CONTRACEPTIVE TECHNOLOGY UPDATE®

Interpreting News and Research on Contraceptives and STIs

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IN THIS ISSUE

- **LARCs:** First-line options for contraception. . . . . cover
- ***Teen Topics:*** Consider implant use for teens 100
- **Postpartum contraception:** New guidance issued 101
- **HIV testing:** At-home options in research pipeline. 103
- **Condoms:** Science explores new options 104
- **Adolescents:** Build skills in taking sexual histories 105

Enclosed in this issue:

- ***STI Quarterly:*** Time to tackle trichomonas vaginalis; Treatment options running out for gonorrhea
- ***CTU Salary Survey***

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AHC Media

Put support behind contraception that is long-acting and reversible

ACOG guidance addresses selecting appropriate candidates

Long-acting reversible contraceptive (LARC) methods — the Copper T 380A intrauterine device (IUD), the levonorgestrel intrauterine system, and the contraceptive implant — are the best tools clinicians have to fight against unintended pregnancies, which account for about half of U.S. pregnancies each year.[1] The American College of Obstetricians and Gynecologists has just issued new guidance to help clinicians identify appropriate candidates for these highly effective methods.[2]

In addition to their high efficacy, LARC methods don't require ongoing effort on the part of the user for long-term, effective use, and they ensure rapid return of fertility after discontinuation. Women who are suitable LARC candidates can avoid the gaps in use and discontinuation of shorter-acting methods that are associated with unintended pregnancy rates in high-risk women.[2]

"The major advantage is that after insertion, LARC methods work without having to do anything else," says guidance co-developer **Eve Espey**, MD, MPH, professor of obstetrics and gynecology in the University of New Mexico School of Medicine, Albuquerque. "There's no maintenance

Health & Human Services includes coverage for contraception — What is the next step?

Get ready: the U.S. Department of Health and Human is recommending inclusion of contraceptive counseling and provision of all methods approved by the Food and Drug Administration without out-of-pocket costs to patients for all new private health plans written on or after Aug. 1, 2012. In adopting these recommendations for women's preventive healthcare as suggested by the Institute of Medicine (IOM), how will this impact access to contraceptives for women?

While the federal agency endorsed the IOM recommendations in full, it also included an exemption that makes it possible for religious employers to opt out of the contraceptive coverage provision. Such an exemption was not required by the healthcare reform law and could potentially inhibit some women's access to contraceptive services and supplies. What does the new guidance mean for family planning clinicians? Look to the next issue of *Contraceptive Technology Update* for more information.

required."

The T380A IUD copper IUD, marketed as ParaGard by Teva Women's Health, North Wales, PA, is approved by the Food and Drug Administration (FDA) for up to 10 continuous years, during which it remains highly effective. It has a reported failure rate at one year of 0.8 per 100 women, and it has a 10-year failure rate comparable with that of female sterilization: 1.9 per 100 women over 10 years.[3] Its most common adverse effects are abnormal bleeding and pain.[4]

The levonorgestrel intrauterine system, marketed as the Mirena IUS by Bayer HealthCare Pharmaceuticals, Wayne, NJ, is FDA-approved for up to five years of use, but it may be effective for up to seven years.[5] The one-year failure rate is 0.2 per 100 women.[3]

Complications with IUDs are uncommon and mainly include expulsion, method failure, and perforation. The expulsion rate is between 2% and 10% during the first year.[3] Perforation occurs in one per 1,000 insertions or fewer.[6]

The contraceptive implant, marketed in the United States as Implanon by Merck & Co., Kenilworth, NJ, is the most effective method of reversible contraception, with a typical-use pregnancy rate of 0.05%.[3] It is FDA-approved for three years of continuous use. Changes in menstrual bleeding patterns are common after implant insertion. They include amenorrhea or infrequent, frequent, or prolonged bleeding.[2]

Who can use LARCs?

Nulliparous women and adolescents can be offered LARC methods, including IUDs, notes the new guidance. In fact, the FDA in 2005 approved a change in the labeling for the Copper T380A: It removed a section titled "recommended patient profile" and deleted language that stated, "T380A is recommended for women who have had at least one child…".[7] *(Read more about appropriate candidates for IUD use; see the* Contraceptive Technology Update *article, "Use of long-term methods moving up; what can you do to increase numbers?," August 2011, p. 85.)*

The U.S. "Medical Eligibility Criteria for Contraceptive Use" (US MEC) assigns a Category 1

EXECUTIVE SUMMARY

Long-acting reversible contraceptive (LARC) methods — the Copper T 380A intrauterine device (IUD, ParaGard), the levonorgestrel intrauterine system (Mirena), and the contraceptive implant (Implanon) — are the best tools clinicians have to fight against unintended pregnancies, which account for about half of U.S. pregnancies each year. The American College of Obstetricians and Gynecologists has just issued new guidance to help clinicians identify appropriate candidates for these highly effective methods.
• The major advantage is that after insertion, LARC methods work without having to do anything else. • • • No maintenance is required on the part of the user to ensure effectiveness.

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(no restrictions) rating to the use of the contraceptive implant by nulliparous women and adolescents.[8] While evidence is limited on the use of the implant in adolescents, data indicates that implants are well-accepted in this population. In a study of 137 postpartum adolescents, at 24 months, continuation rates were higher in contraceptive implant users compared with contraceptive injection and combined contraceptive pill users.[9]

When to use?

When is it an appropriate time to insert an IUD or implant? According to the new guidance, insertion may occur at any time during the menstrual cycle, as long as pregnancy may be reasonably excluded. No backup contraception method is needed after inserting the copper IUD, regardless of when in the menstrual cycle it is inserted; however, backup method, such as condoms, should be used for seven days after insertion of the levonorgestrel intrauterine system or contraceptive implant. The only time backup methods do not need to be used for these methods is when either is inserted within five days of initiating menses, immediately after childbirth or after abortion, or immediately upon switching from another hormonal contraceptive.[10]

IUDs and the contraceptive implant can be used safely by postpartum women; the US MEC rates immediate postpartum copper IUD insertion as Category 1 and immediate postpartum levonorgestrel intrauterine system insertion in nonbreastfeeding and breastfeeding women as Category 2 (advantages generally outweigh risks). For the implant, the US MEC classifies insertion of the implant as safe at any time in nonbreastfeeding women after childbirth Placement of an implant in breastfeeding women less than four weeks after childbirth is rated as Category 2 due to theoretic concerns regarding milk production and infant growth and development. However, use of the implant is rated as Category 1 for women who are breastfeeding and more than four weeks after childbirth.[8]

Eye other opportunities

Insertion of an IUD or implant immediately after an abortion or miscarriage is safe and effective and has many of the same advantages as immediate postpartum insertion, according to the new guidance.

According to a new study, women who receive a IUD immediately following a first trimester abortion experience few complications and were less likely to have an unintended pregnancy than those who delayed getting an IUD by several weeks.[11]

Don't forget use of the Copper T380A for use as an emergency contraceptive. Insertion of a copper IUD is the most effective method of postcoital contraception when inserted up to five days after unprotected intercourse.[12] The levonorgestrel intrauterine system has not been studied for emergency contraception.

