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Interpreting News and Research on Contraceptives and STIs

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FDA approves smaller levonorgestrel intrauterine system— a `mini Mirena'

Smaller size makes Skyla IUS good choice for nulliparous women

The Food and Drug Administration has given approval to Skyla, a new intrauterine system (IUS) from Bayer HealthCare Pharmaceuticals of Wayne, NJ. Available by prescription in February 2013, Skyla is the first new intrauterine contraceptive to receive U.S. approval in more than a decade.

Skyla is Bayer's second intrauterine contraceptive; its Mirena IUS was approved for U.S. contraceptive use in 2000. Skyla's small, flexible plastic T-shaped device measures 28 mm by 30 mm, as compared to Mirena's 32 mm by 32 mm dimensions. Skyla contains 13.5 mg levonorgestrel. The drug is released at an average in vivo rate of approximately 6 mcg/day over three years. Mirena contains 52 mg of levonorgestrel. Its drug is released at a rate of approximately 20 mcg per day, which decreases progressively to half that value after five years.

Skyla's labeled approval is for up to three years of contraceptive use. In comparison, Mirena is labeled for up to five years of birth control.

How does the addition of a new intrauterine device bode for the growth of long-acting reversible contraceptive (LARC) methods of family planning? "It is clear that LARC methods are more popular that ever, as there is an overall recognition that LARC methods are the best way

EXECUTIVE SUMMARY

The Food and Drug Administration has given approval to Skyla, a new intrauterine system (IUS) from Bayer HealthCare Pharmaceuticals. Available by prescription in February 2013, Skyla is the first new intrauterine contraceptive to receive U.S. approval in more than a decade.

- Skyla is smaller and contains a smaller dosage of levonorgestrel than Bayer's other intrauterine contraceptive, Mirena. Skyla is approved for up to three years of contraceptive use. In comparison, Mirena is labeled for up to five years of use.
- The product labeling for Skyla specifically states that it can be used whether or not a woman has had a child, whereas the labeling for Mirena states it is recommended for women who have had at least one child.

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for many women to prevent an unintended pregnancy," says **Susan Wysocki**, WHNP-BC, FAANP, president & chief executive officer of iWomansHealth in Washington, DC, which focuses on information on women's health issues for clinicians and consumers. "The addition of Skyla will give women another excellent option for preventing pregnancy."

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Editorial Questions

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Skyla is an excellent contraceptive option for women looking for long-acting reversible contraception, agrees **Beth Jordan Mynett**, MD, medical director, Association of Reproductive Health Professionals (ARHP) in Washington, DC. Its lower hormonal dose and smaller device size make it a method that may appeal to nulliparous women, especially younger women, notes Mynett. ARHP offers an online educational program on new developments in contraception such as Skyla to help providers be aware of what is in the development pipeline and to help their patients choose the best available contraceptive method. *(To access the ARHP New Developments in Contraception webinar, visit www.arhp.org. Select "Professional Education," then "New Developments in Contraception.")*

Who's a good candidate?

Which women will be good candidates for the long-acting reversible contraceptive? **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, sees three potential categories:

- nulliparous women and those who have delivered only by Caesarean section;
- women who desire shorter-term contraception;
- women who want the lowest hormone levels.

The availability of a smaller progestin-releasing intrauterine system will provide additional choices for women and their clinicians, says **Andrew Kaunitz**, MD, professor and associate chair in the Obstetrics and Gynecology Department at the University of Florida College of Medicine — Jacksonville. A smaller IUS may be advantageous, particularly for nulliparous women, he states. Nelson says she hopes that "by introducing an IUS specifically indicated for nulliparous women, we can erase remaining clinician opposition to the use of this important option to more women."

Labeling should help clinicians determine which intrauterine system is best for a particular woman. The product labeling for Skyla specifically states that it can be used whether or not a woman has had a child, whereas the labeling for Mirena states it is recommended for women who have had at least one child, Wysocki points out.

"Although Skyla has a shorter duration of use than Mirena, for many women, the three years of duration is a perfect length of time, whether they are interested in child spacing or accomplishing a

life goal, such as graduate school," Wysocki states. "The smaller amount of progestin may also be an advantage for some women."

