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AHC Media

Potential HPV vaccine shows promise: What could it mean for young women?

9-valent vaccine candidate may replace quadrivalent formula if approved

Just-released results from international trials indicate a potential vaccine, designed to protect against nine HPV strains, might be the next step in cervical cancer protection.[1-5] In the pivotal Phase III efficacy study, the investigational 9-valent HPV vaccine prevented approximately 97% of cervical, vaginal, and vulvar pre-cancers caused by HPV types 31, 33, 45, 52, and 58.[2] Results from research of the vaccine were presented at the European Research Organisation on Genital Infection and Neoplasia (EUROGIN) Congress in Florence, Italy.

The experimental vaccine, designed by Merck of Whitehouse Station, NJ, adds protection against five cancer-causing HPV types to the four included in the company's current quadrivalent HPV vaccine, Gardasil. This wider set is believed to account for nearly 90% of all cases of cervical cancer globally. The new vaccine, dubbed V503, has the same aluminum salt adjuvant as Gardasil. It is administered on the same three-dose schedule of an initial injection, followed by shots at two months and six months.

Merck was set to submit a Biologics License Application for the vaccine candidate to the U.S. Food and Drug Administration before the end of 2013, according to **Roger Perlmutter**, MD, PhD, president of Merck Research Laboratories.

Cervical cancer is the third most common type of cancer among women

EXECUTIVE SUMMARY

Just-released results from international trials indicate a potential vaccine, designed to protect against nine HPV strains, might be the next step in cervical cancer protection. In the pivotal Phase III efficacy study, the investigational 9-valent HPV vaccine prevented approximately 97% of cervical, vaginal, and vulvar pre-cancers caused by HPV types 31, 33, 45, 52, and 58.

- The experimental Merck vaccine adds protection against five cancer-causing HPV types to the four included in the company's current quadrivalent HPV vaccine, Gardasil.
- This wider set is believed to account for nearly 90% of all cases of cervical cancer globally.

worldwide; about 530,000 women develop cervical cancer annually around the world, with approximately 85% of cases occurring in developing countries.[6] The seven cancer-causing HPV types in V503 (16, 18, 31, 33, 45, 52, and 58) cause approximately 90% of cervical cancer cases, approximately 80% of high-grade cervical dysplasias worldwide, and approximately 50-60% of cases of low-grade cervical dysplasias. The seven HPV types also can cause vaginal, vulvar, and anal cancers and pre-cancers. After HPV types 16 and 18, the five additional HPV types in V503 are the most common cervical cancer-causing types worldwide. HPV types 6 and 11 are linked to 90% of cases of genital warts.[7]

Check the data

The pivotal Phase III study evaluated the efficacy, safety, and immunogenicity of the V503 vaccine compared to Gardasil in females ages 16-26; 7,099 women received the 503 vaccine, while 7,105 women were given Gardasil.

The primary efficacy analysis was conducted in those who received all three doses of vaccine within one year, who were not infected with the relevant HPV types at enrollment and who remained free of infection with the relevant HPV types through month 7. Data indicate 96.7% reduction (95% confidence interval [CI]; 80.9, 99.8) in the combined incidence of high-grade cervical/vulvar/vaginal disease (CIN [cervical intraepithelial neoplasia] 2/3+, vulvar intraepithelial neoplasia [VIN] 2/3+, and vaginal intraepithelial neoplasia [VaIN] 2/3+) caused by HPV types 31, 33, 45, 52, and 58; one case in the group that received V503 versus 30 cases in the group that received Gardasil.

Data indicate a 97.1% reduction (95% CI; 91.8, 99.2) in the combined incidence of cervical/vulvar/vaginal disease of any grade (all CIN, VIN, VaIN) caused by HPV types 31, 33, 45, 52, and 58; three cases in the group that received V503 versus 103 cases in the group that received Gardasil. Statistics show a 96.0% efficacy (95% CI; 94.4, 97.2) against six-month persistent HPV infection with HPV types 31, 33, 45, 52, and 58; 35 cases in the group that received V503 versus 810 cases in the group that received the quadrivalent vaccine.[2]

In an assessment of the 503 vaccine's safety, researchers report the frequencies of adverse event reports generally were comparable between the vaccine candidate and Gardasil.[5] However, scientists note there was a higher frequency of injection-site adverse events (90.8% versus 85.1%), including swelling, pain, and erythema in the V503 group. Injection-site pain mostly was reported as mild or moderate in intensity with both vaccines, with the majority of injection-site swelling and erythema cases of small size.

The most frequently reported vaccine-related systemic adverse events (frequency greater than or equal to 2%) for the V503 candidate compared to the quadrivalent vaccine, respectively, were: headache (14.6% versus 13.7 %), pyrexia (5.0% versus 4.3%), nausea (4.4% versus 3.7%), dizziness (3.0% versus 2.8%),

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and fatigue (2.3% versus 2.1%).[5]

Two open-label immunobridging studies for V503 in adolescents also were presented at the EUROGIN conference.[3,4] Immunobridging studies were used for this population because adolescents are not likely to have been exposed to HPV; therefore, efficacy against disease endpoints cannot be studied directly, researchers state. Immunogenicity "bridging data" is an accepted surrogate for efficacy and is accepted by major regulatory agencies.

The first study was aimed at extending the pivotal efficacy study findings in females ages 16-26 to males and females ages 9-15. Scientists divided 3,074 subjects into three groups: 669 males ages 9-15, 1,935 females ages 9-15, and 470 females ages 16-26. Immune responses to V503 were compared among the groups. All study participants in the per-protocol population received three doses of V503 over six months and were evaluated at the seventh month for geometric mean titers (GMTs) and seroconversion rates.

Data indicated non-inferior immunogenicity of V503 in adolescent males and females compared with females ages 16-26 all nine vaccine HPV types: 99.8-100% of adolescent females and 99.8-100% of adolescent males seroconverted, or developed antibodies, against the nine HPV types at the seventh month compared to 99.5-100% of females ages 16-26. The results support bridging the V503 vaccine efficacy findings in young women ages 16-26 to adolescent girls and boys ages 9 to 15.[3]

In the second study, 600 adolescent females who had not yet received a prophylactic HPV vaccine were randomized into two groups – 300 who received V503 and 300 who received Gardasil – to compare the immune responses in adolescent girls for HPV types 6, 11, 16, and 18. All study participants in the received three doses of Gardasil or V503 over a six-month period and were evaluated at the seventh month for GMTs and seroconversion rates. Data indicate immunogenicity of V503 was non-inferior compared to Gardasil in adolescent females for HPV types 6, 11, 16, and 18 — 100% of adolescent females in both study groups seroconverted against HPV types 6, 11, 16, and 18 at the seventh month.[4]

What's the impact?

