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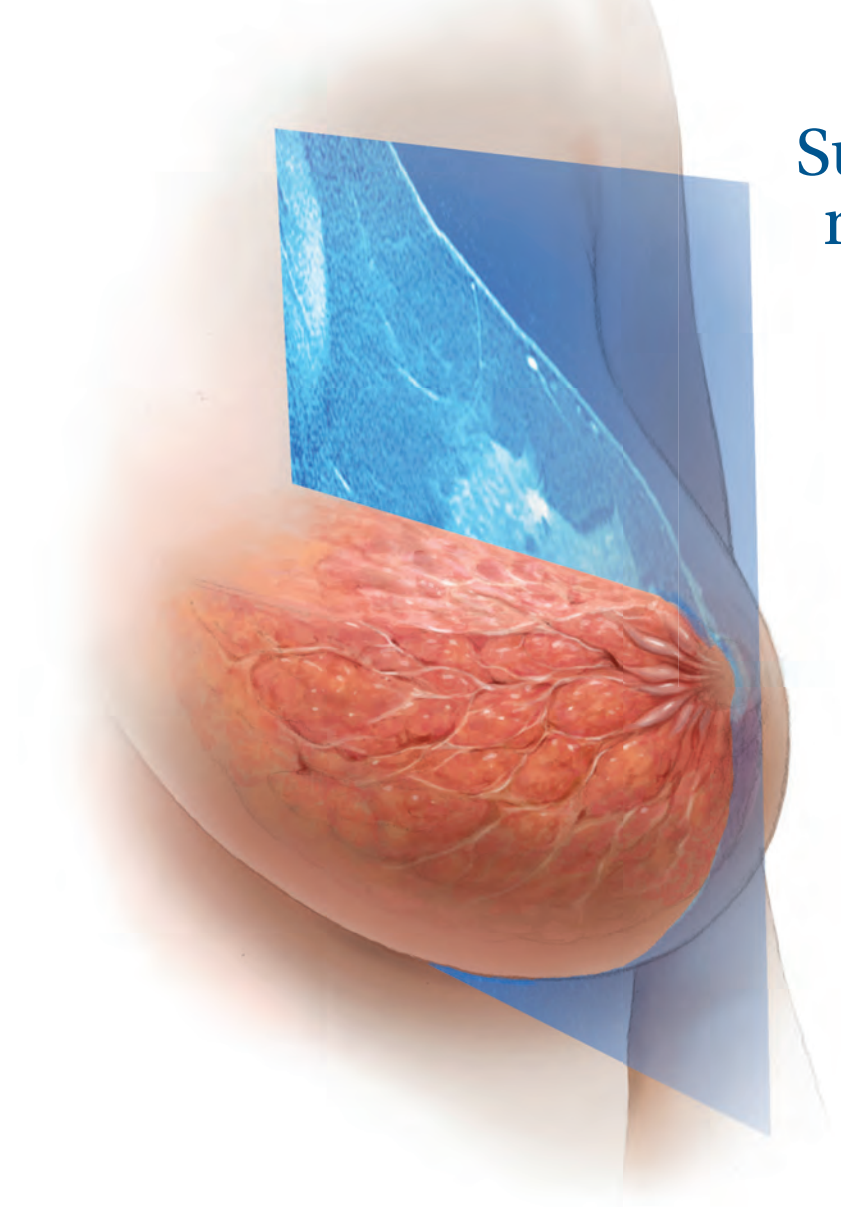
OBG MANAGEMENT

Best options for managing pain in breastfeeding women
Robert L. Barbieri, MD

Top-rated medical translator apps
Kathryn T. Chen, MD, MPH

Where should a baby sleep after delivery?



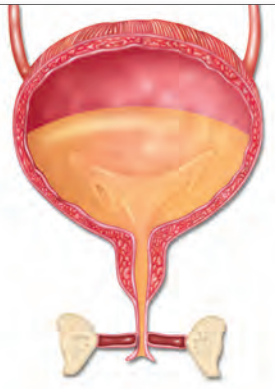
Supplemental imaging recommendations for DENSE BREASTS

Wendie A. Berg, MD, PhD

Tips for a patient-centric office
Joseph S. Sanfilippo, MD, MBA

Woman dies following cervical cone biopsy, $4.25M award

Treating idiopathic overactive bladder
p. 18



In an international multicenter survey of patients treated in tertiary care centers, it was reported that

7 out of 10 endometriosis patients experience **unresolved pain despite management**[1]

Could your endometriosis patients be suffering in silence?
Discover resources at HerEndometriosisReality.com that can help your patients open up about the true impact of their endometriosis pain.

Reference:

1. De Graaff AA, D'Hooghe TM, Dunselman GAJ, Dirksen CD, Hummelshoj L; WERF EndoCost Consortium, Simoens S. The significant effect of endometriosis on physical, mental and social wellbeing: results from an international cross-sectional survey. *Hum Reprod*. 2013;28(10):2677-2685.

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abbvie

#1 IN READERSHIP!*

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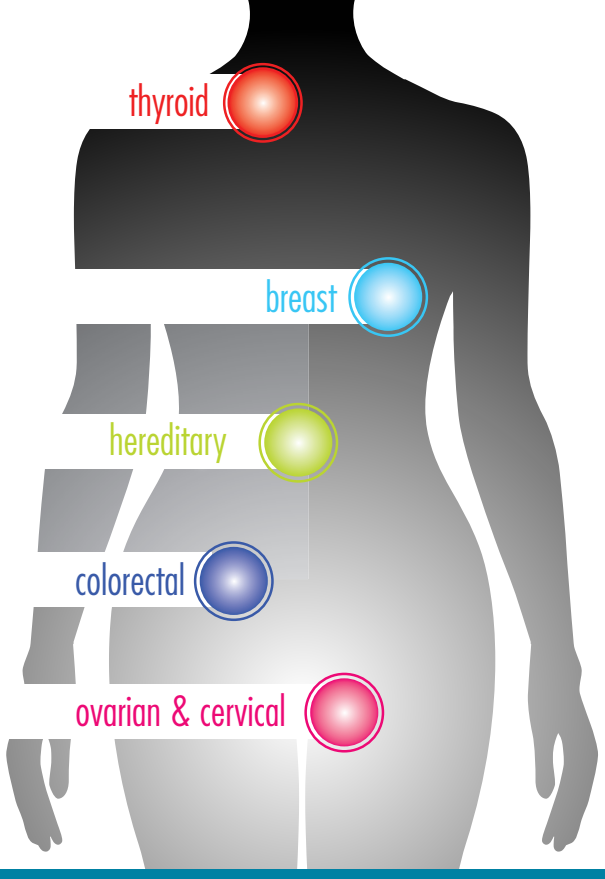
Enhancing the quality of women's health care and the professional development of ObGyns and all women's health care clinicians

*Source: Kantar Media, Medical Surgical Study June 2017, Obstetrics/Gynecology Combined Office & Hospital Readers.



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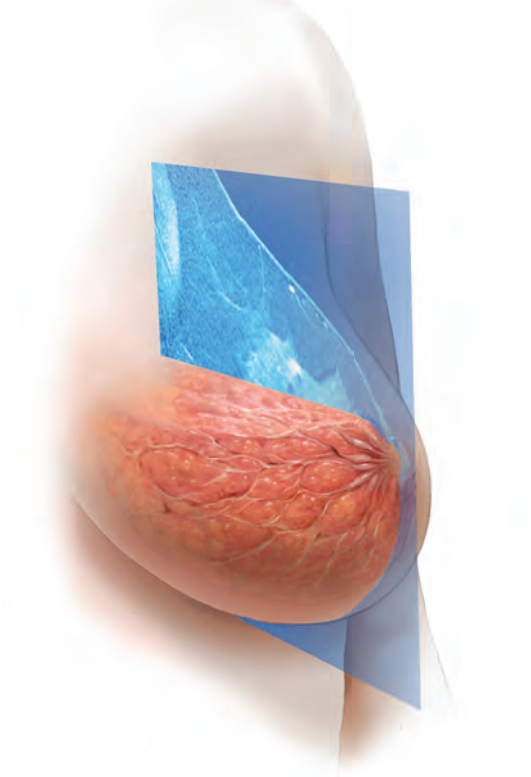
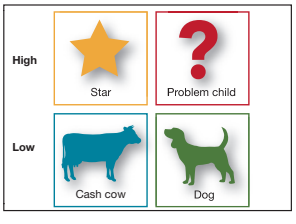


See what's ON THE WEB! page 6

Where should a baby sleep? **16**



Evaluate your business **46**

FAST TRACK is a system to enable you as a reader to move quickly through each issue of **OBG MANAGEMENT**, identifying articles or sections of articles to read in depth.

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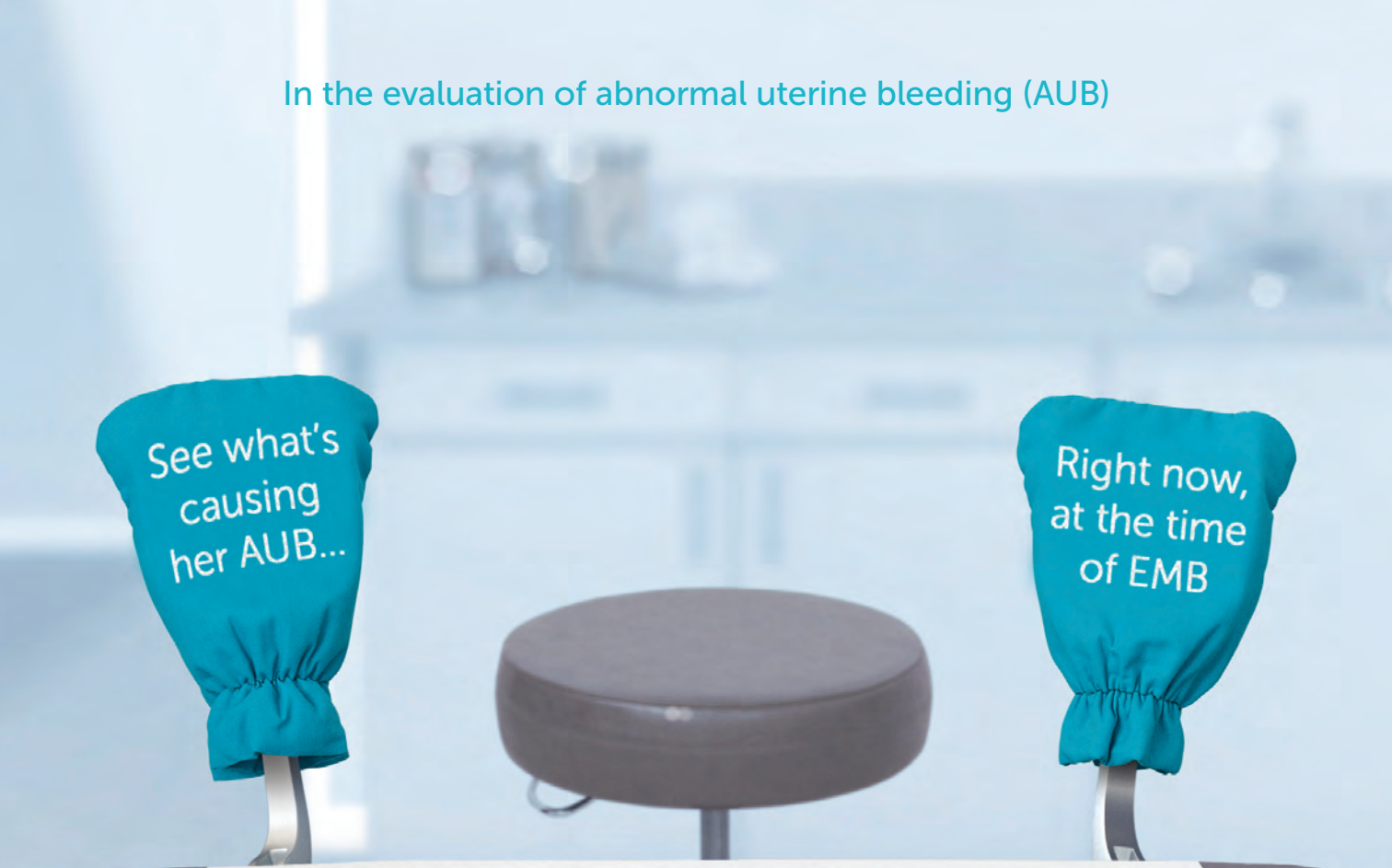
COVER IMAGE: KIMBERLY MARTENS

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.

ON THE WEB
at obgmanagement.com

FROM ENDOMETRIOSIS JOURNAL

Costs and Coping

See more on page 52

WEB EXCLUSIVES

Common questions about newborn circumcision

HENRY M. LERNER, MD

GYN Image Quiz: The many faces of dermoid

DEVARAJU KANMANIRAJA, MD, AND ANDREW M. KAUNITZ, MD

Surviving ovarian cancer: Is there an association between hospital volume and quality of care?

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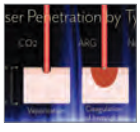
VIDEO LIBRARY



Advances in ablative and non-ablative lasers in gynecology: A clinician's guide

LINDA BURKETT, MD; CHERYL IGLESIA, MD; BRENT VELASCO; VI DUONG, MD

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See QR code on page 13

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Not actual size.

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Prasterone is a precursor that is locally converted to estrogens and androgens with minimal systemic exposure.[1,2] *The mechanism of action of INTRAROSA is not fully established[1]

ONCE-DAILY TREATMENT

Individually wrapped vaginal inserts with disposable applicators[1]

NO FDA BOXED WARNING[2]

No restrictions on duration of use[2,3]

To order samples and learn more about INTRAROSA, including our patient savings program, visit IntrarosaHCP.com

Indication

INTRAROSA is a steroid indicated for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause.

Important Safety Information

INTRAROSA is contraindicated in women with undiagnosed abnormal genital bleeding. Estrogen is a metabolite of prasterone. Use of exogenous estrogen is contraindicated in women with a known or suspected history of breast cancer. INTRAROSA has not been studied in women with a history of breast cancer.

In four 12-week randomized, placebo-controlled clinical trials, the most common adverse reaction with an incidence ≥2 percent was vaginal discharge. In one 52-week open-label clinical trial, the most common adverse reactions with an incidence ≥2 percent were vaginal discharge and abnormal Pap smear.

Brief Summary: Consult full Prescribing Information for complete product information.

CONTRAINDICATIONS

Undiagnosed abnormal genital bleeding: Any postmenopausal woman with undiagnosed, persistent or recurring genital bleeding should be evaluated to determine the cause of the bleeding before consideration of treatment with INTRAROSA.

WARNINGS AND PRECAUTIONS Current or Past History of Breast Cancer

Estrogen is a metabolite of prasterone. Use of exogenous estrogen is contraindicated in women with a known or suspected history of breast cancer. INTRAROSA has not been studied in women with a history of breast cancer.

ADVERSE REACTIONS Clinical Trials Experience

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

In four (4) placebo-controlled, 12-week clinical trials [91% - White Caucasian non-Hispanic women, 7% - Black or African American women, and 2% - "Other" women, average age 58.8 years of age (range 40 to 80 years of age)], vaginal discharge is the most frequently reported treatment-emergent adverse reaction in the INTRAROSA treatment group with an incidence of ≥2 percent and greater than reported in the placebo treatment group. There were 38 cases in 665 participating postmenopausal women (5.71 percent) in the INTRAROSA treatment group compared to 17 cases in 464 participating postmenopausal women (3.66 percent) in the placebo treatment group.

In a 52-week non-comparative clinical trial [92% - White Caucasian non-Hispanic women, 6% - Black or African American women, and 2% - "Other" women, average age 57.9 years of age (range 43 to 75 years of age)], vaginal discharge and abnormal Pap smear at 52 weeks were the most frequently reported treatment-emergent adverse reactions in women receiving INTRAROSA with an incidence of ≥2 percent. There were 74 cases of vaginal discharge (14.2 percent) and 11 cases of abnormal Pap smear (2.1 percent) in 521 participating postmenopausal women. The eleven (11) cases of abnormal Pap smear at 52 weeks include one (1) case of low-grade squamous intraepithelial lesion (LSIL), and ten (10) cases of atypical squamous cells of undetermined significance (ASCUS).

References: 1. Intrarosa [package insert]. Waltham, MA: AMAG Pharmaceuticals, Inc.; 2017. **2.** Archer DF, Labrie F, Bouchard C, et al; VVA Prasterone Group. *Menopause*. 2015;22(9):950-963. **3.** Labrie F, Archer DF, Koltun W, et al; VVA Prasterone Research Group. *Menopause*. 2016;23(3):243-256.

Intrarosa™ Prasterone VAGINAL INSERTS

amag PHARMACEUTICALS

Stop using codeine, oxycodone, hydrocodone, tramadol, and aspirin in women who are breastfeeding

Use acetaminophen and/or ibuprofen for pain management in women who are breastfeeding. If narcotic treatment is necessary consider using the lowest effective dose of morphine for the shortest time possible.

Robert L. Barbieri, MD
Editor in Chief, OBG Management
Chair, Obstetrics and Gynecology
Brigham and Women's Hospital, Boston, Massachusetts
Kate Macy Ladd Professor of Obstetrics, Gynecology and Reproductive Biology
Harvard Medical School, Boston

In 2015 more than 30,000 deaths from opioid overdose were reported (**FIGURE**, page 10).[1] More than 50% of the deaths were due to prescription opioids. The opioid crisis is a public health emergency and clinicians are diligently working to reduce both the number of opioid prescriptions and the doses prescribed per prescription.

In obstetrics, there is growing concern that narcotics used for the treatment of pain in women who are breastfeeding may increase the risk of adverse effects in newborns, including excessive sedation and respiratory depression. The American Academy of Pediatrics (AAP), the US Food and Drug Administration (FDA) and the American College of Obstetricians and Gynecologists (ACOG) recommend against the use of codeine and tramadol in women who are breastfeeding because their newborns may have adverse reactions, including excessive sleepiness, difficulty breathing, and potentially fatal breathing problems.[2–4] In addition, there is growing concern that the use of oxycodone and hydrocodone should also be limited in women who are breastfeeding. In this article, I discuss the rationale for these recommendations.

Instant Poll

Will you prioritize acetaminophen and/or ibuprofen for pain management in women who are breastfeeding?

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

Codeine

Codeine is metabolized to morphine by CYP2D6 and CYP2D7. Both codeine and morphine are excreted into breast milk. Some women are ultrarapid metabolizers of codeine because of high levels of CYP2D6, resulting in higher concentrations of morphine in their breast milk and their breast fed newborn.[2,5] In many women who are ultrarapid metabolizers of codeine, CYP2D6 gene duplication or multiplication is the cause of the increased enzyme activity.[6] Genotyping can identify some women who are ultrarapid metabolizers, but it is not currently utilized widely in clinical practice.

