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IN THIS ISSUE

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Researchers halt HIV vaccine trial — What's the next step?

Study shuttered after interim data showed vaccine was ineffective

Progress toward an effective HIV vaccine has encountered a major roadblock with the cessation of a HIV vaccine clinical trial sponsored by Merck & Co. Meanwhile, the need for an effective vaccine continues to grow: The number of new infections in 2006 rose to 4.3 million around the globe, 400,000 more than in 2004.[1]

"While we are very disappointed that this vaccine candidate did not demonstrate protection, the data from this trial will provide critical insights into this disease and future vaccine development," says **Lawrence Corey**, MD, principal investigator of the HIV Vaccine Trials Network (HVTN), which co-sponsored the Merck trial.

The study had enrolled 3,000 participants at sites in Australia, Brazil, Canada, the Dominican Republic, Haiti, Jamaica, Peru, Puerto Rico, and the United States since its initiation in late 2004. U.S. study sites included Boston; Birmingham, AL; Chicago; Decatur, GA; Denver; Houston; Los Angeles; Miami; New York City; Newark, NJ; Philadelphia; Rochester, NY; St. Louis; San Francisco; and Seattle. Study volunteers all were HIV-negative, between 18 and 45 years of age, and at high risk of HIV infection. Enrollment for the study was closed in March 2007.

EXECUTIVE SUMMARY

Research of a HIV vaccine sponsored by Merck & Co. has been halted after an interim analysis concluded that the vaccine did not prevent infection.

- One study had enrolled 3,000 participants at sites in and outside the United States since its initiation in late 2004. Another trial was ongoing in South Africa. Both were designed to test Merck's MRKAd5 trivalent vaccine.
- Other vaccines continue to be tested as they move through the research pipeline. Trials are upcoming for one candidate that uses a recombinant DNA as a prime and then an adenoviral vector vaccine as a boost.

The trial was designed to test Merck's candidate HIV vaccine, the MRKAd5 trivalent vaccine. Made with a weakened version of adenovirus Type 5, which was used as a delivery vector, the vaccine included three synthetically produced HIV genes, *gag*, *pol*, and *nef*. Its design was aimed to stimulate production of immune system T cells to kill HIV-infected cells. During a scheduled interim efficacy analysis of the study, an independent monitoring group reviewed safety data from some 1,500 volunteers who were expected to have the best response to the vaccine due to their low levels of pre-existing immunity to the adenovirus.

The interim analysis concluded that the vaccine did not prevent infection. In volunteers who received at least one dose of the three-dose vaccine series, 24 cases of HIV infection were observed in the 741 volunteers who received vaccine, and 21 cases of HIV infection were observed in the 762 participants in the placebo group. In the subgroup that had received at least two vaccinations and who were HIV negative for at least the first 12 weeks of the trial, 19 cases of HIV infection were observed in the 672 volunteers in the vaccine arm, and 11 cases were observed in the 691 volunteers in the placebo arm. Data also indicated the vaccine did not reduce the amount of virus in the bloodstream of those who became infected. HIV RNA levels were similar in the vaccine and the placebo arms about eight to 12 weeks after diagnosis of infection.[2]

Study volunteers were followed for about 13 months. Overall adverse event rates generally were similar among the two groups, except for a higher rate of local injection site-related reactions in the vaccine group.

Researchers also have halted a second Phase II trial of the Merck vaccine candidate, known as the Phambili trial, as well as two additional Phase I trials. The Phambili trial was begun earlier in 2007 in South Africa by the HVTN to see whether the Merck vaccine would be effective at preventing infection, reducing viral levels, or both from HIV subtype C, which is more common in southern Africa.

"The next step is really to learn as much as we can about why this vaccine didn't work and then continue to work with the vaccines in the pipeline to keep testing until we find one that will," says **Sarah Alexander**, HVTN spokeswoman.

More vaccines on way

In a conventional vaccine, the immune system is triggered into manufacturing antibodies against an infectious organism. Scientists have been stymied in developing an effective vaccine against the rapidly mutating HIV.

Over the past decade, science has focused on the T cell approach, stimulating T lymphocytes that can identify and kill HIV-infected cells in an effort to

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prevent/limit viral replication and delay disease progression.[3] Researchers have zeroed in on this approach after results of early studies showed that monkeys receiving such vaccines against simian immunodeficiency virus (similar to HIV) lived longer or had lower than usual viral levels.[3] **(*Contraceptive Technology Update* reported on the T cell approach in the article "HIV vaccines: New generation may reduce transmission on virus," *STD Quarterly* supplement, October 2002, p. 1.)**

One vaccine using this premise is nearing an efficacy trial, says Alexander. Developed by the Dale and Betty Bumpers Vaccine Research Center (VRC), part of the National Institutes of Health (NIH), the vaccine uses a recombinant DNA as a prime and then an adenoviral vector vaccine as a boost. The vaccine contains synthetic versions of four HIV genes: *gag*, *pol*, *nef*, and *env*. The *gag*, *pol*, and *nef* genes come from HIV subtype B, the primary virus found in Europe and North America. *Env*, the fourth gene, codes for an HIV coat protein that allows the virus to recognize and attach to human cells.[4] The first portion of the vaccine strategy uses DNA to prime an immune response to internal HIV proteins and external HIV proteins, with the booster portion designed to stimulate specific antibody responses to HIV envelope proteins and internal proteins.[3]

The DNA components of the vaccine were manufactured by Vical in San Diego; the adenovirus vector was developed by the VRC in collaboration with GenVec of Gaithersburg, MD, which also manufactured the adenovirus vector vaccine.[4]

Funding pushes search

An Atlanta-based biotechnology company, GeoVax Labs, has just been awarded an estimated $15 million grant from the NIH's National Institute of Allergy & Infectious Disease to support its HIV/AIDS vaccine program. How does GeoVax's vaccine differ from the Merck candidate? There are multiple differences, says **Harriet Robinson**, PhD, chief scientific advisor for the company and chief of microbiology and immunology at the Yerkes National Primate Research Center based at Emory University in Atlanta.

