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Reproductive-age women with cancer need to have effective options

Consider intrauterine contraception for safe, effective use

Your next patient is 32 years old, married, and recently received a diagnosis of breast cancer. What is your counseling strategy regarding contraception?

A sizable number of reproductive-age women are diagnosed with cancer. It's estimated that 859 out of 100,000 such women receive a cancer diagnosis each year in the United States.¹ With advancements in cancer therapies, women have better chances for survival. Up to 80% of all women diagnosed with cancer prior to age 50 survive at least five years.²

Contraception is a crucial aspect of reproductive care for women with cancer, says **Bat-Sheva Maslow**, MD, fellow in the Division of Reproductive Endocrinology and Infertility in the Department of Obstetrics and Gynecology at the University of Connecticut Health Center in Farmington and lead author of a just-published study of contraceptive choices in women with cancer.² More research is needed regarding contraceptive choices for these women, Maslow states.

To perform the current study, researchers conducted a cross-sectional survey of women ages 18-45 who had been diagnosed with cancer in the prior five years in the University of Pennsylvania healthcare system.² Women contacted for the survey included survivors cared for by a breast

EXECUTIVE SUMMARY

It's estimated that 859 out of 100,000 women of reproductive age receive a cancer diagnosis each year in the United States. Up to 80% of all women diagnosed with cancer prior to age 50 survive at least five years.

- Reproductive-aged women with cancer might be interested in deferring pregnancy temporarily or permanently at cancer diagnosis, during therapy, or after treatment.
- However, there are limited guidelines to aid clinicians in managing the contraceptive needs in this special population.

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cancer specialist, a general oncologist, and a fertility preservation specialist. All women were potentially at risk for pregnancy during or after cancer therapy.

Among the 163 eligible women who were contacted, 139 (85%) agreed to participate and 107 completed the survey. Most participants were older than age 25, Caucasian, nulliparous, and college-

educated. Breast cancer was the most common diagnosis (52%), followed by lymphoma (22%). Almost half (48%) reported experiencing amenorrhea during their cancer treatment.

Almost half (43%) of women reported engaging in heterosexual sexual intercourse. In terms of contraception:

- 25% of women reported current abstinence;
- 14% said they used no contraception;
- 22% reported use of oral/vaginal ring contraceptives;
- 21% choose condoms;
- 4% relied on an intrauterine device (IUD);
- One woman reported a partner's vasectomy.

No women reported use of injectable or implantable contraception, or prior tubal sterilization.

Seventy participants (65%) reported receiving contraceptive counseling from a healthcare professional prior to initiating cancer therapy. Women who received contraceptive counseling were over six times as likely to use such methods as surgical sterilization, long-acting reversible contraceptives, hormonal contraceptives, and diaphragm compared to women who did not report counseling (odds ratio 6.92, 95% confidence interval 1.14-42.11, $p = .036$). Among sexually active women, one-third of those who received counseling reported a Tier I/II contraceptive method compared to 10% of those who were not counseled ($p = .05$).

What are the options?

Reproductive-aged women with cancer might be interested in deferring pregnancy temporarily or permanently at cancer diagnosis, during therapy, or after treatment; however, there are limited guidelines to aid clinicians in managing the contraceptive needs in this special population.

Women of reproductive age who are undergoing cancer treatment generally are advised to avoid pregnancy due to concerns of the teratogenic effects of chemotherapy or radiation. Breast cancer survivors are counseled to avoid pregnancy for three years following cancer treatment due to concerns that pregnancy-related hormonal changes might increase the risk of recurrence.³ Clinicians need to remember that while chemotherapy and radiation reduce fertility and might cause ovarian failure, many cancer survivors remain fertile.⁴⁻⁶

After reviewing available evidence on the safety and efficacy of available contraceptive methods for women who have been diagnosed with cancer, the Philadelphia-based Society of Family Planning

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Editor: **Rebecca Bowers.**

Executive Editor: **Joy Daughtery Dickinson** (404) 262-5410
(joy.dickinson@ahcmedia.com).

Director of Continuing Education and Editorial: **Lee Landenberger.**

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Editorial Questions

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in 2012 issued clinical guidance that recommends women of childbearing age who are being treated for cancer avoid combined hormonal contraceptive methods whenever possible because they might further increase the risk of venous thromboembolism (VTE).⁷ (Readers can download a copy of the guideline at <http://bit.ly/1w25vvc>.)

First-line contraceptive option

The copper T380A intrauterine device, a highly effective, reversible, long-acting, hormone-free method, should be considered the first-line contraceptive option for women with a history of breast cancer, although for women being treated with tamoxifen, the levonorgestrel-containing intrauterine system, which decreases endometrial proliferation, might be preferable, the guidance states.⁷ Women with IUDs can undergo all forms of imaging, including computed tomography and magnetic resonance imaging.⁸

There are limited data on IUD use by women with immunosuppression due to cancer treatment. However, the World Health Organization and the Centers for Disease Control and Prevention state that IUDs can be used safely by women such as these.⁹

Women who develop anemia might benefit from use of a progestin-containing contraceptive; however, women who develop osteopenia or osteoporosis following chemotherapy should avoid the progestin-only contraceptive injection.⁷ For women who have been cancer-free for at least six months and have no history of hormonally mediated cancers, chest wall irradiation, anemia, osteoporosis or VTE, the use of any method of contraception can be recommended, the guidance states.⁷

Overestimating infertility

Contraceptive choices can be challenging for women with cancer, 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. However, contraception is important.