In the United States approximately 5% of women express high levels of CYP2D6 and are ultrarapid metabolizers of codeine.[4] In Ethiopia as many as 29% of women are ultrarapid metabolizers.[7] Newborn central nervous system (CNS) depression is the most common adverse effect of fetal ingestion of excessive codeine and morphine from breast milk and may present as sedation, apnea, bradycardia, or cyanosis.[8] Multiple newborn fatalities have been reported in the literature when lactating mothers who were

CONTINUED ON PAGE 9

2017

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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

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 B. Gebhart, MD, MS
Mayo Clinic

Rosanne M. Kho, MD
Cleveland Clinic

Javier F. Magrina, MD
Mayo Clinic Phoenix

Mark D. Walters, MD
Cleveland Clinic

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: Rosanne M. Kho, MD

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

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

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

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

THURSDAY, DECEMBER 14, 2017

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

7:10 AM **Breakfast Symposium**

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

Pelvic Anatomy

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

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

Incontinence and Prolapse Surgery

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

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

10:25 AM **Break/Exhibits**

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

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

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

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

1:10 PM **Luncheon Symposium**

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

Thursday's Keynote Lecture

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

Fibroid Management & Principles of Electrosurgery

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

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

4:25 PM **Break/Exhibits**

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

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

FRIDAY, DECEMBER 15, 2017

7:00 AM **Breakfast/Exhibits**

7:10 AM **Breakfast Symposium**

Hysterectomy - Technique

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

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

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

10:00 AM **Break /Exhibits**

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

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

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

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

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

1:00 PM **Luncheon Symposium**

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

Friday's Keynote Lecture

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

Oncology For The Generalist

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

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

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

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

SATURDAY, DECEMBER 16, 2017

6:30 AM **Breakfast**

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

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

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

P.E.P. PRACTICE ENHANCEMENT PROGRAM AGENDA

(Optional. Separate fee required)

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

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

SATURDAY, DECEMBER 16, 2017

2:00 PM **Course Overview**

2:10 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 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
- Define quality (outcomes\costs)
- Provide the 7 steps to measure cost-of-care

3:30 PM **Break**

3:45 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 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 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 PM **Q and A**

5:15 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

5:30 PM **Adjourn**

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
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Director, Gynecologic Oncology
Department of Gynecologic Surgery
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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
8:30 AM - 12:30 PM
Director: Rosanne M. Kho, MD
Faculty: Andrew I. Brill, MD; Tommaso Falcone, MD; Keith B. Isaacson, MD

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

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

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

ACCREDITATION

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CONTINUED FROM PAGE 8

ultrarapid metabolizers took codeine. **The FDA and ACOG recommend against the use of codeine in lactating women.**

Hydrocodone

Hydrocodone, a hydrogenated ketone derivative of codeine, is metabolized by CYP2D6 to hydromorphone. Both hydrocodone and hydromorphone are present in breast milk. In lactating mothers taking hydrocodone, up to 9% of the dose may be ingested by the breastfeeding newborn.[9] There is concern that hydrocodone use by women who are breastfeeding and are ultrarapid metabolizers may cause increased fetal consumption of hydromorphone resulting in adverse outcomes in the newborn. The AAP cautions against the use of hydrocodone.[2]

Oxycodone

Oxycodone is metabolized by CYP2D6 to oxymorphone and is concentrated into breast milk.[10] Oxymorphone is more than 10 times more potent than oxycodone. In one study of lactating women taking oxycodone, codeine, or acetaminophen, the rates of neonate CNS depression were 20%, 17%, and 0.5%, respectively.[11] The authors concluded that for mothers who are breastfeeding oxycodone was no safer than codeine because both medications were associated with a high rate of depression in the neonate. Newborns who develop CNS depression from exposure to oxycodone in breast milk will respond to naloxone treatment.[12] The AAP recommends against prescribing oxycodone for women who are breastfeeding their infants.[2]

In a recent communication, the Society for Obstetric Anesthesia and Perinatology (SOAP) observed that in the United States, following cesarean delivery the majority of women receive oxycodone or hydrocodone.[13] SOAP disagreed with the AAP recommendation against the use of oxycodone or hydrocodone in breastfeeding women. SOAP noted that all narcotics can produce adverse effects in newborns of breastfeeding women and that there are no good data that the prescription of oxycodone or hydrocodone is more risky than morphine or hydromorphone. However, based on their assessment of risk and benefit, pediatricians prioritize the use of acetaminophen and morphine and seldom use oxycodone or hydrocodone to treat moderate to severe pain in babies and children.

Tramadol

Tramadol is metabolized by CYP2D6 to O-desmethyltramadol. Both tramadol and O-desmethyltramadol are excreted into breast milk. In ultrarapid metabolizers, a greater concentration of O-desmethyltramadol is excreted into breast milk. The FDA reported that they identified no serious neonatal adverse events in the literature due to the use of tramadol by women who are breastfeeding. However, given that tramadol and its CYP2D6 metabolite enter breast milk and the potential for life-threatening respiratory depression in the infant, the FDA included tramadol in its warning about codeine.[3]

Codeine, hydrocodone, oxycodone, and tramadol are all metabolized to more potent metabolites by the CYP2D6 enzyme. Individuals with low CYP2D6 activity, representing about 5% of the US population, cannot fully activate these narcotics. Hence they may not get adequate pain relief when treated with codeine, oxycodone, hydrocodone, or tramadol. Given their resistance to these medications they may first be placed on a higher dose of the narcotic and then switched from a high ineffective dose of one of the agents activated by CYP2D6 to a high dose of morphine or hydromorphone. This can be dangerous because they may then receive an excessive dose of narcotic and develop respiratory depression.[14]

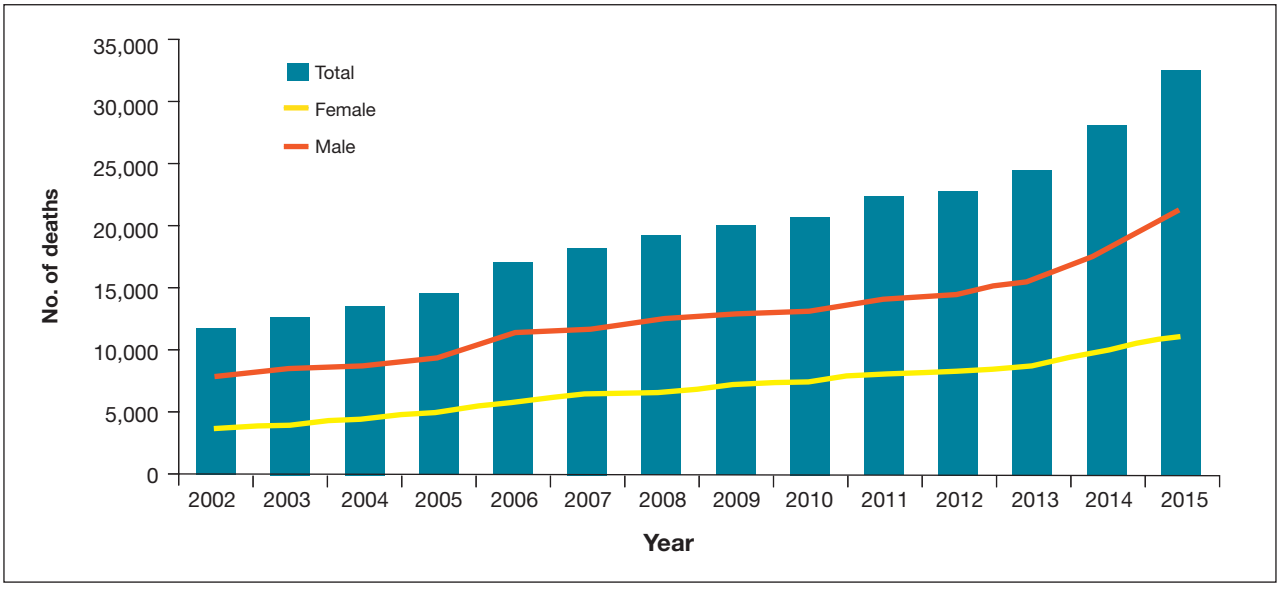
Aspirin

There are very little high quality data about the use of aspirin in women breastfeeding and the effect on the neonate. If a mother takes aspirin, the drug will enter breast milk. It is estimated that the nursing baby receives about 4% to 8% of the mother's dose. The World Health Organization recommends that aspirin is compatible with breastfeeding in occasional small doses, but repeated administration of aspirin in normal doses should be avoided in women who are breastfeeding. If chronic or high-dose aspirin therapy is recommended, the infant should be monitored for side effects including metabolic acidosis[15] and coagulation disorders.[16] The National Reye's Syndrome Foundation recommends against the use of aspirin in women who are breastfeeding because of the theoretical risk of triggering Reye syndrome.[17] Acetaminophen and ibuprofen are recommended by the WHO for chronic treatment of pain during breastfeeding.[16]

Acetaminophen and ibuprofen

For the medication treatment of pain in women who are breastfeeding, the WHO recommends the use of acetaminophen and ibuprofen.[16] Acetaminophen is transferred from the maternal circulation into breast milk, but it is estimated that the dose to the nursing neonate is <0.3%

FIGURE Number of opioid deaths in the United States[1]



of the maternal dose.[18] In mothers taking ibuprofen 1600 mg daily, the concentration of ibuprofen in breast milk was below the level of laboratory detection (<1 mg/L).[19] Ibuprofen treatment is thought to be safe for women who are breastfeeding because of its short half-life (2 hours), low excretion into milk, and few reported adverse effects in infants.

Morphine

Morphine is not metabolized by CYP2D6 and is excreted into breast milk. Many experts believe that women who are breastfeeding may take standard doses of oral morphine with few adverse effects in the newborn.[20,21] For the treatment of moderate to severe pain in opioid-naive adults, morphine doses in the range of 10 mg orally every 4 hours up to 30 mg orally every 4 hours are prescribed. When using a solution of morphine, standard doses are 10 mg to 20 mg every 4 hours, as needed to treat pain. When using morphine tablets, standard doses are 15 mg to 30 mg every 4 hours. The WHO states that occasional doses of morphine are usually safe for women breastfeeding their newborn.[16] The AAP recommends the use of morphine and hydromorphone when narcotic agents are needed to treat pain in breastfeeding women.[2]

Hydromorphone

Hydromorphone, a hydrogenated ketone derivative of morphine, is not metabolized by CYP2D6 and is excreted into breast milk. There are limited data on the safety of hydromorphone during breastfeeding. Breast milk concentrations of hydromorphone are low, and an occasional dose is likely associated with few adverse effects in the breastfeeding newborn.[22] For the treatment of moderate to severe pain in opioid-naive adults, hydromorphone doses in the range of 2 mg orally every 4 hours up to 4 mg orally every 4 hours are prescribed. Like all narcotics, hydromorphone can result in central nervous system depression. If a mother ingests sufficient quantities of hydromorphone, respiratory depression in the breastfeeding newborn can occur. In one case report, a nursing mother was taking hydromorphone 4 mg every 4 hours for pain following a cesarean delivery. On day 6 following birth, her newborn was lethargic and she brought the infant to an emergency room. In the emergency room the infant became apneic and was successfully treated with naloxone, suggesting a narcotic overdose due to the presence of hydromorphone in breast milk.[23] Hydromorphone should only be used at the lowest effective dose and for the shortest time possible.

The bottom line

Pediatricians seldom prescribe codeine, oxycodone, hydrocodone, or tramadol for the treatment of pain in newborns or children. Pediatricians generally use acetaminophen and morphine for the treatment of pain in newborns. Although data from large, high quality clinical trials are not available, expert opinion recommends that acetaminophen and ibuprofen should be prescribed as first-line medications for the

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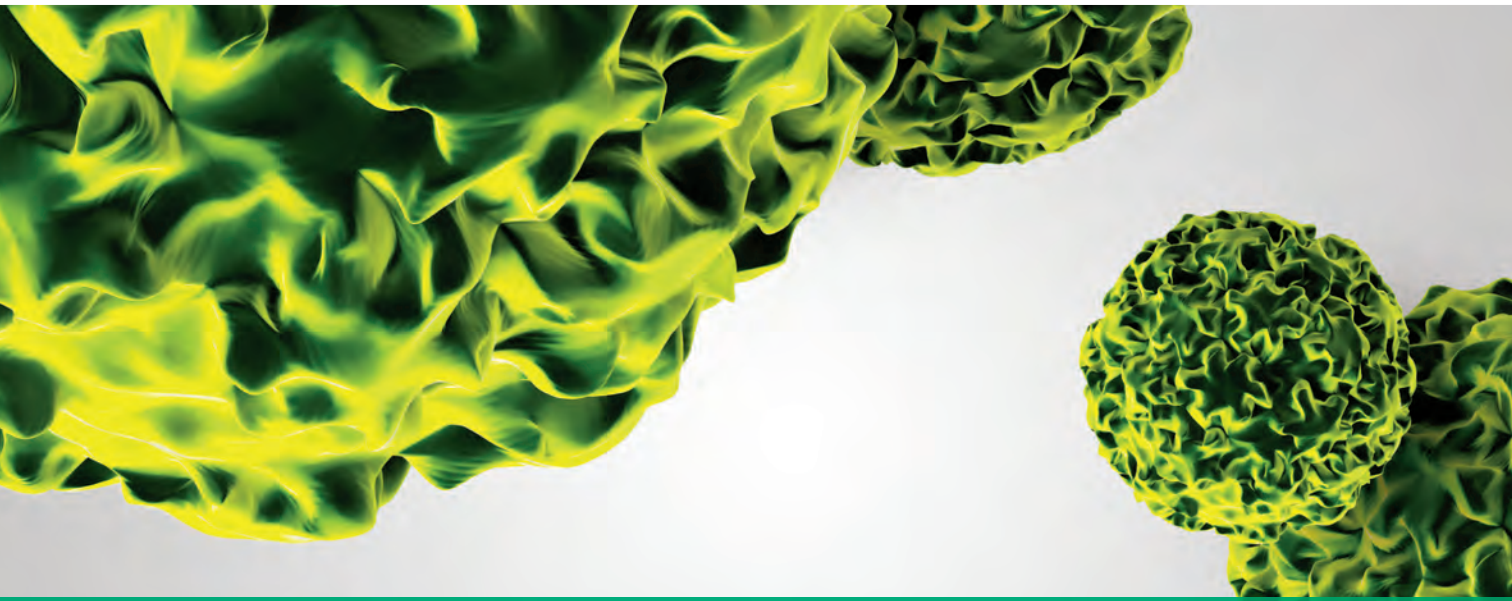
Roche



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[1] Saslow et al. Screening Guidelines for the Prevention and Early Detection of Cervical Cancer. *Am J Clin Pathol* 2012.
[2] **cobas** HPV package insert.

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CONTINUED FROM PAGE 10

treatment of pain in women who are breastfeeding. Use of narcotics that are metabolized by CYP2D6 should be minimized or avoided in women who are breastfeeding. If narcotic medication is necessary, the lowest effective dose of morphine or hydromorphone should be prescribed for the shortest time possible. If morphine is prescribed to women who are breastfeeding, they should be advised to observe their baby for signs of narcotic excess, including drowsiness, poor nursing, slow breathing, or low heart rate.

The goal of reducing morbidity and mortality from opioid use is a top public health priority. Obstetrician-gynecologists can contribute through the optimal use of opioid analgesics. Reducing the number of opioid prescriptions and the quantity of medication prescribed per prescription is an important first step in our effort to reduce opioid-related deaths.

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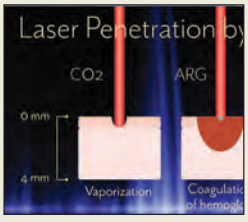
Advances in ablative and non-ablative lasers in gynecology: A clinician's guide

LINDA BURKETT, MD; CHERYL IGLESIA, MD; BRENT VELASCO; VI DUONG, MD



In a recent expansion of laser technology, dozens of manufacturers have started marketing fractional ablative and non-ablative technology for gynecologic office-based procedures. This technology has been used to treat conditions such as atrophic vaginitis, vaginal laxity, lichen sclerosus, and stress urinary incontinence. In this video, the authors describe the biophysics of fractional ablative and non-ablative lasers, provide a procedural demonstration, list outcomes from available research, and discuss ethical concerns.

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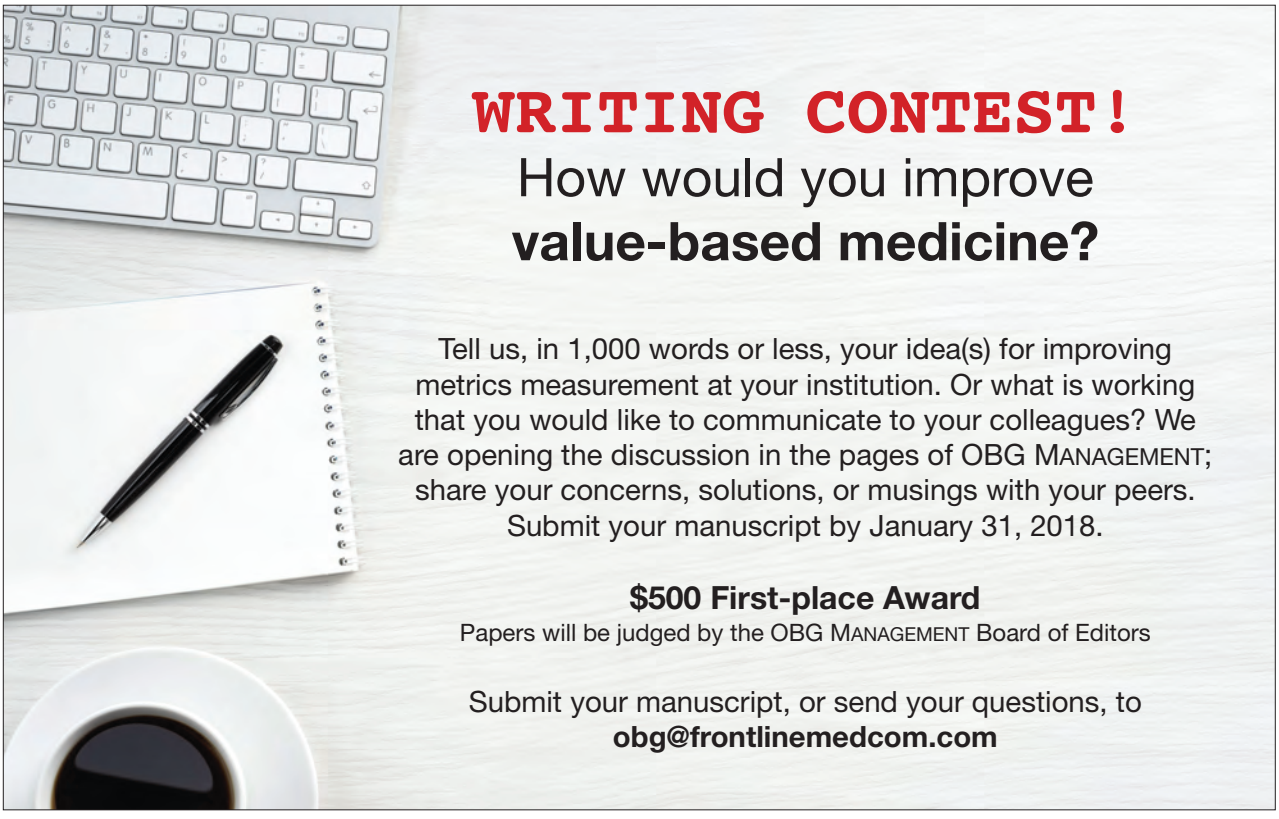

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The benefits of expanded carrier screening: helping your patients make more informed decisions

Following the American Congress of Obstetricians and Gynecologists' (ACOG) recommendation in March 2017 that expanded carrier screening be offered to all women, regardless of ethnicity, many OB/GYNs are revisiting their practice's standard approach to carrier screening for their patients.

