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IN THIS ISSUE

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Adverse event reports spark discussions on safety of Evra contraceptive patch

Review concerns in counseling on combined hormonal contraception

Did the office telephone lines start buzzing when the media broadcasted reports of adverse events linked to use of the transdermal contraceptive Ortho Evra (Ortho-McNeil Pharmaceutical, Raritan, NJ)? There's no doubt that clinicians have, since those reports, fielded many questions about the safety of the patch, which has been used by about 4 million women since its November 2001 approval by the Food and Drug Administration (FDA).

Media reports were prompted by the April 2004 death of an 18-year-old New York City woman who had been using the transdermal contraceptive. An autopsy indicated the cause of death was due to a pulmonary embolism, and the medical examiner ruled it a side effect of the birth control device. The *New York Post* published a report stating that it had obtained FDA records "show[ing] that 17 patch users, ages 17 to 30, suffered fatal heart attacks, blood clots, and possible strokes since August 2002."[1]

The FDA and Ortho-McNeil are examining the adverse event reports; however, both believe that the published numbers may contain duplications, states **Kathleen Quinn**, agency spokeswoman.

EXECUTIVE SUMMARY

Providers may have to answer more questions on the safety of the transdermal contraceptive Evra as evidence is reviewed following the April 2004 death of an 18-year-old woman who was using the patch.

- The risk of death associated with pregnancy is far higher than the risk of death associated with using contraceptive pills or the patch.
- Since all combined hormonal contraceptives carry similar risks, providers need to teach women potential danger signals: abdominal pain, chest pain, severe headaches, eye problems, and severe leg pain.

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"FDA does not see any safety differences between the patch and pill when it comes to mortality/morbidity," states Quinn. "We will, like with all drugs, continue to monitor the issue and take what action is necessary, if any."

Ortho-McNeil is making the warning information about the risks of Evra use more prominent on its web site, www.orthoevra.com, says **Doug Arbesfeld**, company spokesman. "Our representatives are talking to providers, reviewing the data with them, and assuring them that we take this very seriously and that we are investigating it," he adds.

Check talking points

The Washington, DC-based Association of Reproductive Health Professionals (ARHP) has issued a set of "talking points" to help clinicians discuss the media reports with their patients. The professional association maintains that "the [*New York Post]* article is biased and unfortunate, misrepresenting the available data and presenting a skewed picture of adverse events attributable to the contraceptive patch in particular, and medications in general."[2]

Possible adverse drug reports are submitted voluntarily to FDA by clinicians in the United States and are intended to provide a means to identify rare medical problems that had not been anticipated in the clinical studies undertaken for FDA drug approval, the ARHP publication points out.

"Serious medical events are reported whether or not there is a clear cause-and-effect connection to the drug," states the publication. "For any medication that is widely used, therefore, at least some deaths are bound to occur and be reported."

When talking with patients about use of combined hormonal contraception, which includes oral contraceptives as well as the contraceptive vaginal ring (NuvaRing, Organon, West Orange, NJ), the ARHP advises the following discussion points:

- Deaths among young women because of medical problems such as heart attack are very rare, and they also are very rare among young women using contraceptive hormones.
- Taking oral contraceptives or using hormonal contraceptive patches slightly increases the risk of cardiovascular problems — especially for women older than 35 who smoke.
- The rate for cardiovascular problems

estimated for women using the patch is in the range that has been reported for other hormonal contraceptives such as oral contraceptives.

• Health risks for patch users essentially are the same as risks for women using other hormonal contraceptives.

• In context, risks for death associated with other common activities such as driving an automobile (1 in 5,900) or continuing a pregnancy to term (1 in 10,000) are significantly higher than risks associated with use of hormonal contraceptives.

• The risk of death associated with pregnancy — a common outcome among women who don't use contraception — is far higher than the risk of death associated with using contraceptive pills or the patch. Pregnancy-related deaths, including those at delivery, stillbirth, and ectopic pregnancy, claim the lives of two to three U.S. women every day, with 13 deaths reported for every 100,000 live births in 1999.[2]

How to explain risks

Robert Hatcher, MD, MPH, professor of gynecology and obstetrics at Emory University School of Medicine in Atlanta, uses the risk tables published in the latest edition of *Contraceptive Technology* to help explain the risks of patch use[3]:

• If 2 million women become pregnant over a one-year period and carry their pregnancies to term, then one woman out of each 10,000 will die. Of the 2 million women who have become pregnant, 200 will die. If another 2 million women became pregnant the next year, another 200 would die, for a total of 400 deaths in two years.

• If 200,000 nonsmoking women younger than 35 years of age use pills to prevent pregnancy for one year, then one woman will die. Therefore, if 2 million women use birth control pills for one year, then 10 women will die. If 2 million nonsmoking women use birth control pills for two years, then 20 will die.

• If 5,300 women who smoke heavily and are younger than 35 years of age use pills for a year, then one will die. If 2 million who smoke heavily and are younger than the age of 35 use birth control pills for two years, then about 750 will die.

• So the number of deaths for 2 million nonsmoking women who use pills for a year would be about 20; whereas, if they were heavy smokers, the number of deaths would be 750.

"The *New York Post* article found 17 deaths among 2 million women using the patch over a two-year period," Hatcher observes. "This is clearly far fewer deaths than would have occurred if 2 million women had become pregnant each of two years [400 deaths]."

Seventeen deaths among 2 million patch users over a two-year period is in the range of deaths to be expected if those same 2 million women (most of whom were nonsmokers, but some of whom were heavy smokers) were to have used pills for two years, comments Hatcher.

"The *New York Post* article underscores the point that deaths and very serious complications may occur from a contraceptive like the patch, but that the risk of death from using the patch is far, far less than the risk of death from pregnancy," he notes.

Talk about 'ACHES'

The patch, like other forms of combined hormonal contraceptives, carries risks; these risks are spelled out in the product labeling and package insert. The most commonly reported adverse reactions in Evra's clinical trials included breast symptoms, headache, application-site reactions, nausea and vomiting, dysmenorrhea, and abdominal pain.[4,5] In clinical trials, the contraceptive patch was shown to have comparable safety and efficacy with that of oral contraceptives.[6]

Smoking, hypertension, obesity, and diabetes are risk factors that must be taken into account when prescribing any form of combined oral contraception.[7] When providing counseling on combined hormonal contraceptive use, whether patch, pill, or ring, providers should use the "ACHES" mnemonic to teach women potential danger signals:

- **A**bdominal pain;
- **C**hest pain;
- **H**eadaches that are severe;
- **E**ye problems;
- **S**evere leg pain.[3]

Giving women the information they need to monitor themselves can minimize the risks of any method. The ACHES mnemonic is easy to recall and to teach, says **Linda Dominguez**, RNC, NP, assistant medical director of the Albuquerque-based Planned Parenthood of New Mexico. The information fits nicely on a small wallet card that can be personalized with the clinic/office contact information as well as individual health information such as current weight, blood pressure reading, or lab values, she advises.

"This minichart information written on the back of the card will be of interest to the patient and will bring her attention back to the ACHES

teaching method as well," she states.

