

COMMENT & CONTROVERSY

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"The new HPV vaccine: What the ObGyn needs to know," an expert panel moderated by Thomas C. Wright, MD (January)

More questions about the HPV vaccine

The roundtable discussion of the new vaccine was outstanding. Here are 3 more questions about how to integrate the vaccine into clinical practice:

1. Is it ethical to deny the vaccine to a woman over age 26 when it could potentially prevent cervical cancer?
2. What about men and their role in "carrying" the virus?
3. Can the vaccine be used as a treatment, as opposed to prophylaxis, for women with abnormal Pap smears?

I am a faculty member at a school that will not allow "off label" use of the vaccine despite daily requests for it. I hope additional data will help us broaden application of the vaccine to all who could benefit from it.

Daniel M. Avery, MD

Associate Professor and Chairman
Department of Obstetrics and Gynecology
University of Alabama School of Medicine
Tuscaloosa, Ala

Cost of HPV vaccine is patient's responsibility

In the roundtable discussion of the new HPV vaccine, the question was raised—"who pays?" Why is it assumed that we will buy this expensive vaccine, administer it to our patients, and then hope to be reimbursed by someone—either the insurance company or the patient? We advise our patients to be vaccinated against HPV, but address the problem of

reimbursement in a practical fashion. We don't buy anything.

With other injectables and related medical items such as the levonorgestrel-releasing intrauterine system (Mirena), the amount reimbursed by some insurers is less than the true cost of the items. Because we lost money every time we administered these medications, including the HPV vaccine (Gardasil), we decided to change course. Now we write a prescription for the medication and instruct the patient to have it filled at her pharmacy. In the

case of IUDs, the items are mailed directly to our office by the company. Medroxyprogesterone acetate and the HPV vaccine are dispensed to the patient, who brings the medications to our office for injection.

By refusing to buy and stock these agents, we put the financial responsibility back where it belongs: on the patient and her insurance company. If every gynecologist did as we do, these medications would be covered like any other drug we prescribe. Then we could get back to the business of delivering good medicine without taking financial risks that belong elsewhere.

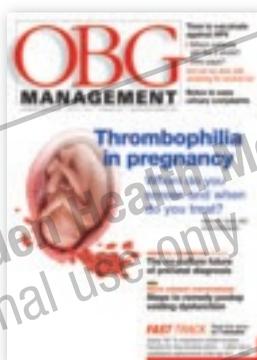
Marion Pandiscio, MD
Bradenton, Fla

Dr. Wright responds:

For now, focus should be on young women

I appreciate Dr. Avery's questions about clinical applications of the new HPV vaccine, and offer the following responses:

1. When considering whether to vaccinate women over age 26, one point in particular is key: The vaccine is not



“Why is it assumed that we will buy this expensive vaccine, administer it to our patients, and then hope to be reimbursed by someone?”

approved for use in this age group, and we lack safety and efficacy data for this application. I believe the vaccine will be proven safe in women over age 26, but its efficacy will probably be lower than in younger women for a couple of reasons. First, as we age, we tend to become less responsive to vaccines. Second, older women are more likely to have been exposed to the vaccine HPV types than young women are.

2. In most instances, men are vectors for the transmission of HPV to women. However, infections typically are spread in a different pattern when they are transmitted sexually, as opposed to other forms of transmission. Core groups are composed of individuals who are especially active, with many sexual partners, and these groups contribute disproportionately to the spread of infection. Although HPV is not restricted to these core groups, a male vaccination program is unlikely to have a significant impact on infections in women until it achieves high coverage rates in men.
3. To date no data indicate that the vaccine can be used as a treatment for women with abnormal Pap tests.

As Dr. Pandiscio points out, reimbursement for expensive vaccines and other medical items is a significant issue for most practitioners—not just ObGyns. Unfortunately, when patients obtain vaccines at a pharmacy, they often pay more for them. There are reports of pharmacies charging up to \$185 per dose for Gardasil, which is more than 50% higher than the wholesale cost.

