

### Important Manuscripts and Updates for Progress in Ob/Gyn 2016

Each division wanted to alert participants to **Choosing Wisely**, an initiative of the ABIM Foundation. Each specialty organization for obstetricians and gynecologists, in collaboration with Consumer Reports, has created lists as resources for clinicians and patients to engage in important conversations about the overuse of medical tests and procedures that provide little benefit and in some cases harm. Our specialty lists are posted to the Progress web site and you can see those and others on the **Choosing Wisely** web site at [www.choosingwisely.org](http://www.choosingwisely.org)

### *Urogynecology*

The faculty of the **Division of Urogynecology and Pelvic Reconstructive Surgery** in the Department of Obstetrics and Gynecology at UAB provides an update regarding one of the more significant events as well as papers of high interest in Urogynecology.

#### **Food and Drug Administration: Up Classification of Mesh**

On January 4, 2016, the FDA announced that transvaginal mesh implants in development for pelvic organ prolapse were being moved from Class II devices (moderate risk device) to Class III devices (high risk device)

- New products for transvaginal mesh prolapse (not currently on the market) are moved from Class II to Class III devices
- New products for transvaginal mesh prolapse must go through a more rigorous PMA process (Pre-market Approval)
- Existing products are required to complete 522 studies.
- Under the 522 Process
  1. New devices can no longer go through the simpler and quicker 510(k) process but will be required to submit rigorous clinical data on any new transvaginal mesh prolapse product brought to market.
  2. With regard to existing transvaginal mesh prolapse products already on the market, data is continuing to be collected through the 522 process.
  3. This effort is being coordinated by American Urogynecologic Society (AUGS) with the FDA and industry through the use of the AUGS Pelvic Floor Disorders Registry (PFDR)
  4. The FDA has already indicated to participating device manufacturers that the 522 studies being performed within the PFDR can qualify as a PMA study for Class III device approval
  5. It is important to note that these FDA changes do not pertain to full-length midurethral slings (retropubic and transobturator) and sacral colpopexy meshes where supportive clinical data exists  
(<http://www.augs.org/p/bl/et/blogaid=246>)

**A Vaginal Bowel-Control System for the Treatment of Fecal Incontinence.** *Obstet Gynecol*,2015;125:540. At one month, 86 percent of women who used Eclipse reported symptoms as “very much better or better”. No device-related serious adverse events were observed, and women experienced a significant improvement in quality of life. The LIFE study results indicate that Eclipse will offer an important new therapeutic option with the use of a vaginal device for women with accidental bowel leakage. **UAB is currently enrolling patients in the LIBERATE Study, a national, multi-center clinical trial evaluating the long-term safety and effectiveness of the next generation of the Eclipse System for the treatment of fecal incontinence with treatment outcomes measured up to 1 year.**

**New United Healthcare policies regarding hysterectomy may impact preauthorization and reimbursement.** *United Healthcare Network Bulletin*, 2015. United Healthcare published a Network Bulletin dated January 2015 announcing a new policy, effective April 6, 2015. Titled “Hysterectomy Prior Notification Requirements”, the policy states the following: “All hysterectomies not coded as outpatient vaginal procedures will require prior authorization. Outpatient

vaginal hysterectomies do not require this authorization prior to surgery. Providers planning other surgical routes for a patient such as laparoscopic, robotic-assisted, or abdominal hysterectomy, or planning an inpatient hospitalization, will be required to call to obtain preauthorization of the planned procedure.” This initiative is reflective of a first consideration of vaginal hysterectomy as it is associated with better outcomes and fewer complications than laparoscopic or abdominal hysterectomies- ACOG Committee Opinion #444 (2009).

**Randomized trial: When a vaginal approach is feasible, the robot offers no advantages for benign hysterectomy.** J Min Invas Gynecol, 2015;22:78. A randomized trial comparing vaginal and laparoscopic hysterectomy vs robot-assisted hysterectomy. A comparison of the cost of vaginal hysterectomy with robot-assisted laparoscopic hysterectomy head to head revealed hospital costs of \$4,579 and \$7,059, respectively, with no other significant differences between approaches. It was concluded that vaginal hysterectomy should be the “first-choice” approach when it is feasible.

