health compromise at an early age. The long-term effects of testosterone on bone have not been well studied. Although bone metabolism is thought to increase over the short term, there are no major changes in bone density over the long term. In fact, in the setting of long-term testosterone therapy, cortical bone was found to be larger in transgender men than in cisgender women.[20] The issue is for patients who stop taking exogenous testosterone after oophorectomy. This subset of patients has not been well studied but clearly needs bone health surveillance and supplementation.

Another concern about oophorectomy is its effect on fertility. Because it is important to discuss fertility-preserving options, during consultation for a hysterectomy I spend a large portion of time addressing fertility goals. Patients who want to become a parent but do not want to carry a child (they want a current or future partner or surrogate to carry) are candidates for hysterectomy; those who do not want a genetic child are candidates for oophorectomy; and those who do not want to preserve their fertility (or have already ended it) and who meet the WPATH criteria for surgery are candidates for oophorectomy concurrent with hysterectomy. The discussion can be particularly challenging with young transgender men, since their ability to project their family planning goals may be compromised by their gender dysphoria. Clinicians can counsel patients about another option: isolated hysterectomy with subsequent staged oophorectomy.

Similar to cisgender women with polycystic ovary syndrome, transgender men on exogenous testosterone therapy are at risk for ovarian cysts,[7] which can cause pain and should be evaluated and managed. As mentioned, these patients may find it difficult to visit a gynecologist and tolerate a vaginal examination, and many fear presenting to an emergency room, as they will need to disclose their transgender status and risk being discriminated against or, worse, not being triaged or cared for properly. Patients should be thoroughly counseled about the risks and benefits of having oophorectomy performed concurrently with hysterectomy.

The question of vaginectomy

Patients and clinicians often ask about concurrent vaginectomy procedures. In some cases, patients with severe gender dysphoria and absence of penetrative vaginal activity request excision or obliteration of the vagina. There is no standard of care, however. Vaginectomy can be done transvaginally or abdominally: open, laparoscopically, or robotically. It therefore should be performed by surgeons experienced in the procedure. Patients should be advised that a portion of the vaginal epithelium is sometimes used for certain phalloplasty procedures and that, if they are considering genital reconstruction in the future, it may be beneficial to preserve the vagina until that time.

There are no guidelines on stopping or continuing testosterone therapy perioperatively. Some clinicians are concerned about possible venous thromboembolic events related to perioperative use of testosterone, but there are no data supporting increased risk. The risk of postoperative vaginal cuff bleeding in patients on and off testosterone has not been well studied. Since patients who stop taking testosterone may develop severe mood swings and malaise, they should be

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Concerns regarding oophorectomy concurrent with hysterectomy include its effects on bone health and fertility

counseled on recognizing and managing such changes. There are also no data on the risk of vaginal cuff dehiscence in this patient population. Testosterone usually causes the vagina to become very atrophic, so proper closure should be ensured to avoid cuff evisceration. In my practice, the vaginal cuff is closed in 2 layers using at least 1 layer of delayed absorbable suture.

Addressing fertility, contraception, and obstetric care

Most transgender men are able to conceive a child.[21] Data in this area, however, are sparse. Most of the literature on reproductive health in this patient population is focused on human immunodeficiency virus (HIV) and other sexually transmitted infections.[22] Nevertheless, patient-physician dialogue on fertility and reproductive health has increased since more patients started seeking surgical transition services (likely a result of improved coverage for these surgeries). In addition, we are learning more about patients' ability and desire to conceive after long-term use of cross-sex hormone therapy. The importance of this dialogue is becoming apparent. One survey study found that more than half of the transgender men who had undergone affirmation surgery wanted to become parents.[23]

Before initiating cross-sex hormone therapy or before undergoing hysterectomy and/or oophorectomy, patients must be counseled about their fertility options. Testosterone may affect fertility and fecundity, but there are case reports of successful pregnancy after discontinuation of testosterone.[21] Reproductive endocrinology and fertility specialists have begun to recognize the importance of fertility preservation in this patient population and to apply the principles of oncofertility care beyond patients with cancer. In a 2015 opinion paper on access to fertility services by transgender persons, the Ethics Committee of the American Society for Reproductive Medicine focused on this population's unique fertility needs.[24] Currently, oocyte and embryo cryopreservation are options for transgender men planning to start cross-sex hormones or undergo surgery.[25] Other methods being investigated may become options in the future.[25]

