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IN THIS ISSUE

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Ovarian cancer — What can be done to prevent spread of the disease?

Prevention approaches eyed for women with and without BRCA mutations

Much media attention has been given lately to actress Angelina Jolie, who underwent prophylactic double mastectomies after learning that she had a breast cancer susceptibility gene 1 (BRCA1) abnormality. But women with harmful BRCA mutations also are at risk for ovarian cancer, which often escapes early detection because laboratory and imaging screening tools are less effective than those developed for breast cancer.[1] Subsequently, ovarian cancer is marked with a less-robust five-year survival rate (44%), compared with nearly 90% for breast cancer.[2]

BRCA1 and BRCA2 belong to a class of genes known as tumor suppressors. In normal cells, BRCA1 and BRCA2 help ensure the stability of the cell's genetic material and stem uncontrolled cell growth. When mutation occurs, however, both have been linked to the development of hereditary breast and ovarian cancer.

According to the National Cancer Institute, the likelihood that a breast

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and/or ovarian cancer is associated with a harmful mutation in BRCA1 or BRCA2 is highest in families with a history of multiple cases of breast cancer, cases of breast and ovarian cancer, one or more family members with two primary cancers, or those with an Ashkenazi (Central and Eastern European) Jewish background. However, not every woman in such families carries a BRCA mutation, and not every cancer in such families is linked to a BRCA mutation. Also, not every woman with a harmful BRCA1 or BRCA2 mutation will develop breast and/or ovarian cancer.[3]

About 12% of women in the general population will develop breast cancer during their lives, compared with about 60% of women who have inherited a harmful BRCA1 or BRCA2 mutation. In comparison, about 1.4% of women in the general population will be diagnosed with ovarian cancer, but 15-40% women with a BRCA1 or BRCA2 mutation will develop the disease.[3]

Genetic tests, performed on blood samples, can detect harmful BRCA mutations. According to the National Cancer Institute, there are no current standard criteria for recommending or referring someone for BRCA1 or BRCA2 mutation testing.[3] Genetic counseling generally is recommended before and after tests to help patients understand their risk assessment.

In a family with a history of breast and/or ovarian cancer, the National Cancer Institute indicates that it might be best to first test a family member who has breast or ovarian cancer. If that person is found to have a harmful BRCA1 or BRCA2 mutation, then other family members can be tested to see if they also have the mutation. Cost for such tests can range from several hundred to several thousand dollars; patients may wish to consult their insurance companies for the extent of coverage for such tests.[3]

Fallopian tube targeted

Like Jolie, many women with harmful BRCA mutations are considering removal of breasts, ovaries, or fallopian tubes to lower their cancer risk. Women who elect such surgery see themselves as "previvors" — getting ahead of possible impact

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Editorial Questions

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EXECUTIVE SUMMARY

Women with breast cancer susceptibility gene (BRCA) mutations are at risk for breast and ovarian cancers. Ovarian cancer often escapes early detection because laboratory and imaging screening tools are less effective than those developed for breast cancer. Ovarian cancer is marked with a less-robust five-year survival rate (44%), compared with nearly 90% for breast cancer.

- About 12% of women in the general population will develop breast cancer, compared with about 60% of women who have inherited a harmful BRCA1 or BRCA2 mutation.
- About 1.4% of women will be diagnosed with ovarian cancer, but 15-40% women with a BRCA1 or BRCA2 mutation will develop the disease.

from cancer spread.[4]

High grade serous ovarian cancer, which causes 70% of ovarian cancer deaths, can originate in the fallopian tubes.[2] For women with harmful BRCA mutations, current medical practice looks to bilateral salpingo-oophorectomy at age 40 or upon completing childbearing. Bilateral salpingo-oophorectomy reduces the risk for ovarian and fallopian tube cancers by 85%-90%.[2] However, removal of ovaries leads to premature menopause, which can have adverse effects.[5]

Because most BRCA-associated ovarian cancers appear to arise in the fallopian tube, salpingectomy might be an alternative to bilateral salpingo-oophorectomy. Researchers recently compared the costs and benefits of salpingectomy with bilateral salpingo-oophorectomy among BRCA mutation carriers. They found that when considering quality-adjusted life expectancy, bilateral salpingectomy with delayed oophorectomy is a cost-effective strategy and might be an acceptable alternative for those unwilling to undergo bilateral salpingo-oophorectomy.[5]

There is an ongoing study in France that is evaluating risk-reducing fimbriectomy (removal of the distal part of the fallopian tube), as opposed to salpingectomy, as an alternative to standard bilateral salpingo-oophorectomy, says **Janice Kwon**, MD MPH FRCSC, assistant professor in the Division of Gynecologic Oncology at the University of British Columbia in Vancouver.

