CONTRACEPTIVE TECHNOLOGY UPDATE®
A Monthly Newsletter for Health Professionals

THOMSON
AMERICAN HEALTH CONSULTANTS

IN THIS ISSUE

DECEMBER 2003
VOL. 24, NO. 12 • (pages 133-144)

Medical abortion update: Death sparks questions on abortion pill

Review facts, counseling strategies to affirm safety

A young woman recently died after undergoing a medical abortion. Patients are anxious and asking questions. How do you respond?

"Medical abortion is very safe and effective," states **Vanessa Cullins**, MD, MPH, vice president of medical affairs at the New York City-based Planned Parenthood Federation of America. "Medical abortion has been used by more than 200,000 women in the United States, and if you look specifically at the Planned Parenthood Federation of America experience, it has been provided very safely, very effectively for more than 58,000 women."

Holly Patterson, an 18-year-old Livermore, CA, woman, sought health care services at a San Francisco Planned Parenthood Golden Gate health center on Sept. 10, 2003. According to news reports, Patterson received mifepristone from Planned Parenthood. Some accounts say Patterson had severe pain and bleeding on Sept. 14, went to a Bay Area hospital, and was sent home with painkillers. She was back at the hospital on Sept. 16 and died the next day.[1] The cause of death is unknown. Planned

EXECUTIVE SUMMARY

Questions surrounding use of the abortion drug mifepristone have arisen following the recent death of a young California woman. While details of the case are not available due to confidentiality laws, the incident places fresh focus on the medical abortion regimen.

- Mifepristone has been used successfully by more than 200,000 women in the United States and by more than a million women worldwide.
- Preparing women for the normal range of side effects that are expected with medical abortion is a critical component of patient counseling and education.

Contraceptive Technology Update® (ISSN 0274-726X), including **STD Quarterly**™, is published monthly by Thomson American Health Consultants, 3525 Piedmont Road, Building Six, Suite 400, Atlanta, GA 30305. Telephone: (404) 262-7436. Periodicals postage paid at Atlanta, GA 30304. POSTMASTER: Send address changes to **Contraceptive Technology Update**®, P.O. Box 740059, Atlanta, GA 30374.

Subscriber Information

Customer Service: (800) 688-2421 or fax (800) 284-3291, (customerservice@ahcpub.com). Hours of operation: 8:30 a.m.-6 p.m. Monday-Thursday; 8:30 a.m.-4:30 p.m. Friday, EST.

Subscription rates: U.S.A., one year (12 issues), $449. Approximately 18 nursing contact hours or Category 1 CME credits, $499; Outside U.S., add $30 per year, total prepaid in U.S. funds. Two to nine additional copies, $359 per year; 10 to 20 additional copies, $269 per year; for more than 20, call (800) 688-2421. **Back issues**, when available, are $75 each.(GST registration number R128870672.)

Parenthood declined further comment on the specifics of the case, citing confidentiality of the doctor-patient relationship.

Rank the risks

What are some talking points that you can use with patients when discussing medical abortion? While every medical procedure involves risk, medical abortion using mifepristone has a track record of safety and effectiveness. Marketed as Mifeprex by Danco Laboratories of New York City, the drug was approved by the Food and Drug Administration (FDA) in September 2000 after an extensive and rigorous scientific screening process and following more than a decade of use in Europe. **(Review the steps leading to the FDA approval in the December 2000 *Contraceptive Technology Update* article, "Mifepristone approval won't remedy the abortion restrictions you face," p. 141.)**

Mifepristone has been used successfully by more than 200,000 women in the United States and by more than a million women worldwide. To put risks into perspective, consider the following information, used by Planned Parenthood in discussing the recent incident:[2]

Two deaths of women who had taken mifepristone have been recorded in North America since its introduction. One death involved an undiagnosed, untreated ectopic pregnancy, which mifepristone does not treat. She died as a result of a hemorrhage due to a ruptured ectopic pregnancy. The other stemmed from an extremely rare bacterial infection. No causal relationship has been established between the drug and the conditions in either of the cases. **(Danco Laboratories issued an advisory to alert providers of these incidents; *CTU* provided coverage in its July 2002 article, "Abortion pill advisory issued," p. 76.)** Of the approximately 3,000 patients involved in trials of the mifepristone/misoprostol regimen, only one case of ectopic pregnancy was reported. The incidence of ectopic pregnancy among patients seeking early surgical abortion at less than six weeks' gestation is 6.7 per 1,000.[3] Confirmed or suspected ectopic pregnancy is a contraindication for use of mifepristone and should be ruled out prior to initiating drug treatment.

No deaths have taken place as a result of the use of mifepristone. In 1991, a woman in France died from cardiac arrest as a result of using the drug sulprostone, an intramuscular, injectable prostaglandin that was once used in place of misoprostol. Sulprostone is not available in the

RESOURCE

For more information on medical abortion, contact:
- **National Abortion Federation**, 1755 Massachusetts Ave. N.W., Suite 600, Washington, DC 20036. Telephone: (202) 667-5881. Fax: (202) 667-5890. E-mail: earlyoptions@prochoice.org. The patient video, "Making Your Choice, A Woman's Guide to Medical Abortion," is available in English and Spanish. Cost is $15 for federation members and $20 for nonmembers. The patient education brochure, available in Chinese, Croatian, English, Russian, Spanish, and Vietnamese, is $5 for 20 (both members and nonmembers); $10 for 50, members, and $14 for 50, nonmember. Contact the federation at (202) 667-5881 for bulk order pricing.

United States, and it is no longer used in France.[4]

Even if the death linked to the infection was the result of having had a medical abortion, the North American rate of death from mifepristone medical abortion would be very low: one per 250,000 medical abortions or four per 1 million medical abortions, according to Planned Parenthood. In comparison:

• The risk of death each year for men and women who drive automobiles is 169 per 1 million automobile drivers.[5]

• The risk of dying from continuing a pregnancy beyond 20 weeks is 107 per million live births.[6]

• The risk of dying from a surgical abortion performed up to eight weeks is one per 1 million surgical abortions, and two per 1 million surgical abortions performed between nine and 10 weeks.[7]

Any woman seeking abortion should be fully counseled about all options, including surgical and medical abortion, delivery, and adoption. Women may choose medical abortion because they fear a surgical procedure. **(*CTU* reported on mifepristone provision and discussion of abortion options in its May 2000 article, "Mifepristone approval delayed, supporters look to action by FDA," p. 53.)**

Review side effects

Preparing women for the normal range of side effects that are expected with medical abortion is a critical component of patient counseling and education, states **Vicki Saporta**, executive director of the Washington, DC-based National Abortion Federation (NAF).

"As a general guiding principle, when women are adequately prepared regarding the steps of the process and what to expect, they are more comfortable with the process and reassured about what is normal and what would warrant a follow-up call to their provider," she says.