To help understand some of the options that are available today, we recently spoke with two leading genetic experts from Quest Diagnostics: Felicitas Lacbawan, MD, Executive Medical Director for Advanced Diagnostics; and Lisa Pike-Buchanan, Genetic Counselor. We asked a number of important questions that highlighted the changing landscape of carrier screening, the solutions currently available, and the role OB/GYNs play in helping their patients take advantage of genetic testing options.

How has expanded genetic screening evolved from traditional carrier screening?

Expanded carrier screening is changing the way we think about genetic diseases. Any patient, regardless of ethnicity, can be a carrier of a severe genetic disorder. Traditionally, we would only screen for likely disorders based on ethnicity, because we realized certain diseases—such as Tay-Sachs disease in the Jewish population, and sickle cell disease in the African-American population—were more present in particular ethnic groups. So, we would test those at-risk populations for a few likely disorders that were of higher prevalence within that ethnicity.

However, carrier screening defined by ethnicity can overlook important insights that you and your patients need. Today, advances in next-generation sequencing (NGS) have led to expanded carrier screening, making it easier to screen for a greater number of disorders—regardless of ethnicity.

"Ethnicity nowadays is not as straightforward as it used to be," said Lisa Pike-Buchanan. "The population is such a mixture of different ethnic groups that sometimes people are unaware of their ancestry. Utilizing pan-ethnic expanded carrier screening panels allows us to test individuals, regardless of their self-identified ancestry, and get a true snapshot of their genetic risk for the diseases we are testing for."

"...particular disorders are less likely to be confined only to a specific high-risk ethnic group because of the increasing frequency of ethnic admixture of reproductive partners."[1]

The American Congress of Obstetricians and Gynecologists

In March, ACOG provided updated guidelines on carrier screening. Who should be screened?

ACOG, the American College of Medical Genetics and Genomics (ACMG), and advocacy groups have highlighted the many advantages of providing expanded carrier screening to all patients, including:

- Overcoming inaccurate knowledge of ancestry in our increasingly multi-ethnic society
- Identifying the genetic conditions that do not occur solely in specific ethnic groups
- Accounting for the diverse genetic makeup of different ethnicities

With advances in NGS, certainly you must be able to test for many genetic disorders. How does an OB/GYN determine which disorders a patient should be screened for?

Expanded carrier screening gives patients valuable information about their pregnancy, or as they begin to discuss family planning with their OB/GYN. But despite the benefits of expanded carrier screening, the volume of results it can yield, and knowing how they apply in a clinical setting, can become overwhelming and therefore of diminishing value. OB/GYNs need guidance from the companies administering these tests so that when they see the genetic information, they know how to interpret it in an actionable way for the patient.

Dr. Lacbawan observed, "We can certainly test for so many conditions—but we have a responsibility to only test for those disorders that are quite severe and debilitating, and that are associated with a clear phenotype so that we have some clear information on how to handle a positive result."

"To minimize the potential for harm, the number of conditions included in the screening panel needs to be considered..."[1]

The American Congress of Obstetricians and Gynecologists

Quest Diagnostics™

Quest Diagnostics recently launched a new test panel, QHerit™ Expanded Carrier Screen. What benefits does it offer for OB/GYNs and their patients?

QHerit Expanded Carrier Screen is a pan-ethnic testing panel for 22 heritable diseases. QHerit is the test that OB/GYNs have been asking for, rolling up testing for some of the most impactful diseases into a single, easy-to-order panel. It's a panel built on national guidelines, recommendations, and testing criteria from groups including ACOG, ACMG, National Society of Genetic Counselors, and other advocacy groups, to include clinically relevant tests and results.

QHerit is ideal for anyone considering starting a family or already pregnant, regardless of ethnic background. QHerit is well-suited to provide highly accurate insights about heritable risk in a wide variety of patients.

Interpreting genetic screening can be challenging for the OB/GYN who may be seeing a positive test result for the first time. How can labs help OB/GYNs have an informed conversation with their patients?

You can take advantage of the latest advances in carrier screening to help you and your patients make more informed decisions. QHerit is fully supported by Quest's genetic experts, including MDs, PhDs and genetic counselors, available to help OB/GYNs with test selection and results interpretation. Pike-Buchanan noted, "Genetic counselors like me are available to help OB/GYNs understand the impact of the results on their patients, so that the OB/GYN can determine approximate next steps for the family."

There are great resources available to help people understand why expanded carrier screening plays a valuable role in their pregnancy. Quest offers several print and online resources to help educate your patients about expanded carrier screening.

How easy is it for patients to get a QHerit test? And for OB/GYNs to order?

QHerit starts with a simple blood collection that can be performed in the doctor's office, or at any one of Quest's 2,200 Patient Service Centers. We are committed to helping families plan for the future by giving patients access to the screening they need. Quest has broad insurance coverage with most major insurance plans, and financial assistance programs for qualified patients.

Ordering QHerit is easy

- Request test code 94372(X)
- For assistance in test selection or result interpretation, contact 1.866.GENE.INFO (1.866.436.3463) 8:30 AM to 8:00 PM EST
- To learn more about QHerit, including testing specifications, please visit **QHerit.com**

Quest Diagnostics is a leader in women's health. They provide a broad continuum of care for fetal aneuploidy testing by offering an extensive menu of first trimester screens as well as comprehensive diagnostic testing. In addition, they provide a wide range of prenatal testing options backed by proven science, from routine to highly specialized, including over 700 genetic tests. QHerit may be ordered by physicians as a component in the spectrum of testing, including pregnancy confirmation testing, general health screening panels, non-invasive prenatal screening, and maternal serum screening that supports healthy pregnancies.

What does QHerit test for?

QHerit tests for 22 diseases, including Spinal Muscular Atrophy, Cystic Fibrosis, Fragile X Syndrome, Tay-Sachs and other disorders that play an important role in patients' healthcare and family planning. QHerit focuses on disorders that:

- Have potentially devastating consequences
- Result in early death
- Create a need for significant early intervention

In line with ACOG guidelines, we chose diseases that are approximately 1% carrier frequency or greater and specifically chose not to include ultra-rare conditions to help mitigate the risk of unnecessarily increasing patient anxiety. QHerit Expanded Carrier Screen provides a clear picture, testing only clinically relevant variants within genes.

Alpha-Thalassemia
Beta-Hemoglobinopathies (Including Sickle-Cell Disease)
Bloom Syndrome
Canavan Disease
Cystic Fibrosis (CF)
Dihydrolipoamide Dehydrogenase Deficiency (DLD Deficiency)
Familial Dysautonomia
Familial Hyperinsulinism
Fanconi Anemia Type C
Fragile X Syndrome
Gaucher Disease
Glycogen Storage Disease Type Ia
Joubert Syndrome 2
Maple Syrup Urine Disease
Mucolipidosis Type IV
Nemaline Myopathy
Niemann-Pick Disease Types A & B
Spinal Muscular Atrophy (SMA)
Tay-Sachs Disease
Usher Syndrome Type 1F
Usher Syndrome Type IIIA
Walker-Warburg Syndrome

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Commentary

›› Laura Baecher-Lind, MD, MPH

Where should a baby sleep after delivery?

In the newborn nursery

Many hospitals across the country have received designation as "Baby Friendly"; many other hospitals are in the process of seeking this designation. In order to be Baby Friendly, a hospital or birth center must prove they have implemented a set of 10 rules to encourage breastfeeding. As Baby Friendly USA puts it in their byline, it has become the gold standard of care.

Importantly, Baby Friendly fails to recognize that there is another equally crucial participant in any childbirth experience—the woman. Although childbirth is natural and usually healthy, it is not easy. Women commonly lose up to 1 L of blood during childbirth.[1] Labor can take 18 to 24 hours for a first-timer and about 12 to 18 hours for an encore performance, often disrupting at least 1 entire night of sleep. The minimally invasive cesarean delivery continues to elude us, and women undergoing cesarean delivery must contend with a sizable incision and the additional pain and associated recovery.

Hospitals adopting the Baby Friendly rules must not allow formula, must prohibit pacifier use, and must go to great lengths to encourage rooming-in. Rooming-in means that the baby shares the same room as the new mother around-the-clock, which is reported to help the new mother distinguish sounds that indicate "feed me" from those that indicate a cool breeze. Rooming-in has been shown to be associated with a modest increase in breastfeeding[2]; however, women who are committed to breastfeeding likely room-in more often than women less committed to breastfeeding. Whether or not forcing the woman who is less committed to breastfeeding or the woman highly committed to breastfeeding who just wants a good night's rest to room-in with her baby has a meaningful impact on breastfeeding remains unknown.

Are we violating ethics rules?

When hospitals adopt the Baby Friendly rules—policies that limit women's choices for themselves and for their baby—we violate medical ethics principles regarding respect for autonomy, beneficence, and truthfulness. For instance, women are told that if they breastfeed their babies will be smarter, healthier, and have stronger emotional bonds. However, when

Dr. Baecher-Lind is Director, Division of General Obstetrics & Gynecology, Tufts Medical Center, and Clerkship Director, Obstetrics & Gynecology Clerkship, Tufts University School of Medicine.

The author reports no financial relationships relevant to this article.

PHOTO: SHUTTERSTOCK

Baby Friendly's 10 steps to successful breastfeeding

1. Have written breastfeeding policy that is routinely communicated to all health care staff.
2. Train all health care staff in skills necessary to implement this policy.
3. Inform all pregnant women about benefits and management of breastfeeding.
4. Help mothers initiate breastfeeding within 1 hour of birth.
5. Show mothers how to breastfeed and how to maintain lactation, even if separated from their infants.
6. Give infants no food or drink other than breast milk, unless medically indicated.
7. Practice rooming in—allow mothers and infants to remain together 24 hours per day.
8. Encourage breastfeeding on demand.
9. Give no pacifiers or artificial nipples to breastfeeding infants.
10. Foster the establishment of breastfeeding support groups and refer mothers to them on discharge.

Reference

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research studies control for factors such as mothers' education level or the amount of time spent talking to the baby, the effect of breastfeeding on intelligence "washes out."[3] Babies who are formula-fed but cuddled experience the same degree of bonding with their mothers as breast-fed babies.[4,5]

Although breast *is* best, the reported benefits that underlie Baby Friendly are overblown and oversold. When we explain to a woman why her newborn cannot spend a few hours in the nursery or why we cannot allow a pacifier, we are denying her the right to parent and make choices for herself and her baby, not acting in the best interest of the woman. We are in fact misrepresenting the truth. We are also acting paternalistic, propagating the long tradition of telling women that we know better about their reproductive health and choices.

Breastfeeding still not fully accepted outside the hospital

The Baby Friendly rules restrict autonomy and prod women to breastfeed for the few days that they remain in the hospital postpartum. However, these women go home to societal and institutional systems that are deeply unsupportive of breastfeeding. In addition to being the birthplace for 98% of babies born in the United States, the health care industry is the single largest employer of US women.[6,7] There are 5 academic hospitals in the Boston area. After contacting the human resources department at each, I found that only 1 has a policy for their breastfeeding employees.

Women should not be forced to choose between breastfeeding and working, between taking a longer maternity leave (often unpaid and professionally detrimental) and shelving the breast pump. What we invest in reveals our values. When we require women to room-in without respecting their choices or needs, and when workplaces fail to provide reasonable flexibility and private space for breast-pumping employees, our values as a society are revealed.

Women and men, hospital users and hospital employees, need to insist that the principles of autonomy, respect for persons, truthfulness, and justice guide breastfeeding policy both within our hospitals and within our workplaces. We need to respect women and the choices that they make for themselves and their families. We need to allow women to decide to recover from their delivery without their baby constantly in arms' reach. We need to ensure that our counseling and our policies are rooted in sound science and not influenced by passionate but biased perspectives.

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PELVIC FLOOR DYSFUNCTION

Treatment of idiopathic overactive bladder often requires third-line therapy, which includes onabotulinumtoxinA, posterior tibial nerve stimulation, and sacral neuromodulation. Until recently, data directly comparing these treatment options were lacking. What do new trials reveal?

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IN THIS ARTICLE

The International Continence Society (ICS) defines overactive bladder (OAB) as a syndrome of "urinary urgency, usually accompanied by frequency and nocturia, with or without urgency urinary incontinence (UUI), in the absence of urinary tract infection [UTI] or obvious pathology."[1] The Agency for Healthcare Research and Quality (AHRQ) reported OAB prevalence to be 15% in US women, with 11% reporting UUI.[2] OAB represents a significant health care burden that impacts nearly every aspect of life, including physical, emotional, and psychological domains.[3,4] The economic impact is notable; the projected cost is estimated to reach $82.6 billion annually by 2020.[5]

The American Urological Association (AUA) and the Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU) have endorsed an algorithm for use in the evaluation of idiopathic OAB (**FIGURE**).[6] If the patient's symptoms are certain, minimal evaluation is needed and it is reasonable to proceed with **first-line therapy**, which includes fluid management (decreasing caffeine intake and limiting evening fluid intake), bladder retraining drills such as timed voiding, and improving pelvic floor muscles with the use of biofeedback and functional electrical stimulation.[6,7] Pelvic floor muscle training can be facilitated with a referral to a physical therapist trained in pelvic floor muscle education.

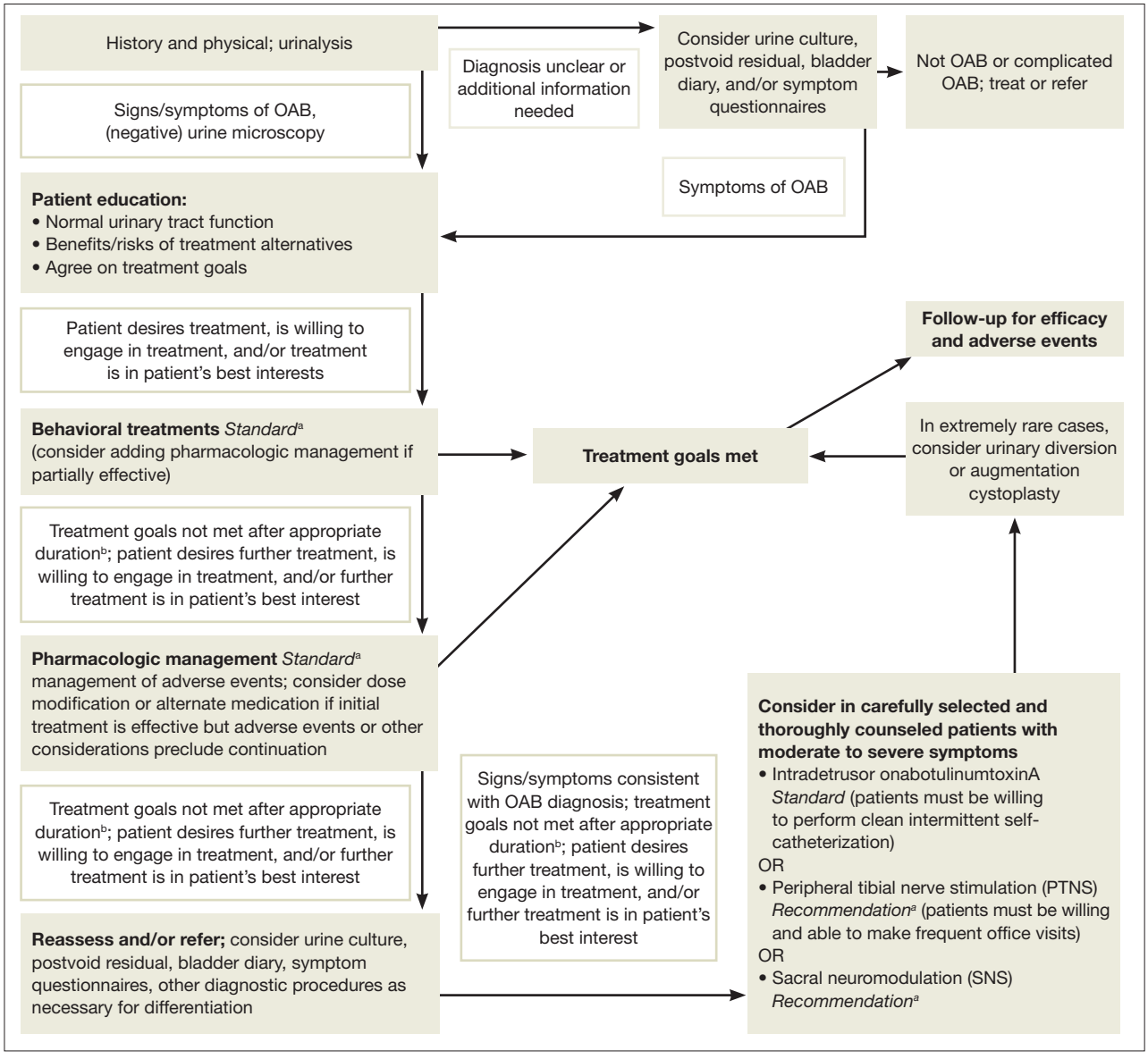
If treatment goals are not met with first-line strategies, **second-line therapy** may be initiated with anticholinergic or β3-adrenergic receptor agonist medications. If symptoms persist after 4 to 8 weeks of pharmacologic therapy, clinicians are encouraged to reassess or refer the patient to a specialist. Further evaluation may include a bladder diary in which the patient documents voided volumes, voiding frequency, and number of incontinent episodes; symptom-specific questionnaires; and/or urodynamic testing.

Based on that evaluation, the patient may be a candidate for **third-line therapy** with either intradetrusor onabotulinumtoxinA, posterior tibial nerve stimulation (PTNS), or sacral neuromodulation.

There is a paucity of information comparing third-line therapies. In this Update, we focus on 4 randomized clinical trials that compare third-line treatment options for idiopathic OAB.

CONTINUED ON PAGE 25

FIGURE Diagnosis and treatment algorithm: AUA/SUFU guideline on nonneurogenic overactive bladder in adults[6]



Abbreviations: AUA, American Urological Association; OAB, overactive bladder; SUFU, Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction.

[a]AUA nomenclature: *Standard*—Directive statement that an action should (benefits outweigh risks/burdens) or should not (risks/burdens outweigh benefits) be taken based on Grade A (high quality; high certainty) or B (moderate quality; moderate certainty) evidence. *Recommendation*—Directive statement that an action should (benefits outweigh risks/burdens) or should not (risks/burdens outweigh benefits) be taken based on Grade C (low quality; low certainty) evidence.

[b]Appropriate duration is 8 to 12 weeks for behavioral therapies and 4 to 8 weeks for pharmacologic therapies.

Are your adult patients with iron deficiency anemia (IDA) getting what they need from oral iron therapy?

Typical oral iron dose*

Ferrous sulfate tablets 325 mg, taken 3x daily for 30 days (dose may vary depending on patient condition)[1,2]

*Not intended to represent all possible oral iron regimens.

Typical oral iron absorption

Even in healthy subjects, less than 10% of oral iron is absorbed[3]

INDICATIONS

Injectafer® (ferric carboxymaltose injection) is an iron replacement product indicated for the treatment of iron deficiency anemia (IDA) in adult patients who have intolerance to oral iron or have had unsatisfactory response to oral iron, and in adult patients with non-dialysis dependent chronic kidney disease.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

Injectafer is contraindicated in patients with hypersensitivity to Injectafer or any of its inactive components.