Results from that study will not be available until several years from now, she states.

Kwon's research team, which published the cost/benefit study, is performing an analysis to evaluate whether salpingectomy, with or without oophorectomy, would be a cost-effective risk-reducing intervention for women in the general population or for women who have a higher-than-average risk, but do not carry a mutation in BRCA1 or 2.

When to remove tubes?

Patients and providers are showing a growing acceptance of routinely removing the fallopian tubes, but preserving the ovaries during hysterectomy to avoid risk of ovarian cancer. Women who do not have harmful BRCA mutations are considering such a move, as indicated in a recent paper presented at the American College of Obstetricians and Gynecologists' annual meeting.[6]

Researchers at the University of California, Los Angeles (UCLA) undertook a retrospective study of women who underwent an abdominal, vaginal, or laparoscopic hysterectomy with ovarian preservation at Olive View-UCLA Medical Center between January 2009 and June 2012. Investigators reviewed medical records for 1,060 patients and collected data on these women about being offered bilateral salpingectomy, as well as actual completion of the procedure at the time of hysterectomy. All but two patients who were offered salpingectomy in the study consented. Six of the consenting patients could not have the procedure due to complications. Bilateral salpingectomy rates rose from 3% in 2009 and 2010 to 33% in 2011 and 77% in the first six months of 2012, data indicate.[6]

"There is high patient and provider acceptance of this practice," says **Susan Park**, MD, UCLA researcher. "Our study aids physicians in assuring patients that there does not appear to be any increased risk of surgical complications associated with performing salpingectomy at time of hysterectomy."

The UCLA study did not look at the possible role or risks and benefits of salpingectomy in patients undergoing tubal sterilization procedures, or the role of salpingectomy in women with a genetic predisposition to ovarian cancer. It examined only surgical morbidity.

"We did not study the important long-term outcomes, such as the risks of developing post-hysterectomy adnexal masses or cancers," stated Park in a press release accompanying the ACOG presentation. "Such a study is an important next step, but would need to be done at a much larger scale than a single institution study."

Despite the progress that has been made in surgical approaches to reducing ovarian cancer risk, there is still work to be done in developing tests that can provide early diagnosis of the disease, says Robert Hatcher, MD, MPH, professor emeritus of gynecology and obstetrics at Emory University School of Medicine in Atlanta.

"We do not have tests that will diagnose ovarian cancer early," says Hatcher.

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U.S. drops age limits for Plan B One-Step

The United States is dropping its appeal against a court order to lift age restrictions on emergency contraceptive pills (ECPs) so the best-known ECP, Plan B One-Step, may be sold over the counter to women of all ages.

The Obama administration said June 10 it would comply with U.S. District Edward Korman's April 2012 ruling to make Plan B One-Step available over the counter without age or point-of-sale restrictions. *(Did you receive the* Contraceptive Technology Update *bulletins issued on June 6 and June 11 on the latest legal moves with emergency contraception? To receive breaking news as it occurs, provide your e-mail address to AHC Media customer service at (800) 688-2421 or customerservice@ahcmedia.com.)*

The Food and Drug Administration (FDA) on June 20 approved the new label for Plan B One-Step, which allows it to be sold over the counter without age restrictions.

According to a June 10 letter submitted by the Department of Justice to District Judge Edward Korman, the department says it expects the sponsors of the generic versions of Plan B One-Step to submit appropriate amendments to their abbreviated new drug applications to the FDA. If FDA grants Teva marketing exclusivity, though, the scope of that exclusivity might affect the labeling that could be approved for generic equivalents of the drug, the letter notes. Plan B One-Step generated $82.6 million in sales in 2012, followed by generic version Next Choice (Actavis, Parsippany, NJ) with $56.3 million, according to data compiled by IMS Health, a Danbury, CT, healthcare technology and information company.

