

## A MESSAGE FROM THE PRESIDENT GREETINGS APAOG MEMBERS AND MONITOR READERS!



It's hard to imagine a more turbulent time in our recent history. From the devastating tsunami in Japan to the unrest in the Middle East to mass protests in Wisconsin, there are so many compelling stories competing for our attention in this dynamic time of change. We hope for peaceful and fair resolutions for the political disputes and wish for healing and resolve to the people of Japan.

If you've visited APAOG's website lately, you'll notice our new design. Our website was updated with advanced security and more accessible member services. We've linked with Advanced Practice Jobs to help viewers find positions and post jobs offers. Another new feature is a section of past Monitor articles listed by topic. We think it has a sleeker look and is more efficiently organized, but would love to hear from you! Please send any comments, criticisms or suggestions.

Another important APAOG project has been our professional practice survey. We appreciate all the responses that we have received so far and anticipate that we will be compiling the responses and preparing the final report soon. The profile can often be used to educate other health care professionals as well as patients about the role of Ob/Gyn PAs and can also be used to coordinate hospital or surgical privileges and even negotiate salaries and benefits.

In other news, APAOG participated in the 2010 American Institute for Ultrasound Medicine (AIUM) Ultrasound Practice Forum last year. AIUM invited representatives from multiple medical specialty organizations to discuss the use of ultrasound at the patient's bedside. I spent the day with radiologists, obstetricians, nurses, midwives and nurse practitioners discussing how we use, document and bill for office based ultrasounds. I think most of the time was just debating what can be considered a "limited" ultrasound, but AIUM's objective is to develop guidelines that can promote standardization and consistency among providers. APAOG has been invited to participate on their committee and we are pleased that AIUM recognizes the role that physician assistants perform as ultrasound providers. APAOG was one of six

PA specialty organizations to participate in the AIUM Ultrasound Practice Forum.

Saving the most exciting news for last, mark your calendars for September 15-17, 2011. We will be back in Las Vegas at the new Cosmopolitan of Las Vegas to host our annual conference. We are collaborating with the Association of Reproductive Health Professionals (ARHP) for this event, and it is slated to be THE conference for women's health care providers. Thank you to those who suggested topics. We will keep you updated with registration and speaker information as details are finalized. In the meantime, APAOG will be in Las Vegas again for AAPA's annual conference, which is going to start after Memorial Day this year. We will be hosting a reception and will have a booth in the Exhibit Hall—hope to see you there!

Respectfully yours in service,



Sarah H. Lindahl PA-C



Did you know that APAOG is partnering with the Association of Reproductive Health Professionals (ARHP) to host our annual meeting in conjunction with the *Reproductive Health 2011* conference this year?

We are very excited about the opportunity to be part of this fabulous meeting and to work with ARHP and the authors of Contraceptive Technology to bring you a powerful agenda. We are committed to delivering a scientific meeting offering the latest in reproductive health research plus significant interactive training experiences and practical learning to apply Monday morning when you return to practice. Let's start gearing up for September - here is your Reproductive Health checklist:

- Mark your calendar for September 15-17 to join us at the fabulous Cosmopolitan Resort and Spa in Las Vegas
- Watch for details on APAOG's pre-conference ultrasound training and let Linda Burdette know if you have suggestions for the workshop content
- Take advantage of the opportunity to become a member of both APAOG and ARHP at discounted joint membership rates (for more on joining ARHP for only \$100/year, visit [www.arhp.org/join](http://www.arhp.org/join))
- Visit [www.ReproductiveHealth2011.org](http://www.ReproductiveHealth2011.org) and watch for registration to open in early May

## SURGEON GENERAL CREATES ACTION PLAN TO PROMOTE BREASTFEEDING

So begins the Executive Summary of Surgeon General Regina M. Benjamin's *Call to Action in Support of Breastfeeding*. While Dr. Benjamin acknowledges that breastfeeding is a personal decision each mother must make, she also notes that many women would like to breastfeed or breastfeed longer than they do but lack the support and resources to continue.

According to the surgeon general, there is significant evidence to support breastfeeding exclusively until six months of age. A recent study performed by Children's Hospital in Boston and Harvard Medical School confirmed these findings showing that feeding an infant solid food before four months of age may raise the baby's risk of becoming obese by the toddler years. Yet, many mothers give up breastfeeding well before the six month mark due to difficulty with breastfeeding, lack of support from spouse and family members (grandmothers and other older relatives are highly influential when it comes to breastfeeding and negative comments can significantly undermine a woman's efforts to breastfeed.) and lack of support and resources in the work place.