"The Merck vaccine used a recombinant adenovirus to introduce HIV proteins into cells," she explains. "We use recombinant DNA, followed by a recombinant poxvirus, so the platforms are different." **(*CTU* reported on the GeoVax vaccine in "HIV vaccine trials are now under way," September 2006, p. 103.)**

GeoVax scientists believe that the company's vaccine raises a form of protection not seen in the Merck candidate, says Robinson. Also, while both candidates raise a T cell response, the GeoVax vaccine includes high frequencies of T cells associated with good long-term control of HIV, she says. "We feel that we have raised a type of T cell that has greater potential for protective responses for battle," Robinson says. Consider the analogy of soldiers, she says. "You want your soldiers to demobilize and rest, and you can't keep them continually in the field," Robinson says.

The government grant will propel GeoVax's research, says Robinson. At this point in time, the company's research team is moving along through its clinical trials to build up its safety and immune response data, she reports. "The next most important result we will have from our vaccine is when we get to the point that Merck is, and at that point, we'll know whether or not we protected humans or not," states Robinson.

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Use of the Pill can offer cancer protection

Some risks increase when method used for 8+ years

Your patients may be asking you about research news that indicates that use of oral contraceptives (OCs) increase cancer risk for women who use the method for more than eight years.[1]

While the data are new, most of the women in the study used pill formulations that are no longer popularly prescribed in U.S. practices. According to a review of the most prescribed pills in the last 10 *Contraceptive Technology Update* Contraception

EXECUTIVE SUMMARY

Data from research on oral contraceptives (OCs) initiated decades ago do not increase a woman's chances of developing cancer and may even reduce the risk for most women. However, there was an increased risk for women who used the method for more than eight years.

- Most of the pill formulations used by women in the study are no longer used today in current practice. Most (75%) of the women used combined OCs containing 50 mcg estrogen; 12% used pills with more than 50 mcg; 10% used pills with less than 50 mcg; and 3% used progestin-only pills.
- For women who used OCs for more than eight years, who represented less than one-quarter of all pill takers, their cancer risk was increased, especially for cancers of the cervix, central nervous system, or pituitary. However, their odds of getting ovarian cancer were much lower.

Surveys, survey participants listed no pills above a 35 mcg dosage.

Most (75%) of the women in the current study used combined oral contraceptives containing 50 mcg of estrogen; 12% used pills with more than 50 mcg estrogen; 10% used pills with less than 50 mcg; and 3% used progestin-only pills. Most of the women used formulations from more than one category, with most moving over time to pills with less estrogen.

What prompted research?

Research in a 2006-published study prompted the current analysis.[2] In that paper, scientists reported a significantly reduced risk of gynecological cancers combined among ever-users of oral contraceptives compared with never-users.[2] The University of Aberdeen researchers used data from that oral contraception study to test the hypothesis that, compared with never-users, ever-users of oral contraception have a reduced overall risk of cancer.

To conduct the study, researchers from the University of Aberdeen in Scotland reviewed data between 1968 and 2004 collected by the Royal College of General Practitioners (RCGP) Oral Contraception Study, a large population-based dataset. The study recruited 46,000 women beginning in 1968. The average age for participants was 29. About half of the women were using oral contraceptives, and the other half had never used the method. Health care providers for the participants entered health information every six months on the women. Three-quarters of the women also were tracked by central registries so that their deaths and cancers were notified to the study even if they had left their recruitment health care provider. Researchers used the data to calculate the risk of developing cancer and also considered the effects of such variables as age, smoking, and social class.

Take a closer look

To perform the analysis, researchers used two sets of data. One set of data related to cancers reported while participants remained registered with their recruiting health care provider. The second main study dataset (the larger dataset) included cancers notified by central health registries after women had left their recruiting provider.

In both data sets, researchers report no overall increased risk of cancer among pill users, in spite of the high dosage of pills used in this study. When looking at the provider dataset alone, women who had taken the Pill at some time during their lives had a 3% reduced risk of developing any cancer. When the larger dataset was used, the reduction was 12%. In the central health registries dataset, women on OCs had statistically significant lower rates of large bowel/rectal, uterine body, and ovarian cancer. The provider dataset (the smaller dataset) showed a reduced risk of uterine and ovarian cancer.

For women who used oral contraceptives for more than eight years, who represented less than one-quarter of all pill takers, their risk was increased for being diagnosed with cancer, especially cancers of the cervix (adjusted relative risk 2.73, 1.61 to 4.61) and central nervous system or pituitary (5.51, 1.38 to 22.05). However, their odds of getting ovarian cancer were much lower (0.38, 0.16 to 0.88), with that protective effect lasting for at least 15 years after they stopped taking the Pill.[1]

What are the strengths of the study? Its cohort design allowed exposure information to be collected before cancer diagnosis, notes **Philip Hannaford**, MD, professor of primary care at the University of Aberdeen in Scotland and lead author of the research. Also, the study had a long follow-up period, so researchers were able to assess long-term effects. Its large numbers allowed calculations of risk estimates for many individual cancers, he reports.

Taking the Pill has important long-term benefits for most users, says Hannaford. While

women who use the Pill for longer periods (eight years or more) may have a small increased risk for cancer, this risk does not affect most pill users, he notes. Three-quarters of the women in the current study had ceased use of the Pill prior to eight years, and this pattern probably exists today, Hannaford observes.

Most of the excess risk in long-term users was due to cervical cancer, he points out. The RCGP study began before comprehensive, regular cervical screening was started in the United Kingdom, so the risks probably were exaggerated, Hannaford notes. Such risks can be minimized by having a regular screen for cervical cancer, he says. "Pill users should be told not to be frightened to use the Pill, even for long durations, but they should have regular cervical cancer screens."

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Update: HPV vaccine offers cross-protection

Good news: Recent research indicates that the human papillomavirus (HPV) vaccine Gardasil (Merck & Co.; Whitehouse Station, NJ) also provides about 40% cross-protection against other common oncogenic strains of HPV, in addition to its established strains.[1]

"Based on the data presented at the Interscience Conference on Antimicrobial Agents and Chemotherapy, we expect that women vaccinated with Gardasil will benefit from an additional degree of protection against cancer-causing HPV types other than HPV 16 and 18," says **Darron Brown**, MD, professor of medicine, microbiology, and immunology at the Indiana University School of Medicine in Indianapolis, who presented the study results. "The next step is to educate families and young women on the benefits of Gardasil in protecting against cervical cancer and other genital tract cancers."