Both forms of intrauterine contraception and the implant should be offered as first-line contraceptive methods and encouraged as options for most women, says Espey.

"The benefits of IUDs and the contraceptive implant in preventing unplanned pregnancy could be profound with widespread adoption of these methods," and women's health providers are in a great position to effect change, she notes.

The success of the Contraceptive Choice Project in St. Louis, headed by Jeffrey Peipert, MD, MPH, MHA, should be out there in front of all clinicians, inspiring all to figure out ways to increase use of LARC methods, says **Robert Hatcher**, MD, MPH, professor of gynecology and obstetrics at Emory University School of Medicine in Atlanta. *(To read more about the project, see these* Contraceptive Technology Update *articles: "Check opportunities for long-acting methods," March 2010, p. 27; "Dramatic upswing reported in use of intrauterine device use," February 2011, p. 13; and "Use of long-term methods moving up — How can you boost numbers?" August 2011, p. 85.)*

"From what I can tell, the single most important factor in St. Louis has not been the free availability of these contraceptives, but rather stressing the high effectiveness rates of these methods," observes Hatcher. "This is what is presented to the patients when they call to ask about the project, when the decision is made as to whether a person can join the project, and in the visit at which the contraceptive chosen by the woman is made."

REFERENCES

1. Finer LB, Henshaw SK., Disparities in rates of unintended pregnancy in the United States, 1994 and 2001. *Perspect Sex Reprod Health* 2006; 38:90-96.
2. Practice bulletin no. 121: long-acting reversible contraception: implants and intrauterine devices. *Obstet Gynecol* 2011; 118:184-196.
3. Hatcher RA, Trussell J, Nelson AL, et al. *Contraceptive Technology*. 19th rev. ed. New York, NY: Ardent Media; 2007.
4. Brockmeyer A, Kishen M, Webb A. Experience of IUD/ IUS insertions and clinical performance in nulliparous women — a pilot study. *Eur J Contracept Reprod Health Care* 2008; 13:248-254.

5. Sivin I, Stern J, Coutinho E, et al. Prolonged intrauterine contraception: a seven-year randomized study of the levonorgestrel 20 mcg/day (LNg 20) and the Copper T380 Ag IUDS. *Contraception* 1991; 44:473-480.
6. World Health Organization (WHO). Mechanism of action, safety and efficacy of intrauterine devices: report of a WHO scientific group. World Health Organization Technical Report Series 753. Geneva: WHO; 1987.
7. Hubacher D, Finer LB, Espey E. Renewed interest in intrauterine contraception in the United States: evidence and explanation. *Contraception* 2011; 83:291-294.
8. Centers for Disease Control and Prevention. U.S. medical eligibility criteria for contraceptive use, 2010. *MMWR Recomm Rep* 2010; 59(RR-4):1-86.
9. Lewis LN, Doherty DA, Hickey M, et al. Implanon as a contraceptive choice for teenage mothers: a comparison of contraceptive choices, acceptability and repeat pregnancy. *Contraception* 2010; 81:421-426.
10. Makarainen L, van Beek A, Tuomivaara L, et al. Ovarian function during the use of a single contraceptive implant: Implanon compared with Norplant. *Fertil Steril* 1998; 69:714-721.
11. Bednarek PH, Creinin MD, Reeves MF, et al; Post-Aspiration IUD Randomization (PAIR) Study Trial Group. Immediate versus delayed IUD insertion after uterine aspiration. *NEJM* 2011; 364:2,208-2,217.
12. Cheng L, Gulmezoglu AM, Piaggio GG, et al. Interventions for emergency contraception. *Cochrane Database of Systematic Reviews* 2008. Doi: 10.1002/14651858. ■

Teen TOPICS

Add subdermal implant to options for teens

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Most adolescents who use contraception rely on combination oral contraceptive pills.[1] Unfortunately, this method poses challenges in daily maintenance. Both the transdermal patch and vaginal ring entail less maintenance, yet still require patients to remember when to remove the method and replace it on the skin or in the vagina on a weekly or monthly basis, respectively. Therefore, long-acting reversible contraceptive (LARC) methods that are provider-inserted and require less user maintenance may be especially useful to adolescent patients who are looking to postpone childbearing for several years.

As reported in this issue of *Contraceptive Technology Update*, the American Congress of Obstetricians and Gynecologists (ACOG) recently released a practice bulletin on LARC methods focusing on intrauterine devices and implants.[2] In addition, much has been written about the benefits of intrauterine contraception for teens and other nulliparous women.[3-5]

Less has been written, however, about the contraceptive implant. Use of this method is not even tracked by the National Survey of Family Growth, the major data source on contraceptive use in the United States, which makes it difficult to assess how well the method is being utilized by adolescents and older women.

The only contraceptive implant available in the United States is Implanon (Merck & Co., Kenilworth, NJ), a single-rod device approved by the Food and Drug Administration in 2006. Implanon is placed as an outpatient procedure subdermally in the upper arm, releases 68 mg of etonorgestrel over time, and prevents pregnancy for up to three years. The implant is 99% effective at preventing pregnancy, and this rate is the same for perfect and typical use, as there is no room for user error once the device is inserted. The mechanisms of action include inhibiting ovulation, as well as thickening cervical mucus.[6]

Check the advantages

Implants have few contraindications and might be especially appropriate for women who have medical conditions that contraindicate using estrogen-based methods.[7] The method's discreet nature might benefit some adolescents who wish to keep their contraceptive use private from parents, partners, or others. The implant is not visible; however it is palpable in the upper arm, and hyperpigmentation of the skin over the rod has been reported.

The initial cost of insertion is $400-$800, which might be prohibitive for many teens or any women with low income or no insurance coverage. Nevertheless, over time the method costs less than short-term hormonal methods that require ongoing

refills or injections.

In addition to their contraceptive benefits, implants might decrease acne. A two-year study investigating contraceptive efficacy and tolerability of Implanon among women ages 18-40 noted 61% of those with acne at insertion reported improvement over the two years. However, 14% of participants who reported no acne at baseline reported having acne at the end of the two-year study. The severity of these changes was not reported.[8]

Counsel on bleeding

One side effect of implants that adolescents might find difficult to deal with is irregular menstrual bleeding. This irregularity can include more or less frequent bleeding, bleeding for longer or shorter duration, or amenorrhea.

A small chart review of 12-24 year old implant users revealed 22% of participants experienced bleeding problems leading to removal.[9] Other rare adverse events reported in trials include effects similar to other hormonal methods.[10]

Adolescents also might be particularly concerned about weight gain occurring after implant insertion, similar to their concern of weight gain with other methods. Participants in clinical trials reported a mean weight gain of 2.8 pounds at the end of the first year and 3.7 pounds at the end of the second year of implant use.[10] In a more recent study, weight gain was reported by 12.7% of participants over two years. In 95% of these cases, gains were considered to be related to the implant.[8] However, no study of the method's effect on weight has included a control group for comparison.

