CONTRACEPTIVE TECHNOLOGY UPDATE®

A Monthly Update on Contraception and Sexually Transmitted Diseases

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IN THIS ISSUE

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Update on HPV vaccine: Will males be the next ones to receive immunization?

Research indicates vaccine can prevent HPV infection in men

Results from a Phase III study in men ages 16 to 26 indicate that the human papillomavirus (HPV) vaccine Gardasil (Merck & Co.) prevented 90% of external genital lesions caused by types 6, 11, 16, and 18 of HPV.[1]

Merck was scheduled to submit an application to the Food and Drug Administration (FDA) before the end of 2008. The company is seeking approval to market Gardasil for use in males ages 9-26 to prevent genital warts and precancerous growths.

Why vaccinate men against HPV? HPV is one of the most common sexually transmitted diseases (STDs) and is frequently presented clinically as anogenital warts in males and females.[2] There is a high rate of transmission of HPV in female partners of men with pre-existing penile warts, and HPV infection in men has been shown to contribute to HPV infection and

EXECUTIVE SUMMARY

Merck & Co. is pursuing Food and Drug Administration (FDA) approval for use of its HPV vaccine, Gardasil, in men following clinical trial results indicating that the vaccine prevented 90% of external genital lesions caused by types 6, 11, 16, and 18 of HPV.

- Some types of HPV can cause penile cancer or anal cancer. Researchers also have found that many oral cancers in men are associated with HPV. A 2008 clinical trial designed to test therapies for advanced tongue and tonsil cancers found that more than 40% of the tumors in men were infected with HPV.
- If large numbers of girls and women do not obtain the recommended vaccinations, then vaccination of men and boys could play a significant role in lowering infection rates among males and females.

subsequent cervical disease in women.[2]

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In weighing the use of HPV vaccine in men, officials will look at "herd immunity." If large numbers of girls and women do not obtain the recommended vaccinations, then vaccination of men and boys could play a significant role in lowering infection rates among males and females.[4]

To examine use of the Gardasil vaccine in men, scientists designed the Phase III study to determine the efficacy of the vaccine in males against HPV types 6-, 11-, 16-, and 18-related external genital lesions, a composite endpoint that included genital warts (condylomata); penile/perineal/perianal intraepithelial neoplasia (PIN); and penile/perineal/perianal cancer.

In performing the analysis, researchers looked at about 3,400 heterosexual males ages 16 through 23, as well as 600 men ages 16-26 who have sex with men. Men participating in the study were randomized in a 1-to-1 ratio to receive Gardasil or placebo at day one, two months, and six months, with 36 months of planned follow-up. At the time of vaccination, participants had no evidence of genital lesions, no history of genital warts, and five or fewer lifetime sexual partners.

Results indicate the vaccine was 90.4% effective at reducing external genital lesions [three cases in the vaccine group vs. 31 cases in placebo group; 95% confidence interval (CI): 69.2, 98.1; p-value < 0.001]. The three cases seen among those vaccinated were caused by genital warts, resulting in the vaccine being 89.4% effective in preventing genital warts (95% CI: 65.5, 97.9). For PIN, there were no cases in the vaccine group vs. three cases of PIN 1 or PIN 2/3 in the placebo group. No cases of penile/perineal/perianal cancer were detected in the vaccine or placebo group. The study had a mean duration of about 29 months at the time of the analysis.

No vaccine-related serious adverse events were reported in the study. Scientists did note a slightly higher proportion of study participants with injection-site adverse events in the vaccine group (60.1%), compared to placebo (53.7%).[1]

More girls get shot

About 25% of adolescent females received at least one dose of the HPV vaccine in 2007, according to estimates released by the Centers for Disease Control and Prevention (CDC).[5] This was the first year for HPV immunizations to be tracked in the National Immunization Survey. The HPV vaccine received FDA approval in June 2006.

The immunization numbers are good for the

first year of the vaccine, says **Lance Rodewald**, MD, director of the Division of Immunization Services at the CDC's National Center for Immunization and Respiratory Diseases.

When another adolescent vaccine, meningococcal conjugate vaccine (Menactra, Sanofi Pasteur; Swiftwater, PA), was introduced, its first-year uptake was about 11%, says Rodewald. By the second year, it grew to 32%. For the HPV vaccine to record a 25% uptake in the first year is promising, he says.

"It always takes a few years for a vaccine to be widely accepted, but we were pretty pleased with this as an initial one," Rodewald says. "But obviously, we're not going to be satisfied until we have high coverage."

Look to a possible announcement on the status of a potential HPV vaccine candidate. Results of a Phase III study of Philadelphia-based GlaxoSmithKline's Cervarix are on track for completion/data submission to the FDA in the first half of 2009, confirms **Liad Diamond**, company spokeswoman. The company decided to augment its FDA application with the addition of the Phase III study data so they may be included in the U.S. label. **(To read more about the vaccine candidate, see "HPV vaccine: Will U.S. see second vaccine?" *Contraceptive Technology Update*, September 2008, p. 102.)**

The Cervarix vaccine has been approved in 67 countries, including Mexico, Australia, Singapore, the Philippines, and the 27 member countries of the European Union.

The vaccine is targeted to prevent infection and lesions from the two most prevalent cancer-causing types of HPV, types HPV 16 and 18. It is formulated with AS04, a proprietary adjuvant system designed to sustain antibody levels over time.

Published research indicates that the vaccine demonstrated protection up to 4.5 years against persistent infection with HPV 16 and HPV 18 and protection from pre-cancerous lesions.[6] Protection also was demonstrated against infection with the third and fourth most prevalent cancer-causing types of HPV, types 45 and 31.[6]

Scientists also are eyeing use of the Cervarix vaccine candidate in young men. Research looked at 181 Finnish males ages 10-18 randomly assigned to receive Cervarix or a hepatitis vaccine. Findings indicate that Cervarix was effective, but individuals who received it were more likely to report pain and swelling after injections. However, vaccine-related symptoms did not affect compliance with the three-dose course, which was equally high (97%) in both groups.[7]

References

1. Palefsky J, Giuliano A, on behalf of the Male Quadrivalent HPV Vaccine Efficacy Trial Study Group. Efficacy of the quadrivalent HPV vaccine against HPV 6/11/16/18-related genital infection in young men. Presented at the European Research Organization on Genital Infection and Neoplasia International Multidisciplinary Conference. Nice, France; November 2008.
2. Giuliano AR. Human papillomavirus vaccination in males. *Gynecol Oncol* 2007; 107(2 Suppl 1):S24-26.
3. Worden FP, Kumar B, Lee JS, et al. Chemoselection as a strategy for organ preservation in advanced oropharynx cancer: Response and survival positively associated with HPV16 copy number. *J Clin Oncol* 2008; 26:3,138-3,146.
4. Elbasha EH, Dasbach EJ, Insinga RP. Model for assessing human papillomavirus vaccination strategies. *Emerg Infect Dis* 2007; 13:28-41.
5. Centers for Disease Control and Prevention (CDC). Vaccination coverage among adolescents aged 13-17 years — United States, 2007. *MMWR* 2008; 57:1,100-1,103.
6. Harper DM, Franco EL, Wheeler CM, et al. Sustained efficacy up to 4.5 years of a bivalent L1 virus-like particle vaccine against human papillomavirus types 16 and 18: Follow-up from a randomised control trial. *Lancet* 2006; 367:1,247-1,255.
7. Petäjä T, Keränen H, Karppa T, et al, Immunogenicity and safety of human papillomavirus (HPV)-16/18 AS04-adjuvanted vaccine in healthy boys aged 10-18 years. *J Adolesc Health* 2008; in press. ■

Research to examine new contraceptive gel

When it comes to current methods of delivery of hormonal contraception, women now can choose among pill, patch, ring, implant, and intrauterine forms of birth control. Another option is being explored. Antares Pharma, of Ewing, NJ, and the New York City-based Population Council, an international, nonprofit research organization, are moving forward with a Phase II trial of a contraceptive advanced transdermal delivery (ATD) gel.

The gel now under scientific review contains Nestorone, a progestin developed by the Population Council, and estradiol. During its research of Nestorone, Population Council scientists discovered that when it is orally ingested, the body rapidly inactivates it. Since the drug remains active when applied to the skin, the council partnered with Antares Pharma to use its patented gel system, a clear and cosmetically acceptable drug delivery gel. After the gel is applied to a woman's arm, leg,

EXECUTIVE SUMMARY

Antares Pharma and the Population Council are moving forward with a Phase II trial of a contraceptive advanced transdermal delivery gel.