Expected side effects of the mifepristone/misoprostol regimen include:

• ***Gastrointestinal symptoms.***

Women experiencing a medical abortion commonly report nausea, vomiting, and diarrhea. Most gastrointestinal symptoms can be managed with reassurance; occasionally, an anti-nausea medication may be needed for persistent vomiting.

• ***Crampy abdominal (uterine) pain.***

Most women will experience crampy abdominal pain. Reassurance, a heating pad, a nonsteroidal anti-inflammatory drug, or a mild narcotic such as acetaminophen with codeine should be sufficient to ease the discomfort.

• ***Other misoprostol-related side effects.***

PMisoprostol is associated with other prostaglandin-like side effects such as headache, chills, and fever may occur, which are usually self-limited.

• ***Bleeding.***

Vaginal bleeding is necessary for a complete medical abortion. Although the amount of blood loss for surgical and medical terminations is fairly comparable, women undergoing a medical procedure observe the bleeding. Bleeding under the medical regimen is heaviest when products of conception are passed within the immediate three to six hours after using misoprostol. Women should be instructed to contact their health care provider on call if they saturate four or more maxi-sanitary napkins over two consecutive hours. For most women, light bleeding persists for nine to 21 days, and about 8% of women continue bleeding for as much as one month.[8]

The most serious complication for mifepristone/misoprostol abortion is excessive bleeding. Excessive bleeding requiring surgical intervention ranges from 0.4% to 2.6%.[9,10] Providers should be skilled to perform an aspiration curettage for an incomplete abortion or have a formal arrangement for such care.

Women who have excessive bleeding from a medical abortion present similarly to women with an incomplete spontaneous abortion. The cervix is typically soft and dilated, and the embryo has partially detached or been expelled. Manual vacuum aspiration with a 60 cc Ipas hand-held syringe and a 6 mm or 7 mm flexible cannula should be sufficient to empty the uterus and provide adequate hemostatis.[7] **(Review further clinical information**

on the mifepristone/misoprostol regimen in the *Contraceptive Technology Reports* monograph, "Gauging the effectiveness of mifepristone and misoprostol," inserted in the February 2001 issue.)

NAF has developed several patient education resources for women seeking information about medical abortion with mifepristone/misoprostol, including an on-line "Woman's Information Guide" at www.earlyoptions.org/w_guide.html and a patient education video and a brochure that compare medical and surgical abortion and describe what to expect during a medical abortion, says Saporta. **(See resource listing on p. 135.)**

The organization has not yet finalized its 2004 training schedule, but providers who are interested in obtaining training in medical abortion should visit the organization's web site, www.prochoice.org, states Saporta. The organization offers its on-line continuing medical education program at www.earlyoptions.org/online_cme/default.asp.

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Contraception forecast: You'll have new options

Just as you have integrated new methods such as the transdermal contraceptive and the contraceptive vaginal ring into your practice, be prepared to see more options added to the contraceptive mix.

Organon Pharmaceuticals of West Orange, NJ has submitted its application to the Food and Drug Administration (FDA) for the single-rod contraceptive implant Implanon. If approved, U.S. providers may see the device in 2004, says **Nancy Alexander**, PhD, director of contraception at Organon.

"The file has been submitted, and we are still contemplating the same time frame [of 2004]," she states.

Implanon is inserted under the skin of the upper arm and provides contraception for up to three years. Consisting of a nonbiodegradable rod measuring 40 mm in length and 2 mm in diameter, the device releases the progestin etonogestrel at an average release rate of 40 mcg per day. Since the device does not contain estrogen, women who do not tolerate or have contraindications to estrogens may safely use it.

In a three-year study investigating the contraceptive efficacy and tolerability of Implanon, findings indicate that the device was well tolerated and had excellent, reversible, contraceptive efficacy.[1] Irregular bleeding was the primary reason for discontinuation (19.0%). Adverse events, other than bleeding irregularities, were generally mild to moderate in intensity and resulted in

EXECUTIVE SUMMARY

Family planning providers may see additions to the contraceptive mix as new options move through the research and regulatory pipeline.

- Implanon, the single-rod contraceptive implant, is under review by the Food and Drug Administration. It provides contraception for up to three months. Also under review is the Today contraceptive sponge, which is available over the counter in Canada and on the Internet.
- There are no immediate plans to return Lunelle, the monthly contraceptive injectable, to the marketplace, says its new corporate parent. The drug was withdrawn from the market in 2002 after some of its pre-filled syringes were found to have less-than-effective potency.

9.3% of discontinuations.[1] The most commonly reported nonbleeding adverse events were breast pain (16%), acne (12.6%), vaginitis (12%), and pharyngitis (10.5%).[1] There is a rapid return to fertility in those women without fertility problems when the implant is discontinued.[2]

Bleeding disturbances are the main adverse events associated with implantable contraceptives.[3] Other minor risks relate to the insertion and removal procedures, which require adequately trained providers as well as aseptic techniques.[3] Provider education will be an important aspect of product introduction should Implanon receive FDA approval. Organon is developing educational models on insertion and removal techniques to ensure clinicians are familiar and comfortable with the device. **(*Contraceptive Technology Update* reported further details on Implanon in the October 2002 article, "Don't count implants out: 2 options may take Norplant's place," p. 109.)**

Where's the sponge?

The Today Sponge, manufactured by Allendale (NJ) Pharmaceuticals, has been available over the counter in Canada for the past six months, reports **Gene Detroyer**, company president and chief executive officer. The FDA has made two inspections of the Norwich, NY, production plant to make sure the product meets export requirements, he adds.

"The inspections went well, as we were told the FDA will take no action to prevent us from continuing to export the product," Detroyer notes. "Further, Allendale was audited by the FDA to determine compliance with U.S. export/import laws, and we were found to be in compliance."

When will the company be cleared to sell the contraceptive sponge in the United States? The company is complying with all requests from the FDA; if all requirements are met, approval may come in spring of 2004, says Detroyer. **(Read more about the sponge in the May 2003 article, "Time for Today sponge in Canada: Will U.S. see vaginal contraceptive?" p. 49.)**

With the introduction of the extended regimen contraceptive Seasonale (Barr Laboratories, Pomona, NY), scientists are examining extended use of other contraceptives, including NuvaRing, Organon's contraceptive vaginal ring.

"There is a continuous use trial with various regimens underway and so far, the results seem positive," says **Ed Baker**, MD, Organon's associate director of contraception.

In a small pharmacokinetic study on the effects of the ring after extended use (five weeks vs. the conventional period of three weeks), findings indicate that ovulation continued to be inhibited, with no unfavorable safety observations.[4]

Researchers affiliated with Ortho-McNeil Pharmaceuticals in Raritan, NJ, also are looking at extending the current regimen of its transdermal contraceptive, Ortho Evra. Data are not yet available on extended use of the contraceptive patch.