While little research has focused on this method in the wider adolescent population, several articles have assessed and found the method to be a safe and effective for adolescent mothers.[11-12]

The most important aspect of counseling female adolescents about this option it to discuss the likelihood, extent, and tolerability of potential bleeding irregularities, because these irregularities are a major reason for implant discontinuation among adult women.[13] Ask adolescent women how they will cope with bleeding changes and how much abnormal bleeding they can tolerate. The implant does not protect against sexually transmitted infections, so counseling should include ways to facilitate condom use.

The implant might be a particularly good choice for female adolescents who wish to delay childbearing for three years. If this time frame fits with an adolescent's childbearing plans, and she is comfortable with the idea of an implant and possible bleeding irregularities, this option might be a better choice than shorter-acting or intrauterine methods.

REFERENCES

1. Mosher WD, Jones J. Use of contraception in the United States: 1982–2008. *Vital Health Stat 23* 2010; 29:1-44.
2. American Congress of Obstetricians and Gynecologists. Practice Bulletin No. 121: long-acting reversible contraception: implants and intrauterine devices. *Obstet Gynecol* 2011; 118:184-196.
3. Lyus R, Lohr P, Prager S. Use of Mirena LNG-IUS and Paragard CuT380A intrauterine devices in nulliparous women. *Contraception* 2010; 81:367-371.
4. American Congress of Obstetricians and Gynecologists. ACOG Committee Opinion No. 392, December 2007. Intrauterine device and adolescents. *Obstet Gynecol* 200; 110:1,493-1,495.
5. Yen S, Saah T, Hillard PJ. IUDs and adolescents — an underutilized opportunity for pregnancy prevention. *J Pediatr Adolesc Gynecol* 2010; 23:123-128.
6. Hatcher RA, Trussell J, Nelson AL, et al. *Contraceptive Technology*. 19th revised ed. New York (NY): Ardent Media; 2007.
7. Centers for Disease Control and Prevention. U.S. medical eligibility criteria for contraceptive use, 2010. *MMWR Recomm Rep* 2010; 59(RR-4):1-86.
8. Funk S, Miller MM, Mishell DR Jr, et al. Safety and efficacy of Implanon, a single-rod implantable contraceptive containing etonogestrel. *Contraception* 2004; 9:39-46.
9. Deokar AM, Jackson W, Omar HA. Menstrual bleeding patterns in adolescents using etonogestrel (ENG) implant. *Int J Adolesc Med Health* 2011; 23:75-77.
10. Organon USA *Implanon*. Physician insert. Roseland, NJ; 2006.
11. Lewis LN, Doherty DA, Hickey M, et al. Implanon as a contraceptive choice for teenage mothers: a comparison of contraceptive choices, acceptability and repeat pregnancy. *Contraception* 2010; 81:421-426.
12. Guazzelli C, Teixeira de Queiroz FT, Barbieri M, et al. Etonogestrel implant in postpartum adolescents: bleeding pattern, efficacy and discontinuation rate. *Contraception* 2010; 82:256-259.
13. Casey PM, Long ME, Marnach ML, et al. Bleeding related to etonogestrel subdermal implant in a US population. *Contraception* 2011; 82:426-30. ■

Contraception guidance for postpartum period

Get ready to revise your practice: the *U.S. Medical Eligibility Criteria for Contraceptive Use* has been updated regarding postpartum contra-

ception.[1]

The new guidance states that postpartum women should not use combined hormonal contraceptives during the first 21 days after delivery because of the high risk for venous thromboembolism (VTE) during this period. During 21-42 days postpartum, women without risk factors for VTE generally can initiate combined hormonal contraceptives, but women with VTE risk factors generally should not use these methods, the new guidance states. After 42 days postpartum, no restrictions on the use of combined hormonal contraceptives based on postpartum status apply.[1]

While this new guidance from the Centers for Disease Control and Prevention (CDC) emphasizes the higher than previously appreciated risk of thrombosis in the first six weeks following childbirth (which is the rationale for avoiding estrogen-progestin contraceptives during this time interval), it also reminds clinicians that it is safe to initiate progestin-only methods immediately postpartum, regardless of lactation status, says **Andrew Kaunitz**, MD, professor and associate chair in the Obstetrics and Gynecology Department at the University of Florida College of Medicine — Jacksonville. Kaunitz served on the review team that led to the revised guidance.

In 2010, the World Health Organization updated its guidance on the safety of combined hormonal contraceptives among postpartum nonbreastfeeding women to be more restrictive regarding the use of combined hormonal contraceptives during the first 42 days postpartum, particularly among women with other risk factors for VTE, based on findings from new evidence.[2,3] Because of the international update, CDC initiated a process to assess whether its guidance similarly should be changed.

Get the word out

Clinicians who have signed up for updates to the U.S. guidance should have received an e-mail alert through the CDC regarding the change, says **Naomi Tepper**, MD, obstetrician/gynecologist with the Division of Reproductive Health at CDC. Tepper served as lead author for the new guidance. *[To sign up for e-mail updates, go to the U.S. Medical Eligibility Criteria for Contraceptive Use web site, www.cdc.gov/reproductivehealth/UnintendedPregnancy/USMEC. Select "Sign up to receive U.S. Medical Eligibility Criteria (USMEC) e-mail updates."]*

The CDC also is developing new provider tools that will include the updated guidance, including a contraceptive choice wheel, similar to pregnancy/gestation calendar wheels used by many reproductive health providers, says Tepper. Software developers also are creating a smartphone application to allow providers to access the criteria on their portable devices, says Tepper.

News of the revised guidance is being disseminated through professional organizations that have been involved in developing the criteria, says Tepper. "We are relying on their help in getting the word out to their memberships," she says.

Check the options

Recommendations for other contraceptives, including progestin-only contraceptives and intrauterine devices, remain unchanged in the new guidance. Such methods are safe for postpartum women, including women who are breastfeeding, and can be initiated immediately postpartum. (*Read about these options; see the* Contraceptive Technology Update *article, "Check contraceptive options for postpartum," January 2010, p. 6.)*

Why is contraception so important for postpartum women? Results from the most recent cycle of the National Survey of Family Growth indicate that 49% of all pregnancies were unintended, and 21% of women gave birth within 24 months of a previous birth.[4] Ovulation can occur as early as 25 days postpartum among nonbreastfeeding women, so time is of the essence when initiating contraception in the postpartum period.[5]

A 2009 review of the types of contraception being used by women 2-9 months postpartum shows that 88.0% of postpartum women report current use of at least one birth control method;

EXECUTIVE SUMMARY

The *U.S. Medical Eligibility Criteria for Contraceptive Use* has been updated regarding postpartum contraception.