Additionally, the FDA will not take steps to change the approval status of the two-pill Plan B or its generic equivalents, states the Department of Justice letter. This move is a reversal of actions following the June 6 appeals court ruling that would have allowed all-age access to two-pill ECP versions. Stock of such product might be limited, however, due to the increased popularity of the one-dose version of the drug.

The FDA is finally taking a "significant step" forward by making Plan B One-Step available over the counter for women of all ages, noted Nancy Northup, president and chief executive officer of the New York City-based Center for Reproductive Rights in a June 10 press statement. However, the Obama Administration continues to unjustifiably deny the same wide availability for generic, more affordable brands of emergency contraception, Northup says. The center will continue to advocate for fair treatment who want and need more affordable options than the branded single-dose ECP, she says.

Advocates hail halt to restrictions

Reproductive health advocates are cheering the removal of age restrictions for Plan B One-Step.

"We finally see light at the end of the tunnel in our decade-long fight to give all women access to a safe, reliable, back-up contraceptive option," said **Susannah Baruch**, interim president and chief executive officer of the Washington, DC-based Reproductive Health Technologies Project. "We will continue to hold the administration accountable in ensuring that all emergency contraception products, including generics, are available over the counter without age restrictions."

Cecile Richardson, president of New York City-based Planned Parenthood Federation of America, issued a press statement on behalf of the organization to encourage manufacturers of emergency contraception to quickly request new labeling, as well as for the FDA to issue immediate approvals, to make all levonorgestrel ECPs available to all women.

Will adolescents, as well as young women, be able to safely use Plan B One-Step now that it will be available over the counter? Data indicates that young and adult women find the label and instructions for

EXECUTIVE SUMMARY

The United States is dropping its appeal against a court order to lift age restrictions on emergency contraceptive pills (ECPs) so the best-known ECP, Plan B One-Step, may be sold over the counter to women of all ages.
- The Food and Drug Administration (FDA) has since approved Plan B One-Step's new label, which allows it to be sold without restrictions.
- Manufacturers of generic versions of the ECP are asked to submit amendments to their FDA abbreviated new drug applications to be considered for over-the-counter sales. If marketing exclusivity is given to Plan B One-Step, however, such access for generics might be limited.

levonorgestrel ECPs easy to understand.[1,2] Research also shows that teens and young women who received multiple ECP supplies at one time did not use the pills repeatedly in place of routine contraceptive methods.[3]

The levonorgestrel-only regimen is simple to follow, and medical supervision is not necessary for correct use.[4]

According to the New York City-based International Consortium for Emergency Contraception, which tracks EC availability around the globe, six countries offer direct access to emergency contraception: Bangladesh, Canada, India, Netherlands, Norway, and Sweden. A total of 65 countries allow access to EC from a pharmacist without a prescription.

It is important for all women of all ages to have access to emergency contraceptive pills, but women who need them once might need them many more times in a year, states **Robert Hatcher**, MD, MPH, professor emeritus of gynecology and obstetrics at Emory University School of Medicine in Atlanta. Because of their cost, very few women use ECPs every time they have totally unprotected sex or make mistakes using combined pills as their regular contraceptive, says Hatcher.

"The global effect of ECPs is close to zero," asserts Hatcher. "The emphasis should shift immediately to the emergency insertion of Copper T 380A [ParaGard] intrauterine devices."

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Effectiveness of training for implants confirmed

Data gathered from a clinical training program instituted at the 2006 introduction of the single-rod etonogestrel contraceptive implant Implanon (Merck & Co., Whitehouse Station, NJ) show that complications in the first five years of device use have been low, indicating the success of the program.[1]

Problems related to insertion and particularly removal led to Wyeth (now Pfizer) removing Norplant, the first generation six-rod contraceptive implant system, from the market, recalls **Andrew Kaunitz**, MD, professor and associate chair in the Obstetrics and Gynecology Department at the University of Florida College of Medicine — Jacksonville. When Implanon was introduced, Merck instituted a unique mandatory clinical training program to ensure that only trained clinicians had access to the implant. A related active monitoring program was instituted as part of the Food and Drug Administration's (FDA) postapproval commitment to monitor the program's effectiveness through tracking insertion, localization, and removal-related events.