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Progress under way on the microbicide front

Promising advances are being made on the microbicide front: U.S. funding appears imminent for microbicide research and development, a new corporate partnership has been struck with an international research group to step up testing of antiviral AIDS gels, and a number of potential candidates are moving through the research pipeline.

Why is progress so important when it comes to microbicide development? With a microbicide in hand, women would have an effective female-controlled form of protection against infection. Even if a candidate were found to be 60% efficacious, it would aid in averting 2.5 million HIV infections across the globe over three years.[1]

The Senate Appropriations Committee has passed its FY 2005 foreign operations bill to include a $10 million increase for microbicide research and development, resulting in a total of $32 million aimed at global aid for microbicide research. Final action on the bill is expected by *Contraceptive Technology Update* press time, estimates **Mark Mitchnick**, MD, director of research and development for the Silver Spring, MD-based International Partnership for Microbicides (IPM), a nonprofit organization established to accelerate the development and accessibility of microbicides. If approved, IPM will receive $2 million of the increased funding.

"IPM spends 60%-70% of its money right now on research and development, and as time goes on, more and more of that money will be spent on clinical trials and access issues," he states.

EXECUTIVE SUMMARY

While no microbicide product yet exists on the commercial market, proponents see positive steps being made toward a female-controlled method of protection against HIV infection.

- The U.S. Senate has approved a $10 million increase for microbicide research, resulting in a total of $32 million aimed at global aid for microbicide research.
- The International Partnership for Microbicides has entered an agreement with GlaxoSmithKline to test several of the company's proprietary AIDS drugs in a topical form.
- Dozens of candidate microbicides are in the research pipeline; 16 are in clinical testing, with five of those entering late-stage testing in 2004.

Partnering for progress

Extra funding will come at a key time in development of potential microbicide products, as IPM has just reached an agreement with London-based GlaxoSmithKline (GSK) to test several of Glaxo's proprietary AIDS drugs in a topical form.

"GSK has sent us about eight ingredients or compounds; from those, we will decide if more need to be tested," states Mitchnick. "GSK has a huge library, of course, and these are eight representative molecules."

IPM is taking a comprehensive approach to identify a topical anti-HIV microbicide that includes different classes of anti-HIV compounds, including compounds that could disable HIV prior to contacting the cell or prevent it from multiplying once it enters cells. The organization acquired rights earlier this year to a potential microbicide agent from the Tibotec Pharmaceuticals unit of Johnson & Johnson, based in Mechelen, Belgium.[2]

After more than a decade of research, dozens of candidate microbicides are in the pipeline; 16 already are in clinical testing, with five of those entering late-stage testing in 2004.[3] These candidates include four sulfated or sulfonated polymers,

all of which inhibit pathogen attachment to target cells[4]:

• **Carraguard**, developed by the New York City-based Population Council. Made of carrageenan derived from seaweed, the potential product entered a large-scale efficacy trial earlier this year at three South African sites.

• **Emmelle**, developed by London-based ML Laboratories. A sulfated polysaccharide known as dextrin sulfate, Emmelle is being tested by the London-based Medical Research Council and the Antwerp, Belgium-based Institute for Tropical Medicine.

• **Ushercell**, developed by Polydex Pharmaceuticals in Scarborough, Ontario, Canada, and the Program for the Topical Prevention of Conception and Disease in Chicago. Also known as cellulose sulfate, the potential product is being tested by the Global Microbicide Project and the HIV Prevention Trials Network, both based in Arlington, VA, and the Geneva-based World Health Organization.

• **PRO 2000**, under development by Indevus Pharmaceuticals of Lexington, MA. A synthetic polymer that binds to the HIV virus, the potential product will be tested by the London-based Microbicide Development Programme in full-scale clinical trials scheduled to begin in 2005 in several African countries.

Another potential microbicide, Savvy, is in two Phase 3 clinical trials in Africa to test its efficacy in the prevention of HIV transmission. Also known as C-31G, Savvy is a surfactant that disrupts the outer surface of pathogens. Savvy is being developed by Huntingdon Valley, PA-based Biosyn, which is set to be acquired by San Francisco-based Cellegy Pharmaceuticals.[5]

Look for more growth

Another potential microbicide, Amphora, has received Food and Drug Administration (FDA) approval for use as a personal lubricant. Clinically known as Acidform, Amphora is an acid-buffering gel that coats the vaginal wall and cervix to maintain a woman's natural pH level between 3.8 and 4.2. Originally created by the Program for the Topical Prevention of Conception and Disease, Amphora was licensed to Instead of La Jolla, CA, in 2002, with patent protection granted in March 2004.

The company is evaluating Amphora in tandem with a version of its Instead Softcup as a possible contraceptive method in addition to its research as a potential microbicide, says **Ariel Cassady**, a company spokeswoman. Contraceptive clinical trials using Amphora and a version of the Instead Softcup are scheduled to begin in Russia in January 2005. **(*CTU* reported on the company's contraceptive research in the October 2003 article, "Research eyes use of OTC 'disposable diaphragm,'" p. 115.)**

"We are still assessing plans to market Amphora as a stand-alone lubricant," she states. "There is a possibility that it will not be introduced to the U.S. marketplace until we have obtained FDA clearance to market it with our Instead Softcup as a contraceptive device."

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Don't time first teen visit to first Pap test

The next patient in your exam room is 20 years old. When you note that this is her first gynecologic visit, she tells you that she didn't think she needed such a checkup until her first Pap test.

Adolescents and their parents may have become confused on when to schedule a teen's first gynecologic exam when updated cervical cancer screening guidelines were issued in November 2002 by the Atlanta-based American Cancer Society (ACS). The 2002 guidelines called for Pap tests beginning either at age 21 or three years after a woman first has sexual intercourse;[1] previous recommendations advised an initial Pap screen shortly after first intercourse or by age 18, whichever occurred first. ***(Contraceptive Technology Update* reported on the ACS update in the article, "Get ready to take cervical cancer screening to the next level," June 2003, p. 61.)** The Washington, DC-based American College of Obstetricians and Gynecologists (ACOG) followed up with similar guidance in July 2003.[2]

EXECUTIVE SUMMARY

The American College of Obstetricians and Gynecologists (ACOG) has just issued a new opinion designed to clear up confusion about the timetable for a teen's initial gynecological exam in an effort to make sure teens receive preventive care.

- When 2002 cervical cancer screening recommendations called for young women to receive their first Pap smear approximately three years after intercourse or by age 21 (whichever occurs first), many teens and their parents interpreted the guidelines as indicating that initial gynecological exams could be delayed until age 21.
- According to the ACOG guidance, teen girls should schedule their first visit between ages 13 and 15, ideally before sexual activity has occurred.

(Review the organization's guidance in the article, "More support voiced for cancer screening test," October 2003, p. 117.)

Now ACOG is clarifying its guidance with the issuance of a new committee opinion on the subject.[3] Because of the changes in cervical cancer screening guidelines, there is concern that teens will delay important preventive care and sexually transmitted disease (STD) testing until they come in for their first Pap screening, says **Paige Hertweck**, MD, immediate past chair of ACOG's Committee on Adolescent Health Care and associate professor in the department of obstetrics, gynecology, and women's health at the University of Louisville (KY) School of Medicine.