WARNINGS AND PRECAUTIONS

Serious hypersensitivity reactions, including anaphylactic-type reactions, some of which have been life-threatening and fatal, have been reported in patients receiving Injectafer. Patients may present with shock, clinically significant hypotension, loss of consciousness, and/or collapse. Monitor patients for signs and symptoms of hypersensitivity during and after Injectafer administration for at least 30 minutes and until clinically stable following completion of the infusion. Only administer Injectafer when personnel and therapies are immediately available for the treatment of serious hypersensitivity reactions. In clinical trials, serious anaphylactic/anaphylactoid reactions were reported in 0.1% (2/1775) of subjects receiving Injectafer. Other serious or severe adverse reactions potentially associated with hypersensitivity which included, but were not limited to, pruritus, rash, urticaria, wheezing, or hypotension were reported in 1.5% (26/1775) of these subjects.

In clinical studies, hypertension was reported in 3.8% (67/1775) of subjects. Transient elevations in systolic blood pressure, sometimes occurring with facial flushing, dizziness, or nausea were observed in 6% (106/1775) of subjects. These elevations generally occurred immediately after dosing and resolved within 30 minutes. Monitor patients for signs and symptoms of hypertension following each Injectafer administration.

In the 24 hours following administration of Injectafer, laboratory assays may overestimate serum iron and transferrin bound iron by also measuring the iron in Injectafer.

ADVERSE REACTIONS

In two randomized clinical studies, a total of 1775 patients were exposed to Injectafer, 15 mg/kg of body weight, up to a single maximum dose of 750 mg of iron on two occasions, separated by at least 7 days, up to a cumulative dose of 1500 mg of iron. Adverse reactions reported by ≥2% of Injectafer-treated patients were nausea (7.2%); hypertension (3.8%); flushing/hot flush (3.6%); blood phosphorus decrease (2.1%); and dizziness (2.0%).

The following serious adverse reactions have been most commonly reported from the post-marketing spontaneous reports: urticaria, dyspnea, pruritus, tachycardia, erythema, pyrexia, chest discomfort, chills, angioedema, back pain, arthralgia, and syncope.

To report adverse events, please contact American Regent† at 1-800-734-9236. You may also contact the FDA at www.fda.gov/medwatch or 1-800-FDA-1088.

Please see brief summary of Full Prescribing Information on the following pages.

Help your patients access the iron they need‡
www.injectafercopay.com
Restrictions apply§

Injectafer provides up to 1500 mg of iron in just 2 administrations separated by at least 7 days[4]

Up to 750 mg in a single dose‖¶

+

Up to 750 mg in a single dose‖¶

=

Total cumulative dose **up to 1500 mg** per course

At least 7 days apart

IV infusion over at least 15 minutes or Slow IV push over 7.5 minutes

injectafer®
ferric carboxymaltose injection

Many IDA patients have iron deficits of approximately 1500 mg[5#]

Monitor your patients. When oral fails, it's time to consider Injectafer.

To learn more, visit **www.injectafer.com**

Injectafer has not been studied in pregnant women. Injectafer should be prescribed during pregnancy only if the potential benefit justifies the potential risk to the fetus.

†American Regent® is a registered trademark of Luitpold Pharmaceuticals, Inc.

‡For appropriate adult IDA patients (see INDICATIONS). Not all patients need 1500 mg of iron. The amount of iron needed for each patient must be determined by the prescribing clinician.

§The Injectafer Savings Program is only available for adults 18 years or older who are commercially insured or cash-paying patients. It provides up to a maximum savings limit of $500 per dose and a $1000 program limit for coverage up to 2 doses. Insurance out of pocket must be over $50. Additional restrictions may apply. Please see full Terms and Conditions.

‖For adult patients weighing less than 50 kg (110 lb), give each dose as 15 mg/kg body weight for a total cumulative dose not to exceed 1500 mg of iron per course of treatment.

¶When administered via IV infusion, dilute up to 750 mg of iron in no more than 250 mL of sterile 0.9% sodium chloride injection, USP, such that the concentration of the infusion is not <2 mg of iron per mL and administer over at least 15 minutes. When administered as a slow IV push, give at the rate of approximately 100 mg (2 mL) per minute.

#Calculated iron deficit based on the modified Ganzoni formula: Subject weight in kg x (15 - current hemoglobin g/dL) x 2.4 + 500. If subject TSAT >20% and ferritin >50 ng/mL, the 500-mg constant is not needed.

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Daiichi-Sankyo

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BRIEF SUMMARY OF PRESCRIBING INFORMATION **Rx Only**
INJECTAFER® (ferric carboxymaltose injection)
Please see package insert for Full Prescribing Information

INDICATIONS AND USAGE: Injectafer is an iron replacement product indicated for the treatment of iron deficiency anemia in adult patients:

- who have intolerance to oral iron or have had unsatisfactory response to oral iron;
- who have non–dialysis-dependent chronic kidney disease.

DOSAGE AND ADMINISTRATION: For patients weighing 50 kg (110 lb) or more: Give Injectafer in two doses separated by at least 7 days. Give each dose as 750 mg for a total cumulative dose not to exceed 1500 mg of iron per course.

For patients weighing less than 50 kg (110 lb): Give Injectafer in two doses separated by at least 7 days. Give each dose as 15 mg/kg body weight for a total cumulative dose not to exceed 1500 mg of iron per course.

The dosage of Injectafer is expressed in mg of elemental iron. Each mL of Injectafer contains 50 mg of elemental iron. Injectafer treatment may be repeated if iron deficiency anemia reoccurs.

Administer Injectafer intravenously, either as an undiluted slow intravenous push or by infusion. When administering as a slow intravenous push, give at the rate of approximately 100 mg (2 mL) per minute. When administered via infusion, dilute up to 750 mg of iron in no more than 250 mL of sterile 0.9% sodium chloride injection, USP, such that the concentration of the infusion is not less than 2 mg of iron per mL and administer over at least 15 minutes.

When added to an infusion bag containing 0.9% sodium chloride injection, USP, at concentrations ranging from 2 mg to 4 mg of iron per mL, Injectafer solution is physically and chemically stable for 72 hours when stored at room temperature. To maintain stability, do not dilute to concentrations less than 2 mg iron/mL.

Inspect parenteral drug products visually for the absence of particulate matter and discoloration prior to administration. The product contains no preservatives. Each vial of Injectafer is intended for single-use only. Any unused drug remaining after injection must be discarded.

Avoid extravasation of Injectafer since brown discoloration of the extravasation site may be long lasting. Monitor for extravasation. If extravasation occurs, discontinue the Injectafer administration at that site.

DOSAGE FORMS AND STRENGTHS: 750 mg iron / 15 mL single-use vial

CONTRAINDICATIONS: Hypersensitivity to Injectafer or any of its components.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions: Serious hypersensitivity reactions, including anaphylactic-type reactions, some of which have been life-threatening and fatal, have been reported in patients receiving Injectafer. Patients may present with shock, clinically significant hypotension, loss of consciousness, and/or collapse. Monitor patients for signs and symptoms of hypersensitivity during and after Injectafer administration for at least 30 minutes and until clinically stable following completion of the infusion. Only administer Injectafer when personnel and therapies are immediately available for the treatment of serious hypersensitivity reactions. In clinical trials, serious anaphylactic/anaphylactoid reactions were reported in 0.1% (2/1775) of subjects receiving Injectafer. Other serious or severe adverse reactions potentially associated with hypersensitivity which included, but not limited to, pruritus, rash, urticaria, wheezing, or hypotension were reported in 1.5% (26/1775) of these subjects.

Hypertension: In clinical studies, hypertension was reported in 3.8% (67/1,775) of subjects in clinical trials 1 and 2. Transient elevations in systolic blood pressure, sometimes occurring with facial flushing, dizziness, or nausea were observed in 6% (106/1,775) of subjects in these two clinical trials. These elevations generally occurred immediately after dosing and resolved within 30 minutes. Monitor patients for signs and symptoms of hypertension following each Injectafer administration.

Laboratory Test Alterations: In the 24 hours following administration of Injectafer, laboratory assays may overestimate serum iron and transferrin bound iron by also measuring the iron in Injectafer.

ADVERSE REACTIONS

Adverse Reactions in Clinical Trials: Because clinical trials are conducted under widely varying conditions, the adverse reaction rates observed cannot be directly compared to rates in other clinical trials and may not reflect the rates observed in clinical practice.

In two randomized clinical studies [Studies 1 and 2, *See Clinical Studies*], a total of 1,775 patients were exposed to Injectafer 15 mg/kg body weight up to a maximum single dose of 750 mg of iron on two occasions separated by at least 7 days up to a cumulative dose of 1500 mg of iron.

Adverse reactions reported by ≥1% of treated patients are shown in the following table.

Table 1. Adverse reactions reported in ≥1% of Study Patients in Clinical Trials 1 and 2

Term	Injectafer (N=1775) %	Pooled Comparators[a] (N=1783) %	Oral iron (N=253) %
Nausea	7.2	1.8	1.2
Hypertension	3.8	1.9	0.4
Flushing/Hot Flush	3.6	0.2	0.0
Blood Phosphorus Decrease	2.1	0.1	0.0
Dizziness	2.0	1.2	0.0
Vomiting	1.7	0.5	0.4
Injection Site Discoloration	1.4	0.3	0.0
Headache	1.2	0.9	0.0
Alanine Aminotransferase Increase	1.1	0.2	0.0
Dysgeusia	1.1	2.1	0.0
Hypotension	1.0	1.9	0.0
Constipation	0.5	0.9	3.2

[a]Includes oral iron and all formulations of IV iron other than Injectafer

Other adverse reactions reported by ≥0.5% of treated patients include abdominal pain, diarrhea, gamma glutamyl transferase increased, injection site pain/irritation, rash, paraesthesia, sneezing. Transient decreases in laboratory blood phosphorus levels (<2 mg/dL) have been observed in 27% (440/1638) patients in clinical trials.

Post-marketing Experience: Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. The following serious adverse reactions have been most commonly reported from the post-marketing spontaneous reports with Injectafer: urticaria, dyspnea, pruritus, tachycardia, erythema, pyrexia, chest discomfort, chills, angioedema, back pain, arthralgia, and syncope. One case of hypophosphatemic osteomalacia was reported in a subject who received 500 mg of Injectafer every 2 weeks for a total of 16 weeks. Partial recovery followed discontinuation of Injectafer.

DRUG INTERACTIONS: Formal drug interaction studies have not been performed with Injectafer.

USE IN SPECIFIC POPULATIONS

Pregnancy: Pregnancy Category C.

Risk Summary

Adequate and well controlled studies in pregnant women have not been conducted. However, animal reproduction studies have been conducted with ferric carboxymaltose. In these studies, administration of ferric carboxymaltose to rabbits during the period of organogenesis caused fetal malformations and increased implantation loss at maternally toxic doses of approximately 12% to 23% of the human weekly dose of 750 mg (based on body surface area). The incidence of major malformations in human pregnancies has not been established for Injectafer. However, all pregnancies, regardless of exposure to any drug, has a background rate of 2 to 4% for major malformations, and 15 to 20% for pregnancy loss. Injectafer should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Animal Data

Administration of ferric carboxymaltose to rats as a one-hour intravenous infusion up to 30 mg/kg/day iron on gestation days 6 to 17 did not result in adverse embryofetal findings. This daily dose in rats is approximately 40% of the human weekly dose of 750 mg based on body surface area. In rabbits, ferric carboxymaltose was administered as a one-hour infusion on gestation days 6 to 19 at iron doses of 4.5, 9, 13.5, and 18 mg/kg/day. Malformations were seen starting at the daily dose of 9 mg/kg (23% of the human weekly dose of 750 mg). Spontaneous abortions occurred starting at the daily iron dose of 4.5 mg/kg (12% of the human weekly dose based on body surface area). Pre-implantation loss was at the highest dose. Adverse embryofetal effects were observed in the presence of maternal toxicity.

A pre- and post-natal development study was conducted in rats at intravenous doses up to 18 mg/kg/day of iron (approximately 23% of the weekly human dose of 750 mg on a body surface area basis). There were no adverse effects on survival of offspring, their behavior, sexual maturation or reproductive parameters.

Nursing Mothers: A study to determine iron concentrations in breast milk after administration of Injectafer (n=11) or oral ferrous sulfate (n=14) was conducted in 25 lactating women with postpartum iron deficiency anemia. Mean breast milk iron levels were higher in lactating women receiving Injectafer than in lactating women receiving oral ferrous sulfate.

Pediatric Use: Safety and effectiveness have not been established in pediatric patients.

Geriatric Use: Of the 1775 subjects in clinical studies of Injectafer, 50% were 65 years and over, while 25% were 75 years and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

OVERDOSAGE: Excessive dosages of Injectafer may lead to accumulation of iron in storage sites potentially leading to hemosiderosis. A patient who received Injectafer 18,000 mg over 6 months developed hemosiderosis with multiple joint disorder, walking disability and asthenia. Hypophosphatemic osteomalacia was reported in a patient who received Injectafer 4000 mg over 4 months. Partial recovery followed discontinuation of Injectafer.

DESCRIPTION: Ferric carboxymaltose, an iron replacement product, is an iron carbohydrate complex with the chemical name of polynuclear iron (III) hydroxide 4(R)-(poly-(1→4)-*O*-α-D-glucopyranosyl)-oxy-2(R),3(S),5(R),6-tetrahydroxy-hexanoate. It has a relative molecular weight of approximately 150,000 Da corresponding to the following empirical formula:

$[FeO_x(OH)_y(H_2O)_z]_n\ [\{(C_6H_{10}O_5)_m\ (C_6H_{12}O7)\}_l]_k$,

where $n \approx 10^3$, $m \approx 8$, $l \approx 11$, and $k \approx 4$

(l represents the mean branching degree of the ligand).

Injectafer (ferric carboxymaltose injection) is a dark brown, sterile, aqueous, isotonic colloidal solution for intravenous injection. Each mL contains 50 mg iron as ferric carboxymaltose in water for injection. Injectafer is available in 15 mL single-use vials. Sodium hydroxide and/or hydrochloric acid may have been added to adjust the pH to 5.0-7.0.

Vial closure is not made with natural rubber latex.

CLINICAL PHARMACOLOGY

Mechanism of Action: Ferric carboxymaltose is a colloidal iron (III) hydroxide in complex with carboxymaltose, a carbohydrate polymer that releases iron.

Pharmacodynamics: Using positron emission tomography (PET) it was demonstrated that red cell uptake of ^{59}Fe and ^{52}Fe from Injectafer ranged from 61% to 99%. In patients with iron deficiency, red cell uptake of radio-labeled iron ranged from 91% to 99% at 24 days after Injectafer dose. In patients with renal anemia red cell uptake of radio-labeled iron ranged from 61% to 84% after 24 days Injectafer dose.

Pharmacokinetics: After administration of a single dose of Injectafer of 100 to 1000 mg of iron in iron deficient patients, maximum iron levels of 37 µg/mL to 333 µg/mL were obtained respectively after 15 minutes to 1.21 hours post dose. The volume of distribution was estimated to be 3 L.

The iron injected or infused was rapidly cleared from the plasma, the terminal half-life ranged from 7 to 12 hours. Renal elimination of iron was negligible.

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility: Carcinogenicity studies have not been performed with ferric carboxymaltose.

Ferric carboxymaltose was not genotoxic in the following genetic toxicology studies: *in vitro* microbial mutagenesis (Ames) assay, *in vitro* chromosome aberration test in human lymphocytes, *in vitro* mammalian cell mutation assay in mouse lymphoma L5178Y/TK+/- cells, *in vivo* mouse micronucleus test at single intravenous doses up to 500 mg/kg.

In a combined male and female fertility study, ferric carboxymaltose was administered intravenously over one hour to male and female rats at iron doses of up to 30 mg/kg. Animals were dosed 3 times per week (on Days 0, 3, and 7). There was no effect on mating function, fertility or early embryonic development. The dose of 30 mg/kg in animals is approximately 40% of the human dose of 750 mg based on body surface area.

CLINICAL STUDIES: The safety and efficacy of Injectafer for treatment of iron deficiency anemia were evaluated in two randomized, open-label, controlled clinical trials (Trial 1 and Trial 2). In these two trials, Injectafer was administered at a dose of 15 mg/kg body weight up to a maximum single dose of 750 mg of iron on two occasions separated by at least 7 days up to a cumulative dose of 1500 mg of iron.

Trial 1: Iron Deficiency Anemia in Patients Who Are Intolerant to Oral Iron or Have Had Unsatisfactory Response to Oral Iron

Trial 1 was a randomized, open-label, controlled clinical study in patients with iron deficiency anemia who had an unsatisfactory response to oral iron (Cohort 1) or who were intolerant to oral iron (Cohort 2) during the 14 day oral iron run-in period. Inclusion criteria prior to randomization included hemoglobin (Hb) <12 g/dL, ferritin ≤100 ng/mL or ferritin ≤300 ng/mL when transferrin saturation (TSAT) ≤30%. Cohort 1 subjects were randomized to Injectafer or oral iron for 14 more days. Cohort 2 subjects were randomized to Injectafer or another IV iron per standard of care [90% of subjects received iron sucrose]. The mean age of study patients was 43 years (range, 18 to 94); 94% were female; 42% were Caucasian, 32% were African American, 24% were Hispanic, and 2% were other races. The primary etiologies of iron deficiency anemia were heavy uterine bleeding (47%) and gastrointestinal disorders (17%).

Table 2 shows the baseline and the change in hemoglobin from baseline to highest value between baseline and Day 35 or time of intervention.

Table 2. Mean Change in Hemoglobin From Baseline to the Highest Value Between Day 35 or Time of Intervention (Modified Intent-to-Treat Population)

Hemoglobin (g/dL) Mean (SD)	Cohort 1		Cohort 2	
	Injectafer (N=244)	Oral Iron (N=251)	Injectafer (N=245)	IV SC[a] (N=237)
Baseline	10.6 (1.0)	10.6 (1.0)	9.1 (1.6)	9.0 (1.5)
Highest Value	12.2 (1.1)	11.4 (1.2)	12.0 (1.2)	11.2 (1.3)
Change (from baseline to highest value)	1.6 (1.2)	0.8 (0.8)	2.9 (1.6)	2.2 (1.3)
p-value	0.001		0.001	

SD=standard deviation; [a]:Intravenous iron per standard of care

Increases from baseline in mean ferritin (264.2 ± 224.2 ng/mL in Cohort 1 and 218.2 ± 211.4 ng/mL in Cohort 2), and transferrin saturation (13 ± 16% in Cohort 1 and 20 ± 15% in Cohort 2) were observed at Day 35 in Injectafer-treated patients.

Trial 2: Iron Deficiency Anemia in Patients with Non–Dialysis-Dependent Chronic Kidney Disease

Trial 2 was a randomized, open-label, controlled clinical study in patients with non–dialysis-dependent chronic kidney disease. Inclusion criteria included hemoglobin (Hb) ≤11.5 g/dL, ferritin ≤100 ng/mL or ferritin ≤300 ng/mL when transferrin saturation (TSAT) ≤30%. Study patients were randomized to either Injectafer or Venofer. The mean age of study patients was 67 years (range, 19 to 96); 64% were female; 54% were Caucasian, 26% were African American, 18% Hispanics, and 2% were other races.

Table 3 shows the baseline and the change in hemoglobin from baseline to highest value between baseline and Day 56 or time of intervention.