The 9-valent vaccine appears to provide excellent protection against diseases caused by the nine types of HPV included in the vaccine. If the 503 vaccine receives regulatory approval, it likely will replace the existing quadrivalent vaccine as the vaccine of choice in unvaccinated young women, assuming pricing is reasonable, observes **Khalil Ghanem**, MD, PhD, associate professor of medicine at the Johns Hopkins University School of Medicine and deputy director of education in the Department of Medicine at Johns Hopkins Bayview Medical Center, both in Baltimore.

The quadrivalent vaccine prevents infections with two types of HPV known to cause 70% of cervical cancers in women; the addition of five types in the new vaccine might help to increase the protection to 90% of all cervical cancers, as well as enhance protection for other anogenital cancers as well, states Ghanem. Given that there are some geographic differences observed between the types of HPV that cause cancers around the globe, the 9-valent vaccine is likely to enhance coverage of the most common types throughout most regions of the world, says Ghanem. The side effects profile appears to be similar to the quadrivalent vaccine, he states.

The important question that needs to be answered is whether the new vaccine, if it is approved, will lead to increased uptake of vaccination among target populations, Ghanem comments.

"Despite some very strong data showing the safety of this vaccine and its great impact in reducing HPV-related diseases on a population level, the majority of eligible young men and women in this country have not received the three doses of HPV vaccine," says Ghanem. "It's great that this newer generation vaccine will provide enhanced coverage, but if patients are not getting vaccinated, what's the point?"

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LARC methods: 7 things you need to know

More women are now choosing long-acting reversible contraception (LARC) methods, such as intrauterine devices (IUDs) and the subdermal contraceptive implant. The number of women using LARC methods rose from 2.4% in 2002 to 8.5% in 2009.[1] What do you need to know about LARC methods to inform counseling and provide such methods in your practice?

Incorporate the following points in your clinical database, suggests **Anne Burke**, MD, MPH, associate professor in the Department of Gynecology and Obstetrics at the Johns Hopkins University of School of Medicine in Baltimore. Burke spoke on the importance of LARC methods at the recent Contraceptive Technology Quest for Excellence conference in Atlanta.[2]

First, clinicians who are committed to driving down rates of unintended pregnancy need to know that LARC methods work, and they work very well. Burke points to results from the Contraceptive CHOICE project in St. Louis, which was designed to evaluate reversible birth control methods. Its research indicates dramatic differences in method effectiveness. Women who used birth control pills, the patch, or vaginal ring were 20 times more likely to have an unintended pregnancy than those who used longer-acting forms such as an intrauterine device or implant.[3] *(To read more about the research, see the* Contraceptive Technology Update *articles, "Research proves LARC methods are best — What happens now in practice?" August 2012, p. 85, and "New data: Long-acting reversible methods superior in effectiveness," July 2012, p. 73.)*

Secondly, further research from the CHOICE project shows that women like LARC methods, notes Burke. In looking at CHOICE data, IUDs and the subdermal implant have the highest rates of satisfaction and 12-month continuation over the Pill, patch, vaginal ring, and contraceptive injection.[4] After 24 months, continuation rates for long-acting reversible contraception and non-LARC methods were 77% and 41%, respectively. Continuation rates for the levonorgestrel and the copper IUDs were similar (79% compared with 77%), whereas the implant continuation rate was lower (69%, P<.001) compared with IUDs at 24 months.[5]

Barriers left to remove

Many clinicians might cling to two-visit protocols for IUD insertion to prescreen for sexually transmitted infections (STIs) to reduce the probability of pelvic inflammatory disease (PID). In making her third point, Burke notes 2012 data that show the risk of developing PID following insertion of an intrauterine device is very low, whether or not women have been screened beforehand for gonorrhea and chlamydia.[6]

How about IUD insertions for young women who will not, with certainty, be in a relationship with only one man?

IUDs do not cause infections, says **Robert Hatcher**, MD, MPH, professor emeritus of gynecology and obstetrics at Emory University School of Medicine in Atlanta. Indeed, it would appear that the levonorgestrel IUD (Mirena, Bayer HealthCare Pharmaceuticals, Wayne, NJ) actually prevent infections because of the thick cervical mucus it causes and perhaps because of the decrease in menstrual blood loss experienced with its use. Hatcher presented this information, along with other contraceptive topics, at the Atlanta conference.[7]

"Sexual intercourse with a man who has an infection is the culprit, and this strongly suggests that women using any contraceptive use a condom consistently if at any risk for acquiring an infection," says Hatcher.

EXECUTIVE SUMMARY

More women are now choosing long-acting reversible contraceptive (LARC) methods, such as intrauterine devices (IUDs) and the subdermal contraceptive implant. The number of women using LARC methods rose from 2.4% in 2002 to 8.5% in 2009.

- IUDs and the subdermal implant have the highest rates of satisfaction and 12-month continuation over the Pill, patch, vaginal ring, and contraceptive injection, according to data from the Contraceptive CHOICE project
- Data from a 2012 published study show the risk of developing pelvic inflammatory disease (PID) following insertion of an intrauterine device is very low, whether or not women have been screened beforehand for gonorrhea and chlamydia.

Teens can use LARC

Adolescents make good candidates for LARC methods, notes Burke in her fourth point. Such use is supported by the American College of Obstetricians and Gynecologists, which issued a 2012 committee opinion stating that LARC methods are safe, effective, and appropriate options for adolescents.[8]

LARC methods also are appropriate methods for women who have never been pregnant, Burke notes in her fifth point. The U.S. Medical Eligibility Guidelines for Contraceptive Use (US MEC) ranks use of the Copper T-380A and the levonorgestrel IUDs as a "2" (a condition for which the advantages of using the method generally outweigh the theoretical or proven risks) for nulliparous women; the contraceptive implant is rated as a "1" (no restrictions on use).[9]

When it comes to postpartum contraception, LARC methods represent safe, effective choices for such women, says Burke in her sixth point. For the contraceptive implant (Nexplanon, Merck, Whitehouse Station, NJ), immediate postpartum use is safe and effective with no adverse effects on breastfeeding.[10]

Use for EC lags

Despite top-shelf effectiveness, IUD insertion for emergency contraception (EC) continues to lag, Burke notes in her final point. According to a secondary analysis of data obtained from a prospective cohort study of women who received EC insertions of the Copper T380A IUD (ParaGard, Teva North America, North Wales, PA), if the urine pregnancy test is negative prior to IUD placement, the copper IUD is highly effective for EC at any point in the menstrual cycle.[11]

Think of IUD insertion as "something for women who want a little more Plan A than Plan B," which is the EC pill, says Burke.