- The gel candidate contains Nestorone, a progestin developed by the Population Council, and estradiol. The Phase II trial of the Nestorone contraceptive gel will determine the lowest safe and effective dose to suppress ovulation.
- The Population Council continues to look at other delivery options of Nestorone, including a vaginal ring, which combines the progestin with ethinyl estradiol; a subdermal implant aimed at use in breast-feeding mothers; and a contraceptive spray.

or abdomen, the drug is slowly absorbed across the skin into the systemic circulation. ***(Contraceptive Technology Update* reported on Nestorone research in "Progestin eyed for use in contraceptive gel," October 2006, pp. 113-115.)**

One other drug on the market uses the ADT technology, says **Paul Wotton**, PhD, Antares Pharma's CEO. It is Elestrin, an estradiol gel from BioSante Pharmaceuticals of Lincolnshire, IL. Approved by the Food and Drug Administration in 2006 for the treatment of hot flashes, Elestrin uses a metered-dose applicator to deliver 12.5 mcg estradiol.

The Phase II trial of the Nestorone contraceptive gel will determine the lowest safe and effective dose to suppress ovulation. Three active strengths of the combination gel will be examined in 18 healthy, ovulating women. At different times during the study, each woman will receive different dosages, with appropriate washout periods between applications.

In conducting the Phase I study, scientists identified an effective dose of Nestorone and estradiol that would consistently result in blood levels that would be expected to provide effective contraception, as well as maintain a woman's normal estrogen levels and bleeding patterns.

"We believe this new formulation combining Nestorone and estradiol is likely to achieve a very high inhibition of ovulation, and has the potential to become a safe and effective contraceptive that would be easy to use and convenient for women," says **Regine Sitruk-Ware**, MD, executive director of research and development at the Population Council.

The Population Council continues to look at other delivery options of Nestorone, says Sitruk-Ware. The most advanced in the research pipeline is a vaginal ring, which combines the progestin with ethinyl estradiol. Researchers concluded a Phase III trial in December 2008, she notes. Earlier research indicates the ring, used on a 21-day-in and seven-day-out regimen, provided women safe and effective contraception.[1]

Council scientists also are studying use of Nestorone in subdermal implants for use in breast-feeding mothers, she reports.

While Nestorone is quite potent when given by nonoral routes, it is destroyed very quickly when it is taken orally, explains Sitruk-Ware. If any small quantity of the drug gets to the milk of the mother who is breast-feeding and is then ingested by the infant, it is destroyed and therefore does not affect the infant, says Sitruk-Ware. This characteristic would be an advantage in providing postpartum contraception, she notes.

The Population Council is in partnership with Acrux, a Melbourne, Australia, pharmaceutical company, to develop a Nestorone contraceptive spray. **(To read more about spray research, see "Spray-on contraceptive moves to next step," *CTU*, May 2006, p. 57.)**

An early pharmacokinetic trial of the transdermal steroid delivery system indicates the spray system has the feasibility of achieving serum levels of Nestorone sufficient to block ovulation and potentially provide effective contraception.[2]

What are some of the qualities of Nestorone that may make it suitable for contraceptive use? "One of them is that it is extremely active," Sitruk-Ware says. "It is one of the most potent for ovulation suppression, compared to other progestins, so we can use a very small dose in a delivery system, like a gel, a spray, or the vaginal ring."

The progestin does not exhibit androgenic properties, notes Sitruk-Ware. This yields an advantage in terms of tolerability.[3] Women could use the drug without developing acne or oily skin, and it would not affect the lipid profile, she states.

References

1. Sivin I, Mishell DR Jr., Alvarez F, et al. Contraceptive vaginal rings releasing Nestorone and ethinyl estradiol: A 1-year dose-finding trial. *Contraception* 2005; 71:122-129.
2. Fraser IS, Weisberg E, Kumar N, et al. An initial pharmacokinetic study with a Metered Dose Transdermal System for delivery of the progestogen Nestorone as a possible future contraceptive. *Contraception* 2007; 76:432-438.
3. Sitruk-Ware R. New progestagens for contraceptive use. *Hum Reprod Update* 2006; 12:169-178. ■

PID in teens ups risk for subsequent STDs

Results from a just-published study indicate that teens who are treated for pelvic inflammatory disease (PID) are at risk for subsequent sexually transmitted infections (STIs) and/or PID for 48 months.[1] What can clinicians do to stem subsequent infection?

PID covers a spectrum of inflammatory disorders of the upper female genital tract, including any combination of endometritis, salpingitis, tubo-ovarian abscess, and pelvic peritonitis.[2] Without treatment, PID can cause permanent damage to the female reproductive organs.

Adolescents already are at high risk for STIs, observes **Jeffrey Peipert**, MD, MPH, MHA, professor in the Department of Obstetrics and Gynecology at the Washington University School of Medicine in St. Louis. Sexually active adolescents have the highest incidence of *Chlamydia trachomatis, Neisseria gonorrhoeae*, and PID of any sexually active age group.[2]

After one episode of STI (either *N. gonorrhoeae, C. trachomatis,* or PID), teens are at increased risk for additional STIs, explains Peipert. Adolescents who have had PID have a lot at stake: With each repeated episode of PID, the rate of infertility increases. Thus, it is extremely important to prevent STIs after an episode of PID, he states.

To make sure that antibiotic treatment is effective, the Centers for Disease Control and Prevention (CDC) recommends that all women diagnosed with PID be re-evaluated within 72 hours. This second visit ensures that patients defervesce (show abatement of fever) and do not have signs of complications,[3] explains **Maria Trent**, MD, MPH, a pediatrician and adolescent medicine specialist at Johns Hopkins Children's Center in Baltimore. Trent served as lead author for the current study. **(See story on p. 18 for CDC recommendations on treatment options.)**

Previous research by Trent and associates indicates that teens often are unable to make these 72-hour follow-up appointments.[4] "Unfortunately, it is during this visit that they receive the comprehensive, patient-centered contraceptive and risk-reduction counseling that cannot be performed during a visit in an urgent/emergency care environment," she explains.

To perform the current study, researchers used a longitudinal approach to assess the frequency of recurrent STIs and/or PID, the average time until subsequent infection after a baseline diagnosis of PID, and age- and insurance-related associations with subsequent diagnoses. Using electronic medical records, the researchers looked at 110 adolescent girls ages 15-21 treated for PID as outpatients in Baltimore pediatric ambulatory sites, with prospective longitudinal follow-up data including subsequent PID diagnoses and/or infections with *N. gonorrhoeae* or *C. trachomatis.* In the four-year study, 80 girls returned for follow-up during the 48-month study period. Under the study protocol, those with confirmed diagnoses of PID were given a course of free medication and asked to return within 72 hours and advised to follow up again at three months and again in six months with a primary care provider.

Of the 80, 27 (34%) were diagnosed with at least one subsequent sexually transmitted infection over a six-month period. Within that 34% subset, eight adolescents had two or more STIs in the six-month period.

Teens need information on STD prevention when it comes to PID, says Peipert. He suggests that counseling messages include the following points:

- Limit the number of sexual partners.
- Always use a condom — consistently and correctly — every time. Research has shown that consistent condom use offers protection (though not absolute) and reduces the chances of repeat PID and chronic pelvic pain.[5]
- Be careful when choosing a new partner. Never have sex with a man with sores, blisters, lumps, bumps, or discharge.

EXECUTIVE SUMMARY

Results from a recent study indicate that teens who are treated for pelvic inflammatory disease (PID) are at risk for subsequent sexually transmitted infections and/or PID for 48 months.

- To make sure that antibiotic treatment is effective, the Centers for Disease Control and Prevention recommends that all women diagnosed with PID be re-evaluated within 72 hours. However, research indicates many adolescents fail to return for the re-evaluation, which usually includes comprehensive, patient-centered contraceptive and risk-reduction counseling.
- Researchers have launched a pilot program that involves showing an educational video to teen girls coming to the hospital emergency department with PID. Scientists also plan to test the value of house calls to patients by a nurse within 72 hours of diagnosis.

• An important way to stem subsequent infections is to be sure your partner was treated. *[Editor's note: For counseling on PID, use a patient handout developed by the Office on Women's Health in the Department of Health and Human Services, available with the online version of this issue at ahcmedia.com. Contact AHC Media Customer Service at customer service@ahcmedia.com or (800) 688-2421 if assistance is needed in accessing the handout.]*

Hopkins researchers are looking at several ways to improve follow-up after PID treatment. They are testing a pilot program that involves showing an educational video to teenage girls coming to the hospital emergency department with PID. The team also plans to test the value of house calls to patients by a nurse within 72 hours of diagnosis.