- Postpartum women should not use combined hormonal contraceptives during the first 21 days after delivery because of the high risk for venous thromboembolism (VTE) during this period, the new guidance states.
- During 21-42 days postpartum, women without risk factors for VTE generally can initiate combined hormonal contraceptives, but women with VTE risk factors generally should not use these methods.
- After 42 days postpartum, no restrictions on the use of combined hormonal contraceptives based on postpartum status apply.

61.7% report using a method defined as highly effective, 20.0% use a method defined as moderately effective, and 6.4% use less effective methods.[6] Rates of using highly effective contraceptive methods postpartum were lowest among women who had no prenatal care (54.5%).[6]

REFERENCES

1. Tepper NK, Curtis KM, Jamieson DJ, et al. Update to CDC's *U.S. Medical Eligibility Criteria for Contraceptive Use, 2010*: Revised recommendations for the use of contraceptive methods during the postpartum period. *MMWR* 2011; 60:878-883.
2. Jackson E, Curtis K, Gaffield M. Risk of venous thromboembolism during the postpartum period: a systematic review. *Obstet Gynecol* 2011; 117:691-703.
3. World Health Organization. *Combined Hormonal Contraceptive Use During the Postpartum Period*. Geneva, Switzerland: World Health Organization; 2010. Accessed at http://whqlibdoc.who.int/hq/2010/WHO_RHR_10.15_eng.pdf.
4. Chandra A, Martinez GM, Mosher WD, et al. Fertility, family planning, and reproductive health of U.S. women: data from the 2002 National Survey of Family Growth. *Vital Health Stat* 2005; 23:1-160.
5. Jackson E, Glasier A. Return of ovulation and menses in postpartum, non-lactating women: a systematic review. *Obstet Gynecol* 2011;117:657-662.
6. Centers for Disease Control and Prevention (CDC). Contraceptive use among postpartum women — 12 states and New York City, 2004-2006. *MMWR* 2009; 58:821-826. ■

Research explores at-home HIV testing

While only one company has received Food and Drug Administration (FDA) approval for an HIV home collection-test system that requires users to collect a blood specimen, then mail it to a laboratory for professional testing, no test kit is available to allow consumers to interpret test results at home. Other companies are seeking FDA approval for such tests for over-the-counter (OTC) use.

The sole home collection test system approved by the FDA is marketed as "The Home Access HIV-1 Test System" or "The Home Access Express HIV-1 Test System." It is manufactured by Home Access Health Corp. of Hoffman Estates, IL. Persons who take the test, approved by the FDA in 1996, receive results in 3-7 days by calling a toll-free number.

Chembio Diagnostics of Medford, NY, has begun studies required for submission of an investigational device exemption to the FDA for its Sure Check Rapid HIV Test as a first step toward over-the-counter product approval. The test is marketed to professional laboratories by Alere of Waltham, MA, as Clearview Complete HIV 1/2, says **Lawrence Siebert**, Chembio's chief executive officer.

Chembio's test uses a barrel system with a sample port at one end of the barrel that houses a HIV test strip. The blood sample enters the barrel simply by touching the sample port to the fingertip pricked with a provided safety lancet. The barrel technology confines the sample and reagents and, thereby, minimizes potential exposure to the user or other parties.

Chembio must complete two studies to accompany its device exemption request, one which is a market study of the test's intended users. If the FDA approves the investigational device exemption, a Phase II trial will commence in early 2012, says Siebert.

OraSure Technologies of Bethlehem, PA, has begun a clinical trial of its OraQuick Rapid HIV-1/2 test to gain FDA approval for OTC sale. The company received an investigational device exemption from the FDA in November 2010. In the clinical trials, individuals will conduct unsupervised oral fluid self-testing using the investigational OTC version of the OraQuick Advance Rapid HIV-1/2 test.

Home-use kits are now in place for testing fecal occult blood, glucose, cholesterol, and pregnancy. However, there are no tests yet approved to test for infectious diseases in the home environment.

Goal: More will know

At-home testing might be one way to help achieve the one of the major goals of the National HIV/AIDS Strategy: to increase from 79% to 90% the percentage of people living with HIV who know their serostatus by 2015.[1]

What are the benefits of at-home testing? "About

EXECUTIVE SUMMARY

Research is now exploring at-home diagnostics for detection of HIV. There is no test kit available to allow U.S. consumers to interpret test results at home.
- Home Access Health Corp. of Hoffman Estates, IL, is the only company that has received regulatory approval for a home collection-test system. However, the test requires users to collect a blood specimen, then mail it to a laboratory for professional testing.
- Two companies are seeking regulatory approval of over-the-counter tests that will allow users to test and receive rapid results in the privacy of their homes.

25% of individuals in North America and Canada and about 70% worldwide, are unaware of their serostatus," says **Nitika Pant Pai**, MD, MPH, PhD, assistant professor of medicine in the Division of Clinical Epidemiology and Infectious Diseases at McGill University in Montreal, Quebec, Canada. "So those individuals who desire and do not wish to get tested in centers and desire confidentiality can get to know their status in the comfort of their home."

Pai, whose research has focused on point-of-care diagnostics and assessing the impact of treatment regimens in HIV/AIDS and related co-infections, sees at-home testing as a way for people to know their status and then act on it.

What are some of the potential disadvantages of at-home testing? Because rapid tests are antibody-based, they are unable to detect acute infection, notes Pai. In instances in which a patient might suspect a risky exposure but obtains a negative test result, he or she will need to consider additional blood-based confirmatory testing and post-test counseling, she notes.[2]

Building in a strategy to link at-home testers with post-testing counseling will be an important part of self-testing, says Pai. Post-test counseling provides triage to care, social support, prevention services, prevention of adverse psychological outcomes, and risk of suicide and litigation.[2]

Testing without the presence of a health care professional or a counselor can prove to be stressful. Developers of at-home tests will need to incorporate links to counseling services to help test users accurately understand and comprehend the implications and interpretations of a test result. Such links will be important in helping at-home testers deal with reactive, false-positive/-negative, or indeterminate test results.[2]

"Most of these self-tests are preliminary tests; they are accurate, but they do not detect acute infection, so you have to get a confirmatory test if you suspect a recent unprotected exposure," emphasizes Pai. "In cases where you get a positive test, it is extremely important to contact the healthcare provider or the nearest available counselor for seeking confirmatory testing and post-test counseling."

REFERENCES

1. White House Office of National AIDS Policy. *National HIV/AIDS Strategy*. Fact sheet. Accessed at http://www.aids.gov/federal-resources/policies/national-hiv-aids-strategy/nhas-fact-sheet.pdf.

2. Pai NP, Klein MB. Are we ready for home-based, self-testing for HIV? *Future HIV Therapy* 2008; 2:515-520. ■

New condoms eyed for men, women

A California-based company is looking at new condom designs, including a male non-rolled silicone condom, a female silicone condom, and a silicone condom designed specifically for receptive anal intercourse. All three designs of Origami condoms are in early research stages at Culver City, CA-based Strata Various Product Designs.