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Put US SPR guidance into your practice

Have you put the U.S. Selected Practice Recommendations for Contraceptive Use, 2013 (US SPR) into practice?[1] A new American College of Obstetricians and Gynecologists (ACOG) committee opinion has endorsed use of the guidance in counseling patients about how to most effectively use current birth control methods.[2] *(Read the US SPR online at http://1.usa.gov/1crWrWH, and the ACOG opinion at http://bit.ly/1agyF1P.)*

The Centers for Disease Control and Prevention (CDC) released the US SPR as a companion document to its previously published U.S. Medical Eligibility Criteria for Contraceptive Use, 2010 (US MEC).[3] While the US MEC provides guidance for which contraceptive methods are safe for women with selected characteristics and medical conditions, the US SPR offers guidance on how to use these methods most effectively. Both publications have been adapted from global guidance published by the Geneva, Switzerland-based World Health Organization; a panel of U.S. family planning experts aided the CDC in adapting material for U.S. use.

The US SPR decreases medical barriers to contraception, says **Tara Cleary**, MD, MPH, research assistant professor at the University of North Carolina — Chapel Hill, and guest researcher at the CDC. Cleary presented an update on the US SPR at the recent Contraceptive Technology Quest for Excellence conference.[4]

It is important that clinicians understand that the US SPR guidance is not comprehensive, nor is it the US MEC, says Cleary. Its purpose is to assist healthcare providers when they counsel patients about contraceptive use, she states. The medical eligibility criteria tell clinicians who can use various methods, says Cleary. The selected practice recommendations tell clinicians and counselors how to use various contraceptives, she notes.

The US SPR provides clear, evidence-based recommendations in three general categories: initiation of contraceptive methods, follow-up conditions to routinely check, and management of problems during method use, states a recent editorial by **Herbert Peterson**, MD, Kenan Distinguished Professor and chair of the Department of Maternal and Child Health in the Gillings School of Global Public Health at the University of North Carolina at Chapel Hill and **Ward Cates**, MD, MPH, president emeritus and distinguished scientist at FHI 360 in Durham, NC.[5]

"Managing modern contraceptive choices has become a clinical subspecialty of its own, and more than ever, providers need synthetic access to the evidence base upon which their practice depends," the editorial states. "The US SPR answers this need."

When to start a method?

One of the many important points contained in the US SPR is that any contraceptive method can be started at any time during the menstrual cycle, as long as there is reasonable certainty that a woman is not pregnant. This point means that the Quick Start method of initiating contraception doesn't apply just to combined hormonal contraceptives, such as the Pill, says Cleary.

For clinicians who follow patients who use combined hormonal pills, missed pills represent a major reason for oral contraceptive failure leading to unintended pregnancies. The U.S. SPR provides algorithms for what to do if women miss pills, as well as offers recommendations for provision of a one-year supply of pills.

The guidance also offers information on the management of bleeding abnormalities with intrauterine contraceptives, progestin-only pills, and extended use of combined hormonal contraceptives. It covers initiation of contraception following emergency contraception and information for when a woman can stop use of birth control. Guidance also is provided on when women and men can rely on female and male sterilization after such procedures are performed.

What tests are needed?

Most women can start most contraceptive methods at any time, and few examinations or tests, if any, are needed before starting a contraceptive method, says Cleary. The US SPR provides a chart for necessary exams and tests prior to method initiation. For example, the only essential, mandatory procedure prior to IUD use include bimanual examination and cervical inspection; for combined hormonal methods, a blood pressure measurement must be obtained.[1]

The US SPR provides evidence-based guidance to help clinicians provide quality family planning care, says Cleary.

"It can help individuals use methods correctly and consistently," she notes. "It also decrease medical barriers to contraceptive use."

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EXECUTIVE SUMMARY

A new American College of Obstetricians and Gynecologists committee opinion has endorsed use of the U.S. Selected Practice Recommendations for Contraceptive Use, 2013 (US SPR) in counseling patients about how to most effectively use current birth control methods.

- The new guidance is devised as a companion document to the U.S. Medical Eligibility Criteria for Contraceptive Use, 2010 (US MEC).
- While the US MEC provides guidance for which contraceptive methods are safe for women with selected characteristics and medical conditions, the US SPR offers guidance on how to use these methods most effectively.

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Classify the causes of abnormal uterine bleeding

Menstrual disorders are a common cause for office visits. In a national study, menstrual disorders accounted for 19.1% of 20.1 million visits to physician offices for gynecologic conditions over a two-year period.[1] Before implementing treatment strategies, clinicians must check their approach to diagnosing causes of bleeding.

A normal menstrual cycle typically lasts between 21 and 35 days, with menstruation generally lasting for five days. With abnormal uterine bleeding (AUB), clinicians are looking at bleeding that is more or less frequent or heavier than normal, or menstrual cycles that are shorter or longer than average. In reproductive-age women, causes of AUB can vary greatly and might include uterine fibroids or polyps, irregular ovulation, endometrial problems, underlying bleeding disorders such as von Willebrand disease, or cancer.

Abnormal uterine bleeding also can be caused by a wide variety of local and systemic diseases, such as leukemia and liver failure, or can be related to medications, such as anticoagulants or chemotherapeutic agents, notes **Andrew Kaunitz**, MD, professor and associate chair in the Obstetrics and Gynecology Department at the University of Florida College of Medicine — Jacksonville.

There are many definitions of heavy menstrual bleeding (HMB). In their chapter on menstrual disorders in Contraceptive Technology, authors **Anita Nelson**, MD, and **Susie Baldwin**, MD, MPH, simplify this complex issue.[2]

"A practical new definition of HMB advances the idea that a woman's blood loss is excessive when she says it is excessive," the authors state. "This definition illustrates that the key factor in making a diagnosis of HMB is not the amount of blood the woman loses, which is difficult to ascertain, but how a woman's HMB disrupts her life."