"If the first exam is done around ages 13-14, we can assess their reproductive health and do some risk-taking analysis," she explains. "If a person waits until age 21, we will miss determining such conditions as PCOS [polycystic ovarian syndrome], eating disorders, and screening for STDs."

ACOG recommends that an adolescent girl's first visit to an OB/GYN for health guidance, screening, and preventive health occur between ages 13 and 15, ideally before sexual activity has occurred. It is estimated that 24% of 15-year-old girls have had sexual intercourse.[4]

A teen's initial visit does not necessarily have to include a pelvic examination or a Pap test. **(See the story on p. 139 on what to include in the initial exam.)** Annual adolescent visits, whether they include a Pap or not, are strongly recommended, are strongly recommended by ACOG.

Do your adolescent patients understand the difference between a Pap test and a pelvic exam? Few teen girls do, according to the results of a just-published study.[5] In a survey performed at the UMass Memorial Adolescent Clinic in Worcester, MA, researchers asked 111 teens ages 14 and older and any mothers accompanying them to give a definition of a Pap test and to identify whether a Pap test is equivalent to a pregnancy test, a test for sexually transmitted diseases, a cervical cancer screening, a pelvic exam or a checkup. Just 2.7% of the teens could give an accurate definition; 68% believed that a Pap smear was the same as a pelvic examination. Only 40% of the mothers could properly define a Pap test.[5]

Such findings don't surprise providers such as **Melanie Gold**, DO, associate professor of pediatrics at the University of Pittsburgh School of Medicine and associate professor at the University of Pittsburgh Graduate School of Public Health.

"The biggest confusion is that people don't understand that the Pap smear is a test and a pelvic exam is a type of a exam," she notes. Women may incorrectly assume that a Pap smear is being performed any time a speculum is inserted during a physical exam unless each portion of the procedure is explained to her, she notes.

Don't overdo treatment

The new ACOG opinion also stresses the need to avoid overtreatment of abnormal cervical cytology in adolescents. Adolescents may be more susceptible than adults to human papillomavirus (HPV) infection due to biologic or physical factors. Risk factors for HPV include multiple sexual partners, having a male partner with multiple sexual partners, history of other STDs, and early age of first intercourse (including sexual abuse).[3] Teens also have a higher prevalence of abnormal Pap test results compared with adult women, but the severity of their cervical lesions generally is lower.[6]

According to ACOG, adolescents with abnormal Pap screen results should be counseled and monitored closely to avoid aggressive treatment of benign lesions because most lesions regress on their own without treatment and do not result in cervical cancer. Surgical excision or destruction of cervical tissue in the adolescent female may affect future fertility, ACOG notes.[3]

"There is a lot of confusion about what an abnormality is," says Gold. "We usually talk about the fact that just because your Pap smear is abnormal doesn't mean you have cancer."

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Tips on what to cover in an initial teen exam

What do you cover when you conduct a teen's first gynecologic exam? Understand that an adolescent's initial visit may not necessarily include a pelvic examination or a Pap test, but that it should cover a wide spectrum of issues facing a young woman of reproductive age.

The Washington, DC-based American College of Obstetricians and Gynecologists (ACOG) has developed a confidential questionnaire based on the Chicago-based American Medical Association *Guidelines for Adolescent Preventive Services* (GAPS), a comprehensive set of recommendations for teen preventive health services. **(See the resource box on p. 140 for information on these resources.)**

The ACOG questionnaire provides a quick overview of several subjects, including such issues as depression and substance abuse, says **Paige Hertweck**, MD, immediate past chair of ACOG's Committee on Adolescent Health Care and associate professor in the department of obstetrics, gynecology, and women's health at the University of Louisville (KY) School of Medicine.

"In my office, it is given to the patient to fill out after her blood pressure and weight are checked, and before the patient goes into the exam room with the family member," she notes. "That way, I can review the information and discuss any problems during the confidential portion of the exam."

Hertweck also gives out the questionnaire at follow-up visits to see if any of the situations have changed for her patients. Such information can help determine if the teen needs contraception, if she has become sexually active, or needs a referral for counseling if she is dealing with a substance abuse problem.

'Am I normal?'

A teen's first question during her first gynecologic exam may well be, "Am I normal?" says Hertweck. At this time, talk about pubertal development and get an overview of the patient's menstrual cycle, she adds.

Ask a first-time teen patient about her cycle: its frequency, duration, and flow, advises **Melanie Gold**, DO, associate professor of pediatrics at the University of Pittsburgh School of Medicine and associate professor at the University of Pittsburgh Graduate School of Public Health. Discuss cramps and the impact they have on daily activities, she notes.

Sexual orientation is another subject for discussion: Ask the patient if she is attracted to "guys or girls, or both or neither, or she's not sure yet," she suggests. **(Check the article, "Lesbians, bisexual women need to have screenings," in *Contraceptive Technology Update*, October 2004, p.114.)** Do not assume that the patient is sexually active; however, if she is, then take a sexual history, she states.

Perform a general physical exam, and assess pubertal staging, Gold suggests. Do a physical examination of the breasts; note when there is asymmetry or masses. Help the teen to understand what is normal, and encourage her to feel comfortable in touching her breasts, not necessarily for cancer detection, but "just for knowing what is normal for her," she says.

When performing the genital exam, include a general discussion on hygiene and discourage douching for this purpose, Gold advises. As you move through the external exam of the genital area, explain what you are checking and offer to have the patient use a hand mirror to see the area, says Gold. Most teen patients may not be comfortable in using a mirror at the time of the exam, but encourage them to do so later at home, she states.

Gold performs the genital exam with the patient's feet up in the stirrups just to have them become comfortable with the examination position. This way, the patient is more comfortable when a speculum is used in a later visit.

The initial gynecologic exam should cover

primary health issues such as depression, eating disorders, and substance abuse, because patients may not have a primary care provider, she says. Assess whether the patient has another source of primary care; and if she doesn't, include them in the visit, she advises.

"I think the first thing is that the purpose of the visit is not for the pelvic exam," Gold states. "The purpose of the visit is to address a spectrum of reproductive health issues that a teen may have." ■

RESOURCES

- **Review and download free materials developed under the American Medical Association's *Guidelines for Adolescent Preventive Services* (GAPS)** at the association's web site, www.ama-assn.org. Click on "Physicians and Medical Students," "Public Health," "Adolescent Health," and "Clinical Preventive Services," to access the GAPS material. Downloadable material includes a younger adolescent questionnaire, a middle/older adolescent questionnaire, and a parent/guardian questionnaire, all in English and Spanish versions.