Of 42,238 clinicians who completed the training from July 2006 to October 2011, 4,294 (10.2%) enrolled in the monitoring program. A total of 25,629 forms (20,466 insertions, 5,163 removals) were collected and subsequently submitted to the FDA. A total of 1,227 insertion, localization, and removal-related events were reported from 538 women.

Among insertion-related events, "difficult insertion" was the most common (80%, 156/195). "Difficult removal" was the most common removal-related event that was reported, and it represented 95% (316/334) of events in this category. Most of the difficult removals related to the need for incision enlargement, difficulty dissecting fibrous tissue surrounding the implant, or difficulty grasping the implant. The remaining 698 reports were categorized as localization-related or other.[1]

Clinically important events included noninsertion (n = 4, two pregnancies), serum ENG positive, but

EXECUTIVE SUMMARY

An analysis of a clinical training program instituted at the 2006 introduction of the single-rod etonogestrel contraceptive implant Implanon shows that complications in the first five years have been low.

- Problems related to device insertion and removal led to the market withdrawal of Norplant, the first generation six-rod contraceptive implant system. With Implanon, the manufacturer instituted a unique mandatory clinical training program to ensure that only trained clinicians had access to the implant. A related active monitoring program was instituted to assess insertion, localization, and removal-related events.
- In received reports reflecting more than 25,000 single-rod implant insertions and removals, the overall complication rate for the implant was very low, and no complications resulted in hospitalization.

rod not found (n = 1), and possible associated nerve (n = 5) or vascular (n = 4) injury. No event-associated hospitalizations were reported. Seven (0.6%) reports described possible referral for surgical implant removal.[1]

"In reports received reflecting over 25,000 single-rod implant insertions and removals, the overall complication rate was very low, and no complications resulted in hospitalization," says Kaunitz, who presented findings along with colleagues at the recent annual clinical meeting of the American College of Obstetricians and Gynecologists. "These observations indicate that the mandatory clinical training necessary for clinicians to access the single rod contraceptive implant has been successful."

Check implant as option

The clinical training program has helped Implanon and its successor, Nexplanon, gain solid footing among providers. When Norplant entered the United States market in 1993, it enjoyed brisk initial sales; however, difficulties surrounding its insertion and removal eventually led to its withdrawal from the market.

Nexplanon, introduced in late 2011, is similar to the Implanon device; however, it features an easier-to-use inserter. Also, the implant is radiopaque, which allows it to be located by two-dimensional X-ray, computed tomography (CT), ultrasound scanning, or magnetic resonance imaging (MRI). The Nexplanon implant is approved by the FDA for up to three years of contraceptive use.

It is extremely effective: to date, no pregnancies have been observed in prospective or retrospective cohort studies of the contraceptive implant, which included more than 4,500 women and more than 7,000 women-years of exposure.[2] *(To read more about Nexplanon's debut, see the* Contraceptive Technology Update *article, "New year, new implant: Time to add Nexplanon to contraceptive options," January 2012, p. 1.)*

Due to its top-tier effectiveness, "set it and forget it" ease of use, and reversible nature, the American College of Obstetricians and Gynecologists has issued a committee opinion advocating the use of the contraceptive implant and intrauterine contraception as safe, effective, and appropriate options for adolescents.[3] *(To check the guidance, see the* CTU *article, "Long-acting methods safe for teens — Include options in your counseling," December 2012, p. 133.)*

Like all progestin-only methods, Nexplanon causes vaginal bleeding changes in a large proportion of women. These changes may include amenorrhea, infrequent bleeding, irregular bleeding, or less often, prolonged or frequent bleeding. The best approach to reducing the impact of this side effect is to forewarn women about it and counsel that it is generally not dangerous.[3] From previous experience with the Norplant implant, research indicates that the quality of counseling before insertion can improve a patient's satisfaction with her implant and reduce the likelihood she will discontinue it due to side effects.[4]

Investigators evaluated the use of implants and other reversible birth control methods in the Contraceptive CHOICE project in St. Louis. Seventeen percent of women enrolled in the study chose the contraceptive implant, compared to 46% opting for the levonorgestrel intrauterine device (IUD), and 12% selecting the Copper T 380A IUD. *(To read more about the CHOICE project, see these* Contraceptive Technology Update *articles: "More women moving to LARC methods — Will your facility follow the trend?" April 2013, p. 37, and "The 'Get It and Forget It' methods are here: Remove obstacles to use," April 2012, p. 37.)*

Bleeding with the implant is irregular and is impossible to predict, says **Jeffrey Peipert**, MD, MPH, MHA, Robert J. Perry professor of obstetrics and gynecology and vice chair for clinical research at Washington University School of Medicine in St. Louis. Peipert spoke on the importance of long-acting reversible contraception (LARC) methods at the 2013 Contraceptive Technology conferences in San Francisco and Washington, DC.[5] The bottom line is that unpredictable bleeding is part of implant use, and patients must be willing to accept irregular bleeding, he stated.