Classify the causes

The London-based International Federation of Gynecology and Obstetrics (FIGO) has developed a revised classification system for causes of abnormal uterine bleeding in nongravid reproductive-age women.[3] Introduced in 2011 following an international consensus process, the etiologies of AUB are classified as "related to uterine structural abnormalities" and "unrelated to uterine structural abnormalities" and categorized following the acronym PALM–COEIN:

- polyp;
- adenomyosis;
- leiomyoma;
- malignancy and hyperplasia;
- coagulopathy;
- ovulatory dysfunction;
- endometrial;
- iatrogenic;
- not otherwise classified.

The PALM-COEIN classification is a systematic approach that is translatable to multiple languages, says **Malcolm Munro**, MD, co-chair of the FIGO Menstrual Disorders Committee, professor in the David Geffen School of Medicine at the University of California, Los Angeles, and director of gynecological services at Kaiser Permanente, Los Angeles Medical Center. It seeks to remove such outdated terms as dysfunctional uterine bleeding, menorrhagia, and menometrorrhagia to create consistency in research, help define roles in diagnosis and treatment, and aid to standardize the approach to diagnosis and treatment. Coagulopathy, endometrial dysfunction, and ovulatory disorders now replace the collection of disorders previously encompassed under dysfunctional uterine bleeding. Heavy menstrual bleeding now describes excess menstrual bleeding, instead of menorrhagia. Intermenstrual bleeding that occurs between clearly defined cyclic and predictable menses now replaces the outdated term "metrorrhagia."[3]

In FIGO meetings, experts agreed that chronic abnormal uterine bleeding is classified as bleeding

EXECUTIVE SUMMARY

In a national study, menstrual disorders accounted for 19.1% of 20.1 million physician office visits for gynecologic conditions over two years.

- The International Federation of Gynecology and Obstetrics has developed a revised classification system for causes of abnormal uterine bleeding in nongravid reproductive-age women. The PALM–COEIN system classifies the etiologies of abnormal uterine bleeding as "related to uterine structural abnormalities" and "unrelated to uterine structural abnormalities."
- The PALM–COEIN system removes such outdated terms as dysfunctional uterine bleeding, menorrhagia, and menometrorrhagia to create consistency in research, define diagnosis and treatment roles, and standardize diagnosis and treatment approaches.

from the uterine corpus that is abnormal in volume, regularity, and/or timing, and has been present for most of the past six months.[2] Acute AUB is defined as an episode of heavy bleeding that, in the opinion of the clinician, is of sufficient quantity to require immediate treatment.[3]

The American College of Obstetricians and Gynecologists has adopted the PALM-COEIN system. It issued a *Practice Bulletin* on diagnosis of AUB in 2012 and a Committee Opinion on management of acute abnormal uterine bleeding in nonpregnant reproductive-age women in 2013.[4,5] It also released a *Practice Bulletin* in 2013 on management of abnormal uterine bleeding associated with ovulatory dysfunction.[6]

Look at method options

Several options are available for long-term treatment of chronic AUB. Effective medical therapies include the levonorgestrel intrauterine system (Mirena, Bayer HealthCare Pharmaceuticals, Wayne, NJ), oral contraceptives (monthly or extended cycles), progestin therapy (oral or intramuscular), tranexamic acid, and nonsteroidal anti-inflammatory drugs (NSAIDs).[5]

For the reduction in mean blood loss in women with heavy menstrual bleeding presumed secondary to abnormal uterine bleeding presumed secondary to endometrial dysfunction, results of a recent analysis of available data suggest that use of the levonorgestrel intrauterine system is indicated over oral contraceptives, luteal-phase progestins, and NSAIDs.[7]

The levonorgestrel intrauterine system appears to be a highly effective treatment option in women with heavy menstrual bleeding, including those with organic causes and bleeding disorders, notes Kaunitz.

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How to get into heads of teens in initial visit

How can clinicians make the first reproductive health visit for a young teen a successful one? Use the HEEADSSS method of interviewing to perform a psychosocial review of systems, says **Melissa Kottke**, MD, MPH, MBA, assistant professor in the Department of Gynecology and Obstetrics at Emory University School of Medicine in Atlanta.[1] HEEADSSS is a mnemonic for Home environment, Education and employment, Eating, peer-related Activities, Drugs, Sexuality, Suicide/depression, and Safety from injury and violence. Kottke presented on the subject at the recent Contraceptive Technology Quest for Excellence conference.[2]

The major causes of morbidity and mortality in the adolescent population are unintentional injuries, many of which are related to alcohol and drug use.[3] Other causes of morbidity, such as unintended pregnancy, sexually transmitted infections, eating disorders, and depression, often are not teased out during the traditional patient/physician model of health interviewing; this is where the HEEADSSS method is most effective.[3]

The HEEADSSS method allows clinicians to explore a wide range of topics in an efficient manner during the initial reproductive visit, says Kottke. Questions in the HEEADSSS method give clinicians a "key opportunity" to spot risky behavior in adolescents and talk with them about it, particularly when it comes to risky sexual behavior, says Kottke.

Adolescence is a time of increased risk-taking, and HEEADSSS questions about sexual health, such as "Have any of your relations ever been sexual relationships?" and "What are you using for birth control?" can help identify potential problems.

Many teens are sexually active. According to the

most recent Youth Risk Behavior Surveillance System, a survey conducted by the Centers for Disease Control and Prevention (CDC) to monitor priority health-risk behavior in youth and young adults, 47.4% said they had ever had sexual intercourse, with 33.7% having sexual intercourse during the previous three months. Of sexually active youth, 39.8% said they did not use a condom the last time they had sex.[4]

Set the stage

The HEEADDSSS method of history taking helps clinicians understand how an adolescent is functioning in life, says **Melanie Gold**, DO, FAAP, clinical professor of pediatrics at the University of Pittsburgh School of Medicine and a staff physician at the University's Student Health Service. By telling teens, "I am asking you these questions to help me find out if there is anything that may be putting your health at risk and to tell me what kind of exam and tests I should do," clinicians are helping to set the stage for sensitive questions that lie ahead, says Gold.[5]

If a clinician just looks at a teen's body mass index (BMI), a possible eating disorder might be missed, notes Gold. Asking such questions as "How do you feel about your weight? Do you want to weigh more or less or stay the same?" can help tease out such information, she notes.

When to schedule visit?

