CONTRACEPTIVE TECHNOLOGY UPDATE®

35TH ANNIVERSARY

INSIDE

AHC Media

SEPTEMBER 2015 Vol. 36, No. 9; p. 97-108

Counseling on LARC methods cuts unintended pregnancy rates

Intervention is first randomized trial to reduce unintended pregnancies

Training clinicians to inform women that different birth control methods have very different levels of effectiveness proved key in cutting the number of unintended pregnancies among young women seeking family planning services, data suggests from a new national study from the Bixby Center for Global and Reproductive Health at the University of California, San Francisco (UCSF).[1] By educating young women about the safety and effectiveness of long-acting reversible contraceptives (LARCs) such as intrauterine devices and the contraceptive implant, unintended pregnancy rates dropped by nearly half — from 15 to eight per 100 women — in women seeking family planning services.

"IT'S IMPORTANT THAT WOMEN ALSO LEARN ABOUT METHODS THAT GIVE A HIGHER LEVEL OF PROTECTION AGAINST PREGNANCY WHEN THEY SEEK CONTRACEPTIVE CARE."
— CYNTHIA HARPER, UCSF AND BIXBY CENTERS

The study was conducted in 40 U.S. Planned Parenthood centers. It is the first clinic-based intervention in a randomized trial to reduce unintended pregnancies, according to researchers.

There has been a heavy reliance in the United States on the Pill and condoms for young people, observed **Cynthia Harper**, PhD, professor of obstetrics, gynecology, and reproductive sciences at UCSF and Bixby Center faculty member. It is easy for people to forget to use these methods, which can lead to accidental pregnancies, said Harper in a press statement accompanying the online publication of the research.

"It's important that women also learn about methods that give a higher level

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CONTRACEPTIVE TECHNOLOGY UPDATE®

Contraceptive Technology Update®
ISSN 0274-726X, is published monthly by
AHC Media, LLC
One Atlanta Plaza
950 East Paces Ferry Road NE, Suite 2850
Atlanta, GA 30326.
Periodicals Postage Paid at Atlanta, GA 30304 and at additional mailing offices.

POSTMASTER: Send address changes to:
Contraceptive Technology Update
P.O. Box 550669
Atlanta, GA 30355.

SUBSCRIBER INFORMATION:
Customer Service: (800) 688-2421.
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Hours of operation: 8:30 a.m. - 6 p.m. Monday-Thursday; 8:30 a.m. - 4:30 p.m. Friday, EST.

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GST Registration Number: R128870672.

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of protection against pregnancy when they seek contraceptive care," noted Harper, who served as lead author of the research paper. "Women consider healthcare providers a highly trusted source of information on birth control, so it's especially important that providers tell women about all of the methods they can use."

Training cited

The study shows how important it is that women's healthcare providers have full information about available birth control methods and are trained to provide all of these methods to patients at the same visit, said **Carolyn Westhoff**, MD, MSc, senior medical advisor at Planned Parenthood Federation of America.

"It's one very important part of making sure that women can have the birth control of their choosing, without any barriers," noted Westhoff, who is professor of epidemiology and population and family health at the New York Presbyterian Hospital and at the Columbia University Medical Center and professor of obstetrics and gynecology at the New York Presbyterian Hospital and at the Columbia University Medical Center, College of Physicians and Surgeons, all in New York City.

To conduct the study, researchers tested the training at Planned Parenthood health centers across the country, some of which provided abortion and others that provided only family planning services. The research team assigned half of the health centers at random to receive the contraceptive training, with the other half proceeding with their standard course of care. To enter the study, women had to be between age 18 and 25, attending family planning or abortion care visits, and not desiring pregnancy in the next 12 months. A total of 1,500 women were enrolled.

For example, providers would explain that while less than 1% of women using an implant or intrauterine device will get pregnant in a year, while on average, 9% of women on the Pill and 18% of women whose male partners use condoms will get pregnant in that same period of time.

What did researchers find? While

EXECUTIVE SUMMARY

Training clinicians to inform women that different birth control methods have very different levels of effectiveness proved key in cutting the number of unintended pregnancies among young women seeking family planning services, data suggests from a new national study from the Bixby Center for Global and Reproductive Health at the University of California, San Francisco.

- By educating young women about the safety and effectiveness of long-acting reversible contraceptives such as intrauterine devices and the contraceptive implant, unintended pregnancy rates dropped by nearly half — from 15 to eight per 100 women — in women seeking family planning services.
- The study was conducted in 40 U.S. Planned Parenthood centers. It is the first clinic-based intervention in a randomized trial to reduce unintended pregnancies, according to researchers.

71% of the providers who received the training discussed LARC methods with their patients, just 39% of providers in the control group did. As a result, 28% of women in the intervention group chose LARC methods, compared with 17% in the control group. Women reported a high level of autonomy in choosing their birth control methods and said they made the choice on their own or did it with their providers.

When it came to reduction in the number of unintended pregnancies, researchers report rates dropped from 15 to eight per 100 women over a year, but only among the women who had come to clinics seeking family planning services. For reasons that are not entirely clear, there was no effect among the women who sought birth control after an abortion, researchers note. Fewer women wanting to use intrauterine devices or implants post-abortion were able to obtain them, and nearly a quarter were pregnant again within a year, researchers report. Restrictions on using public funding for contraception in places that provide abortions might have discouraged many women; nearly 38% of the women in the study had no medical insurance.[1]

Program goes wide

In 2011, Planned Parenthood made a major shift in policy and increased access to health services and education, says **Robert Hatcher**, MD, MPH, professor emeritus of gynecology and obstetrics at Emory University School of Medicine in Atlanta. This new approach follows suit, he explains.

"Once again, Planned Parenthood has led the way," observes Hatcher. "This organization has been the leader in providing contraceptive services since the 1920s, and its comprehensive approach to birth control services and well-woman services is simply remarkable."

The Bixby Center is now offering its "Beyond the Pill" training to healthcare providers outside of Planned Parenthood, says Harper.

> ... A NEW PUBLICATION, *INTRAUTERINE DEVICES AND IMPLANTS: A GUIDE TO REIMBURSEMENT,* ... PROVIDE[S] INFORMATION ON PATIENT COVERAGE, STOCKING, AND REIMBURSEMENT.