There are even fewer data on transgender men's contraceptive needs. Many clinicians mistakenly think these patients are at low risk for pregnancy. Some patients have male partners and engage in penetrative penile-vaginal intercourse; others are not on testosterone therapy; and still others, despite taking testosterone, are not always amenorrheic and may be ovulating. In a small cross-sectional study, Light and colleagues found that 12% of transgender men who were surveyed after conceiving had been amenorrheic on testosterone therapy, and 24% of these pregnancies were not planned.[21]

In a study by Cipres and colleagues, half of the 26 transgender men were considered at risk for pregnancy: These patients still had a uterus, not all were on testosterone, not all on testosterone were amenorrheic, they were having vaginal intercourse with cisgender men, and none were using condoms or other contraception.[26] The authors noted several potential underlying reasons for poor counseling on contraceptive needs: patients feel stigmatized, clinicians assume these patients are not candidates for "female" hormone therapy, patients fear these modalities may feminize them and compromise their affirmed identities, patients poorly understand how testosterone works and have mistaken ideas about its contraceptive properties, and clinician discomfort with broaching fertility and reproductive health discussions.

Data are also limited on pregnancy in transgender men. We do know that clinicians are not well equipped to help patients during the peripartum period and better resources are needed.[21] Gender dysphoria can worsen during and immediately after pregnancy, and patients may be at significant risk for postpartum depression. More research is needed.

Gynecologists play key role in transgender care

Transgender men's unique health care needs can be addressed only by gynecologists.

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Contraceptive counseling is important, since some transgender men have male partners and have intercourse, others are not on testosterone, and others may be ovulating despite taking testosterone

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It is important to become comfortable with and educated about these needs and their subtleties. This starts with understanding transgender patients' gender dysphoria associated with the gynecologic visit and examination. Learning more about these patients and their needs will improve health care delivery.

