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New year, new oral contraceptives: 2 new OCs join birth control options

Beyaz, Lo Loestrin Fe gain Food and Drug Administration approval

Add Beyaz and Lo Loestrin Fe to the list of birth control choices for U.S. women. Both oral contraceptives (OCs) received Food and Drug Administration (FDA) approval in late 2010.

Beyaz, manufactured by Bayer HealthCare Pharmaceuticals of Wayne, NJ, is now stocked on pharmacy shelves; Warner Chilcott LLC of Rockaway, NJ, says it anticipates the commercial launch of Lo Loestrin Fe in early 2011.

Beyaz is based on Bayer's approved product Yaz, which contains the same doses of estrogen and progestin: 3 mg of drospirenone and 0.02 mg of ethinyl estradiol. The combined oral contraceptive also contains a folate (0.451 mg of levomefolate calcium). Beyaz is approved for the previously approved indications for Yaz, which include pregnancy prevention; treatment of premenstrual dysphoric disorder symptoms in women who choose to use an oral contraceptive for contraception; and treatment of moderate acne vulgaris in women at least 14 years of age, only if the patient desires an oral contraceptive for birth control. Beyaz also is approved for the secondary indication in women who choose to use an oral contraceptive as their method of contraception, to raise folate levels

EXECUTIVE SUMMARY

Add Beyaz and Lo Loestrin Fe to the growing list of birth control pill options. Beyaz is now stocked on pharmacy shelves. The commercial launch of Lo Loestrin Fe is scheduled for early 2011.

- Beyaz carries the same indications as its counterpart, Yaz. The drug also is approved to raise folate levels in women who choose an OC for birth control. In these women, Beyaz raises folate levels to reduce the risk of a neural tube defect in a pregnancy conceived while taking the pill or shortly after discontinuing the drug.
- Lo Loestrin Fe's daily estrogen component is 10 mcg of ethinyl estradiol, the lowest estrogen dosage of any U.S. OC.

for the purpose of reducing the risk of a neural tube defect in a pregnancy conceived while taking the OC or shortly after discontinuing the drug. Women need 400 mcg of folate each day to help prevent major birth defects in the brain and spine, according to the Centers for Disease Control and Prevention.[1] The concept of adding folate to OCs is not new. It has been championed for several years by Godfrey Oakley, MD, MSPM, former director of the CDC's Division of Birth Defects and Developmental Disabilities. (Contraceptive Technology Update *reported on the push for folate supplementation in "Folic acid and oral contraceptives: Will women see a combined product?" October 2003, p. 109.)*

To some clinicians, supplementing OCs with folate seems counterintuitive, or even a mixed message, says **Andrew Kaunitz**, MD, professor and associate chair in the Obstetrics and Gynecology Department at the University of Florida College of Medicine — Jacksonville. However, many reproductive-age patients are not consistently taking multivitamins with folate, Kaunitz notes. Birth control pills represent a popular contraceptive choice, albeit one with a relatively high failure rate, says Kaunitz.

"From this perspective, an OC that also contains folate replete has appeal, increasing the likelihood that women will be folate replete at the time of conception," Kaunitz states. "Given the potential individual and public health benefits, it is my hope that going forward, many OC formulations supplemented with folate will become available."

Research presented at the recent 66th Annual Meeting of the American Society for Reproductive Medicine (ASRM) suggests that addition of folate could indeed benefit women. Study results indicate that adding folic acid to oral contraceptives could reduce neural tube defects by between 24% and 31% a year.[2] **William Gibbons**, MD, ASRM president, says, "Women currently using contraception, but who may soon wish to have a child, would seem a natural target for folic acid supplementation. Fortifying birth control pills could be a novel way to increase folic acid levels in women of childbearing age."

Lo Loestrin Fe takes another tack in approaching contraception; its daily dosage of 10 mcg of ethinyl estradiol represents the lowest dosage of estrogen of any oral contraceptive available in the United States. Its 28-day dosing schedules includes 24 tablets, each containing 1 mg of the progestin norethindrone acetate and 10 mcg of ethinyl estradiol; two tablets each containing 10 mcg of ethinyl estradiol; and two tablets, each containing 75 mg of ferrous fumarate.

Check study results

For folate supplementation, the primary efficacy study using Beyaz was a multicenter,

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double-blind, randomized, active-controlled U.S. trial in 379 healthy women ages 18-40 who were treated with Beyaz or Yaz for up to 24 weeks. Results of the randomized, double-blind, parallel group study found that Beyaz treatment increased folate levels from baseline. The study evaluated the effect of Beyaz on red blood cell (RBC) folate and plasma folate levels compared to Yaz. At week 24, the mean changes from baseline were significantly higher ($p < 0.0001$) for women who took Beyaz as compared to women who took Yaz, for RBC folate (420 ± 347 nanomole/liter (nmol/L) versus 34.3 ± 171 nmol/L) and plasma folate (15.8 ± 20.4 nmol/L versus 2.2 ± 14.6 nmol/L) levels.

Adverse reactions seen across the three indications for Beyaz (contraception, acne, folate supplementation) overlapped and were reported using the frequencies from the pooled dataset. The most common treatment-emergent adverse reactions in 2% or more of users were headache/migraine (5.9%), menstrual irregularities (spotting, metrorrhagia, and menorrhagia) (4.1%), nausea/vomiting (3.5%), and breast pain/tenderness (3.2%).[3]

In a one-year (13 28-day cycles) multicenter open-label clinical trial, 1,270 women ages 18 to 35 were studied to assess the efficacy of Lo Loestrin Fe, completing the equivalent of 12,482 28-day evaluable cycles of exposure. The weight range for women treated was 89 to 260 pounds, with a mean weight of 150 pounds. Among the women in the study, 51% had not used hormonal contraception immediately prior to enrolling in the study. Of those women treated, 13.7% were lost to follow-up, 10.7% discontinued due to an adverse event, and 8.9% discontinued by withdrawing their consent.

The pregnancy rate (Pearl Index) in women ages 18-35 was 2.92 pregnancies per 100 women-years of use (95% confidence interval 1.94 – 4.21), based on 28 pregnancies that occurred after the onset of treatment and extending through the seven days following the last dose of Lo Loestrin Fe. Cycles in which conception did not occur, but which included the use of backup contraception, were not included in the calculation of the Pearl Index. The index calculation includes women who did not take the drug correctly.[4]

Common adverse reactions occurring in 2% or more of all women using the study drug include nausea/vomiting (7%), headache (7%), bleeding irregularities (including metrorrhagia, irregular menstruation, menorrhagia, vaginal hemorrhage, and dysfunctional uterine bleeding) (5%), dysmenorrhea (4%), weight fluctuation (4%), breast tenderness (4%), acne (3%), abdominal pain (3%), anxiety (2%), and depression (2%).[4]

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What are the top myths about pills?

Your next patient tells you she would like to use oral contraceptives (OCs) for birth control, but she says a family member told her using pills would affect her long-term fertility. What information do you provide her regarding OCs?