- **The American College of Obstetricians and Gynecologists' (ACOG) *Tool Kit for Teen Care***, designed by the ACOG Committee on Adolescent Health Care, includes an adolescent visit questionnaire and adolescent visit record; tools for adolescent assessment, including laminated cards with the stages of pubertal development, blood pressure readings, and body mass index calculations; educational materials and fact sheets for teens and their parents; and tips for creating an adolescent-friendly office environment. The tool kit (Item AA415) is $45 for ACOG members and $55 for nonmembers, plus an $8.95 shipping/handling fee. Credit card orders may be made on-line at the ACOG store web site, http://sales.acog.org, telephoned to (800) 762-2264, ext. 315, or (304) 725-8410, ext. 339; or faxed to (800) 525-5562 (United States and Canada) and (304) 728-2171 (international.) Orders also may be mailed to ACOG Distribution Center, P.O. Box 4500, Kearneysville, WV 25430-4500. Several of the fact sheets in the Tool Kit are available free at the Medem web site (www.medem.com), a web resource developed by several leading professional medical organizations. Type in "Tool Kit for Teen Care" in the search box at the home page; the search engine will display the fact sheets.

Emergency contraception moves into mainstream

What is the policy for providing emergency contraception (EC) at your facility? About 81% of respondents to the 2004 *Contraceptive Technology Update* Contraception Survey say their facilities prescribe EC on site and provide emergency contraceptive pills (ECPs) at any time, which continues a trend of strong support for the method.

Stephani Cox, APN, CNP, DPS, director of patient services at Planned Parenthood Springfield (IL) Area, says the number of EC users have increased significantly over the past year.

"We accept patients in need of EC at any time on any day as walk-in," she says. "We talk about it with all of our patients when they are here for their annuals, negative pregnancy tests, and [at] just about any other opportunity."

The nurse practitioners carry a weekend pager for EC, and the number is advertised on the telephone message system, Cox says. "We also have included the pager number and EC information in with our monthly billing statements."

Tina Mladenka, MSN, OGNP, a Pocatello, ID-based community health nurse practitioner, also reports that the number of EC patients has grown in the last year. "We get the word out primarily through talking with women during their annual exams," she says.

Custer Family Planning, a not-for-profit family planning agency in Bismarck, ND, provides emergency contraception information at its front door with free condom packs, reports **JoElle Thomas**, WHCNP, nurse practitioner. Every patient receives information about the method at annual examination time, she states.

When it comes to advance provision of EC, more than half (54%) of 2004 survey respondents say their facilities now offer such a service. This year marks *CTU*'s first analysis of advance provision practice. The Washington, DC-based American College of Obstetricians and Gynecologists urged its members in March 2002 to issue advance EC prescriptions. **(For *CTU*'s report on the group, see "Emergency contraception is gaining momentum from local to national levels," May 2002, p. 49.)**

It is easier to offer advance provision, says Thomas. It gives the patients more control, and patients like it, she reports.

"Often, patients are relieved just to know they can have that convenience," observes Cox. "Usually,

EXECUTIVE SUMMARY

Providing emergency contraception (EC) now is an established practice in family planning facilities: about 81% of survey respondents to the 2004 *Contraceptive Technology Update* Contraception Survey say their facilities prescribe EC on site and provide emergency contraceptive pills at any time.

- More than half (54%) say their facility offers advance provision of EC.
- Most facilities (63%) report use of the levonorgestrel ECP Plan B; about 9% say they use Preven. Barr Pharmaceuticals, which markets Plan B and Preven, announced in mid-2004 that it would cease distribution of Preven to focus its attention on Plan B.

the patients who don't choose to take it to have on hand relate that it is due to the financial outlay at that particular time, but they often will come back and get one later."

According to *A Pocket Guide to Managing Contraception,* clinicians can choose from two approaches in offering advance provision: Give women pills in advance, or give them a prescription with refills in advance.[1]

Most facilities are using the levonorgestrel-only EC pill Plan B, marketed by Barr Pharmaceuticals of Pomona, NY. About 63% say they are using the drug, up from 2003's 58% figure. About 9% report use of Preven, also marketed by Barr, and about 10% select from one of the 19 oral contraceptives approved by the Food and Drug Administration (FDA) for EC use. The remaining percentage did not list a particular choice.

"Our patients experience far less nausea with Plan B and so are more willing to take it, and it is more effective than other EC methods," states Cox. "The evidence-based method of taking both Plan B pills at the same time also is especially attractive to patients."

Clinicians who prescribe progestin-only EC are moving to administering a single dose (1.5 mg) of the drug following research conducted by the Geneva-based World Health Organization that indicates a single dose of levonorgestrel to be as effective in reducing the risk of pregnancy as two 0.75 mg doses taken 12 hours apart.[2] **(Review the article, "Clinicians change practice when it comes to EC," January 2004 *CTU*, p. 9.)**

Clinicians who have relied on Preven as an EC option will have to substitute the FDA-approved OCs with Barr Pharmaceuticals' recent decision to withdraw the dedicated ECP from the market. The company says it made the move to better focus its EC efforts on Plan B. **(*CTU* reported on the company's decision in the article, "And then there was one: Barr withdraws Preven," September 2004, p. 101.)**

Family planning providers are waiting to see if the FDA will approve Barr Pharmaceuticals' request to take Plan B over the counter. If the measure is approved, Plan B may be available over the counter (OTC) to women ages 16 and older.

The company changed its request to seek dual marketing of the drug after the FDA denied the company's original request for OTC status. **(See the article, "Plan B seeks OTC status for women ages 16-plus," September 2004 *CTU*, p. 103, and the article," What is next for over-the-counter access to emergency contraception?" July 2004 *CTU*, p. 73. For more information on the 2004 *CTU* Contraception Survey results, see the November 2004 issue.)**

"The company currently anticipates a decision on its application by the FDA by January 2005," says **Carol Cox**, Barr Pharmaceuticals' vice president of investor relations and corporate communications.

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Check funding, science of abstinence-only program

By **Cynthia Dailard**
Senior Public Policy Associate
The Alan Guttmacher Institute
Washington, DC

The increasing federal investment in abstinence-only education is one of the more notable social policy trends of the past decade.

Programs must *exclusively* promote abstinence and therefore cannot discuss the positive benefits of

contraception or condoms, because doing so would purportedly undermine the abstinence message.

Federal funding for abstinence-only education has skyrocketed absent any reliable data supporting its effectiveness. In contrast, a significant body of evaluation research indicates that comprehensive approaches to sex education — which promote abstinence but also provide information about contraception and condoms — can be effective in helping young people to delay sexual activity or reduce teenage pregnancy.[1]

In 1997, Congress acknowledged the need for a federally funded evaluation of abstinence-only education programs and provided funds to support that effort. That evaluation, however, is more than a year overdue. However, there are two new reports by the Washington, DC-based Advocates for Youth (AFY). The first reviews the findings from the 10 available state evaluations of federally funded abstinence-only programs.[2]

The analysis found "few short-term benefits and no lasting, positive impact. A few programs showed mild success at improving attitudes and intentions to abstain. No program was able to demonstrate a positive impact on sexual behavior over time."[2]

The report concludes, "Abstinence-only programs show little evidence of sustained (long-term) impact on attitudes and intentions. Worse, they show some negative impacts on youth's willingness to use contraception, including condoms, to prevent sexual health outcomes related to sexual intercourse. Importantly, only in one state did any program demonstrate short-term success in delaying the initiation of sex; *none* of these programs demonstrates evidence of long-term success in delaying sexual initiation among youth exposed to the program or any evidence of success in reducing other sexual risk-taking behaviors among participants."[2]

The second AFY report analyzed annual data released by the Centers for Disease Control and Prevention, which collects information on the sexual and other risk behaviors of high school students.[3]

AFY analyzed trend data for four sexual behaviors and compared changes in teens' sexual behaviors that took place during 1991-1997 with those in 1999-2003. The former period, according to AFY, "corresponds with the widespread implementation of comprehensive sex education, including HIV prevention programming." In contrast, the latter period covers the first five-year period of federal abstinence-only education.