References

1. Xavier JM, Simmons R. The Washington Transgender Needs Assessment Survey, 2000. http://www.glaa.org/archive/2000/tgneedsassessment1112.shtml. Accessed January 2, 2017.
2. Jaffee KD, Shires DA, Stroumsa D. Discrimination and delayed health care among transgender women and men: implications for improving medical education and health care delivery. Med Care. 2016;54(11):1010–1016.
3. Unger CA. Care of the transgender patient: a survey of gynecologists' current knowledge and practice. J Womens Health. 2015;24(2):114–118.
4. Obedin-Maliver J, Goldsmith ES, Stewart L, et al. Lesbian, gay, bisexual, and transgender-related content in undergraduate medical education. JAMA. 2011;306(9):971–977.
5. Feldman J. Medical and surgical management of the transgender patient: what the primary care clinician needs to know. In: Makadon H, Mayer K, Potter J, Goldhammer H, eds. Fenway Guide to Lesbian, Gay, Bisexual, and Transgender Health. Philadelphia, PA: American College of Physicians; 2008:365–392.
6. Hickok LR, Toomey C, Speroff L. A comparison of esterified estrogens with and without methyltestosterone: effects on endometrial histology and serum lipoproteins in postmenopausal women. Obstet Gynecol. 1993;82(6):919–924.
7. Loverro G, Resta L, Dellino M, et al. Uterine and ovarian changes during testosterone administration in young female-to-male transsexuals. Taiwan J Obstet Gynecol. 2016;55(5):686–691.
8. Mertens HJ, Heineman MJ, Koudstaal J, Theunissen P, Evers JL. Androgen receptor content in human endometrium. Eur J Obstet Gynecol Reprod Biol. 1996;70(1):11–13.
9. Urban RR, Teng NN, Kapp DS. Gynecologic malignancies in female-to-male transgender patients: the need of original gender surveillance. Am J Obstet Gynecol. 2011;204(5):e9–e12.
10. Mueller A, Gooren L. Hormone-related tumors in transsexuals receiving treatment with cross-sex hormones. Eur J Endocrinol. 2008;159(3):197–202.
11. Allen NE, Key TJ, Dossus L, et al. Endogenous sex hormones and endometrial cancer risk in women in the European Prospective Investigation into Cancer and Nutrition (EPIC). Endocr Relat Cancer. 2008;15(2):485–497.
12. Hage JJ, Dekker JJ, Karim RB, Verheijen RH, Bloemena E. Ovarian cancer in female-to-male transsexuals: report of two cases. Gynecol Oncol. 2000;76(3):413–415.
13. Dizon DS, Tejada-Berges T, Keolliker S, Steinhoff M, Grania CO. Ovarian cancer associated with testosterone supplementation in a female-to-male transsexual patient. Gynecol Oncol Invest. 2006;62(4):226–228.
14. Schenck TL, Holzbach T, Zantl N, et al. Vaginal carcinoma in a female-to-male transsexual. J Sex Med. 2010;7(8):2899–2902.
15. Peitzmeier SM, Reisner SL, Harigopal P, Potter J. Female-to-male patients have high prevalence of unsatisfactory Paps compared to non-transgender females: implications for cervical cancer screening. J Gen Intern Med. 2014;29(5):778–784.
16. Potter J, Peitzmeier SM, Bernstein I, et al. Cervical cancer screening for patients on the female-to-male spectrum: a narrative review and guide for clinicians. J Gen Intern Med. 2015;30(12):1857–1864.
17. Coleman E, Bockting W, Botzer M, et al; World Professional Association for Transgender Health. Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People, Version 7. https://s3.amazonaws.com/amo_hub_content/Association140/files/Standards%20of%20Care%20V7%20-%202011%20WPATH%20(2)(1).pdf. Published 2011. Accessed January 21, 2017.
18. Obedin-Maliver J, Light A, de Haan G, Jackson RA. Feasibility of vaginal hysterectomy for female-to-male transgender men. Obstet Gynecol. 2017;129(3):457–463.
19. American College of Obstetricians and Gynecologists. ACOG Committee Opinion No. 444: Choosing the route of hysterectomy for benign disease. Obstet Gynecol. 2009;114(5):1156–1158.
20. Van Caenegem E, T'Sjoen G. Bone in trans persons. Curr Opin Endocrinol Diabetes Obes. 2015;22(6):459–466.
21. Light AD, Obedin-Maliver J, Sevelius JM, Kerns JL. Transgender men who experienced pregnancy after female-to-male gender transitioning. Obstet Gynecol. 2014;124(6):1120–1127.
22. Stephens SC, Bernstein KT, Philip SS. Male to female and female to male transgender persons have different sexual risk behaviors yet similar rates of STDs and HIV. AIDS Behav. 2011;15(3):683–686.
23. Wierckx K, Van Caenegem E, Pennings G, et al. Reproductive wish in transsexual men. Hum Reprod. 2012;27(2):483–487.
24. Ethics Committee of the American Society for Reproductive Medicine. Access to fertility services by transgender persons: an Ethics Committee opinion. Fertil Steril. 2015;104(5):1111–1115.
25. Wallace SA, Blough KL, Kondapalli LA. Fertility preservation in the transgender patient: expanding oncofertility care beyond cancer. Gynecol Endocrinol. 2014;30(12):868–871.
26. Cipres D, Seidman D, Cloniger C 3rd, Nova C, O'Shea A, Obedin-Maliver J. Contraceptive use and pregnancy intentions among transgender men presenting to a clinic for sex workers and their families in San Francisco. Contraception. 2016;95(2):186–189.

LISTEN:

›› Dr. Beth Cronin details how to begin treating transgender patients as well as how to create a nonjudgmental office environment that is conducive to transgender patients.

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CONTINUED FROM PAGE 23

600 clinicians and patients and representatives of medical and professional organizations endorsing a more appropriate evidence-based label for low-dose vaginal estrogen. The FDA is continuing to review and deliberate on these issues but has not yet made a final decision.