Skyla has a smaller inserter diameter. It is 3.8 mm in diameter compared to Mirena's 4.75 mm diameter. Although developed for use by young women, clinicians may find it much easier to insert in perimenopausal women as a progestin for hormone therapy use, says **James Trussell**, PhD, professor of economics and public affairs and director of the Office of Population Research at Princeton (NJ) University. While not specifically labeled for this indication, such use might prove beneficial, Trussell notes.

Is it effective?

The contraceptive method has proven efficacy, as evidenced by results of a Phase III multicenter, multinational, randomized open-label trial. The study included 1,432 women ages 18-35 who received Skyla, of which 38.8% (556) had not yet had a child. The Pearl Index estimate for the first year of use based on the five pregnancies that occurred after the onset of treatment and within seven days after Skyla removal or expulsion was 0.41 with a 95% upper confidence limit of 0.96. The cumulative three-year pregnancy rate, based on 10 pregnancies, estimated by the Kaplan-Meier method was 0.9 per 100 women or 0.9%, with a 95% upper confidence limit of 1.7%.[1]

Most common adverse reactions noted in clinical trials included vulvovaginitis (20.2%), abdominal/pelvic pain (18.9%), acne/seborrhea (15.0%), ovarian cyst (13.2%), headache (12.4%), dysmenorrhea (8.6%), breast pain/discomfort (8.6%), increased bleeding (7.8%), and nausea (5.5%).

Rapid return to fertility is seen with the device. According to its product labeling, about three out of four women who want to become pregnant will become pregnant in the first year after Skyla is removed.

Counsel on changes

Changes in menstrual patterns are the most common side effect of intrauterine contraception.[2] According to Skyla's prescribing information, women should be counseled that for the first three to six months, their periods might become irregular and their number of bleeding days might increase. Women also might have frequent spotting or light bleeding; some women have heavy bleeding during this time.

"After you have used Skyla for a while, the number of bleeding and spotting days is likely to lessen," the prescribing information reads. "There is a small chance that your periods will stop altogether."

Tell women to call the office, however, if bleeding remains heavier than usual or increases after it has been light for a while, the prescribing information advises.

Is it safe to breastfeed while using Skyla? Women may use Skyla when breastfeeding if more than six weeks have passed since the baby was born, the prescribing information states. If a woman is breastfeeding, Skyla is not likely to affect the quality or amount of her breast milk or the health of the nursing baby. However, isolated cases of decreased milk production have been reported among women using progestin-only birth control pills.[3]

Often, lesser is better, suggests **Robert Hatcher**, MD, MPH, professor of gynecology and obstetrics at Emory University School of Medicine in Atlanta.

"The hope is, of course, that the smaller size of the 'mini-Mirena' IUS, Skyla, will be better tolerated by women with a smaller uterus, such as young teens and perimenopausal women, says Hatcher. "The hope also is the smaller size of the inserter will make this intrauterine device (IUD) easier to insert in some women."

However, in this case, lesser is worse when it comes to duration of contraceptive effectiveness, as women getting a Skyla device are only protected for three years, notes Hatcher. In their book, "A Clinical Guide For Contraception," Speroff and Darney say "the LNG IUD can be used for at least seven years and probably for 10 years," Hatcher says. They are, of course, referring to the Mirena IUS, he says.[4] The Skyla IUS is approved for up to three years; this is not better, states Hatcher.

"In the not too distant future, a cheaper generic form of Mirena may be available; when this happens, it will be both less expensive and will be made effective for a longer period of time than the Skyla IUS," says Hatcher. "Therefore, a challenge for clinicians will be to decide who can use the slightly larger Mirena IUS that remains effective for so much longer than the Skyla [device]."