When should such a teen's initial reproductive health visit be scheduled? The American College of Obstetricians and Gynecologists (ACOG) recommends that the first dedicated reproductive health visit take place between age 13 and 15. During the visit, the clinician should provide health guidance, screening, and preventive health care services.[6] Stay tuned: updated guidance from ACOG is slated to be released in the next few months, says Kottke. *(Review the current guidance, as well as other ACOG teen resources, in its free Tool Kit for Teen Care, available at http://bit.ly/1d5WZn9.)*

Realize that the first time an adolescent accesses an adult healthcare facility, it can be quite a different environment from the "happy" office surroundings previously encountered in a pediatric care setting, notes Kottke. Take steps to make your clinic welcoming, says Kottke. The CDC has developed an infographic on a teen-friendly reproductive health visit. Download it at http://1.usa.gov/10965gP.

Be sure to use the initial reproductive health visit as a time to review needed vaccinations, including immunization against human papillomavirus (HPV). An analysis of 2012 survey data shows that not receiving a healthcare provider's recommendation for HPV vaccine was one of the five main reasons parents reported for not vaccinating their daughters.[7]

Do not downplay the importance of counseling, for it is as important as tests and physical exams, says **Eva Lathrop**, MD, MPH, assistant professor in the Department of Gynecology and Obstetrics at Emory University School of Medicine. Speaking at the Quest for Excellence conference, Lathrop said her previous day in the teen clinic was filled with adolescent patients. However, her contact was never physical; all of her work involved listening and talking to each teenager, she noted.[8]

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EXECUTIVE SUMMARY

Make the first reproductive health visit for a young teen a successful one by using the HEEADSSS (Home environment, Education and employment, Eating, peer-related Activities, Drugs, Sexuality, Suicide/depression, and Safety from injury and violence) method of interviewing in performing a psychosocial review of systems.

- The major causes of morbidity and mortality in the adolescent population are unintentional injuries, many of which are related to alcohol and drug use.
- Other causes of morbidity, such as unintended pregnancy, sexually transmitted infections, eating disorders, and depression, often are not teased out during the traditional patient/physician model of health interviewing. The HEEADSSS method is most effective in highlighting potential risks.

papillomavirus vaccination coverage among adolescent girls, 2007-2012, and postlicensure vaccine safety monitoring, 2006-2013 — United States. *MMWR* 2013; 62(29):591-595.
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Lawmakers step in to protect confidentiality

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

One problem that policymakers are confronting as they implement the Affordable Care Act (ACA) is that even if people gain health insurance coverage, they might not always be willing to use it.

In many cases, persons might be concerned that if they use their insurance, someone else in their families, such as a parent or a spouse, will learn about it. This can happen through routine billing and claims processing procedures, most notably the explanation of benefits (EOB) forms that private insurers send to policyholders when care is obtained by someone covered under a policy.[1] These EOBs typically identify who received care, from whom, and of what type, as well as the amount charged, the portion reimbursed by the insurer, and any amount still unpaid. The forms are designed to prevent fraud and to ensure that policyholders are aware of their financial responsibilities, but they also inadvertently interfere with confidentiality for insured dependents.[2]

Confidential care might be needed by adolescents and young adults, as well as spouses and domestic partners who are separated or estranged, in abusive relationships, or otherwise in need of privacy. Confidentiality is needed for a wide range of healthcare services, from mental health care and substance abuse treatment to reproductive healthcare, including contraception, abortion, sexually transmitted infection (STI) testing and treatment, and pregnancy-related care. Indeed, people often seek out subsidized care at publicly supported family planning centers in lieu of using their insurance: Among insured clients who did not plan to use their insurance to pay for their care, 18%, including 31% of teens, cited confidentiality concerns as the reason.[3]

The extent of these confidentiality problems for dependents is growing under the ACA. The law requires private plans to allow young adults to stay on their parents' plans as dependents through age 26, and millions of Americans have gained coverage through this provision.[4] Moreover, the law's broader expansions to private coverage in 2014, through the new marketplaces and federal subsidies, should result in millions more gaining coverage as dependents.

Policymakers have been exploring multiple solutions for these confidentiality problems, according to Rachel Benson Gold, acting vice president for public policy in the Washington, DC, office of the New York City-based Guttmacher Institute.[5]

One option under consideration is to allow people insured as dependents to request that EOBs and similar information not be sent to the policyholder. Depending on how the system is designed, a dependent might make that request for specific services or all services and might provide an alternative address so that she, instead of the policyholder, receives necessary information.

California enacted a law in October 2013 along these lines that requires insurers to grant dependents' requests for confidentiality when they obtain sensitive services, without requiring them to provide documentation of the potential harm they might experience. This law builds on protections under the federal Health Insurance Portability and Accountability Act (HIPAA), which requires confidentiality protections when disclosure could endanger the individual receiving care. Other states have enacted similar requirements in prior years, but the laws have been poorly publicized and rarely used. One lesson that advocates in California have learned is that healthcare providers and patients need to be educated about this option and how to exercise it. In November 2013, the Colorado Division of Insurance issued rules requiring health plans to protect the health information of adults (whether children, spouses, or domestic partners) who are covered as dependents. The rules require plans to develop a way to communicate directly with the dependent so that information would not be sent to the policyholder without the dependent's consent.

A second option for policymakers is to eliminate EOBs automatically whenever there is no financial liability for the policyholder — for example, when no cost-sharing is required. The ACA has increased the number of such situations. Specifically, it requires

most private health plans to cover a wide range of preventive care services without any copayments, deductibles, or other out-of-pocket costs for the patient. That list includes contraceptive methods and services, testing for HIV and other STIs, cervical cancer testing and vaccination, and prenatal care.

Policymakers and healthcare advocates in Massachusetts are exploring options to eliminate EOBs in these circumstances. They are taking advantage of an opportunity created when the state legislature directed insurance regulators to develop a standard "summary of payments" form to replace EOBs in the state. This change would not solve all confidentiality problems for dependents, however. The federal cost-sharing protections do not apply to all sensitive services (for example, STI treatment) nor in all circumstances (for example, when care is received from an out-of-network provider). In those cases, an EOB still could be eliminated if the cost-sharing is paid in full at the time of the service, but not if that cost-sharing counts toward a policy's deductible, because policyholders must be able to keep track of their progress toward the deductible.

Other states can be expected to explore these and additional options in the coming years. State-level efforts, moreover, might pave the way for Congress or the U.S. Department of Health and Human Services to adopt a nationwide solution. Numerous national organization have demanded this move, including the American Academy of Pediatrics, the American Congress of Obstetricians and Gynecologists, the Center for Adolescent Health & the Law, the Society for Adolescent Health and Medicine, and my organization, the Guttmacher Institute.

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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.