Patients aren't the only ones with misperceptions about pills. Clinicians have them as well, says **Deborah Kowal**, MA, PA, adjunct assistant professor in the Department of Global Health in the Rollins School of Public Health at Emory University in Atlanta. Kowal presented information on the leading myths surrounding oral

EXECUTIVE SUMMARY

Use clinical evidence to banish common misperceptions about combined oral contraceptives. A 2009 review lists cognitive factors, such as false information, misconceptions, and irrational fears, as one of the leading reasons for Pill noncompliance.

- After more than 50 studies and 50 years, most experts believe that the Pill has little, if any, effect on the risk of developing breast cancer.
- Women might believe that use of pills will negatively impact their future fertility; however, this is not the case. Counsel that return to fertility is rapid following pill discontinuation.

contraceptives as part of a sneak preview of the soon-to-be-released 20th edition of *Contraceptive Technology* at the recent Quest for Excellence Conference in Atlanta.[1]

The gap between correct and real use of pills remains vast. A 2009 review lists cognitive factors, such as false information, misconceptions, and irrational fears, as one of the leading reasons for Pill noncompliance.[2] What are the chief misperceptions regarding birth control pills? Check the following list, and add the evidence to your counseling knowledge base.

How about breast cancer?

After more than 50 studies and 50 years, most experts believe that the Pill has little, if any, effect on the risk of developing breast cancer.[3] While older studies of early high-dose pills found a slight increase in the risk of breast cancer,[4] in a study that separated women who used pills before 1975 from those who used pills after 1975, earlier users had an increased risk of subsequent breast cancer, while those using the post-1975 low-dose formulations did not.[5] Women wishing to use combined OCs can be reassured that their decision is unlikely to place them at higher risk of developing cancer.[6]

According to *Managing Contraception for your Pocket*, while there are still unanswered questions about pills and breast cancer, the overall conclusion is that pills do not cause breast cancer.[3] "Many years after stopping oral contraceptives use, the main effect may be protection against metastatic disease,"[4] it states.

What about fertility?

Ever since OCs have been available in the United States, it has been believed that pills will make it difficult for women to become pregnant when pill taking is ended. Women may believe that use of pills will negatively impact their future fertility, says Kowal. However, this is not the case; return to fertility is rapid following pill discontinuation.

A 2009 review looked at studies that have evaluated the return to fertility following cessation of oral contraceptives, including recent evidence in women discontinuing extended-cycle and continuous-use regimens. It concluded that return of fertility in former OC users (cyclic and extended/continuous regimens) who stop use in order to conceive is comparable to that observed with other contraceptive methods.[7] Reported 12-month conception rates in former cyclic pill users range from 72%-94%, in comparison to those discontinuing intrauterine devices (71%-92%), progestin-only contraceptives (70%-95%), condoms (91%), and natural family planning (92%). While there is a limited amount of data on the time to conception in women stopping extended-cycle and continuous-use OCs, data suggest that subsequent return to fertility is generally comparable to that of cyclic pill users.[7]

Counsel women that the return to fertility following pill use is so rapid and consistent that they should expect no more than a two-week delay in menses once pill usage is discontinued.

What about pregnancy?

Ever since pills arrived in 1960, women have been asking this question: "What if I get pregnant while I'm on the Pill?"

While the Pill is highly effective when used correctly and consistently, 8% of women become pregnant in the first year of typical use of oral contraceptives because of inconsistent use.[8]

Advise women that Pill users have no higher rates of spontaneous abortion, preterm deliveries, birth defects, or complications in the health of their offspring than do non-users, says Kowal.[9-13] No additional testing is required during the prenatal period for women who continue to use pills in the early months of pregnancy. If a woman experiences a spontaneous loss following Pill use, she should be counseled that the Pill was not a factor in the loss.

Can OCs impact libido?

Can OCs impact libido? Yes, pills definitely can impact libido. What is a myth is the generalization that pills adversely affect most women's libido. The opposite might be true, because pills diminish a women's fear of pregnancy and lead to less days of vaginal bleeding. Another myth would be that pills have no effect on women's sexual functioning. While oral contraceptives provide safe, effective, and reversible contraception, a review of recent literature indicates women experience positive effects, negative effects, as well as no effect on libido during OC use.[14]

A recent study looked at the impact of two contraceptive pills with different doses of the same components (ethinyl estradiol [EE] 30 mcg and levonorgestrel (LNG) 150 mcg, or EE 20 mcg and LNG 100 mcg) on plasma androgen levels and

female sexual function among women without previous sexual dysfunction. Both groups showed improvements according to the Female Sexual Function Index, a standardized questionnaire.[15]

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Tenofovir gel makes strides in development

Microbicide research is moving forward with two new developments: the Food and Drug Administration (FDA) has granted Fast Track approval designation for 1% tenofovir gel, which will facilitate the development and expedite the review of the drug. Also, in a second development, the microbicide will be examined in a separate early phase trial to determine its safety and acceptability in rectal use.

The FDA met with key stakeholders in October 2010 to determine the next steps required for U.S. licensure of 1% tenofovir gel, which recently was found to be effective at reducing the rate of HIV and herpes infection in women when used before and after sex.[1] In the recent CAPRISA 004 clinical trial, the microbicide was found to be 39% effective in reducing a woman's risk of becoming infected with HIV during sex. Women who reported using the gel more than 80% of the time they engaged in sexual relations had a 54% reduction in HIV infection, whereas those who used the gel less than half the time had a 28% reduction.[1] The study also showed that the gel was effective in preventing transmission of genital herpes simplex virus (HSV-2). The women using the tenofovir gel had 51% fewer cases of HSV-2 infection than the control group.[1] Results of that clinical trial represent the first "proof of concept" for a vaginal microbicide. *(To read more about the CAPRISA 004 trial, see the* Contraceptive Technology Update *article, "HIV breakthrough: Trial results*

EXECUTIVE SUMMARY

The Food and Drug Administration has granted Fast Track approval designation for 1% tenofovir gel, which will facilitate the drug's development and review. In a second development, the microbicide will be examined in a separate early phase trial to determine its safety and acceptability in rectal use.

- Proponents await the 2013 results of the VOICE (Vaginal and Oral Interventions to Control the Epidemic) trial managed by the Microbicides Trial Network. If successful, the trial's results will be used in seek drug approval.
- Tenofovir also is being eyed for rectal use. Results of a separate study will help determine if the gel should be evaluated further for its potential to prevent HIV among men and women who engage in receptive anal intercourse.

offer promise," October 2010, p. 114.)

Fast Track status is granted to drugs in development that have the ability to impact a serious, life-threatening condition and also address an unmet medical need, explains **Jill Schwartz**, MD, medical director for CONRAD, a division of the Eastern Virginia Medical School in Norfolk, VA. CONRAD was one of the partners in the CAPRISA 004 study. CONRAD and the International Partnership for Microbicides based in Silver Springs, MD, hold a co-exclusive, royalty-free license from Gilead Sciences in Foster City, CA, to develop the microbicide for HIV prevention.