[Did you receive the Contraceptive Technology Update *ebulletin sent Jan. 11 on the Skyla approval? 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.]*

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Longer-acting method that is injectable probed

Contraceptive injectables are a popular form of birth control for women around the world, with more than 35 million women relying on the method. The contraceptive shot is a popular form of family planning in the United States, particularly among teens. About 20% of females ages 15-19 in 2002 and 2006-2010 reported contraceptive injectable use in the United States.[1]

Contraceptive injections, given every one to three months, represent an effective form of birth control that does not require daily compliance and can be used discreetly. Despite their popularity, many users might discontinue use early due to missed reinjection appointments.[2]

With funding from the Bill & Melinda Gates Foundation of Seattle, FHI 360, a global nonprofit human development organization based in Durham, NC, has launched a project to support early testing of innovative approaches to developing an injectable contraceptive that would last for six months. As part of this project, FHI 360 in 2012 issued a Request for Proposals for proof-of-concept testing of candidates that have the potential to be developed into a longer-acting injectable. Concepts were received from lead drug delivery research groups in the United States, Europe, India, and China, and they represented a wide range of innovative approaches. After a rigorous review by internal and external experts, three proposals were selected to move forward with proof-of-concept testing.

As the next step, FHI 360 will work with its new partners to evaluate these three promising technologies, states **Vera Halpern**, MD, FHI 360's director of the development of a longer-acting injectable contraceptive project. "For the products that successfully complete proof-of-concept testing, we will move as rapidly as possible to begin human clinical trials and complete the studies necessary to obtain regulatory approvals for broader product use," says Halpern. "The development of a longer-acting injectable would improve continuation rates for women around the world, resulting in fewer unwanted pregnancies."

Different tactics eyed

Three proposals were selected to move forward for proof-of-concept testing:

- poly(lactic) and poly(lactic-co-glycolic) (PLA/PGLA) microspheres releasing levonorgestrel, in research by Shanghai (China) Institute of Planned Parenthood Research;
- nanostructured porous silicon microparticles releasing a contraceptive steroid, under study by the University of California, San Diego in La Jolla;
- biodegradable polymeric gel formulation releasing levonorgestrel, in formulation at the University of Tennessee Health Science Center in Memphis.

At the University of California, San Diego, the major challenge is to engineer the nanomaterial to deliver drug at a constant rate for the duration of the therapy, and then disappear very quickly when the drug reservoir is exhausted, explains Michael Sailor, professor and Leslie E. Orgel

EXECUTIVE SUMMARY

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Scholar in Inorganic Chemistry in the Department of Chemistry and Biochemistry. The scientific team is designing the system such that the contraceptive drug will be delivered at a therapeutic concentration for up to six months, then quickly taper to allow the individual to rapidly regain fertility, Sailor states.

At the University of Tennessee Health Science Center in Memphis, scientists are looking at a biodegradable polymeric gel formulation, constituted from biodegradable polyesters, the active pharmaceutical ingredient levonorgestrel, and a vehicle for injection, explains **Tao Lowe**, PhD, associate professor of pharmaceutical sciences & biomedical engineering at the university. After injection, the formulation forms a solid implant at the injection site within a short time. The active pharmaceutical ingredient, levonorgestrel, is slowly released out from the in-situ formed implant into the surrounding body fluid, where it eventually enters the bloodstream, states Lowe. By designing the dosage forms, the release of the drug will be adjusted to the desired six months, and the polyesters in the dosage form will gradually degrade on site after injection, she states.

Due to the complete degradation of material, no polymers will accumulate in in the body, and no surgical removal will be required, states Lowe. After discontinuation, the return to fertility will be fairly rapid and predictable, scientists believe.

Research is first step

Injectables currently used around the world are effective for 1 to 3 months, depending on the formulation, which requires women to return to their provider 4 to 12 times per year. Missed follow-up appointments are an important reason for discontinuation. A longer-acting injectable would likely increase compliance, improve continuation rates, and increase typical-use contraceptive effectiveness, and thus help reduce rates of unintended pregnancies, say FHI 360 officials.

"This project is the first step toward bringing a game-changing injectable contraceptive to market that provides six months of protection, thereby expanding contraceptive access and choice for women around the world," says Halpern.

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Sterilization option now under research

Sterilization continues to be a leading contraceptive choice for women in the United States; between 2006 and 2008, 10.3 million women looked to the method for birth control.[1] Worldwide, 220 million couples use tubal sterilization or vasectomy as their chosen contraception method.[2]

"Globally, surgical sterilization is the most common and effective method of birth control," notes **Jeffrey Jensen**, MD, MPH, Leon Speroff Professor & Vice Chair of Research in the Department of Obstetrics & Gynecology at the Oregon Health & Science University in Portland. "Unfortunately, the acceptability of this important method is limited by its high cost, scarcity of providers, and surgical risks, particularly in lesser-developed nations."