"Since study completion, we have entered our implementation science phase, where we are bringing the training to many practices throughout the country, including large urban departments of health, public hospitals, teen clinics, and primary care community clinics," reports Harper in an interview with *Contraceptive Technology Update.* "We continue to train Planned Parenthood health centers as well, and other reproductive health specialist sites."

The continuing education-accredited training consists of a half-day program with components for all staff. It offers up-to-date science and professional guidelines on LARC methods, features patient-centered counseling skills, and emphasizes shared decision-making. The training includes information on client eligibility for intrauterine devices and the implant, common misunderstandings about LARC methods, and billing and clinic flow troubleshooting.

A health educators' practicum provides opportunities to role play client counseling scenarios and build counseling skills, while a clinician practicum provides hands-on insertion practice with pelvic models and clinical pearls for insertion and removal. *[For training information, contact national training coordinator Jennifer Grand, MS, at Jennifer.Grand@ucsf.edu, or phone (415) 502-0331.]*

Publication available

The Bixby Center also has released a new publication, *Intrauterine Devices and Implants: A Guide to Reimbursement*, to provide information on patient coverage, stocking, and reimbursement.

The guide is a joint project of the Bixby Center and the American College of Obstetricians and Gynecologists National Family Planning and Reproductive Health Association, National Health Law Program, and the National Women's Law Center. *(To access the guide, visit http://bit.ly/1MhrmeA.)*

"Intrauterine devices and implants are safe and highly effective forms of contraception, but their high cost often creates obstacles for providers to offer these methods to women," Bixby Center officials state. "This new guide aims to decrease the cost barriers for providers and patients alike."

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Single-size Caya diaphragm is available by prescription in U.S.

The Caya single-size diaphragm, the first new cervical barrier method to enter the market in more than 10 years, is available by prescription from U.S. healthcare providers.

The device gained regulatory approval from the Food and Drug Administration in late 2014. *(*Contraceptive Technology Update *reported on the approval. See "New year, new device — Offer barrier method option to your patients," January 2015, p. 4.)*

The Caya device, known as the SILCS diaphragm during its development phase, was designed through a unique collaboration between the Seattle-based global health nonprofit PATH, the Norfolk, VA-based reproductive health product development organization CONRAD, the United States Agency for International Development, and other partners. The device was licensed in 2010 to Frankfurt, Germany-based Kessel medintim GmbH. The company has selected Salem, VA-based HPSRx Enterprises to introduce the Caya to the U.S. market. The device already is available in Europe, Canada, Malaysia, and Australia.

Clinical studies indicate the single-size design fits most women who could wear a traditional diaphragm, said **Gustavo Doncel**, MD, PhD, scientific and executive director of CONRAD, in a press statement. Results from the contraceptive effectiveness study indicated 76% of women were able to insert and correctly position the diaphragm simply using instructions. With coaching, 94% of women were able to insert, correctly position, and remove the diaphragm,[1] he noted. The ease of using the diaphragm should make it easier to provide and use consistently, said Doncel.

Who can use the device?

The Caya device is constructed with a silicone membrane that is placed over the cervix and prevents entry of the sperm cells into the uterus. Its flexible rim ensures correct position, with grip dimples to facilitate vaginal insertion. The removal dome is on the front of the diaphragm to aid in removal from the vagina.

Which women are potential users of the Caya device? Along with women who desire to use a nonhormonal method, consider patients who:

- medically require use of nonhormonal contraception, such as those with cardiovascular disease, hypertension, congenital severe lipid metabolic disorders, acute pancreatitis, or impaired glucose tolerance;
- are nursing mothers;
- have a latex allergy;
- desire to use the device in combination with natural methods of contraception;
- opt to use self-determined contraception;
- seek a nonhormonal method between pregnancies;
- wish to use in combination with other methods of contraception, such as condoms;
- or choose to use in case of infrequent intercourse.

Which women should not use Caya? Absolute contraindications include the following:

- application in the first six weeks after childbirth;
- if used previously, diaphragms of size 60 mm or 85 mm and larger have been used;
- acute or chronic-recurrent urinary tract infections;
- infections of the genital organs and the true pelvis;
- pronounced descensus uteri and vaginae;
- cystocele with obliteration of the retropubic niche in the vagina;
- or weakly formed or absent retropubic niche.

Relative contraindications include marked and/or fixed retroversion/retroflexion, as well psychological or somatic difficulties with the application of the device.

EXECUTIVE SUMMARY

The Caya single-size diaphragm, the first new cervical barrier method to enter the market in more than 10 years, is available by prescription from U.S. healthcare providers.

- Results from the contraceptive effectiveness study indicated 76% of women were able to insert and correctly position the diaphragm simply using instructions. With coaching, 94% of women were able to insert, correctly position, and remove the diaphragm.
- The device is constructed with a silicone membrane that is placed over the cervix and prevents entry of the sperm cells into the uterus. Its flexible rim ensures correct position, with grip dimples to facilitate vaginal insertion. The removal dome is on the front of the diaphragm to aid in removal.

Be sure to instruct patients to always use water-soluble contraceptive gels such as Gynol II (Revive Personal Products Co., Madison, NJ) when using the Caya diaphragm. The device is **not** compatible with silicone-based gels and should not be used with them.

How to get device

Estimated consumer cost for the Caya should be about $80, says **Robert Patane**, founder of HPSRx Enterprises. Depending on the specific retailer or provider, it could vary from $75 to $90, he notes.

"We have already had some success with the product being covered by many of the insurers with zero co-pay to the patient," Patane comments. The device can be used for two years from the first application.

When prescribing Caya, clinicians might consider stocking the device in office for direct dispensing. This provides convenience for the patient not having to go to the pharmacy to obtain the device, and it might offer a potential cost savings for the patient if the provider passes along its lower cost. According to Patane, healthcare providers purchasing direct from HPSRx are able to acquire the product at a lower cost due to there being fewer logistic entities involved, which results in fewer additional markups. *(See resource listing at end of this story for company contact information.)*

"With the provider stocking and supplying the product directly, there is no risk that the patient's pharmacy will not have the product in stock, eliminating the delay and/or complication of the pharmacy having to source and order the product before filling the patient's prescription," notes Patane. "Thus, [this offers] much improved and secure access for the patient."