Keep in mind that female patients have been shown to overestimate their chance of becoming infertile from treatment, which might encourage risky sexual behavior.¹⁰ The usual signs of fertility might not be reliable in women who have undergone cancer treatments. Pregnancy has been reported in

cancer survivors despite amenorrhea and follicle-stimulating hormone levels that are suggestive of menopause.¹¹

By referring appropriate reproductive age female cancer survivors to clinicians who are up to date with and able to provide a broad range of contraceptives, oncologists can help optimize care and outcomes for this unique group of women, says Kaunitz.

Lines of communication are important among all members of a woman's healthcare team when it comes to cancer, say researchers of the current paper.

“Increasing awareness among oncologists to the critical role of contraceptive counseling, as well as establishing better referral networks between oncologist and family planning specialists, would go a long way toward providing comprehensive care to women with cancer,” they state.

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What's next after ruling on contraceptive services?

Reproductive health advocates are moving quickly following the June 30 Supreme Court ruling that closely held corporations that assert a religious objection do not have to cover contraceptive services and methods in their employer-sponsored health plans as required under the Affordable Care Act.

The 5-4 ruling, written by Justice Samuel Alito, was in response to two challenges to the act's contraceptive coverage guarantee: *Sebelius v. Hobby Lobby Stores*, in which the 10th Circuit Court of Appeals sided with an Oklahoma-based craft supply chain store, and *Conestoga Wood Specialties v. Sebelius*, in which the Third Circuit ruled against a Pennsylvania-based furniture manufacturer. (Contraceptive Technology Update reported on the challenges in its Washington Watch column. See "Contraception coverage heads to Supreme Court," March 2014, p. 34.)

The Supreme Court decision holds that the Department of Health and Human Services' requirement that employers cover all forms of contraception approved by the Food and Drug Administration violates the Religious Freedom Restoration Act of 1993. In Justice Alito's majority opinion, the requirement violates "the sincerely held religious beliefs of the companies' owners." In a dissent written by Justice Ruth Bader Ginsburg notes, "the cost of an IUD (intrauterine device) is nearly equivalent to a month's full-time pay for workers earning the minimum wage." While owners of Hobby Lobby "and all who share their beliefs may decline to acquire for themselves the contraceptives in question," that choice should not be imposed on employees who hold other beliefs, Ginsburg writes.

"Working for Hobby Lobby or Conestoga, in other words, should not deprive employees of the preventive care available to workers at the shop next door," Ginsburg notes. (Read the Supreme Court ruling at <http://1.usa.gov/V2vRBZ>.)

Advocates speak out

Women's health advocates immediately called for action to protect contraceptive coverage following the court ruling, issuing statements on the subject.

"On behalf of the 12,000 healthcare professionals represented by ARHP [Association of Reproductive Health Professionals], I am outraged by today's mis-

guided ruling that treats companies like individual citizens and grants them the right to interfere in employee clinical decisions," said Wayne Shields, ARHP president and CEO. "ARHP's position is that everyone should have access their contraceptive method of choice, based on informed decision-making, the latest science, and respect for individual autonomy."

According to Nancy Northup, president and CEO of the New York City-based Center for Reproductive Rights, the court's ruling gives employers "the power to dictate how their employees can and cannot use their health insurance, allowing them to intrude into their employees' private decisions based on whatever personal beliefs their employers happen to hold."

"Especially disturbing is the majority's acceptance of the business owners' objection to certain common forms of contraception based on the patently false characterization that they are tantamount to abortion," said Northup. "This decision gives employers license to withhold insurance benefits for safe, effective contraceptive methods, such as IUDs, based on unscientific beliefs."

Planned Parenthood Action Fund moved quickly to launch a text helpline for people who are being denied coverage or have questions about their access to birth control in light of the court ruling. By texting "birth control" to 69866 to report a denial of coverage or to obtain help accessing birth control, people will get an immediate response and receive follow-up by email or phone.

"No woman should lose access to birth control because her boss doesn't approve of it," said Cecile Richards, president of the action fund. "We're hear-

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ing from women across the country who are concerned and confused about what these court rulings mean for them, so we're launching a text helpline to get people information and assistance quickly."

Stay tuned for Congress

More legal action is on the way. The two cases heard before the Supreme Court are part of more than 40 similar lawsuits that have been filed by for-profit, private companies in courts across the country.

However, Congressional action to reverse the Court's decision was denied in July. A bill drafted by Sen. Patty Murray (D-WA) and Sen. Mark Udall (D-CO) failed to obtain the necessary 60 votes to cross a procedural hurdle, while a move by Democrats to force the issue in the House was similarly shut down.¹

"I urge Congress to counteract the court's damaging decision today and to increase Title X funding while they are at it," said **Clare Coleman**, president and chief executive officer of National Family Planning & Reproductive Health Association. "That's the best way to support millions of families that need access to no-cost or low-cost contraceptive services to make responsible decisions for their own health and well-being."

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Mirena obtains approval on new insertion device

Bayer HealthCare Pharmaceuticals recently received Food and Drug Administration approval for a new inserter for its Mirena intrauterine system (IUS). The new inserter uses the same insertion steps as its sister intrauterine contraceptive, Skyla, and the two share a uniform insertion technique.

The new inserter features a thin, flexible insertion tube. The inserter is preloaded with a small, rounded, flexible T-body and enables single-handed loading. The diameter of the insertion tube is 3.8 mm for Skyla and 4.4 mm for Mirena.