In issuing this call to action, the Surgeon General further states,

*"Given the importance of breastfeeding for the health and well-being of mothers and children, it is critical that we take action across the country to support breastfeeding."*

The Surgeon General has identified these 20 key action steps to increase breastfeeding.

### **ACTIONS FOR MOTHERS AND THEIR FAMILIES:**

1. Give mothers the support they need to breastfeed their babies.
2. Develop programs to educate fathers and grandmothers about breastfeeding.

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**ACTIONS FOR COMMUNITIES:**

3. Strengthen programs that provide mother-to-mother support and peer counseling.
4. Use community-based organizations to promote and support breastfeeding.
5. Create a national campaign to promote breastfeeding.
6. Ensure that the marketing of infant formula is conducted in a way that minimizes its negative impacts on exclusive breastfeeding.

**ACTIONS FOR HEALTH CARE:**

7. Ensure that maternity care practices around the United States are fully supportive of breastfeeding.
8. Develop systems to guarantee continuity of skilled support for lactation between hospitals and health care settings in the community.
9. Provide education and training in breastfeeding for all health professionals who care for women and children.
10. Include basic support for breastfeeding as a standard of care for midwives, obstetricians, family physicians, nurse practitioners, and pediatricians.
11. Ensure access to services provided by International Board Certified Lactation Consultants.
12. Identify and address obstacles to greater availability of safe banked donor milk for fragile infants.

**ACTIONS FOR EMPLOYMENT:**

13. Work toward establishing paid maternity leave for all employed mothers.
14. Ensure that employers establish and maintain comprehensive, high-quality lactation support programs for their employees.

15. Expand the use of programs in the workplace that allow lactating mothers to have direct access to their babies.
16. Ensure that all child care providers accommodate the needs of breastfeeding mothers and infants.

**ACTIONS FOR RESEARCH AND SURVEILLANCE:**

17. Increase funding of high-quality research on breastfeeding.
18. Strengthen existing capacity and develop future capacity for conducting research on breastfeeding.
19. Develop a national monitoring system to improve the tracking of breastfeeding rates as well as the policies and environmental factors that affect breastfeeding.

**ACTION FOR PUBLIC HEALTH INFRASTRUCTURE:**

20. Improve national leadership on the promotion and support of breastfeeding.

The United States can improve the success of breastfeeding for mothers who wish to do so. However, it is going to take an aggressive, national effort to educate the public on the benefits of exclusive breastfeeding for the first six months of life. Additionally, there will have to be changes in employment environments and community services so that the support breastfeeding mothers need is readily available.

For more information, visit [www.surgeongeneral.gov](http://www.surgeongeneral.gov).

## MORE BENEFITS TO HPV VACCINATION: UPDATED INDICATION EXTENDS PREVENTION OF ANAL CANCERS CAUSED BY HPV TYPES 16 AND 18

In December 2010, the FDA added prevention of anal intraepithelial neoplasia (AIN) grades 1-3 and anal cancer to the indication for the HPV vaccine, Gardasil. Gardasil is now approved to be used for girls, women, boys and men from the ages of 9-26 for the prevention of cervical, vulvar, vaginal and anal cancers caused by HPV types 16 and 18 as well as genital warts caused by HPV types 6 and 11.

Although anal cancer is considered uncommon, there has been a documented increase in reported cases over the past thirty years and in the United States 5,260 new cases are diagnosed each year. In the 1960s, it was believed that anal cancer derived from chronic

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# ASCCP \$5,000 Trainee Research Awards

The American Society for Colposcopy and Cervical Pathology has newly established a research award in the area of lower genital tract disease. The purpose of this award is to provide seed funding to junior investigators to advance knowledge in the field of cervical, vaginal and vulvar disease and to present their research at the ASCCP Biennial Meeting.

## Eligibility:

The applicant must be within a health-related graduate training program at the time the application is submitted (i.e., medical residency, physician's assistant program or certified nurse midwifery program)

The applicant must have written approval from the program director of the training program or institutional administrator to receive a non-educational grant.

## Application Guidelines:

The application must include the following four (4) required components:

- Write the scientific research proposal in eight (8) pages or less and include the following: Hypothesis; Specific Aims; Background and Significance; Experimental Design; and, References.
- A one-page research budget
- Curriculum vitae
- Letter of support from program director, departmental chair or laboratory director

**Application deadline: May 20, 2011**

## Award:

Two (2) awards will be given biennially for \$5,000 each. The awards will include research materials, registration, travel and accommodations to the 2012 ASCCP Biennial Meeting being held March 14–17, 2012, Hyatt Regency Embarcadero, in San Francisco, CA.

Recipients of the awards will be announced no later than June 17, 2011.