If providers don't wish to stock the device, there are two nationally licensed mail order pharmacies that have product in stock: Warren, MI-based American Mail Order Pharmacy and Florence, KY-based Healthwarehouse.com Inc. Providers can call, fax, or e-script the prescription to these pharmacies for faster service, or patients can mail the written prescription along with the order form. *(See resource listing at end of this story for pharmacy contact information. Also go to the Caya healthcare providers' web page at http://bit.ly/1L76eYm, where PDFs of order forms are available for printing.)*

HPSRx Enterprises also offers test units free of charge, which are one-time use disposable units that can be used for demonstration, test fitting, or for the patient to actually try insertion and removal while in the office.

In addition, providers can print a benefits and features handout, as well as a consulting guide and a flyer, from the Caya website, www.caya.us.com. Click on the "Health Care Providers" tab.

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RESOURCES

- American Mail Order Pharmacy, 23290 Schoenherr Road, Warren, MI 48089. Telephone: (888) 772-3811. Fax: (586) 772-6873. Web: http://www.amoprx.com.
- Healthwarehouse.com Inc., 7107 Industrial Road, Florence, KY 41042. Telephone (800) 748-7001. Fax: (888) 870-2808. Web: www.healthwarehouse.com.
- HPSRx Enterprises, 1640 Roanoke Blvd., Salem, VA 24153. Telephone: (800) 850-1657. Email melissa@hpsrx.com. Web: www.hpsrx.com. ■

What are the options available for medication prior to IUD placement?

While the American College of Obstetricians and Gynecologists recommends taking over-the-counter pain medication prior to intrauterine device (IUD) insertion, no specific drug is recommended.[1] Research has just been published that looks at the use of ketorolac, an injectable drug often used in the postoperative setting.[2]

To evaluate the use of intramuscular injection of ketorolac compared with placebo saline injection for pain control with IUD placement, researchers conducted a randomized, double-blind, placebo-controlled trial between July 2012 and March 2014. Patients received 30 mg ketorolac or placebo saline intramuscular injection 30 minutes before IUD placement. The primary outcome was pain with IUD placement on a 10-cm visual analog scale. Sample size was calculated to provide 80% power to show a 2.0-cm difference (p=0.05) in the primary outcome. Secondary outcomes included pain with study drug injection, speculum insertion, tenaculum placement, uterine

sounding, and at five and 15 minutes after IUD placement. Sixty-seven women participated in the study; 33 were placed in the ketorolac arm, and 34 were placed in the placebo arm. There were no differences in baseline demographics including age, body mass index, and race.

In the data analysis, there were no differences in median pain scores for IUD placement in the placebo compared with ketorolac groups (5.2 compared with 3.6 cm, p=.99). While there was a decrease in median pain scores at five minutes (2.2 compared with 0.3 cm, p≤.001) and 15 minutes (1.6 compared with 0.1 cm, p≤.001) after IUD placement, no difference was noted for all other time points. Nulliparous participants (n=16, eight per arm) had a decrease in pain scores with IUD placement (8.1 compared with 5.4 cm, p=.02). In this study, 22% of participants in the placebo group and 18% in the ketorolac group reported injection pain was as painful as IUD placement.[1] While ketorolac did not reduce pain with IUD placement, it did reduce pain at five and 15 minutes after placement, the researchers conclude.

"The demonstrated efficacy of ketorolac in this study is encouraging," the scientists note. "However, it is limited by the need for a potentially painful intramuscular injection and an in-clinic 30-minute wait time."

Is injection worth it?

As the study authors point out, the maximum analgesia provided by ketorolac occurs 1-2 hours post-injection, notes **Andrew Kaunitz**, MD, University of Florida Research Foundation professor and associate chairman of the Department of Obstetrics and Gynecology at the University of Florida College of Medicine – Jacksonville. This observation might explain why pain reduction was noted only after the procedure, he points out. While ketorolac is not expensive, logistical considerations might make routine use of pre-IUD placement injectable analgesia unrealistic in many ambulatory settings, says Kaunitz.

Prior studies suggest that pre-placement oral nonsteroidal anti-inflammatory drugs (NSAIDs) aren't effective in reducing placement pain involving analgesic administration in the clinic less than one hour pre-IUD placement.[3] Kaunitz agrees with the study authors that future trials of oral NSAID administration prior to arrival at the clinic are warranted.

What are the options?

A comparative study design against oral NSAIDs would be appropriate before ketorolac use is endorsed, says **Anita Nelson**, MD, professor in the Obstetrics and Gynecology Department at the David Geffen School of Medicine at the University of California in Los Angeles.

Studies that have looked at IUD insertions indicate that there is no treatment effective for general use for pain associated with device placement,[4-7] notes Nelson. Nelson presented information on contraception at the April 2014 Montana Family Planning Training in Helena.

Results from a 2011 study conducted to examine the effects of prophylactic misoprostol prior to intrauterine device placement in nulliparous women suggest the drug did not reduce patient perceived pain, but it did appear to increase preinsertion side effects,[8] Nelson comments.

A 2013 literature review indicates that NSAIDs do reduce later cramping and bleeding associated with new Copper T380A IUD users,[9] says Nelson.

EXECUTIVE SUMMARY

New research looks at the use of ketorolac, an injectable drug often used in the postoperative setting, as a possible option for easing pain prior to intrauterine device (IUD) insertion.

- While the American College of Obstetricians and Gynecologists recommends taking over-the-counter pain medication prior to IUD insertion, no specific drug is recommended.
- While ketorolac doesn't reduce pain with IUD placement, it does reduce pain at five and 15 minutes after placement, researchers note. However, use of the drug calls for a potentially painful intramuscular injection and an in-clinic 30-minute wait time.

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Long-acting reversible contraceptives used by few women after delivery

Researchers recently looked at national data to investigate women's patterns of contraceptive use after delivery and the association between method use and risk of pregnancy within 18 months.[1] What did they find?

By three months postpartum, 72% of women were using some type of contraceptive; 6% used long-acting reversible contraceptives (LARCs), and 0.5% of these women became pregnant within 18 months of delivery. In comparison, 28% of women relied on hormonal methods, and 25% used less effective forms of contraception. Data indicate 13-18% of these women became pregnant within 18 months, as did 23% of women using no contraception.[1]

The most troubling statistic? At least 70% of pregnancies among U.S. women in the first year after delivery of a child were unintended. Unintended and closely spaced pregnancies are associated with adverse maternal and child health outcomes, researchers note.[1]

The research was conducted by the Austin-based Texas Policy Evaluation Project, which includes researchers from The University of Texas at Austin's Population Research Center, Oakland, CA-based Ibis Reproductive Health, and the University of Alabama – Birmingham. To perform the analysis, the scientists looked at data from the 2006–2010 National Survey of Family Growth (NSFG).