According to package labeling, Mirena is indicated for intrauterine contraception for up to five

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- The new inserter features a thin, flexible insertion tube. The inserter is preloaded with a small, rounded, flexible T-body and enables single-handed loading. Centimeter markings are now on both sides of the insertion tube.
- At press time, the new inserter was scheduled for shipment in late summer of 2014.

years. Mirena also is indicated to treat heavy menstrual bleeding in women who choose to use intrauterine contraception as their birth control method. Mirena is recommended for women who have had a child. The device should be replaced after five years if continued use is desired.

Skyla's package labeling indicates it might be used for the prevention of pregnancy for up to three years. The device should be replaced after three years if continued use is desired, package labeling states.

At press time, the Bayer inserter for Mirena was scheduled to be available later in the summer of 2014, says **Tara DiFlumeri**, a Bayer spokesperson. "There will be a transition period when we will ship product with the original inserter and the Bayer inserter," says DiFlumeri. "We will work to minimize this transition period so that the Bayer inserter for Mirena will be shipping exclusively as soon as possible."

What is different about the new inserter? Some highlights are: The threads are contained within the handle, which makes it non-reloadable. The T-body of the levonorgestrel IUS is pre-loaded and secured in position on the insertion tube. Centimeter markings are now on both sides of the insertion tube. The insertion tube outer diameter is now thinner, measuring 4.4 mm. (*Download a copy of the new prescribing information at <http://bit.ly/1znsRjr>.*)

The insertion device for the smaller Skyla IUS does not have external strings. It is easier, as well as quicker, to load, than the older insertion device used with the Mirena IUS, observes **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. "My sense is that updating the Mirena insertion device will facilitate placement of this IUS," states Kaunitz.

“In addition, having the same insertion mechanism for both the Skyla and the Mirena will minimize confusion and missteps for clinicians like myself, who place both devices.”

Having one inserter device for Mirena and Skyla is a step forward for reducing confusion about placing these two devices, agrees **Susan Wysocki**, WHNP-BC, FAANP, president and chief executive officer of iWomansHealth in Washington, DC, which focuses on information on women’s health issues for clinicians and consumers. The fact that the inserter device for Mirena also is thinner than the previous inserter device is an additional plus, she states.

The copper-T 380A intrauterine device has a very different placement technique than the technique for Mirena or Skyla, observes Wysocki. “If there is any one take-home on placing intrauterine contraceptives, it is to read and follow the package insert to make sure that the placement technique is correct,” states Wysocki. “Contact representatives from the companies that sell IUSs for training if you have any questions.”

As with any intrauterine contraceptive method, Mirena should be inserted by a trained healthcare provider. Healthcare providers should become thoroughly familiar with the updated insertion instructions before attempting insertion with the Bayer inserter for Mirena, says DiFlumeri. Clinicians are encouraged to take advantage of the many resources and interactive education opportunities that became available for Mirena and Skyla as of July 2014, she notes.

These resources include Bayer inserter speaker programs, which provide an overview of the Bayer inserter and hands-on insertion education so clinicians can train on Mirena and Skyla in the same session. Resources also include one-on-one insertion consultations using pelvic models and “lunch & learn” sessions that are scheduled in clinicians’ offices. Also, interactive insertion and removal resources and an animated insertion video are scheduled to be available on the Mirena website at www.MirenaLearningCenter.com.

How is the company getting the word out to providers about the new inserter? According to DiFlumeri, sales consultants will provide customers with the updated prescribing information, which reflects the updated insertion procedure. The insertion steps for the original Mirena inserter will continue to be available on the Mirena website until at least six months after the initial shipment of the Bayer inserter for Mirena, says DiFlumeri.

With the July 2014 kickoff for the insertion education phase, the company will provide an updated inserter guide, which will give an overview of the characteristics of the original inserter and the Bayer inserter for Mirena, while highlighting the features of the new inserter. Combined IUS (Skyla and Mirena) healthcare provider educational kits will be available for insertion education. The websites, www.mirena-us.com/hcp and www.MirenaLearningCenter.com, will be updated with the updated inserter information, says DiFlumeri. ■

Teen condom use drops — What can providers do?

Results from the 2013 National Youth Risk Behavior Survey indicate that among high school students who are sexually active, condom use has declined from 63% in 2003 to 59% in 2013. This decline follows a period of increased condom use throughout the 1990s and early 2000s.¹

The Centers for Disease Control and Prevention (CDC) conducts the national survey among a national sample of approximately 13,000 U.S. high school students. In addition, the current report includes results from 42 states and 21 large urban school districts that conducted their own surveys.

The 2013 analysis indicates fewer teens are engaging in many behaviors that place their health at risk, says **Stephanie Zaza**, MD, director of the CDC’s Division of Adolescent and School Health. These positive steps include reducing cigarette smoking and dropping rates of physical fights. However, the results also indicate that some behaviors that can protect their health, such as using condoms, also are decreasing, notes Zaza.

“While this is still significantly higher than condom use was [which was 46%] in 1991 when the survey first began, we must address these behaviors that increase the risk of HIV and other sexually transmitted diseases, before they become lifelong habits that put young people’s health and safety at risk,” says Zaza.

Other public health officials and youth advocates also voiced concern about the drop in condom use among American adolescents. In a statement accompanying the release of survey data, **William Smith**, executive director of the National Coalition of STD Directors, said, “This data is deeply troubling, especially given that we already know young people bear a disproportionate burden of sexually transmitted

diseases [STDs], including HIV. We must be clear: Condoms are the best way to protect against STDs, including HIV, for those who are sexually active, and if youth continue to report a decrease in condom use, efforts to improve sexual health outcomes among this group will not be possible.”