Researchers are looking at the development of novel, non-surgical methods of sterilization to improve access to the fertility control option, and thus reduce the number of unintended pregnancies, says Jensen. Jensen's research team is eyeing the use of polidocanol foam, currently used in varicose vein therapy, as a potential low-cost, nonsurgical long-term contraceptive method.[3]

The team recently has received Phase II funding for its project through the Grand Challenges Explorations, an initiative created by the Bill & Melinda Gates Foundation in Seattle. The initiative allows scientists to test ideas to address persistent

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- An Oregon Health & Science University research team is now eyeing the use of polidocanol foam, currently used in varicose vein therapy, as a potential low-cost, nonsurgical long-term contraceptive method.
- Sterilization continues to be a leading contraceptive choice for women in the United States; between 2006 and 2008, 10.3 million women looked to the method for birth control. Worldwide, 220 million couples use tubal sterilization or vasectomy as their chosen contraception method.

health and development challenges. The Portland research team received similar Phase I testing funds in 2010 to examine the potential sterilization option.

Several chemical agents have been evaluated for possible use in sterilization, but only quinacrine has been tested in humans. However, the use of quinacrine for nonsurgical sterilization has been halted in several countries due to safety, efficacy, and ethical concerns.[4]

Could approach work?

Polidocanol works by causing excess connective tissue to form within the cell lining of blood vessels, thereby collapsing and closing the vessels. It was first used in the 1960s in Germany as a sclerosing agent for the cosmetic treatment of veins, and it quickly was adopted for that use in many European countries. It is approved by the Food and Drug Administration for treatment of varicose and spider veins. The drug has been intensely studied, and it has a high therapeutic index of safety.[5]

Since polidocanol is a registered drug for sclerosis of veins, the regulatory pathway for approval of this drug for use as a nonsurgical method of female sterilization would be much faster than for a new chemical entity that has not yet been cleared by regulatory authorities, says Jensen.

Polidocanol foam administered through the cervix via a small balloon catheter by a non-physician health care worker could "revolutionize" access to permanent contraception, says Jensen. "We could move sterilization from a risky surgical technique to a safe, well-tolerated procedure easily accessed in any village," states Jensen. "Healthcare workers could literally transport all the needed equipment to provide this service to a rural community in a small backpack."

Consider this explanation

How could such an approach work? Jensen provides the following scenario: on approximately day 5 of the menstrual cycle, a balloon catheter is inserted transcervically into the uterine cavity, and the balloon is inflated above the internal os. The polidocanol foam is introduced through the catheter into the uterine cavity, and it then flows out the fallopian tubes. This technique does not require visualization or canalization of the tubal ostia, explains Jensen. This treatment results in scaring confined to the intramural portion of the tube, states Jensen.

Experiments are underway in nonhuman primate models to optimize the approach such that a single treatment results in bilateral occlusion without adverse nontarget effects, says Jensen. Once an optimal strategy is developed, a contraceptive study will be initiated in nonhuman primates, and early phase clinical trials in women will begin. Concurrent with these efforts will be additional research to determine acceptability and product design characteristics to facilitate introduction of the technology in low-resource settings, he states.

While the research is still in early phases, it is important that science continue to explore such contraceptive options, says **Mitchell Creinin**, MD, professor and chair of the Department of Obstetrics and Gynecology at the University of California, Davis School of Medicine.

"I think the biggest thing is that we continue to strive for things to give women the options that they want, that potentially build on what we already have," observes Creinin. "There are companies who make 'me too' products, [but] is there a way we can provide women with highly-effective methods in a way that is cheaper, easier to access, and that is not only good for people with lots of money, but for those in developing countries, or people in our own country who are poor?"

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A decade past WHI — what have we learned?