Table 3. Mean Change in Hemoglobin From Baseline to the Highest Value Between Baseline and Day 56 or Time of Intervention (Modified Intent-to-Treat Population)

Hemoglobin (g/dL) Mean (SD)	Injectafer (N=1249)	Venofer (N=1244)
Baseline	10.3 (0.8)	10.3 (0.8)
Highest Value	11.4 (1.2)	11.3 (1.1)
Change (from baseline to highest value)	1.1 (1.0)	0.9 (0.92)
Treatment Difference (95% CI)	0.21 (0.13, 0.28)	

Increases from baseline in mean ferritin (734.7 ± 337.8 ng/mL), and transferrin saturation (30 ± 17%) were observed at Day 56 in Injectafer-treated patients.

PATIENT COUNSELING INFORMATION

- Question patients regarding any prior history of reactions to parenteral iron products.
- Advise patients of the risks associated with Injectafer.
- Advise patients to report any signs and symptoms of hypersensitivity that may develop during and following Injectafer administration, such as rash, itching, dizziness, lightheadedness, swelling and breathing problems.

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This is not all the risk information for Injectafer.
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Anticholinergic therapy and onabotulinumtoxinA produce equivalent reductions in the frequency of daily UUI episodes

Visco AG, Brubaker L, Richter HE, et al; for the Pelvic Floor Disorders Network. Anticholinergic therapy vs onabotulinumtoxinA for urgency urinary incontinence. N Engl J Med. 2012;367(19):1803–1813.

In a double-blind, double-placebo-controlled randomized trial, Visco and colleagues compared anticholinergic medication with onabotulinumtoxinA 100 U for the treatment of women with UUI.

Details of the study

Two hundred forty-one women with moderate to severe UUI received either 6 months of oral anticholinergic therapy (solifenacin 5 mg daily with the option of dose escalation to 10 mg daily or change to trospium XR 60 mg daily based on the Patient Global Symptom Control score) plus a single intradetrusor injection of saline, or a single intradetrusor injection of onabotulinumtoxinA 100 U plus a 6-month oral placebo regimen.

Inclusion criteria were 5 or more UUI episodes on a 3-day diary, insufficient resolution of symptoms after 2 medications, or being drug naive. Exclusions included a postvoid residual (PVR) urine volume greater than 150 mL or previous therapy with onabotulinumtoxinA.

Participants were scheduled for follow up every 2 to 6 months post randomization, at which time all study medications were discontinued. The primary outcome was reduction from baseline in the mean number of UUI episodes per day over the 6-month period, as recorded in the monthly 3-day bladder diaries. Secondary outcomes included the proportion of participants with complete resolution of UUI, the proportion of participants with 75% or more reduction in UUI episodes, Overactive Bladder Questionnaire Short Form (OABq-SF) scores, other symptom-specific questionnaire scores, and adverse events.

Both treatments significantly reduced UUI episodes

At baseline, participants reported a mean (SD) of 5.0 (2.7) UUI episodes per day, and 41% of participants were drug naive. Both treatment groups experienced significant reductions compared with baseline in mean UUI episodes, and the reductions were similar between the 2 groups (reduction of 3.4 episodes per day in the anticholinergic group, reduction of 3.3 episodes in the onabotulinumtoxinA group; P = .81). Complete resolution of UUI was more common in the onabotulinumtoxinA group (27%) as compared with the anticholinergic group (13%) (P = .003). There were no differences in improvement in OABq-SF scores (37.05 in the anticholinergic group vs 37.13 in the onabotulinumtoxinA group; P = .98) or other quality-of-life measures.

Adverse events. The anticholinergic group experienced a higher rate of dry mouth compared with the onabotulinumtoxinA group (46% vs 31%; P = .02) but had lower rates of intermittent catheterization use at 2 months (0% vs 5%, P = .01) and UTIs (13% vs 33%, P<.001).

Strengths and limitations. This was a well-designed, multicenter, randomized double-blind, double placebo-controlled trial. The study design allowed for dose escalation and change to another medication for inadequate symptom control and included

FAST TRACK

27% of women in the onabotulinumtoxinA group had complete resolution of UUI; 13% in the anticholinergic group had complete resolution

drug-naive participants, which increases the generalizability of the results. However, current guidelines recommend reserving onabotulinumtoxinA therapy for third-line therapy, thus deterring this treatment's use in the drug-naive population. Additionally, the lack of a pure placebo arm makes it difficult to interpret the extent to which a placebo effect contributed to observed improvements in clinical symptoms.

WHAT THIS EVIDENCE MEANS FOR PRACTICE

Through 6 months, both a single intradetrusor injection of onabotulinumtoxinA 100 U and anticholinergic therapy reduce UUI episodes and improve quality-of-life measures in women who have failed medications or are drug naive. Use of onabotulinumtoxinA, however, more likely will lead to complete resolution of UUI, although with an increased risk of transient urinary retention and UTI. Even given the study findings supporting the use of onabotulinumtoxinA over anticholinergic therapy for complete resolution of UUI, it is most appropriate to align with current practice, which includes a trial of pharmacotherapy before proceeding with third-line onabotulinumtoxinA.

OnabotulinumtoxinA has greater 9-month durability for OAB symptoms compared with 12 weeks of PTNS

FAST TRACK

Current practice for UUI is to proceed with a trial of pharmacotherapy before introducing the third-line treatment of onabotulinumtoxinA

Sherif H, Khalil M, Omar R. Management of refractory idiopathic overactive bladder: intradetrusor injection of botulinum toxin type A versus posterior tibial nerve stimulation. Can J Urol. 2017;24(3):8838–8846.

In this randomized clinical trial, Sherif and colleagues compared the safety and efficacy of a single intradetrusor injection of onabotulinumtoxinA 100 U with that of PTNS for OAB.

Details of the study

Sixty adult men and women with OAB who did not respond to medical therapy were randomly assigned to treatment with either onabotulinumtoxinA 100 U or PTNS. Criteria for exclusion were current UTI, PVR urine volume of more than 150 mL, previous radiation therapy or chemotherapy, previous incontinence surgery or bladder malignancy, or presence of mixed urinary incontinence.

At baseline, participants completed a 3-day bladder diary, an OAB symptom score (OABSS) questionnaire, and urodynamic testing. The OABSS questionnaire included 7 questions (scoring range, 0–28), with higher scores indicating worse symptoms, and included subscales for urgency and quality-of-life measures. Total OABSS, urgency score, quality-of-life score, bladder diary records, and urodynamic testing parameters were assessed at 6, 12, 24, and 36 weeks, along with adverse events.

OnabotulinumtoxinA injections were performed under spinal anesthesia. If PVR urine volume was greater than 200 mL at any follow-up visit, participants were instructed to begin clean intermittent self-catheterization. PTNS was administered as weekly 30-minute sessions for 12 consecutive weeks.

Participants' baseline demographics and symptoms were similar. Average age was 45 years. Averages (SD) for duration of anticholinergic use was 13 (0.8) weeks, UUI

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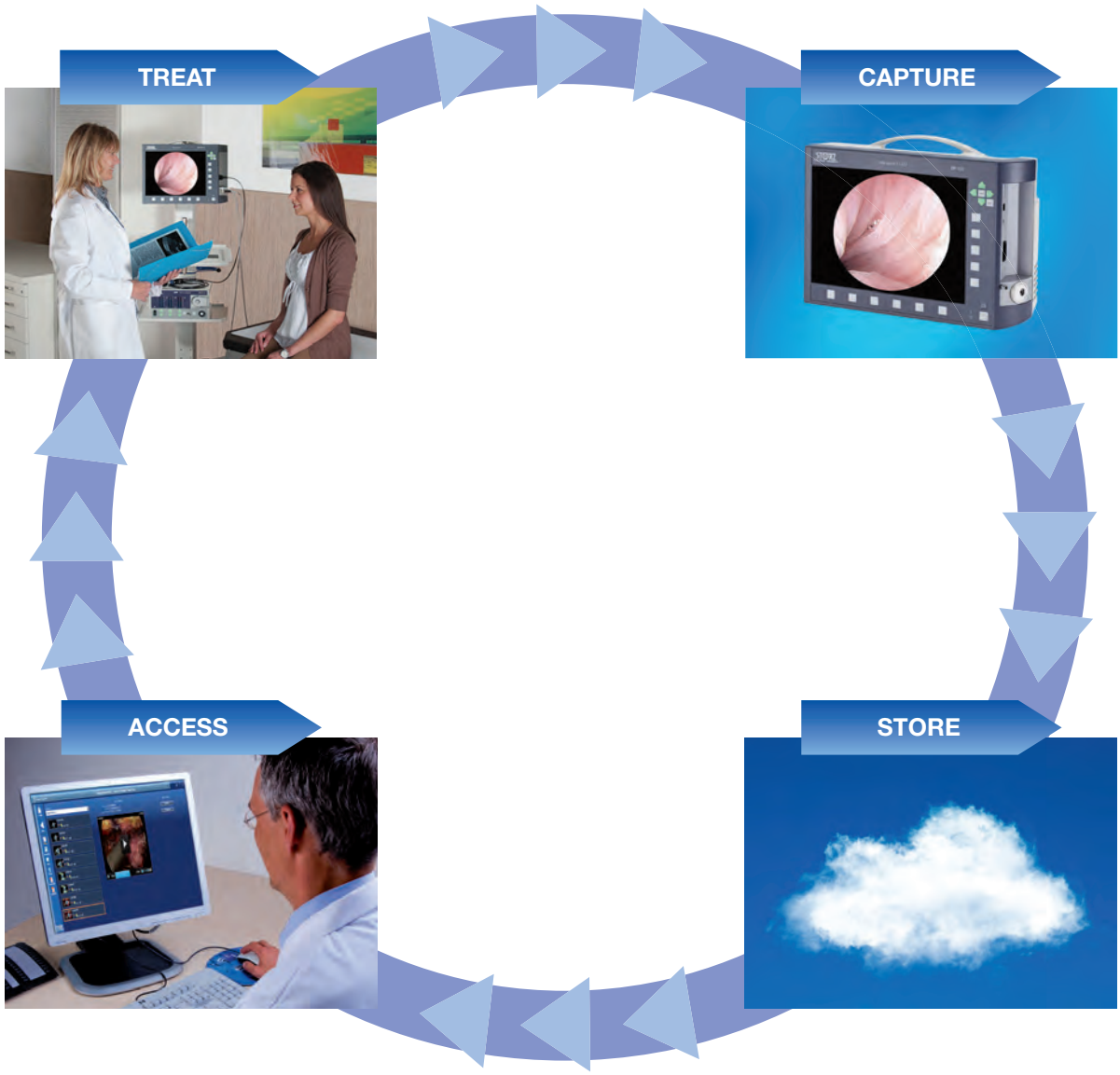

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episode score was 4.5 (1) on 3-day bladder diary, and OABSS was 22 (2.7). Nine-month data were available for 29 participants in the onabotulinumtoxinA group and for 8 in the PTNS group.

OnabotulinumtoxinA treatment benefits sustained for 9 months

Through 6 months, compared with baseline assessments, both treatment groups had significant improvements in clinical symptoms and OABSS total score, as well as urgency and quality-of-life subscales. At 3 months, urodynamic study parameters were similarly improved from baseline in both groups.

At 9 months, however, only the onabotulinumtoxinA group, compared with the PTNS group, maintained the significant improvement from baseline in 3-day bladder diary voiding episodes (average [SD], 10.7 [1.01] vs 11.6 [1.09]; P = .009), 3-day bladder diary nocturia episodes (average [SD], 3.8 [1.09] vs 4.4 [0.8]; P = .02), and average [SD] UUI episodes over 3 days (3.5 [1.2] vs 4.2 [1.04]; P = .02). Similarly, onabotulinumtoxinA-treated participants, compared with those treated with PTNS, maintained improvements at 9 months in average (SD): OABSS total score (19.2 [2.4] vs 20.4 [1.7]; P = .03), urgency scores (10.9 [1.3] vs 11.8 [1.4]; P = .009), urine volume at first desire (177.8 [9.2] vs 171.8 [7.7]), maximum cystometric capacity (304 [17.6] vs 290 [13.1]), and Qmax (mL/sec) (20.7 [1.6] vs 22.2 [1.2]).

Adverse events. Average PVR urine volumes were higher in the onabotulinumtoxinA group compared with the PTNS group (36.8 [2.7] vs 32.4 [3.03]; P = .0001) at all time points, and self-catheterization was required in 6.6% of onabotulinumtoxinA-treated participants. Urinary tract infection occurred in 6.6% of participants in the onabotulinumtoxinA group and in none of the PTNS group. In the PTNS group, few experienced pain and minor bleeding at the needle site.

Strengths and limitations. This randomized, open-label trial comparing treatment with onabotulinumtoxinA 100 U and PTNS included both men and women with idiopathic OAB symptoms. The participants were assessed at regular intervals with various measures, and follow-up adherence was good. The sample size was small, so the study may not have been powered to see differences prior to 9 months.

Although at 9 months only the onabotulinumtoxinA group maintained significant improvement over baseline levels, the improvement was diminished, and therefore the clinical meaningfulness is uncertain. Further, participants in the PTNS group did not undergo monthly maintenance therapy after 3 months, which is recommended for those with a 12-week therapeutic response; this may have affected 9-month outcomes in this group. Since the one-time onabotulinumtoxinA 100 U injection was performed under spinal anesthesia, cost comparisons should be considered, since future onabotulinumtoxinA injections would be necessary.

WHAT THIS EVIDENCE MEANS FOR PRACTICE

A one-time onabotulinumtoxinA 100 U injection and 12 weeks of PTNS therapy are reasonable short-term options for symptomatic OAB relief after unsuccessful therapy with medications. OnabotulinumtoxinA injection may provide more durable OAB symptom control at 9 months but with a risk of UTI and need for self-catheterization.

FAST TRACK

Women treated with onabotulinumtoxinA (vs PTNS) experienced improvements at 9 months in OABSS and urgency scores, urine volume at first desire, maximum cystometric capacity, and Qmax

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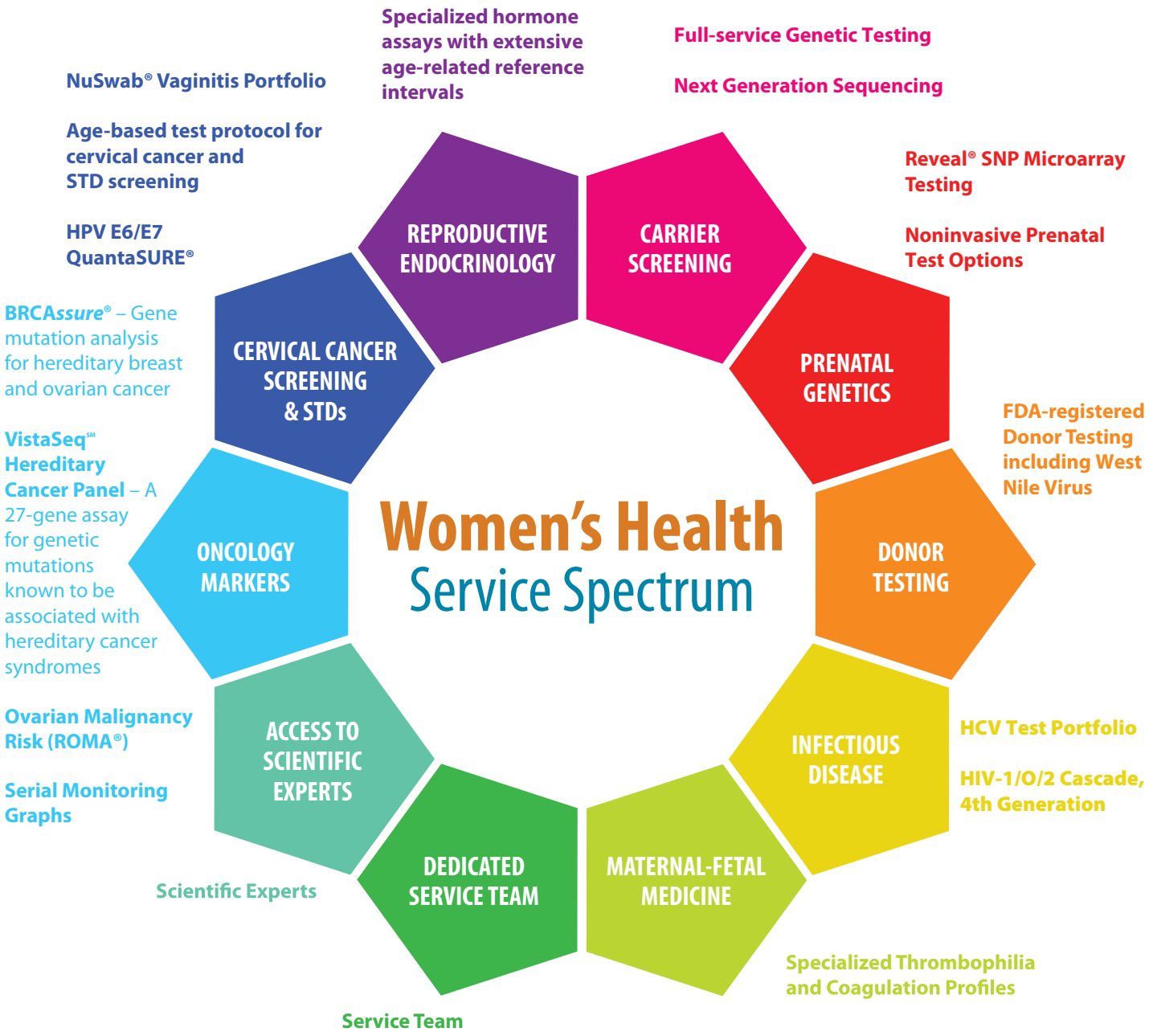

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OnabotulinumtoxinA 200-U injection provides longer OAB symptom improvement than 100-U injection

Abdelwahab O, Sherif H, Soliman T, Elbarky I, Eshazly A. Efficacy of botulinum toxin type A 100 units versus 200 units for treatment of refractory idiopathic overactive bladder. Int Braz J Urol. 2015;41(6):1132–1140.

FAST TRACK

Adverse events associated with a 200-U injection of onabotulinumtoxinA include postoperative hematuria (in 23% of patients), UTI (in 17.5%), and dysuria (in 37.5%)

Abdelwahab and colleagues conducted a single-center, randomized clinical trial to investigate the safety and efficacy of a single injection of intradetrusor onabotulinumtoxinA in 2 different doses (100 U and 200 U) for treatment of OAB.

Details of the study

Eighty adults (63 women, 17 men) who did not benefit from anticholinergic medication during the previous 3 months were randomly assigned to receive either a 100-U (n = 40) or a 200-U (n = 40) injection of onabotulinumtoxinA. Exclusion criteria were PVR urine volume greater than 150 mL and previous radiation therapy or chemotherapy.

Initial assessments—completed at baseline and at 1, 3, 6, and 9 months—included the health-related quality-of-life (HR-QOL) questionnaire (maximum score, 100; higher score indicates better quality of life), an abbreviated OABSS questionnaire (4 questions; score range, 0–15; higher score indicates more severe symptoms), and urodynamic evaluation. Outcomes included OABSS, HR-QOL score, and urodynamic parameters at the various time points.