This series of studies is designed to determine the best and most cost-effective method to ensure that adolescents get the much needed clinical follow-up for PID, explains Trent.

"The final results of these studies are pending, but we hope they will yield data that will enable us to develop alternative public health strategies to protect the reproductive health and future fertility of affected patients," she states.

References

1. Trent M, Chung SE, Forrest L, et al. Subsequent sexually transmitted infection after outpatient treatment of pelvic inflammatory disease. *Arch Pediatr Adolesc Med* 2008; 162: 1,022-1,025.

2. Gray-Swain MR, Peipert JF. Pelvic inflammatory disease in adolescents. *Curr Opin Obstet Gynecol* 2006; 18:503-510.

3. Centers for Disease Control and Prevention, Workowski KA, Berman SM. Sexually transmitted diseases treatment guidelines, 2006. *MMWR Recomm Rep* 2006; 55(RR-11):58-61.

4. Trent M, Judy SL, Ellen JM, et al. Use of an institutional intervention to improve quality of care for adolescents Treated in pediatric ambulatory settings for pelvic inflammatory disease. *J Adolesc Health* 2006; 39:50-56.

5. Ness RB, Randall H, Richter HE, et al. Condom use and the risk of recurrent pelvic inflammatory disease, chronic pelvic pain, or infertility following an episode of pelvic inflammatory disease. *Am J Public Health* 2004; 94:1,327-1,329. ■

Review PID treatment options from the CDC

Following are pelvic inflammatory disease (PID) treatment options from the *Updated Recommended Treatment Regimens for Gonococcal Infections and Associated Conditions — United States, April 2007,* published by the Centers for Disease Control and Prevention.[1] The agency published the updated options to its Sexually Transmitted Diseases Treatment Guidelines, 2006 following the rise of fluoroquinolone-resistant diseases.[2,3] **(To read more on the subject, see the *Contraceptive Technology Update* article, "New recommendations out for gonorrhea treatment," June 2007, p. 64.)**

• **Parenteral treatment.** Parenteral and oral therapy appear to have similar clinical efficacy treating women with PID of mild or moderate severity. Clinical experience should guide decisions regarding transition to oral therapy, which usually can be initiated within 24 hours of clinical improvement.

— Recommended parenteral regimen A: cefotetan 2 g intravenous (IV) every 12 hours; or cefoxitin 2 g IV every six hours plus doxycycline 100 mg orally or IV every 12 hours.

— **Recommended parenteral regimen B**: clindamycin 900 mg IV every eight hours plus gentamicin loading dose IV or intramuscular (IM) (2 mg/kg of body weight), followed by a maintenance dose (1.5 mg/kg) every eight hours. Single daily dosing may be substituted.

— **Alternative parenteral regimens**: ampicillin/sulbactam 3 g IV every six hours plus doxycycline 100 mg orally or IV every 12 hours.

• **Oral treatment.** Oral therapy can be considered for women with mild to moderately severe acute PID, as the clinical outcomes among women treated with oral therapy are similar to those treated with parenteral therapy. Women who do not respond to oral therapy within 72 hours should be re-evaluated to confirm the diagnosis and should be administered parenteral therapy on an outpatient or inpatient basis.

— **Recommended oral regimen**: ceftriaxone 250 mg IM in a single dose plus doxycycline 100 mg orally twice a day for 14 days, with or without metronidazole 500 mg orally twice a day for 14 days; or cefoxitin 2 g IM in a single dose and probenecid, 1 g orally administered concurrently in a single dose, plus doxycycline 100 mg orally twice a day for 14 days, with or without metronidazole 500 mg orally twice a day for 14 days; or other parenteral third-generation cephalosporin (e.g., ceftizoxime or cefotaxime), plus doxycycline 100 mg orally twice a day for 14 days, with or without metronidazole 500 mg orally twice a day for 14 days.

• **Alternative oral regimens.** If parenteral cephalosporin therapy is not feasible, use of

fluoroquinolones (levofloxacin 500 mg orally once daily or ofloxacin 400 mg twice daily for 14 days) with or without metronidazole (500 mg orally twice daily for 14 days) may be considered if the community prevalence and individual risk of gonorrhea is low. (See "Gonococcal Infections in Adolescents and Adults" in *Sexually Transmitted Disease Treatment Guidelines,* 2006.) Tests for gonorrhea must be performed prior to instituting therapy, and the patient must be managed as follows if the test is positive:

- If nucleic acid amplification test is positive, parenteral cephalosporin is recommended.
- If culture for gonorrhea is positive, treatment should be based on results of antimicrobial susceptibility. If isolate is fluoroquinolone-resistant *N. gonorrhoeae,* or antimicrobial susceptibility cannot be assessed, parenteral cephalosporin is recommended.

Although information regarding other outpatient regimens is limited, amoxicillin/clavulanic acid and doxycycline or azithromycin with metronidazole have demonstrated short-term clinical cure. No data have been published regarding the use of oral cephalosporins for the treatment of PID.

References

1. Centers for Disease Control and Prevention (CDC). Update to CDC's sexually transmitted diseases treatment guidelines, 2006: Fluoroquinolones no longer recommended for treatment of gonococcal infections. *MMWR* 2007; 56:332-336.
2. Workowski KA, Berman SM. Sexually transmitted diseases treatment guidelines, 2006. *MMWR Recomm Rep* 2006; 55(RR-11):58-61. ■

At-home test checks post-vasectomy fertility

EXECUTIVE SUMMARY

The SpermCheck Vasectomy diagnostic test from ContraVac now is poised to enter the commercial market. The device, which gained approval from the Food and Drug Administration in March 2008, will enable men to test their post-vasectomy fertility status at home rather than requiring the patient to return to the physician's office or a laboratory.

- Most physicians require two post-vasectomy sperm tests to determine fertility status. However, research indicates many do not return post-procedure for a semen analysis.
- The testing device uses monoclonal antibodies that bind specifically to the SP-10 protein to measure the amount in nanograms of SP-10 protein present, which yields a direct correlation to the number of sperm present.

How many of your patients rely on vasectomy for contraception? About 500,000 vasectomies are performed each year in the United States; about one out of six U.S. men over age 35 has been vasectomized, with prevalence increasing with education and income.[1,2]

Vasectomy represents one of the most cost-effective methods of contraception, along with the copper-T and levonorgestrel (LNG) intrauterine devices (IUDs).[1] Recent research calculated to estimate the relative cost-effectiveness of contraceptives in the United States from a payer's perspective found that vasectomy ($713) falls between the copper-T IUD ($647) and the LNG IUD ($930) as the three least expensive birth control methods over time.[3]

Most physicians require two post-vasectomy sperm tests to determine fertility status. However, research indicates many do not return post-procedure for a semen analysis. Results from one study indicate that 25% of men who had vasectomies at a Cleveland clinic provided no follow-up semen specimens, and only 21% followed the full instructions to provide two consecutive negative semen analyses, while results of another study show 34% of men never returned to a Michigan private urological practice following their sterilization procedures.[4,5] **(For the data, see "Men are missing in action when it comes to post-vasectomy testing," *Contraceptive Technology Update,* July 2006, p. 73.)**

Patients now can check their post-vasectomy sterility at home, as the SpermCheck Vasectomy diagnostic test is now poised to enter the commercial market. The device, which gained Food and Drug Administration approval in March 2008, will enable men to test their post-vasectomy fertility status at home rather than requiring them to return to the physician's office or a laboratory. By placing a few drops of the man's semen in the well of the test device, SpermCheck Vasectomy is designed to return accurate results of negative or positive in less than 10 minutes after the semen sample is added to the device. A negative result indicates a sperm concentration is below 300,000 sperm per milliliter of semen, and it is the desired outcome when testing a man who has undergone a vasectomy.

Following vasectomy, men are required to return to the physician, usually for two follow-up visits to monitor their sperm count, notes **John Herr**, PhD,

director of the University of Virginia Center for Research in Contraceptive and Reproductive Health, and the founder of ContraVac, both based in Charlottesville, VA. Many men do not comply, and pregnancy may occur in the post-vasectomy period before sperm has been "cleared" from the system, Herr explains.

"With a SpermCheck test, a man can take the device home after the operation and perform the test at home, or purchase it directly from the company or in a drug store, eliminating the need to return to the doctor's office," says Herr. "Thus, the device is predicted to improve the determination of the exact timing when the man can engage in safe sex after the operation."