The research, an analysis of two large Phase III clinical trials of the vaccine, found that Gardasil showed cross-protection against precancerous lesions caused by an additional 10 HPV strains: 31, 33, 35, 39, 45, 51, 52, 56, 58, and 59. The 10 HPV strains, which are members of the A9 and A7 species, are responsible for more than 20% of all cervical cancers worldwide and a large proportion of high- and low-grade cervical lesions.[2,3]

EXECUTIVE SUMMARY

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- The research, an analysis of two large Phase III clinical trials of the vaccine, found that Gardasil showed cross-protection against precancerous lesions caused by an additional 10 HPV strains: 31, 33, 35, 39, 45, 51, 52, 56, 58, and 59.
- Providers may see another HPV vaccine in 2008 if the Food and Drug Administration gives approval to Cervarix, a HPV vaccine candidate. It already has been approved for sale and marketing in the European Union and Australia.

The clinical trials involved administering three doses of Gardasil or a placebo to females ages 15-26. Participants also underwent cervical-vaginal sampling and Pap tests at the beginning of the study and at six- to 12-month intervals for up to 48 months.

Merck is working with partners in the international community to develop sustainable solutions to bring Gardasil to the developing world. The company has announced that it will donate at least 3 million doses of Gardasil to developing countries. Gardasil was launched in the United States in June 2006 and in Europe in September 2006. **(See the article, "HPV vaccine, with nod from FDA, is first one approved to prevent cervical cancer, *Contraceptive Technology Update*, September 2006, p. 97.)**

Another vaccine on the way?

Providers may see another HPV vaccine in 2008 if the Food and Drug Administration (FDA) gives approval to Cervarix, a HPV vaccine candidate from GlaxoSmithKline USA of Philadelphia. The Biologics License Application for the vaccine is being reviewed by the FDA under a 10-month review period, says **Liad Diamond**, a company spokeswoman. The application was submitted in late March 2007, and the company expects to hear

from the FDA in early 2008, she states. ***(Contraceptive Technology Update* reported on the application submission in the article, "What is next on the HPV vaccine horizon?" June 2007, p. 65.)**

The European Commission approved Cervarix for sale and marketing in the European Union in September 2007. Cervarix already is available in Australia; the vaccine came online in that country last May.

Cervarix and Gardasil are being studied in a head-to-head comparison. The trial is designed to compare the immune responses to HPV types 16 and 18 in U.S. women ages 18-26, as well as evaluate the immune responses to HPV 16 and 18 in women ages 27-35 and 36-45. In addition, the study will compare immune responses to other cancer-causing HPV types. **(The Phase III study was launched earlier in 2007. See the article, "Head-to-head study of cervical cancer vaccines now under way at about 50 different sites," in the *STD Quarterly* supplement inserted in the April 2007 issue, p. 1.)**

What's the next step?

What about an HPV vaccine for men? Merck is sponsoring a clinical trial of Gardasil in 4,000 men, including 500 self-identified gay men. Initial results are expected toward the end of 2008.[4]

The trial includes a heterosexual male cohort evaluating the efficacy of the quadrivalent vaccine for preventing genital warts and a gay male cohort in evaluating the efficacy of the quadrivalent vaccine in preventing anal carcinoma. With no data yet available, the Gardasil vaccine is not currently recommended for men.

How about use of the vaccine in older women? Merck is conducting Gardasil clinical trials in women as old as 45, but results are not yet available. Research released earlier in 2007 indicates that at 18 months after the first of a three-dose regimen, 100% of women up to age 55 vaccinated with the candidate vaccine had antibodies present against the two most common cancer-causing HPV types, 16 and 18.[5] **(Check the study results in "Research eyes HPV vaccine effectiveness," *CTU*, September 2007, p. 103.)**

"Women are not infected with HPV by breathing in infected air or drinking infected water, " notes **Robert Hatcher**, MD, MPH, professor of gynecology and obstetrics at Emory University School of Medicine in Atlanta. "They are usually infected by sexual intimacy with a man, and a vaccine for men is of paramount importance."

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Condom conundrum: What spells program success?

Officials at the District of Columbia Department of Health (DOH) are retooling the city's condom distribution program after meeting public resistance to its customized condoms.

The city launched its own private-label condoms, DC Condoms, in February 2007 as part of its "One Million Ways to Stop HIV" condom program. The condoms, packaged in a purple and mustard-yellow package, carried the message, "Coming together to stop HIV in DC." **(New York City health officials launched their own private-label condom the same month. See *Contraceptive Technology Update*'s "Start spreading the news: NYC Condom unwrapped," September 2007, p. 102.)**

In its work order for the private-label condoms, the DOH specified that Food and Drug Administration and American Society for Testing and Materials standards must be met in order to offer reliable protection.

To kick off the condom campaign, the DOH partnered with a variety of community providers to distribute an initial 250,000 DC-branded condoms. However, sites that signed up for the distribution

EXECUTIVE SUMMARY

Officials at the District of Columbia Department of Health (DOH) are retooling the city's condom distribution program after meeting public resistance to its customized condoms. The city launched its own private-label condoms, DC Condoms, in February 2007.

- Sites who signed up for the distribution program began to see a drop-off in interest in the free condoms as months progressed. Complaints were raised that packets were ripping in purses or bursting open in pockets.
- The public health department held a meeting with community partners to discuss the program. As a result of the meeting, the manufacturer is replacing all remaining supplies with brand-name condoms usually found on drugstore shelves. The DOH has collected condoms in storage for return to the manufacturer.

program began to see a drop-off in interest in the free condoms as months progressed. Complaints were raised that packets were ripping in purses or bursting open in pockets. As a result, many recipients said they had little confidence that the condoms would offer protection.[1]

As of September 2007, the DOH said 650,000 condoms had been distributed through 50 community organizations across the city, including DOH clinics, health care and community groups, street outreach projects, youth-serving organizations, as well as at nontraditional locations, including dance clubs, bars, barber shops, beauty salons, and Laundromats.[2] The private-label condoms were purchased from Boston-based Global Protection Corp. Some of the condoms were manufactured in China, while others were produced in Malaysia.[3]

Health officials met with community organization representatives in mid-September. Following that meeting, the public health department has worked with community partners to collect condoms still in storage for return to the manufacturer, says **Leila Abrar**, MPH, department spokeswoman. Condoms in storage at DOH also are being returned, she reports. The manufacturer is replacing all remaining supplies with brand-name condoms usually found on drugstore shelves.[4]

What steps are public health officials taking to bolster the condom distribution program? According to Abrar, plans for specific packaging of a DC condom are on hold, based on feedback received from community stakeholders during a Sept. 13 meeting.