Recipients must submit their research abstract electronically to the ASCCP no later than October 28, 2011 in order to receive financial support for the 2012 ASCCP Biennial meeting. Any paper developed as a result of this award must be first submitted for consideration for publication to *The Journal of Lower Genital Tract Disease*. Manuscripts must be submitted prior to January 31, 2012.

## Mail application to:

ASCCP National Office  
Attention: Research Committee  
152 W. Washington St.  
Hagerstown, MD 21740



*The society for lower genital tract disease since 1964*

MARCH 14–17, 2012  
Hyatt Regency Embarcadero  
San Francisco, California

ASCCP  
2012 Biennial  
SCIENTIFIC Meeting

perianal inflammation. However as an increased association was seen with female patients, HPV infection, genital warts, cigarette smoking, lifetime numbers of sexual partners, and HIV infection, it had been noted that anal cancer is more similar to genital malignancies than other gastrointestinal cancers.

Epidemiologic studies have identified that up to 93 percent of anal squamous cell cancers are linked to HPV infection. The spectrum of "high risk" HPV types in the anal canal is similar to those that affect the cervical canal, and HPV type 16 is most frequently isolated stain in anal malignancies. Its presence is predictive for pre-invasive and invasive cancers. Women are more likely to have HPV-associated anal cancer than men.

At this point in time, the United States Public Health Service has not issued any guidelines for anal cancer screening. Some specialists have recommended anal pap smears for men and women infected with HIV. There is a scientific rationale to consider screening in individuals with perianal HPV lesions, women with high grade vulva, vaginal or cervical dysplasia and solid organ transplant recipients. Evaluating the cost effectiveness of screening has been limited to MSM (men having sex with men). Annual screening of HIV positive MSM and screening every 2-3 years for HIV negative MSM provides similar benefits to life expectancy as other strategies for HIV positive patients.

However, despite the established benefits of HPV vaccination, it is estimated that only twenty percent of females between the ages of 11-26 have received the complete series of the vaccine. Dr Neal M. Lonky identified eight barriers to HPV vaccination.

**1. Economic Disparities:** Uninsured and low income women often do not get regular pap smears as they cannot afford them, and often cannot afford the average cost of \$400.00 for each injection. Federal childhood immunization programs only provide coverage until the age of 18.

**2. Fear:** Despite the low rate of adverse events, reports of thromboembolism, sudden death or neurological injury may deter patients from the vaccination.

**3. Long Latency Period:** As the benefits of the vaccine are not readily apparent, patients may not appreciate the need for vaccination.

**4. Cultural and Religious Beliefs:** As the targeted types of HPV are sexually transmitted, there is a concern that vaccination may encourage sexually promiscuity.

**5. Premarket Push:** Aggressive marketing strategies and proposed legislation to mandate the vaccine while it was still in Phase-3 trials may have raised some skepticism and reduced acceptance.

**6. Lack of Legislation:** States that do not mandate the vaccine will have lower vaccination rates, and will be less likely to have funding programs.

**7. Reduced Involvement of Ob/Gyns:** Pediatricians and Primary Care providers are traditionally the primary providers of vaccines. Many Ob/Gyn offices do not have work flows to ensure ordering, reimbursement and follow up for the complete vaccine series.

**8. Failure to Complete the Series:** Cost, side effects and forgetfulness lead many women to abandon the vaccine series.

What are some things you can do to overcome these barriers?

*References:*

Gardasil Prescribing Information, [www.gardasil.com](http://www.gardasil.com)

Lonky, Neal M., 2 Vaccines, 7 Questions that you need answered, OBG Management, Vol 22. No. 8 August 2010 33-46.

Palefsky, JM, Cranston, RD, Anal intraepithelial neoplasia: Diagnosis, screening and treatment, [www.uptodate.com](http://www.uptodate.com), September 16, 2010

Ryan, DP, Willett, CG, Classification and Epidemiology of Anal Cancer, [www.uptodate.com](http://www.uptodate.com), September 9, 2010.

## KUDOS!

Congratulations to APAOG member Rachel Farrell P.A.-C.,L.M. from California for winning the 2011 PA Service to the Underserved PAargon Award. She will be honored at the 39th AAPA Annual Conference at the PAramount Evening reception on June 1, 2011. We are so proud of her and thankful for all her hard work!

# MY WOMEN'S HEALTH ROTATION

*Aleece Fosnight, PA-S III,  
APAOG Student Representative*

When starting a new clinical rotation, I always get really nervous. Will the preceptor be nice? Will the site be good and I get to see lots of cool stuff? Will I have enough time to study? But on the night before my women's health rotation, I wasn't nervous or filled with these kinds of questions. One of my classmates had completed a rotation with the same preceptor for her women's health rotation and had many wonderful things to say about her time spent with Dr. Griffin. Recognizing that women's healthcare held a special place in my heart during my didactic year, I was extremely excited to implement months of reading into hands-on experience. Now, the questions I had were; how many babies will I help deliver? What was the prenatal patient population? Would I be able to find the cervix while performing a pap smear?