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- Effective strategies for breaking bad news
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CNE/CME QUESTIONS

1. The investigational HPV vaccine candidate V503 protects against how many types of HPV?
   A. 9
   B. 8
   C. 7
   D. 6

2. According to Sufrin CB, et al. Obstet Gynecol 2012; 120(6):1,314-1,321, developing pelvic inflammatory disease following insertion of an intrauterine device is very low, whether or not women have been screened beforehand for which sexually transmitted infections?
   A. Syphilis and gonorrhea
   B. Chlamydia and gonorrhea
   C. Chlamydia and bacterial vaginosis
   D. Syphilis and mycoplasma genitalium

3. According to the U.S. Medical Eligibility Criteria for Contraceptive Use, 2010, which forms of birth control CANNOT be started at any time during the menstrual cycle, as long as there is reasonable certainty that a woman is not pregnant?
   A. Subdermal implant
   B. Copper-T 380A intrauterine device
   C. None. All methods may be started in this method
   D. Levonorgestrel intrauterine system

4. What is the acronym developed by the International Federation of Gynecology and Obstetrics for the classification system of causes of abnormal uterine bleeding in nongravid reproductive-age women?
   A. HAS-BLED
   B. DEPT
   C. RED
   D. PALM–COEIN

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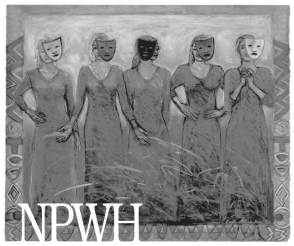


2013 SALARY SURVEY RESULTS

CONTRACEPTIVE TECHNOLOGY UPDATE®

A Monthly Update on Contraception and Sexually Transmitted Diseases

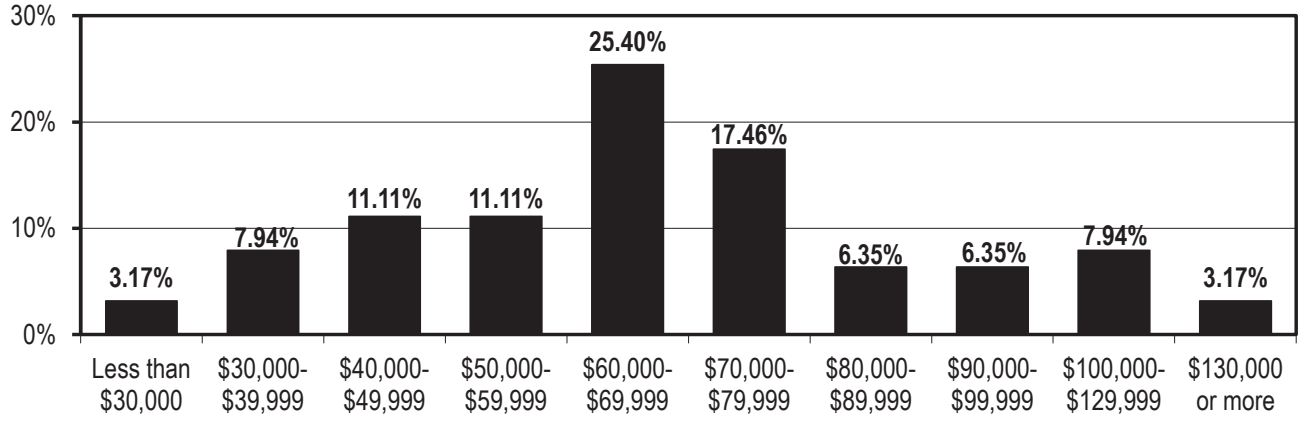
As healthcare reform rolls in, what is the forecast for family planners?

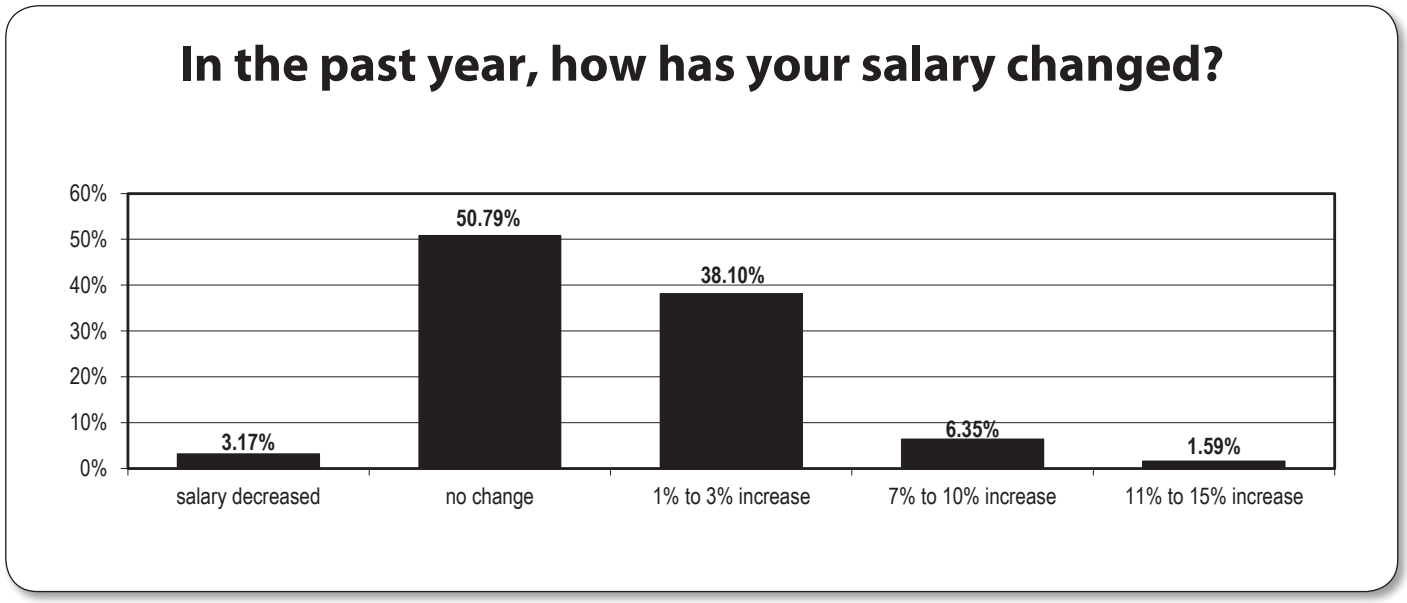
As of Jan. 1, 2014, the federal Affordable Care Act (ACA) requires most U.S. citizens and legal residents to have minimum essential health coverage. As the landscape of healthcare provision changes, what does it mean for family planning clinicians?