"Community partners stressed their preference for brand-name condoms that are clearly identifiable as having been produced by a leading manufacturer," states Abrar. "DOH will continue to seek out recommendations from community partners on retooling the DC condom distribution program to obtain more brand-name condoms; identify more accessible, nontraditional locations; and improve overall public awareness and education on the importance of condom use."

Public health officials also will continue to seek recommendations from its community partners relating to consumer feedback and how to improve the condom distribution program, she states.

What spells success?

The Washington, DC, condom distribution program was designed to complement the health department's goals to encourage residents to be screened for HIV, institute routine screening in all health care settings, educate and equip residents to prevent HIV, and provide care and treatment to people with HIV/AIDS. Public health officials are facing an uphill battle: In 2005, the District of Columbia had the highest rate of AIDS cases — 128.4 cases per 100,000 people — among all jurisdictions in the country conducting AIDS surveillance.[2]

What aids in implementing a successful condom program? Developing a reliable distribution program is an important factor, says **Thomas Farley**, MD, MPH, professor and department chair of community health sciences at Tulane University School of Public Health and Tropical Medicine, New Orleans. Farley was involved with the first statewide condom social marketing intervention in the United States. The program, "Operation Protect," was implemented in Louisiana in the mid-1990s.[5] **(To learn more about the program, see "Keep condom use high, retain no-charge status," October 1999, p. 118.)**

"Since they [condoms] are not paid for by users, you can't distribute them through regular business channels," he says. "In a good program, condoms will be distributed by the millions, so any agency involved has to have a robust system to deliver them and make sure the highest-priority sites — e.g., gay bars — have them displayed consistently and prominently."

Program staff and partners alike need to understand that condoms are extremely inexpensive and should be distributed in abundance, says Farley. Staff members often want to distribute condoms very stingily and express vague fears that people

will "waste" them, he notes. "Condoms are like clean water in a refugee camp: the more the better," Farley states.

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Where is intrauterine contraception offered?

EXECUTIVE SUMMARY

Intrauterine contraception is safe and effective, but many clinicians continue to exclude it from their list of contraceptive options.

- About 40% of respondents to the 2007 *Contraceptive Technology Update* survey say they inserted six or more intrauterine devices (IUDs) in the last year, compared to 2006's 45% figure. The drop in insertions reverses the 10% jump recorded in 2006 and the 5% increase noted in 2005.
- Results of a recently published study indicate that IUDs were acceptable and not associated with a significant increase in gynecologic infections in women at high risk for sexually transmitted infections.

Intrauterine contraception is safe and effective, but many clinicians continue to exclude it from their list of contraceptive options. About 40% of respondents to the 2007 *Contraceptive Technology Update* survey say they inserted six or more intrauterine devices (IUDs) in the last year, compared to 2006's 45% figure. The drop in insertions reverses the 10% jump recorded in 2006 and the 5% increase noted in 2005. About 40% reported no insertions in 2007, similar to previous years' figures.

It is disappointing that more clinicians aren't offering women IUDs, says **Susan Wysocki**, RNC, NP, president and chief executive officer of the Washington, DC-based National Association of Nurse Practitioners in Women's Health. "Surely, there are many more than six women in every clinician's practice who want a very reliable, safe, completely reversible contraceptive method that they don't have to think about for years, so why are so few clinicians offering these women an intrauterine contraceptive?" observes Wysocki. "Cost may be a barrier in some cases, but it seems worth it to work out ways to make it more available."

Some clinicians such as **Philip Ivey**, MD, a physician at Southwest Women's Health in Casa Grande, AZ, and Peter Marks, MD, an obstetrician/gynecologist at Primary Care Partners — Southeast OB/GYN in Grand Rapids, MI, also report upticks in use of intrauterine contraception in their facilities. "I was the only person who would insert an IUD when I came to town in 2000," says Ivey. "Now other providers are willing to try."

Intrauterine contraception use has increased at the Lee County Health Department in Fort Myers, FL, says **Cindy Romeis**, RNC, ARNP, ACHND, assistant community health nurse director. The facility has offered the Copper T 380A intrauterine device (ParaGard IUD; Duramed, a subsidiary of Barr Pharmaceuticals, Pomona, NY) for many years, and soon will have a limited supply of the levonorgestrel intrauterine system (Mirena LNG IUS; Bayer HealthCare Pharmaceuticals, Wayne, NJ).

The World Health Organization eligibility criteria classes use of IUDs in young women age 20 and younger, as well as for nulliparous women, as a "2," in which the advantages of using the method generally outweigh the theoretical or proven risks.[1] The ParaGard IUD is now approved for use for nulliparous women in stable relationships from ages 16 through menopause. ***(Contraceptive Technology Update* reported on the labeling change in the article "Intrauterine method sees upswing in use," November 2005, p. 131.)** Research indicates that the previous use of a copper IUD is not associated with an increased risk of tubal occlusion among nulligravid women.[2] Women with a history of sexually transmitted diseases or pelvic inflammatory disease (PID) are no longer contraindicated for use of ParaGard, unless a patient currently has acute PID or engages in sexual behavior suggesting a high risk for the disease, the labeling states.

For HIV-positive women, the WHO gives a classification of "3," in which the theoretical or proven

risks usually outweigh the advantages of using the method.[1] Results from a prospective cohort study of HIV-infected and noninfected women in Nairobi, Kenya, suggest, however, that the IUD may be an appropriate contraceptive method for HIV-infected women with ongoing access to medical services.[3] **(See "Update your practice when it comes to IUDs," *CTU*, June 2007, p. 70.)**

Results of a recently published study indicate that IUDs were acceptable and not associated with a significant increase in gynecologic infections in women at high risk for sexually transmitted infections and pregnancy. Researchers performed a retrospective chart review of a cohort of women who attended an urban university-based obstetrics and gynecology resident clinic to develop the analysis. One-third of the women who received an IUD had a history of sexually transmitted disease before the insertion.[4]

Expand your contraceptive knowledge base by participating in intrauterine contraception educational opportunities offered by the Association of Reproductive Health Professionals. The organization offers a continuing medical education program, *A Clinical Update on Intrauterine Contraception*. (ARHP speakers are available to present this medical education lecture at your event, including clinical conferences or grand rounds sessions. Speaker honoraria and travel expenses will be covered by ARHP. To request a lecture, visit the web page, www.arhp.org/IUC.) The organization also offers patient information on intrauterine contraception options.