The next step in development is to obtain results of the VOICE (Vaginal and Oral Interventions to Control the Epidemic) trial, which is an ongoing study managed by the Microbicides Trial Network (MTN) based at the University of Pittsburgh and Magee-Womens Research Institute in Pittsburgh to evaluate daily use of tenofovir gel. Study results might be available by early 2013. If the trial is successful, advocates can move forward in filing a New Drug Application for the gel. The FDA also has asked for data on use of the gel in adolescents as well as post-menopausal women, as well as in vivo drug interaction studies with commonly used vaginal products, says Schwartz.

"I think the FDA has provided us a clear path for testing and licensure of 1% tenofovir gel," says Schwartz. "That's where we are moving forward."

Study eyes rectal use

In other research news, tenofovir gel is the subject of a new trial looking at its safety and acceptability when used rectally. The results of the MTN-007 study, being led by the Microbicide Trials Network, will help determine if the gel should be evaluated further for its potential to prevent HIV among men and women who engage in receptive anal intercourse.

While condoms are protective against HIV and other sexually transmitted infections, most acts of anal sex go unprotected. Research indicates unprotected anal intercourse is a high-risk practice for HIV transmission in heterosexuals and men who have sex with men (MSM).[2]

While the CAPRISA 004 results are promising for vaginal use, it is important to look at how the gel functions in rectal use, says **Ian McGowan**, MD, PhD, co-principal investigator of the MTN and professor of medicine in the Division of Gastroenterology, Hepatology, and Nutrition at the University of Pittsburgh School of Medicine. "We can't just assume that a product developed for use as a vaginal microbicide will be equally safe or effective when used in the rectum for preventing HIV transmitted through receptive anal intercourse," said McGowan in a statement announcing the new trial. "So while VOICE or other trials may very well prove tenofovir gel is highly effective for preventing vaginal transmission, we need to understand much more about what happens to the cells and tissue when tenofovir gel is used rectally before considering a trial testing its effectiveness against HIV."

The new study will enroll 60 men and women at the trial sites at the University of Pittsburgh, University of Alabama at Birmingham, and Fenway Health in Boston. It is designed to see if rectal use of tenofovir gel is safe, as well as acceptable for use to men and women as a rectal microbicide. The trial will study enroll men who have sex with men, as well as heterosexual men and women, says **Clare Collins**, a MTN spokesperson. Estimated completion date for this early phase trial is June or July 2011, she states.

MTN researchers recently have completed a Phase I trial of tenofovir gel in rectal use. While results of the study, conducted in collaboration with the Microbicide Development Program at the University of California, Los Angeles are not expected until early 2011, researchers already have recommended modifications to the gel's formulation. The upcoming MTN-007 trial will evaluate the new formulation, which contains the same amount of active drug (1% tenofovir) but has a lower concentration of glycerin to make it more amenable for rectal use.

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More data emerge from Women's Health Initiative

Results from a long-term follow-up analysis of participants in the Women's Health Initiative (WHI) suggest that among postmenopausal women, use of estrogen plus progestin is associ-

ated with an increased incidence of breast cancers that are more advanced, and with a higher risk of deaths attributable to breast cancer.[1]

In the original WHI study,16,608 U.S. postmenopausal women ages 50-79 who had not undergone hysterectomy were assigned randomly to receive combined conjugated equine estrogens 0.625 mg per day plus medroxyprogesterone acetate 2.5 mg/day, or a placebo. After the original trial completion date, investigators sought reconsent for continued follow-up for breast cancer incidence; 83% (12,788) of the surviving participants complied.

In the new WHI publication, researchers report after an average intervention time of 5.6 years and an average follow-up of 7.9 years, breast cancer incidence was increased among women who received the combined hormone therapy.

The researchers found that in intention-to-treat analyses including all randomized participants and censoring those not consenting to additional follow-up, estrogen plus progestin compared with placebo increased the incidence of invasive breast cancer: 385 cases (0.42% per year) versus 293 cases (0.34% per year). Women in the combined hormone therapy group had more breast cancers with positive lymph nodes compared with women in the placebo group: 81 (23.7%) versus 43 (16.2 %). In addition, more women died of breast cancer in the combined hormone therapy group compared with the placebo group: 25 deaths (0.03% per year) versus 12 deaths (0.01% per year), representing 2.6 versus 1.3 deaths per 10,000 women per year, respectively, the investigators note.[1]

What does it mean?

So what is the take-home message from the new WHI analysis? According to a response issued by the North American Menopause Society, the primary finding is of one to two extra deaths from breast cancer per 10,000 women per year randomized to combined hormone therapy. For every 10,000 women in the study who were randomized to placebo, there were 1.3 deaths from breast cancer per year. For every 10,000 women randomized to combined hormone therapy, there were 2.6 deaths from breast cancer per year, the response notes.[2]

"Clinicians can help women put the breast cancer risk into perspective by informing them that the increased risk of breast cancer using estrogen plus progestogen for five years is very similar to the increased risk of breast cancer associated with having menopause five years later," the NAMS response notes. "This increased risk of breast cancer occurs with a woman's own internal, natural estrogen and progesterone."

There are a few things to keep in mind regarding data from the current WHI analysis, says **Susan Wysocki**, WHNP-BC, FAANP, president and chief executive officer of the National Association of Nurse Practitioners in Women's Health.

"The first is that these data do not relate to women on estrogen alone," notes Wysocki. "Those data appear to have favorable or a null effect on breast cancer." *(Editor's note: unopposed estrogen therapy is used for hysterectomized women.)*

"One other issue to consider is whether increased breast density, as a result of taking hormones, is part of the problem," Wysocki states. "It is important to note that new technologies such as tomosynthesis (3D mammographic views of the breast) may be something, that in the future, will increase the detection of breast abnormalities in women who take hormones."

Definitions are varied

Current recommendations call for using hormone therapy only when needed to treat moderate to severe symptoms of menopause and using the lowest effective dose for the shortest amount of time.[3,4] But what constitutes "lowest" and "shortest"?

"Clinicians who prescribe brief courses of hormone therapy for relief of menopausal symptoms should be aware that this approach has not been proven in rigorous clinical trials and that the downstream negative consequences for their patients are of uncertain magnitude," states an accompanying editorial to the current analysis publication.[5] (**See the story on p. 8 for practical tips to alleviate common menopausal symptoms.**)

The current "lowest dose" of combined hormone therapy is about half the dosage of the preparation examined in the WHI study, notes **Rowan Chlebowski**, MD, PhD, an oncologist at the Los Angeles Biomedical Research Institute at Harbor — UCLA Medical Center and principal investigator of the current WHI analysis. However, the Food and Drug Administration continues to use the same labeling for lower-dose preparations because they have not submitted additional data to show in effect that they are indeed safer, he notes. In the same vein, no randomized clinical trial has established parameters for what constitutes the "shortest" duration of time for symptom relief, states Chlebowski.