One of the primary reasons researchers decided to use the NSFG for the study was because it allowed them to determine when women initiated contraception postpartum and track the types of methods they used in the months following delivery, notes lead author **Kari White**, PhD, assistant professor of Health Care Organization and Policy at the University of Alabama at Birmingham.

"This information is not available or is much more limited in other data sources, such as hospital discharge surveys or the Pregnancy Risk Assessment Monitoring System," White explains. "Another advantage of the NSFG is that it is a nationally representative sample of reproductive aged women in the U.S. and, therefore, can show what is happening at the national level with respect to postpartum contraception."

Why such low use?

While it is not clear why few postpartum women make use of highly effective methods, chances are it might be due to insurance-related barriers that prevent many women

EXECUTIVE SUMMARY

New national data of U.S. reproductive-age women indicates that by three months postpartum, 72% of women were using some type of contraceptive, with only 6% using long-acting reversible contraceptives. In women who chose these methods, just 0.5% of these women became pregnant within 18 months of delivery.

- In comparison, 28% of women relied on hormonal methods and 25% used less effective forms of contraception, data indicate. Study findings indicate that 13-18% of these women became pregnant within 18 months, as did 23% of women using no contraception.
- Insurance-related barriers prevent many women from obtaining long-acting reversible contraception before being discharged from the hospital, researchers note.

from obtaining long-acting reversible contraception before being discharged from the hospital, researchers note.

In most states, intrauterine devices or the contraceptive implant are not included in the "global" obstetric fee, meaning hospitals will incur a financial loss if a postpartum patient receives a LARC prior to discharge,[2] notes **Andrew Kaunitz**, MD, University of Florida Research Foundation professor and associate chairman of the Department of Obstetrics and Gynecology at the University of Florida College of Medicine — Jacksonville.

"Some state Medicaid programs have addressed this issue," says Kaunitz. "If more states follow suit, this would mean more postpartum women in the U.S. will have access to highly effective reversible contraceptives."

Indeed, more state Medicaid programs are reimbursing for immediate postpartum placement of IUDs and implants, notes **Anita Nelso**n, MD, professor in the Obstetrics and Gynecology Department at the David Geffen School of Medicine at the University of California in Los Angeles. California just announced such coverage in its MediCal program, she points out. *(To check the progress nationwide, see the American College of Obstetricians and Gynecologists' LARC web site. It can be accessed at http://bit.ly/1tlMUPw.)*

Texas is set to implement separate Medicaid reimbursement for LARC methods immediately following delivery in January 2016. This step is an important one; 74% of unplanned births in the state are publicly funded, according to the Texas Policy Evaluation Project.

White says, "Our team is in the process of following up on our study of unmet demand for postpartum contraception by conducting another prospective study of postpartum women's contraceptive use in Texas, with a larger sample drawn from six cities in the state. We will be looking at any changes in women's unmet demand and uptake of immediate postpartum LARC with these data."

Check your practice

Are you up to date on postpartum LARC use? Clinicians can check out a 2014 webinar on the subject sponsored by the American College of Obstetricians and Gynecologists. Visit the web site at http://bit.ly/1K9R3ui for the webinar.

Looking for information on postpartum insertion of LARC methods? Check out free online training developed by Cardea, a training, organizational development research group with offices in Austin, TX, Oakland, CA, and Seattle for the Olympia-based Washington State Department of Health. Presented by **Sarah Prager**, MD, MAS, vice chair of the ACOG Committee on Health Care for Underserved Women, the online training offers information and resources on providing intrauterine and subdermal contraception immediately following childbirth. The course addresses indications for immediate postpartum LARC insertion, features videos to demonstrate best practices for postpartum IUD insertion (including how to construct a postpartum uterus model for simulation training), and describes possible complications and appropriate management strategies. It's designed for healthcare providers, counselors, and administrative staff who work in prenatal care or labor and delivery settings. Visit http://bit.ly/16ZoO2i for more information.

Nelson reminds clinicians that postpartum implants provide at least equivalent pregnancy protection with no worries for consent prior to delivery since they can be placed at any time before the woman is discharged home.

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Study: Obese teens less likely to use contraception

A study of nearly 1,000 Michigan teens found that sexually active obese adolescents were significantly less likely to use contraception than normal weight peers.[1]

Among obese adolescents who did use contraception, researchers found that these teens were less likely to use contraception on a consistent basis, notes **Tammy Chang**, MD, MPH, MS, an assistant professor of family medicine at the University of Michigan Medical School and a member of the university's Institute for Healthcare Policy and Innovation, both in Ann Arbor. For example, the data indicate these teens may use condoms, but not 100% of the time, she points out.

"As a family physician who cares for many adolescents, it is

crucial for me to know who might be at increased risk for unintended pregnancy so that I can ensure that every adolescent gets the resources and care they need," states Chang, who served as lead author of the research paper. "These findings are important so I can tailor my care to empower all adolescents, including obese adolescents, to make healthier sexual choices."

Take a closer look

To conduct the study, researchers examined 26,545 weekly journal surveys measuring sexual practices and contraceptive use from a longitudinal study of 900 women ages 18-19 in Michigan. Scientists then analyzed the association between weight and sexual behaviors, with outcomes including proportion of weeks with a partner, proportion of weeks with sexual intercourse, number of partners, average length of relationships, proportion of weeks with contraception use, and proportion of weeks when contraception was used consistently.

The mean proportion of weeks in which adolescents reported sexual intercourse was 52%; there was no difference by weight status, the analysis indicates. Among weeks in which adolescents reported sexual activity, obese adolescents had a lower proportion of weeks in which any contraception was used compared with normal weight adolescents (84% vs. 91%, p = .011). Among weeks in which adolescents reported sexual activity and contraceptive use, obese adolescents had a lower proportion of weeks with consistent contraceptive use (68% vs. 78%, p=.016) and oral contraceptive pill use (27% vs. 45%, p=.001) compared with normal weight adolescents. All other relationships by weight status were not statistically significant, researchers note.[1]

EXECUTIVE SUMMARY

A study of nearly 1,000 Michigan teens found that sexually active obese adolescents were significantly less likely to use contraception than normal weight peers.