"ARHP believes that IUDs represent an excellent opportunity in the U.S. to reduce unintended pregnancy and will be working over the next several years to help raise awareness about this method," says **Wayne Shields**, ARHP chief executive officer.

The crisis surrounding the Dalkon Shield intrauterine device (IUD) during the 1970s and early '80s drove the U.S. market for the IUD to a standstill, and it still has not fully recovered, states a recently published editorial on intrauterine contraception.[5] "The Dalkon Shield is no longer relevant," states Wysocki. "However, the importance of offering women all methods to choose from remains." **(Editor's note: For more results from the 2007 Contraception Survey, see the November 2007 issue of *CTU*.)**

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Global AIDS program: A new push for prevention

By **Adam Sonfield**
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Guttmacher Institute
Washington, DC

The richer nations of the world have stepped up their collective response to the global AIDS pandemic, with the number of HIV-positive people in low- and middle-income countries receiving treatment increasing from 400,000 to 2 million between 2003 and 2006.[1] The U.S. response, through the President's Emergency Plan for AIDS Relief (PEPFAR), deserves a good measure of credit for this progress, both for its rapid implementation of treatment programs and for setting an example for other donors.

Despite this progress, however, HIV infections still are outpacing treatment efforts, and the AIDS community is looking to refocus the world's response onto a sustainable, long-term strategy that emphasizes prevention. One of the first tests of this shift in thinking will come next year, as Congress works to reauthorize a PEPFAR program slated to expire in September 2008. Because of the politics surrounding sexuality, this test may be a difficult one.

The reluctance of many leaders to openly discuss and confront HIV as a sexually transmitted infection leaves two groups — women and young people — at particularly high risk. Half of the world's

HIV-positive population is female, up from one-third in the mid-1980s, and women have higher infection rates than men.[2] Key to treating these women is overcoming and overturning traditional gender norms that make it difficult for women to protect themselves. These norms include male promiscuity and risk-taking and female subservience — sexually, legally, and economically. The United States and other donors have taken some small steps to counter these norms through targeted programs and encouraging systemic changes, but greater steps are possible and needed.

Perhaps more difficult politically will be the efforts needed to address the pandemic among young people, who account for four in 10 new HIV cases. Contrary to conventional wisdom, females and males in developing as well as industrialized countries are likely to first have sex during their teenage years and often before marriage.[3] In countries with high rates of HIV prevalence, anyone who is sexually active is at substantial risk of infection. Thus, the challenge is twofold: help teens delay having sex and provide them with the information and skills they will need when they become sexually active. The best evidence, including a 2007 review of 80 studies worldwide, demonstrates that success on both fronts can be obtained through comprehensive sex education that urges abstinence while also promoting protective behaviors such as condom use.[4]

Problems with PEPFAR

U.S. policy under PEPFAR works against a comprehensive strategy. First, the program limits comprehensive messages to a narrow range of groups defined as being at high risk, such as commercial sex workers and men who have sex with men. For the rest of the population, including sexually active youth, PEPFAR focuses on abstinence outside of marriage and monogamy within marriage. To avoid a "conflicting message" that may "encourage sexual activity," groups that receive U.S. HIV money cannot use these funds to promote condom use among young people or to provide them with condoms; they may not provide young teens with any school-based education about condoms.[5]

Second, the PEPFAR law requires that at least one-third of all HIV prevention funds be used for abstinence-until-marriage programs. A 2006 report by the Government Accountability Office found that this requirement has resulted in cuts to proven programs, including those aimed at preventing mother-to-infant transmission,[6] and a 2007 report by the Institute of Medicine calls for its elimination.[7] Also in 2007, a broad review of HIV-prevention programs in developed countries by University of Oxford researchers found abstinence-only programs "ineffective for preventing or decreasing sexually activity among most participants,"[8] and a nine-year, $8 million, congressionally mandated evaluation of U.S.-based abstinence-only programs found that them to have no beneficial impact.[9]

During the reauthorization of PEPFAR next year, Congress will have an opportunity to rectify these problems. As a first step toward that goal, the House and the Senate voted earlier this year to nullify for FY 2008 the abstinence-until-marriage spending requirement. It remains to be seen whether Congress will take the additional steps needed to once and for all put U.S. global AIDS policy in line with the strategies that the best research says will be most effective.

A related question is whether Congress will muster the political will next year to bring a similar level of evidence-based policy-making to PEPFAR's domestic counterparts. During the past decade, Congress has directed more than $1 billion toward the promotion of abstinence outside of marriage among Americans. Congress has funded programs that are required to ignore or denigrate the effectiveness of contraceptives and safer-sex behaviors. Reversing this strategy remains the highest priority for proponents of an evidence-based approach in the United States.

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COMING IN FUTURE MONTHS

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- Hot flashes: What spells relief?
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- How to boost chlamydia screening in young women
- Microbicides as contraception: Will they work?

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CTUPDATES
News ■ Resources ■ Events

Plan now for 2008 *Contraceptive Technology*

Circle the calendar now for the annual *Contraceptive Technology* conference. Sessions will be held March 6-8, 2008, in Boston, and April 3-5, 2008, in San Francisco.

Join *Contraceptive Technology* authors and other national women's health experts in reviewing the latest methods of contraception and expanding knowledge of reproductive health issues. Take advantage of four preconference sessions: "Focus on Adolescent Health Care," "Contraception for

CNE/CME Instructions

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

CNE/CME Questions

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

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

21. A vaccine now under research by the Dale and Betty Bumpers Vaccine Research Center contains the following synthetic genes:

A. *Gag*, *pol*, *nef*, and *env*
B. *Gag*, *pol*, and *env*
C. *Env*, *pol*, and *nef*
D. *Gag*, *env*, and *nef*

22. While research data (Hannaford PC, et al., *Br Med J* 2007) indicate that use of oral contraceptives do not increase a woman's chances of developing cancer and may even reduce the risk for most women, there was an increased risk for women who used the method for more than _____.

A. 10 years
B. eight years
C. six years
D. four years

23. Research (Brown D. Presented at the 47th Interscience Conference on Antimicrobial Agents and Chemotherapy) shows that Gardasil showed cross-protection against precancerous lesions caused by an additional _____ HPV strains.