Higher dose, greater symptom improvement and higher adverse event rate

At baseline, participants (average age, 31 years) had an average (SD) OABSS of 1.7 (1.6). OnabotulinumtoxinA treatment with both a 100-U and a 200-U dose resulted in significant improvements (compared with baseline levels) in frequency, nocturia, UUI episodes, OABSS, and urodynamic parameters throughout the 9 months. At 9 months, however, the group treated with the 200-U dose had greater improvements, compared with the group who received a 100-U dose, in urinary frequency symptom scores (mean [SD], 0.32 [0.47] vs 1.1 [0.51]; $P<.05$), nocturia symptom scores (mean [SD], 0.13 [0.34] vs 0.36 [0.49]; $P<.05$), UUI symptom scores (mean [SD], 0.68 [0.16] vs 1.26 [1.1]; $P<.05$), and mean (SD) total OABSS (2.6 [2.31] vs 5.3 [2.11]; $P<.05$). Similarly, at 9 months the 200-U dose resulted in greater improvements in volume at first desire (mean [SD], 291.8 [42.8] vs 246.8 [53.8] mL; $P<.05$), volume at strong desire (mean [SD], 392.1 [37.3] vs 313.1 [67.4] mL; $P<.05$), detrusor pressure (mean [SD], 10.4 [4.0] vs 19.2 [7.8] cm H_2O; $P<.05$), and maximum cystometric capacity (mean [SD], 430.5 [34.2] vs 350 [69.1] mL; $P<.05$) compared with the 100-U dose.

Adverse events. No participant had a PVR urine volume greater than 100 mL at any follow-up visit. Postoperative hematuria occurred in 23% of the group treated with onabotulinumtoxinA 200 U versus in 15% of those treated with a 100-U dose. Similarly, UTIs occurred in 17.5% of the 200-U dose group and in 7.5% of the 100-U dose group. Dysuria was reported in 37.5% and 15% of the 200-U and 100-U dose groups, respectively.

Strengths and limitations. This randomized, open-label trial comparing a single injection of 100 U versus 200 U of onabotulinumtoxinA included mostly women. OAB symptoms and urodynamic parameters improved after treatment with both dose levels, but a longer duration of improvement was seen with the 200-U dose. The cohort had a low baseline OAB severity, based on the

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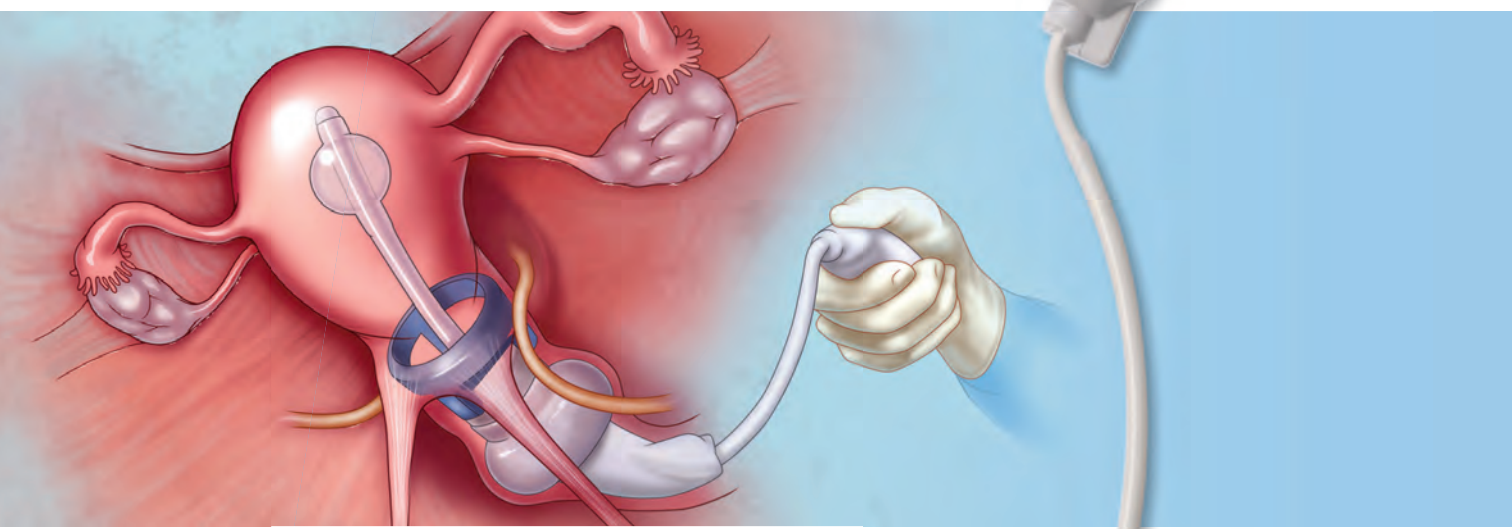

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OABSS questionnaire, and a young average age of participants, which limits the generalizability of the study results to a population with refractory OAB. The 0% rate of clean intermittent self-catheterization postinjection might be based on the study's criteria for requiring clean intermittent catheterization. In addition, the initial postinjection visit occurred at 1 month, possibly missing participants who had symptoms of retention soon after injection.

WHAT THIS EVIDENCE MEANS FOR PRACTICE

Two dose levels (100 U and 200 U) of a single injection of onabotulinumtoxinA are associated with comparable OAB symptom and urodyanamic improvements. The benefits of a longer duration of effect with the 200-U dose must be weighed against the possible higher risks of transient hematuria, dysuria, and UTI.

Treatment with onabotulinumtoxinA may control UUI symptoms better than sacral neuromodulation therapy

FAST TRACK

Symptom bother reductions were greater in the onabotulinumtoxinA group than in the sacral neuromodulation group at 6 months

Amundsen CL, Richter HE, Menefee SA, et al; Pelvic Floor Disorders Network. OnabotulinumtoxinA vs sacral neuromodulation on refractory urgency urinary incontinence in women: a randomized clinical trial. JAMA. 2016;316(13):1366–1374.

In this multicenter open-label randomized trial, Amundsen and colleagues compared the efficacy and safety of onabotulinumtoxinA 200 U with that of sacral neuromodulation.

Details of the study

Three hundred sixty-four women with UUI had data available for primary analysis at 6 months. Women were considered eligible for the study if they had 6 or more UUI episodes on a 3-day bladder diary, persistent symptoms despite anticholinergic therapy, a PVR urine volume of less than 150 mL, and had never previously received either study treatment.

There were no differences in baseline characteristics of the participants. The average (SD) age of the study population was 63 (11.6) years, with an average (SD) daily number of UUI episodes of 5.3 (2.8). The average (SD) body mass index was 32 (8) kg/m^2.

Participants were randomly assigned to undergo either sacral neuromodulation (n = 174) or intradetrusor injection of onabotulinumtoxinA 200 U (n = 190). The primary outcome was change from baseline in mean number of daily UUI episodes averaged over 6 months as recorded on a monthly 3-day bladder diary. Secondary outcomes included complete resolution of urgency incontinence, 75% or more reduction in UUI episodes, the Overactive Bladder Questionnaire Short Form (SF) score (range, 0–100; higher score indicates higher symptom severity), the Overactive Bladder Satisfaction of Treatment questionnaire (range, 0–100; higher score indicates better satisfaction), other quality-of-life measures, and adverse events.

Greater symptom bother improvement, treatment satisfaction with onabotulinumtoxinA 200 U

Participants treated with onabotulinumtoxinA had a greater mean reduction of 3.9 UUI

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Top translator apps can help you communicate with patients who have limited English proficiency

Add these medical phrase and general language translator apps to your clinician's toolkit

Katherine T. Chen, MD, MPH

IN THIS ARTICLE

Recommended translator apps
page 36

As the population of patients with limited English proficiency increases throughout English-speaking countries, health care providers often need translator services. Medical translator smartphone applications (apps) are useful tools that can provide ad hoc translator services.

According to the US Census Bureau in 2015, more than 60 million individuals—about 19% of Americans—reported speaking a language other than English at home, and more than 25 million said that they speak English "less than very well."[1,2] The top 5 non-English languages spoken at home were Spanish, French, Chinese, Tagalog, and Vietnamese, encompassing 72% of non-English speakers.

In the health care sector, translator services are essential for providing accurate and culturally competent care. Current options for translator services include face-to-face interpreters, phone-based translator services, and translator apps on mobile devices. In settings where face-to-face interpreters or phone-based translator services are not available, translator apps may provide reasonable alternatives. My colleagues, Dr. Amrin Khander and Dr. Sara Farag, and I identified and evaluated medical translator apps that are available from the Apple iTunes and Google Play stores to aid clinicians in using such apps during clinical encounters.[3]

Dr. Chen is Professor of Obstetrics, Gynecology, and Reproductive Science and Medical Education, Vice-Chair of Ob-Gyn Education for the Mount Sinai Health System, Icahn School of Medicine, Mount Sinai, New York, New York.

The author reports receiving royalties from UpToDate, Inc.

Three types of translator apps

Preset medical phrase translator apps require the user to search for or find a question or statement in order to facilitate a conversation. With these types of apps, a health care provider can choose fully conjugated sentences, which then can be played or read back to the patient in the chosen translated language. Within this group of apps, Canopy Speak and Universal Doctor Speaker are highly accessible, since both apps are available from the Apple iTunes and Google Play stores and both are free.

Medical dictionary apps require the user to search for a medical term in one language to receive a translation in another language. These apps are less useful, but they can help providers find and define specific terms in a given language.

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TABLE Top recommended translator applications

App	App comprehensiveness	Price	Platform	Literature used	Important special features
 **Canopy Speak** iTunes: https://itunes.apple.com/us/app/canopy-speak/id792808936?mt=8 Google Play: https://play.google.com/store/apps/details?id=com.canopyapps.translator&hl=en	• Preset medical phrase translator app • 15 languages	Free	iTunes and Google Play store	None reported	• Subspecialty specific • Displays phrases with text • Plays with audio • Allows dial-out to a phone interpreter
 **Google Translate** iTunes: https://itunes.apple.com/us/app/google-translate/id414706506?mt=8 Google Play: https://play.google.com/store/apps/details?id=com.google.android.apps.translate&hl=en	• General language translator app • At least 30 languages with important special features • Over 100 languages with display phrases with text	Free	iTunes and Google Play store	None reported	• Displays phrases with text • Plays with audio • Translates text in images instantly by just pointing or taking photo with your phone camera • Translates bilingual conversations on the fly • Draws text characters instead of typing
 **Universal Doctor Speaker** iTunes: https://itunes.apple.com/us/app/universal-doctor-speaker-medical-translator-with-audios/id389202856?mt=8 Google Play: https://play.google.com/store/apps/details?id=com.universaldoctor.drspeaker&hl=en	• Preset medical phrase translator app • 17 languages	Free	iTunes and Google Play store	None listed	• Subspecialty specific • Displays phrases with text • Plays with audio
 **Vocre Translate** iTunes: https://itunes.apple.com/us/app/vocre-translate-voice-and-text-translator/id454405637?mt=8 Google Play: https://play.google.com/store/apps/details?id=com.Vocre.Translate&hl=en	• General language translator app • 36 languages	$4.99	iTunes and Google Play store	None reported	• Displays phrases with text • Plays with audio • Translates bilingual conversations on the fly

General language translator apps require the user to enter a term, statement, or question in one language and then provide a translation in another language. Google Translate and Vocre Translate are examples.

The top recommended translator apps are listed in the **TABLE** alphabetically and are detailed with a shortened version of the APPLICATIONS scoring system, APPLI (app comprehensiveness, price, platform, literature use, and important special features).[4] I hope the apps described here will help you enhance communication with your patients who have limited English proficiency.

References

1. United States Census Bureau. Detailed language spoken at home and ability to speak English for the population 5 years and over: 2009–2013. http://www.census.gov/data/tables/2013/demo/2009-2013-lang-tables.html. Published October 2015. Accessed August 31, 2017.
2. United States Census Bureau. US population world clock. http://www.census.gov/popclock/?intcmp=home_pop. Accessed August 31, 2017.
3. Khander A, Farag S, Chen KT. Identification and rating of medical translator mobile applications using the APPLICATIONS scoring system [abstract 321]. Obstet Gynecol. 2017;129(5 suppl):101S. doi:10.1097/01.AOG.0000514971.96123.20
4. Chyjek K, Farag S, Chen KT. Rating pregnancy wheel applications using the APPLICATIONS scoring system. Obstet Gynecol. 2015;125(6):1478–1483.

Breast density and optimal screening for breast cancer

An expert with a personal story outlines the best imaging options for detecting cancer in dense breasts

Wendie A. Berg, MD, PhD

IN THIS ARTICLE

MY STORY Prologue

My aunt received a breast cancer diagnosis at age 40, and she died at age 60, in 1970. Then, in 1975, my mother's breast cancer was found at age 55, but only after she was examined for nipple retraction; on mammography, the cancer had been obscured by dense breast tissue. Mom had 2 metastatic nodes but participated in the earliest clinical trials of chemotherapy and lived free of breast cancer for another 41 years. Naturally I thought that, were I to develop this disease, I would want it found earlier. Ironically, it was, but only because I had spent my career trying to understand the optimal screening approaches for women with dense breasts—women like me.

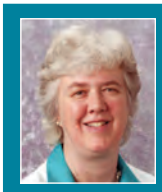
Cancers are masked on mammography in dense breasts

For women, screening mammography is an important step in reducing the risk of dying from breast cancer. The greatest benefits are realized by those who start annual screening at age 40, or 45 at the latest.[1] As it takes 9 to 10 years to see a benefit from breast cancer screening at the population level, it is not logical to continue this testing when life expectancy is less than 10 years, as is the case with women age 85 or older, even those in the healthiest quartile.[2–4] However, despite recent advances, the development of 3D mammography (tomosynthesis) (**FIGURE 1,** page 40) in particular, cancers can still be masked by dense breast tissue. Both 2D and 3D mammograms are x-rays; both dense tissue and cancers absorb x-rays and appear white.

Breast density is determined on mammography and is categorized as fatty, scattered fibroglandular, heterogeneously dense, or extremely dense (**FIGURE 2,** page 41).[5] Tissue in the heterogeneous and extreme categories is considered *dense*. More than half of women in their 40s have dense breasts; with some fatty involution occurring around menopause, the proportion drops to 25% for women in their 60s.[6] About half of breast cancers have calcifications, which on mammography are usually easily visible even in dense breasts. The problem is with noncalcified invasive cancers that can be hidden by dense tissue (**FIGURE 3,** page 41).

3D mammography improves cancer detection but is of minimal benefit in extremely dense breasts

Although 3D mammography improves cancer detection in most women, any benefit is minimal in women with extremely dense breasts, as there is no inherent soft-tissue contrast.[7] Masked cancers are often only discovered because of a lump after a normal screening mammogram, as so-called



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The author reports no financial relationships relevant to this article.

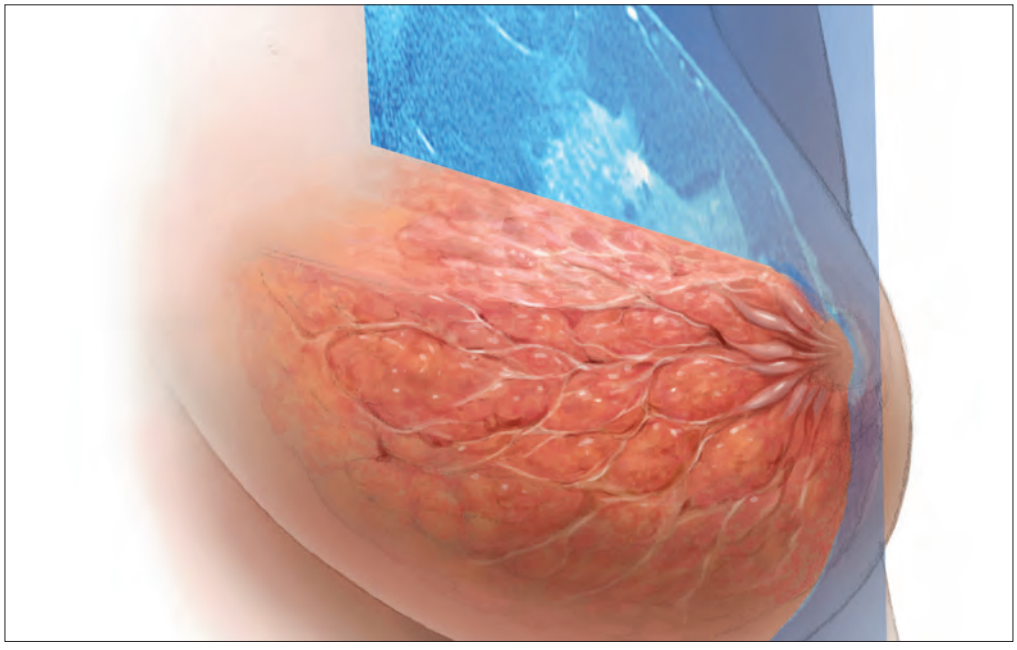


ILLUSTRATION: KIMBERLY MARTENS FOR OBG MANAGEMENT/COURTESY OF WENDIE A. BERG, MD, PHD

"interval cancers." Compared with screen-detected cancers, interval cancers tend to be more biologically aggressive, to have spread to lymph nodes, and to have worse prognoses. However, even some small screen-detected cancers are biologically aggressive and can spread to lymph nodes quickly, and no screening test or combination of screening tests can prevent this occurrence completely, regardless of breast density.