Additional randomized trials are needed to determine whether lower doses or shorter durations of hormone therapy can safely treat menopausal symptoms without increasing cancer risk, says Chlebowski. Also more information is needed on women who start hormone therapy for the first time between the ages of 50 and 55; the average age in the WHI study was 63. Two randomized trials might provide such information within a few years: the Kronos Early Estrogen Prevention Study and the Early vs. Late Intervention Trial with Estradiol.

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Practical tips to ease menopause symptoms

Looking for practical, non-hormonal measures to help patients cope with common menopausal symptoms? Use the following suggestions from **Margery Gass**, MD, executive director of the North American Menopause Society:

• **Hot flashes.** Advise women to be sensitive to their environment, says Gass. Avoid anything that increases their sensation of warmth. Sometimes it can be as subtle as avoiding sitting under bright lights. One way to combat environmental elements is to wear clothing that can be removed when it gets too warm in a room, notes Gass. Avoid wearing close-fitting clothing items such as turtlenecks.

Alternative over-the-counter products, such as black cohosh, are available for relief of hot flashes. While such products have not been shown to be highly effective, most of them are safe enough to use if patients want to try them and see if they are one of the lucky women who finds an advantage from using such products, Gass states.

• **Vaginal dryness.** Counsel women on the use of lubricants and moisturizers designed for the vagina, says Gass. These are different kinds of products, so women need to be aware that they can use both of them, she states. "Women can use a moisturizer regularly that has carryover benefit for sexual activity, and/or they can just use the lubricant at the time of intercourse," says Gass.

• **Night sweats.** Explain that night sweats are simply hot flashes that occur at night. Avoid allowing the body to get too hot at night, says Gass.

"With winter, it is important for women to know that down comforters are some of the worst offenders because they trap the heat too well," states Gass. "You want something that is not going to be such a good heat trap, something that will allow the air to circulate more."

Some women have tried wearing loosely woven exercise clothing with wicking properties to help keep the skin cool at night, says Gass. An overhead fan on a very low level of oscillation can help keep the body a little bit cooler, she advises. *[See menopause patient handout enclosed with the online issue. For assistance, contact customer service at (800) 688-2421 or customerservice@ahcmedia.com.]* ■

ASK THE EXPERTS

What's the evidence for using two condoms?

Question: What is the evidence that two condoms may be used at once? Who does this? What are their reasons for doing this? What are the other things that can do done to prevent condom breakage? Are there some men and some women who have sexual intercourse in a manner that predisposes them to have repeated condom breaks or repeated condom slippage?

Answer from **Robert Hatcher**, MD, MPH, professor of gynecology and obstetrics at Emory University School of Medicine in Atlanta: Typical

condom breakage rates range from 0.5% to 6.7%. Falling-off rates range from 0.6% to 5.4%. More recently, attention has focused on condoms that slip down the penis but not completely off, known as partial slippage.[1,2]

In Nevada, men going to legal brothels are required to use a condom during every sexual act. Many acts of intercourse are protected by two condoms. Legal prostitutes in Nevada are extraordinarily effective in preventing HIV and other infections. Do they use more than one condom? The answer is often "yes." Many of their acts of intercourse are protected by two condoms.

A 1995 study analyzed condom use among legal prostitutes in Nevada brothels.[1] Here are some of the techniques these women used to prevent breakage: use of additional water-soluble lubricant (64%); monitoring the condition of the condom regularly throughout intercourse (20%); refraining from rough, vigorous sex (18%); using appropriately sized condoms (5%); and changing condoms during prolonged intercourse (5%).

Use of multiple condoms simultaneously also was a frequently reported method (9%) to prevent breakage. Twenty-nine women (66%) reported that at least one client had worn two condoms concurrently during intercourse in the previous year, for a total of more than 5,000 concurrent uses. Eight women reported doubling up condoms during every act of commercial intercourse in the previous year. Visual inspection of the used condoms from the prospective trial revealed that condoms were doubled up in 10.8% of the 372 sexual episodes. Condoms were doubled up primarily to prevent breakage when women had experienced a prior condom break, when the client's penis was very large, when the client presented with unidentifiable penile sores or track marks, when a thin condom was being used, and when the client requested it. To avoid friction, women reported applying additional lubricant between the condoms.[1]

Albert and fellow investigators reported a retrospective breakage rate much lower than other reported studies. There were 49 breaks reported in the course of 41,127 acts of intercourse (0.12%). This comes to a breakage rate of one condom break per 849 acts of intercourse.

In Albert's prospective study, 41 women used condoms during 353 acts of vaginal intercourse. A water-based lubricant was used 89% of the time, and oil-based lubricants were not used at all. There were no breaks at all (0/353), and lack of breakage was confirmed by visual inspection of all condoms by the senior author of the paper. (Condoms had been placed in zip-locked bags).

When women receive a license to be a prostitute in Nevada, they must be HIV-negative. Nevada law requires that registered brothel prostitutes be tested weekly for gonorrhea and chlamydia, and monthly for HIV and syphilis. Between July 1, 1988, and Dec. 31, 1993, more than 20,000 HIV tests were conducted on licensed prostitutes. None of the women employed in any Nevada brothel tested positive at the time of follow-up HIV testing. These rates are in sharp contrast to HIV prevalence rates in other female prostitutes in the United States and elsewhere.

Although the actual exposure level of brothel workers to clients with HIV and other sexually transmitted disease infections is not known, the absence of HIV and other sexually transmitted diseases might be explained by the fact that clients are required to use condoms during every sexual act.

Clearly, Albert has documented that use of two condoms in a high-risk group of women does not place them at risk for increased rates of condom breakage or increased rate of infection.

There is a final lesson to be learned from Albert's fascinating study. Condom mishaps are not evenly distributed among all condom users. In the retrospective phase of the study, the 44 women relating their experience with condom breakage, slippage, and falling off reported that of the 49 total breaks in the year prior to the study, 20 (41%) were reported by one woman. Fourteen of the 42 instances of slippage in the previous month (33%) were reported by another woman. Likewise, 48 of the 103 instances of slippage in the previous year (47%) were reported by only three women.[1]

In summary, use of two condoms is a common practice among legal prostitutes in Nevada. Condom breakage rates are extraordinarily low among these women. Therein lies an important practical lesson: When clinicians see women and men who have experienced multiple breaks or slippages, it would be wise to encourage them to use two condoms.

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WASHINGTON WATCH

Women begin to see impact of health reform

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

The end of September, marking six months after President Obama signed into law the Patient Protection and Affordable Care Act, was the effective date for numerous provisions intended to expand patients' rights and coverage under private insurance.[1] This is the interim period between the law's passage and the 2014 start date for its most expansive changes to Medicaid and the private insurance market. Several provisions should be important in helping women and men meet their reproductive health care needs, although important questions are unanswered, particularly in the wake of the November 2010 elections.

One provision garnering considerable public attention requires all new private health plans to cover a range of preventive health services without any out-of-pocket costs to consumers, such as copayments or deductibles. An initial list of protected services, based on three sets of existing government-supported guidelines, technically took effect on Sept. 23, although in practice, cost-sharing-free coverage of those services will be phased in more gradually. That list includes cervical cancer screening, screening and counseling for HIV and several other sexually transmitted infections (STIs), and vaccination for human papillomavirus, among many others.