Since the July 2002 publication of the first Women's Health Initiative (WHI) report, many changes have been made in the approach to hormone therapy (HT). A just-published review of evi-

dence over the last 10 years looks to the return to a "classic use" of HT, initiated near the menopause, to aid women who have such indications as significant menopausal symptoms or osteoporosis.[1]

When clinicians assess the lessons learned from the WHI, as well as from large observational studies, it becomes clear that the benefit/risk profile for menopausal hormone therapy is most favorable when it is used to treat vasomotor symptom in women considered "young" (those younger than age 60) or "recently menopausal'" (within one decade of menopause), says **Andrew Kaunitz**, MD, professor and associate chair in the Obstetrics and Gynecology Department at the University of Florida College of Medicine — Jacksonville. Kaunitz serves as a co-author of the current review

If a symptomatic menopausal woman is post-hysterectomy, estrogen–alone hormone therapy is safe for most "young/recently menopausal" candidates, notes Kaunitz. If such women are obese, Kaunitz says his preference is for transdermal over oral estrogen therapy. Results from observational studies indicate that transdermal estrogen, which was not studied in the WHI, has less impact on the risk of venous thrombosis than does oral estrogen,[2,3] states Kaunitz. "If a symptomatic menopausal woman has an intact uterus, combination estrogen-progestin HT is safe with short-term use," he says. "However, such women such be counseled that with more than 3-5 years of combination HT, a modest increase risk of breast cancer is observed."

Changes seen since WHI

Clinicians and women have seen a sea change in menopause treatment since the first WHI studies were published in 2002. Prior to that time, prescriptions for hormone therapy were rising, professional organizations advocated hormone therapy for prevention of osteoporosis and coronary heart disease (CHD), and one-third of HT prescriptions were for women older than age 60.

In 2002, the WHI trial of estrogen plus progestin in women with an intact uterus was halted when early data indicated increased risks of breast cancer, CHD, stroke, and pulmonary embolism outweighed potential benefits.[4] In 2004, scientists also ceased the companion trial of estrogen alone in hysterectomized women, due to an increased risk of stroke.[5]

The findings from the two initial Women's Health Initiative studies led to a sharp decline in postmenopausal hormone therapy use. According to a retrospective database analyses of national pharmacy claims, by the end of 2002, the total number of hormone therapy claims dropped approximately 30% from 2002 second quarter claims. This trend continued during the next seven years; by 2009, hormone therapy claims were reduced by more than 70%.[6]

Move to "classic" use

A 2012 major reappraisal of post WHI-data by international experts recently was published in the journal Climacteric, the official journal of the International Menopause Society in Geneva, Switzerland.[7] The results of the re-analyses of the WHI data and new data from other studies do not justify the continuing negative attitude to hormone therapy in symptomatic women who start treatment near menopause, experts note.[8] Data indicates that in women with symptoms or other indications, initiating HT near menopause, which is the classic pattern of use, probably will provide a favorable benefit/risk ratio, the experts conclude.[7]

The International Menopause Society hosted a 2012 "think tank" to review the WHI studies 10 years out; one participant was **Susan Wysocki**, WHNP-BC, FAANP. The discussion among the world leaders in menopause was a "full circle" back to where clinicians were 10 years ago before the WHI, says Wysocki, who serves as president & chief executive officer of iWomansHealth in Washington, DC, which focuses on information on women's health issues for clinicians and consumers.

Headlines generated following the 2002 WHI results were premature; as a result, many women became terrified of estrogen, and still are, says Wysocki. "Now we have this new Rossouw paper, as well as a number of innovative products that are coming down the line that are non-hormonal," she says. "Both the 'lessons learned' and new

EXECUTIVE SUMMARY

A just-published review of evidence over the last 10 years after publication of the first Women's Health Initiative report looks to the return to a "classic use" of hormone therapy, initiated near menopause, to aid women who have such indications as significant menopausal symptoms or osteoporosis.

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- According to a retrospective database analyses of national pharmacy claims, by the end of 2002, the total number of hormone therapy claims dropped approximately 30% from 2002 second quarter claims. This trend continued during the next seven years; by 2009, hormone therapy claims were reduced by more than 70%.

products should expand women's choices." *(See the* Contraceptive Technology Update *article, "Antidepressant eyed to reduce hot flashes," May 2011, p. 56, on research of non-hormonal treatments of menopausal symptoms.)*

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Clinicians continue unneeded pelvic exams

Results of a new national survey of obstetricians and gynecologists (OB/GYNs) show that many physicians mistakenly believe a routine annual bimanual pelvic examination is important in screening for ovarian cancer.[1] The study reveals physicians continue to perform the exam in part because women have come to expect it.