I love pregnant bellies and when I saw that the schedule on my first day was filled with prenatal visits, I couldn't wait to splash on the ultrasound jelly and find those fetal heart tones! My first patient was a mother of two expecting her third child, 30 weeks along, and was a pro at these prenatal visits. I was a little nervous and had a hard time finding the baby's heart beat, but with a little guidance from the mom-to-be, I found it! It was a healthy 152 beats per minute. After wiping off her belly and telling her that Dr. Griffin would be in shortly, I walked out the door to find Dr. Griffin in a speed-walker's pace down the hall, shouting, "Let's go, Aleece, baby on the way." I ran quietly down the hall and we took the elevator to the first floor and headed across the street to Suburban Hospital. I quickly changed into scrubs and got back to the birthing room to

see a tiny head poking out for everyone to see. Dr. Griffin acted quickly, suctioning out her mouth and little nose, and then pulled out her shoulders. The miracle of child birth is so amazing and being able to share that experience with the family was very special. I have to admit that I got a little teary-eyed. After all the excitement was over, we made sure mom was doing well and then we headed back to the office. Apparently, this was a normal day for Dr. Griffin.

Back at the office, I went to see a patient, 39 weeks pregnant with her first child with her husband also in attendance. I walked in and started talking to the couple about their soon-to-be-here bundle of joy. Of course, with being first-time parents and one week from her due date, the questions started to pour. What if she goes past her due date? How long will we let her go past her due date? What do we do when her water breaks? What will we have to do at the hospital? At that time, Dr. Griffin poked his head in the room and reassured the couple of all their apprehensions. My next patient was 10 weeks along, first pregnancy and first OB appointment. I started off by introducing myself, explaining what we would be doing at this first appointment and asking if she had any concerns or questions. She seemed a little nervous but once I started feeling for her uterus on the abdominal exam and pulled out the jelly for the Doppler she became very talkative. I explained that sometimes 10 weeks might be too early to find the baby's heart-beat, but we would try and she should not get discouraged if we couldn't find it. I made sure the Doppler was turned on and started the search for some fetal heart tones. My patient got quiet as I said, "There it is. A healthy heart beat." She was still quiet and as I looked up at her face, I could see tears sliding down her cheek. She was so happy to hear her baby's heart beat and it was so special to be the one that allowed her to hear that special sound.

Although vaginal deliveries are very unique, cesarean sections are a whole other ball

game. So my second day started first thing in the morning as Dr. Griffin had several surgeries scheduled: 2 cesareans, a tubal ligation, D&C with endometrial biopsy, a cerclage, plus gynecological appointments to see in the afternoon. Cesarean sections, to me, are a lot more fun because I can be right there in all the action. I got to clamp and cut the umbilical cord, suction his little nose out, and carry him over to the warming bed for pediatrics to assess. Then, I got to staple her incision closed. What an awesome morning! At the next cesarean, the patient also wanted a tubal ligation and after we closed the uterus, we found her fallopian tubes and ovaries, tied the tubes off and cut about an inch segment out. Seeing the female anatomy in a living body is way cooler than seeing the anatomy on a cadaver. We then went across the highway to another hospital for the D&C with endometrial biopsy and then performed a cerclage procedure. Assisting Dr. Griffin with these procedures made me realize the true excitement I have for women's health. We helped a woman deliver a baby, we helped another woman by preventing her from having more babies, helped another woman find out why she was having postmenopausal bleeding and then tightened a women's incompetent cervix so she would be able to carry her baby to term.

My entire women's health rotation was so much fun and I am so excited to be going to the University of Wolverhampton in England for my elective rotation in urogynecology. It is very satisfying to talk with female patients and explain what is going on with their bodies, and I feel honored that they felt comfortable to ask me their personal questions—no matter how weird the question might be! I am looking forward to the possibility of working as an OB/GYN physician assistant and truly making a difference in the lives of my female patients.

# INFERTILITY UPDATE

Sarah Lindahl PA-C

Our practice was recently visited by Reproductive Endocrinologist Louis Weckstein, MD of the Reproductive Science Center of the San Francisco Bay Area in San Ramon, California. Here are some of the pearls he shared for evaluating and referring patients as well as some new trends in assisted reproduction.