In the laboratory, Herr and research associates worked to identify a gene, named ACRV1, that encoded a protein that could serve as a sperm-specific biomarker. The protein, known as sperm protein-10 (SP-10), is soluble and highly expressed, which makes it an ideal target for diagnostic testing, as in the SpermCheck Vasectomy home test. The testing device uses monoclonal antibodies that bind specifically to the SP-10 protein to measure the amount in nanograms of SP-10 protein present, which yields a direct correlation to the number of sperm present.[6]

SpermCheck Vasectomy is calibrated to give a positive result when the sperm concentration is greater than 250,000/milliliter (ml), which is a level associated with little or no risk of causing pregnancy. This concentration corresponds to one sperm or fewer per standard high-power microscopic field.

In the clinical trial of the device, researchers used SpermCheck to evaluate a cohort of 144 post-vasectomy semen samples. The test achieved an accuracy rate of 96% in identifying whether sperm counts were greater or less than a threshold of 250,000 sperm per ml. Results indicate SpermCheck to be 100% accurate in identifying whether sperm counts were greater or less than 384,000 sperm per ml.[7]

The test is easy to use, research indicates. In the consumer study of SpermCheck, 109 lay volunteers demonstrated its ease of use. Volunteers obtained the correct or expected test result in every case and achieved a 97% correct response rate on a 20-question survey about the test.[7]

It is important for patients to understand that failures can occur with vasectomies. Research estimates there is a probability of 11 failures per 1,000 procedures over two years; half of the failures occurred in the first three months after the vasectomy, and no failures occurred after 72 weeks.[8]

ContraVac is in talks with biotechnology companies who are interested in national distribution of SpermCheck Vasectomy. The company is close to finalizing distribution terms, reports **Ed Leary**, ContraVac president.

"These companies have their own sales force that call on urologists," he says. "We envision our primary sales channel as our national distributor selling to the urologist, who will sell to the patient following his vasectomy procedure."

Depending on the distribution agreement, Leary estimates retail sales price (direct to consumers) for a two-test kit at $39.99, with provider price estimated at about $29.99. Discounted pricing will be available for volume purchasers, he says. The company is looking at handling consumer orders via telephone, as well as its web site, www.contravac.com.

References

1. Haws JM, Morgan GT, Pollack AE, et al. Clinical aspects of vasectomies performed in the United States in 1995. *Urology* 1998; 52:685-691.
2. Department of Health and Human Services. Facts About Vasectomy Safety. Fact sheet. Accessed at: www.nichd.nih.gov/publications/pubs/vasectomy_safety.cfm.
3. Trussell J, Lalla AM, Doan QV, et al. Cost effectiveness of contraceptives in the United States. *Contraception* 2009; 79:5-14.
4. Dhar NB, Bhatt A, Jones JS. Determining the success of vasectomy. *BJU Int* 2006; 97:773-776.
5. Maatman TJ, Aldrin L, Carothers GG. Patient noncompliance after vasectomy. *Fertil Steril* 1997; 68:552-555.
6. Estabrook M. U.Va. Researcher's Sperm-Check Home Test Receives FDA OK. Press release. March 5, 2008. Accessed at www.virginia.edu/uvatoday/newsRelease.php?id=4397.
7. Klotz KL, Coppola MA, Labrecque M, et al. Clinical and consumer trial performance of a sensitive immunodiagnostic home test that qualitatively detects low concentrations of sperm following vasectomy. *J Urol* 2008; 180:2,569-2,576.
8. Jamieson DJ, Costello C, Trussell J, et al. The risk of pregnancy after vasectomy. *Obstet Gynecol* 2004; 103:848-850. ■

HIV testing increases, but more is needed

Two years after the government implemented routine HIV testing for all patients ages 13-64 without regard to risk, public health officials say improvements have been made, yet still one in five people infected with the AIDS virus is unaware of his/her status.[1]

"With HIV, ignorance is not bliss; those who are unaware of their infection cannot seek treatment

EXECUTIVE SUMMARY

Some 300 HIV researchers, providers, and policy-makers gathered at the 2008 National Summit on HIV Diagnosis, Prevention, and Access to Care to share new data on the advances and barriers to early, routine HIV testing for all patients ages 13-64 without regard to risk, which is considered a key to slowing the spread of the disease.

- The recommendations for routine screening without regard to risk issued by the Centers for Disease Control and Prevention have been adopted by several professional organizations, including the American College of Obstetricians and Gynecologists in August 2008 and the American College of Physicians in December 2008.
- Several states have changed or are changing laws to allow for routine testing. Since 2006, 11 states have removed requirements for separate written consent.

and are at least three times more likely to transmit the virus," says **Veronica Miller**, PhD, director of the Washington, DC-based Forum for Collaborative HIV Research. "Two years after the Centers for Disease Control and Prevention [CDC] recommended routine testing, initial successes show its potentially powerful impact, but major barriers keep it from being the national norm."

The forum, an independent public-private partnership designed to facilitate discussion on emerging issues in HIV research, convened the 2008 National Summit on HIV Diagnosis, Prevention, and Access to Care in Arlington, VA. Summit partners included the HIV Medicine Association in Arlington, VA; the CDC in Atlanta; Office of AIDS Research in Bethesda, MD; Kaiser Permanente in Oakland, CA; Human Resources and Services Administration in Rockville, MD; and the American Academy of HIV Medicine, National Black Gay Men's Advocacy Coalition, and Veterans Affairs (VA), all based in Washington, DC.

Some 300 HIV researchers, health care providers, and policy-makers gathered at the summit to share new data on the advances and barriers to early, routine HIV testing, which is considered a key to slowing the U.S. epidemic, which now encompasses more than 1.1 million Americans living with HIV.[1]

Numerous examples of progress toward HIV screening in health care settings have been noted since the release of the CDC's recommendations in Septembe, 2006, reports **Bernard Branson**, MD, associate director for laboratory diagnostics in the Divisions of HIV/AIDS Prevention in the CDC's National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention.

The recommendations for routine screening without regard to risk also have been adopted by several professional organizations, including the American College of Obstetricians and Gynecologists (ACOG) in August 2008 and, most recently, the American College of Physicians in December 2008, he says.[2,3]

Many public health officials have taken steps to expand HIV screening, says Branson. Numerous localities and facilities have implemented testing initiatives, such as citywide testing initiatives in New York City and Washington, DC, to routine testing in emergency departments and health systems across the nation, he states.[4]

Several states have changed or are changing laws to allow for routine testing, Branson notes. Since 2006, 11 states have removed requirements for separate written consent, states Branson. They are: Arizona, California, Iowa, Illinois, Indiana, Louisiana, Maine, Maryland, New Hampshire, New Mexico, and North Carolina. *(Editor's note: To check your state's requirements, visit the web site for the National HIV/AIDS Clinicians' Consultation Center, www.nccc.ucsf.edu. Under "Featured Highlights," click on "Updated Compendium of State HIV Testing Laws.")*

A recent nationwide study of VA hospitals showed that fewer than 10% of inpatients and fewer than 5% of outpatients were tested during the year ending Sept. 30, 2006. Look to see VA testing numbers change: In October 2008, Congress passed and President Bush signed into law a repeal of an earlier prohibition of widespread HIV testing programs and requirements for separate written consent in the VA health system, says Branson. The VA is working to revise its internal guidelines, according to information presented at the 2008 summit.[5]

Progress is being made on the reimbursement front, reports Branson. An increasing number of insurers provide reimbursement for HIV screening, and a recent California law requires that all health insurers in that state must pay for HIV screening, he states.

"While more work remains to be done, we are encouraged by the progress that we have seen to date," states Branson.

References

1. Centers for Disease Control and Prevention (CDC).

HIV prevalence estimates — United States, 2006. *MMWR* 2008; 57:1,073-1,076.

2. American College of Obstetricians and Gynecologists. ACOG committee opinion. Routine human immunodeficiency virus screening. *Obstet Gynecol* 2008; 112 (2 Pt 1):401-403.

3. Qaseem A, Snow V, Shekelle P, et al. Screening for HIV in health care settings: A guidance statement from the American College of Physicians and HIV Medicine Association. *Ann Intern Med* 2008; Nov 30. [Epub ahead of print.]

4. Branson BM. Overview of routine/expanded HIV testing in the U.S. Presented at the 2008 National Summit on HIV Diagnosis, Prevention, and Access to Care. Arlington, VA; November 2008.

5. Valdiserri RO, Rodriguez F, Holodniy M. Frequency of HIV screening in the Veterans Health Administration: Implications for early diagnosis of HIV infection. *AIDS Educ Prev* 2008; 20:258-264. ■

Advocates press agenda for new administration

By **Adam Sonfield**
Senior Public Policy Associate
Guttmacher Institute
Washington, DC

With the inauguration of President Barack Obama and with expanded Democratic majorities in both chambers of Congress, reproductive health supporters — in the administration, in Congress, and outside the government — are entering the new year with renewed optimism.