A. 20
B. 15
C. 10
D. five

24. The World Health Organization eligibility criteria classify use of IUDs for HIV-positive women as:

A. 1 — no restrictions
B. 2 — benefits of using the method generally outweigh the theoretical or proven risks
C. 3 — theoretical or proven risks usually outweigh the advantages of using the method
D. 4 — use indicates an unacceptable health risk

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

Women with Chronic Medical Conditions," "Endometrial and Vulvar Biopsy Skills Training," and "Managing Abnormal Paps and Vulvar Disease." The preconference sessions will be held March 5 in Boston and April 2 in San Francisco. Continuing education credits are available for all sessions.

For more information, contact Contemporary Forums, 11900 Silvergate Drive, Attn.: Registrar, Dublin, CA 94568. Phone: (925) 828-7100, ext. 5252. Fax: (800) 329-9923. E-mail: info@cforums.com. Web: www.cforums.com. ▼

New guide available for ED-based HIV testing

Free resource based on interviews, visits

To guide clinicians and administrators through planning, implementing, or expanding emergency department (ED)-based HIV testing programs, the Health Research and Educational Trust, an affiliate of the American Hospital Association, has developed a web-based operational guide, *HIV Testing in the Emergency Department: A Practical Guide*.

The free comprehensive resource is based on interviews and site visits with EDs that have pioneered ED-based HIV testing. The guide may be accessed at the web site, www.edhivtestguide.org. ■

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.*

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2007 SALARY SURVEY RESULTS

CONTRACEPTIVE TECHNOLOGY UPDATE®

A Monthly Newsletter for Health Professionals

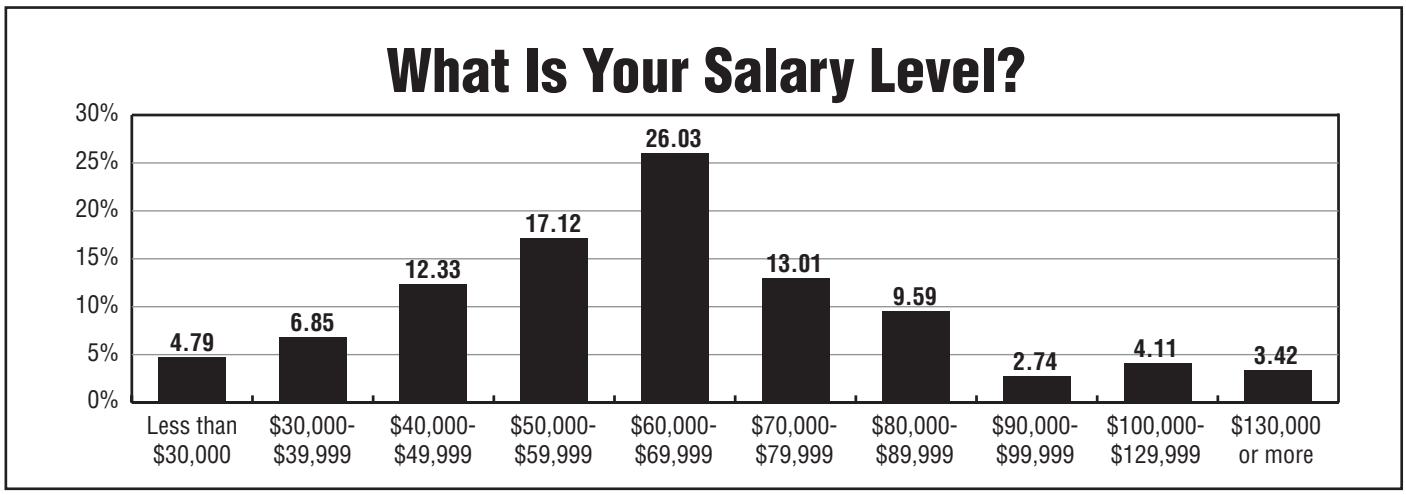
Salary snapshot: Family planning providers see very little increase in 2007 paychecks

Explore options to open up career opportunities in health care field

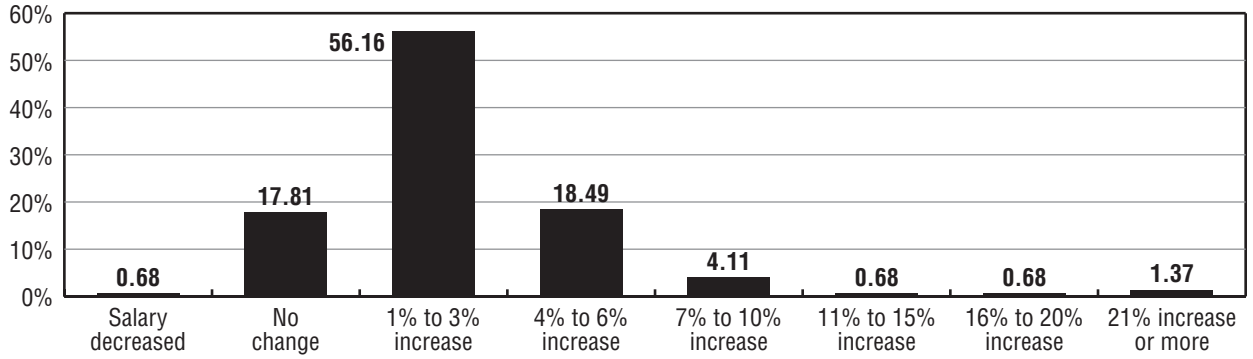
When payday rolls around in your office, are envelopes met with grins or grimaces? For providers in family planning, 2007 proved to bring fewer smiles on the salary scene. More than 50% (56%) of respondents to the 2007 *Contraceptive Technology Update* Salary Survey reported a 1%-3% increase, with less than 20% bringing in a 4%-6% increase. About 18% noted no change in pay. **(See "What is Your Salary Level" graphic below, as well as "In the past year, how has your salary changed?" graphic on p. 2.)**

When analyzed by profession, salaries showed little change from 2006 figures. Median salaries for nurse practitioners (NPs) grew slightly from $62,500 to $64,078, while pay for registered nurses dropped from $49,545 to $45,500. Administrators reported a median salary of $67,096, slightly less than 2006's $71,667 figure. Nurses and administrators comprise about 82% of the current year's responses. About 8% identified themselves as physicians, with 4% as nurse-midwives, about 3% as physician assistants, and 2% as health educators. The survey was mailed in July 2007 to 1,474 subscribers with 146 responses, for a response rate of 9.9%.