On another contraceptive front, people still are asking for the Lunelle shot, says **Theresa Rundell**, ARNP, a nurse practitioner at the Klickitat County Health Department in White Salmon, WA. The monthly contraceptive injectable, with 25 mg medroxyprogesterone acetate and 5 mg estradiol cypionate, combines the convenience and efficacy of long-acting progestational methods with the cycle control and side effect profile of combined oral contraceptives.[5]

Pre-filled syringes of the product underwent a recall in 2002 when its manufacturer, Pharmacia Corp. of Peapack, NJ, discovered that the amount of medication in a small number of the syringes may have been insufficient to protect against pregnancy. The company subsequently discontinued production of the syringes and vials of the product. **(Review the recall information in the December 2002 article, "Family planning facilities meet the challenge of Lunelle syringe recall," p. 133.)**

Pharmacia merged with New York City-based Pfizer in 2003, so it is now up to Pfizer to determine if the product will return to the market. According to **Daniel Watts**, Pfizer media spokesman, Lunelle "is still not available on the market, and there are no immediate plans to bring it back to the market at this time."

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Barr to acquire Plan B: EC access to expand?

Emergency contraception (EC), once considered "the nation's best-kept secret," may be a secret no longer when a major pharmaceutical company takes over a popular dedicated EC product.

Pomona, NY-based Barr Laboratories Inc. has announced its intentions to acquire Plan B, the levonorgestrel-only pill manufactured by Washington, DC-based Women's Capital Corp. At press time, the acquisition was set to close. Annual sales of Plan B reached about $10 million in 2002; Barr reported $903 million in sales in its most recent fiscal year.[1] Plan B was listed as the leading EC pill in the 2003 *CTU* Contraception Survey; about 58% of respondents said their facility provided the drug.

"As a leading pharmaceutical company with sizable resources, Barr has the ability to greatly expand outreach to the medical community and to provide much-needed education and awareness to consumers," states **Ellen Chesler**, chairwoman of Women's Capital Corp. "In addition, Barr will continue to pursue over-the-counter [OTC] status for Plan B and is committing resources to support the OTC switch."

Women's Capital Corp. filed with the Food and Drug Administration (FDA) in April 2003 to switch the status of Plan B from prescription-only to OTC. The review of the OTC submission is on schedule, and no major problems have arisen to date, according to the company. An FDA advisory hearing of the reproductive health and nonprescription drugs panels is scheduled for mid-December 2003.

Women Capital Corp.'s 59-volume, 15,000-page application contains clinical study data on nearly 11,000 women who have taken the pills used in Plan B after sex to prevent pregnancy. Included in the application were results of the label comprehension study[2] and the just-published OTC actual use study, designed to mimic OTC distribution.[3] **(To review the results of label comprehension study, see "EC access initiatives moving forward in U.S.," *Contraceptive Technology Update,* October 2002, p. 113.)**

To conduct the actual use study, women at U.S. family planning clinics and pharmacies were enrolled; the facilities did not provide unsolicited counseling about or evaluations for EC pills. Women who requested EC were asked to examine a package that was modified for OTC use and were provided with the study drug (levonorgestrel, two 0.75-mg tablets). Women were contacted one and four weeks later and asked about use of the product, side effects, and pregnancy. Most women used EC pills appropriately without provider evaluation and counseling, study findings indicate.[3]

Timely access is important for EC, say access proponents. It must be taken within a few days of a contraceptive accident to be effective. If a condom breaks on a Friday night, many women cannot get a provider's prescription and get it filled in the prescribed 72 hours. OTC status will give women access to the pills quickly, when they are most effective, proponents advocate.

EXECUTIVE SUMMARY

Barr Laboratories has entered an agreement with the Washington, DC-based Women's Capital Corp. to acquire the firm's levonorgestrel-only emergency contraceptive, Plan B.

- Barr Labs will continue to pursue over-the-counter status for Plan B from the Food and Drug Administration.
- The addition of Plan B will complement Barr Labs' existing contraceptive products, which include 15 generic oral contraceptives and its first branded birth-control pill, Seasonale.

Track EC issues with new web site

Where can you get the latest information on access to emergency contraception (EC)? Visit www.GO2EC.org, a new web site for pharmacists, EC leaders, public health professionals, and community health advocates.

The web site is designed to highlight what states are doing to improve access, increase understanding around the options to improve access in pharmacies, help advocates connect with a broader community of professionals, and share best practices. It is operated by the Pharmacy Access Partnership, part of the Oakland, CA-based Public Health Institute, a public health nonprofit agency.

The web site offers information on all 50 states, with an in-depth look at states providing direct access to EC in pharmacies. Additional sections include models for EC pharmacies, collaborative practice agreements, legislation, resources, personal stories, and the latest on the switch from prescription-only to over the counter. ■

The acquisition of Plan B by a major pharmaceutical company bodes well for EC access, observes **James Trussell**, PhD, professor of economics and public affairs, faculty associate of the Office of Population Research and associate dean of the Woodrow Wilson School of Public and International Affairs at Princeton (NJ) University. The resources afforded by Barr Labs, such as a larger sales and marketing staff, will allow the drug to be more widely presented to prescribers and pharmacists. If Plan B does gain FDA approval to go OTC, Barr is better positioned to increase awareness of the drug, with such tools as direct-to-consumer advertising, he explains.

Barr sells 15 generic oral contraceptives (OCs) and is launching its first branded birth-control pill, Seasonale, an extended OC regimen product. The addition of Plan B complements the company's existing product line, says **Bruce Downey**, Barr's chairman and CEO.

"As part of our commitment to women's health care, which includes the expansion of our franchise of oral contraceptive products, we recognize that some women may need a product such as Plan B in the event of an expected contraceptive failure or in the event that no method of contraception was used," states Downey. "By acquiring this product and certain assets from [Women's Capital Corp.], we offer women an important emergency contraceptive option."

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Providers back access for EC, but not for OCs

While medical and reproductive rights groups have petitioned the Food and Drug Administration to make emergency contraception (EC) available over the counter (OTC),[1] many clinicians are less than enthusiastic when it comes to such availability for oral contraceptives (OCs). Why?

"I am not in favor of making OCs over the counter, because even with instruction, I see many women taking pills incorrectly, resulting in side effects, as well as pregnancy," states **Deborah Wright**, OGNP, a nurse practitioner at the Marshfield Clinic, a private, multispecialty group practice in Eau Claire, WI. "Also by having to come in, they are more likely to receive STD [sexually transmitted disease] screening and education."

She says she will prescribe pills without an exam if the exam is the barrier to taking contraception.

"Education related to correct use is the biggest stumbling block related to the OTC issue of OCs for me," observes **Ruth Napolitan**, RNC, BSN, WHNP, a nurse practitioner at the St. Clair County Health Department in Port Huron, MI.