As always, the first step in evaluating the infertile patient starts with a good patient history and physical exam. Although a day 3 FSH and Estradiol level has been used to sense ovarian reserve and possible response to stimulation, testing for Anti-müllerian hormone (AMH) is gaining more favor. AMH is expressed by preantral and early antral follicles and reflects the primordial follicle pool. It declines with age and is undetectable at menopause. AMH testing can be performed at any time during the menstrual cycle and can even be drawn on a woman taking oral contraceptives. There is not a consensus regarding the interpretation of levels at this time. However, Dr Weckstein notes in his experience a measurement less than 1.0 represents concern for diminished ovarian reserve and a level of 0.1 indicates almost zero possibility of pregnancy. A result greater than 2.0 generally indicates good fertility, but a level greater than 4.0 is suggestive of PCOS. Some insurance companies are not reimbursing AMH, so prepare your patients to check on coverage or pay out of pocket. Antral follicle counts (AFC) can be obtained with transvaginal ultrasound and if the AFC is less than expected, (See Table 1.) seek earlier referral.

A hysterosalpingogram (HSG) is an optimal initial test to evaluate the uterine cavity and tubal patency. If hydrosalpinx is present, it is recommended to isolate the tube from the uterus as there is a 50% reduction in pregnancy rates with IVF when a hydrosalpinx is present. This can be achieved with a laparoscopic bilateral tubal ligation or with a transcervical approach (Essure® or Adiana®). A hysteroscopy can further evaluate any cavity defects and can resect any submucosal fibroids, polyps or septum if present. As part of the work up for the infertile couple, consider obtaining genetic screening for cystic fibrosis, thalassemia and Jewish genetic disorders as applicable.

Appropriate candidates for referral to a reproductive specialist include women with PCOS or other anovulatory women who have failed to ovulate or conceive after five rounds of clomiphene citrate (clomid) going up to a dose of 150mg. Women who have evidence of ovulation and no other identifying factors of male or female infertility will have higher success rates with artificial insemination and clomiphene citrate than with clomid alone. Women 35 and older will benefit from earlier referral to reproductive specialists. It is now recommended to refer patients with recurrent pregnancy loss to reproductive endocrinologists after two losses rather than three. Addition-

ally, many same sex couples will need assistance to achieve a pregnancy, please make sure your local colleagues will accommodate them.

It is also important to know what your local providers use as a BMI cutoff. BMI guidelines were actually imposed by anesthesiologists at various outpatient surgery sites, but it is in the interest of the patient and the obstetrician to avoid the high risks associated with a pregnancy in an obese woman. Patients should be encouraged to lose weight prior to attempting assisted conception as live birth rates are decreased by about 25% in women with a BMI over 30. Consider referring obese patients for weight reduction surgery, as evidence shows that these women are able to have successful pregnancies with fewer complications. The unfortunate reality is that some women will run down their fertility clock as they work to achieve a healthy weight. Regarding age, any woman over 43 should be counseled to consider egg donation as live birth rates in this age group are less than 5% even with gonadotropin or clomid therapy. It is also recommended to make sure that women over 40 are up to date with clinical breast exams, mammograms and cholesterol screening and it may be beneficial to obtain an echocardiogram in women over 45 to assess cardiac status prior to pregnancy.

Multiple pregnancies continue to be a burden for reproductive endocrinologists and obstetricians. Unfortunately, many patients desire twins and do not seem to understand the risks and are sometimes unwilling to undergo selective reduction of higher order multiples. The Reproductive Science Center of the San Francisco Bay Area established elective single embryo transfer (eSET) as a major initiative for 2011. It utilizes a different nutritional system and requires a highly experienced IVF lab with excellent culture conditions to work with day 5 embryos. These embryos can also be frozen for a subsequent transfer attempt as success rates with frozen embryo transfers are similar to (and sometimes higher than) fresh transfers. Women under 35 or those using donor eggs are often the best candidates for eSET.

Infertility can be a frustrating experience for patients and their partners. Keeping up with current trends and working closely with your local reproductive specialists can provide them with realistic expectations and can ease the process of assisted reproduction.

TABLE 1.

AGE	Expected AFC
25	15
30	13
35	10
40	6

Reference: Louis Weckstein, MD, Personal Communication March 10, 2011.