In November, a panel convened by the Institute of Medicine began deliberation of more comprehensive recommendations for women's preventive health care that also will receive a guarantee of coverage without cost-sharing, although several factors might conspire so that most women will not benefit until January 2013. This fourth set of guidelines was required under an amendment to the legislation authored by Sen. Barbara Mikulski (D-MD) that was intended by its supporters to include contraceptive counseling, services, and supplies, as well as other key services, such as an annual well-woman exam. The Institute of Medicine was brought in to ensure that the recommendations reflect current, reputable scientific evidence, as well as the legislative history of the amendment and precedents in federal law and policy.[2]

Patients' rights expand

Several other provisions that went into effect on Sept. 23 were dubbed a "Patient's Bill of Rights" by the law's authors. They include prohibitions on lifetime coverage limits, retroactive coverage rescissions, and exclusions for children's preexisting medical conditions, which is a protection that will be extended to adults in 2014. Of particular relevance for reproductive health, all new private plans must now allow women to visit obstetric or gynecologic care specialists without referral or prior authorization, building on similar "direct access" laws previously enacted in many states.

Another well-publicized provision requires private plans that cover dependent children to extent that coverage to adult children younger than age 26. Previously, plans typically ended dependent coverage at age 19 or upon college graduation. This change should be a boon to young adults, an age group with high levels of uninsurance, unintended pregnancies, and STIs, although reproductive health advocates are concerned that private insurers might end up undermining confidentiality for sensitive services through such practices as sending explanation-of-benefits forms to the policyholder, who might be a parent or spouse.[3]

Moving toward 2014

A week later, on Oct. 1, the administration rolled out another health reform initiative, the second phase of a nationwide Internet portal for individuals and small businesses to learn about their coverage

COMING IN FUTURE MONTHS

- Text messages: New counseling tool?
- Research eyes HPV cost effectiveness
- Survey covers condom use
- How to boost chlamydia screening in teens
- Review treatment options for genital warts

options in the private and public sectors. Compared with the initial phase introduced in July, the new version includes more detailed information about premiums, cost-sharing, and benefits, although for now, maternity care is the only specific reproductive health service singled out, and only some plans provide information on which contraceptive and other drugs are included in their formulary.

This portal is a precursor and model for one of the central components of health reform, the state-level insurance exchanges that, if all goes as planned, will serve as marketplaces for private coverage starting in 2014. Oct. 4 was the closing date for public comments on a wide range of questions posed by the administration about how these new exchanges should be designed and operated, in preparation for regulations expected in the coming year. Those regulations will influence other aspects of health reform, such as the law's requirement that insurance plans in the exchanges contract with family planning centers and other safety-net providers.

Whether the law ends up meeting Americans' reproductive health care needs is contingent in part on whether it is fully and properly implemented, something that was put further in doubt by the November 2010 elections. The incoming Republican leadership in the House has put its opposition to the health reform law high on its agenda. Democrats in the Senate and President Obama appear capable of blocking a full-fledged repeal of the law. However, the law's opponents in Congress might be able to disrupt the funding needed for the administration to issue regulations and set up new programs, and state governors, leg-

CNE/CME INSTRUCTIONS

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

CNE 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;
- provide practical information that is evidence-based to help clinicians deliver contraceptives sensitively and effectively.

1. According to the Centers for Disease Control and Prevention, how much folate do women need each day to help prevent major birth defects in the brain and spine?
A. 200 mcg
B. 400 mcg
C. 500 mcg
D. 800 mcg

2. The upcoming MTN-007 trial of tenofovir contains the same amount of active drug as was used in the vaginal trial, but will provide the tenofovir
A. Orally
B. As a dermal cream
C. Rectally
D. As a monthly IV injection

3. A vaginal tenofovir gel used 80% of the time by couples having vaginal intercourse was found to decrease HIV transmission by:
A. 28%
B. 39%
C. 54%
D. 90%

4. When condoms slip down the penis but not completely off, it is termed as
A. Breakage
B. Tearing
C. Slippage
D. Partial slippage

Answers: 1. B; 2. C; 3. C; 4. D

islators, insurance commissioners, and Medicaid officials will have numerous opportunities to limit their states' cooperation with the law.

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1. Public Law 111-148, March 23, 2010.
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3. Gold RB. Unintended consequences: how insurance processes inadvertently abrogate patient confidentiality. *Guttmacher Policy Rev* 2009;12(4):12-16. ■

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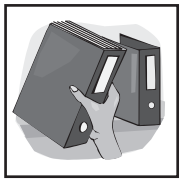

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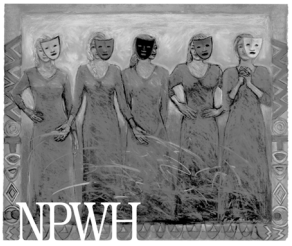


Association of Reproductive Health Professionals

2010 SALARY SURVEY RESULTS

CONTRACEPTIVE TECHNOLOGY UPDATE®

A Monthly Update on Contraception and Sexually Transmitted Diseases

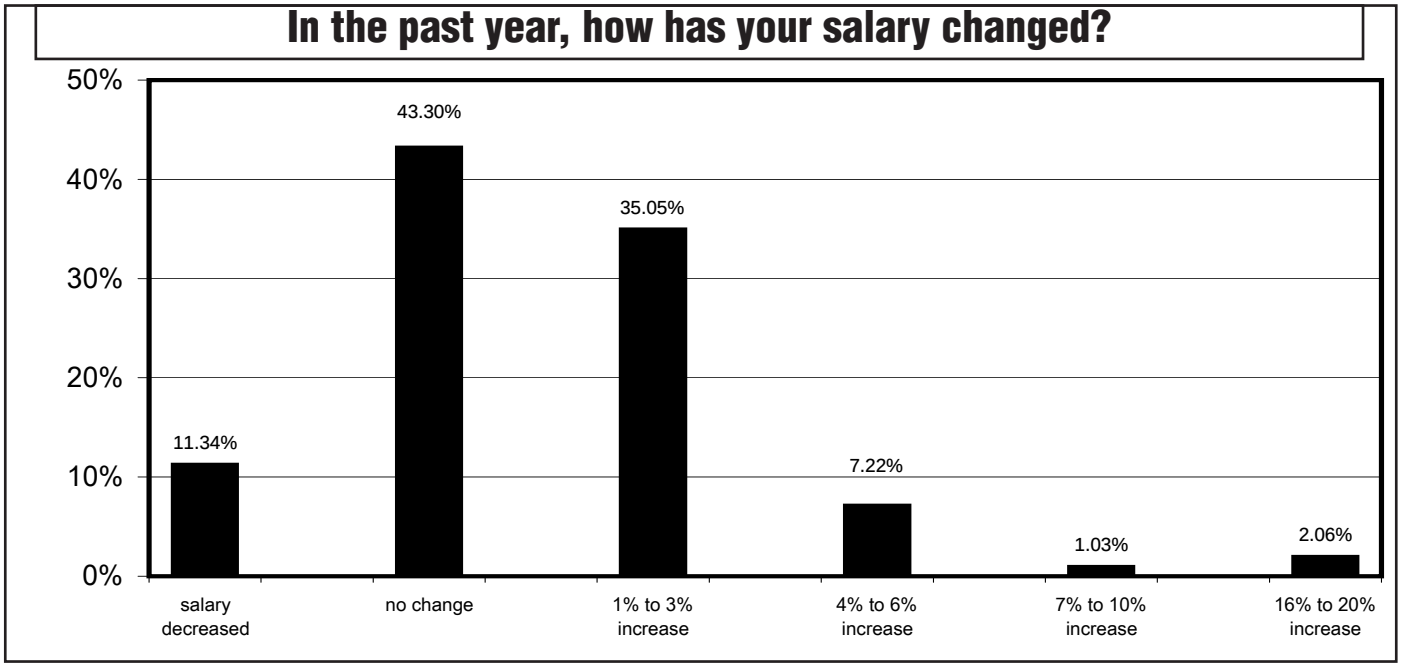
Family planners hold the line on salaries, jobs — Keep an eye on legislation, economy in coming year