Did you read "Focus on treating genital atrophy symptoms" from Dr. Andrew Kaunitz from January 2017? Find it in the archive at **obgmanagement.com**

References

1. Manson JM, Kaunitz AM. Menopause management—Getting clinical care back on track. N Engl J Med. 2016;374(9):803–806.
2. Parish SJ, Nappi RE, Krychman ML, et al. Impact of vulvovaginal health on postmenopausal women: a review of surveys on symptoms of vulvovaginal atrophy. Int J Womens Health. 2013;5:437–447.
3. The 2017 hormone therapy position statement of The North American Menopause Society [published online ahead of print June 2017]. Menopause.
4. Pinkerton JV. Hormone therapy: 2016 NAMS position statement [abstract]. Menopause. 2016;23:1365.
5. Manson JE, Chlebowski RT, Stefanick ML, et al. Menopausal hormone therapy and health outcomes during the intervention and extended poststopping phases of the Women's Health Initiative randomized trials. JAMA. 2013;310(13):1353–1368.
6. Faubion SS, Kuhle CL, Shuster LT, Rocca WA. Long-term health consequences of premature or early menopause and considerations for management. Climacteric. 2015;18(4):483–491.
7. Lethaby A, Ayeleke RO, Roberts H. Local oestrogen for vaginal atrophy in postmenopausal women. Cochrane Database Sys Rev. 2016;8:CD001500.
8. Management of symptomatic vulvovaginal atrophy: 2013 position statement of The North American Menopause Society. Menopause. 2013;20(9):888–902.
9. Farrell R; American College of Obstetricians and Gynecologists' Committee on Gynecologic Practice. ACOG Committee Opinion No. 659 summary: The use of vaginal estrogen in women with a history of estrogen-dependent breast cancer. Obstet Gynecol. 2016;127(3):618–619.
10. Hodis HN, Mack WJ, Henderson VW, et al; ELITE Research Group. Vascular effects of early versus late postmenopausal treatment with estradiol. N Engl J Med. 2016;374(13):1221–1231.
11. Marjoribanks J, Farquhar C, Roberts H, Lethaby A, Lee J. Long-term hormone therapy for perimenopausal and postmenopausal women. Cochrane Database Syst Rev. 2017;1:CD004143.
12. Boardman HM, Hartley L, Eisinga A, et al. Hormone therapy for preventing cardiovascular disease in post-menopausal women. Cochrane Database Syst Rev. 2015;(3):CD002229.
13. Chai X, Domchek S, Kauff N, Rebbeck T, Chen J. RE: Breast cancer risk after salpingo-oophorectomy in healthy BRCA1/2 mutation carriers: revisiting the evidence for risk reduction. J Natl Cancer Inst. 2015;107(9).
14. Parish S, Nappi RE, Krychman ML, et al. Impact of vulvovaginal health on postmenopausal women: a review of surveys on symptoms of vulvovaginal atrophy. Int J Womens Health. 2013;5:437–447.
15. Manson JE, Goldstein SR, Kagan R, et al; Working Group on Women's Health and Well-Being in Menopause. Why the product labeling for low-dose vaginal estrogen should be changed. Menopause. 2014;21(9):911–916.
16. Kaunitz AM, Manson JE. Management of menopausal symptoms. Obstet Gynecol. 2015;126(4):859-876.