Robert Hatcher, MD, MPH, professor emeritus of gynecology and obstetrics at Emory University School of Medicine in Atlanta, points out two reasons why couples are most likely to not use condoms when condom use would be beneficial: “First, when they think they are not at risk; this would be risk for either pregnancy, infection or both,” Hatcher observes. “Second, they don’t have a condom when they need it.”

These two issues should be dealt with in every program seeking to increase condom use, and they must be explained to every individual or couple for whom condom use would be important, states Hatcher.

Condom use was 59% in 2013

Between 1991 and 2003, condom use increased from 46.2% to 63%. It stands at 59% in 2013. According to the group Advocates for Youth, young people need greater exposure to positive portrayals of condom use to remove the stigma, discomfort, and embarrassment associated with condoms and condom negotiation. Such messages need to be voiced in schools, in communities, and in the media, said **Debra Hauser**, MPH, Advocates for Youth president in a statement accompanying the publication of survey results.

“There are a few exceptions, but when was the last time we saw characters discuss condoms on TV?” observed Hauser. “Young people need continuous reinforcement that condoms are one of the most effective ways to stay safe and healthy.”

Zaza says the CDC is committed to working with partners across the nation to protect young people from HIV, STDs, and unintended pregnancy, but such efforts must be done together.

“Everyone has a role to play — public health officials, healthcare providers, schools, and parents — in ensuring the safety, health, and well-being of youth across the United States,” states Zaza. “A number of resources for healthcare providers serving adolescent patients that include information on how to talk to teens about condom use are available from CDC’s Division of Reproductive Health.” (*To access the CDC resources, visit <http://1.usa.gov/1mHi8bC>.*)

According to *Contraceptive Technology*, condom

EXECUTIVE SUMMARY

Results from the 2013 National Youth Risk Behavior Survey indicate that among high school students who are sexually active, condom use has declined from 63% in 2003 to 59% in 2013. This decline follows a period of increased condom use throughout the 1990s and early 2000s.

- When providing instruction on how to use condoms, have patients unroll a condom onto a model of a penis or a banana, with eyes open and then again in the dark.
- Offer to help patients select a condom that is most suitable to their needs. Many clinics provide condoms in different sizes and textures to help patients find what best works for them.

effectiveness depends heavily on the skill level and experience of the user.² Encourage patients to practice using condoms. When providing instruction on how to use condoms, have patients unroll a condom onto a model of a penis or a banana, with eyes open and then again in the dark. Offer to help patients select a condom that is most suitable to their needs, which might include the female condom. Many clinics provide condoms in different sizes and textures to help patients find what works best for them.

Use “What You Need to Know About Condoms” from the *Sexual Health: An Adolescent Provider Toolkit* produced by the Adolescent Health Working Group to help illustrate how to use condoms.³ (*Access the toolkit at <http://bit.ly/1nUYWYf>.*)

Remind patients that a new condom must be used with every act of intercourse if any risk of pregnancy or sexually transmitted infection exists. Also condoms should be donned before any genital contact, with the condom unrolled all the way to the base of erect penis. Immediately after ejaculation, the rim of the condom should be held while the penis is withdrawn, with the used condom disposed of safely.²

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Teen TOPICS

Period problems: Can contraception help?

By **Anita Brakman, MS**
Senior Director of Education, Research & Training
Physicians for Reproductive Health
New York City

Melanie Gold, DO, FAAP
Clinical Professor of Pediatrics
University of Pittsburgh School of Medicine
Staff Physician
University of Pittsburgh Student Health Service

Up to 90% of female adolescents report experiencing painful periods or other menstrual complaints. Problems associated with menses are the primary reported cause for absenteeism from school and work for female adolescents.¹ While diagnosis and treatment differ depending on specific menstrual disorders or complaints, contraceptive methods often offer a solution for teens and adults.

Dysmenorrhea is the most common menstrual complaint. It includes cramps and pain in the lower abdomen before and during menses. It often is accompanied by nausea, back pain, headache, vomiting, and diarrhea. These symptoms are more common during mid- or late adolescence because they are more likely to occur once ovulation begins. The production of prostaglandins following progesterone withdrawal is the part of a normal menstrual cycle that leads to an inflammatory response that can cause pain and other symptoms. Most dysmenorrhea occurs in women with normal cycles and no pelvic pathologies, which is termed primary dysmenorrhea.

Treatment for primary dysmenorrhea includes the use of around the clock non-steroidal anti-inflammatory drugs (NSAIDs) for two to three days prior as well as throughout menses to reduce prostaglandin production. If this treatment is not effective within three cycles, a cycled combination

hormonal contraceptive, such as an oral contraceptive pill (OCP) usually is the next suggested treatment. OCPs reduce prostaglandin production, thin the endometrial lining, and inhibit ovulation, which might provide relief. Women who still experience pain and other symptoms during withdrawal bleeds might want to consider continuous cycling.² Using dedicated continuous cycling pills, or using the vaginal ring without a withdrawal bleed, would produce similar relief.

While NSAIDs and OCPs historically have been considered first-line options for relieving dysmenorrhea, studies indicate depot medroxyprogesterone acetate injections can reduce symptoms by up to two-thirds.³ Also, there is growing support for use of the five-year levonorgestrel intrauterine system (LNG-IUS) (Mirena, Bayer HealthCare Pharmaceuticals, Whippany, PA) for management of dysmenorrhea. A 10 mcg combination pill, such as Lo Loestrin (Actavis, Parsippany, NJ) often causes amenorrhea and can act as another way to manage dysmenorrhea. If dysmenorrhea continues, providers might suspect secondary dysmenorrhea caused by pelvic pathology such as pelvic inflammatory disease or endometriosis. Further interventions might be necessary to identify the cause.