“Postpartum hemorrhage: Solutions to 2 intractable cases,” by Michael L. Stitely, MD, and Robert B. Gherman, MD (April 2007)

No mention of hypogastric artery ligation?

Although I enjoyed the article on postpartum hemorrhage, I was disappointed that the authors left out hypogastric artery ligation when they discussed man-

agement options for intractable hemorrhage. Bilateral ligation is effective and can spare patients from hysterectomy.

Eric Rothschild, MD
Fort Lauderdale, Fla

Dr. Stitely and Dr. Gherman respond:

Technique is useful in select circumstances

Although we did not mention it in our article, we do agree that hypogastric artery ligation is useful in select circumstances. However, under emergent conditions in the face of ongoing massive hemorrhage, the technique can be risky. The decision to use it should be based on the physician's level of surgical skill and, to a more limited degree, clinical experience. Many chief residents graduating today have rarely, if ever, performed this procedure. Even some seasoned obstetricians have never had the opportunity to practice it. Moreover, small community-based hospitals may not have the surgical assistants or instruments necessary for this technique, whereas the other conservative measures described in our paper, such as the B-Lynch suture, are easily executed by inexperienced providers, involve limited maternal morbidity, and take only a few moments to perform.

Although hypogastric artery ligation can reduce pulse pressure by 50%, maternal risks include vascular injury to the hypogastric artery or iliac vein, ureteral damage, sloughing of the gluteal muscles, and femoral artery insufficiency. There is also a concern that hypogastric artery ligation will fail and could potentially delay hysterectomy, leading to more blood loss. In Clark's series, 57% of patients (11/19) required hysterectomy after hypogastric artery ligation. These patients had more blood loss and significant intraoperative morbidity, compared with patients who underwent hysterectomy without it.¹

Reference

1. Clark SL, Phelan JP, Yeh SY, Bruce SR, Paul RH. Hypogastric artery ligation for obstetric hemorrhage. *Obstet Gynecol.* 1985;66:353-356.

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“There are reports of pharmacies charging up to \$185 per dose for Gardasil, which is more than 50% higher than the wholesale cost”

References

1. Kaunitz AM. Update on menopause. *OBG Management*. 2006;18(5):45-54.
2. Rossouw JE, Anderson GL, Prentice RL, et al. Risks and benefits of estrogen plus progestin in healthy postmenopausal women. Principal results from the Women's Health Initiative. Writing Group for the Women's Health Initiative. *JAMA*. 2002;288:321-333.
3. Berry D, et al. Presented at the 29th annual San Antonio Breast Cancer Symposium, December 14, 2006, San Antonio, Tex.
4. Anderson GL, Limacher M, Assaf AR, et al. Effects of conjugated equine estrogen in postmenopausal women with hysterectomy: the Women's Health Initiative randomized controlled trial. Women's Health Initiative Steering Committee. *JAMA*. 2004;291:1701-1712.
5. Kaunitz AM. Hormone therapy and breast cancer risk—trumping fear with facts. *Menopause*. 2006;13:160-163.
6. Collins JA, Blake JM, Crosignani PE. Breast cancer risk with postmenopausal hormonal treatment. *Hum Reprod Update*. 2005;11:545-560.
7. de Laet C, Oden A, Johansson H, Johnell O, Jansson B, Kanis JA. The impact of the use of multiple risk indicators for fracture on case-finding strategies: a mathematical approach. *Osteoporosis Int*. 2005;16:313-318.
8. McClung MR. Do current management strategies and guidelines adequately address fracture risk? *Bone*. 2006;38(Suppl 2):S13-S17.
9. Mellstrom DD, Sorensen OH, Goemaere S, Roux C, Johnson TD, Chines AA. Seven years of treatment with risedronate in women with postmenopausal osteoporosis. *Calcif Tissue Int*. 2004;75:462-468.
10. Bone HG, Hosking D, Devogelaer JP, et al, for the Alendronate Phase III Osteoporosis Treatment Study Group. Ten years' experience with alendronate for osteoporosis in postmenopausal women. *N Engl J Med*. 2004;350:1189-1199.
11. Black DM, Schwartz AV, Ensrud KE, et al, for the FLEX Research Group. Effects of continuing or stopping alendronate after 5 years of treatment: the Fracture Intervention Trial Long-term Extension (FLEX): a randomized trial. *JAMA*. 2006;296:2927-2938.
12. Odvina CV, Zerwekh JE, Rao DS, Maalouf N, Gottschalk FA, Pak CY. Severely suppressed bone turnover: a potential complication of alendronate therapy. *J Clin Endocrinol Metab*. 2005;90:1294-1301.
13. Ste-Marie LG, Sod E, Johnson T, Chines A. Five years of treatment with risedronate and its effects on bone safety in women with postmenopausal osteoporosis. *Calcif Tissue Int*. 2004;75:469-476.
14. Cummings SR, Black DM, Thompson DE, et al. Effect of alendronate on risk of fracture in women with low bone density but without vertebral fractures: results from the Fracture Intervention Trial. *JAMA*. 1998;280:2077-2082.
15. Black DM, Cummings SR, Karpf DB, et al. Randomised trial of effect of alendronate on risk of fracture in women with existing vertebral fractures. *Lancet*. 1996;348:1535-1541.