Although policy-makers will need to devote considerable attention to the economy, the wars in Iraq and Afghanistan, and other priorities, they also will look to reverse eight years of setbacks for reproductive health, and even make real progress.

Anticipating the change in administration, a coalition of 63 national organizations supporting women's and reproductive health spent 2008 working on a unified proposed agenda for the president's first 100 days and beyond. The agenda was submitted to the president's transition team in November and published on the transition team's web site in accordance with its policy of transparency.[1] *(Editor's note: The Guttmacher Institute is among the list of co-signers.)*

Several items on the coalition's proposed agenda were ones that the new president could accomplish in his first days in office (and, indeed, they might already have been accomplished by the time this column sees print). One expected action is an executive order rescinding the "global gag rule," which denies U.S. family planning funds to indigenous foreign organizations that use their own money for abortion-related services, information, or advocacy. President Obama also is expected to signal his intent to restore a U.S. contribution to the United Nations Population Fund (UNFPA).

The Obama administration, and perhaps Congress as well, is expected to move swiftly to reverse a "midnight" regulation that expands the right of health care personnel and institutions to refuse to provide or assist in the provision of services on moral or religious grounds. The Department of Health and Human Services finalized the rule in December 2008, despite receiving more than 200,000 letters in opposition from the general public and from a long list of medical professional associations, state officials, members of Congress (including Obama himself), advocacy groups, and even other federal agencies. Critics of the rule cite its potential to impede patients' access to necessary services and information, in the field of reproductive health and far beyond, and its conflicts with established standards of medical ethics and the government's own antidiscrimination policies.

Funding on way?

As the administration works to submit a FY 2010 federal budget, the reproductive health coalition is hoping to make up for eight years of stagnant funding. It is requesting major increases

COMING IN FUTURE MONTHS

■ Female condom gains footing

■ Do oral contraceptives affect sex drive?

■ HIV physician shortage predicted

■ Don't skip health behavior talks with teens

■ How to reach Hispanic immigrants with safe-sex message

for domestic and international family planning, as well as for sexually transmitted infection (STI) prevention and maternal and child health programs, including more than double the current appropriation for the Title X national family planning program (to $700 million) and for international family planning assistance (to $1 billion).

The budget also gives the president an opportunity to support the establishment of new programs and the reversal of current legislative restrictions. To that end, the coalition's agenda asks that the budget "assume" that Congress will act to require all states to expand Medicaid coverage of family planning services up to the same income eligibility levels used for pregnancy-related care. That move would help women prevent 500,000 unplanned pregnancies annually and, in the process, achieve considerable federal and state savings. President Obama was a co-sponsor of such legislation in the Senate.

At the same time, advocates are asking that the president signal his opposition to a range of perennial "riders" on the annual appropriations laws that bar federal funding for abortion in almost any circumstance under Medicaid and numerous other programs. They also are looking for a request to defund abstinence-only education programs, which have received more than $1.3 billion from the federal government despite mounting evidence of their ineffectiveness and potential for harm. They hope eventually to replace those programs with new investments in proven, comprehensive sex education that promotes abstinence while providing scientifically accurate information about contraception and STI prevention.

The coalition's proposed agenda includes several additional priorities, for the first 100 days of

CNE/CME Instructions

Physicians and nurses participate in this continuing medical education/continuing education program by reading the articles, using the provided references for further research, and studying the questions at the end of the issue. Participants should select what they believe to be the correct answers and refer to the list of correct answers to test their knowledge. To clarify confusion surrounding any questions answered incorrectly, please consult the source material. After completing this activity with the **June** issue, you must complete the evaluation form provided and return it in the reply envelope provided in that issue to receive a certificate of completion. When your evaluation is received, a certificate will be mailed to you. ■

CNE/CME Questions

After reading *Contraceptive Technology Update*, the participant will be able to:

- **identify** clinical, legal, or scientific issues related to development and provisions of contraceptive technology or other reproductive services.
- **describe** how those issues affect services and patient care.
- **integrate** practical solutions to problems and information into daily practices, according to advice from nationally recognized family planning experts.

5. According to results from the National Immunization Survey, how many U.S. adolescent females received at least one dose of the HPV vaccine in 2007?

A. 10%
B. 15%
C. 20%
D. About 25%

6. What are the hormonal components in the contraceptive gel under development by the Population Council and Antares Pharma?

A. Nestorone and estradiol
B. Nestorone and ethinyl estradiol
C. Dienogest and estradiol
D. Dienogest and ethinyl estradiol

7. To make sure that antibiotic treatment is effective for treatment of PID, the Centers for Disease Control and Prevention recommends that all women diagnosed with PID be re-evaluated within what time frame?

A. 24 hours
B. 72 hours
C. One week
D. Two weeks

8. What is the protein marker used in the SpermCheck Vasectomy test?

A. Sperm protein (SP)-A RAH
B. SP-17
C. SP-10
D. SP-11

Answers: 5. D; 6. A; 7. B; 8. C.

the Obama presidency and beyond. High on the list of shorter-term requests are regulatory and administrative action to reverse harmful and unscientific decisions made by the Bush administration, including those that:

• increased the price of birth control and other drugs at college health centers and many other safety net providers;

• restricted or limited women's access to and information about emergency contraception;

• hindered HIV prevention efforts under the U.S. President's Emergency Plan for AIDS Relief.

Reproductive health advocates also have joined the far broader chorus of voices lending their support to the president's call for health care reform, and emphasized the importance of comprehensive, high-quality, and affordable health care for all. This goal, and many others, will require considerable cooperation, patience, and political capital, particularly in a time of war and recession, and with a new president committed to seeking common ground and bipartisanship.

Reference

1. Advancing Reproductive Rights and Health in a New Administration; November 2008. Accessed at http://otrans.3cdn.net/6b265fe24790d11598_f7m6bwstn.pdf. ■

2008 SALARY SURVEY RESULTS

CONTRACEPTIVE TECHNOLOGY UPDATE®

A Monthly Update on Contraception and Sexually Transmitted Diseases

Family planning providers record little uptick in 2008 paychecks

Explore options to open up career opportunities

Good news: About 75% of respondents to the 2008 *Contraceptive Technology Update* Salary Survey say they received increases in their paychecks in the last year. Bad news: The majority (57%) saw only a 1%-3% increase. **(See "In the past year, how has your salary changed?" graphic on p. 2.)**

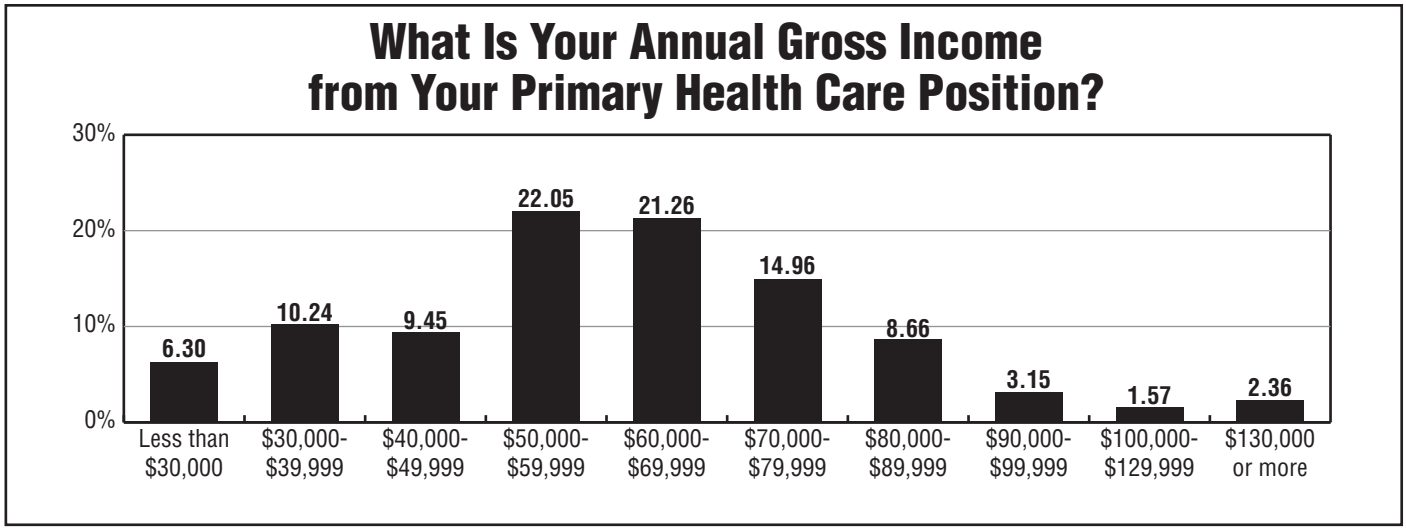
The nursing profession is well represented in the survey; 49% of respondents identified themselves as nurse practitioners, with 16% as registered nurses, and 6% as nurse-midwives. Administrators comprised about 19% of the current year's responses. About 5% identified themselves as health educators, with 3% as physicians. Less than 1% said they were physician assistants.