- Among obese adolescents who used contraception, researchers found that these teens were less likely to use contraception on a consistent basis.
- In a separate study, findings indicate that for U.S. women, giving birth as a teen is associated with subsequent overweight/obese status later in life.

Teens at risk

Teens, no matter their weight, are at a higher risk for unplanned pregnancy than adults. In the United States, the unplanned pregnancy rate is 82% for adolescents compared to 49% for adults,[2] states **Alison Edelma**n, MD, MPH, assistant professor in the Department of Obstetrics & Gynecology at Oregon Health & Science University School of Medicine in Portland. This rate puts teens at a high unmet need for contraception, she notes.

"Obese teens typically have not manifested the many co-morbidities associated with obesity, and thus their options for birth control are usually unrestricted," states Edelman. "Long-acting methods like the intrauterine device and implant are 20 times more effective than shorter-acting methods in women, [and they] are safe to use in young women."

Women of all ages face weight challenges, and the perception that weight has changed while using contraception is a common reason for women to stop their birth control method, observes Edelman. There is evidence that most methods don't cause a change in weight; the one exception is that a certain sub-group of teens might be more susceptible to weight gain with the contraceptive injection (depot medroxyprogesterone acetate, DMPA, Depo Provera). Teens who demonstrate a 5% increase in body weight during the first six months of DMPA use might be at risk for continuing to gain while using this method,[3] she notes. (Contraceptive Technology Update *reported on the research. See "Predict later weight gain for teens taking DMPA?" June 2011.)*

On the other hand, evidence clearly demonstrates that pregnancy adversely impacts a woman's future weight especially if, after pregnancy, she doesn't re-achieve her pre-pregnancy weight, Edelman observes. In a 2013 published study, Chang and fellow researchers examined whether teen birth is independently associated with overweight and obesity in a multiyear U.S. cohort using the 2001-2010 National Health and Nutrition Examination Survey, a nationally representative cross-sectional survey of the U.S. civilian, noninstitutionalized population. Their research indicated that for women in the United States, giving birth as a teen is associated with subsequent overweight/obese status later in life.[4]

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TEEN TOPICS

Gay, lesbian, and bisexual youth grouped, show increased risk for unintended pregnancy

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The United States has seen significant advances in rights for lesbian and gay populations this summer, with the Supreme Court's decision affirming same-sex marriage nationwide. As we celebrate this victory, however, we remain aware of the many challenges still facing lesbian, gay, and bisexual populations, including health disparities. Many such disparities affect youth, especially in the areas of sexual and reproductive health.

For example, new research reports that lesbian, gay, and bisexual (LGB) youth are nearly twice as likely as their heterosexual peers to experience an unintended pregnancy.[1] This current study has limitations in that it was not able to separate bisexual students from gay or lesbian students.

The study, published in the *American Journal of Public Health*, analyzed data from the 2005, 2007, and 2009 New York City Youth Risk Behavior Surveys and examined sexual orientations as well as sexual behaviors of nearly 10,000 sexually active high school students.[1]

The study found 23% of lesbian or bisexual female students experienced a pregnancy, compared to 13% of heterosexual female students. Looking at behaviors, rather than reported orientation, 20% of female students who reported sexual activity with males and females experienced a pregnancy. Pregnancy was reported by 14% of female students who reported sex only with males.[1]

The study also assessed involvement in pregnancy among male students. Ten percent of males who reported only female partners or who identified as heterosexual had been involved in a pregnancy. Twenty-nine percent of gay or bisexual males and 38% of males reporting sexual activity with males and females had a pregnancy with a past or current partner. Students of all genders who reported exclusively same-sex sexual behaviors were excluded from the data.[1]

Similar findings have been reported before, but only in studies that were limited in sample size and/or only included female participants.[2,3] None of these studies assessed pregnancy risk among gender non-conforming or transgender youth.

There are a variety of factors, behaviorally and socially, that lead LGB youth to be at increased risk for unintended pregnancy. Overall, LGB youth are likely to initiate sexual intercourse at an earlier age than their peers, have more sexual partners, and are less likely to use effective methods of contraception.[4-6] All of these factors contribute to pregnancy risk. These populations also are over-represented among homeless and street-involved youth, which puts them at risk for sexual assault or for survival sex.[5]

Stigma, and negative coping strategies for dealing with stigma, also contribute to increased risk-taking behaviors for LGB youth. Harassment, discrimination, and sexual or physical violence at home, school, or in the community might all be present in the lives of LGB youth and are sometimes referred to as "enacted stigma."[7] Some youth might deal with enacted stigma through "camouflage" behaviors or having sex and/or relationships with partners of the opposite gender to hide same-sex sexual behaviors or attraction. Others might use or abuse alcohol or drugs. Both of these behaviors put LGB youth at further risk of poor health outcomes, including unintended pregnancy.[7]

Additionally, sexuality education programs, especially those based in "abstinence only" models, often

ignore and sometimes denigrate LGB youth instead of educating them on how to protect themselves against pregnancy and sexually transmitted infections.[8]

Even so, many LGB youth lead healthy, productive lives and develop resilient adaptations to social biases and stigma. Effects of discrimination also can be mitigated by social support and family acceptance.[9]

Healthcare providers have a unique opportunity to educate LGB youth, and all adolescent patients, about contraception and other safer sex practices to protect themselves and their partners. Offering information about emergency contraception (EC) might be especially helpful if youth are not anticipating sex with partners that might result in pregnancy.

Some forms of EC are available over the counter and can be purchased by males or females, regardless of age. Female adolescents also can receive an advanced prescription for ella, a form of EC shown to be consistently effective in preventing pregnancy for five days after unprotected sex. Condoms remain the only method for protection against sexually transmitted infections and should be offered to all adolescents of all sexual identities.

Data showing that LGB youth are at increased risk of pregnancy re-affirm the need to take a detailed sexual history of all adolescents and offer them information and services based on their individual risk behaviors, rather than their sexual orientation. Opening up discussions about sexual behaviors also creates the opportunity to discuss relationships and healthy decision-making strategies more broadly.

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Liletta IUD available in the United States

The LILETTA intrauterine device (IUD) is for sale in the United States. The device was launched through partners Medicines360, a San Francisco-based nonprofit pharmaceutical company, and Actavis, a Dublin, Ireland-based pharmaceutical company.