"Operative vaginal delivery: 10 components of success," by Michael A. Belfort, MD, PhD (February)

Obesity complicates the operative-delivery decision

Dr. Belfort outlined a strategy for determining the likelihood of success of operative vaginal delivery: "the rule of fifths." I agree that this rule can be very helpful at the time of abdominal palpation, but it can be difficult to apply when the patient is obese. This is discouraging because the incidence of obesity is especially high in the United States, and obese women have an increased incidence of macrosomia and difficult operative delivery.

Another way to determine the likelihood of success is to ask the patient to bear down as you perform a vaginal examination. If the fetal head exhibits mobility and some descent, success is more likely. A "tight fit" would be an indication for a trial of forceps in the operating room.

In some cases, an ultrasound scan may help determine the position of the fetal head.

The most important determination is whether forceps delivery can be performed in the labor and delivery suite or is better limited to a trial of forceps in the operating room. The proper application of the forceps is vital to avoid maternal and fetal injury.

Raymond Michael, MD
Marshall, Minn

Dr. Belfort responds:

Informative abdominal exam is possible even in the obese

I agree that determining the number of fifths of the fetal head above the maternal symphysis pubis may be more difficult in an obese patient. However, even in an extremely obese woman, it is still possible to elevate the pannus and feel the symphysis in most cases (even if an assistant has to help). If there is any doubt that the head is palpated, further efforts may be appropriate to ensure that the fetal head is engaged, including, as Dr. Michael suggested, use of ultrasound.

While I agree in theory that descent of the fetal head with maternal pushing efforts is important, I would not