While OCs are not going to cause severe health problems in the majority of women, the side effects related to initial use can be more than troublesome, Napolitan says.

"Many women who visit our clinic have stopped pills and state they can't use them, [but] after our interview, we can usually dispel the reason of 'can't use' as a side effect or misuse," she says.

The clinician's ability to counsel and test women for STDs is "paramount" for the fertility of many women, who would otherwise not seek medical care, Napolitan states. "I tell our clients all the time that [prescription] for contraception is a form of medical blackmail," she notes. "How many women would make an annual appointment for a pelvic exam if they didn't have to?"

Most participants in *Contraceptive Technology Update*'s 2003 Contraception Survey voted "thumbs down" for OTC access to birth control pills. Almost 69% indicated they were not in favor in such a move, which reflected an increase from 2002's 62.9% figures.

"I take a public health, preventive medicine approach to this issue: I am convinced that unplanned pregnancy is a major public health issue and that OCs are safe for the vast majority of women," states **Christine Peterson**, MD, director of gynecology in the department of student health at the Charlottesville-based University of Virginia. "Yet I also believe that what we have to offer by way of the screening and education that should take place during an OC-related visit addresses additional, equally important, long-term health outcomes for virtually all women."

Such screening should not be limited to sexual activity-related issues, but also to nutrition, exercise, safety, stress, substance use, and other lifestyle matters, she comments.

"I do not think women would be well served if

their contraceptive needs were separated from their overall health needs," states Peterson. "Rather than making OCs available over the counter, we should work to make superb comprehensive women's health care accessible and affordable for all women."

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Intrauterine methods move up in acceptance

More women are taking a second look at intrauterine devices (IUDs), and not all of them are considering such use for contraception.

Recently published research indicates that the levonorgestrel intrauterine system (IUS) Mirena (Berlex Laboratories, Montville, NJ), traditionally used for contraception, also reduces menstrual bleeding associated with uterine fibroids.[1] Use of the IUS use was associated with significant reduction in menstrual blood loss and an improvement in hematologic parameters during a 12-month study among women with small leiomyomatous uteri.[1]

"The progestin-releasing IUS' convenience and high efficacy are strong selling points, with the reduction in menstrual blood loss representing the clincher for many candidates," reports **Andrew Kaunitz**, MD, professor and assistant chair in the obstetrics and gynecology department at the University of Florida Health Science Center/Jacksonville. "In about one-quarter of women having insertions of the progestin-releasing IUS, the patient has not needed contraception — e.g., not sexually active, patient or partner sterilized — with the reduction in bleeding representing the reason for insertion."

Research using the Mirena IUS indicates decrease in pain and dyspareunia from rectovaginal endometriomas, and the device may be effective in treatment of adenomyosis as well,[2,3] observes **Sharon Schnare**, RN, FNP, CNM, MSN, clinician at South Kitsap Family Care Clinic in Port Orchard, WA. Research estimates that the levonorgestrel IUS may be nearly as effective as endometrial resection for treatment of endometrial bleeding and may decrease the need for resection by 75%,[4] she points out.

"I believe that women facing hysterectomy for menorrhagia should be advised of the availability of the levonorgestrel IUS as an alternative to surgery," she states.

EXECUTIVE SUMMARY

Interest is increasing in the use of intrauterine contraception following the U.S. introduction of the levonorgestrel intrauterine system (IUS).

- Research findings suggest use of the IUS reduces menstrual bleeding associated with uterine fibroids. It also may decrease pain and dyspareunia from rectovaginal endometriomas.
- A new study reveals that the two types of intrauterine contraception, the Mirena IUS and the Copper T 380A IUD (ParaGard Intrauterine Copper Contraceptive), are the two most cost-effective methods of birth control available to women in the United States.

Insertions on the rise

Clinicians report increased use of IUDs. According to **Kimberly Carson**, RN, clinical services supervisor at the Aberdeen, WA-based Grays Harbor County Public Health, 51 insertions have been performed so far at her facility in 2003, compared to 33 in 2002. She contends that the introduction of the Mirena has added to the upswing.

Carson says some patients at the agency have received free Mirena IUS devices through the auspices of the ARCH (Access and Resources in Contraceptive Health) Foundation, a not-for-profit Charlotte, NC-based organization funded by Berlex Laboratories. The foundation operates a patient assistance program designed to assist low-income patients who don't have insurance coverage for the device. **(*CTU* reported on the Foundation's services in its January 2003 article, "Check your options to expand IUD access," p. 10; see resource box on p. 141 for contact information.)**

Such financial aid is important; while Medicaid in 47 states covers IUD insertion and removal, the device's price tag may be prohibitive for family planning facilities that serve lower-income women who may not be covered by Medicaid.[5] According to *A Pocket Guide to Managing Contraception*, average wholesale price for the Mirena is $395.[6]

Cost is the primary factor at Planned Parenthood of Southern Arizona in Tucson; Mirena is not offered as an option due to its cost, says **Patti Caldwell**, MSW, the agency's president and CEO.

RESOURCE

For information on the Access and Resources in Contraceptive Health (ARCH) Foundation, contact:

- **ARCH Foundation**, P.O. Box 220908, Charlotte, NC 28222-0908. Telephone: (877) 393-9071. Fax: (704) 357-0036. Web: www.archfoundation.com.

Indeed, many women are put off by the initial cost of the IUD, observes Schnare. However, women need to understand that the method's initial cost is offset by its years of use. A new study reveals that the two types of intrauterine contraception, the Mirena IUS and the Copper T 380A IUD (ParaGard Intrauterine Copper Contraceptive, Ortho-McNeil Pharmaceutical, Raritan, NJ), are the top two most cost-effective methods of birth control available to women in the United States.[7]

Help women see the overall cost benefit of IUD use, says Schnare. When used for five years, the new analysis shows that the three least costly methods are the levonorgestrel-releasing IUS, Copper T 380A IUD, and the three-month injectable [depot medroxyprogesterone acetate (DMPA), also known as Depo-Provera, Pharmacia Corp., Peapack, NJ], with total five-year costs per person of $1,646, $1,678 and $2,195, respectively. The five most effective methods, based on success rates, are tubal ligation (99.7%), the IUS (98.9%), the IUD (98.5%), DMPA (98.3%), and oral contraceptives (96.2%).[7]

"The currently available Copper T and levonorgestrel-releasing IUDs come as close to a perfect contraceptive as any method currently available, in terms of safety, ease of insertion, reversibility, minimal side effects, and an effectiveness equal to sterilization," observes **Allan Rosenfield**, MD, dean of the Mailman School of Public Health at the New York City-based Columbia University. "American women generally have received inadequate information about these IUDs, which is a disservice to our patients."

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ASK THE EXPERTS

New starts of the Pill — What's your approach?