The four behaviors include: ever had sexual intercourse; had four or more sexual partners during lifetime; currently sexually active; and condom use during last sexual intercourse.

The analysis found that "sexual behaviors that place teens at risk for pregnancy and infection with HIV and [sexually transmitted infections] declined significantly from 1991-1997. From 1999-2003, however, results show little change in these behaviors."

The report notes that the analysis does not prove that a causal relationship exists between federally funded abstinence-only education programs "and the end of significant improvement in adolescent sexual risk-taking behaviors after 1999," but suggests that future research address this question.[3]

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ASK THE EXPERTS

Answering your questions on DMPA use and weight

Should a woman who is obese and continues to gain weight on Depo-Provera [depot medroxyprogesterone acetate (DMPA), Pfizer, New York

COMING IN FUTURE MONTHS

- Strategies for managing hormonal methods and irregular bleeding
- Integrate HIV rapid testing in your practice
- Female condom update: Protection option?
- Male contraception research: When will a method emerge?
- Amenorrhea: When to treat, when to follow

City] be allowed to continue its use if she so desires? Are providers contributing to the health risk of obesity by allowing a woman to do so?

These questions are addressed by two members of the *Contraceptive Technology Update* editorial advisory board: **Robert Hatcher**, MD, MPH, professor of gynecology and obstetrics at Emory University School of Medicine in Atlanta, and **Andrew Kaunitz**, MD, professor and assistant chair in the obstetrics and gynecology department at the University of Florida Health Science Center/Jacksonville.

Hatcher: You raise several very important questions:

- How much weight gain is to be expected in Depo-Provera patients?
- How much is too much weight gain?
- Are we neglecting major amounts of weight gain in our Depo patients?
- What should be our approach to weight gain when we see it happening?

The Depo-Provera package insert informs each clinician prescribing and each woman using it that after one year, the average weight gain is 5.4 pounds; and after five years, the average gain is 16.5 pounds.[1]

In my opinion, and all do not agree with me, we need to become quite concerned when a woman gains 10, 20, and then 30 pounds, and we need to counsel her repeatedly that this weight gain may be in part related to her use of Depo, that it should not continue indefinitely, that she should consider switching to other methods, and that there are a number of approaches to losing weight that should become a priority for her.

Seldom is it wise to categorically refuse to give Depo-Provera against the patient's wishes (even after 40, 50, or 60 pounds of weight gain). Better to get her to consider an effective alternative. Refusal to provide Depo can lead, of course, to an unwanted pregnancy.

Do these approaches make sense to you? This is such a tough problem.Unfortunately, we see so many very overweight patients that we occasionally fail to realize that it is a drug we have administered that has caused one of our patients to increase from an acceptable initial weight of 125 to 175 pounds, for example.

Kaunitz: One component of this clinical case relates to the question: What impact does DMPA use have on weight? Because no large randomized clinical trials address the impact (if any) that use of DMPA has on weight, this issue continues to be surrounded by controversy.

What seems likely is that some women who use DMPA contraception have an intrinsically higher risk for weight gain than do women who choose to use other birth control methods.[2]

A second component of this question relates to the safety of DMPA use by overweight women. Obesity represents an independent risk factor for venous thromboembolic disease (VTE). In addition, obesity in the setting of pregnancy is associated with higher maternal risks. Use of combination estrogen-progestin contraceptives increases VTE risk, while use of progestin-only methods (notwithstanding outdated package labeling for many progestin-only medications) does not increase VTE risk, and therefore is safe in high-risk women.

Finally, it is possible, but certainly not proven, that the efficacy of combination oral contraceptives is reduced in obese women.

Putting all of the above observations together, this woman's obesity should be addressed focusing on conventional lifestyle recommendations (e.g., exercise and diet). Given her obesity, ongoing DMPA use strikes me as a particularly appropriate contraceptive choice from the perspectives of safety and efficacy.

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CE/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. **The semester ends with this issue.** You must complete the evaluation form included in this issue and return it in the provided reply envelope addressed "Education Department" to receive a certificate of completion. When your evaluation is received, a certificate will be mailed to you. ■

CE/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. (See **"Progress under way on the microbicide front."**)
- **Describe** how those issues affect service delivery and note the benefits or problems created in patient care in the participant's practice area. (See **"Don't time first teen visit to first Pap test."**)
- **Cite** practical solutions to problems and integrate information into daily practices, according to advice from nationally recognized family planning experts. (See **"Adverse event reports spark discussions on safety of Evra contraceptive patch"** and **"Answering your questions on DMPA use and weight."**)

21. In the "ACHES" mnemonic used to teach women potential danger signals of combined hormonal contraceptives, the "S" stands for:

A. Spotting and vaginal discharge.
B. Severe leg pain.
C. Sleep disorders.
D. Skin hyperpigmentation.

22. Four potential microbicide candidates (Carraguard, Emmelle, Ushercell, and PRO-2000) are all sulfated or sulfonated polymers, which act by:

A. Enhancing vaginal defense mechanisms.
B. Killing or inactivating infectious pathogens.
C. Inhibiting pathogen attachment to target cells.
D. Inhibiting post-fusion activity.

23. Current cervical cancer screening guidelines call for the first Pap smear to occur:

A. Beginning at age 16 or three years after a woman first has sexual intercourse, whichever is first.
B. Beginning at age 18 or three years after a woman first has sexual intercourse, whichever is first.
C. Beginning at age 21 or two years after a woman first has sexual intercourse, whichever is first.
D. Beginning at age 21 or three years after a woman first has sexual intercourse, whichever is first.

24. According to the package insert for Depo-Provera (depot medroxyprogesterone acetate or DMPA), what is the average weight gain after one year of use?

A. 3 pounds
B. 5.4 pounds
C. 10 pounds
D. 15 pounds

Answers: 21. B; 22. C; 23. D; 24. B.