The device, similar in size to Mirena (Bayer Healthcare Pharmaceuticals, Wayne, NJ), was approved by the Food and Drug Administration in February. LILETTA is a flexible, plastic T-shaped system, measuring 32 mm by 32 mm. It releases the progestin levonorgestrel at an initial release rate of 18.6 mcg per day with an average in vivo release rate of about 15.6 mcg per day over three years. The device is labeled for three years of effective use.

The information site (http://bit.ly/1S8SJeM) offers a video on insertion and removal. ■

COMING IN FUTURE MONTHS

- Few states require HPV vaccine
- How has ACA impacted contraceptive costs?
- STIs & UTIs often misdiagnosed in EDs
- Unintended pregnancy: One state's approach

CONTRACEPTIVE TECHNOLOGY UPDATE®

CNE/CME INSTRUCTIONS

To earn credit for this activity, please follow these instructions:

1. Read and study the activity, using the provided references for further research.

2. Scan the QR code to the right or log on to the AHCMedia.com site to take a post-test. Go to "My Account" to view your available CE activities. Tests are taken after each issue. First-time users will have to register on the site using the subscriber number on their mailing label, invoice, or renewal notice.

3. Pass the online tests with a score of 100%; you will be allowed to answer the questions as many times as needed to achieve a score of 100%.

4. After successfully completing the test, your browser will be automatically directed to the activity evaluation form, which you will submit online.

5. Once the completed evaluation is received, a credit letter will be e-mailed to you instantly.

CNE/CME QUESTIONS

1. What is the name of the single-size diaphragm released in the United States in 2015?

A. Caya
B. Reality
C. FemCap
D. Today

2. What is the injectable drug that was studied in a 2015 paper for its potential in decreasing intrauterine device insertion pain?

A. DepoDur
B. Ketorolac
C. Methylprednisolone
D. Butorphanol

3. According to 2015 guidance, first-line treatment for gonorrhea is 250 mg of ceftriaxone delivered intramuscularly plus

A. 1 g of oral tetracycline
B. 1 g of oral streptomycin
C. 1 g of oral azithromycin
D. 1 g of oral doxycycline

4. According to 2015 guidance, routine screening for extragenital gonorrhea and chlamydia should be performed in which populations?

A. Adolescent females and men who have sex with men
B. Women ages 16-24 and people with HIV infection
C. Adolescent females and people with HIV infection
D. Men who have sex with men and people with HIV infection

CNE/CME OBJECTIVES

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

1. identify clinical, legal, or scientific issues related to development and provisions of contraceptive technology or other reproductive services;
2. describe how those issues affect services and patient care;
3. integrate practical solutions to problems and information into daily practices, according to advice from nationally recognized family planning experts;
4. provide practical information that is evidence-based to help clinicians deliver contraceptives sensitively and effectively.

STI QUARTERLY™

A SUPPLEMENT TO CONTRACEPTIVE TECHNOLOGY UPDATE

Time to update your clinical practice: *2015 STD Treatment Guidelines* available

App, wall chart, and webinar developed to aid clinicians

The Centers for Disease Control and Prevention (CDC) has released the *2015 STD Treatment Guidelines*.[1] This update was written after a 2013 consultation with experts knowledgeable in the field of sexually transmitted diseases (STDs). The peer review document was released in 2014 to obtain input on the final draft. (Contraceptive Technology Update *reported on the draft guidance. See "New STD guidance on the way: Be prepared," January 2015.)*

"These recommendations should be regarded as a source of clinical guidance rather than prescriptive standards; health-care providers should always consider the clinical circumstances of each person in the context of local disease prevalence," the guidance states.

> "THESE RECOMMENDATIONS SHOULD BE REGARDED AS A SOURCE OF CLINICAL GUIDANCE RATHER THAN PRESCRIPTIVE STANDARDS..."

The testing, treatment, and the prevention of STDs is constantly evolving, and the CDC's ongoing investment in this intensive effort through development of these guidelines is commendable, said **William Smith**, executive director of the National Coalition of STD Directors (NCSD) in a statement. The document represents a comprehensive and authoritative source for promoting sexual health through STD prevention and treatment, he notes. The NCSD encourages clinicians to educate themselves on the new guidelines to ensure they are providing the best sexual healthcare to all patients, states Smith.

Clinicians with iPhones can download the free 2015 STD Treatment (Tx) Guide app, an easy-to-use reference that combines information from the guidelines, as well as updates. The app features a streamlined interface so providers can easily access treatment and diagnostic information. An Android app is being developed and will be available soon. *(Check the guidance web page at http://1.usa.gov/1BBIUi6 for updates. Also use the link to order limited numbers of wall charts and pocket guides, as well as to print out free copies for use. Clinicians also can earn free continuing education by watching a webinar on the guidance. A link to the webinar is available on the web page under the "Highlights" heading.)*

What are the key changes?

The new guidance updates previous information released in 2010. What are some of the most important changes in the new document?

Pre-exposure prophylaxis (PrEP) for the prevention of HIV is now included in the "Clinical Prevention Guidance" section, which lists methods for the prevention and control of STDs. The full CDC PrEP guidelines also include recommendations for frequent testing for other STDs for those on PrEP. The agency issued clinical guidance for use of PrEP in 2014 following data publication that shows when taken daily as directed, PrEP can reduce the risk of HIV infection by more than 90%.[2-4]

Make note that frontline treatment recommendations for gonorrhea are included in this update. The CDC recommends treating gonorrhea with 250 mg of

Financial Disclosure: Consulting Editor Robert A. Hatcher, MD, MPH, Nurse Reviewer Melanie Deal, Author Rebecca Bowers, and Executive Editor Joy Dickinson report no consultant, stockholder, speaker's bureau, research, or other financial relationships with companies having ties to this field of study.

EXECUTIVE SUMMARY

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- The app features a streamlined interface so providers can easily access treatment and diagnostic information. An Android app is being developed and will be available soon.

ceftriaxone delivered intramuscularly plus 1 g of oral azithromycin. Treatment with ceftriaxone plus doxycycline has now been moved to an alternative treatment recommendation for use in case of azithromycin allergy.

Reasons for the change

Why was this change made? It allows for the convenience of a single-dose therapy, as well as offers a response to the increased gonococcal resistance to the class of drug that includes doxycycline.