What is the accepted practice for checking blood pressure following initial starts on oral contraceptives? Following are observations from two members of the *Contraceptive Technology Update* Editorial Advisory Board, **David Archer**, MD, professor of obstetrics and gynecology and director of the Clinical Research Center at the Eastern Virginia Medical Center in Norfolk, and **Andrew Kaunitz**, MD, professor and assistant chair in the obstetrics and gynecology department at the University of Florida Health Science Center/Jacksonville.

Question: Have there been any recent surveys to see how many clinicians do rechecks (blood pressure) with initial starts on oral contraceptives? Since we are using lower and lower estrogen pills, is there still a need for close follow-up to check blood pressure, particularly in healthy college-age young adults?

Archer: Increased blood pressure in oral contraceptive users is rare. It appears to only occur in women who have an exaggerated response of the renin-angiotensin system from the steroids. All women are at risk since there is no way to predict who will have a significant elevation in blood pressure. Re-evaluation of blood pressure at three months is recommended. Significant changes > 140/90 should be monitored and, if persistent, oral contraceptives should be discontinued. If the increase in blood pressure is due to the oral contraceptive, it should have returned to normal within three months. Obviously, a nonsteroidal method of contraception should be used while following the patient.

Kaunitz: I continue to encourage patients starting any new hormonal or intrauterine method to return for a follow-up visit between four to 12 weeks post-initiation. Although the follow-up visit may represent an inconvenience for some patients, it provides a useful opportunity to review compliance and side effect issues. Accordingly, a brief follow-up visit can prevent premature contraceptive discontinuation, which enhances the likelihood of long-term successful contraceptive use. In the case of combination (estrogen-progestin) contraceptives (oral, patch, ring), the follow-up visit also provides an opportunity to check blood pressure, which in a few users, may rise in response to contraceptive initiation. Regarding follow-up after combination OC initiation, the World Health Organization recommends an annual follow-up visit, and indicates there are added benefits to a three-month follow-up contact.[1]

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Medicaid cuts: What is the impact on your services?

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

Today, more than 6 million women of reproductive age rely on Medicaid for their basic health care, including family planning services. In fact, Medicaid is the largest source of public funding for family planning services and supplies, and the federal Medicaid statute contains a number of important provisions designed to facilitate access to family planning care among women enrolled in the program. That is why family planning advocates were so concerned when, earlier this year, the Bush administration announced its proposal to revamp the Medicaid program.

Specifically, the administration proposed ending the individual entitlement to care that has been the cornerstone of the program since its inception. Instead, states would have received a fixed allotment to run the program, and, in exchange, would have received much greater flexibility to set benefit levels and to determine which populations would be served.

The proposal was intended to reign in the program's rapidly escalating costs, which, by their very nature, rise during economic downturns when caseloads increase. It was also designed to respond to mounting calls from the nation's governors for greater latitude in designing and administering their programs, which account for 20% of state spending.

Subsequently, the administration was taken by surprise when the states failed to embrace the proposal — largely due to the federal funding cap that would leave states on the hook for any expenditures incurred beyond their specified allotments. In fact, a bipartisan task force comprised of 10 governors charged with reviewing the proposal and making recommendations disbanded after finding itself deadlocked, which doomed the administration's proposal.

Yet with states facing their worst fiscal crisis since World War II — involving an estimated collective budget shortfall of almost $70 billion in fiscal year 2004 — many increasingly desperate governors have enacted deep cuts to their Medicaid programs to achieve savings. Many of these cuts have eliminated critical services or placed them out of reach of some recipients. Still others have resulted in a loss of coverage, either directly by trimming enrollment or indirectly by making the enrollment process more cumbersome. These cuts fall into four basic categories that may reduce access to family planning and other reproductive health services for low-income women:

• **Reductions in program eligibility levels. For example, Alaska's income-eligibility level will no longer rise with inflation.** The state also reduced the income ceiling for pregnant women from 200% to 175% of poverty. Texas is reducing its Medicaid eligibility for pregnant women from 185% of poverty to 158%.

• **Changes in enrollment procedures.** States are turning back the clock on efforts begun in the 1980s to ease the process of applying for and retaining Medicaid coverage. Texas, for example, imposed a 90-day waiting period for Medicaid enrollment and reduced the amount of assets a family could have and still qualify for Medicaid.

• **Freezes or cuts in provider reimbursement.** Virtually all states adopted such a strategy as part of their 2004 budgets, according to the Kaiser Commission on Medicaid and the Uninsured. California enacted a 5% cut in reimbursement to most health care providers (down from the 15% cut initially proposed in the governor's budget). Planned Parenthood Affiliates of California in Sacramento estimates that this will result in a loss of $15 million to family planning providers in the state.

• **Limitations on covered benefits.** Because family planning services are mandated by federal law, they have been largely shielded from state efforts to cut back specific benefits. The exception was Missouri, which in 2002 scaled back its demonstration program providing family planning to women following a Medicaid-funded birth from two years to one year.

Congress responded to the state crisis this spring by providing $10 billion to the states in the form of a temporary increase in the proportion of Medicaid costs reimbursed by the federal government. Experts believe that this infusion of cash was critical to preventing additional scale-backs, at least in the short term.

States, however, are rightly concerned about what may happen next year when this temporary boost in funding ceases before fiscal conditions improve, particularly with additional aid from Congress unlikely. And if the picture were not bleak enough already, recent census bureau statistics showed that the number of Americans without health insurance rose by 2.4 million last year, the largest increase in a decade, which raised the total number of uninsured to 43.6 million.

But one thing is clear: Should states be forced to implement further cuts to their Medicaid program, the impact on women's access to family planning services could be enormous. ■

Mark your calendars for women's conference

Attend the first International Conference on Women and Infectious Diseases, scheduled for Feb. 27-28, 2004, in Atlanta. The conference is sponsored by the Atlanta-based Centers for Control and Prevention's National Center for Infectious Diseases in partnership with other health organizations.

The conference will be held at the Atlanta Marriott Marquis, which also will serve as the site of the Feb. 29-March 3, 2004, International Conference on Emerging Infectious Diseases.

The goal of the conference is to enhance prevention and control of infectious diseases among women worldwide. Objectives include prevention and control of infectious diseases that disproportionately impact women and identification and exploration of gender-appropriate interventions. Seminars will cover the impact of globalization, women and HIV, perinatal infectious diseases, immunizations, antimicrobial resistance, and links between infectious and chronic diseases.

Pre-registration deadline is Feb. 14. The pre-registration fee is $175, with $225 for on-site registration. Registration can be processed on-line at the conference's web site, www.womenshealthconf.org.