The Origami Male Condom is a unique, non-rolled, one-size-fits-all condom, made of biocompatible silicone, says **Ray Chavez**, project coordinator. It is designed to help resolve many of the issues that have prevented the rolled latex condom to be used consistently and correctly, he notes; for example, its non-rolled design will allow a quick, easily managed donning procedure. The focus of the new design is aimed at providing pleasure for both partners while affording increased safety and protection, he notes.

"Pre-clinical testing at a leading independent microbiology lab showed the material was 100% viral impermeable, compared with one of the leading brand of latex condoms, which had a 5% failure for viral permeability," states Chavez. "This test was repeated with pinholes punctured into the condom walls, and the results were again 100% viral impermeable in both directions with the silicone prototype."

A pilot study of the male condom was conducted in 2005 by the California Family Health Council in Los Angeles. The device was further developed in research and development for a subsequent Phase I feasibility & acceptability study by the council, scheduled to begin in August 2011. The National Institutes of Health contributed funds toward the Phase I trial, says Chavez.

The Origami female condom is designed with a no-fumble insertion method, part of a patent-pending feature based on a user-friendly telescoping design. The condom is inserted as a small dome-shaped cap that lodges in the vagina. The condom then deploys to its full length at the start of intercourse. Phase I testing also is scheduled for 2011 at the San Francisco office of RTI International. *(Read more about the female condom; see the* Contraceptive Technology Update *article, "Female condoms hit the spotlight — Will U.S. women see more options?" May 2011, p. 49.)*

Phase 1 testing has begun at the Boston-based Fenway Institute Research Center for the Origami

R.A.I. Condom, an inserted, dedicated device designed for receptive anal intercourse. The active male partner does not need to wear a male condom at all, thus simulating the sensation of sex without a condom, explains Chavez. It is the first condom ever designed for this use, he states.

More designs equals more use?

Will these new condom designs offer more choices for different "endowments"? asks **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. Men's penile dimensions vary widely, and the size limitations of condoms impede condom use, points out a recent editorial co-authored by Nelson.[1]

According to a 2010 study, men who report wearing poorly-fitting condoms are more likely to remove condoms before penile–vaginal sex.[2] Men with ill-fitting condoms reported much higher rates of multiple problems including condom breakage and slippage, more difficulty for either partner to achieve orgasm, diminished pleasure for both partners, penile irritation, difficulty with or lost erection, early removal of condom, and condom drying out during sex.[2] *(*CTU *reported on the study; see "Study shows condom fit impacts its usage," June 2010, p. 64.)*

Findings from the largest nationally representative study of sexual and sexual health behaviors ever fielded give reproductive health clinicians a window on current condom usage.[3] In the study, a national probability sample of 5,865 U.S. adolescents and adults ages 14 to 94, condom use was highest among unmarried adults, higher among adolescents than adults, and higher among black and Hispanic individuals when compared with other racial groups.[3]

In looking at adolescents who participated in the study, researchers report condom use for penile-vaginal intercourse was reported for a majority of events.[4] However, in looking at men and women above age 50, researchers found low rates of condom use, despite the fact that 20-30% remained sexually active into their 80s.[5]

"Although these individuals may not be as concerned about pregnancy, this suggests the need to enhance education efforts for older individuals regarding STI [sexually transmitted infection] risks and prevention," said **Michael Reece**, PhD, MPH, director of the Center for Sexual Health Promotion in Bloomington-based Indiana University's School of Health, Physical Education, and Recreation in a statement accompanying the research.

EXECUTIVE SUMMARY

A California-based company, Strata Various Product Designs, is looking at new condom designs, including a male non-rolled silicone condom, a female silicone condom, and a silicone condom designed specifically for receptive anal intercourse. All three are in early stages of clinical testing.

- The Origami Male Condom is a unique non-rolled, one-size-fits-all condom, made of biocompatible silicone.
- The Origami female condom is designed with a no-fumble insertion method, part of a patent-pending feature based on a user-friendly telescoping design.
- The Origami R.A.I. Condom is an inserted, dedicated device designed for receptive anal intercourse.

REFERENCES

1. Cecil M, Nelson AL, Trussell J, et al. If the condom doesn't fit, you must resize it. *Contraception* 2010; 82:489-490.
2. Crosby RA, Yarber WL, Graham CA, et al. Does it fit okay? Problems with condom use as a function of self-reported poor fit. *Sex Transm Infect* 2010; 86:36-38.
3. Reece M, Herbenick D, Schick V, et al. Condom use rates in a national probability sample of males and females ages 14 to 94 in the United States. *J Sex Med* 2010; 7 Suppl 5:266-276.
4. Fortenberry JD, Schick V, Herbenick D, et al Sexual behaviors and condom use at last vaginal intercourse: a national sample of adolescents ages 14 to 17 years. *J Sex Med* 2010; 7 Suppl 5:305-314.
5. Schick V, Herbenick D, Reece M, et al. Sexual behaviors, condom use, and sexual health of Americans over 50: implications for sexual health promotion for older adults. *J Sex Med* 2010; 7 Suppl 5:315-329. ■

Build skill in taking teen sexual histories

Why is it so important that providers develop their skills when it comes to taking an adolescent sexual history? Each year in the United States, there are about 19 million new sexually transmitted infections (STIs), almost half of which are in young people ages 15-24.[1]

Taking an adolescent sexual history is a critical skill to develop for adolescent health providers,

says **Alicia St. Andrews**, MPH, CHES, coordinator of the San Francisco-based Adolescent Health Working Group, a nonprofit group aimed at strengthening the adolescent health provider network. Healthcare providers, including pediatricians and other primary care physicians, are in an ideal position to provide sexual health information, screening, and treatment to adolescents as part of preventive health care, observes St. Andrews. Unfortunately, while two-thirds of adolescent patients report wanting information about STIs and pregnancy from their healthcare providers, few have ever discussed these issues with their provider.[2]

"Many primary care providers lack the training or are uncomfortable discussing sexual health issues with their adolescent patients," notes St. Andrews. "In fact, fewer than half of primary care providers routinely ask adolescents about their sexual activity, and far fewer ask specifically about STIs, condom use, sexual orientation, number of partners, or sexual abuse, despite the fact that care guidelines universally recommend obtaining comprehensive sexual histories from adolescents."

The Adolescent Health Working Group has recently released *Sexual Health: An Adolescent Provider Toolkit*, an updated and expanded version of its 2003 California-based version.[3] The new toolkit champions a paradigm shift from a deficit/risk-based perspective to one that embraces adolescent sexuality as positive and normative in this stage of development, says St. Andrews. *(To download a free copy, go to the group's web site, www.ahwg.net. Under "Resources," select "For Providers," "Adolescent Provider Toolkit Series," and "Sexual Health, 2010, 2nd edition.")*

What has been the response to the toolkit? St. Andrews says the group has received positive responses from primary care providers, school-based health providers, educators, and advocates who have utilized the Sexual Health Toolkit module and participated in related training.