When asked why they perform pelvic examinations for asymptomatic women, nearly half reported that ovarian cancer screening was a very important reason for the exam, despite longstanding evidence that the exam is ineffective for preventing ovarian cancer deaths, notes **Jillian Henderson**, PhD, MPH, research associate at the Kaiser Permanente Center for Health Research in Portland. In fact, its use for this purpose can lead to serious harms from treatment of false positive results, states Henderson, who served as lead author for the paper.

Most physicians also reported that pelvic exams were very important for detection of benign uterine and benign ovarian conditions, such as fibroids and cysts, in women without any symptoms, states Henderson. Other important reasons were to reassure patients of their health and accommodate patient expectations, as well as adherence to standard medical practice, states Henderson.

"Finally, nearly half of OB/GYNs indicated that the exam was very important or moderately important to conduct in order to ensure adequate financial compensation for a visit," says Henderson. "This highlights the need for better mechanisms to compensate OB/GYNs for their valuable contraceptive, sexual, and reproductive health counseling, regardless of whether or not a physical exam is conducted."

Why the persistence?

Results of a 2011 published survey of 1,250 U.S. internists, family practitioners/general practitioners (FP/GPs), and OB/GYNs found that half of all physicians reported conducting routine pelvic exams as part of a well-woman exam.[2] When it came to ovarian cancer screening, routine pelvic exams were reported by 95.2% of OB/GYNs, 55.2% of FP/GPs, and 29.7% of internists; for screening for other gynecological cancers, the percentages were 96%, 68%, and 41.2%, respectively. More than 90% of OB/GYNs said they routinely performed such exams to screen for sexually transmitted infections (STIs), compared to 72.9% of FP/GPs and 39.9% of internists. *(To read more about the study, see the*

EXECUTIVE SUMMARY

Results of a new national survey of obstetricians and gynecologists show that many physicians mistakenly believe a routine annual bimanual pelvic examination is important in screening for ovarian cancer.

- Nearly half of surveyed providers reported that ovarian cancer screening was a very important reason for the exam, despite longstanding evidence that the exam is ineffective for preventing ovarian cancer deaths.
- The American College of Obstetricians and Gynecologists issued a committee pinion in August 2012 to supplement its 2011 physical exam recommendations to better help clinicians understand when pelvic exams are needed.

Contraceptive Technology Update *article, "Many providers continue unnecessary pelvic exams," March 2012, p. 30.)*

The current survey delves deeper into the practices of OB/GYNs, notes co-author **George Sawaya,** MD, professor in the Department of Obstetrics, Gynecology, and Reproductive Sciences at the University of California, San Francisco. The current research team asked specific reasons for the exam and used vignettes to better understand if the clinical situation affected the performance of, and the importance the clinicians placed on, the exam, he explains.

What do experts say?

The American College of Obstetricians and Gynecologists (ACOG) issued a committee opinion in August 2012 to supplement its 2011 physical exam recommendations to better help clinicians understand when pelvic exams are needed.[3,4]

What constitutes a pelvic exam? According to ACOG, it includes three parts: an external inspection, an internal speculum exam, and a combination internal/external exam. Annual pelvic exams should begin at age 21, the organization notes. For younger women, however, an internal exam is not recommended unless a patient has signs of a menstrual disorder, vaginal discharge, pelvic pain, or other reproductive-related symptom.[3]

Screening for STIs, especially in certain age groups, is an important part of the annual exam, but STI testing now can be done using urine samples or vaginal swabs without an internal pelvic exam, ACOG notes. Pelvic exams also are not necessary before prescribing birth control pills. *(Providers have gotten the message on this fact. See the* CTU *article, "Pelvic exam necessary for contraception Rx?" March 2011, p. 32.)*

When are pelvic exams appropriate? Check the following scenarios as listed by ACOG:

- as part of a comprehensive evaluation of any patient who reports or exhibits symptoms suggestive of female genital tract problems;
- when patients present with menstrual disorders, vaginal discharge, infertility, or pelvic pain;
- when perimenopausal patients present with abnormal uterine bleeding, changes in bowel or bladder function, or symptoms of vaginal discomfort;
- when patients in later reproductive years and menopause present with pelvic symptoms related to abnormal bleeding, vaginal bulge, urinary or fecal incontinence, or vaginal dryness.[3]

Bimanual examination also is indicated before procedures, such as an endometrial biopsy, inserting an intrauterine device, or fitting a diaphragm or pessary, ACOG guidance states.[3]

A patient's personal and family medical history and known risk factors for gynecologic malignancies can affect the decision regarding the indications for a pelvic examination, the guidance notes. Sound clinical judgment always must be the guiding factor in determining when a pelvic examination is indicated, the guidance states.

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Abortion coverage alters for servicewomen

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

In one of its final acts, the lame-duck 112th Congress did something unprecedented over its two-year term: It expanded access to publicly financed abortion, ever so slightly. The 2013 National Defense Authorization Act, which was approved by Congress in late December 2012 and signed by President Obama on Jan. 2, 2013, includes a provision authored by Sen. Jeanne Shaheen (D-NH) that reverses a decades-long ban

on federally supported insurance coverage for abortion in cases of rape and incest for military servicewomen and female military dependents. Since 1981, federal law had limited military abortion coverage to cases in which the woman's life is endangered.

The prohibition on abortion coverage in cases of rape was particularly harmful for the more than 200,000 women serving on active duty in the military. Defense Department statistics for a single year, 2010, identify more than 3,000 reported sexual assaults, including roughly 875 rapes; yet the extent of the problem is considerably larger, with an estimated 86% of assaults going unreported.[1] In an interview with Mother Jones in June 2012, Sen. Shaheen noted, "Most of the women affected here are enlisted women who are making about $18,000 a year. They're young, they don't have access to a lot of resources. Many of them are overseas."[2]

The Shaheen Amendment garnered support from dozens of retired military leaders, including Colin Powell, the former secretary of state and chairman of the Joint Chiefs of Staff, and it had significant bipartisan support in Congress. By banning coverage of abortion in cases of rape and incest, the restrictions on the military insurance program, known as TRICARE, were more severe than restrictions on most other federally supported insurance programs, including the most famous of the policies: the Hyde Amendment, which bars federal payments for abortion under Medicaid, except in cases of life endangerment, rape, or incest. Advocates of changing the military policy could point to the fact that servicewomen were receiving worse coverage than the civilians they risk their life to protect.

Restrictions to change?

Several other federal abortion restrictions fit this same mold — more restrictive than the Hyde Amendment — and are being looked to by abortion rights advocates as the best short-run opportunities for further progress at the federal level. Federal law, for example, restricts abortion coverage even in cases of life endangerment, rape, or incest for members of the Peace Corps, and federal policy bars U.S. funding of abortion even in those same extreme cases in the nation's international aid programs.[3] Another provision bars the District of Columbia from using its own locally raised revenue to pay for abortion coverage for its low-income residents. That ban was briefly eliminated for FY 2010 — proponents of lifting the ban focused on its infringement on the District's right to home rule — but it was reinstated again the next year at the demand of House Republicans as part of a broader budget deal. Finally, the Shaheen Amendment leaves in place a separate statutory restriction affecting military servicewomen that prohibits abortions from being provided at military medical facilities, even if a servicewoman were to pay for the procedure entirely with her own funds.[4] That restriction is particularly harmful for women stationed overseas, many of whom are in countries where abortion is illegal and unsafe.

Neither the Shaheen Amendment nor any of these other short-run opportunities challenge the essence of the Hyde Amendment or its progenies, including abortion coverage restrictions affecting federal employees and their dependents, Native American women, and women in federal prisons and detention centers. Those restrictions have set a federal standard that coverage for abortion, unlike coverage for other types of healthcare, is at best permissible only in the most extreme circumstances.