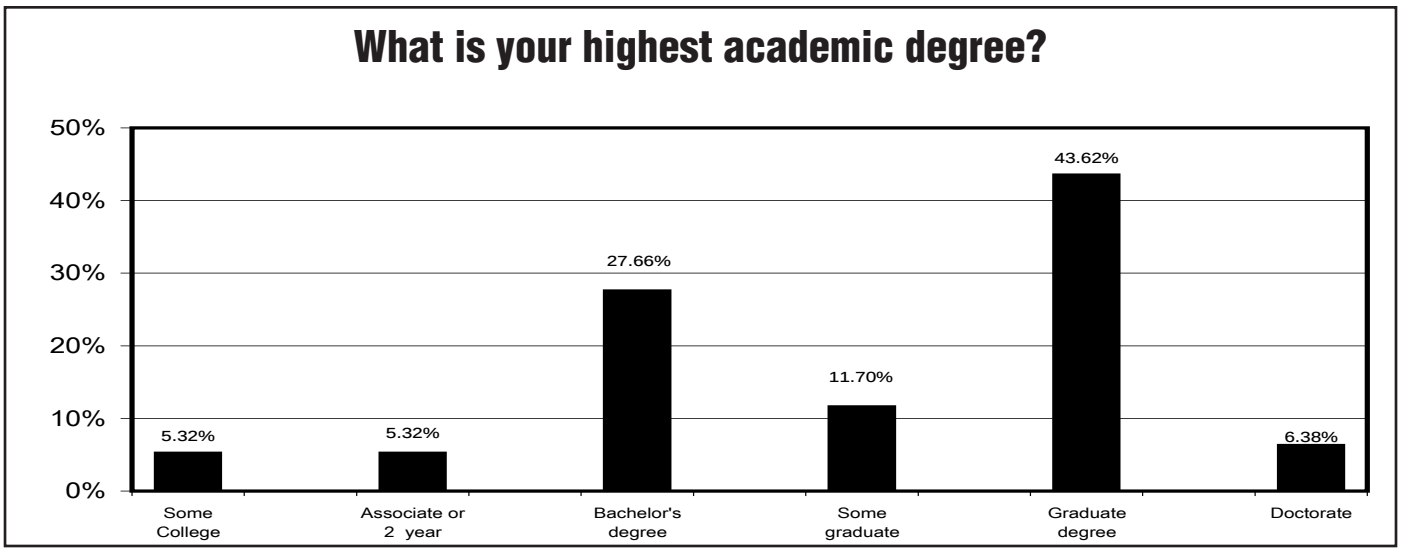
In a year when belt-tightening seemed to be a national pastime, about 35% of participants in the Contraceptive Technology Update Salary Survey reported a 1-3% uptick in salary, with 43% seeing no change in pay levels.

This finding is consistent with results from the previous year, when 38% said they got a 1-3% bump and 40% noting no change. (See "In the past year, how has your salary changed?" graphic, below.)

For the 43% of survey respondents who identified their employers as state/county/city government, know that the past two years have seen changes in the employment landscape, says **Donna Brown**, *government affairs counsel for the National Association of County and City Health Officials (NACCHO) in Washington, DC. The organization represents the nation's 2,800 local governmental health departments.*

"In our most recent research brief, which covered calendar year 2009, in maternal and child health, 25% of health departments had cut programs, and 12% had cut them in communicable disease screening and treatment," says Brown. (Read the full report on NACCHO's Job Loss and Program Cuts survey at www.naccho.org/topics/infrastructure/lhdbudget/upload/Job-Losses-and-Program-Cuts-5-10.pdf.)





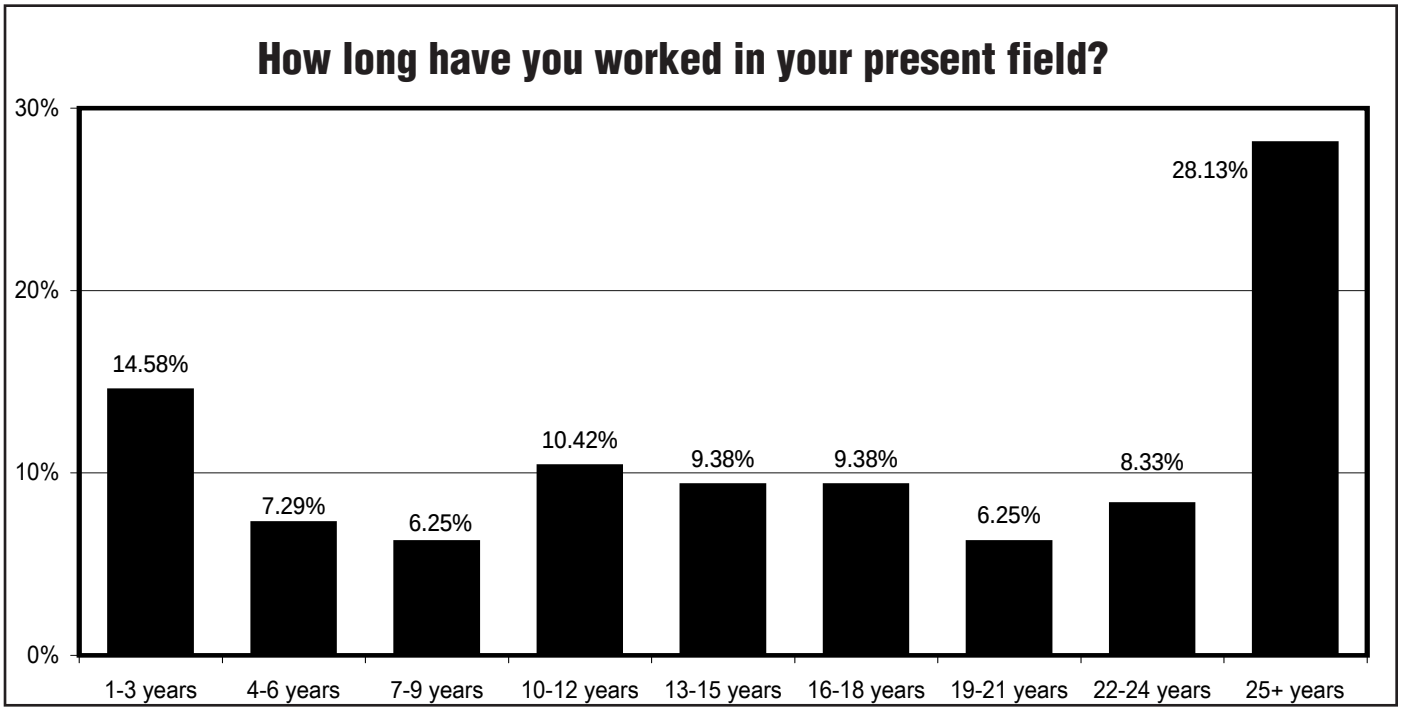
In this year's salary survey responses, 38% said they worked in a health department, while 30% said they were in a clinic facility. A total of 16% were in a college health center, while 10% worked for an agency.