There can be several causes of abnormal uterine bleeding. The first step in addressing this problem is assessing the amount of bleeding and ensuring the patient is hemodynamically stable. Providers should evaluate for the cause of the abnormal bleeding and offer appropriate treatments to reduce bleeding irregularities. Anovulation accounts for nearly 90% of abnormal bleeding during adolescence.² Without ovulation, a lack of progesterone creates an unstable endometrial lining. This lining breaks down, which leads to excessively long and heavy periods and irregular bleeding. Anovulatory cycles are extremely common in the first years after menarche; combination hormonal contraceptives can produce regular bleeding patterns. However, combined pills do not affect the body's ability to regularly ovulate.³ Adolescents with mild to moderate bleeding with no anemia require minimal intervention, with the exception of tracking their menses on a calendar and maintaining their dietary iron intake. Teens experiencing heavy menstrual bleeding or menorrhagia might require additional work-up for diagnosis and should be offered a range of treatment options.

Menorrhagia can be a symptom of more serious bleeding disorders. Up to 20% of adolescents admitted to hospitals with severe menorrhagia have an underlying clotting disorder or bleeding diathesis, the

most common of which is Von Willenbrand disease.⁴ Other disorders might include platelet dysfunction, clotting factor deficiencies, or thrombocytopenia, which might be primarily hematologic in origin or a result of liver function abnormalities. Treatment of menorrhagia is based on the amount of flow, degree of anemia, and shared decision-making between the patient, provider, and parents.

For patients with mild to moderate bleeding and no signs of anemia, NSAIDs and combination hormonal contraceptives, or a LNG-IUS, can reduce bleeding.^{2, 4-6} Adolescents with active bleeding and signs of moderate to severe or acute anemia, especially if they are hemodynamically unstable, will require more aggressive hormonal intervention, or even hospitalization, for treatment.

It should be noted that pregnancy, including ectopic or spontaneous abortion, also might be a cause of bleeding, as well as amenorrhea. A urine pregnancy test is recommended for female adolescents experiencing bleeding or amenorrhea.

While there is no research available specifically on the use of intrauterine devices (IUDs) by female adolescents to relieve menstrual complaints and disorders, the research on levonorgestrel-releasing intrauterine systems in adult women provides useful guidance for the care of younger patients. Numerous studies have shown this method to significantly improve dysmenorrhea in older women ages 25-47.⁶ One such study found a 30% reduction in menstrual pain in LNG-IUS users after 36 months.⁷ Studies of young adult women ages 18-25 also have reported the LNG-IUS providing more relief from dysmenorrhea compared to OCPs.⁸

There is a lack of adolescent-specific research on the treatment of heavy menstrual bleeding using the IUS, but data on adult women is encouraging.⁹ One study of women with heavy menstrual bleeding found an 86% reduction in bleeding after three months, and it found a 97% reduction after 12 months of LNG-IUS use.¹⁰ A Cochrane review later reported that LNG-IUS led to greater reductions in bleeding than OCPs for adult women with heavy menstrual bleeding.¹¹ Even among women with normal bleeding patterns, the LNG-IUS reduces significantly more bleeding than OCPs, studies indicate.⁸

While offering adolescents effective contraceptive options for preventing pregnancy is always a best practices, these studies reveal how many methods, especially combination hormonal contraceptives, progestin-only injections, and the LNG-IUS, also contribute important noncontraceptive benefits by resolving menstrual problems and disorders for ado-

lescents, regardless of their need for pregnancy prevention.

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Boost chlamydia screens in adolescent females

New chlamydia prevalence estimates confirm that young women — particularly young African American women — continue to bear a disproportionate burden of disease in the United States.¹

Researchers at the Centers for Disease Prevention and Control (CDC) used 2007-2012 National Health and Nutrition Examination Survey

(NHANES) data to calculate nationally representative estimates for chlamydia prevalence overall, as well as by sex, age, and race. The analysis found an overall chlamydia prevalence of 1.7% among survey participants of men and women ages 14-39, which suggests an estimated 1.8 million prevalent infections nationally. Compared to the 1.4 million infections reported annually, this prevalence estimate suggests that many chlamydial infections go undiagnosed, the researchers note.

When researchers looked at sexually active female adolescents ages 14-19, they found an estimated chlamydia prevalence of 6.4%. For sexually active male adolescents ages 14-19, there was an estimated chlamydia prevalence of 2.4%, researchers report. The estimated prevalence among sexually active black female teens was 18.6%, compared to 3.2% among sexually active white female teens.¹

How do these findings compare with earlier figures from NHANES, a survey of a nationally representative sample of the U.S. non-institutionalized, civilian population? The new research underscores that the chlamydia burden in the United States remains high, especially among young women, says **Elizabeth Torrone**, MSPH, PhD, an epidemiologist in the CDC's Division of STD Prevention.

The new overall estimate of 1.7% is similar to previous prevalence estimates, says Torrone, lead author of the current report. A similar analysis of NHANES data from 2005-2008 found that there were 1.6 million estimated prevalent infections, observes Torrone. Because NHANES data are based on probability surveys, there is uncertainty in the estimates, she points out.

"We found that in 2012, the estimated number of infections could range from 1.4 to 2.1 million, which is not statistically different than the 2008 estimate," she notes. "Additionally, in recent years, chlamydia prevalence among youth has been stable as well."