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What avenues will raise LARC method awareness?

Findings from a new community-based research study indicate using social networks and peer education might be a way to increase acceptance of long-acting reversible contraception (LARC) among low-income women.[1]

Use of intrauterine devices (IUDs) and the contraceptive implant in the United States is among the lowest of any developed country.[2,3] Intrauterine and implant contraceptive methods are used by 15% of contraceptors worldwide, including 11% in Great Britain, 23% in France, 27% in Norway, and 41% in China. Most of those contraceptors rely on the IUD.[4]

Charlene Collier, MD, MPH, a Robert Wood Johnson Foundation Clinical Scholar at Yale University in New Haven, CT, and fellow investigators developed and administered a survey given to urban women with family incomes below 200% of the federal poverty level. They distributed the survey at outdoor health fairs, local beauty salons, and bus stops. Along with community partner New Haven Healthy Start, a nonprofit agency aimed at reducing infant mortality and morbidity, the team recruited 200 women, with an average age of 27, to take the survey. The survey assessed women's contraceptive experience, reproductive intentions, and LARC awareness, knowledge, and interest. Of the women, 39% were black, 40% were Hispanic, and 14% were white.

More than half (54%) of study participants were current contraceptive users, and 39% reported not desiring pregnancy within five years. Sixty-three percent were aware of IUDs, and 37% knew how long an IUD could be used; however, many were unsure if IUDs were safe (59%) or effective (64%). Almost half (45%) were aware of implants, yet most reported not knowing how long they lasted (90%) or if they were safe (72%) or effective (77%).

Among women aware of IUDs, about one-fifth (21%) said they could consider using one. Interest in using an IUD was associated with having a friend who had one, as well as wanting to delay pregnancy for two to five years. Among women aware of implants, 18% said they would consider using one. Implant interest was associated with Hispanic ethnicity and having a friend with an implant.

Researchers hope the survey findings will promote efforts to dispel misinformation and increase education about these highly effective forms of birth control. Many of the responses centered on fear of side effects, Collier noted in a press statement issued with the findings' presentation. Information needs to reach women about misconceptions that LARC methods cause cancer or infertility, she stated.

Get out the message

Providers need to dispel common myths about IUDs, agrees **Jeffrey Peipert**, MD, MPH, MHA, Robert J. Perry professor of obstetrics and gynecology and vice chair for clinical research at Washington University School of Medicine in St. Louis. Peipert spoke on the importance of LARC methods at the 2013 Contraceptive Technology conferences.[5] Peipert and colleagues at the Washington University School of Medicine evaluated the use of IUDs and other reversible birth control methods in the Contraceptive CHOICE project in St. Louis. *(To read more the CHOICE project, see the* Contraceptive Technology Update *article, "More women moving to LARC methods — Will your facility follow the trend?" April 2013, p. 37, and "The 'Get It and Forget It' methods are here: Remove obstacles to use," April 2012, p. 37.)*

Emphasize the following facts about IUDs, says Peipert. They

- do NOT cause pelvic infection;
- are NOT abortifacients;
- do NOT decrease the likelihood of future pregnancies;
- do NOT cause ectopic pregnancies;
- do NOT cause cancer.[5]

To survey knowledge and attitudes about intrauterine contraception among reproductive-aged women in the St. Louis area, CHOICE researchers mailed an eight-page survey to 12,500 randomly selected households in the area. Just half of women surveyed said they believed intrauterine contraception was safe. About 11-36% of respondents indicated concerns that

EXECUTIVE SUMMARY

Findings from a new community-based research study indicate using social networks and peer education might be a way to increase acceptance of long-acting reversible contraception (LARC) among low-income women.