# FDA APPROVES USE OF 17P FOR PREVENTION OF PRETERM LABOR, BUT AT WHAT!?! COST?

Darline Turner-Lee, PA-C

On February 4, 2011, the US Food and Drug Administration approved the use of 17 alpha OHP (Alpha Hydroxyprogesterone Caproate) injections for the prevention of preterm labor. We in the high risk pregnancy world were jumping for joy! 17P (the name by which the injections are often referred) have been long shown to prevent preterm labor in studies carried out by the National Institute of Child and Health Development and have been used for decades “off label”. Everyone from the **March of Dimes to The American Congress of Obstetricians and Gynecologists (ACOG)** and the **American Academy of Pediatrics (AAP)** and **The Society of Maternal-Fetal Medicine (SMFM)** has recommended that the shots receive this particular indication. So yes, it was a great day when K-V Pharmaceutical Company and its subsidiary Ther-RX received the go-ahead from the FDA to market 17P injections as Makena for the treatment of preterm labor.

But our joy was very short lived. Immediately following approval from the FDA, K-V Pharmaceuticals increased the price of 17P injections from about \$10 per shot to **\$1,500 per shot**. There has been no change to the formulation, no change to the method of administration and no change to how the medication acts once administered. The only change is that the FDA has given exclusive rights to K-V Pharmaceuticals and its subsidiary Ther-RX to market and distribute the 17P injections as Makena. ***Ther-RX has taken what was once a \$150-\$200 (\$10 per injection for approximately 20 injections) treatment and turned it into a \$30,000 treatment.*** To date, the drug is not covered by many insurance companies, so women who need the medication are required to pay for the drug out of pocket. K-V Pharmaceuticals and Ther-RX have taken what is a lifesaving medication for thousands of unborn children and has made it inaccessible to their mothers unless they can pay this “extortion” fee. Additionally, K-V Pharmaceuticals has launched a campaign against compounding pharmacies insisting that they “cease and desist” from compounding 17P.

Outrage has been swift and fiery. Angela Davids who created and runs the website **KeepEmCookin.com** has been following the 17P debate and has posted responses and resources in the news section of KeepEmCookin.com. These news items are truly worth reading because many of the leaders in the field of Maternal, Child and Fetal Health have spoken out vehemently against the excessive rate hike and have demanded that Ther-

RX change their pricing structure. The Presidents of ACOG, AAP and SMFM collaborated and wrote a letter to the Sr. Vice President of Marketing for K-V Pharmaceuticals expressing their outrage. They are encouraging K-V Pharmaceuticals to re-evaluate their pricing structure and to consider making the cost of Makena affordable to the thousands of high-risk pregnant women who need it.

While K-V Pharmaceuticals/Ther-RX has not budged on its price, they have instituted an assistance program for those unable to afford Makena as part of their Makena Care Connection, a one stop resource for patients. Here is a summary of the program provided by KeepEmCookin.com.

The financial support program for Makena offers assistance to both uninsured and insured patients, and is based on income. According to K-V Pharmaceutical:

**Insured patients** with annual household incomes of up to \$100,000 who apply for and are eligible for co-pay assistance will have a co-pay of \$20 or less per injection for Makena.

**Uninsured patients** with annual household incomes of up to \$60,000 who apply for and are eligible for patient assistance will receive Makena at no cost. Uninsured patients with annual household incomes between \$60,000 and \$100,000 will be able to acquire Makena at a cost that is comparable to the average co-pay assigned by commercial insurance plans. Makena will not be carried by retail pharmacies. The prescription process for Makena will be managed by the Makena Care Connection, which is available by calling 1-800-847-3418 from 8 a.m. to 9 p.m. EST, Monday through Friday.

While the Makena Care Connection is a step in the right direction, it in no way atones for the unspeakable markup of 17P by K-V Pharmaceuticals and Ther-Rx. Under this price structure, thousands of women who need 17P to maintain their pregnancies and have a chance at having a healthy full term baby will not receive the treatment that they need. This is a particular situation when our patients need our voices. Please write a letter to your representatives, senators and even the FDA to voice your opposition. The battle wages on.

# REVIEWING THE NEW CDC GROUP B STREP GUIDELINES

In November 2010, The Centers for Disease Control and Prevention issued an update of their 2002 recommendations for Group B Streptococcal (GBS) infection prevention, which called for universal screening of all pregnant women at 35-37 weeks. Although rates of early onset neonatal GBS disease have declined to 0.4 per 1,000, there is still much room for improvement. Currently, 85% of pregnant women in the US are screened and 87% of those who test positive receive antibiotic prophylaxis in labor. Only 63% of women presenting with preterm labor with an unknown GBS status receive antibiotics prior to delivery. Additionally, only 14% of penicillin allergic patients receive appropriate alternatives. The CDC calculates that resistance for erythromycin is 25-32% and 13-20% for clindamycin. Only a small number of clinicians order sensitivity testing for women with a known penicillin allergy, and most labs do not use the correct testing methods. Previous guidelines had not addressed how to approach GBS bacteriuria, nor did they establish the duration of antibiotic therapy required to prevent GBS transmission. In 1992, the American Academy of Pediatrics (AAP) had issued a recommendation to allow for four hours of antibiotic therapy prior to delivery. Recent studies have demonstrated that therapeutic levels of ampicillin are reached five minutes after infusion.