Contraceptive Technology Update *is endorsed by the National Association of Nurse Practitioners in Women's Health and the Association of Reproductive Health Professionals as a vital information source for health care professionals.*

2004 SALARY SURVEY RESULTS

CONTRACEPTIVE TECHNOLOGY UPDATE®

A Monthly Newsletter for Health Professionals

Family planning providers hold the line in salary and staffing levels in 2004

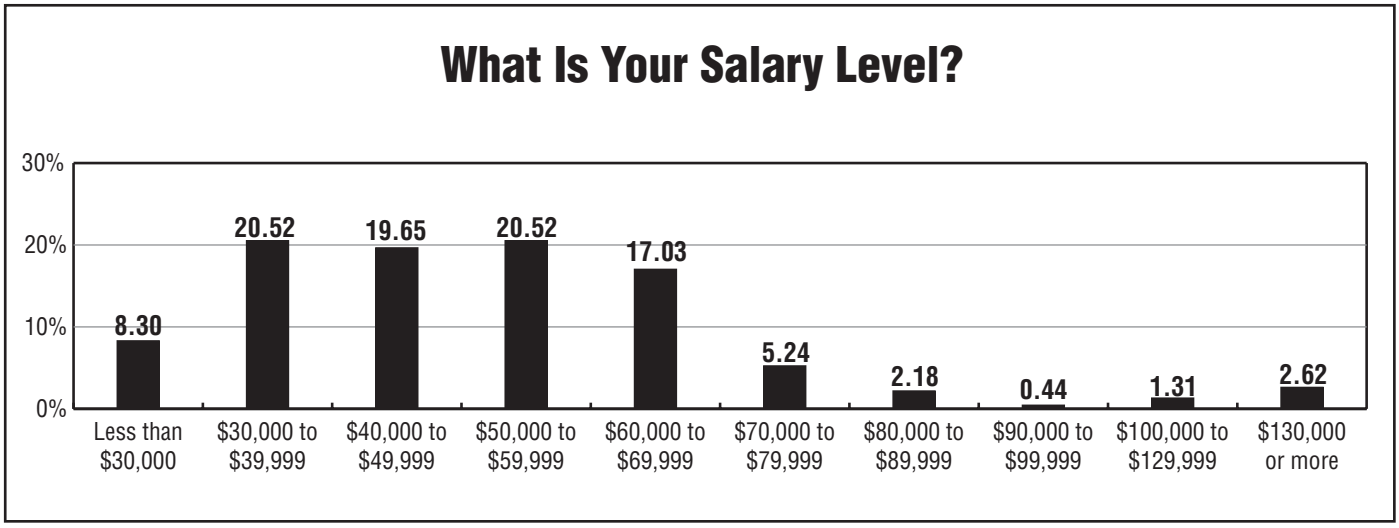
Slight increases seen in pay, and most providers say staffing has remained steady

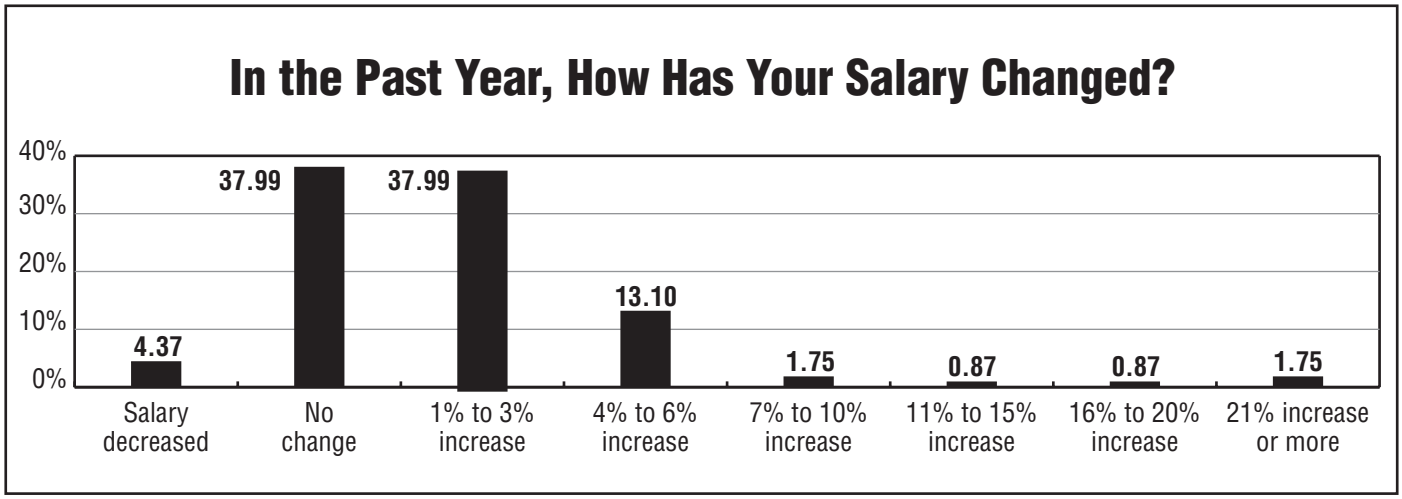
Good news for family planning providers: Salary levels are reflecting a modest increase in 2004, according to the results of the annual *Contraceptive Technology Update* salary survey. **(See "What is Your Salary Level?" below, and "In the Past Year, How Has Your Salary Changed?" p. 2.)** The survey was mailed in July 2004 to 1,247 subscribers and had a response of 229, for a response rate of 18.36%.

Average salary for nurse practitioners (NPs) rose to $55,265 in 2004, up from $51,472 in 2003, according to the 2004 results. Median salaries for this group also moved up to $55,465, climbing from 2003's $52,368 level. The gain in pay offsets a decline in salaries reported in 2003; NPs had recorded slight increases in their paychecks in 2001 and 2002. Nurse practitioners represent almost half (41.92%) of the 2004 responses.

"It is encouraging that salaries are going up," says **Susan Wysocki**, RNC, NP, president and chief executive officer of the Washington, DC-based National Association of Nurse Practitioners in Women's Health.

When it comes to pay, location and place of employment can make a difference in compensation, she reports. About half (45.41%) of *CTU* responses came from those working in health departments, while another 24% said they were





employed in a clinic setting. When analyzed by geographic location, 35% of *CTU* responses came from the Southeast, with about 23% from the Midwest and 21% from the Southwest. Jobs in Southeastern public health settings typically record lower levels of pay, Wysocki notes.

Other groups also recorded upward movement on the compensation front, according to the *CTU* annual report: Administrators reported a median salary of $60,000, compared with 2003's $59,000 figure, while registered nurses (RNs) recorded a median salary of $53,725, climbing from $42,000 in 2003. Nurses comprised about 28% of the 2004 responses, while administrators represented about 17% of the total number. Physicians, nurse midwives, and health educators each were about 3% of the 2004 responses, with physician assistants at 2%.