Although the rate of chlamydia diagnoses has been increasing over the last two decades, these trends likely reflect increased screening and expanded use of more sensitive tests, says Torrone. Estimates from NHANES data suggest that overall prevalence is stable, she states.

It is critical to increase screening and awareness, especially among young people, says Torrone. "Screening is the essential first step, yet many sexually transmitted diseases [STDs] go untreated because they often have no symptoms and individuals are unaware that they are infected," notes Torrone. "With timely diagnosis and appropriate

treatment, however, most STDs are curable."

Providers should screen all sexually active young females annually and ensure that all sex partners of patients diagnosed with chlamydia are treated appropriately, state the CDC researchers. The CDC recommends yearly chlamydia screening of all sexually active women age 25 or younger and older women with risk factors for chlamydial infections, such as those who have a new or more than one sex partner.

To help clinicians address chlamydia in patients, CDC spokesperson **Salina Smith** offers the following resources:

- ***Why Screen for Chlamydia: An Implementation Guide for Healthcare Providers*** is a printable guide from the National Chlamydia Coalition. It provides information on sexual history-taking, consent, and confidentiality, and it provides examples of ways to increase screening rates. Providers can download the guide for free at <http://bit.ly/1rHCO9g>.

- The National Coalition of Sexual Health offers a guide, ***Take Charge of Your Sexual Health***, which includes a comprehensive guide of preventive sexual health services for women, including information on chlamydia screening. (Download at <http://bit.ly/1ldca0q>.) To download a checklist on recommended preventive health services for women, go to <http://bit.ly/1lNUfNk>.

- **GYT (Get Yourself Tested)**, a collaborative effort of the American College Health Association, the Kaiser Family Foundation, MTV, the National Coalition of STD Directors, and Planned Parenthood Federation of America, is designed to promote sexual health and address the disproportionately high rates of STDs among those under age 25. Get materials that address how providers can use GYT in their clinics at <http://on.mtv.com/1r3eDzu>.

- The **California STD/HIV Prevention Training Center** offers several online training courses available for practicing clinicians who care for women of reproductive age, including one on chlamydia screening and partner management. Continuing medical education credits are available. Visit <http://bit.ly/1r3fBM0>.

Everyone can play a role in protecting young people from the potentially devastating effects of STDs, such as chlamydia, says Torrone. Preventing STDs among youth remains a top priority for the CDC, she states.

For clinicians, the CDC is recommending the most effective treatments and encouraging expedited partner therapy (EPT) when appropriate. It also is

advancing sound health policy, such as developing disease screening and treatment recommendations that help the most-affected populations gain access to prevention services and overcome barriers, observes Torrone. However, the CDC cannot do it alone. There is a shared responsibility to reduce sexually transmitted infections among youth, says Torrone. Individuals should talk openly, get tested, and reduce risk with proven prevention strategies such as abstinence, vaccination, condoms, and mutual monogamy, Torrone says. Clinicians should discuss STDs with patients and increase testing, she states.

“Community leaders should encourage parents to talk to teens about prevention and fight stigma,” says Torrone. “Researchers and pharmaceutical companies must jump-start research to identify or develop new, effective drugs or drug combinations.”

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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;
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CNE/CME QUESTIONS

1. What is considered the first-line contraceptive option for women with a history of breast cancer?

- A. Copper T380A intrauterine device
- B. Combined hormonal pills
- C. Contraceptive vaginal ring
- D. Contraceptive injection

2. What is one the main differences about the new inserter for the Mirena levonorgestrel intrauterine contraceptive?

- A. Centimeter markings are on just one side of the insertion tube.
- B. The insertion tube outer diameter is now thinner, measuring 4.4 mm.
- C. The insertion tube is reloadable.
- D. It features a new type of spring loader.

3. According to the 2013 National Youth Risk Behavior Survey, among high school students who are sexually active, how many reported condom use?

- A. 75%
- B. 63%
- C. 59%
- D. 33%

4. The Centers for Disease Control and Prevention recommends annual chlamydia for all sexually active women in what age bracket?

- A. Age 40 or older
- B. Age 30 or older
- C. Age 20 or younger
- D. Age 25 or younger

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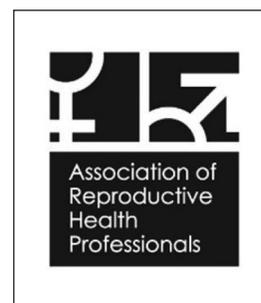
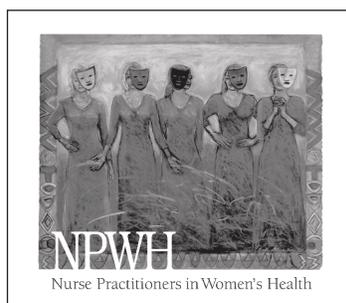
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S · T · I Q U A R T E R L Y

CDC backs new HIV testing approach — Update your clinical lab practices

Approach banks on latest technology to up acute infection diagnosis

Since the Centers for Disease Control and Prevention (CDC) issued a 2006 recommendation that all Americans ages 13-64 get tested for HIV, the proportion of people who are unaware of their HIV infection has seen a steady decline, from about 20% to 16%. As of 2009, an estimated 83 million adults ages 18-64 reported they had been tested for HIV.¹

The CDC has just issued a new approach for HIV testing in laboratories that capitalizes on the latest technology to improve diagnosis of acute infection, the earliest stage of HIV infection when people are most likely to transmit the virus.²

The guidance might help the nation reduce the number of people who are unaware of their HIV status, says **Jonathan Mermin**, MD, MPH, director of the CDC's National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention. (Go to the CDC's HIV/AIDS Laboratory Tests web site, <http://1.usa.gov/1md3gUZ>, to download the updated recommendations, as well as Quick Reference: Recommended Laboratory HIV Testing Algorithm for Serum or Plasma Specimens. Both are under "Laboratory Testing Guidance." A step-by-step guide is available by going to <http://1.usa.gov/1md48Je>.)