Oral cefixime still is recommended as an alternative treatment for gonorrhea if ceftriaxone isn't available. Oral cefixime also is indicated for expedited partner therapy (EPT) for heterosexual men and women with gonorrhea. EPT with cefixime 400 mg and azithromycin 1 g can be delivered to the partner by the patient, a disease investigation specialist, or a collaborating pharmacy as permitted by law. The guidance explicitly recommends the delivery of EPT by providing patients with appropriately packaged medication as the preferred approach, as compared to providing prescriptions, as data on the efficacy of EPT using prescriptions is very limited, and many persons don't fill prescriptions given to them by their partners.

EPT shouldn't be considered a routine partner management strategy in men who have sex with men (MSM) who are infected with gonorrhea, because there is a high risk for coexisting infections, especially HIV infection, and there are no data on treatment efficacy in this population, the CDC states.[1]

How about screening?

What do clinicians need to understand about screening for gonorrhea and chlamydia, based on the new guidance?

The CDC has harmonized with the U.S. Preventive Services Task Force's recommendation that sexually active women younger than 25 get screened annually for chlamydia and gonorrhea, states **Kimberly Workowski**, MD, FACP, FIDSA, professor of medicine in the Division of Infectious Diseases at Atlanta-based Emory University. *(To read about the Task Force guidance, see "Nearly 5% of young U.S. women have chlamydia," in the* STI Quarterly *supplement in the December 2014 issue of* Contraceptive Technology Update.) Additionally, the guidelines recommend annual chlamydia and gonorrhea screening for older women with risk factors, such as new or multiple sex partners, or a sex partner who has a sexually transmitted disease, says Workowski, who served as lead author of the guidance.

Check MSM information

The new guidance recommends the following tests on at least an annual basis in sexually active MSM, including those with HIV:

- HIV serology, if HIV status is unknown or negative and the patient himself or his sex partner(s) has had more than one sex partner since the most recent HIV test;
- syphilis serology to establish whether persons with reactive tests have untreated syphilis, have partially treated syphilis, are manifesting a slow serologic response to appropriate prior therapy, or are serofast;
- a test for urethral infection with *Neisseria gonorrhoeae* and *Chlamydia trachomatis* in men who have had insertive intercourse during the preceding year. Urine testing using nucleic acid amplification testing (NAAT) is the preferred approach, the CDC recommends;
- a test for rectal infection with *N. gonorrhoeae* and *C. trachomatis* in men who have had receptive anal intercourse during the preceding year; a rectal specimen NAAT is preferred;
- a test for pharyngeal infection with *N. gonorrhoeae* in men who have had receptive oral intercourse during the preceding year, using a pharyngeal specimen for NAAT screening. Testing for *C. trachomatis* pharyngeal infection is not recommended;

The new guidance also highlights that sexual transmission of hepatitis C virus (HCV) can occur, especially among MSM with HIV infection. As a result, serologic screening for HCV is recommended at initial evaluation of persons with newly diagnosed HIV infection. Due to accumulating evidence of acute HCV infection acquisition among persons with HIV infection, especially MSM with

HIV infection, the CDC states that MSM with HIV infection should be regularly screened for HCV.

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Data suggest genital screening misses many STI cases in women

Data from a recent study that looked at more than 10,000 people who attended a Baltimore public health clinic indicate the occurrence of gonorrhea or chlamydia in extragenital areas such as the throat or rectum is significant in women, particularly younger women.[1]

Researchers from Johns Hopkins University School of Medicine in Baltimore looked at health records from 10,389 people (4,402 women, 5,218 heterosexual men, and 769 men who have sex with men [MSM]) who visited the Baltimore City Health Department Eastern Health District or the Druid STD Clinic between June 2011 and May 2013. All of the people included in the study had reported recent exposure to oral and/or anal sexual intercourse.

Current public health guidelines call for routine screening for extragenital gonorrhea and chlamydia in MSM and people with HIV, given the high burden of these sexually transmitted infections (STIs) in these at-risk populations. However, there are no current recommendations to routinely screen women at extragenital sites.

When infections from gonorrhea and chlamydia occur in extragenital areas, they are typically asymptomatic, said **Joshua Trebach**, a third-year student at the Johns Hopkins University School of Medicine in a press statement accompanying the research publication. "These types of infections pose a large and hidden public health threat, because they can be transmitted to unwitting sexual partners and form an active infection," he noted.

Screening cost-effective?

If the women examined in the Johns Hopkins University study had received only genital STI tests, nearly 14% of chlamydia infections and more than 30% of gonorrhea infections would have been missed. Researchers found the total prevalence of extragenital gonorrhea or chlamydia among the more than 4,000 women screened was 2.4% and 3.7%, respectively. By comparison, the extragenital rates for MSM were 18.9% for gonorrhea and 11.8% for chlamydia.

While the prevalence of extragenital gonorrhea and chlamydia is highest in MSM, a significant number of gonorrhea and chlamydia infections in young women would be missed with genital-only testing, researchers note. Cost-effectiveness analyses are needed to help inform national guidelines on extragenital screening in young women, they state.

To understand the cost effectiveness of screening women for extragenital infections, first there needs to be an understanding of how such infections impact reproductive health in women, says one of the

EXECUTIVE SUMMARY

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- Current public health guidelines call for routine screening for extragenital gonorrhea and chlamydia in men who have sex with men and people with HIV, given the high burden of these sexually transmitted infections in these at-risk populations.
- However, there are no current recommendations to routinely screen women at extragenital sites.

research paper co-authors, **Khalil Ghanem,** MD, PhD, associate professor of medicine at the University. By not detecting and treating these infections, what is the impact on the likelihood of transmission to male partners and the probability that these male partners will transmit the infection to their female partners in the genital tract, leading to poor reproductive outcomes?

"This seems like it would be a rare occurrence, but on a population level, it might not be so rare," notes Ghanem.

3 questions

The issue goes to the questions of the role of extragenital infections in driving the prevalence of *Neisseria gonorrhoeae* and *Chlamydia trachomatis* in a population, how these infections impact HIV transmission/acquisition in women and their sexual partners, and how these infections contribute to the emergence of resistance, says Ghanem. These questions are particularly important for gonorrhea, as it is believed that pharyngeal infections are the source of many, if not most, resistant mutations.[2]

"None of these questions have easy answers," observes Ghanem. "Ideally, the next step is to try and develop models to help gauge the potential impact of extragenital infections on reproductive outcomes, HIV acquisition/transmission, and emergence of resistance."

Such action might be easier said than done because researchers will have to input variables in a model." Because many of these variables are not known, and cannot be easily extrapolated from a clinical setting, such research presents "a very big challenge," notes Ghanem.