Work hard for the money

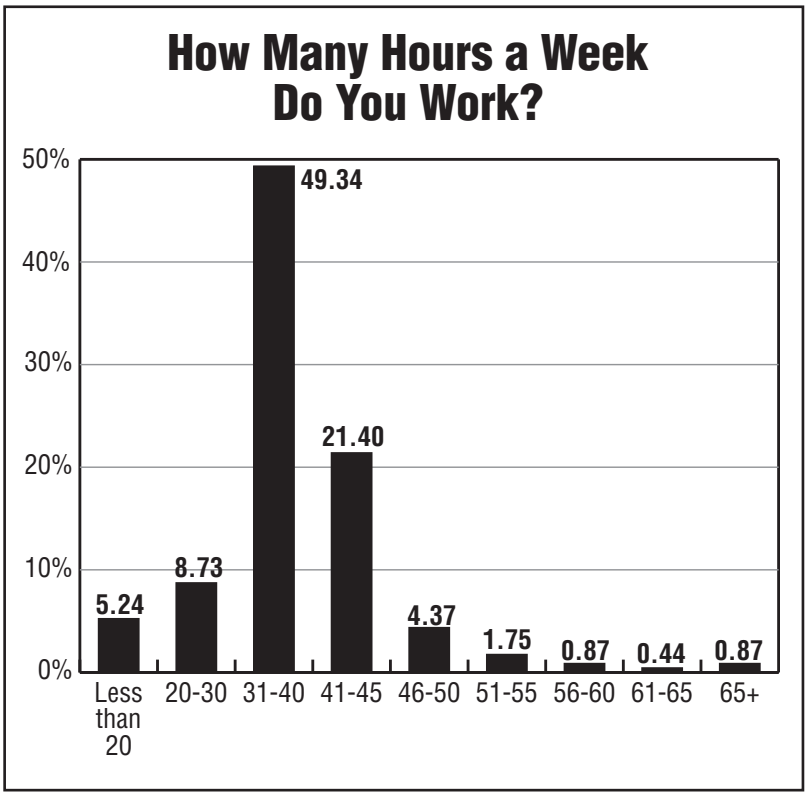
Productivity may be a key component when it comes to compensation at your facility. Such attention has impacted pay, particularly for physicians: 2003 was the third consecutive year that increases in production outpaced increases in compensation, according to the Denver-based Medical Group Management Association.[1]

According to the association, OB/GYNs recorded a five-year compensation increase of 8.3%, while their charges grew by 15.5% during the same period. With rising costs and declining reimbursements, providers are working harder for the same amount of money or are taking home less pay.[1]

"I suspect that this is also true for nurse practitioners, that the expectation is that clients have to be served," says Wysocki.

About 40% of *CTU* survey respondents say staffing levels have remained steady in the past year, while about 22% report employee increases. About 30% say employee numbers have dropped in 2004. More workers are putting a little extra time in the office: About 21% say they worked 41-45 hours per week in 2004, compared to about 14% in 2003. **(See "How Many Hours a Week Do You Work?" below.)** About half of respondents say they worked an average 31-40 hours per week. Supervisory duties have changed somewhat for providers; about 42% of respondents say they supervise one to three people. Sixty percent registered similar numbers in the 2003 survey. **(See "How Many People Do You Supervise?" p. 3.)**