MRI provides early detection across all breast densities

In all tissue densities, contrast-enhanced magnetic resonance imaging (MRI) is far better than mammography in detecting breast cancer.[8] Women at high risk for breast cancer caused by mutations in *BRCA1, BRCA2, p53,* and other genes have poor outcomes with screening mammography alone—up to 50% of cancers are interval cancers. Annual screening MRI reduces this percentage significantly, to 11% in women with pathogenic *BRCA1* mutations and to 4% in women with *BRCA2* mutations.[9] Warner and colleagues found a decrease in late-stage cancers in high-risk women who underwent annual MRI screenings compared to high-risk women unable to have MRI.[10]

The use of MRI for screening is limited by availability, patient tolerance,[11] and high cost. Research is being conducted to further validate approaches using shortened screening MRI times (so-called "abbreviated" or "fast" MRI) and, thereby, improve access, tolerance, and reduce associated costs; several investigators already have reported promising results, and a few centers offer this modality directly to patients willing to pay $300 to $350 out of pocket.[12,13] Even in normal-risk women, MRI significantly increases detection of early breast cancer after a normal mammogram and ultrasound, and the cancer detection benefit of MRI is seen across all breast densities.[14]

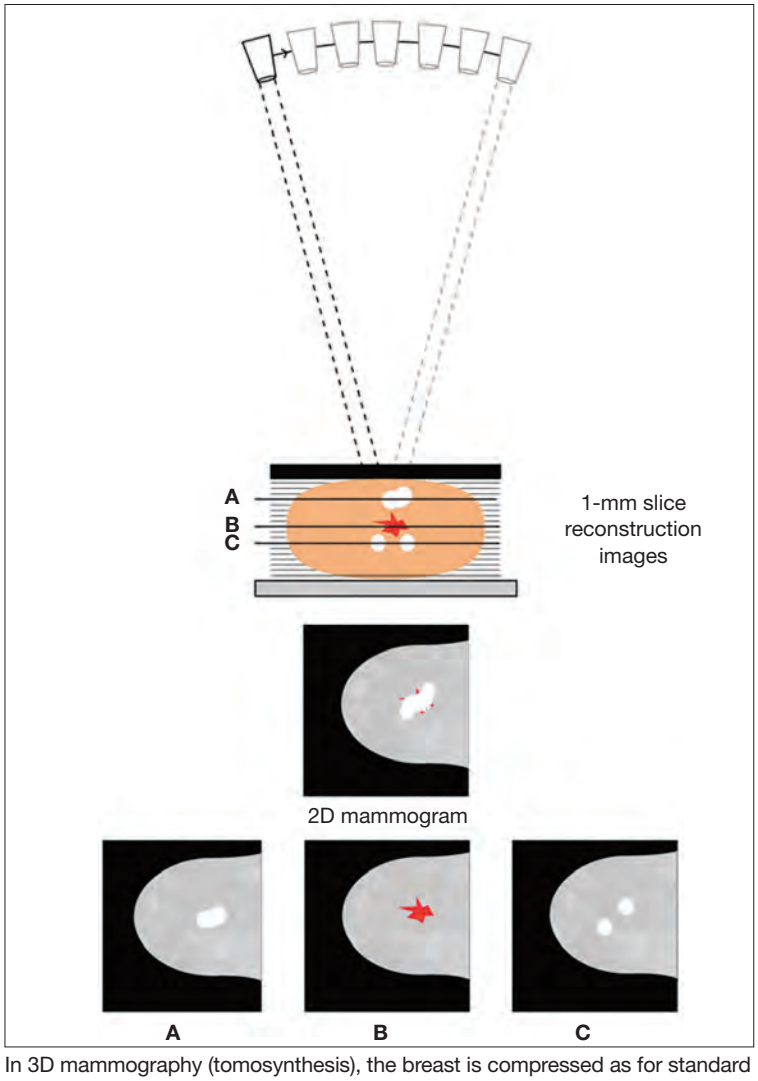
Most health insurance plans cover screening MRI only for women who meet defined risk criteria, including women who have a known disease-causing mutation—or are suspected of having one, given a family history of breast cancer with higher than 20% to 25% lifetime risk by a model that predicts mutation carrier status—as well as women who had chest radiation therapy before age 30, typically for Hodgkin lymphoma, and at least 8 years earlier.[15] In addition, MRI can be considered in women with atypical breast biopsy results or a personal history of lobular carcinoma in situ (LCIS).[16]

Screening MRI should start by age 25 in

FAST TRACK

In all tissue densities, contrast-enhanced MRI is far better than mammography in detecting breast cancer, but the use of MRI is limited by availability, patient tolerance, and high cost

FIGURE 1 Tomosynthesis (3D mammography)



In 3D mammography (tomosynthesis), the breast is compressed as for standard 2D mammography, and the x-ray tube moves over the breast in an arc, creating multiple projection images. These images are used to create 1-mm slice reconstructions. Unlike in 2D mammography, in which tissues and masses are often on top of each other, in 3D mammography discrete masses are usually seen on at least a few slices. Here, slice **A** shows a circumscribed, lobulated, benign-appearing mass; slice **B** shows a spiculated (red) mass compatible with cancer; and slice **C** shows 2 circumscribed, round, benign-appearing masses. The same cancer is difficult to see on 2D mammography.

Figure courtesy of www.DenseBreast-info.org, Jeremy M. Berg, PhD, and Wendie A. Berg, MD, PhD.

women with disease-causing mutations, or at the time of atypical or LCIS biopsy results, and should be performed annually unless the woman is pregnant or has a metallic implant, renal insufficiency, or another contraindication to MRI. MRI can be beneficial in women with a personal history of cancer, although annual mammography remains the standard of care.[17–19]

MRI and mammography can be performed at the same time or on an alternating 6-month basis, with mammography usually starting only after age 30 because of the small risk that radiation poses for younger women. There are a few other impediments to having breast MRI: The woman must lie on her stomach within a confined space (tunnel), the contrast that is injected may not be well tolerated, and insurance does not cover the test for women who do not meet the defined risk criteria.[11]

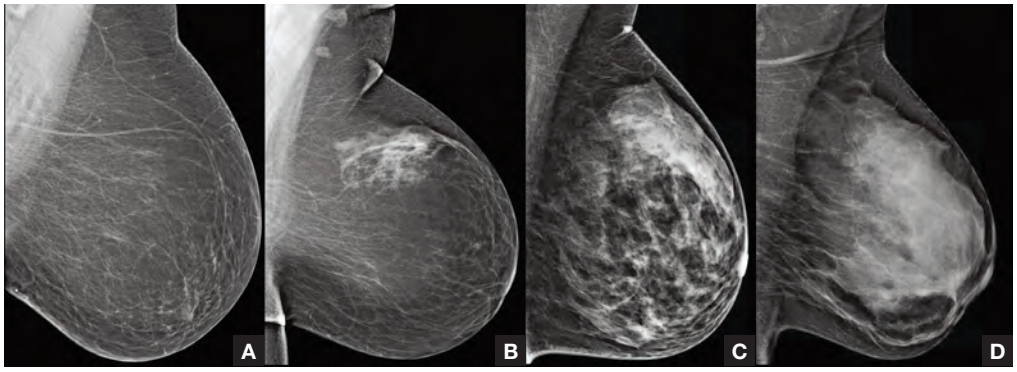
Ultrasonography supplements mammography

Mammography supplemented with ultrasonography (US) has been studied as a "Goldilocks" or best-fit solution for the screening of women with dense breasts, as detection of invasive cancers is improved with the 2 modalities over mammography alone, and US is less invasive, better tolerated, and lower in cost than the more sensitive MRI.

In women with dense breasts, US has been found to improve cancer detection over mammography alone, and early results suggest a larger cancer detection benefit from US than from 3D mammography, although research is ongoing.[20] Adding US reduces the interval cancer rate in women with dense breasts to less than 10% of all cancers found—similar to results for women with fatty breasts.[17,21,22]

US can be performed by a trained technologist or a physician using a small transducer, which usually provides diagnostic images (so that most callbacks would be for a true finding), or a larger transducer and an automated system can be used to create more than a thousand images for radiologist review.[23,24] Use of a hybrid system, a small transducer with an automated arm, has been validated as well.[25] Screening US is not available universally, and with all these approaches optimal performance requires trained personnel. Supplemental screening US usually is covered by insurance but is nearly always subject to a deductible/copay.

FIGURE 2 Four-category visual description of breast density



According to the American College of Radiology (ACR) Breast Imaging Reporting and Data System (BI-RADS), mammography reports categorize breast density on the basis of appearance: (**A**) almost entirely fatty; (**B**) scattered areas of fibroglandular density; (**C**) heterogeneously dense, which could obscure detection of small masses; and (**D**) extremely dense, which lowers the sensitivity of mammography. Breasts in category C or D are considered *dense*; about half of cancers in such breasts may go undetected on mammography. Thirty states require that the mammography results given to patients include some information about breast density (legislation and regulations: http://densebreast-info.org/legislation.aspx).

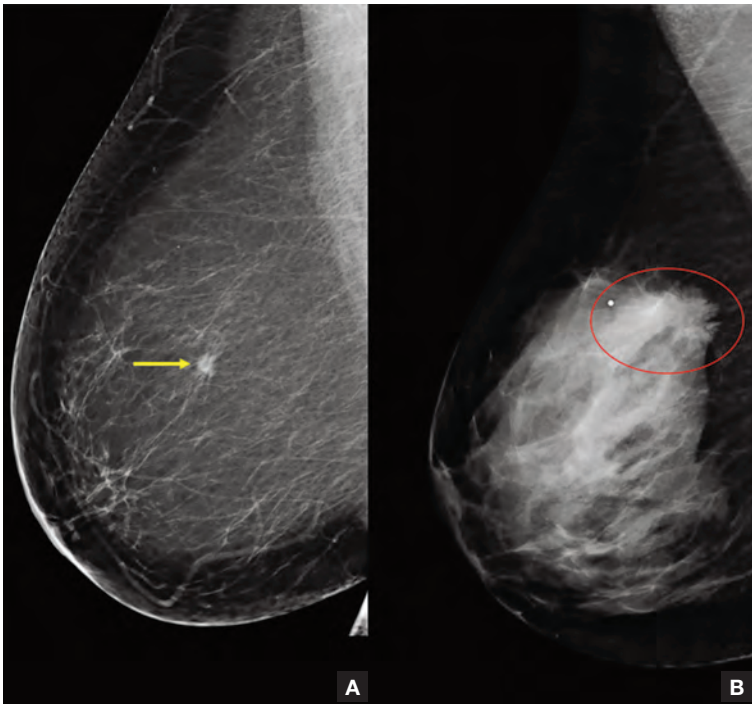
Figure courtesy of www.DenseBreast-info.org and Wendie A. Berg, MD, PhD.

Reducing false-positives, callbacks, and additional testing

Mammography carries a risk of false-positives. On average, 11% to 12% of women are called back for additional testing after a screening mammogram, and in more than 95% of women brought back for extra testing, no cancer is found.[26] Women with dense breasts are more likely than those with less dense breasts to be called back.[27] US and MRI improve cancer detection and therefore yield additional positive, but also false-positive, findings. Notably, callbacks decrease after the first round of screening with any modality or combination of tests, as long as prior examinations are available for comparison.

One advantage of 3D over 2D mammography is a decrease in extra testing for areas of asymmetry, which are often recognizable on 3D mammography as representing normal superimposed tissue.[28–30] Architectural distortion, which is better seen on 3D mammography and usually represents either cancer or a benign radial scar, can lead to false-positive biopsies, although the average biopsy rate is no higher for 3D than for 2D alone.[31] Typically, the 3D and 2D examinations are performed together (slightly more than doubling the radiation dose), or synthetic 2D images

FIGURE 3 Cancer detection in fatty vs dense breasts



In fatty breasts (**A**), small cancers (yellow arrow) are usually easily seen on mammography. In dense breasts (**B**), cancers (red circle) are often hidden by dense tissue, are often larger on detection, and are more likely to require more extensive treatment.

Figure courtesy of www.DenseBreast-info.org and Wendie A. Berg, MD, PhD.

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TABLE Additional breast cancer detection with methods supplementing standard 2D mammography[a]

Method	Additional cancer detection per 1,000 women screened per year, n	Change in callback rate, n per 1,000 women screened per year
3D mammography (tomosynthesis)	1–2	–20
Automated ultrasonography	2	+130 in first round
Handheld ultrasonography	2–5	+150 in first round +70 in subsequent rounds
3D mammography and ultrasonography	4–6[b,20]	Unknown
Magnetic resonance imaging in average-risk women	≥10 in first round 7 in subsequent rounds	+100 in first round +50 in subsequent rounds

[a]With use of only 2D mammography (no supplemental methods), if 1,000 women are screened per year, on average 113 will be called back for additional testing, and, on average 5, cancers will be detected.

[b]These numbers reflect preliminary results from an ongoing study in Italy[20]; 3D mammography with synthetic 2D views is starting to replace standard 2D mammography and further studies are ongoing to establish the benefit of ultrasonography after 3D mammography.

Table courtesy of Wendie A. Berg, MD, PhD.

FAST TRACK

Some aggressive high-grade breast cancers go undetected even when mammography is supplemented with US. MRI is particularly effective in depicting high-grade cancers, even small ones.

can be created from the 3D slices (resulting in a total radiation dose almost the same as standard 2D alone).

Most additional cancers seen on 3D mammography or US are lower-grade invasive cancers with good prognoses. Some aggressive high-grade breast cancers go undetected even when mammography is supplemented with US, either because they are too small to be seen or because they resemble common benign masses and may not be recognized. MRI is particularly effective in depicting high-grade cancers, even small ones.

The **TABLE** summarizes the relative rates of cancer detection and additional testing by various breast screening tests or combinations of tests. Neither clinical breast examination by a physician or other health care professional nor routine breast self-examination reduces the number of deaths caused by breast cancer. Nevertheless, women should monitor any changes in their breasts and report these changes to their clinician. A new lump, skin or nipple retraction, or a spontaneous clear or bloody nipple discharge merits diagnostic breast imaging even if a recent screening mammogram was normal.

FIGURE 4 is an updated decision support tool that suggests strategies for optimizing cancer detection with widely available screening methods.

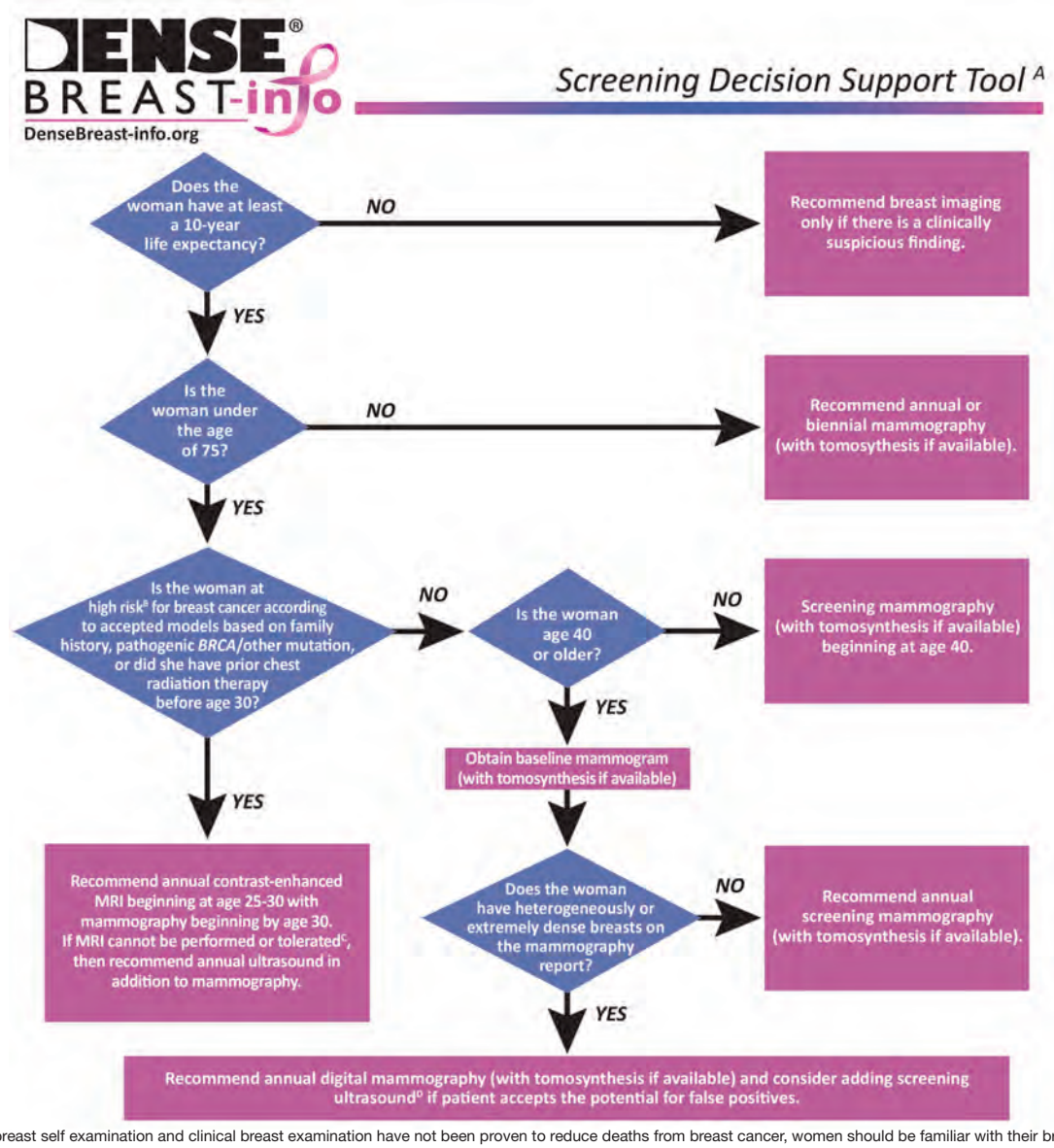
MY STORY Epilogue

My annual 3D mammograms were normal, even the year my cancer was present. In 2014, I entered my family history into the IBIS Breast Cancer Risk Evaluation Tool (Tyrer-Cuzick model of breast cancer risk) (http://www.ems-trials.org/riskevaluator/) and calculated my lifetime risk at 19.7%. That is when I decided to have a screening MRI. My invasive breast cancer was easily seen on MRI and then on US. The cancer was node-negative, easily confirmed with needle biopsy, and treated with lumpectomy and radiation. There was no need for chemotherapy.

My personal experience prompted me to join JoAnn Pushkin and Cindy Henke-Sarmento, RT(R)(M), BA, in developing a website, www.DenseBreast-info.org, to give women and their physicians easy access to information on making decisions about screening in dense breasts.

My colleagues and I are often asked what is the best way to order supplemental imaging for a patient who may have dense breasts. Even in cases in which a mammogram does not exist or is unavailable, the following prescription can be implemented easily at centers that offer US: "2D plus 3D mammogram if available; if dense, perform ultrasound as needed."

FIGURE 4 Breast cancer screening strategy flowchart



[A]While breast self examination and clinical breast examination have not been proven to reduce deaths from breast cancer, women should be familiar with their breasts and promptly report changes to their health provider. For information about cancer detection by modality, see DenseBreast-info.org (Technology tab Table: Summary of Cancer Detection Rates for Commonly Available Breast Screening Tests).

[B]See Densebreast-info.org (Health Professional tab/Risk Models).

[C]Contrast-enhanced MRI is not recommended in women who are pregnant, have a pacemaker, have a non-MRI compatible metallic implant near vital structures, or who have decreased renal function. If you have a screening MRI, there is no added benefit from screening ultrasound.

[D]In women with dense breasts, several studies have shown that ultrasound significantly improved cancer detection even after 2D and 3D (tomosynthesis) mammography, though further research is ongoing.

Note: This flow chart was developed as an educational tool and reflects the consensus opinion of our medical reviewers based on the best available scientific evidence. The proposed strategy is relatively aggressive, designed to optimize cancer detection. Every technology may not be available at every site. Other guidelines may recommend a later start or different screening frequency. This is not intended to be a substitute for medical advice from a physician or to create a standard of care for health care providers.

Developed by members of the medical advisory board of DenseBreast-info, this flowchart depicts a breast cancer screening strategy that optimizes detection by supplementing mammography with either annual magnetic resonance imaging (MRI), in women at high risk starting at age 25, or annual ultrasonography, in women age 40 or older with dense breasts or high-risk women unable to have MRI.

Figure courtesy of www.DenseBreast-info.org.

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Breast density screening: Take advantage of today's technology

Breast screening and diagnostic imaging have improved significantly since the 1970s, when many of the randomized trials of mammography were conducted. Breast density is one of the most common and important risk factors for development of breast cancer and is now incorporated into the Breast Cancer Surveillance Consortium model (https://tools.bcsc-scc.org/BC5yearRisk/calculator.htm) and the Tyrer-Cuzick model (see also http://densebreast-info.org/explanation-of-dense-breast-risk-models.aspx).[32] Although we continue to validate newer approaches, women should take advantage of the improved methods of early cancer detection, particularly if they have dense breasts or are at high risk for breast cancer.

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episodes per day than the sacral neuromodulation group's reduction of 3.3 UUI episodes per day (mean difference, 0.63; 95% confidence interval [CI], 0.13–1.14; $P = .01$). In addition, complete UUI resolution was higher in the onabotulinumtoxinA group as compared with the sacral neuromodulation group (20% vs 4%; $P<.001$). The onabotulinumtoxinA group also had higher rates of 75% or more reduction of UUI episodes compared with the sacral neuromodulation group (46% vs 26%; $P<.001$). Over 6 months, both groups had improvements in all quality-of-life measures, but the onabotulinumtoxinA group had greater improvement in symptom bother compared with the sacral neuromodulation group (-46.7 vs -38.6; mean difference, 8.1; 95% CI, 3.0–13.3; $P = .002$). Furthermore, the onabotulinumtoxinA group had greater treatment satisfaction compared with the sacral neuromodulation group (mean difference, 7.8; 95% CI, 1.6–14.1; $P = .01$).