- Use of intrauterine devices (IUDs) and the contraceptive implant in the United States is among the lowest of any developed country. Intrauterine and implant contraceptive methods are used by 15% of contraceptors worldwide.
- Many of the women surveyed in the study were unsure if IUDs were safe (59%) or effective (64%). Almost half (45%) were aware of implants, yet most reported not knowing how long they lasted (90%) or if they were safe (72%) or effective.

intrauterine contraception is associated with complications such as infection, infertility, and cancer. More than one-half (61%) underestimated its effectiveness.[6]

LARC methods are the most effective contraceptive options, noted Peipert at the conference. They are forgettable and not dependent on compliance or adherence. In the CHOICE Project, LARC methods were first-line, and all contraceptive methods were free, Peipert noted. Research published by the CHOICE Project investigators shows that the effectiveness of LARC is superior to that of contraceptive pills, patch, or ring and is not altered in adolescents and young women.[7]

The policy implications lie in LARC methods' cost-savings, said Peipert. Use of LARC methods reduces unintended pregnancies, he stated.

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What's your approach to PID treatment in teens?

According to a new survey of clinicians who treat teen girls with pelvic inflammatory disease (PID), national guidance designed to inform decisions about hospitalization versus outpatient care leaves some scratching their heads.[1] Why is there uncertainty among providers in choosing the most effective treatment for the infection?

Pelvic inflammatory disease affects more than 800,000 women each year in the United States.[2] Due to biologic and behavioral factors, teens are vulnerable to developing PID, which can result in an increased risk for ectopic pregnancy, tubal infertility, and chronic pelvic pain.

There have been major shifts in PID care in the United States in the last 15 years, notes the study's lead author, **Maria Trent**, MD, MPH, associate professor of pediatrics in the Division of General Pediatrics and Adolescent Medicine at the Johns Hopkins School of Medicine in Baltimore. The primary change stems from the fact that the Centers for Disease Control and Prevention (CDC) no longer universally recommends treating adolescents with mild to moderate disease in the inpatient setting,[3] Trent states. However, the medical and psychosocial factors that make adolescents vulnerable continue to exist, and there is limited data on how to best manage early and middle adolescents, she notes.

In the current study, researchers specifically evaluated when clinicians think that inpatient treatment for an adolescent with mild to moderate PID is indicated, states Trent. They used common clinical scenarios for which a patient's ability to tolerate an outpatient regimen (a CDC criteria for hospitalization) could be difficult as a first step in understanding and refining the national guidance for adolescent management, she explains. Patients who are treated at home receive antibiotics by mouth for 14 days and are asked to return to the clinician's office within 72 hours for re-evaluation. *(See box on p. 93 for recommended outpatient oral treatment.)*

Despite data showing that teens with PID often fail to adhere to outpatient treatment regimens and miss follow-up appointments,[4] the CDC no longer recommends in-hospital treatment, although clinicians have

EXECUTIVE SUMMARY

According to a new survey of clinicians who treat teen girls with pelvic inflammatory disease (PID), national guidance designed to inform decisions about hospitalization versus outpatient care has lead to provider uncertainty in choosing the most effective treatment approach.

- Due to biologic and behavioral factors, teens are vulnerable to developing PID, which can result in an increased risk for ectopic pregnancy, tubal infertility, and chronic pelvic pain.
- National guidance no longer universally recommends treating adolescents with mild to moderate disease in an inpatient setting. Patients who are treated at home receive antibiotics by mouth for 14 days and are asked to return to the clinician's office within 72 hours for re-evaluation.

CDC Recommended Regimen for Outpatient Treatment

• Ceftriaxone 250 mg IM in a single dose PLUS doxycycline 100 mg orally twice a day for 14 days WITH or WITHOUT metronidazole 500 mg orally twice a day for 14 days;

OR

• Cefoxitin 2 g IM in a single dose and probenecid, 1 g orally administered concurrently in a single dose PLUS doxycycline 100 mg orally twice a day for 14 days WITH or WITHOUT metronidazole 500 mg orally twice a day for 14 days;

OR

• Other parenteral third-generation cephalosporin (e.g., ceftizoxime or cefotaxime) PLUS doxycycline 100 mg orally twice a day for 14 days WITH or WITHOUT metronidazole 500 mg orally twice a day for 14 days.