Registrants also can print out the form on-line and mail it to International Conference on Women and Infectious Diseases, c/o ExpoExchange, P.O. Box 3867, Frederick, MD 21705-3867, or fax it to (301) 694-5124. ■

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 "Intrauterine methods move up in acceptance" in this issue.)**
- Describe how those issues affect service delivery and note the benefits or problems created in patient care in the participant's practice area. **(See "Contraception forecast: You'll have new options.")**
- Cite practical solutions to problems and integrate information into daily practices, according to advice from nationally recognized family planning experts. **(See "Medical abortion update: Death sparks questions on abortion pill" and "Barr to acquire Plan B: EC access to expand?)**

21. What are expected side effects of the mifepristone/misoprostol regimen of medical abortion?
A. Gastrointestinal symptoms, crampy abdominal pain, misoprostol-related side effects, bleeding
B. Gastrointestinal symptoms, crampy abdominal pain, joint pain, bleeding
C. Edema, crampy abdominal pain, misoprostol-related side effects, bleeding
D. Skin rash, crampy abdominal pain, misoprostol-related side effects, bleeding

22. What is the chief reason women discontinued use of Implanon, according to Croxatto HB?
A. Headache
B. Irregular bleeding
C. Painful menses
D. Edema

23. What is the chief finding of Raymond EG, et al., regarding actual over the counter use of emergency contraceptives (EC)?
A. Few women used EC pills appropriately without provider evaluation and counseling.
B. All women used EC pills appropriately without provider evaluation and counseling.
C. None of the women in the study used EC pills in an appropriate manner.
D. Most women used EC pills appropriately without provider evaluation and counseling.

24. What are the two most cost-effective methods of birth control available to women in the United States, according to Chiou CF, et al.?
A. Oral contraceptives and condoms
B. Levonorgestrel intrauterine system and the Copper T 380A intrauterine device
C. Cervical cap and condoms
D. Transdermal contraceptive and contraceptive vaginal ring

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

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2003 SALARY SURVEY RESULTS

CONTRACEPTIVE TECHNOLOGY UPDATE®

A Monthly Newsletter for Health Professionals

Little gain seen in salaries for family planning providers

Are you making strides on the salary front? If the answer is "no," count yourself among the majority of family planning providers. According to results of the 2003 *Contraceptive Technology Update* Salary Survey, about half (46.6%) of respondents said they are earning just 1%-3% more than in 2002. The survey was mailed in July 2003 and had a response of 105, for a response rate of 8%.

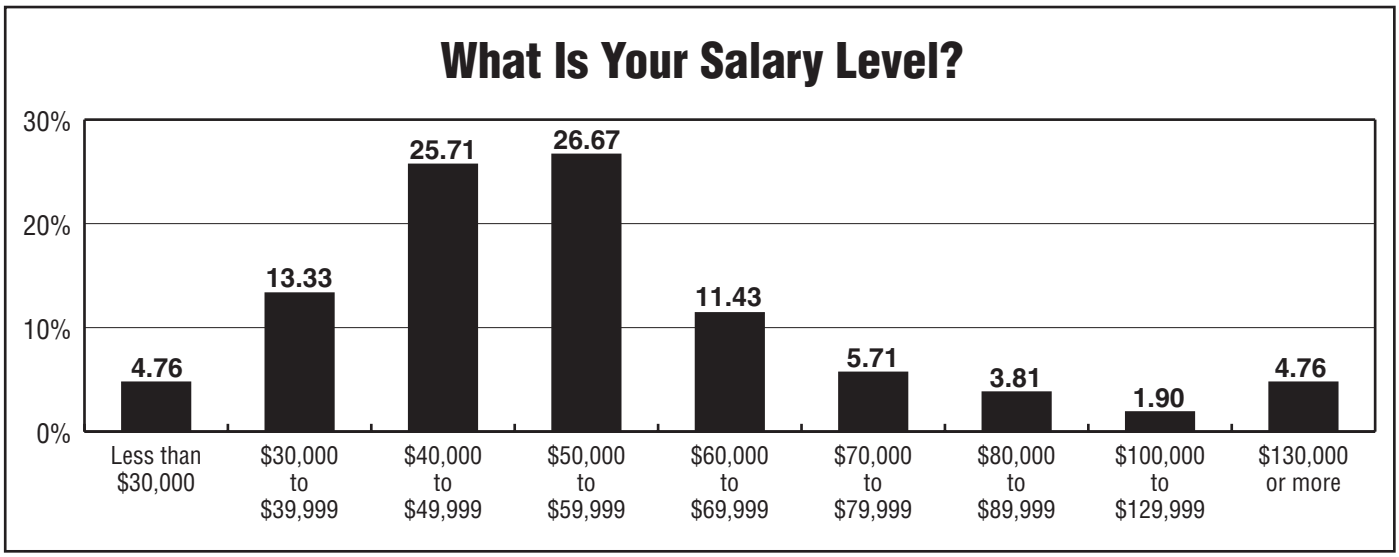
More than half (52.3%) of 2003 survey responses came from nurse practitioners (NPs). A closer look at survey results shows that average salary for NPs fell to $51,472 in 2003, compared to $55,710 in 2002 and $53,043 in 2001. Median salaries for NPs dipped to $52,368 from 2002's $55,313 figure. Average salary for administrators/coordinators rose to $66,735, jumping from $49,230 in 2002. Median salary for this group, which comprised 16.1% of 2003's total responses, also increased from $52,778 in 2002 to $59,000 in 2003.

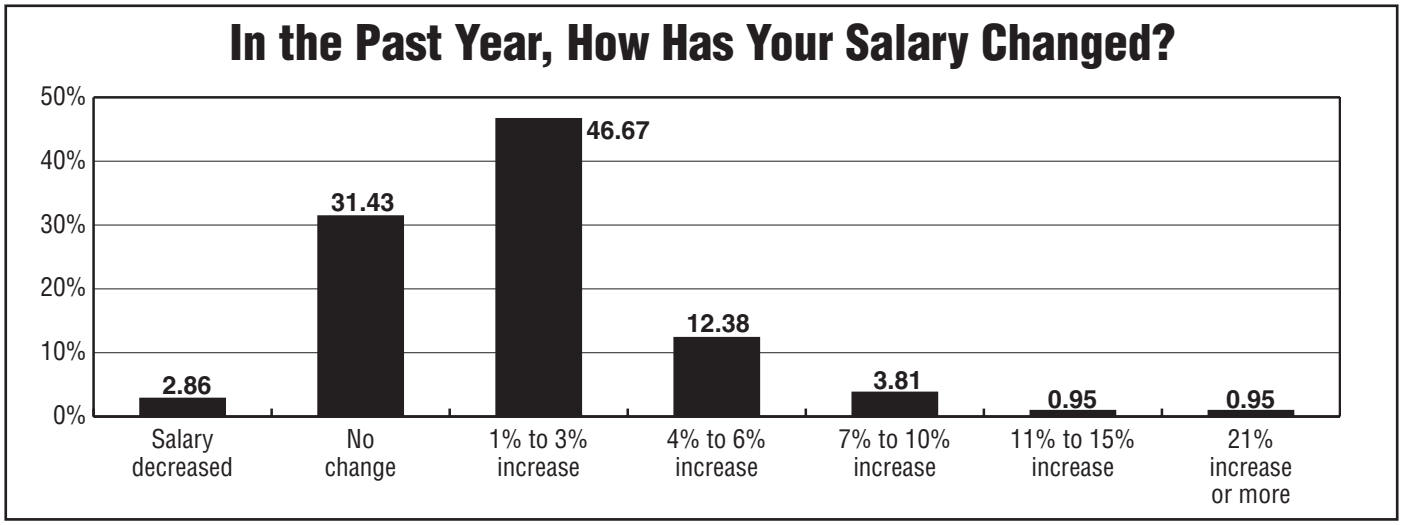
It is hard to know what accounts for the fluctuation in salaries, observes **Susan Wysocki**, RNC, NP, president and chief executive officer of the Washington, DC-based National Association of Nurse Practitioners in Women's Health.