What motivates you when it comes to staying

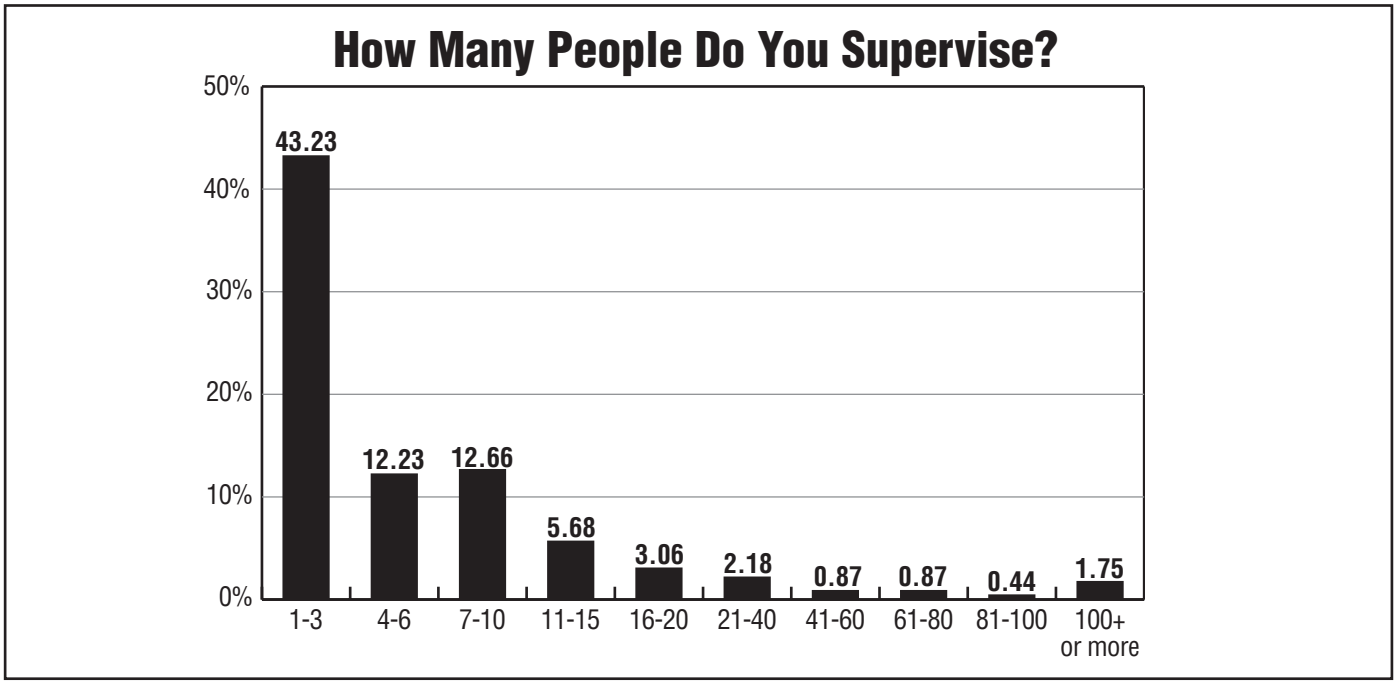


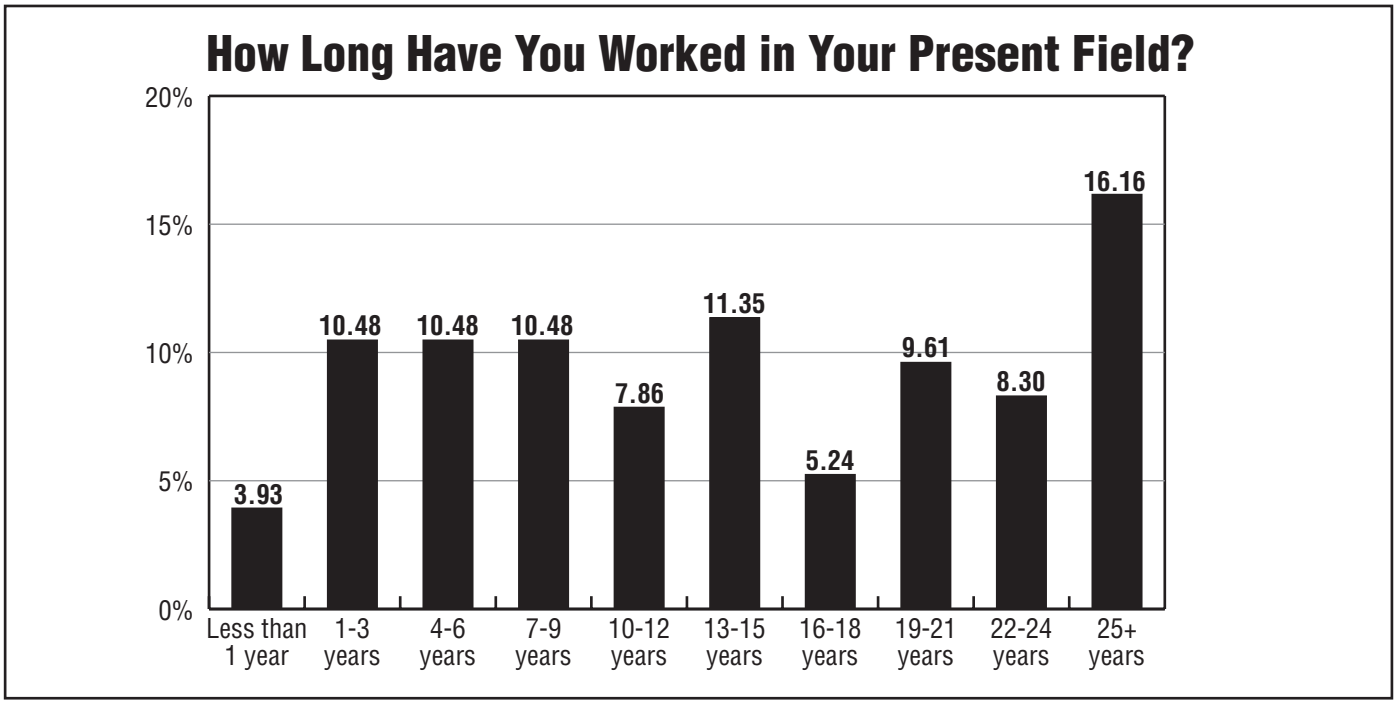
in your current job? The rewards of working in family planning cannot be measured in just monetary compensation, sources say.

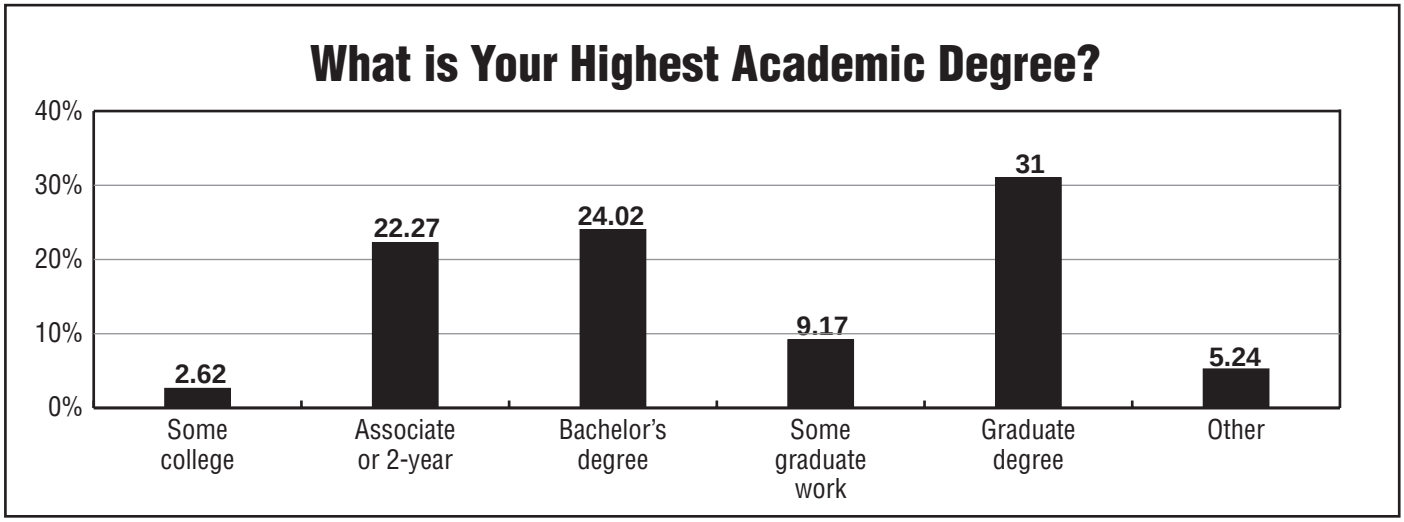
"One of the best things about being a nurse-midwife is the ability to work in settings that provide family planning, gynecology, and/or maternity care," says **Deanne Williams**, CNM, MS, executive director of the Silver Spring, MD-based American College of Nurse-Midwives (ACNM). "This flexibility is very attractive for those who are committed to providing compassionate health care to women while still balancing their career and family needs."

There is job stability for those who work in public health; about 60% of 2004 survey respondents say they have been in their present field for more than 10 years. **(See "How Long Have You Worked in Your Present Field?" below.)**

Look for more job opportunities to open up in public health: The largest increase in RN employment from 1996-2000 was recorded in public and community health settings,[2] and there is an escalating shortage of qualified public health workers, according to a recently released report issued by the Washington, DC-based Association of State and Territorial Health Officials.[3] According to the







2004 report's findings, the average age of public health workers is about 47, retirement rates in public health can rise as high as 45% in some states over the next five years, and job vacancy rates are as high as 20% in some parts of the country.[3] The most severe shortages will occur in the fields of nursing, epidemiology, and laboratory sciences, findings indicate.[3]

Funding will be a critical part of attracting and retaining public health staff; state health officials are eyeing are considering benefits such as advanced education, flexible work hours, and telecommuting opportunities in light of budget constraints that restrict pay increases.[3] Educational opportunities may be attractive to family planning providers. About 40% of survey respondents say they hold a graduate degree, while about 24% have a bachelor's degree. About 25% say they have some college or an associate degree. **(See "What is Your Highest Academic Degree?" above.)**

Is a change imminent?

If your present employment scene needs changing, the Internet may offer valuable job resources. Nurse-midwives can check professional opportunities across the nation and internationally at ACNM's dedicated web site, www.MidwifeJobs.com. The web site allows nurse-midwife job seekers to freely link to hospitals, birth centers, physicians, and any health care organization seeking midwives to expand their services.

The Washington, DC-based Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN) has launched its own on-line nursing career center, www.NursingCareerCenter.com, as a one-stop shopping for employers, recruiters, nurses, and people considering a career in nursing. The on-line resource includes a searchable database of nurses' resumes to allow employers to scan for specific criteria; position listings with opportunities ranging from staff nurses to nurse executives; a clearinghouse of information about various nursing specialties, nursing schools, scholarships, the Nurse Reinvestment Act, and becoming a nurse; career management advice for nurses interested in a career change or development; and links to numerous web sites.

The site is open and available to nurses and persons interested in nursing free of charge; applicants can confidentially post their resumes on the site. The site offers a search engine that can be set to periodically scan posted resumes for specific nursing qualifications and notify an employer when qualifying resumes are posted.

"The demand for nurses overall, and for women's health nurses, in particular, remains high," says **Gail Kincaide**, AWHONN executive director. "The increasing emphasis on promoting prevention and healthy lifestyles to help women prevent conditions like osteoporosis and breast cancer makes women's health nursing a positive and rewarding specialty that also provides important growth and leadership opportunities."

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