COMING IN FUTURE MONTHS

- HIV prevention: More options come to light
- More states eye abortion restrictions
- Adolescent birth rate shows drop
- Contraceptive vaginal ring: Good fit for teens?
- Check your use of HPV tests

EXECUTIVE SUMMARY

Taking an adolescent sexual history is a critical skill for adolescent health providers. Taking a more effective history might help identify teens at risk for disease. Each year in the United States, there are about 19 million new sexually transmitted infections (STIs); almost half are in young people ages 15-24.

- While two-thirds of adolescent patients report wanting information about STIs and pregnancy from their healthcare providers, few say they have ever discussed these issues with their provider.
- Create a safe and confidential environment for teens to discuss potential sexual health concerns before the visit. Post your clinic's confidentiality policy in the waiting room and exam room, as well as on your facility's web site.

It is important that providers create a safe and confidential environment for teens to discuss potential sexual health concerns before the visit, just as it is important to build safe conversations when taking a sexual history, advises **Gail Bolan**, MD, director of the Division of Sexually Transmitted Disease Prevention at the Centers for Disease Control and Prevention.

Strategies include having open-ended sexual health questions as part of a computer-based or paper-based general health assessment and making the confidentiality policy of the clinic available to the teen in the waiting room, exam room, or through a web site, notes Bolan. *(Visit the AHWG web site, ww.ahwg.net. Under "Resources," select "For Youth." Under "Understanding Minor Consent and Confidentiality in CA," select "Quiz: How Well do you Know Your Health Rights and Responsibilities?" Resource also is available in Spanish.)*

Making resources available for parents on the importance of a confidential visit to providing the best care possible for their teen also can help set the stage, she notes. *(Visit the AHWG web site, www.ahwg.net. Under "Resources," select "For Parents/Caregivers." Under "Understanding Minor Consent and Confidentiality in CA," select "Helping Your Teen Take Responsibility For Their Health." The source also is available in Spanish and Chinese.)*

Confidentiality is a key element in talking with adolescents, according to Bolan. Teens are more likely to disclose sensitive information if consent and confidentiality are explained to them. Be sure to review the laws and limits of confidentiality, and review situations in which confidentiality may have

to be breached, such as in cases of reported abuse or suicidal thoughts. (To *check the Guttmacher Institute's overview of minor consent laws, go to its web site, www.guttmacher.org. Select "Adolescents," then under "State Policies in Brief," select "An Overview of Minors' Consent Laws".)*

Cover the "5 P's"

What needs to be covered during the sexual health history? Use the "5 Ps" as a general guide [4]

• **Partners:** Use open-ended questions to determine the number, sex, and concurrency of the teen's sex partners.

• **Practices:** Be sure to explore what constitutes sex, whether it is vaginal, anal, or oral. Learn to be comfortable discussing the full range of sexual activities in which teens often engage, 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. Why? Results of a 2010 study indicate pharyngeal gonorrhea is as high in adolescent women from a children's hospital as in adult women from an STI clinic.[5]

• **Protection against STIs:** This is a chance to check condom use: in what situations they are and aren't used, and those situations that make it harder or easier to employ their use.

• **Past STI history:** Check the patient's history of STIs, including whether their partners have ever had an infection. Explain that adolescents who

continued on p. 108

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. Log on to **www.cmecity.com** to take a post-test; tests can be taken after each issue or collectively at the end of the semester. *First-time users will have to register on the site using the 8-digit subscriber number printed 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 last test of the semester, 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

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

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

9. The levonorgestrel intrauterine system is approved by the Food and Drug Administration for up to five years of use, but may be effective for up to what length of time?
   A. Six years
   B. Seven years
   C. 10 years
   D. 15 years

10. The updated *U.S. Medical Eligibility Criteria for Contraceptive Use* does not recommend use of combined hormonal contraception in postpartum women the first 21 days after birth due to concerns about:
   A. Hemorrhage.
   B. Thyroid dysfunction.
   C. Venous thromboembolism.
   D. Clinical depression.

11. What is the 2015 goal of the National HIV/AIDS Strategy?
   A. 75% of people with HIV will know their serostatus.
   B. 80% of people with HIV will know their serostatus.
   C. 85% of people with HIV will know their serostatus.
   D. 90% of people with HIV will know their serostatus.

12. Of the 19 million new sexually transmitted diseases in the United States, what percentage is in young people ages 15-24?
   A. 10%
   B. 25%
   C. About 50%
   D. More than 50%

continued from p. 107

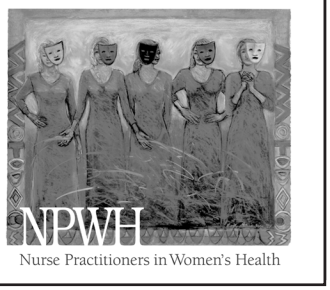
have had a previous STI are more likely to get another infection in the next few months; rescreening can greatly reduce the risk.

• **Pregnancy prevention:** Discuss whether your teen patient wants to become pregnant. Review current and future contraceptive options.

REFERENCES

1. Forhan SE, Gottlieb SL, Sternberg MR, et al. Prevalence of sexually transmitted infections among female adolescents aged 14 to 19 in the United States. *Pediatrics* 2009; 124:1,505-1,512.
2. American Academy of Pediatrics: Committee on Psychosocial Aspects of Child and Family Health and Committee on Adolescence. Sexuality education for children and adolescents. *Pediatrics* 2001; 108:498-502.
3. Monasterio E, Combs N, Warner L, et al. *Sexual Health: An Adolescent Provider Toolkit*. San Francisco: Adolescent Health Working Group, San Francisco; 2010.
4. Bolan G. *Taking An Adolescent's Sexual History*. Podcast. Accessed at http://www.medscape.com/viewarticle/743130.
5. Giannini CM, Kim HK, Mortensen J, et al. Culture of non-genital sites increases the detection of gonorrhea in women. *J Pediatr Adolesc Gynecol* 2010; 23:246-252. ■

Contraceptive Technology Update is endorsed by the National Association of Nurse Practitioners in Women's Health and the Association of Reproductive Health Professionals as a vital information source for healthcare professionals.



S·T·I
QUARTERLY

Test now for *trichomonas* infection: New data shows spread of disease

Infection more than twice as common in women over age 40

Trichomoniasis, caused by the parasite *Trichomonas vaginalis*, is the most common sexually transmitted infection (STI) in the nation, with an estimated 7.4 million men and women newly infected each year.[1]

New study evidence now indicates the STI is more than twice as common in women over 40 than previously thought.[2] Among 7,593 U.S. women between ages 18-89, women 50 and older had the highest trichomonas infection rate, at 13%, with 11.3% of women in their 40s testing positive for the infection. In comparison, adolescents ages 18-19 recorded an 8.5% infection rate.[2] The study, which collected test samples from women in 28 states, is believed to be the largest and most in-depth analysis of the STI ever performed.