## THE NEW GUIDELINES

The 2010 CDC recommendations have been endorsed by the AAP and well as American College of Obstetrics and Gynecology (ACOG). Here is a brief summary, to read the full document go to <http://www.cdc.gov/groupbstrep/guidelines/guidelines.html>.

### GBS Bacteriuria

Women with GBS bacteriuria greater than 10,000 colony-forming units, should be regarded as GBS positive and should receive prophylactic antibiotics in labor. They do not need to be screened in the third trimester. Women who have colonization greater than 100,000 should be treated with antibiotics for 3-7 days to prevent pyelonephritis.

### Women with a planned C/section

All pregnant women including those with a scheduled C/section should have recto-vaginal GBS screening at 35-37 weeks. Women who test positive for GBS should receive antibiotic prophylaxis in the event of spontaneous rupture of membranes or onset of labor.

### Unknown or Unavailable GBS results

In this situation at the time of labor, antibiotics should be administered if the patient is preterm, has premature rupture of membranes (PROM) longer than 18 hours or a temperature greater than 100.4°F. If available, PCR based Nucleic Acid

Amplification Testing (NAAT) intrapartum rectovaginal testing can be performed. Antibiotics should be administered to women with positive results, or women who develop any of the aforementioned risk factors regardless of the results.

### Preterm labor

Women presenting with PTL or PROM before 37 weeks should have GBS screening performed. Antibiotics should be administered to women with a known positive GBS result, or unknown GBS status. Antibiotics should be discontinued if it is determined that she is not in labor, or the results are negative. Women who test positive do not need to be re-screened and should be treated at the time of true labor. Women with a negative screen should have repeat screening at 35-37 weeks. Patients who present with preterm PROM and are not in active labor should receive GBS prophylaxis for a duration of 48 hours.

### Antibiotic Selection

Penicillin is still the first agent of choice. The recommended dose is 5 million units IV followed by 2.5-3.0 million units every 4 hours. Cefazolin is the preferred alternative for women who have an allergy to penicillin with a mild reaction. Clindamycin may be employed for patients who have an anaphylactic reaction to penicillin if there is documented sensitivity. (It is important to confirm that your lab is employing methods to test for inducible clindamycin resistance.) Erythromycin should not be used. Vancomycin is to be used when clindamycin resistance is encountered. GBS positive patients with an intended cesarean delivery who present in active labor or with ruptured membranes can benefit from 2g of Cefazolin IV, which provides GBS and surgical prophylaxis.

### Time Issues

GBS screening is considered to be accurate for five weeks. If a patient is undelivered five weeks after the testing was performed, it should be repeated. No medically necessary obstetrical procedures should be delayed to achieve 4 hours of antibiotic administration. If a GBS positive woman at term received little to no antibiotic prophylaxis due to a precipitous or extramural delivery, her infant should be monitored for 48 hours and as long as the infant is well appearing and duration of PROM was less than 18 hours. No diagnostic testing is required unless indicated by the infant's condition.

To read the entire CDC report, go to this link: <http://www.cdc.gov/groupbstrep/guidelines/guidelines.html>

### Reference:

Lockwood, CJ, Understanding the new CDC group B streptococcal guideline, Contemporary OB/GYN, January 2011.

# THE BIG V

Sarah Lindahl, PA-C

Although male sterilization is easier, safer, more effective and less expensive than female sterilization, it remains one of the most underutilized methods worldwide. International statistics note that 43 million couples cite a vasectomy as their birth control method while 210 million women employ forms of female sterilization. Only five countries (Bhutan, Denmark, the Netherlands, Great Britain and New Zealand) perform more vasectomies than female sterilization procedures. In the United States, only 20 percent of white men married to a woman of reproductive age report to receiving a vasectomy. This article will review international trends of vasectomy practices and will discuss ways to promote vasectomies to patients and their partners.

Vasectomy use is highest in New Zealand, where 19.3% rely on male sterilization, and a study in the late 1990s noted that more than half of men aged 40-49 had received a vasectomy. Asia boasts a high number of vasectomy recipients with 22.5 million and accounts for 77% of vasectomies worldwide. Vasectomy use is extremely low in developing countries. In sub-Saharan Africa the prevalence is less than 0.1%, and the two African countries with the highest vasectomy rates are Namibia and South Africa at 0.8%. Countries in Latin America and the Caribbean, with the exception of Brazil, Columbia, Guatemala and Mexico, also underutilize vasectomies, with less than 1% of men receiving this procedure.