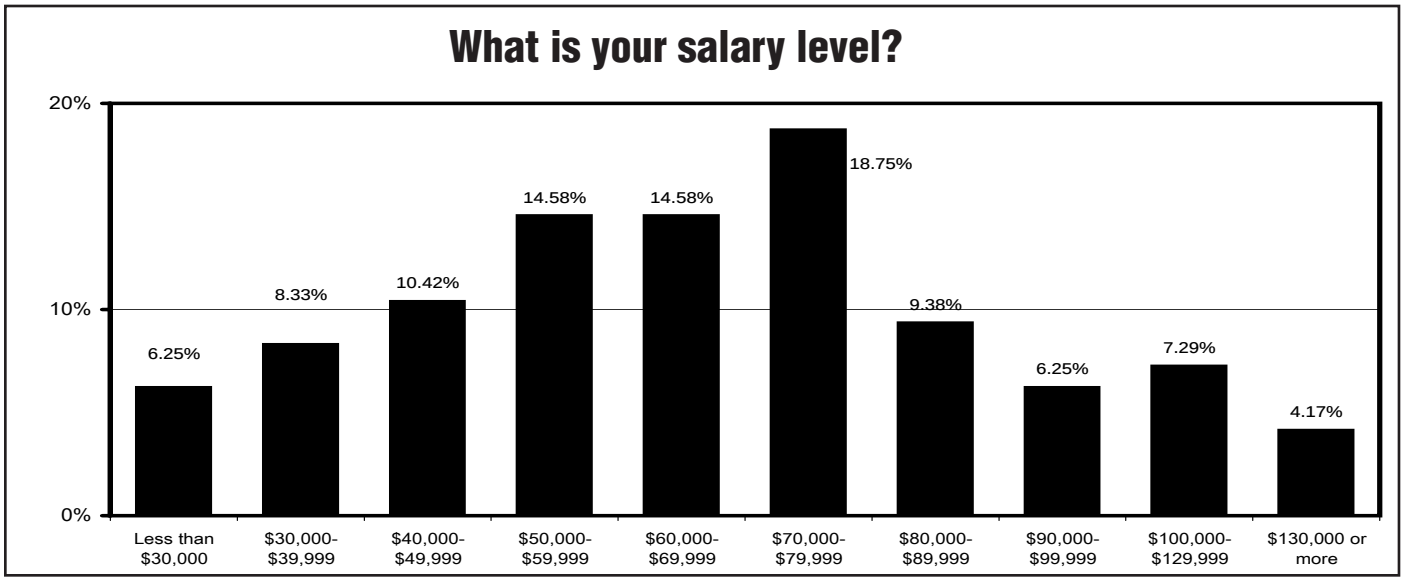
Location also plays a part in the employment scenario: 45% said their practice was in a rural location; 22% were in an urban setting, with 20% in a medium-sized city. The remaining 11% said they practiced in a suburban location. (See the salary survey snapshot on p. 4 for an overview of the results.)

Public health advocates are pushing to protect vulnerable funding for reproductive health programs.

NACCHO was a chief proponent of the 2010 proposed Local Jobs for America Act (H.R. 4812), submitted by House Education and Labor Committee Chairman George Miller (D-CA). The proposed bill took steps to address the impacts of current local government budgetary shortfalls. It would have enabled local governments to provide local health departments with the resources necessary to reinstate laid-off personnel, return furloughed employees to full-time work, and restore core public health services. The bill, however, failed to move in 2010. With Congressional leadership changes coming in the upcoming session, it is unlikely to gain traction, says Brown.

When it comes to staffing levels, 53% of CTU survey respondents reported no change in head count in the last year. About 36% reported a





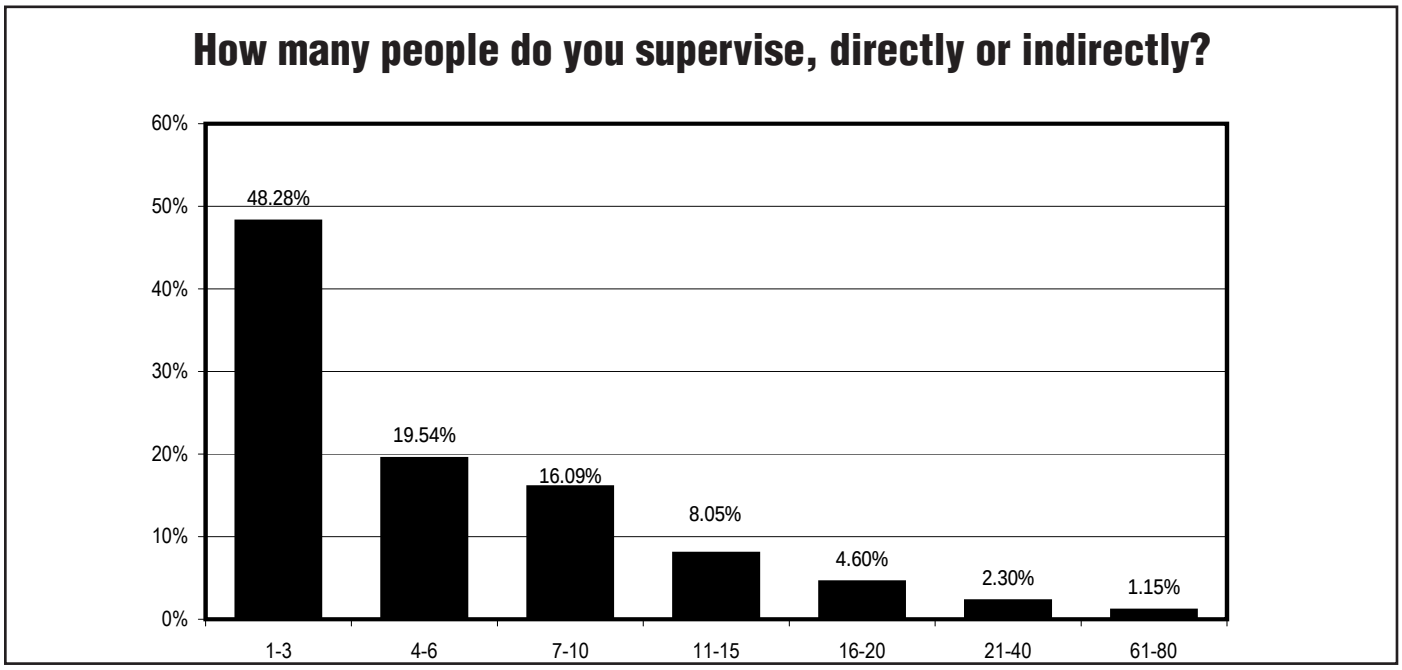
staffing decrease, while 10% reported an increase in positions, similar to statistics reported in the previous year.