Family planning providers may not be keeping up with others in their profession when it comes to salary matters. Average annual full-time salary for a nurse practitioner reached $74,812 in 2005, an 8.1% increase over the average in 2003, according



In the Past Year, How Has Your Salary Changed?



to a national nurse practitioner survey. A similar gain is expected in upcoming results scheduled to be released in 2008.[1]

For physicians, obstetricians/gynecologists saw an income drop from $215,000 to $210,000 from 2004 to 2005, according to a national report.[2] They are not alone; primary care physicians recorded a 10% inflation-adjusted decline in income between 1995 and 2003, according to the Center for Studying Health System Change.[2]

A 2005 snapshot compiled by the American College of Nurse-Midwives shows a $70,000 median salary for the profession.[3] Mean income for full-time clinically practicing physician assistants increased from $81,129 to $84,396 from 2005 to 2006, states the American Academy of Physician Assistants.[4]

More providers on way

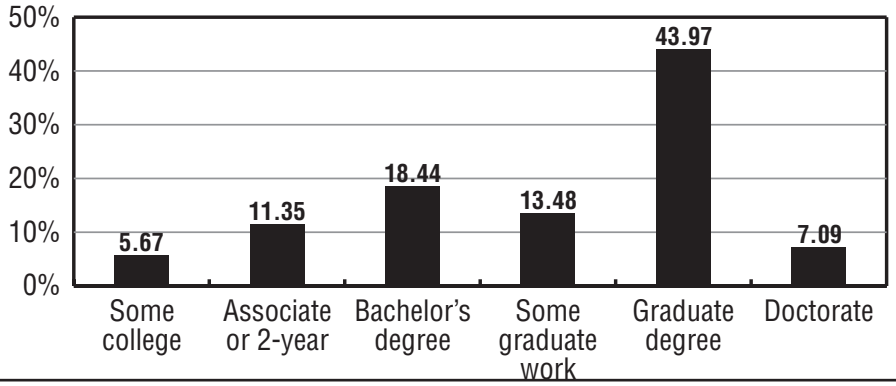
New faces soon may appear in your office. The American Association of Colleges of Nursing, working with the National Organization of Nurse Practitioner Faculties, reports that 7,197 potential nurse practitioners were prepared to enter the work force after July 31, 2006.[5] These graduates were those who had completed master's-level nurse practitioner programs, NP certificate programs, or post-master's NP programs. This trend is set to continue: In 2006, NP program enrollments increased 14%, and graduations increased 10%.[5]

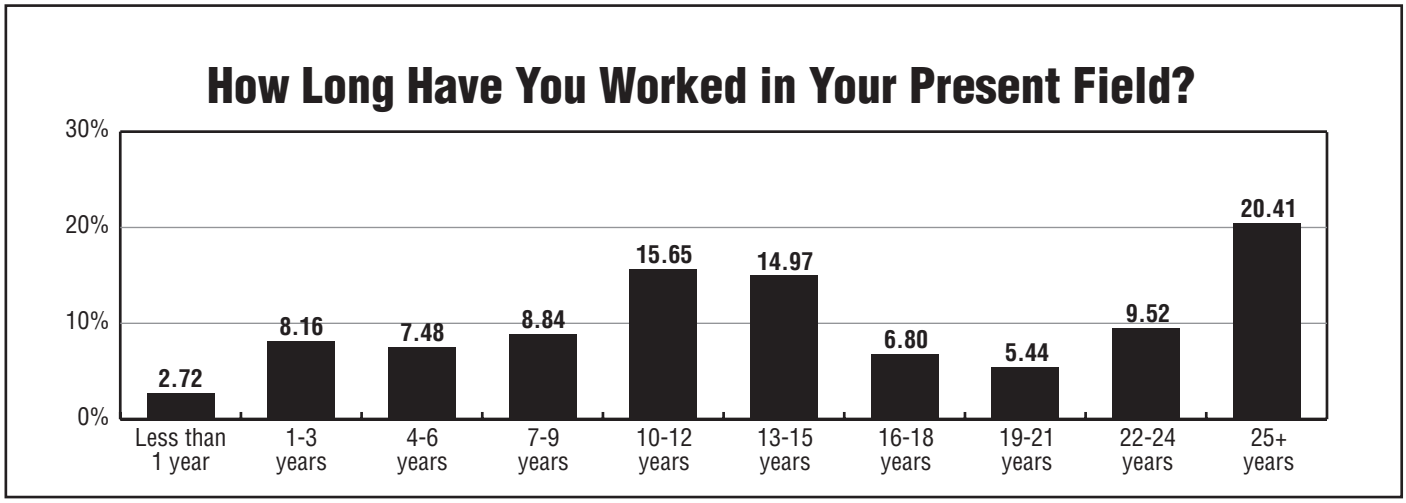
News of fresh troops will be welcomed in family planning clinics. Almost 60% of *CTU* salary survey respondents said they were age 50 or older. About 30% said they had worked in their present field for 22 years or more. **(See "How Long Have You Worked in Your Present Field?" on p. 3.)**

Ready for a change?

What if you are ready for a change, but not in the range for retirement? If you are a nurse practitioner, you may consider establishing an independent practice. According to **Carolyn Zaumeyer**, NP, author of *How to Start an Independent Practice*

What Is Your Highest Academic Degree?





— *The Nurse Practitioner's Guide to Starting a Successful Business* (Davis, 2003), more NPs are looking at this career option. **(For more information on Zaumeyer's book, see her web site, www.independentnp.com.)**

When Zaumeyer first started speaking about independent practice in 1995, three years after she began her own business, she says there was interest in the idea. However, it seemed out of reach for many. That situation has now changed, Zaumeyer reports.

"Over the years, my audience has changed to many NPs who have established independent practice, as well as many that are seriously considering the possibilities," notes Zaumeyer. "To be able to practice autonomously in an environment that you create and control is very appealing to many NPs."