**Is hysterectomy alone adequate treatment for POP? Addressing multi-compartment defects at the time of surgery for prolapse.** Am J Obstet Gynecol, 2016;214:262.e1-7. Rates of colpopexy and colporrhaphy at the time of hysterectomy for prolapse have shown that addressing apical support at the time of hysterectomy for pelvic organ prolapse (POP) reduces recurrence and reoperation rates. Often anterior and posterior colporrhaphy are performed **without** a colpopexy and hysterectomy alone is utilized for treatment of prolapse, according to this study where POP was an indication in 1,557 hysterectomies. Results determined that colpopexy and colporrhaphy may be underutilized and are potential targets for quality improvement.

## ***Gynecologic Oncology***

The faculty of the **Division of Gynecologic Oncology** in the Department of Obstetrics and Gynecology at UAB provides an update regarding one of the more significant events as well as papers of high interest in Gynecologic Oncology.

Huh WK, Ault KA, Chelmow D, Davey DD, Goulart RA, Garcia FAR, Kinney WK, Massad LS, Mayeaux EJ, Saslow D, Schiffman M, Wentzensen N, Lawson HW, Einstein MH. Use of primary high-risk human papillomavirus testing for cervical cancer screening: interim clinical guidance. Obstet Gynecol 2015;125:330-7.

*The interim guidance document on primary HPV screening (co-published in the Obstetrics & Gynecology, Gynecologic Oncology, and Journal of Lower Genital Tract Disease). Published in 2015 in response to the recent FDA approval of the Roche Cobas 4800 test for primary HPV testing for cervical cancer screening.*

Four additional manuscripts published in 2015 from our Division:

1. Joura EA, Giuliano AR, Iversen OE, Bouchard C, Mao C, Mehlsen J, Moreira ED Jr, Ngan Y, Petersen LK, Lazcano-Ponce E, Pitisuttithum P, Restrepo JA, Stuart G, Woelber L, Yang YC, Cuzick J, Garland SM, Huh W, Kjaer SK, Bautista OM, Chan IS, Chen J, Gesser R, Moeller E, Ritter M, Vuocolo S, Luxembourg A; Broad Spectrum HPV Vaccine Study. A 9-valent HPV vaccine against infection and intraepithelial neoplasia in women. N Engl J Med 2015 Feb 19;372(8):711-23.

*Randomized, international, placebo-controlled trial assessing the efficacy and immunogenicity of the new 9-valent HPV vaccine in women 16 to 26 years of age.*

2. Smith HJ, Walters Haygood CL, Arend RC, Leath CA 3rd, Straughn JM Jr. PARP inhibitor maintenance therapy for patients with platinum-sensitive recurrent ovarian cancer: a cost-effectiveness analysis. Gynecol Oncol 2015 Oct;139(1):59-62.

*A study to determine the cost-effectiveness of olaparib, a PARP inhibitor, as maintenance therapy for platinum-sensitive recurrent ovarian cancer.*

3. Phippen NT, Leath CA 3rd, Havrilesky LJ, Barnett JC. Bevacizumab in recurrent, persistent, or advanced stage carcinoma of the cervix: is it cost-effective? Gynecol Oncol 2015 Jan;136(1):43-7

*A study to evaluate the cost-effectiveness of incorporating bevacizumab into the treatment regimen for recurrent, persistent, or advanced stage carcinoma of the cervix.*

4. Fuh KC, Secord AA, Bevis KS, Huh W, ElNaggar A, Blansit K, Previs R, Tillmanns T, Kapp DS, Chan JK. Comparison of bevacizumab alone or with chemotherapy in recurrent ovarian cancer patients. *Gynecol Oncol* 2015 Dec;139(3):413-8.