There are several key factors for successful survival of family planning clinics, says **Michael Policar**, MD, MPH, clinical professor of obstetrics, gynecology, and reproductive sciences at University of California, San Francisco (UCSF) and medical director of the UCSF Family PACT Evaluation in the California Office of Family Planning in Sacramento. Policar presented information on ACA and Title X, the federal family planning program, at the recent Contraceptive Technology Quest for Excellence conference.[1]

Drawing from information from the National Family Planning and Reproductive Health Association (NFPRHA), Policar says that capacity to accept insurance is essential, and clinics will need to contract with plans at good rates. Provider credentials and privileges must be in place, and correct coding and billing will be highlighted. Initial enrollment of those with insurance will be part of the process, with maintenance of enrollment to be expected. Assessment and management of cost of care is essential to improving efficiency of services, Policar states.

What is your salary level?





Five options are available for family planning clinics in light of full ACA implementation, says Policar:

- subcontract with a primary care clinic or provider group to provide sexual and reproductive health services to them;
- add on limited primary care services to help "shoulder the load;"
- evolve into a "full scope" primary care practice that emphasizes sexual and reproductive health;
- merge with an existing primary care clinic or practice in the community;
- continue to operate "as is."

Those who chose the last option won't last long, Policar predicts.

Public health takes hit

During 2012, nearly one-half (48%) of all local health departments reduced or eliminated services in at least one program area, with maternal and child health, immunization, and emergency preparedness services most frequently affected, according to the Washington, DC-based National Association of County and City Health Officials (NACCHO).[2]

Twenty percent of health departments reported cuts in immunization services, followed by 15% for maternal and child health, as well as emergency preparedness services. In the six economic surveillance studies NACCHO has conducted since 2009, maternal and child health services has been among the top three most frequently reduced programs.

While workforce losses are lessening, capacity loss remains, NACCHO statistics show.[2] Workforce losses and gains were roughly equal in 2012, with local health departments collectively adding 4,000 positions and reducing 4,300 positions. However, since 2008, local health departments have shed nearly 44,000 jobs.[2]

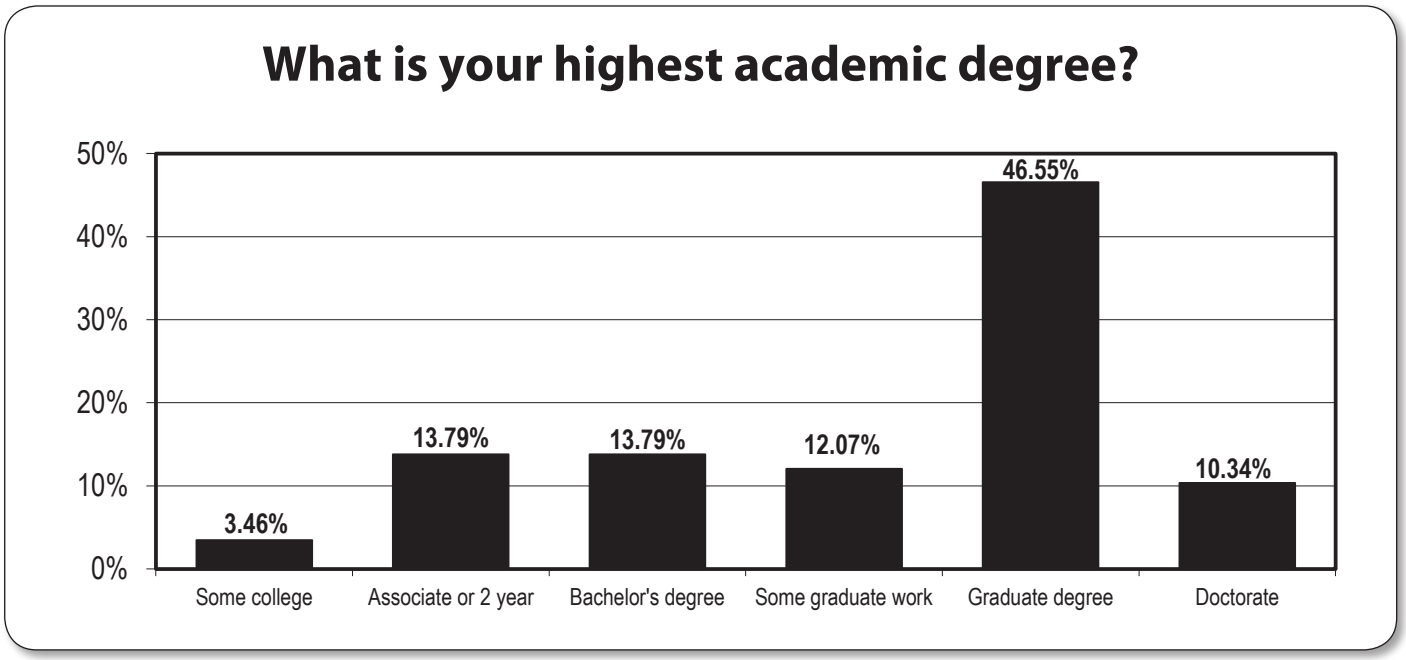
Focus on Title X clinics

Fulfilling the promise of the ACA depends on the continued support and success of existing programs such as Title X, asserts a new white paper from the Washington, DC-based Roosevelt Institute.[3] Title X provides critical medical care and "wrap-around" services for family planning clinics across the United States and enables them to pay for and maintain facilities, train and hire staff, purchase equipment and supplies, and provide services.

"Title X will remain a last line of defense for the low-income uninsured," the white paper states. "The variability of Medicaid eligibility thresholds in various states (due to the number of states that have rejected federal funding for Medicaid expansion) will only compound the demand for Title X services."