"Identifying acute infections has long been one of our nation's biggest HIV prevention challenges, since these infections eluded traditional testing technologies," said Mermin in a statement accompanying the guidance's publication. "But with consistent and widespread use of this new testing method, we can diagnose people several weeks earlier than before."

The new approach for HIV testing in laboratories will help avoid missing early infections that go undetected, explains **Bernard Branson**, MD, a medical epidemiologist in CDC's Division of HIV/AIDS Prevention. The new recommendations call for a series of tests to first detect the virus before antibodies develop and then correctly distinguish between HIV-1 and HIV-2 to ensure correct treatment, Branson states. This recommendation reflects a major shift away from the HIV-1 Western Blot test, which is no longer recommended because it is negative during early HIV-1 infections and also misclassifies HIV-2 infections.

The new recommendation includes "fourth generation" tests approved by the Food and Drug Administration (FDA) as the initial HIV test, explains Branson. Fourth generation tests detect antibodies to HIV-1 and HIV-2, as well as the HIV-1 p24 antigen that is present before antibodies develop, Branson states.

"Using the updated testing recommendations, HIV infection can be diagnosed as much as three to four weeks earlier than with the previous testing approach," says Branson. "Early diagnosis, particularly in the highly infectious acute phase of HIV infection, is essential for stopping HIV transmission and ensuring that people with HIV receive life-saving treatment and care."

Algorithm offers aid

The CDC and the Association of Public Health Laboratories issued the recommendations based on

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HIV tests approved by the FDA as of December 2012, as well as scientific evidence, laboratory experience, and expert opinion collected from 2007 through December 2013. The recommendations do not include the rapid HIV-1/HIV-2 antigen/antibody combination test approved by the FDA in August 2013, because evidence of performance in the algorithm was insufficient, or HIV-2 nucleic acid tests (NATs), which lack FDA approval.²

The recommended algorithm has several advantages over previous recommendations, because it offers:

- more accurate laboratory diagnosis of acute HIV-1 infection;
- equally accurate laboratory diagnosis of established HIV-1 infection;
- more accurate laboratory diagnosis of HIV-2 infection;
- fewer indeterminate results;
- faster turnaround time for most test results.²

The CDC and the Association of Public Health Laboratories will continue to monitor the introduction and FDA approval of diagnostic assays for HIV infection, and they will update recommendations when necessary. The two agencies will continue to monitor the performance of the laboratory testing algorithm and review the performance of the recommended algorithm at least every five years.

How does it differ?

How does the new guidance differ from previous recommendations? The previously recommended HIV testing algorithms centered on screening for HIV-1 antibodies.³ Specific testing for HIV-2 antibodies was recommended in limited circumstances.⁴

The new algorithm screens for HIV-1 and HIV-2 antibodies, and it distinguishes HIV-1 from HIV-2 antibodies using a single supplemental antibody differentiation immunoassay. According to public health officials, this approach is simpler and more accurate than the 1992 guidance, because it no longer depends on laboratory access to clinical, demographic, or behavioral information suggestive of possible HIV-2 exposure.² Because the new algorithm no longer relies on HIV-1 Western blot or HIV-1 indirect immunofluorescence assay (IFA) as a supplemental test, it returns fewer specimens with indeterminate results that require resolution by a follow-up test conducted several months later.²

Supplemental testing with HIV-1 Western blot or

EXECUTIVE SUMMARY

The Centers for Disease Control and Prevention has issued a new approach for HIV testing in laboratories that capitalizes on the latest technology to improve diagnosis of acute infection, the earliest stage of HIV infection when people are most likely to transmit the virus.

- The new approach for HIV testing in laboratories will help avoid missing early infections that go undetected. Using the updated testing recommendations, HIV infection can be diagnosed as much as three to four weeks earlier than with the previous testing approach.
- The HIV-1 Western Blot test is no longer recommended because it is negative during early HIV-1 infections and also misclassifies HIV-2 infections.

HIV-1 IFA previously had been recommended for all specimens submitted for testing after a reactive rapid HIV test result, even if the initial laboratory immunoassay was nonreactive. Now, specimens submitted after any reactive rapid HIV test result — including the HIV-1/HIV-2 antibody differentiation assay, when it is used as an initial rapid test, and the HIV-1/HIV-2 antigen/antibody combination rapid test — are tested according to the same algorithm as all other specimens. No further supplemental testing is required if the result of the initial antigen/antibody combination immunoassay is nonreactive, the new guidance states.²

Follow the steps

With the new guidance, all testing begins with a “fourth generation” HIV test, which detects HIV in the blood earlier than previously recommended antibody tests.

The fourth generation tests identify the HIV-1 p24 antigen, a viral protein which appears in the blood sooner than antibodies. If the test is negative, no further testing is required.

If the fourth generation test is positive, obtain an immunoassay that differentiates HIV-1 from HIV-2 antibodies. Such a test produces results faster than the previously recommended Western Blot. It also distinguishes between HIV-1 and HIV-2, which the Western Blot cannot. Such a distinction can have important treatment implications for a patient, states the CDC.