*A study to compare the efficacy of chemotherapy combined with bevacizumab versus bevacizumab alone in recurrent, heavily pretreated epithelial ovarian cancer*

**Useful Tool:** ASCCP Screening Guidelines Mobile App  
<http://www.asccp.org/Bookstore/ASCCP-Mobile-App>

## **Maternal-Fetal Medicine**

The faculty of the **Division of Maternal-Fetal Medicine** in the Department of Obstetrics and Gynecology at UAB provides an update regarding one of the more significant updates as well as papers of high interest in Obstetrics/Maternal-Fetal Medicine.

1. Gyamfi-Bannerman C, Thom EA, Blackwell SC, Tita ATN, Reddy UM, Saade GR, Rouse DJ, McKenna DS, Clark EAS, Thorp JM, Chien EK, Peaceman AM, Gibbs RS, Swamy GK, Norton ME, Casey BM, Caritis SN, Tolosa JE, Sorokin Y, VanDorsten JP, Jain L for the NICHD MFMU Network. Antenatal betamethasone for women at risk for late preterm delivery. *NEJM* 2016 Feb 4 [Epub ahead of print] PMID 26842679
2. Tuuli MG, Liu J, Stout MJ, Martin S, Cahill AG, Odibo AO, Colditz GA, Macones GA. A randomized trial comparing skin antiseptic agents at cesarean delivery. *NEJM* 2016 Feb 4 [Epub ahead of print] PMID 26844840
3. Belfort MA, Saade GR, Thom E, Blackwell SC, Reddy UM, Thorp JM, Tita ATN, Miller RS, Peaceman AM, McKenna DS, Chien EKS, Rouse DJ, Gibbs RS, El-Sayed YY, Sorokin Y, Caritis SN, VanDorsten JP for the NICHD MFMU Network. A randomized trial of intrapartum fetal ECG ST-segment analysis. *NEJM* 2015;373:632-41.
4. Tolia VN, Patrick SW, Bennett MM, Murthy K, Sousa J, Smith PB, Clark RH, Spitzer AR. Increasing incidence of neonatal abstinence syndrome in the US neonatal ICUs. *NEJM* 2015;372:2118-26.
5. Henderson JT, Whitlock EP, O'Connor E, Senger CA, Thompson JH, Rowland MG. Low-dose aspirin for prevention of morbidity and mortality from preeclampsia: A systematic evidence review for the US Preventive Services Task Force. *Ann Intern Med* 2014;160:695-703.
6. Coomarasamy A, Williams H, Truchanowicz E, Seed PT, et al. Randomized trial of progesterone in women with recurrent miscarriages. *NEJM* 2015;373:2141-2148.
7. Magnesium use in obstetrics. Committee Opinion No. 652. ACOG. *Obstet Gynecol* 2016;127:e52-3.
8. Emergent therapy for acute-onset, severe hypertension during pregnancy and the postpartum period. Committee Opinion No. 623. ACOG. *Obstet Gynecol* 2015;125:51-5.
9. Cell-free DNA screening for fetal aneuploidy. Committee Opinion No. 640. ACOG. *Obstet Gynecol* 2015;126:e31-7.

**Choosing Wisely: Five things physicians and patients should question** (see attached handout).

### **New ACOG app** (iTunes and Google Play)

"The EDD Calculator has ACOG guidelines built into the logic, therefore it is the most accurate tool available for ob-gyns and their staff," stated Nathaniel DeNicola, MD, MSHP, FACOG, ACOG Digital & Social Media Expert Consultant and Senior Fellow at the Penn Social Media and Health Innovation Lab. "This is the only app that is based on ACOG guidelines and was beta tested by ob-gyn experts. It's made by ob-gyns, for ob-gyns."

### **NICHD Neonatal Research Network: Extremely Preterm Birth Outcome Data**

[https://www.nichd.nih.gov/about/org/der/branches/ppb/programs/epbo/pages/epbo\\_case.aspx](https://www.nichd.nih.gov/about/org/der/branches/ppb/programs/epbo/pages/epbo_case.aspx)

This Web- based tool is designed to help better inform health care professionals and families about possible infant outcomes (EGA 22-25 wks) based on standardized assessment. The tool uses study data to calculate an infant's probability of health survival. ***These data are not intended to be predictive of individual infant outcomes. Instead, the data provide a range of possible outcomes based on specific characteristics.***

### **NICHD MFMU Network: VBAC Success Calculator**

<https://mfmu.bsc.gwu.edu/PublicBSC/MFMU/VGBirthCalc/vagbirth.html>

VBAC success calculator is based on the MFMU Network Cesarean Registry. This can be used in clinic to estimate a patient's chance of successful trial of labor after caesarean based on information available.