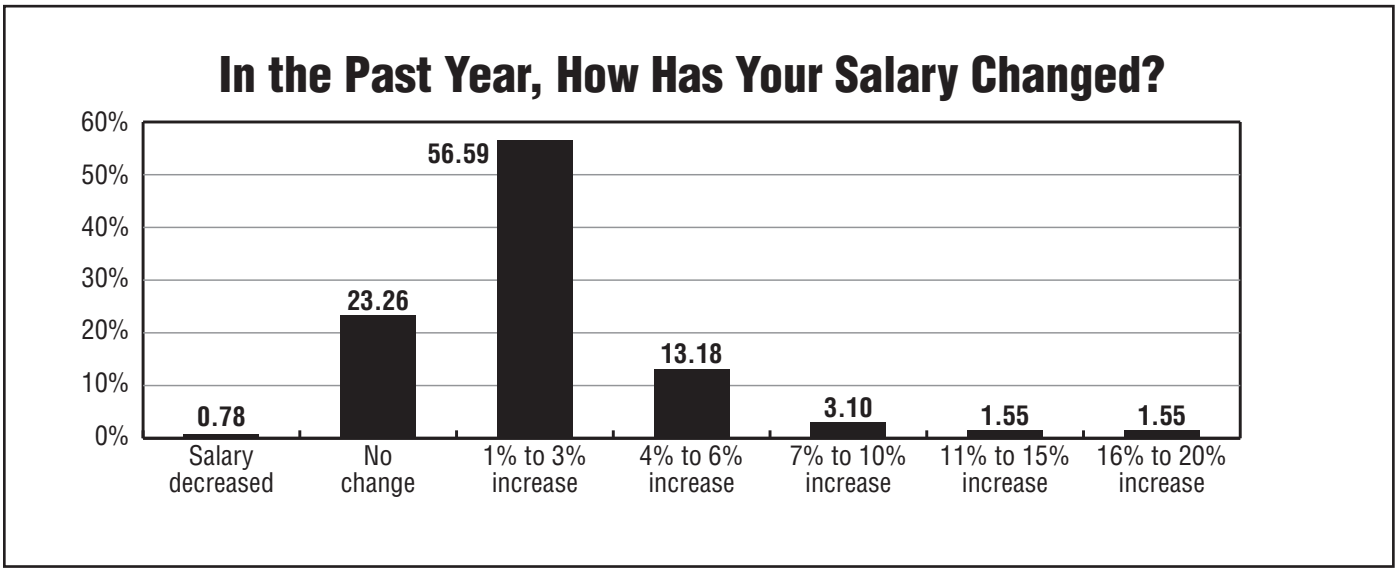
The survey was mailed in July 2008 to 1,456 subscribers with 127 responses, for a response rate of 8.7%.

About 48% of all respondents indicated they made $59,000 or less; about 48% reported salaries between $59,000 and $99,999. About 4% said they earned a six-figure salary. **(See "What is your annual gross income from your primary health care position?" graphic, below.)**

Where do you stand?

Family planning providers might not be keeping up with others in their profession when it comes to salary matters. Results from





a recent national nurse practitioners' salary survey show that the average nurse practitioner's salary rose 8.8% over the past two years, from $74,812 in 2005 to $81,397 in 2007.[1]

For physicians, results from a national physicians' survey indicate that obstetricians/gynecologists recorded a 2007 median income of $237,500, compared to $240,000 in 2006.[2]

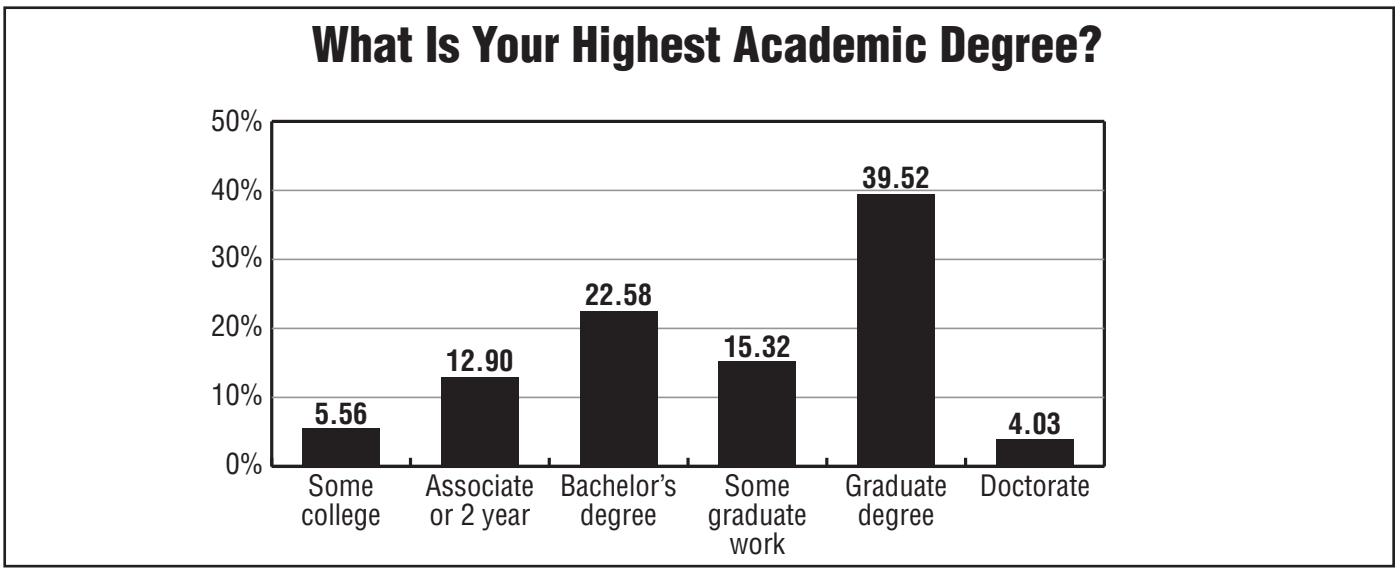
A 2007 salary survey conducted by the American College of Nurse-Midwives shows a median salary range of $79,093-$89,916 for full-time employment positions.[3] Results of a 2008 national physician assistant survey indicate a mean total income of $89,987 for those who were not self-employed and who worked at least 32 hours per week for their primary employer.[4]

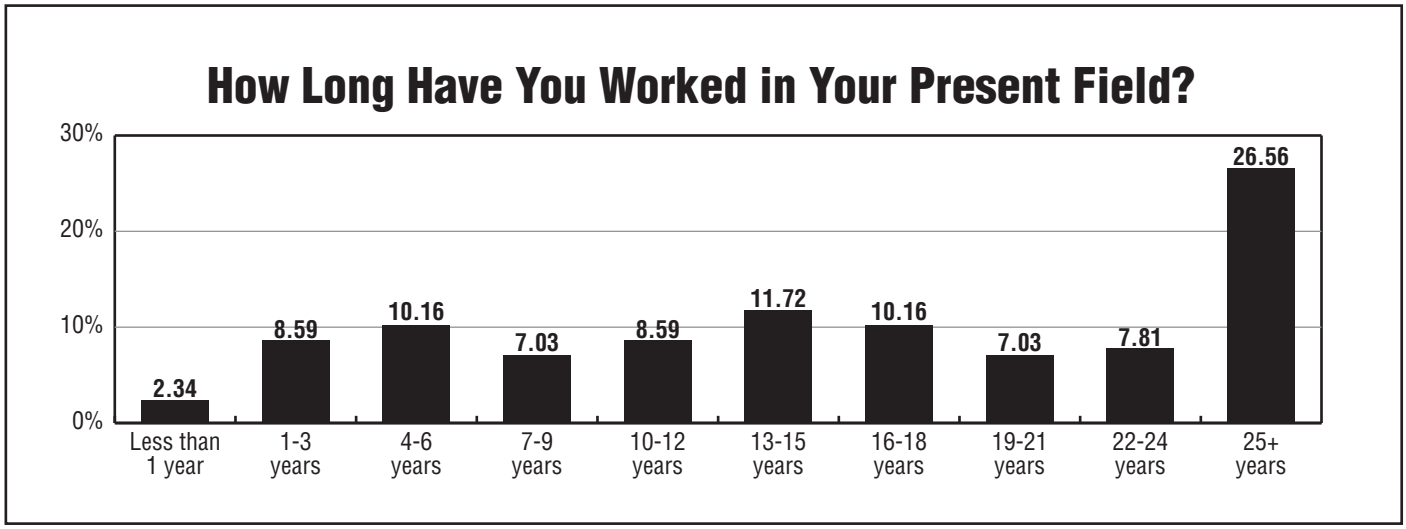
Many of 2008's survey responses come from those employed in the public health field: 39% said they worked in a health department. If working in this capacity, you may be working at a disadvantage when it comes to salary issues.