Adverse events. Six women (3%) underwent sacral neuromodulation device revision or removal. Approximately 8% of onabotulinumtoxinA-treated participants required intermittent self-catheterization at 1 month, 4% at 3 months, and 2% at 6 months. The risk of UTI was higher in the onabotulinumtoxinA group compared with the sacral neuromodulation group (35% vs 11%; risk difference, 23%; 95% CI, -33% to -13%; $P<.001$).

WHAT THIS EVIDENCE MEANS FOR PRACTICE

Both onabotulinumtoxinA 200 U and sacral neuromodulation provide significant improvement in UUI episodes and quality of life over 6 months. However, while treatment with onabotulinumtoxinA has a likelihood of complete UUI resolution, greater improvements in symptom bother and treatment satisfaction, these benefits must be weighed against the risks of transient catheterization and UTI.

Strengths and limitations. This is a well-designed randomized clinical trial comparing clinical outcomes and adverse events after treatment with onabotulinumtoxinA 200-U versus sacral neuromodulation. The interventions were standardized across investigators at multiple sites, and the study design required close follow-up to assess efficacy and adverse events. The study used a 200-U dose based on reported durability of effect at that time and findings of equivalency between onabotulinumtoxinA 100 U and anticholinergic therapy. The US Food and Drug Administration's recommendation to use a 100-U dose in all patients with idiopathic OAB might dissuade clinicians from considering the higher dose of onabotulinumtoxinA. The study was limited by the lack of a placebo group.

FAST TRACK

Both onabotulinumtoxinA and sacral neuromodulation result in quality-of-life improvements but onabotulinumtoxinA treatment is associated with transient catheterization and UTI

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THE BUSINESS OF MEDICINE

Reengineering your office to be perfect for your patients

The focus of your practice must be the patient. What steps can you take to ensure patient satisfaction and service excellence?

Joseph S. Sanfilippo, MD, MBA

IN THIS ARTICLE

Independent of the Affordable Care Act or any upcoming changes in health care, the focus of an ObGyn practice remains paramount: **the patient comes first**.

The "recipe" for creating patient satisfaction and service excellence is predicated upon the mission of your practice and creating a shared vision with your employees. An action plan that is created and "visited/revisited" on a regular basis will serve to keep all abreast of the latest information to enhance the quality of patient care. It goes without saying, the ObGyn must first "lead by example" and always strive for satisfied patients who will tell their friends about your practice.

Start with the right tools

To organize a practice well, you need the right tools, which ideally include mission and vision statements and an action plan with goals and objectives.

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Mission statement

A mission statement can be developed by the ObGyn(s) in your office or in concert with your staff. It should include:

- the "here and now" focus on the current approach to patient care
- why the practice exists (Develop a brief description of your practice, including the desired patient population.)
- the products and services offered and why and how those services are provided.

Here is an example of a mission statement for an ObGyn practice: "Our mission is to provide excellent, exceptional, personalized care for women of all ages in a warm and friendly environment. We incorporate leading-edge technology in our practice and continue to be a leader in obstetrics and gynecology."

Vision statement

A vision statement should be developed in concert with your staff. It should include:

- the "then and there" focus on the historic perspective of your practice
- the ObGyn(s) and staff vision of the future
- what the ObGyn(s) and staff want to create.

The vision statement should energize and excite your personnel, create a shared and meaningful purpose, inspire passion and interest, and convey the values you want to share in your practice.

Here is an example of a vision statement for an ObGyn practice: "We aim to become

the premier obstetrics and gynecology provider to residents of (location) community."

Action plan: Setting goals

To succeed, an ObGyn practice needs to:

- develop targets and challenges reflecting periodic (quarterly) meetings with staff and new entity development in the practice
- establish benchmarks and measurable parameters (How do you compare with other local practices? Set criteria/metrics to assess your progress.)
- ensure that the objectives support the goals (Develop goals and objectives over a defined period of time.)
- revisit the goals (Have they have been met? Do they need revision?)

Goals and objectives are essential for the continued health of your practice. This is all predicated upon developing a competitive advantage and then maintaining it.

Is the environment welcoming?

When we examine a practice from the patient's point of view, a good starting place is with the front desk. Have you looked at your front desk "from the outside in?" In one sense, this is the showcase of your practice.

The first impression: Appointment scheduling

The first impression a patient receives about your practice occurs when she attempts to set up an appointment. Perhaps you might ask someone to call in to schedule an appointment. Is the caller immediately put on hold? Are your personnel courteous on the phone? Can she be seen quickly if she has a problem? How long is the wait for an annual exam? A test run can be very revealing.

Walk in the front door

When a patient walks in the door, does the physical office space radiate a friendly, relaxed atmosphere? Walk through the waiting room, then consultation and exam rooms as if you are a patient seeing it for the first time. Have you created an environment in which patients sense a well-organized office and the esprit de corps of the personnel? Does it look and smell fresh and clean? This all sends a loud and clear positive message about your practice.[1–3]

Here are some suggestions for making a waiting room more inviting:

- Provide a seating arrangement that is "patient centered." For example, semicircular arrangements allow easy viewing of any monitors in the waiting room.
- WiFi is a great addition. Post several signs with the user name and password.
- Offer computers for patients to use to complete registration
- Set up a fish tank. If well-maintained, it can be soothing to many people.
- Display medical information pamphlets, even if they are rarely taken.
- Provide a big screen television that offers information about your practice, including personnel and procedures.

Streaming ads for physician offices are available. One platform, Outcome Health (https://www.outcomehealth.com), provides flat-screen TVs and tablets that show patient education videos.[4] Another vendor, Patient Point (http://patientpoint.com), offers waiting room networks, editorials, and other communications designed to support "the goals of improving healthcare."[5] Other available media include channel news and music programming to relax patients.[6]

Wait times. A patient's perceived wait time and the actual wait time are often quite different. How long she waits to see the ObGyn is "numero uno" with regard to patient satisfaction and can be a key source of annoyance, irritability, stress, and anger.

Does someone inform waiting patients that the ObGyn is running late? Does staff at the front desk or perhaps your medical assistant inquire, "Can I get you anything? The doctor is running late," or "Dr. Jones has just finished delivering a baby. He'll be here in 10 minutes. He'll see you first."

Consultation and exam rooms

Suggestions to develop a relaxing environment in your consultation and exam rooms are[7]:

- decorate the walls with soft, pastel colors
- use "spa aesthetics" to create a colorful

FAST TRACK

Examine your practice from the patient's point of view, from scheduling a first appointment to walking in the front door. Does the environment send a positive message?

atmosphere with appropriate lighting, artwork, and modern furnishings
- present a few magazines neatly and update them periodically
- stock and appropriately maintain the patients rooms with medical supplies
- remember, "Subjects perceive people more positively in beautiful rooms than in ugly rooms."[5]

Set the lead example

The need for open and supportive communication between you and your office staff cannot be overly emphasized. An ideal office staff member understands and shares in the vision, is aware of stated goals and objectives, is responsive to patient needs, and wants to create a win-win environment.

Frequently discuss your expectations with your staff. Expect them to be responsive, courteous, competent, have good communication skills, and be influenced by the appearance of the physical environment. Provide support and educational tools to help them successfully perform their work.

FAST TRACK

The need for open and supportive communication between you and your office staff cannot be overly emphasized

Discover your patients' vision of customer service

Formal measurement of patient satisfaction began with Professor Irwin Press at the University of Notre Dame. Rod Ganey, a sociologist and statistician, then developed the Press Ganey Patient Satisfaction Survey. These points earlier conveyed by Maslow and Mintz[8] addressed the "effects of esthetic surroundings." Color and art proved to be preferences in an esthetically pleasing environment. Additional historical information has been provided by Siegrist, who addressed "the patient experience."[9] He cites the myth that patients do not fill out satisfaction surveys. Indeed they do. Patient satisfaction is not a personality contest but rather a reflection of the health care provider's investment of time and effort to offer patient-centered care. Siegrist also notes that the patient's family plays a key role in how a patient perceives her experience with her health care professional.[9]

The federal government has been actively involved in assessing patient satisfaction in the hospital setting since 2002. This is reflected in the Centers for Medicare and Medicaid Services, the Agency for Healthcare Research and Quality, and Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) surveys. The HCAHPS is a 27-question survey randomly administered to adult inpatients after discharge.[10–12]

The following metrics are often included in patient satisfaction surveys[9,10]:
- rating of hospital care from 0 (lowest) to 10 (highest)
- percentage of patients who would recommend a practice to family and friends
- number of patients who say their health care providers always communicate well
- the number of patients who report that the office is always clean and friendly.

Use of search engines focused on health care patient surveys can provide a number of options for clinicians to use in their practice.

Tips on patient satisfaction

Several interesting tips from the business world can be applied to an ObGyn's practice[14]:
- You will only hear from 4% of unhappy customers.
- One dissatisfied customer tells 9.
- 95% of customers with resolved issues will do business with you again.
- If a problem is not addressed, that patient will tell 10 others.
- Resolve the problem and 5 people will know about it.
- It costs 5 times as much effort to gain 1 new customer.
- Loyal customers in 1 area of service are good prospects for other (new) services.

Tell stories about good, satisfied patients

Sharing the stories of satisfied patients motivates others to consider coming to your

Talking cents: Assessing your practice

To assess the monetary value of your practice, you need to know what contributes to your profit margin and overhead. What investments are the most profitable? Then monitor each segment of the office practice.

Should you proceed with a purchase? Should you take on a new hire? Let's look at one excellent model from the Boston Consulting Group (**FIGURE**) that provides insight into "low and high performance" aspects of business or practice.[1]

In the matrix, **Stars** use large amounts of cash and are leaders in cash generation. Stars lead to development of a **Cash Cow**, which are entities that generate profits and cash with low investment prerequisites. **Dogs** are segments of product and service line(s) that should be carefully reevaluated. A decision must be made to liquidate if the problem cannot be corrected. **Question Marks** have the worst cash characteristics of all and are associated with high demands and low profit margin(s).[1]

SWOT analysis

A SWOT analysis is most helpful when assessing a practice in real time. The basic tenets are[2]:

Strengths:
- prestigious reputation
- technological expertise

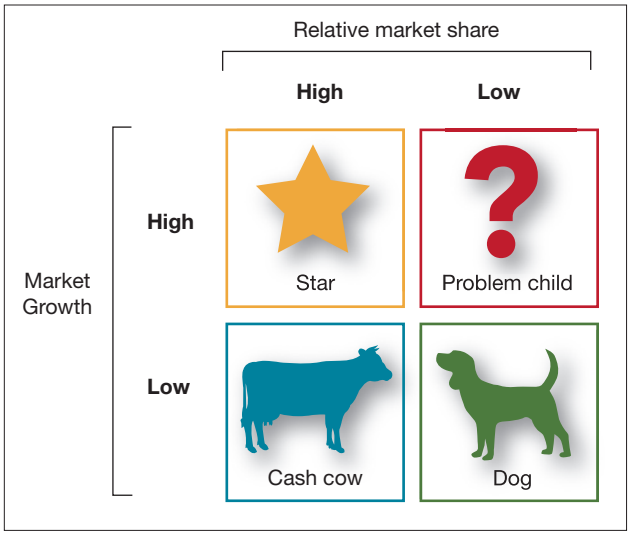
Weaknesses:
- antiquated computer system
- lack of experience in specific areas

Opportunities:
- growing market demand for a specific product or procedure
- provision of unique services

Threats:
- changing demographics
- competitive practices
- changes in health care third-party payers.

The American College of Obstetricians and Gynecologists (ACOG) has developed an "ACOG Medical Home Toolkit" to allow ObGyns to assess how significant the changes regarding payers will be to their practice. Sections include the patient/practice partnership support; clinical care information; community resources; care delivery management; performance measurement and improvement; and payment and finance.[3] The toolkit is available for download from the ACOG website.

FIGURE Boston Consulting Group Matrix provides a useful tool to assess your services[1]



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practice. To develop these stories, offer a "suggestion box" where patients can leave compliments or comments about their experiences. Ask patients to record their positive reviews (be sure to obtain written consent before recording and publishing). Show the videos on the big-screen TVs in your waiting room and include patient reviews (written, audio, and video) on your website.[15]

Reevaluate periodically

Encouraging team spirit makes good business sense. Offer staff members bonuses for coming up with improved processes. Provide educational programs for staff on patient care, technology, etc. If a difficult experience occurs, discuss it openly with staff members without accusing, asking them for suggestions to improve the situation.[16]

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Bottom line

Ensuring that your patients have an outstanding experience is a smart business strategy. A unified approach that includes team members' involvement to create a patient-centered environment will provide a quality experience and encourage patients to recommend your ObGyn practice to others.

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Woman dies following cervical cone biopsy: $4.25M award

A 46-YEAR-OLD WOMAN UNDERWENT a cervical cone biopsy at a Veterans Administration (VA) hospital on July 18. Following the test, significant bleeding occurred. The gynecologic surgeon attempted to control the hemorrhage by injecting ferric subsulfate (Monsel's) solution into the patient's vagina. The bleeding abated, but the patient went into hypovolemic shock. During emergency laparotomy, a uterine perforation and injuries to both uterine arteries were detected. A hysterectomy was performed to stop the hemorrhage. The patient improved at first, but developed sepsis, small-bowel necrosis, and other complications. A bowel resection procedure was performed on July 26. She died on September 5.

ESTATE'S CLAIM: The surgeon's actions were negligent. She removed too much tissue during the biopsy, injured the vaginal and uterine walls, and failed to timely diagnose and appropriately treat the injuries. The ferric subsulfate solution entered the abdominal cavity via the perforation, causing peritonitis and bowel injuries. A pathology report from the bowel resection surgery informed the surgeon that the bowel was not properly reconnected after the damaged portion was removed, but this condition was neither detected intraoperatively nor treated postoperatively.

DEFENDANTS' DEFENSE: The surgeon moved for summary judgment, countering that, as a federal employee, she was exempt from personal liability for the services performed as an employee of the VA. That motion was denied. She then argued that injury to the vaginal/uterine wall is a known complication of the biopsy procedure.

VERDICT: A $4.25 million Illinois verdict was returned in federal court.

Needle stick not reported to patient

A WOMAN DELIVERED A BABY assisted by an on-call ObGyn. When the baby developed fetal tachycardia, the ObGyn recommended expediting delivery and discussed various options and the risks of each option. The mother chose a vaginal forceps delivery. During the procedure, the mother experienced a 3rd-degree perineal laceration and a few minor lacerations, which were repaired. The mother was in pain, so the ObGyn performed a revision repair. During the procedure, the ObGyn accidentally stuck himself with a clean needle. He replaced the needle and changed his glove. The mother reported instant pain relief following revision and was discharged. After the needle incident, the ObGyn's thumb became red and swollen, so he took antibiotics.

Two days after discharge, the patient reported to the ObGyn's office with fever, pain, and a foul odor emanating from the surgery site. She was given the diagnosis of pelvic incisional cellulitis and was taken to the operating room for exploration and debridement. The patient developed septic shock and necrotizing fasciitis. She was placed on a ventilator and underwent 13 surgeries.

PATIENT'S CLAIM: The ObGyn was negligent. The patient claimed breach of duty: the ObGyn did not disclose that his thumb was swollen and that he took antibiotics.

PHYSICIAN'S DEFENSE: There was no breach of duty. He did not feel the need to concern the patient about an injury to himself that did not affect her.

VERDICT: A Kansas defense verdict was returned.

Catheter removal, air embolism: $3.5M settlement

A 44-YEAR-OLD WOMAN underwent gynecologic surgery on April 22. She developed a rectovaginal fistula and other complications. Intravenous antibiotics were required and parenteral nutrition was delivered through a central venous catheter. On May 22, after a hospital nurse removed the catheter, an air embolism developed, causing a brain injury. The patient has a mental disability and residual leg tremors.

PATIENT'S CLAIM: Because of the surgeon's negligence during surgery, a fistula developed. The nurse negligently removed the catheter, causing the embolism.

DEFENDANTS' DEFENSE: The case settled during the trial.

VERDICT: A $3.5 million Illinois settlement was reached, including payments of $1 million from the surgeon and $2.5 million from the hospital.

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

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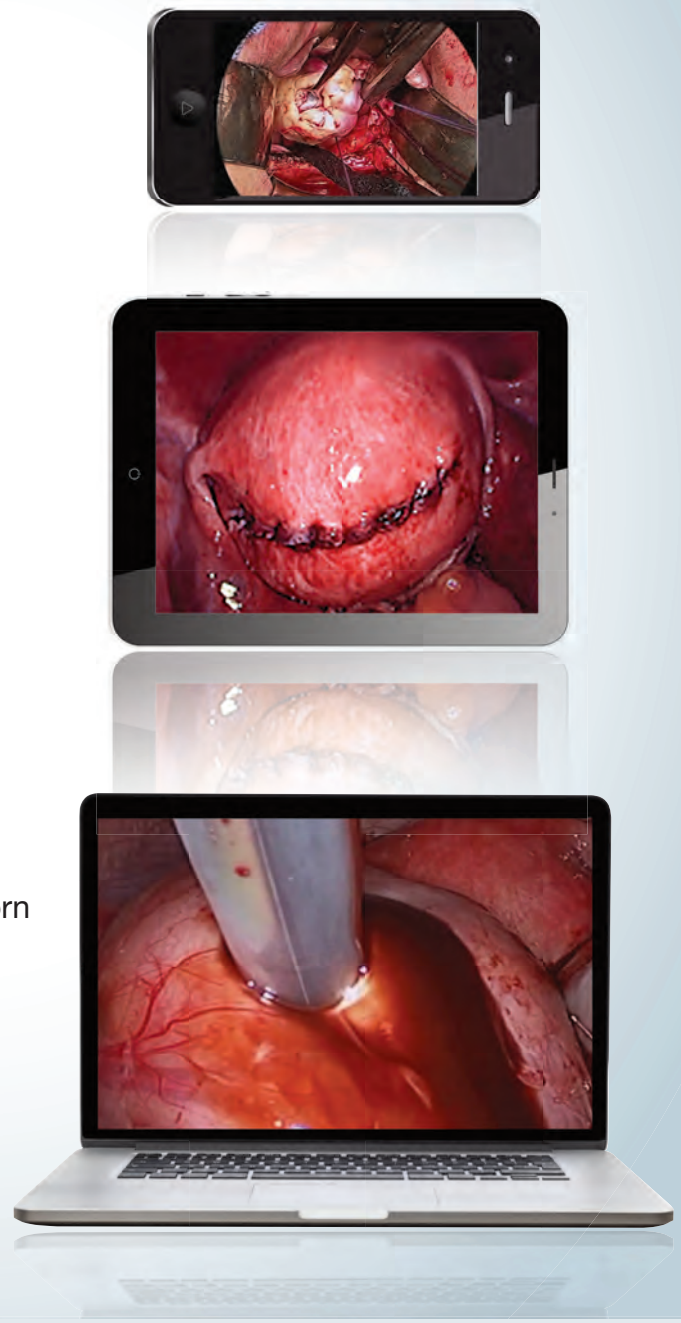

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