<https://mfmu.bsc.gwu.edu/PublicBSC/MFMU/VGBirthCalc/vagbrth2.html>

This VBAC calculator is from the same database but uses additional information that may be available at the time of admission.

## ***Reproductive Endocrinology and Infertility***

The faculty of the **Division of Reproductive Endocrinology and Infertility** in the Department of Obstetrics and Gynecology at UAB provides an update regarding one of the more significant updates/clinical pearls as well as papers of high interest in REI.

### **PEARLS FOR PRACTICE IMPROVEMENT**

The American Society for Reproductive Medicine (ASRM) in conjunction with the American Board of Internal Medicine Foundation (ABIM) and numerous other specialty boards are asking providers to **“choose wisely”** by identifying tests or procedures commonly used in their field whose necessity should be questioned.

#### Test Physicians and Patients Should Question

- Don't perform routine diagnostic laparoscopy for the evaluation of unexplained infertility.
- Don't perform advanced sperm function testing, such as sperm penetration or hemizona assays, in the initial evaluation of the infertile couple.
- Don't perform a postcoital test (PCT) for the evaluation of infertility.
- Don't routinely order thrombophilia testing on patients undergoing a routine infertility evaluation.
- Don't perform immunological testing as part of the routine infertility evaluation.
- Don't obtain a karyotype as part of the initial evaluation for amenorrhea.
- Don't prescribe testosterone or testosterone products to men contemplating/attempting to initiate pregnancy.
- Don't obtain follicle-stimulating hormone (FSH) levels in women in their 40s to identify the menopausal transition as a cause of irregular or abnormal menstrual bleeding.
- Don't perform endometrial biopsy in the routine evaluation of infertility.
- Don't perform prolactin testing as part of the routine infertility evaluation in women with regular cycle
- Don't order MTHFR genetic testing for the risk assessment of hereditary thrombophilia.

### **KEY PAPERS & TAKE AWAY POINTS**

Letrozole, Gonadotropin, or Clomiphene for Unexplained Infertility (AMIGOS trial) NEJM 2015; 373: 1230-40.

*RCT comparing agents for superovulation/IUI for unexplained infertility. Take home: Letrozole resulted in a lower pregnancy rate but also lower twin/triplet rate than gonadotropins; head-to-head comparison of letrozole and clomiphene not performed, however data suggest clomiphene may provide higher pregnancy rates than letrozole.*

Adverse pregnancy and birth outcomes associated with underlying diagnosis with and without ART. Fertil Steril 2015; 103:1438-45. *Large registry cohort study examining the link between adverse pregnancy outcomes and use of ART. Take home: Underlying infertility appears to contribute to adverse pregnancy outcomes even in the absence of ART treatment.*

Arterial imaging outcomes and cardiovascular risk factors in recently menopausal women. *Ann Intern Med* 2014; 161:249-60. *RCT investigating the cardiovascular impact of MHT started in recently menopausal women (KEEPS). Take home: 4-year study results showed favorable changes in cholesterol and insulin resistance but no measurable change in atherosclerosis progression. Effective for vasomotor symptoms, early data do not support CV protection.*

Uterine fibroids, *New England Journal of Medicine* 2015; 372:1646-55.  
*Excellent review of evidence based medical and surgical treatment of leiomyomas.*

The effect of bipolar electrocoagulation during ovarian cystectomy on ovarian reserve: a systematic review. *AJOG* 2015; 213(5):620-8. *Use of bipolar coagulation during ovarian cystectomy compared with intra ovarian sutures decreased ovarian reserve three months post operatively and may persist during the first year following surgery.*

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OBSTETRICS & GYNECOLOGY