"It could be the economy in general, increases in costs without increases in grant monies for those in the public sector, or the state of the health care system," she surmises.

Check national figures

Tight financial times aren't just limited to those in the family planning field. According to annual income surveys conducted by two medical group





associations, the trend of physicians working harder for about the same or even less pay continues for many.[1] Obstetricians/gynecologists recorded an average salary of $231,000 in 2001, a 3.5% increase over the previous year.[2]

Advanced practice providers are noting an increase in salaries. Respondents to the 2002 census from the Alexandria, VA-based American Academy of Physician Assistants (AAPA) showed a salary mean of $72,241, up from $63,168 in its 2001 census.[3]

What are you worth?

To get your salary dollars moving, know what you are worth, says Wysocki.

"Most NPs do not know how much reimbursement they bring into the practice or know what it costs, separate from them — overhead, etc. — what it costs a practice to see a patient," she states. "NPs can ask the practice's manager or the billing person to help them get an idea of what his/her average day brings in — from routine exams to counseling visits to high-level procedures, like colposcopy."

Most offices can generate reports of NP productivity through billing software. Many practices will furnish NPs with this information; however, if you want to generate your own records, take a look at the following formula, offered by health care employment expert **Carolyn Buppert**, JD, an attorney in Annapolis, MD:

1. Write down the number of encounters per day by CPT code. Keep a notebook with a page for each day worked. An example:

Tuesday, March 14

- Office visit, level 3, established patient — 8
- Office visit, level 4, established patient — 5
- Office visit, level 2, established patient — 5
- Office visit, level 2, new patient — 3
- Office visit level 4, new patient — 1
- Immunization — 3
- Wet mounts — 2
- Cryosurgery , 1 lesion — 1

2. Obtain the office charge for each of the procedures listed above.

3. Multiply the procedure charge by the number of encounters conducted.

4. Sum the charges for the procedures conducted that day.

5. Sum the charges per week, per month, and per year.[4]

Also, take a look at productivity-based compensation. Under such an arrangement, a compensation package is based on a percentage what your position generates. If aiming for this form of compensation, Buppert suggests NPs ask the following questions:

- Does the percent cover my benefits?
- Who pays various practice expenses?
- How efficient is the practice at collections?
- What is the differential between the practice's charges and actual receipts?
- How often is the accounting done?
- How is the draw against earnings handled?
- How are the appointments triaged at the front desk?
- How can I review the accounting?[4]

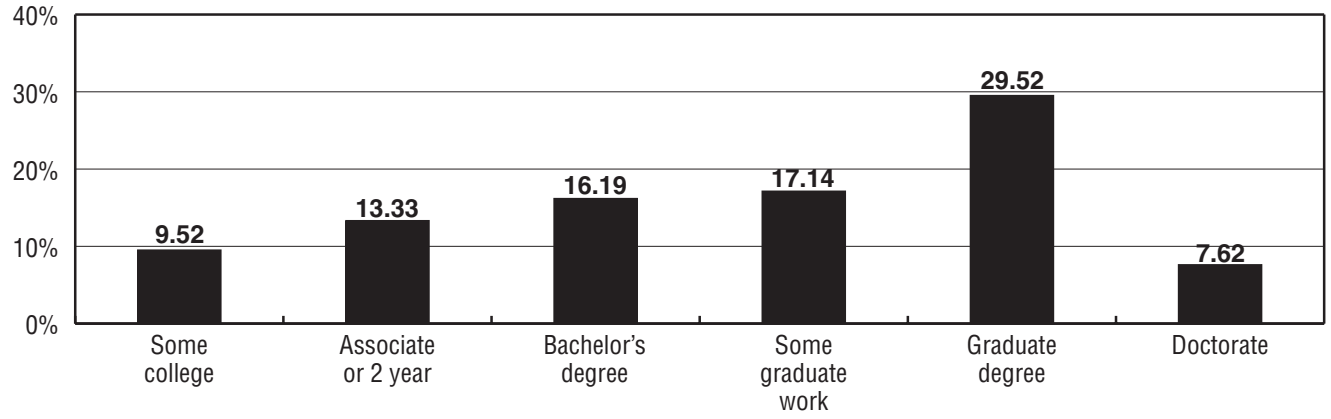
Check your agreement

Still steamed about your salary? Know that in today's health care environment, it takes effort to push the numbers forward.

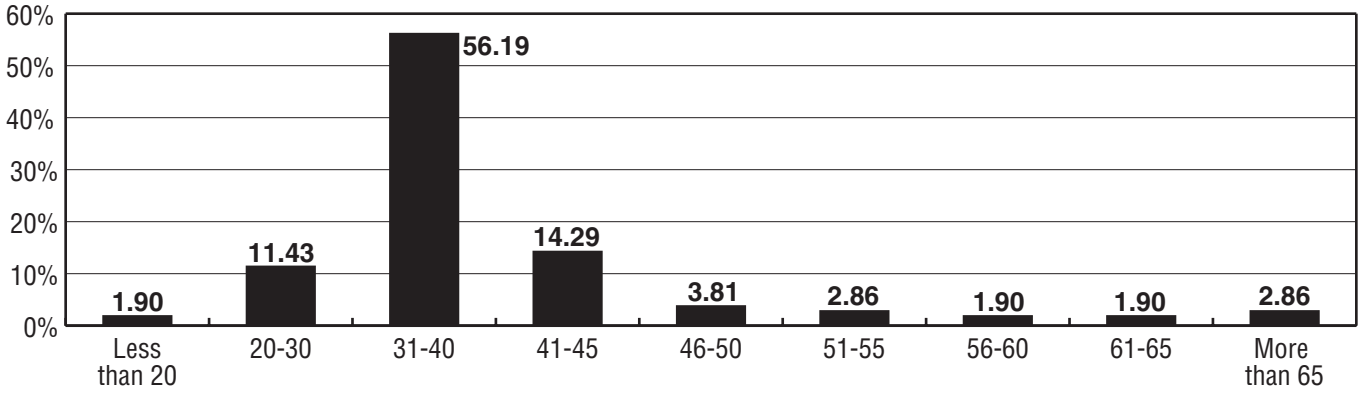
Check your employment agreement for what is