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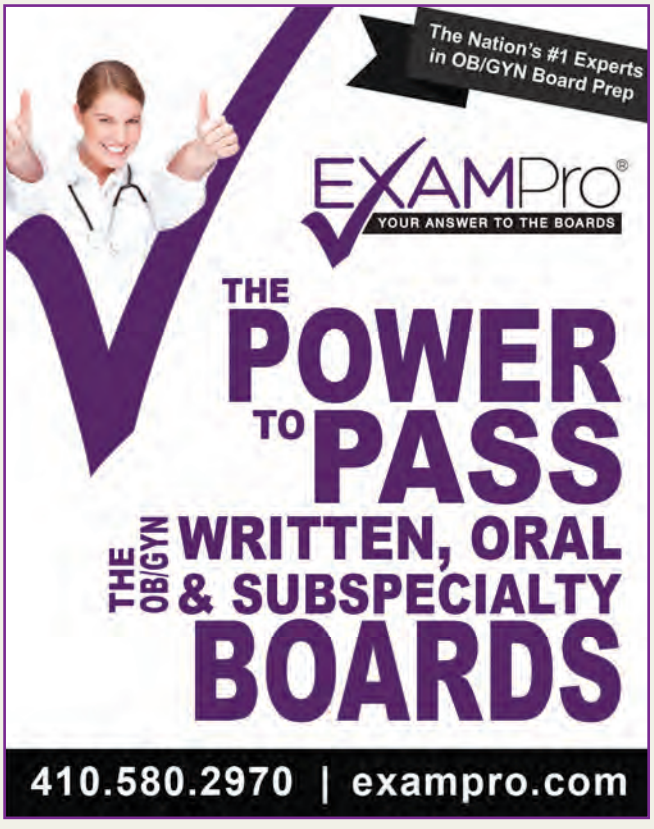

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PARAGARD C3, C4

BRIEF SUMMARY OF PRESCRIBING INFORMATION FOR
ParaGard® T 380A Intrauterine Copper Contraceptive

SEE PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION

INDICATIONS AND USAGE

ParaGard® is indicated for intrauterine contraception for up to 10 years. The pregnancy rate in clinical studies has been less than 1 pregnancy per 100 women each year.

CONTRAINDICATIONS

ParaGard® should not be placed when one or more of the following conditions exist:

1. Pregnancy or suspicion of pregnancy
2. Abnormalities of the uterus resulting in distortion of the uterine cavity
3. Acute pelvic inflammatory disease, or current behavior suggesting a high risk for pelvic inflammatory disease
4. Postpartum endometritis or postabortal endometritis in the past 3 months
5. Known or suspected uterine or cervical malignancy
6. Genital bleeding of unknown etiology
7. Mucopurulent cervicitis
8. Wilson's disease
9. Allergy to any component of ParaGard®
10. A previously placed IUD that has not been removed

WARNINGS

1. Intrauterine Pregnancy

If intrauterine pregnancy occurs with ParaGard® in place and the string is visible, ParaGard® should be removed because of the risk of spontaneous abortion, premature delivery, sepsis, septic shock, and, rarely, death. Removal may be followed by pregnancy loss.

If the string is not visible, and the woman decides to continue her pregnancy, check if the ParaGard® is in her uterus (for example, by ultrasound). If ParaGard® is in her uterus, warn her that there is an increased risk of spontaneous abortion and sepsis, septic shock, and rarely, death. In addition, the risk of premature labor and delivery is increased.

Human data about risk of birth defects from copper exposure are limited. However, studies have not detected a pattern of abnormalities, and published reports do not suggest a risk that is higher than the baseline risk for birth defects.

2. Ectopic Pregnancy

Women who become pregnant while using ParaGard® should be evaluated for ectopic pregnancy. A pregnancy that occurs with ParaGard® in place is more likely to be ectopic than a pregnancy in the general population. However, because ParaGard® prevents most pregnancies, women who use ParaGard® have a lower risk of an ectopic pregnancy than sexually active women who do not use any contraception.

3. Pelvic Infection

Although pelvic inflammatory disease (PID) in women using IUDs is uncommon, IUDs may be associated with an increased relative risk of PID compared to other forms of contraception and to no contraception. The highest incidence of PID occurs within 20 days following insertion. Therefore, the visit following the first post-insertion menstrual period is an opportunity to assess the patient for infection, as well as to check that the IUD is in place. Since pelvic infection is most frequently associated with sexually transmitted organisms, IUDs are not recommended for women at high risk for sexual infection. Prophylactic antibiotics at the time of insertion do not appear to lower the incidence of PID.

PID can have serious consequences, such as tubal damage (leading to ectopic pregnancy or infertility), hysterectomy, sepsis, and, rarely, death. It is therefore important to promptly assess and treat any woman who develops signs or symptoms of PID. Guidelines for treatment of PID are available from the Centers for Disease Control and Prevention (CDC), Atlanta, Georgia at www.cdc.gov or 1-800-311-3435. Antibiotics are the mainstay of therapy. Most healthcare professionals also remove the IUD.