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4. Al-Sunaidi M, Tulandi T. Adhesion-related bowel obstruction after hysterectomy for benign conditions. *Obstet Gynecol.* 2006;108:1162–1166.
5. Tulandi T, Al-Jaroudi D. Non-closure of peritoneum: a reappraisal. *Am J Obstet Gynecol.* 2003;189:609–612.
6. Tulandi T, Hum HS, Gelfand MM. Closure of laparotomy incisions with or without peritoneal suturing and second-look laparoscopy. *Am J Obstet Gynecol.* 1988;158:536–537.
7. Ellis H. Medicolegal consequences of postoperative intra-abdominal adhesions. *J R Soc Med.* 2001;94:331–332.
8. Franklin R, Haney A, Kettel L, et al. An expanded polytetrafluoroethylene barrier (Gore-Tex surgical membrane) reduces post-myomectomy adhesion formation. Myomectomy Adhesion Multicenter Study Group. *Fertil Steril.* 1995;63:491–493.
9. Haney A, Hesla J, Hurst B, et al. Expanded polytetrafluoroethylene (Gore-Tex surgical membrane) is superior to oxidized regenerated cellulose (Interceed TC7) in preventing adhesions. *Fertil Steril.* 1995;63:1021–1026.
10. Diamond MP, and the Seprafilm Adhesion Study Group. Reduction of adhesions after uterine myomectomy by Seprafilm membrane (HAL-F): a blinded, prospective, randomized, multicenter clinical study. *Fertil Steril.* 1996;66:904–910.
11. Vrijland WW, Tseng LN, Eijkman HJ, et al. Fewer intraperitoneal adhesions with use of hyaluronic acid–carboxymethylcellulose membrane: a randomized clinical trial. *Ann Surg.* 2002;235:193–199.
12. Sekiba K. The use of Interceed (TC7) absorbable adhesion barrier to reduce postoperative adhesion reformation in infertility and endometriosis surgery. Obstetrics and Gynecology Adhesion Prevention Committee. *Obstet Gynecol.* 1992;79:518–522.
13. Azziz R, and the Interceed (TC7) Adhesion Barrier Study Group II. Microsurgery alone or with Interceed absorbable adhesion barrier for pelvic side wall adhesion reformation. *Surg Gynecol Obstet.* 1993;77:135–139.
14. Nordic Adhesion Prevention Study Group. The efficacy of Interceed (TC7) for prevention of reformation of postoperative adhesions on ovaries, fallopian tubes, and fimbriae in microsurgical operations for fertility: a multicenter study. *Fertil Steril.* 1995;63:709–714.
15. DiZerega GS, Verco SJ, Young P, et al. A randomized, controlled pilot study of the safety and efficacy of 4% icodextrin solution in the reduction of adhesions following laparoscopic gynaecological surgery. *Human Reprod.* 2002;17:1031–1038.
16. Hill-West JL, Dunn RC, Hubbell JA. Local release of fibrinolytic agents for adhesion prevention. *J Surg Res.* 1995;59:759–763.
17. Diamond MP. Reduction of de novo postsurgical adhesions by intraoperative precoating with Sepracoat (HAL-C) solution: a prospective, randomized, blinded, placebo-controlled multicenter study. The Sepracoat Adhesion Study Group. *Fertil Steril.* 1998;69:1067–1074.
18. Mettler L, Audebert A, Lehmann-Willenbrock E, Schive-Peterhansl K, Jacobs VR. A randomized, prospective, controlled, multicenter clinical trial of a sprayable, site-specific adhesion barrier system in patients undergoing myomectomy. *Fertil Steril.* 2004;82:398–404.

rely solely on this mobility to determine whether or not a trial of forceps or vacuum is indicated. Because the basovertical diameter of the fetal head can be elongated, it is possible to palpate the leading edge of the skull below the ischial spines and still have an unengaged fetal head. This is exactly the circumstance in which a vaginal examination will give false reassurance of the chance of success. In this circumstance, although part of the skull is below the plane of the ischial spines, the widest diameter of the fetal head (usually the biparietal diameter) is still above the plane of the maternal pelvic brim, and the fetal head is unengaged.

I would argue against moving ahead with a “trial of forceps in the OR” in cases with a “tight fit.” As discussed in the article, significant molding implies stretching of the underlying soft tissue. In my opinion, proceeding with an operative vaginal delivery in the case of a fetus with 3+ molding would be riskier than is justified. Operative vaginal delivery should be offered only when it is almost certain to succeed. For that reason, I would also caution against using a trial of forceps in cases where the outcome is uncertain. Cesarean section may be the safest option in such cases.

I agree completely that liberal use of ultrasound to determine head position and station (if possible) should be encouraged.

I recommend that any forceps delivery that is anything other than an outlet delivery take place in the operating room. In addition, I recommend always having neonatal and anesthesia backup readily available with any operative vaginal delivery attempt unless it is an emergency.

Finally, I agree that the correct application of the forceps is essential. In fact, the most important part of the forceps procedure is what happens before the actual application of traction! If the correct indications have been followed, the patient has been properly assessed and prepared for the procedure, and if all ancillary services are available, the traction effort is usually the least stressful part of the delivery, since it is bound to succeed. ■