Public vs. private sector pay

Nurse salaries in public health agencies typically pale in comparison to those available in the private sector. For example, the average salary in 2006 for a public health staff nurse in Georgia was $36,753; in comparison, a nurse in a similar position in the private sector could expect an average salary of $61,206.[5] The nursing vacancy rate in Georgia hovers at about 20%.[6]

To add to the public health staffing challenge, more employees are needed at the public health level.[7] Data from a 2008 survey by the Association





of State and Territorial Health Officials (ASTHO) show that the public health work force is shrinking, the pool of new public health professionals is limited, and states are at a disadvantage in competing for the few workers available.[7]

Economic constraints at the local, state, and federal levels might compound those problems when it comes to salary increases or new hires. For example, in Georgia, fall 2008 state budget cutbacks of at least 6% may fray the public health safety net.[6] The cuts have been driven by the state's $1.6 billion shortfall.

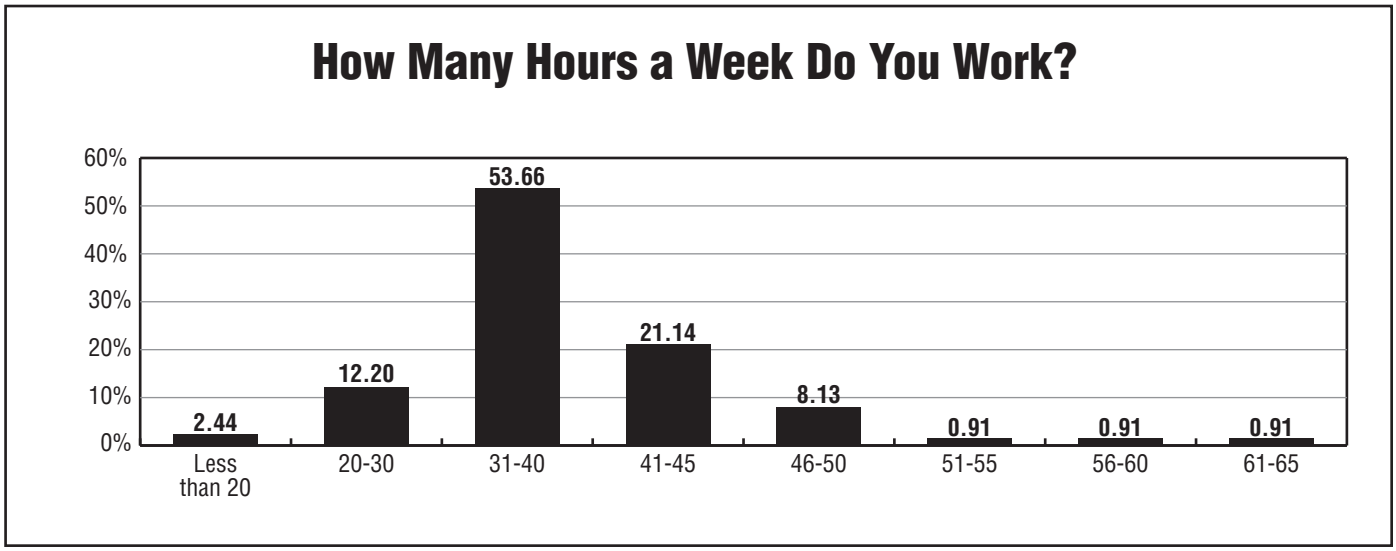
Many local jurisdictions are slashing their budgets due to the economic downturn, reports **Mary Jane Gallagher**, president and CEO of the National Family Planning and Reproductive Health Association. However, any time there is a reduction in funding for family planning services, taxpayers end up paying even more for the increased costs of unintended pregnancies, she notes.

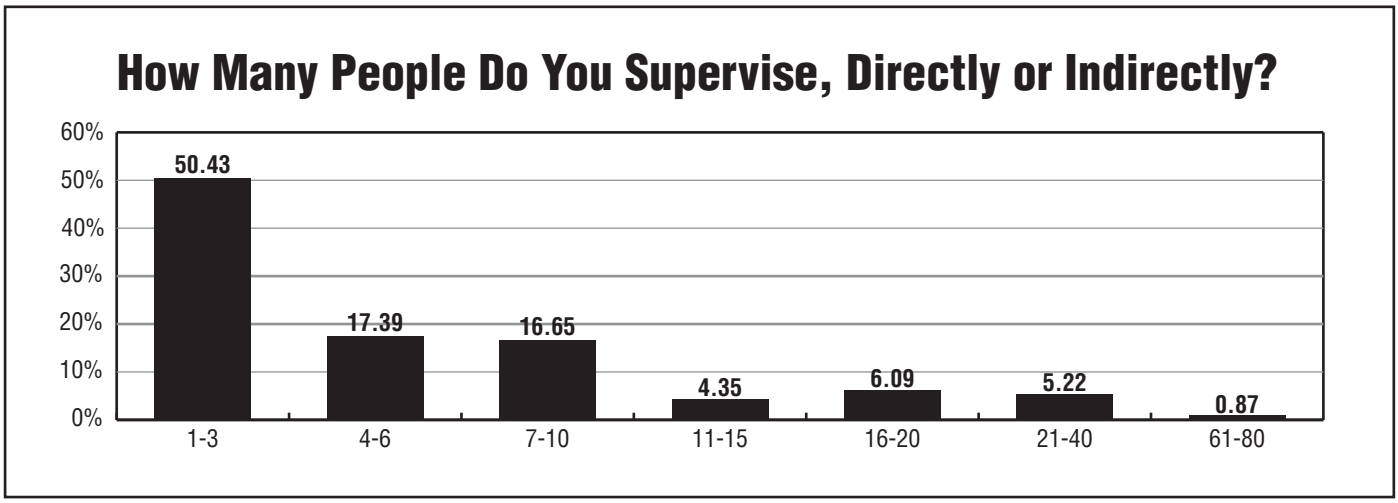
If you are in family planning, salary issues might not move you from your job: More than 50% of 2008 *CTU* survey respondents say they have been in their present field 16 or more years. But how can you manage your career in light of budget uncertainties and possible cutbacks?

Career management is an ongoing process of professional and personal development designed to enhance your current and future career opportunities, says **Donna Cardillo**, RN, BS, a national speaker on nursing career issues and author of *The Ultimate Career Guide for Nurses* (Gannett Healthcare Group).

What can you do?

Change is the operative word in clinicians' professional lives these days, she says. The world around health care providers is changing, health care is changing, and certainly nursing is changing, observes Cardillo. Those changes mean that





clinicians need to be ready to reinvent themselves at any time, whether forced into the job market by layoffs, facility closures, disability, or lifestyle change; presented with a promotion or new opportunity; or choosing to change to stay challenged, motivated, and moving forward, she says.

Be ready for job changes

To be ready for job changes, Cardillo offers the following strategies:

- Attend career fairs, which allow you to network with peers, find out what is happening in your specialty at other facilities, attend continuing education classes, and meet with representatives from educational institutions who offer information about higher learning and specialty training.
- Network at nursing and health care conventions, professional association meetings, and social events — anywhere you can stay in touch with your profession.
- Set specific written goals for your career, as well as for your continuing education. With those goals in front of you, you will have a clear understanding of what you need to do to manage and further your career.[8]

References

1. Rollet J, Lebo S. A decade of growth: Salaries increase as profession matures. *ADVANCE* 2008; 16:29-35.

2. Terry K. 2008 exclusive survey — Earnings: Good news for primary care income. *Med Econ* 2008; accessed at medicaleconomics.modernmedicine.com/memag/Medical+Economics/2008-Exclusive-SurveymdashEarnings-Good-news-forp/ArticleStandard/Article/detail/532638?contextCategoryId=8426#.