The significance of actinomyces-like organisms on Papanicolaou smear in an asymptomatic IUD user is unknown, and so this finding alone does not always require IUD removal and treatment. However, because pelvic actinomycosis is a serious infection, a woman who has *symptoms* of pelvic infection possibly due to actinomyces should be treated and have her IUD removed.

4. Immunocompromise

Women with AIDS should not have IUDs inserted unless they are clinically stable on antiretroviral therapy. Limited data suggest that asymptomatic women infected with human immunodeficiency virus may use intrauterine devices. Little is known about the use of IUDs in women who have illnesses causing serious immunocompromise. Therefore these women should be carefully monitored for infection if they choose to use an IUD. The risk of pregnancy should be weighed against the theoretical risk of infection.

5. Embedment

Partial penetration or embedment of ParaGard® in the myometrium can make removal difficult. In some cases, surgical removal may be necessary.

6. Perforation

Partial or total perforation of the uterine wall or cervix may occur rarely during placement, although it may not be detected until later. Spontaneous migration has also been reported. If perforation does occur, remove ParaGard® promptly, since the copper can lead to intraperitoneal adhesions. Intestinal penetration, intestinal obstruction, and/or damage to adjacent organs may result if an IUD is left in the peritoneal cavity. Pre-operative imaging followed by laparoscopy or laparotomy is often required to remove an IUD from the peritoneal cavity.

7. Expulsion

Expulsion can occur, usually during the menses and usually in the first few months after insertion. There is an increased risk of expulsion in the nulliparous patient. If unnoticed, an unintended pregnancy could occur.

8. Wilson's Disease

Theoretically, ParaGard® can exacerbate Wilson's disease, a rare genetic disease affecting copper excretion.

PRECAUTIONS

Patients should be counseled that this product does not protect against HIV infection (AIDS) and other sexually transmitted diseases.

1. Information for patients

Before inserting ParaGard® discuss the Patient Package Insert with the patient, and give her time to read the information. Discuss any questions she may have concerning ParaGard® as well as other methods of contraception. Instruct her to promptly report symptoms of infection, pregnancy, or missing strings.

2. Insertion precautions, continuing care, and removal.

3. Vaginal bleeding

In the 2 largest clinical trials with ParaGard®, menstrual changes were the most common medical reason for discontinuation of ParaGard®. Discontinuation rates for pain and bleeding combined are highest in the first year of use and diminish thereafter. The percentage of women who discontinued ParaGard® because of bleeding problems or pain during these studies ranged from 11.9% in the first year to 2.2 % in year 9. Women complaining of heavy vaginal bleeding should be evaluated and treated, and may need to discontinue ParaGard®.

4. Vasovagal reactions, including fainting

Some women have vasovagal reactions immediately after insertion. Hence, patients should remain supine until feeling well and should be cautious when getting up.

5. Expulsion following placement after a birth or abortion

ParaGard® has been placed immediately after delivery, although risk of expulsion may be higher than when ParaGard® is placed at times unrelated to delivery. However, unless done immediately postpartum, insertion should be delayed to the second postpartum month because insertion during the first postpartum month (except for immediately after delivery) has been associated with increased risk of perforation.

ParaGard® can be placed immediately after abortion, although immediate placement has a slightly higher risk of expulsion than placement at other times. Placement after second trimester abortion is associated with a higher risk of expulsion than placement after the first trimester abortion.

6. Magnetic resonance imaging (MRI)

Limited data suggest that MRI at the level of 1.5 Tesla is acceptable in women using ParaGard®. One study examined the effect of MRI on the CU-7® Intrauterine Copper Contraceptive and Lippes Loop™ intrauterine devices. Neither device moved under the influence of the magnetic field or heated during the spin-echo sequences usually employed for pelvic imaging. An in vitro study did not detect movement or temperature change when ParaGard® was subjected to MRI.