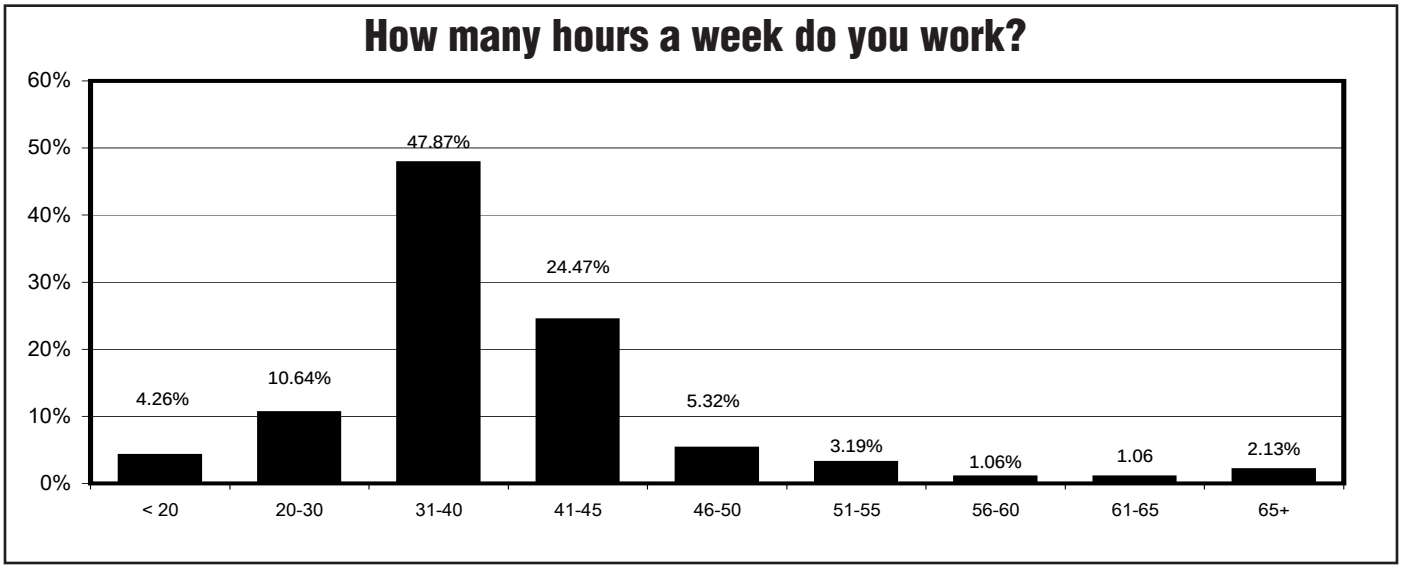
In terms of adding to the public health workforce, NACCHO has been a solid proponent of training and job development for those employed in local health departments. It rallied in September 2010 to combat a Senate amendment that would removed funding for the Prevention and Public Health Fund. The Fund, afforded through the Patient Protection and Affordable Care Act, provides expanded and sustained federal support for prevention and public health programs such as those provided by local health departments.

Nurses who work in the public health sector should pay particular attention to the fate of the Patient Protection and Affordable Care Act. It contains several provisions that will accelerate mid-career training and provide loan repayment for persons in the public health profession sector, including nurses and nurse practitioners, says Brown.

About 42% of 2010 CTU survey respondents have a graduate degree; about 47% have worked in their present field for 15 years or less. (See "What is your highest academic degree?" and "How long have you worked in your present field?" graphics on p. 2.)

With a new Congress coming in session, public health advocates are gearing up for battle to implement the Patient Protection and Affordable Care Act, says Brown. "We were very pleased to





see that [training section] authorized in the Affordable Care Act," Brown states. "The next battle is to actually get it funded."

Keep eye on Title X

Those who work in Title X family planning clinics also are keeping a weather eye on the fate of health care reform. According to the National Family Planning and Reproductive Health Association (NFPRHA) in Washington, DC, the propensity for change in family planning service delivery is greater than any since the program's 1970 inception.

The federal Title X-funded network is impacted on several fronts, since it also is funded by Medicaid, Maternal and Child Health, Social Services Block Grant, and sexually transmitted disease programs, as well as other state and federal programs, as well as patient fees and commercial insurance.

As the federal government dramatically increases the role of Medicaid and commercial insurance exchanges as sources for coverage for patient care, the Title X network will need to adapt and change in order to meet new realities, NFPRHA officials state. With changes swirling, it is difficult to predict what may happen to those working in the public health setting and particularly in the Title X setting, says **Susan Wysocki**, *WHNP-BC, FAANP, president and chief executive officer of the Washington, DC-based National Association of Nurse Practitioners in Women's Health.*

"On one hand, if there is universal access to contraception through health care reform, one might argue that the need for Title X clinics would go down," Wysocki says. "On the other, and possibly more likely side, is the challenge of having enough providers with health care reform. So whether or not women can get contraception regardless of where they go for care, access to methods alone will not be enough."

There simply are not enough providers to provide contraceptive care without the public health systems, including Title X clinics, says Wysocki.

"I suspect the system will look different over time," she states. "However, I do not see major changes overnight." ■

Survey Snapshot

• About half of the *2010 Contraceptive Technology Update Salary Survey* respondents identified themselves as nurse practitioners (NPs), with about 20% as registered nurses, and 5% as nurse-midwives. Administrators comprised about 22% of the current year's responses. About 4% identified themselves as physicians. The survey was mailed in August 2010 to 874 subscribers with 97 responses, for a response rate of 11%.

• About 40% of all respondents indicated they made $59,000 or less; about 49% reported salaries between $59,000 and $99,999. About 11% said they earned a six-figure salary. (*See "What is your salary level" graphic on p. 3.*)

• About 35% say they supervise between 4-10 people. (See "How many people do you supervise, directly or indirectly?" graphic on p. 3.) About 60% report working 40 hours or less a week. *(See "How many hours a week do you work?" graphic above.)*

Source: 2010 *Contraceptive Technology Update* Salary Survey results.