Put your skills to work

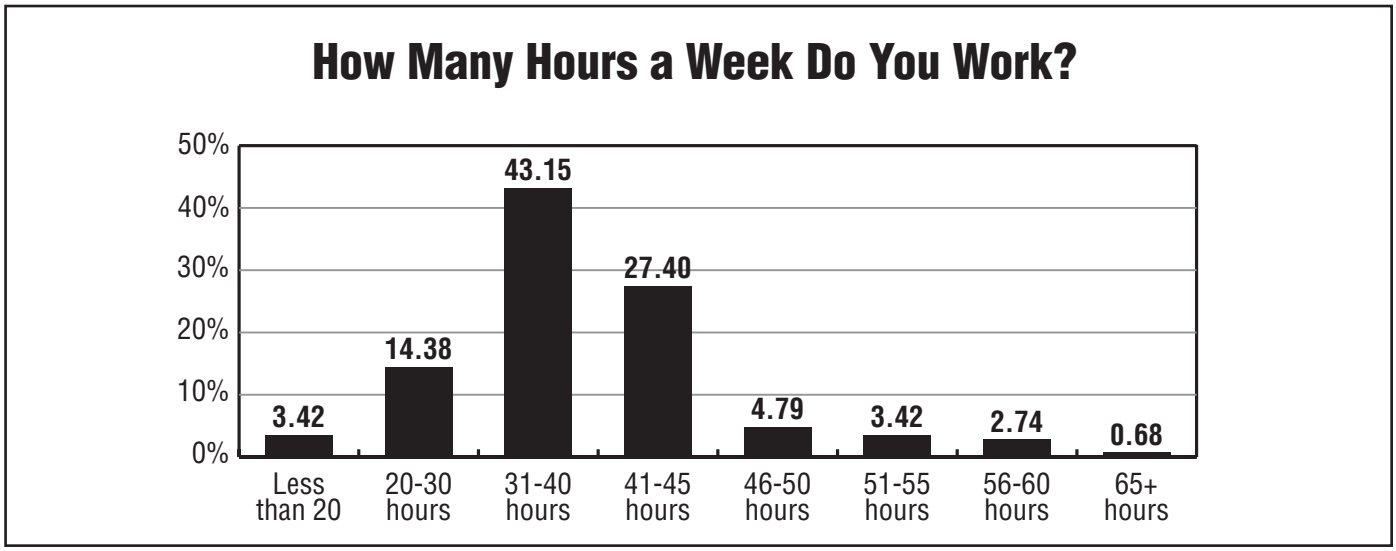
What skills do nurse practitioners bring to the table when it comes delivering quality women's health care? Zaumeyer should know: When she sold her practice, Women's Health Watch in Fort Lauderdale, FL, she had more than 4,000 female patients ranging from age 7 to 88.

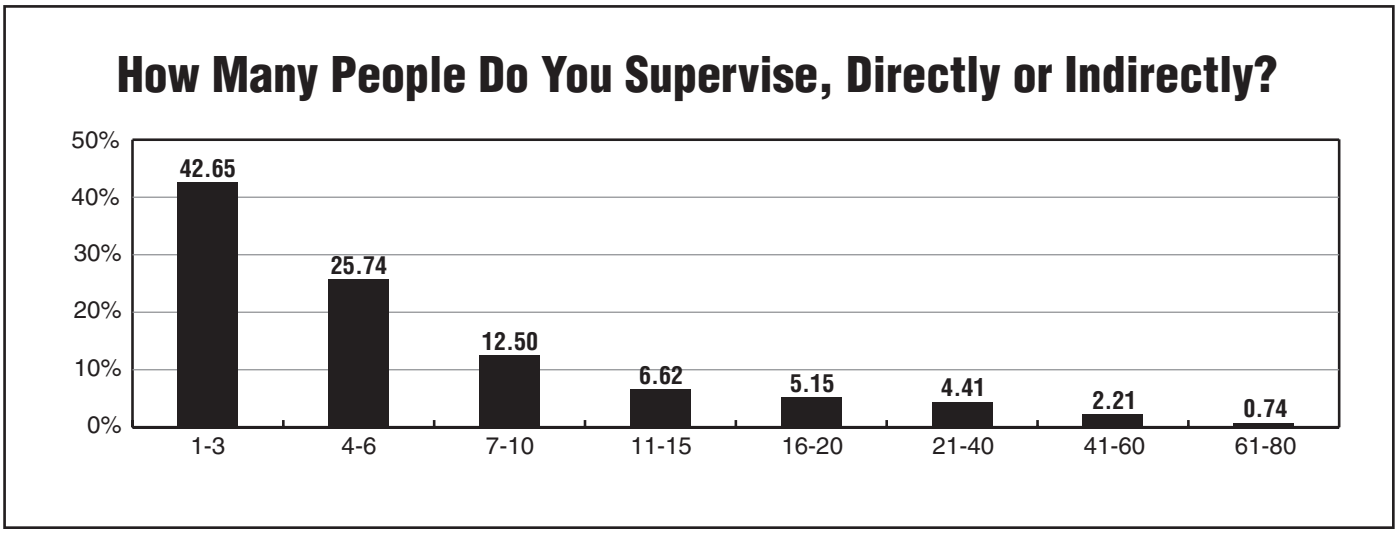
NP training in physical assessment, diagnostic skills, and listening/communication is key, says Zaumeyer. Delivery of patient education clearly is a plus, she states. Nurse practitioners are taught to look at the "whole package," assessing family, environment, work situations, stress levels, and other factors in combination with the patient's health, she notes.

Don't step over boundaries

In beginning an independent practice, nurse practitioners need to consider their scope of practice and legal limitations, says Zaumeyer.

"We are not doing anyone any favors, to the patients or for ourselves, in stepping over our boundaries," she notes. "We must have a clear





understanding of the state laws and regulations."

Having a good referral network of providers in the area is key, Zaumeyer advises. Know when and to whom to refer to and do it, she states.

Do your homework

What are some key objectives NPs need to have in hand before considering establishment of an independent practice?

Start with a thorough self-assessment, says Zaumeyer. Ask, do you:

- really want this?
- feel professionally ready?
- have any business experience?
- have the support of your family?
- work well alone, or are you better in a group environment?

Making the decision to start your own practice is not to be taken lightly, advises Zaumeyer. Evaluate the following before making the commitment to independent practice:

- **Perform a self-assessment.**

Review your personal, professional, financial, family, business knowledge, and support factors.

- **Develop research and planning.**

Establish the need for your practice, and develop a list for start-up costs, location, and other items.

- **Analyze your potential practice.**

Do your homework when it comes to financial income vs. expenses, marketing, and collaboration, Zaumeyer advises.

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