If a positive result is reached on the initial immunoassay, but a negative or indeterminate result on the antibody differentiation assay, the recommenda-

tions call for proceeding to HIV-1 nucleic acid testing for resolution. Such testing will ensure accurate detection of early infection or indicate a false positive from the fourth generation test.²

Testing is “linchpin”

The CDC is calling for laboratories to adopt the new guidance as quickly as possible. Because it can identify infection several weeks earlier than before, it might give public health officials a jump on pinpointing infection.

HIV testing is the linchpin for prevention and treatment, said Mermin.

“For people who test HIV-positive, diagnosis opens the door to life-saving treatment, which also reduces the risk of transmitting HIV to others,” stated Mermin. “For those who test negative, knowing their status empowers them to remain HIV-free.”

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New campaign spurs conversations on HIV

A new campaign, “Start Talking. Stop HIV,” developed by the Centers for Disease Control and Prevention (CDC), encourages gay and bisexual men to talk openly with their sexual partners about HIV risk and prevention strategies. Getting such conversations going is important. Men who have sex with men (MSM), including those who inject drugs, continue to be the most severely affected group by HIV in the United States. They account for 57% of

the 1.1 million people living with HIV and about 66% of all new HIV infections each year.¹

“Given the range of HIV prevention options available today, talking about HIV prevention has never been more important for gay and bisexual men,” said Jonathan Mermin, MD, MPH, director of CDC’s National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, in a statement accompanying the campaign’s launch. “Only after having open and honest conversations can partners make informed choices about which strategies will work for them.”

With more prevention options available today than ever before, the dialogue is more complex than it has ever been, says Nick DeLuca, PhD, branch chief of the CDC’s Division of HIV/AIDS Prevention. “It is critical that partners talk about HIV testing and their HIV status, as well as the full range of prevention strategies such as condoms and medicines that prevent and treat HIV, including pre-exposure prophylaxis (PrEP), post-exposure prophylaxis (PEP), and antiretroviral therapy (ART),” notes DeLuca.

Research shows that communication between partners is associated with condom use, HIV testing, and status disclosure,² says DeLuca.

Campaign reaches out

To tap into real-life concerns, the “Start Talking. Stop HIV” campaign was created in consultation with more than 500 gay and bisexual men.

It is designed to reach men of all races and ethnicities in all types of relationships, whether casual or

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long-term. (Visit the campaign web site at <http://1.usa.gov/Ref0tz>.) The campaign includes online and print advertisements, as well as social media outreach and online videos. (Go to the campaign's Facebook page at <http://on.fb.me/1vNpopD> and Twitter page at <http://bit.ly/1rCzADM>.) It uses real-world individuals and couples to encourage gay and bisexual men to talk to their sexual partners about such issues as HIV testing and HIV status; safer sex practices, such as using condoms and lowering risky sexual behaviors; availability of prescription drugs for prevention and treatment of HIV; and how to maintain healthy relationships.

The campaign offers a wide assortment of resources, including posters, brochures, banners, videos, and cheat sheets. All are available for free download.

Go digital for young men

New research indicates digital outreach efforts delivered via text messages, interactive games, chat rooms, and social networks might be an effective way to reach at-risk younger men.³

Among adolescent males aged 13-19, about 91% of all diagnosed HIV infections are from male-to-male sexual contact, according to CDC estimates.⁴ Black young men who have sex with men are especially at risk. About two-thirds (63%) of all young men ages 13-24 who have sex with men who were diagnosed with HIV infection in 2009 were black.³ Black young men who have sex with men also experienced the largest increase of all racial/ethnic groups in diagnosed HIV infections, with numbers rising from 2,416 in 2006 to 3,777 in 2009.³

Why does technology offer potential as an effective prevention tool? **Rebecca Schnall**, PhD, RN, an assistant professor at Columbia University School of Nursing in New York, says young adults are "very used to technology, and there is built-in privacy and immediacy with digital communication that may be especially appealing to men who aren't comfortable disclosing their sexual orientation or their HIV status in a face-to-face encounter." Schnall served as lead author of the current research.

To conduct the investigation, Schnall's research team performed a systematic literature review to determine the effectiveness of ehealth interventions for HIV prevention among men who have sex with men. Studies included in the report had to be focused exclusively on e-health, limited to HIV pre-

vention and testing rather than treatment, targeted only to adult men who have sex with men, written in English, designed as experimental or randomized controlled trials, and published between January 2000 and April 2014. The team's review shows evidence that ehealth for HIV prevention in high-risk men who have sex with men has the potential to be effective in the short term for reducing HIV risk behaviors and increasing testing rates.

"If we want to reduce HIV infection rates, particularly among younger men, we need to explore the use of technology to meet them where they live: online and on their phones," Schnall said in a press statement accompanying the research publication.

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CDC offers webcast on hepatitis C

Get up to speed on the latest testing and treatment modalities on the hepatitis C virus (HCV) by watching the archived webcast of the Centers for Disease Control and Prevention's (CDC's) Public Health Grand Rounds: *The 25th anniversary of the discovery of the hepatitis C virus: looking back to look forward*.

With about 3 million adults infected with HCV, most of whom are baby boomers, the CDC continues to call attention to the virus and the need for prevention, testing, and linkage to care. Hepatitis C remains the most common chronic bloodborne infection in the United States. Up to 50% of HCV-infected persons are unaware of their infection.

To access the webcast, go to <http://1.usa.gov/1rgmw3V> and select the presentation video. ■