Medicaid plays role

Significant investment in Medicaid is a de facto investment in family planning and its providers, says **Lauren Levenstein**, NFPRHA communications manager. Medicaid is the largest funding source for publicly funded family planning; the ACA impacts Medicaid through the general Medicaid expansion and through the state plan amendment option for family planning, she notes. *(See the Washington Watch column, "Health reform rolls on post-election," in* Contraceptive Technology Update, *January 2013, p. 10.)*



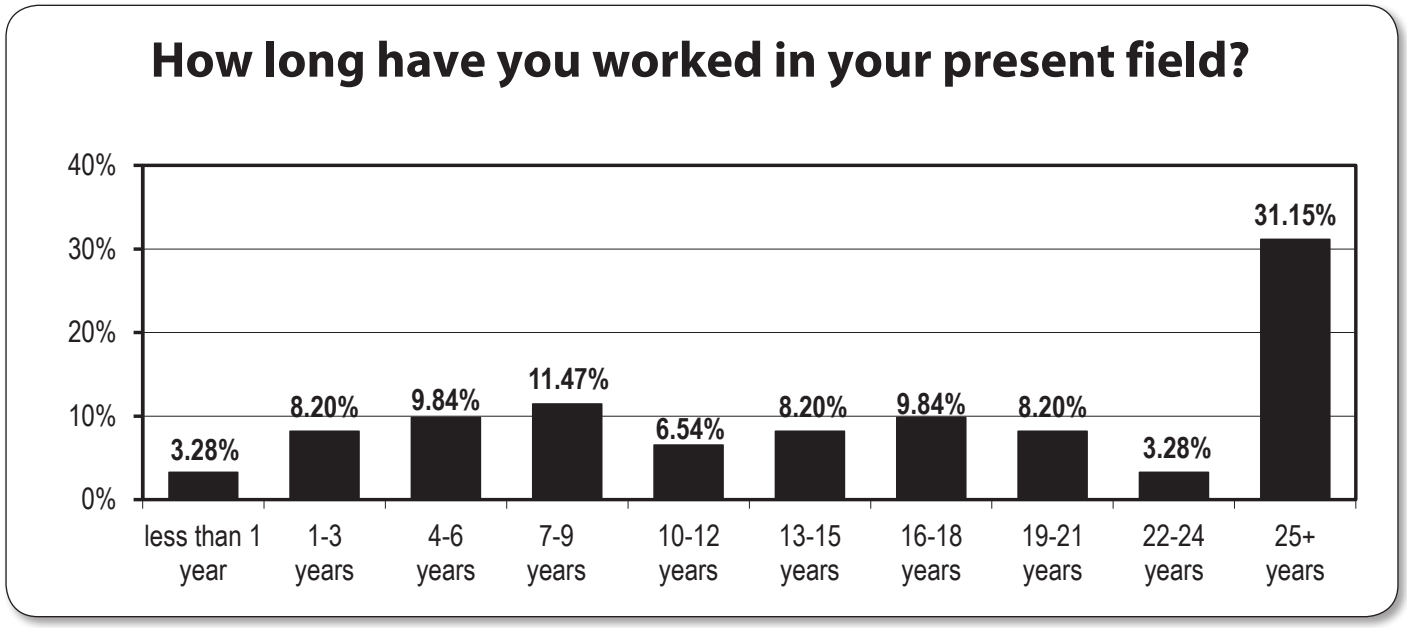
The biggest potential new source of revenue for clinics will come from more clients covered by Medicaid or private insurance, says **Adam Sonfield**, senior public policy associate at the Washington, DC, branch of the New York City-based Guttmacher Institute.

While reimbursement may not cover the full cost of care, it is much better than no insurance at all, says Sonfield, who pens CTU's "Washington Watch" column. It might require some investments by clinics to get themselves in plan networks.

"For all family planning centers, becoming adept at working with health plans as a way to secure third-party reimbursement for insured clients will be necessary to thrive in the emerging health care marketplace," states a report co-authored by Sonfield and **Rachel Benson Gold**, the Institute's acting vice president for public policy.[4]

Any funding for training?

There is no dedicated funding under the ACA specifically for family planning providers to continue education and other efforts, states Levenstein. While that is unfortunate for the family planning network, there have been several other funding opportunities which many family planning providers have secured, she notes.



Several family planning centers received navigator grants to do outreach and enrollment, including Planned Parenthood affiliates in Iowa and Oklahoma. Montana, and northern New England, as well as Public Health Solutions in New Jersey, a current Title X grantee, states Levenstein. Federally qualified health centers, several of which receive Title X funding and/or provide family planning services, have received money for dedicated outreach and enrollment staff in their centers, she states.

"Publicly funded family planning providers have been encouraged to become in-person assistors, if funding is available through their state exchanges, or certified application counselors, seeking community funding if possible," says Levenstein. "The ACA also contains generous funding for the National Health Service Corps – a program to help support health centers in areas of provider shortage — and family planning providers became included in the types of entities that can participate."

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What's the overview of 2013 salary landscape?

Many family planning clinicians are glad to see a new calendar year. More than half (55.7%) of all participants in the *Contraceptive Technology Update 2013 Salary Survey* said the number of employees decreased at their facility, up from 36% in 2012.

However, salaries for family planning clinicians appear to be evening out. While 51% of 2013 survey participants saw no change in pay, 38% reported 1-3% increases, with 8% getting 7-15% bumps. Just 3% reported decreases; this percentage compares to 13% in 2012. *(See "In the past year, how has your salary changed?" graphic on p. 2.)*

Extra hours don't enter into the picture for most survey respondents. About 67% report working 40 hours or less a week. About 80% say they supervise between 4-10 people.

Does location make a difference in pay? Just more than half (54%) reported working in a rural area, with about 25% in an urban location. About 18% said they worked in a medium-size city, with 3% in a suburban location. While most (about 61%) respondents said they worked in a public health agency, some 26% reported clinic employment. About 5% said they worked in a college health service environment, with 3% at an agency. *(Check the snapshot below for an overview of 2013 respondents.)*

Considering adding to your academic credentials? About 47% of 2013 *CTU Salary Survey* respondents have a graduate degree. About 48% 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. 3.)* ■

Survey Snapshot

About 46% of the *2013 Contraceptive Technology Update Salary Survey* respondents identified themselves as nurse practitioners (NPs), with about 17% identifying themselves as registered nurses and 5% as nurse-midwives. Administrators made up about 25% of the current year's responses. About 5% identified themselves as physicians; 2% were physician assistants. The survey was mailed in October 2013 to 740 subscribers with 63 responses, for a response rate of 8.5%.

About 56% of all respondents reported salaries between $59,000 and $99,999; about 33% indicated they made $59,000 or less. About 11% said they earned a six-figure salary. *(See "What is your salary level" graphic on p. 1.)* ■

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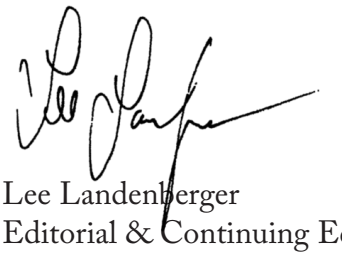

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Editorial & Continuing Education Director