(Continued on page 4)

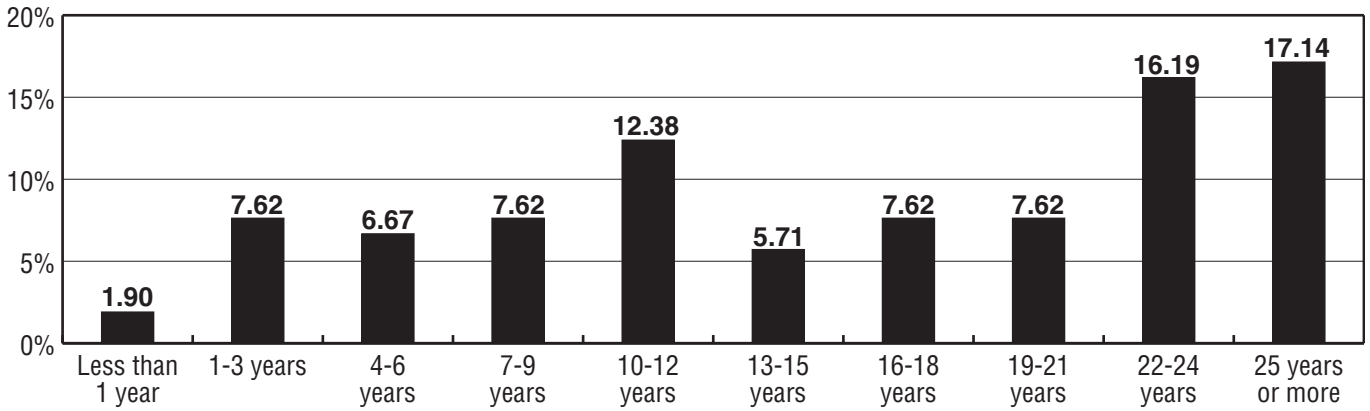
What Is Your Highest Academic Degree?

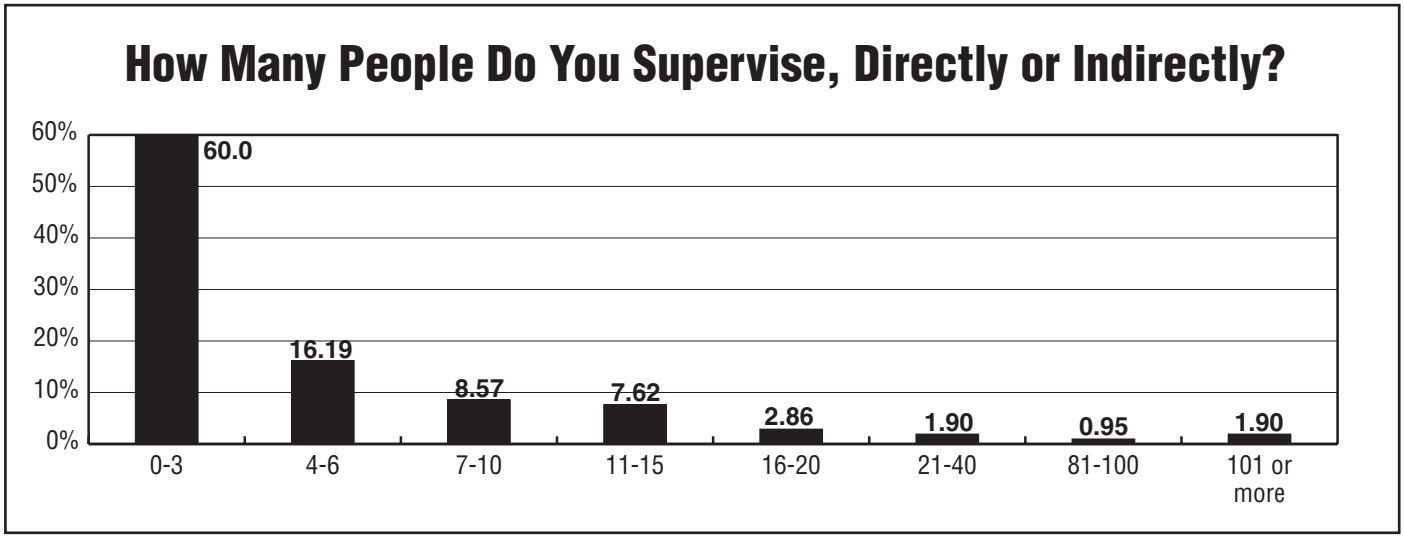


How Many Hours a Week Do You Work?



How Long Have You Worked in Your Present Field?





known as an "evergreen provision." While such a provision is useful since it prevents annual contract negotiations, if your agreement doesn't provide for an annual salary review, you may be getting stuck with an automatic salary renewal.

Look for language similar to this wording: "This agreement shall last for a period of one year from Jan. 1, 200__ , through Dec. 31, 200__ , and shall continue from year to year thereafter."[5]

Also, if your agreement asks for you to "devote all time and energies" to your job, see if you can negotiate for more pay. If you consent to give full time and energies to your current employer, you are not pursuing other paying, available positions in your off hours. Negotiating on adhering to such an agreement may be an opening to more dollars in your paycheck.[6]

Just remember the road to progress begins with that first step. Take a tip from Wysocki: "I sometimes hear people complain that they haven't gotten a raise, and when I ask them the last time they asked for a raise, they haven't," she states. "Ask."

What's the job outlook?

If you decide to change jobs, know that the demand for advanced practice providers, including nurse practitioners, physician assistants, and certified nurse midwives (CNMs), is increasing. The versatility and cost effectiveness of such clinicians are making them attractive to practices, according to national reports.[3]

Demand is keeping up with the supply: only 1.2% of respondents in the AAPA's 2002 annual census reported being unemployed and looking for work.[3] The AANP reported about 5,400 NP program graduates in 2002, with at least that many graduates anticipated for 2003.[3] The AAPA saw an increase in PA graduates in 2003: about 4,600, compared with 2002's 4,300 figure.[3]

The employment outlook for advanced providers such as nurse midwives is good, agrees **Deanne Williams**, CNM, executive director of the Washington, DC-based American College of Nurse-Midwives (ACNM). For nurse midwives, the profession is reaching a tipping point, where the mid-1980s influx of CNMs is evolving toward those looking at retirement plans, she states.

The national shortage of registered nurses has not yet translated into the world of advanced practice providers, but it may be coming, says Williams.

"I don't think there's a relationship between the nursing shortage and the demand for nurse midwives," she states. "We do think that over time it will hit us, because if there are fewer people entering the nursing profession, there will be fewer people to choose from to become nurse midwives."

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2003 Index

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