7. Medical diathermy

Theoretically, medical (non-surgical) diathermy (short-wave and microwave heat therapy) in a patient with a metal-containing IUD may cause heat injury to the surrounding tissue. However, a small study of eight women did not detect a significant elevation of intrauterine temperature when diathermy was performed in the presence of a copper IUD.

8. Pregnancy

ParaGard® is contraindicated during pregnancy.

9. Nursing mothers

Nursing mothers may use ParaGard®. No difference has been detected in concentration of copper in human milk before and after insertion of copper IUDs. The literature is conflicting, but limited data suggest that there may be an increased risk of perforation and expulsion if a woman is lactating.

10. Pediatric use

ParaGard® is not indicated before menarche. Safety and efficacy have been established in women over 16 years old.

ADVERSE REACTIONS

The most serious adverse events associated with intrauterine contraception are discussed in **WARNINGS** and **PRECAUTIONS**. These include:

Intrauterine pregnancy	Pelvic infection
Septic abortion	Perforation
Ectopic pregnancy	Embedment

The following adverse events have also been observed. These are listed alphabetically and not by order of frequency or severity.

Anemia	Menstrual flow, prolonged
Backache	Menstrual spotting
Dysmenorrhea	Pain and cramping
Dyspareunia	Urticarial allergic skin reaction
Expulsion, complete or partial	Vaginitis
Leukorrhea	

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This brief summary is based on the ParaGard full prescribing information dated September 2014.

PAR-41071 10/16

Does she KNOW WHAT SHE WANTS from her birth control?

Consider PARAGARD® (intrauterine copper contraceptive)— **the only highly effective, reversible birth control that is** *hormone free*[1,2]

- **100% hormone free**[1,2]
- **Patient satisfaction with bleeding and cramping**[3*]
- **Removable whenever she decides—for up to 10 years**[1†]
- **>99% effective**[1]

High patient satisfaction

~94% of women reported that they were satisfied with PARAGARD when considering their bleeding and cramping at 3 and 6 months postplacement[3*]

INDICATION

PARAGARD is indicated for intrauterine contraception for up to 10 years.

IMPORTANT SAFETY INFORMATION

- **PARAGARD does not protect against HIV/AIDS or other sexually transmitted infections (STI).**
- PARAGARD must not be used by women who are pregnant or may be pregnant as this can be life threatening and may result in loss of pregnancy or fertility.
- PARAGARD must not be used by women who have acute pelvic inflammatory disease (PID) or current behavior suggesting a high risk of PID; have had a postpregnancy or postabortion uterine infection in the past 3 months; have cancer of the uterus or cervix; have an infection of the cervix; have an allergy to any component; or have Wilson's disease.
- The most common side effects of PARAGARD are heavier and longer periods and spotting between periods; for most women, these typically subside after 2 to 3 months.
- If a woman misses her period, she must be promptly evaluated for pregnancy.
- Some possible serious complications that have been associated with intrauterine contraceptives, including PARAGARD, are PID, embedment, perforation of the uterus, and expulsion.

Please see the following page for a brief summary of full Prescribing Information.

*Data are from the Contraceptive CHOICE Project. The study evaluated 3- and 6-month self-reported bleeding and cramping patterns in 5011 long-acting reversible contraceptive (LARC) users (n=826, PARAGARD), and the association of these symptoms with method satisfaction. Study participants rated satisfaction with their LARC method as "very satisfied," "somewhat satisfied," or "not satisfied." For the data analyses, "satisfied" and "very satisfied" were grouped together as "satisfied."[3]

†PARAGARD must be removed by a healthcare professional.[1]

References: 1. PARAGARD® T 380A [Prescribing Information]. North Wales, PA: Teva Women's Health, Inc.; September 2014. **2.** Kaneshiro B, Aeby T. Long-term safety, efficacy, and patient acceptability of the intrauterine Copper T-380A contraceptive device. *Int J Womens Health*. 2010;2:211-220. **3.** Diedrich JT, Desai S, Zhao Q, Secura G, Madden T, Peipert JF. Association of short-term bleeding and cramping patterns with long-acting reversible contraceptive method satisfaction. *Am J Obstet Gynecol*. 2015;212(1):50.e1-50.e8.

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