Source: Workowski KA, Berman S; Centers for Disease Control and Prevention (CDC). Sexually transmitted diseases treatment guidelines, 2010. *MMWR Recomm Rep* 2010; 59(RR-12):1-110.

the flexibility to hospitalize patients if they so choose.

Clinicians were presented with 17 clinical vignettes involving a hypothetical teen with PID, then were asked to choose between hospital and outpatient treatment for each scenario. The clinicians had to weigh various factors, such as the patient's severity of illness and age, if she was pregnant, had recent surgical procedures, was afraid of sharing her diagnosis with a partner, or was able and willing to follow outpatient treatment regimen.

Data from the current study indicate the guidelines might be falling short of informing flexibility in choosing inpatient or outpatient care, particularly in cases that involve patients with recent abortions or whose social circumstances make it unlikely they would comply with the complex outpatient treatment, researchers note. Such ambivalence was apparent in the survey when clinicians were uncertain about patients' ability to care for themselves, their willingness to take medications, or their willingness to share diagnoses with sexual partners, they state. Decision-making algorithms would be helpful in providing guidance, while giving physicians autonomy and flexibility, note researchers. Lack of clarity, however, might lead clinicians to make decisions predicated on personal bias rather than on evidence stemming from best practices, they state.

Taking the next step

What might be the next step in helping clinicians make the most informed treatment when it comes to PID treatment, particularly in teens?

Trent says additional research is warranted to explore alternative, developmentally appropriate and cost-effective management strategies designed to improve short-term adherence and prevention of adverse outcomes, such as infertility, ectopic pregnancy, and chronic pelvic pain.

"Our team is currently evaluating a technology-enhanced community health nursing intervention as a potential strategy to meet this need in clinical and public health practice," she notes.

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Contraception safety message Is not received

Clinicians might want to spend more time emphasizing the safety of hormonal contraception. Why? A new survey of women presenting for pregnancy counseling at a university family planning clinic showed about half of pregnant women incorrectly believe that hormonal contraception is more dangerous than pregnancy.[1]

Worldwide, 342,900 women die each year from pregnancy and pregnancy-related causes.[2] In comparison, for nonsmoking women ages 15-34 in the United

States, the risk of dying with use of oral contraceptives (OCs) is about one in 1.67 million, which is similar to the risk of being struck by lightning.[3] *(See box on p. 95 on putting voluntary risks in perspective.)*

Researchers at the University of Rochester (NY) offered an anonymous survey to women receiving pregnancy counseling at the university's family planning clinic in an effort to evaluate patients' knowledge of medical risks from hormonal contraception compared with risks from pregnancy.

Only 16% the women surveyed were actively using contraception. Most said they thought that hormonal contraception (84%) and pregnancy (88%) were safe. However, when asked which was safer, 46% chose pregnancy over contraception.

When asked about specific risks, 57% of the women felt there were no concerns with pregnancy versus no concerns with contraception (31%). Significantly more women expressed more concerns with contraception use than pregnancy: pulmonary embolism (40% with contraception versus 7% with pregnancy), cancer risk (24% with contraception versus 2% with pregnancy) and infertility (29% with contraception versus 7% with pregnancy).[1]

In a 2011 study performed to assess women's knowledge of the health risks of pregnancy, more than 75% of respondents rated birth control pills as more hazardous to a woman's health than pregnancy.[4] The greater the women's education, the more likely she was to believe that oral contraceptives were riskier than pregnancy, research indicated.[4]

Women do not know the medical risks of pregnancy, observes **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. Education is needed is to help women understand pregnancy's health risks, says Nelson, who co-authored the 2011 study.

The study was presented at the recent American College of Obstetricians and Gynecologists annual clinical meeting. In a press statement accompanying the presentation, **Brandy Becker**, MD, co-author, said, "The risks of pregnancy, deemed such a natural and healthy process by society, get overshadowed by the highly publicized reports of contraceptive-related complications. If women continue to receive more influence on their contraceptive choices from media than their healthcare providers, we will never make progress at lowering unplanned pregnancy rates."

Use the U.S. MEC

How can clinicians best address some of the common misperceptions when it comes to hormonal contraceptive safety?