> "THESE TYPES OF INFECTIONS POSE A LARGE AND HIDDEN PUBLIC HEALTH THREAT, BECAUSE THEY CAN BE TRANSMITTED TO UNWITTING SEXUAL PARTNERS AND FORM AN ACTIVE INFECTION."

Screening is important

In MSM, most of the screening benefit comes from HIV acquisition/transmission reduction that comes with extragenital screening, Ghanem comments. This reduction is why extragenital screening is recommended in this population, he notes.

Gonorrhea and chlamydia are much more prevalent in the MSM population than in the heterosexual population. Data from a review of 42 U.S. clinics show extragenital gonorrhea and chlamydia was common among MSM attending STI clinics.[3] As such, the impact is much greater and can be quantified, says Ghanem.

"Most of the impact in women would have to come from how these infections impact reproductive health," Ghanem states. "That's a big unknown."

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Get CDC fact sheet on shigellosis

The Centers for Disease Control and Prevention have a patient information sheet on shigellosis. Shigellosis is a common diarrheal disease caused by a group of bacteria called *Shigella*. Symptoms of shigellosis typically start 1–2 days after exposure and include diarrhea (sometimes bloody), fever, abdominal pain, and tenesmus, a painful sensation of needing to pass stools when bowels are empty.

Men who have sex with men (MSM) are more likely to acquire shigellosis than the general adult population and more likely than others to get infected with *Shigella* that is resistant to antibiotics commonly used to treat adults who have shigellosis. MSM may require injectable antibiotics rather than antibiotics that can be taken by mouth. Access the free handout at http://1.usa.gov/1LSZtIz. ■

Contraceptive Technology Update

Confidential Salary Survey

This confidential salary survey is being conducted to gather information for a special report. Watch in coming months for your issue detailing the results of this survey and the overall state of employment in your field.

Instructions: Select your answers by filling in the appropriate bubbles **completely.** Please answer each question as accurately as possible. If you are unsure of how to answer any question, use your best judgment. Your responses will be strictly confidential. Do not put your name or any other identifying information on this survey form.

1. What is your current title?

- O A. Administrator
- O B. Nurse practitioner
- O C. Registered nurse
- O D. Health educator
- O E. MD
- O F. Nurse midwife
- O G. Physician assistant

2. What is your highest degree?

- O A. Some college
- O B. Associate or 2-year
- O C. Bachelor's degree
- O D. Some graduate work
- O E. Graduate degree
- O F. Doctorate

3. What is your sex?

- O A. male
- O B. female

4. What is your age?

- O A. 20-25
- O B. 26-30
- O C. 31-35
- O D. 36-40
- O E. 41-45
- O F. 46-50
- O G. 51-55
- O H. 56-60
- O I. 61-65
- O J. 66+

5. What is your annual gross income from your primary healthcare position?

- O A. Less than $30,000
- O B. $30,000 to $39,999
- O C. $40,000 to $49,999
- O D. $50,000 to $59,999
- O E. $60,000 to $69,999
- O F. $70,000 to $79,999
- O G. $80,000 to $89,999
- O H. $90,000 to $99,999
- O I. $100,000 to $129,999
- O J. $130,000 or more

6. Where is your facility located?

- O A. urban area
- O B. suburban area
- O C. medium-sized city
- O D. rural area

7. In the last year, how has your salary changed?

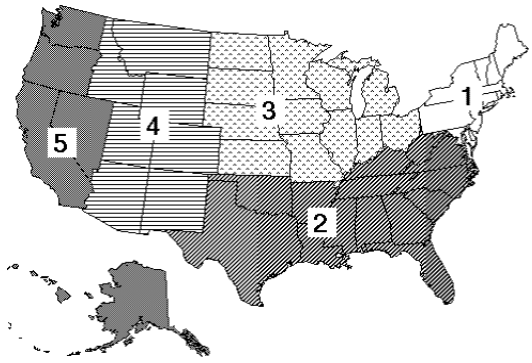
- O A. salary decreased
- O B. no change
- O C. 1% to 3% increase
- O D. 4% to 6% increase
- O E. 7% to 10% increase
- O F. 11% to 15% increase
- O G. 16% to 20% increase
- O H. 21% increase or more

8. What is the work environment of your employer?

- O A. academic
- O B. agency
- O C. health department
- O D. clinic
- O E. college health service
- O F. consulting
- O G. hospital
- O H. private practice

9. Please indicate where your employer is located.

- O A. region 1
- O B. region 2
- O C. region 3
- O D. region 4
- O E. region 5
- O F. Canada
- O G. other



10. Which best describes the ownership or control of your employer?

- O A. college or university
- O B. federal government
- O C. state, county, or city government
- O D. nonprofit
- O E. for profit

11. How long have you worked in your present field?

- O A. less than 1 year
- O B. 1-3 years
- O C. 4-6 years
- O D. 7-9 years
- O E. 10-12 years
- O F. 13-15 years
- O G. 16-18 years
- O H. 19-21 years
- O I. 22-24 years
- O J. 25+ years

12. How long have you worked in healthcare?

- O A. less than 1 year
- O B. 1-3 years
- O C. 4-6 years
- O D. 7-9 years
- O E. 10-12 years
- O F. 13-15 years
- O G. 16-18 years
- O H. 19-21 years
- O I. 22-24 years
- O J. 25+ years

13. How many people do you supervise?

- O A. 1-3
- O B. 4-6
- O C. 7-10
- O D. 11-15
- O E. 16-20
- O F. 21-40
- O G. 41-60
- O H. 61-80
- O I. 81-100
- O J. 101 or more

14. How many hours a week do you work?

- O A. less than 20
- O B. 20-30
- O C. 31-40
- O D. 41-45
- O E. 46-50
- O F. 51-55
- O G. 56-60
- O H. 61-65
- O I. 65+

15. In the past 12 months, how has the number of employees in your company or department changed?

- O A. increased
- O B. decreased
- O C. no change

Deadline for Responses: Nov. 2, 2015

Thank you very much for your time. The results of the survey will be reported in an upcoming issue of the newsletter, along with an analysis of the economic state of your field. Please return this form in the enclosed, postage-paid envelope as soon as possible. If the envelope is not available, mail the form to: Salary Survey, AHC Media LLC, P.O. Box 550669, Atlanta, GA 30355.