3. American College of Nurse-Midwives. *ACNM Compensation and Benefits Survey 2007*. Accessed at www.midwife.org/siteFiles/education/ACNM_Salary_Survey_2007.pdf.

4. American Academy of Physician Assistants. Facts At A Glance. Accessed at www.aapa.org/glance.html.

5. Robert Wood Johnson Foundation. Strengthening public health nursing — Part I. *Charting Nursling's Future* 2008; accessed at www.rwjf.org/pr/product.jsp?id=35348.

6. Miller A. Concerns mount that budget cuts could worsen public health crisis. *Atlanta J Constitution*; Nov. 23, 2008; accessed at www.ajc.com/hp/content/metro/stories/2008/11/23/public_health_budget.html.

7. Association of State and Territorial Health Officials. *2007 State Public Health Workforce Shortage Report*. Accessed at www.astho.org/pubs/WorkforceReport.pdf.

8. Cardillo DS. *Career Management Is a State of Mind*. Accessed at www.dcardillo.com/articles/careermgmt.html. ■

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Pelvic Inflammatory Disease

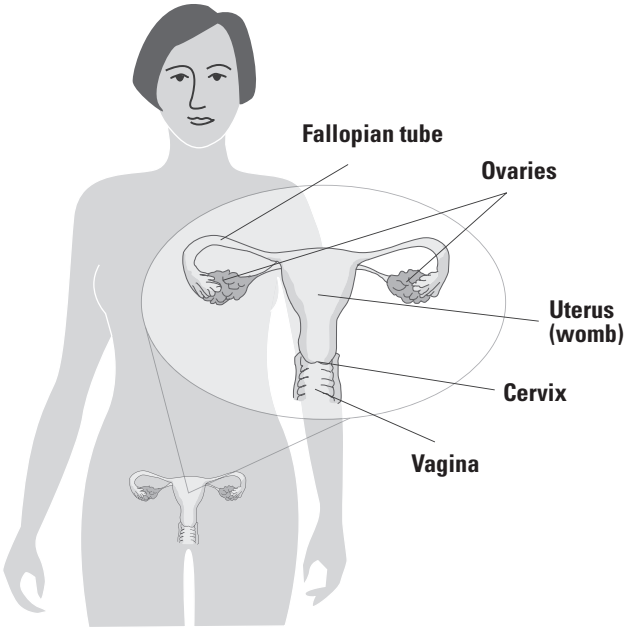
Q: What is pelvic inflammatory disease (PID)?

A: PID is an infection of a woman's pelvic organs. The pelvic organs include the uterus (womb), fallopian tubes (tubes), ovaries, and other organs related to having babies.

Q: What causes PID?

A: Bacteria (a type of germ) moves up from a woman's vagina, infecting her tubes, ovaries, and womb. Many different types of germs can cause PID. But, germs found in two common sexually transmitted diseases (STDs)–gonorrhea and chlamydia–are most often the cause of PID. After a person is infected, it can take from a few days to a few months to turn into PID.

It is rare, but you can get PID without having an STD. No one is sure why, but normal bacteria found in the vagina and on the cervix can sometimes cause PID.



Q: Are some women more likely to get PID?

A: Yes. You are more likely to get PID if you:

- have had an STD
- are under 25 and are having sex
- have more than one sex partner
- douche. Douching can push germs into the womb, ovaries, and tubes, causing infection. Douching can also hide the signs of an infection.
- have an intrauterine device (IUD). You're less likely to get PID if you're tested and treated for any infections before getting an IUD.

Q: How do I know if I have PID?

A: Many women have PID and don't know it. This is because sometimes women with PID don't have any symptoms. Still, some women do have symptoms, which can range from mild to severe. The most common symptom of PID is pain in your lower abdomen (stomach area). Other symptoms include:

- fever (99.6° or higher)
- vaginal discharge that may smell

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- painful sex
- painful urination
- irregular periods
- pain in the upper right abdomen (stomach area)

PID can come on fast with extreme pain and fever, especially if it is caused by gonorrhea.

Q: Are there any tests for PID?

A: It can be hard for your doctor to figure out if you have PID. Symptoms can be mild and are like symptoms of some other diseases. **If you think that you may have PID, see a doctor right away.** If you are treated right away, you'll be less likely to have long-term problems, such as infertility.

If you have pain in your lower abdomen (stomach area), your doctor will perform a physical exam. This will include a pelvic (internal) exam, which will help your doctor learn more about your pain. Your doctor will check for:

- abnormal vaginal or cervical discharge
- lumps near your ovaries and tubes
- tenderness or pain of your pelvic organs

Your doctor will also give you tests for STDs, urinary tract infection, and if needed, pregnancy. Your doctor also might test you for HIV and syphilis.

If needed, your doctor may do other tests.

- Ultrasound (sonogram) – a test that uses sound waves to take pictures of the pelvic area
- Endometrial (uterine) biopsy – a small piece of the endometrium (the inside lining of the womb) is removed and tested
- Laparoscopy – a small tube with a light inside is inserted through your abdomen (stomach area) to look at your pelvic organs

These tests will help your doctor find out if you have PID or if you have a different problem that looks like PID.

Q: How is PID treated?

A: PID can be cured with antibiotics. Your doctor will work with you to find the best treatment for you. **You must take all your medicine, even if your symptoms go away.** The infection will not be fully cured if you do not take all of the medicine.

If PID is not treated, it can lead to severe problems like infertility, ectopic pregnancy, and constant pelvic pain.

Any damage done to your pelvic organs before you start treatment cannot be undone. Still, don't put off getting treatment. If you do, you may not be able to have children. **If you think you may have PID, see a doctor right away.**

Your doctor may suggest going into the hospital to treat your PID if you:

- are very sick
- are pregnant
- do not respond to or cannot take medicine through your mouth; if this is the case, you will need intravenous (in the vein or IV) antibiotics
- have a sore in a tube or ovary

If you still have symptoms or if the sore doesn't go away, you may need surgery. Problems of PID such as constant pelvic pain and scarring are often hard to treat,

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but sometimes they get better after surgery.

Q: What if my partner is infected?

A: Even if your sex partner doesn't have any symptoms, she or he could still be infected with bacteria that can cause PID. Protect yourself from being re-infected with PID.

- Your sex partner(s) should be treated even if she or he doesn't have symptoms.
- Don't have sex with a partner who hasn't been treated.

Q: My friend was told she can't get pregnant because she has PID. Is this true?

A: The more times you have PID, the more likely it is that you won't be able to have children. When you have PID, bacteria infect the tubes or cause inflammation of the tubes. This turns normal tissue into scar tissue, which can block your tubes and make it harder to get pregnant. Even having just a little scar tissue can keep you from getting pregnant.

Q: How can I keep myself from getting PID?

A: PID is most often caused by an STD that hasn't been treated. You can keep from getting PID by not getting an STD.

- The best way to prevent an STD is to not have sex of any kind.
- Have sex with one partner who doesn't have any STDs.
- Use condoms every time you have vaginal, anal, or oral sex. Read and follow the directions on the package. If condoms are used correctly, they can lower your chances of getting an STD.
- Don't douche. Douching removes some of the normal bacteria in the vagina that protect you from infection. This makes it easier for you to get an STD.
- If you're having sex, ask your doctor to test you for STDs. STDs found early are easier to treat.
- Learn the common symptoms of STDs. If you think you might have an STD, see your doctor right away.

Q: What should I do if I think I have an STD?

A: You may feel scared or shy about asking for information or help. Keep in mind, the sooner you seek treatment, the less likely the STD will cause you severe harm. And the sooner you tell your sex partner(s) that you have an STD, the less likely they are to re-infect you or spread the disease to others.

If you think you may have an STD, see a doctor right away. Doctors, local health departments, and STD and family planning clinics have information about STDs and many offer testing. The American Social Health Association (ASHA) keeps lists of clinics and doctors who provide treatment for STDs. Call ASHA at (800) 227-8922. You can get information from the phone line without leaving your name. ■

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For more information…

You can find out more about PID by contacting womenshealth.gov at 1-800-994-9662 or the following organizations:

Centers for Disease Control and Prevention
National Prevention Information Network
Phone Number(s): (800) 458-5231
Internet Address: http://www.cdcnpin.org

National Institute of Allergy and Infectious Diseases
Phone Number(s): (301) 496-5717
Internet Address:
http://www.niaid.nih.gov

American College of Obstetricians and Gynecologists
Phone Number(s): (800) 762-2264
Internet Address: http://www.acog.org

American Social Health Association
Phone Number(s): (800) 783-9877
Internet Address: http://www.ashastd.org

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