Use evidence-based resources, says **Sarah Betstadt**, MD, MPH, assistant professor in the Department of Obstetrics and Gynecology in the Division of General Obstetrics and Gynecology at the University of Rochester (NY). For contraception, the gold standard resource is the Centers for Disease Control's (CDC's) U.S. Medical Eligibility Criteria for Contraceptive Use.[5]

The guidance from the CDC is a resource that summarizes all of the available literature on contraceptive use as it relates to different medical conditions, states Betstadt, who is a co-author of the current paper. From this literature review, the CDC has made recommendations on the safety of each contraceptive method in the context of individual medical conditions, she notes.

The CDC has provided an excellent summary chart that can be easily downloaded from its website that all clinicians can use in the office, notes Betstadt. *(Go to http://1.usa.gov/chY2AV. Links to download the summary charts in English and Spanish are available at the bottom of the page.)* For example, a contraceptive method that can be used safely, without risk is given a recommendation of "1", while a method that should not be used, because risk outweighs benefit, is a "4", explains Betstadt. A good example of a "4" recommendation would be using a combined hormonal contraceptive pill in the setting of an acute deep venous thrombosis, she notes.

"This is an excellent resource that clinicians can use to allow [patients] to see that most contraceptive methods are safe for women, even with medical conditions such as hypertension and diabetes," explains Betstadt. "It is much riskier for these women to have an unplanned pregnancy."

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EXECUTIVE SUMMARY

A new survey of women presenting for pregnancy counseling at a university family planning clinic showed about half of pregnant women incorrectly believe that hormonal contraception is more dangerous than pregnancy.

- Worldwide, 342,900 women die each year from pregnancy and pregnancy-related causes. In comparison, for non-smoking women ages 15-34 in the United States, the risk of dying with use of oral contraceptives (OCs) is about one in 1.67 million, which is similar to the risk of being struck by lightning.
- Use evidence-based resources to address safety concerns, such as the U.S. Medical Eligibility Criteria for Contraceptive Use.

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Patient Risk Put into Perspective

Mortality risk in the United States per year	
While skydiving	1 in 1,000
From an accident	1 in 2,900
From an automobile accident	1 in 5,000
In an airplane crash	1 in 250,000
From being struck by lightning	1 in two million

Risk per year for women preventing pregnancy using combined oral contraceptives	
Nonsmoker, ages 15-34	1 in 1.67 million
Nonsmoker, ages 35-44	1 in 33,000
Smoker, ages 15-34	1 in 57,800
Smoker, ages 35-44	1 in 5,200

Undergoing tubal sterilization	1 in 66,700

Risk from pregnancy	1 in 6,900

Source: Trussell J, Guthrie KA. Choosing a contraceptive: efficacy, safety, and personal considerations. In: Hatcher RA, Trussell J, Nelson AL, et al. *Contraceptive Technology*: 20th revised edition. New York: Ardent Media; 2011.

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

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CNE/CME QUESTIONS

1. While about 1.4% of women in the general population will be diagnosed with ovarian cancer, what percentage of women with a harmful BRCA1 or BRCA2 mutation will develop the disease?
   A. 5%
   B. 7-10%
   C. 12%
   D. 15-40%

2. What is the hormone found in the contraceptive implant Implanon/Nexplanon?
   A. Etonogestrel
   B. Levonorgestrel
   C. Norgestimate
   D. Desogestrel

3. Patients who receive outpatient treatment for pelvic inflammatory disease
   A. Receive antibiotics by mouth for seven days and are asked to return to the clinician's office within 48 hours for re-evaluation.
   B. Receive antibiotics by mouth for 14 days and are asked to return to the clinician's office within 72 hours for re-evaluation.
   C. Receive antibiotics by mouth for 21 days and are asked to return to the clinician's office within 72 hours for re-evaluation.
   D. Receive antibiotics by mouth for 14 days and are asked to return to the clinician's office within 24 hours for re-evaluation.

4. For nonsmoking women ages 15-34 in the United States, the risk of dying with use of oral contraceptives is about one in 1.67 million, similar to the risk of:
   A. Skydiving
   B. An automobile accident
   C. Being struck by lightning
   D. An airplane crash

COMING IN FUTURE MONTHS

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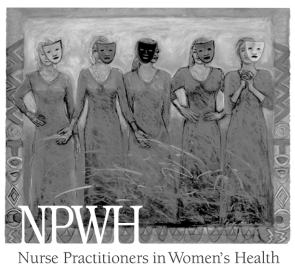

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