"We usually think of STIs as more prevalent in young people, but our study results clearly show that with trichomonas, while too many young people have it, even more, older women are infected," says **Charlotte Gaydos**, MS, DrPH, professor of medicine in the Division of Infectious Diseases at Johns Hopkins University in Baltimore, MD, and senior study investigator.

Trichomonas infections are quite treatable with antibiotics, says Gaydos. The high numbers of infections found in the current study warrant older women getting screened by family physicians and gynecologists during routine check-ups to make sure they are not infected and are not inadvertently spreading it to others, she states.

Clinicians are not aware that new research indicates that trichomonas infection has been associated with HIV acquisition,[3,4] says Gaydos. It also is highly associated with adverse birth outcomes, such as low birth weight and premature rupture of membranes,[5] she notes. With current evidence

EXECUTIVE SUMMARY

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- Among 7,593 U.S. women between ages 18-89, women 50 and older had the highest trichomonas infection rate, at 13%, with 11.3% of women in their 40s testing positive for the infection. In comparison, adolescents ages 18-19 recorded an 8.5% infection rate.
- Gen-Probe of San Diego received approval in April 2011 from the Food and Drug Administration for its Aptima trichomonas assay.
- Treatment of the infection is simple, with recommended regimens calling for metronidazole, 2 g orally in a single dose, or tinidazole, 2 g orally in a single dose.

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Consulting Editor **Robert A. Hatcher**, MD, MPH, 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. **Sharon Schnare** (Nurse Reviewer) discloses that she is a retained consultant and a speaker for Barr Laboratories, Berlex, and Organon; she is a consultant for 3M Pharmaceuticals; and she is a speaker for FEI Women's Health, Ortho-McNeil Pharmaceuticals, and Wyeth-Ayerst Pharmaceuticals.

now in hand, trichomonas infection should now be added to the list of reportable STIs, says Gaydos.

STI gets no respect

However, trichomonas is the "Rodney Dangerfield" of the STIs in the way it is perceived by clinicians and often by laboratory people as well, says **Marcia Hobbs**, PhD, research associate professor of medicine, microbiology, and immunology at the University of North Carolina at Chapel Hill School of Medicine. Hobbs, a molecular microbiologist, presented on the subject at the Quebec City conference.[6]

Because it is not a bacteria or a virus, for many people, trichomonas "falls off the radar" in terms of being an important microorganism and pathogen, Hobbs observes. Given that it is more difficult to manipulate in the laboratory, inadequate and insensitive diagnostics have been developed to detect it, she notes.

Why hasn't more attention been given to detecting trichomonas infection? Hobbs uses the analogy of looking for missing car keys under a street light, not because the keys were lost in that location, but that the light is shining there. "We know how to look for other things, and we look for what we know how to look for," she observes. "Because we haven't had very good tools to look for trichomonas, we therefore have not looked for it, and so we don't really know a lot about it."

Gaydos agrees with Hobbs' assessment and notes that available tests in the past have included wet preparation, which offers about 50% sensitivity, and culture, which takes several days and is only about 70% sensitive. Thus, if no one tests, or uses a substandard test, not many receive treatment, says Gaydos.

New test now available

Testing for trichomonas might change with the advent of a new assay. Gen-Probe of San Diego received approval in April 2011 from the Food and Drug Administration (FDA) for its Aptima Trichomonas assay for use on its fully automated Tigris system. *(*Contraceptive Technology Update *reported on the test; see "New test approved for* trichomonas vaginalis*," June 2011, p. 66.)*

Results of the clinical trial used to gain FDA clearance for the assay were presented at the Quebec City conference. To perform the study, researchers tested 933 women attending nine obstetric/gynecology, adolescent, family planning or sexually transmitted disease clinics in the United States. Data indicates sensitivity of the assay was high in all specimens tested and much higher than that usually reported for wet mount and culture, researchers report.[7] The amplified nucleic acid assay may be used to test clinician-collected endocervical or vaginal swabs, urine, and specimens collected in PreservCyt solution from symptomatic or asymptomatic women.

STI is often silent

While trichomonas infection can cause symptoms such as vaginitis and cervicitis in women and urethritis in women and men, in most cases, the infection is asymptomatic.[8]

Because confirmed cases of trichomonas infection do not have to be reported to local public health officials and the Centers for Disease Control and Prevention (CDC), public health officials are not made aware how prevalent it really is, observes Gaydos.

Treatment of the infection is simple, says Hobbs. The CDC recommended regimens for trichomoniasis treatment call for metronidazole, 2 g orally in a single dose, or tinidazole, 2 g orally in a single dose.[9] An alternate regimen is metronidazole, 500 mg orally twice a day for seven days. Advise patients to avoid consuming alcohol during treatment with metronidazole or tinidazole; abstinence from alcohol use should continue for 24 hours after completion of metronidazole or 72 hours after completion of tinidazole.[9]

Resistance to metronidazole is on the rise,[10] says Hobbs. Trichomonas is a microorganism that has the ability to change its genetic coding capacity; therefore, it will evolve resistance as time goes on, she notes. "Development of new treatments is definitely going to be needed," says Hobbs. "Because the more we look for it and treat, the more likely resistance is to emerge."

REFERENCES

1. Centers for Disease Control and Prevention. Trichomoniasis. Fact sheet. Accessed at http://www.cdc.gov/std/trichomonas/STDFact-Trichomoniasis.htm.
2. Ginocchio CC, Chapin K, Smith JS, et al. *Prevalence of* Trichomonas vaginalis *and coinfection with* Chlamydia trachomatis *and* Neisseria gonorrhoea *in the USA as determined by the Aptima* Trichomonas vaginalis *nucleic acid amplification assay*. Presented at the International Society for STD Research. Quebec City, Canada; 2011.
3. McClelland RS, Sangare L, Hassan WM, et al. Infection with *Trichomonas vaginalis* increases the risk of HIV-1 acqui-

sition. *J Infect Dis* 2007; 195:698-702.
4. Mavedzenge SN, Pol BV, Cheng H, et al. Epidemiological synergy of *Trichomonas vaginalis* and HIV in Zimbabwean and South African women. *Sex Transm Dis* 2010; 37:460-466.
5. Cotch MF, Pastorek JG 2nd, Nugent RP, et al. *Trichomonas vaginalis* associated with low birth weight and preterm delivery. The Vaginal Infections and Prematurity Study Group. *Sex Transm Dis* 1997; 24:353-360.
6. Hobbs, MM. *Trichomoniasis: why is it the neglected STD?* Presented at the International Society for STD Research. Quebec City, Canada; 2011.
7. Schwebke JR. *Clinical evaluation of the Aptima* trichomonas vaginalis *assay in asymptomatic and symptomatic female subjects*. Presented at the International Society for STD Research. Quebec City, Canada; 2011.
8. Hobbs MM, Kazembe P, Reed AW, et al. Trichomonas vaginalis as a cause of urethritis in Malawian men. *Sex Transm Dis* 1999; 26:381-387.
9. Centers for Disease Control and Prevention. Sexually transmitted diseases treatment guidelines, 2010. *MMWR* 2010; *59*(RR12);1-110.
10. Dunne RL, Dunn LA, Upcroft P, et al. Drug resistance in the sexually transmitted protozoan *Trichomonas vaginalis*. *Cell Res* 2003; 13:239-249. ■