Although the low vasectomy rate is often thought to be attributed to men's reluctance, studies have noted that more men are expressing a desire to be more involved with family planning; service delivery is a significant barrier. Many countries lack skilled providers, or do not have appropriate facilities for counseling and surgical procedures. Worldwide, vasectomies are more difficult to obtain than any other birth control method.

Additionally, vasectomy seems to be less well known compared to other methods of birth control. There is also misinformation about vasectomies present, where some societies believe that a vasectomy is a form of castration. Misperceptions that a vasectomy will cause impotence diminish sexual pleasure or even decrease physical strength also exist. In certain cultures, a man dictates whether or not his wife will use birth control, and is not expected to be responsible for family planning. Some men may also wish to preserve their fertility to make themselves available to a younger woman who wants to have a family, in the event that they will re-marry.

Multimedia educational campaigns providing proper education on vasectomies have been demonstrated to effectively promote their use. Programs employed in Brazil, Columbia and Guatemala doubled the number of procedures performed. Telephone hotlines can provide a confidential service, and have been well received. Peer-to-peer counseling from men who are satisfied with their choice of a vasectomy is also very effective. Creating an environment in the clinic that is welcoming to male clients or even designating certain hours for counseling, procedures and follow up testing will be likely to increase acceptability.

Although vasectomy is not an available option to women who do not have a stable and monogamous male partner, all providers who discuss contraceptive options to their patients should include vasectomy and should be able to provide accurate information. If male partners present during a prenatal visit, there is a great opportunity to provide direct counseling. Some of the key features to include are:

- It is considered a minor surgical procedure, but is often performed in an office or clinic setting with only local anesthesia. Usually takes about 10-20 minutes
- Some providers are skilled in the "no scalpel" vasectomy, where a pair of dissecting forceps is used to puncture the skin and give the surgeon access to the vas deferens. It is considered to be less traumatic and yields fewer complications
- Men can expect to experience some pain, swelling and bruising for the next few days after the procedure. Using ice packs and a scrotal support can help
- Chronic pain occurs in less than 2% of recipients and is usually limited to less than one year
- It is not effective immediately, and it can take up to 20 ejaculations or 12 weeks to clear sperm from the tubes. An alternative method of birth control is needed until two semen analyses document azospermia
- About 1% of men who have a vasectomy seek a reversal
- Reversal procedures are expensive, usually not covered by insurance and although 90% of attempts result in the man being able to ejaculate sperm, the pregnancy rates are only 50%
- Recanalization of the vas deferens can occur even years after the procedure was performed. It is recommended to repeat the semen analysis every few years.
- Does not provide protection against transmitting STIs

It is always best to get to know your local colleagues to make seamless referrals. In addition to urologists, some family physicians also perform vasectomies and many Planned Parenthood clinics also offer vasectomy services. Here are some additional resources.

**[www.vasectomy.com](http://www.vasectomy.com)** – Provides list of providers who perform vasectomies and reversals

**[www.noscalpelvasectomy.com](http://www.noscalpelvasectomy.com)** – Includes a database of providers who perform no scalpel procedure.

**[www.engenderhealth.org/pubs/family-planning/vasectomy.php](http://www.engenderhealth.org/pubs/family-planning/vasectomy.php)** Technical Publications on Vasectomy training as well as other publications

Resources:

Corey, Liz, The Global Pattern of Vasectomy Use, December 13, 2009, <http://www.managingcontraception.com/qa/questions.php?questionid=3442>

Zieman M, Hatcher RA et al. A Pocket Guide to Managing Contraception. Tiger, Georgia: Bridging the Gap Foundation, 2007.

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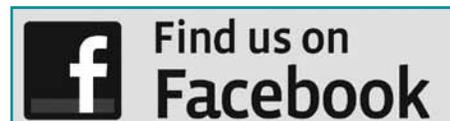
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### **Free Online CME Activity: STI Screening in Gynecologic Practice**

To link to this activity, go to:  
[www.paobgyn.org/Education---Training/CME-Opportunities](http://www.paobgyn.org/Education---Training/CME-Opportunities)

### **Advanced in Health Care for Women over 40**

May 18-20, 2011  
Scottsdale, AZ  
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[www.contemporaryforums.com](http://www.contemporaryforums.com)

### **Southwest Fertility Forum**

May 21-22, 2011  
Hotel ZaZa  
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[www.omniaeducation.com](http://www.omniaeducation.com)

### **AAPA 39th Annual Conference**

May 30-June 4, 2011  
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### **UC Davis Women's Health Conference**

June 6-9, 2011  
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<http://cme.ucdavis.edu/conferences>

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