Options running out for gonorrhea treatment

Although there have been no documented treatment failures in the United States, untreatable gonorrhea might become a reality in this country, according to a new report from the Centers for Disease Control and Prevention (CDC).[1] Time is of the essence in determining a new course of action. An international research team has just discovered a strain of gonorrhea resistant to all available antibiotics.[2]

The research team reported its findings at the July 2011 annual conference of the International Society for Sexually Transmitted Disease Research in Quebec City, Canada. The scientists have been able to successfully identify a heretofore-unknown variant of the bacterium that causes gonorrhea, Neisseria gonorrhoeae. By examining the new strain, now dubbed H041, investigators have been able to identify the genetic mutations responsible for the bacterium's extreme resistance to all cephalosporin-class antibiotics, the last remaining drugs still effective in treating the sexually transmitted infection (STI).

"Cephalosporins are our last line of defense for treating gonorrhea, and as far as I'm aware, no new antibiotics are in the research pipeline," says **Bob Kirkcaldy**, MD, MPH, medical officer in the CDC's Division of STD Prevention and author of the CDC report. "This is why CDC is calling on both public and private partners to make finding new treatment solutions a high priority."

Gonorrhea control relies heavily on antibiotics, and researchers need to identify new effective drugs or drug combinations, Kirkcaldy observes. There are existing efforts to study existing antibiotics to see if they are safe and effective for the treatment of gonorrhea, one which includes a collaboration between the National Institutes of Health and the CDC. "However, we can't predict the results of the current studies, so additional studies of drugs or drug combinations are urgently needed," says Kirkcaldy.

Public health on lookout

The CDC reports notes the highest level of resistance to cephalosporins, regardless of sexual partner, was found in the Western region of the United States, particularly Hawaii and California, as well as in men who have sex with men in all regions.

The new data outlines what state and local health departments have been seeing on the front lines: that highly untreatable gonorrhea is near, said **William Smith**, executive director of the Washington, DC-based National Coalition of STD Directors, in a statement following the CDC report. "There are currently no new drugs in development for this infection," said Smith. "If this last class of drugs fails, we will have no definitive treatment options for gonorrhea."

Since 1986, the CDC's Gonococcal Isolate Surveillance Project routinely has monitored gonorrhea drug susceptibility by collecting samples from men with urethral gonorrhea at STD clinics in about 30 U.S. cities. The project has been able to detect the

EXECUTIVE SUMMARY

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- An international research team has just discovered a strain of gonorrhea resistant to all available antibiotics.
- Providers should obtain cultures to test for decreased susceptibility from any patients with suspected or documented gonorrhea treatment failures. Any suspected treatment failure should be reported within 24 hours to local or state public health officials to help ensure that any future resistance is recognized early, CDC guidance states.

disease's resistance to many classes of antimicrobials once recommended for treatment. Quinolone-resistant Neisseria gonorrhoeae strains are widely disseminated throughout the United States and the world, and as a result, quinolones are not recommended for the treatment of gonorrhea. *(*Contraceptive Technology Update *reported on the change in recommendations; see "New recommendations out for gonorrhea treatment," June 2007, p. 64.)*

Use the latest CDC guidelines for treatment. For uncomplicated gonococcal infections of the cervix, urethra, and rectum, the recommended regimens are

- ceftriaxone 250 mg intramuscular injection in a single dose; or if not an option:
- cefixime 400 mg orally in a single dose;
- or single-dose injectable cephalosporin regimens, plus azithromycin 1g orally in a single dose OR doxycycline 100 mg orally twice a day for seven days.[3]

In addition, CDC officials ask that healthcare providers obtain cultures to test for decreased susceptibility from any patients with suspected or documented gonorrhea treatment failures. Clinicians also should report any suspected treatment failure to local or state public health officials within 24 hours to help ensure that any future resistance is recognized early.[4]

The CDC is calling for state and local health departments and other laboratories to maintain culture capacity so that antibiotic resistance testing can be quickly performed and reported. If antibiotic resistance testing cannot be performed locally, facilities should identify and partner with other labs that can perform such testing, CDC officials note. The agency asks health departments to develop local response plans and immediately notify the agency of treatment failures. Laboratories also should report isolates with decreased susceptibility to cefixime or ceftriaxone to local or state public health officials, CDC officials state.[4]

REFERENCES

1. Centers for Disease Control and Prevention (CDC). Cephalosporin susceptibility among Neisseria gonorrhoeae isolates — United States, 2000-2010. *MMWR* 2011; 60:873-877.
2. Ohnishi M, Unemo M, Golparian D, et al. The new superbug Neisseria gonorrhoeae makes gonorrhoea untreatable? First high-level ceftriaxone resistance worldwide and public health importance. *Sex Transm Infect* 2011. Doi:10.1136/sextrans-2011-050109.121.
3. Centers for Disease Control and Prevention. Sexually transmitted diseases treatment guidelines, 2010. *MMWR* 2010; 59(RR12); 1-110.
4. Centers for Disease Control and Prevention. Antibiotic Treatment of Gonorrhea. Fact sheet. Accessed at http://www.cdc.gov/nchhstp/Newsroom/docs/Antibiotic-Treatment-of-GC-fact-sheet.pdf. ■

Submit abstracts now for 2012 STD conference

Received a promising program aimed at preventing transmission of sexually transmitted diseases (STDs)? Circle Oct. 14 as the deadline for abstract submission for the 2012 National STD Prevention Conference March 12-15 in Minneapolis.

Organizers for the national meeting are inviting program staff from project areas funded by the Division of STD Prevention at the Centers for Disease Control and Prevention to submit one poster abstract profiling a promising program activity or series of activities. In choosing a potential project, consideration should be given to such elements as preliminary or final results and implications from promising programs; program development and implementation challenges and successes along with lessons learned; the use of or opportunities for quality improvement; and/or innovative new methods for STD prevention and control within project areas. Project areas should consider submission of activities that have succeeded, partially succeeded, or failed in achieving anticipated results, and should include cost and/or cost-effectiveness data when available.

Only one abstract may be submitted per project area, conference organizers emphasize. Project organizers are encouraged to partner with local health departments or community-based organizations if the activity presented is implemented through one of these venues. Presenters should be prepared to discuss their submission in roundtable format should their project be selected for inclusion in the program showcase roundtable session.

To submit abstracts, visit the conference website, http://www.cdc.gov/stdconference. Click on "Submit Abstracts Online."

Reproductive health clinicians should make plans to attend the conference because it is taking place prior to the scheduled implementation of key provisions in the upcoming federal Affordable Care Act. The theme of the conference, "STD Prevention Innovation: Solutions for the Era of Healthcare Reform," reflects how the field of STD prevention and control is positioning itself to respond to changes in the healthcare system. ■