Abortion rights advocates were cautiously hopeful when President Obama first took office in 2009 that he would lend his weight to challenging that standard. Yet, he failed to take any steps in that direction during his first term in office. Moreover, he agreed to extend the federal restrictions on abortion coverage to millions of additional women under the Patient Protection and Affordable Care Act as a condition of support for the health reform legislation from antiabortion Democrats.[5]

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CTUPDATES
News ■ Resources ■ Events

Make plans now to attend ACOG annual meeting

New Orleans will be the site of 61st Annual Clinical Meeting of the American College of Obstetricians and Gynecologists May 4-8, 2013. The 2013 educational program will focus on practical clinical topics, with particular emphasis directed toward the advancement of healthcare services for women worldwide. Many state-of-the-art hands-on sessions, instructive didactic postgraduate courses, informative poster sessions, and engaging clinical seminars are planned.

Symposia will address such diverse areas of interest such as environmental toxins that impact reproduction, noninvasive prenatal testing, maternal mortality reduction, cervical cancer diagnosis guidelines, endometrial cancer staging, and global health. Several modifications and improvements have been made for the 2013 meeting: increased space allocation has been provided for the interactive clinical seminars; courses have designed to address practice management and electronic health records, including a new hands-on course addressing "medical apps" for smart phones; and interactive surgical tutorials will be provided regarding such topics as minimally invasive hysterectomy and techniques of abdominal wound closure.

To get more information on the event and register, visit the organization's web site, www.acog.org. Select the Annual Clinical Meeting icon on the opening page. ■

COMING IN FUTURE MONTHS

- Contraceptive choices for women with migraine with aura
- How can clinicians increase LARC method use?
- HIV vaccine update — Is science closer to a candidate?
- HPV vaccination — time to boost numbers

CNE/CME Obj ECtiv Es & iNst RUCti ONs

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CNE/CME QUESTIONS

1. What is the stated lengh of use for the intrauterine contraceptive Skyla?
   A. Three years
   B. Five years
   C. Seven years
   D. 10 years

2. Research underway on contraceptive injectables is seeking to extend the duration to what time period?
   A. Five months
   B. Six months
   C. 10 months
   D. 2 years

3. What is the chemical agent now being studied for potential use in female sterilization?
   A. Gabapentin
   B. Raloxifene
   C. Polidocanol
   D. Letrozole

4. According to American College of Obstetricians and Gynecologists guidance,
   when should a pelvic exam NOT be performed?
   A. To evaluate a patient who reports or exhibits symptoms suggestive of female genital tract problems.
   B. To evaluate when patients present with menstrual disorders, vaginal discharge, infertility, or pelvic pain.
   C. When perimenopausal patients present with abnormal uterine bleeding, changes in bowel or bladder function, or symptoms of vaginal discomfort.
   D. To screen for ovarian cancer.

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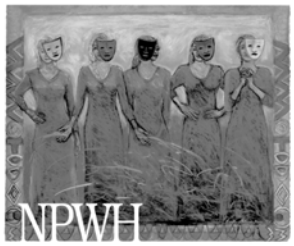

S·T·I
QUARTERLY

STI snapshot: Chlamydia leads in national rates — Young most at risk

Americans 15-24 at greatest risk of contracting the infection

According to a just-released analysis of the latest national sexually transmitted infection (STI) surveillance data, 1.4 million new cases of chlamydia were reported in the United States in 2011. This number corresponds to a rate of 457.6 cases per 100,000 population, an increase of 8% compared with the 2010 rate of 423.6.[1]

The rise in chlamydia cases is most likely due to increased screening, expanded use of more sensitive tests, and more complete national reporting, says the Centers for Disease Control and Prevention (CDC), which released the surveillance report. Seventy percent of the chlamydia cases reported in 2011 were in young adults ages 24 and below, the report notes.

While young men and young women are heavily affected by STIs, young women face the most serious long-term health consequences, the CDC report notes. Left untreated, diseases such as chlamydia and gonorrhea can negatively impact a woman's chance to have children later in life. The CDC estimates that undiagnosed STIs cause 24,000 women to become infertile each year.

The CDC advises annual screening for chlamydia in sexually active women ages 25 and under.[2] However, results of a 2012 analysis, indicates 62% — more than 9 million young women — were not screened as recommended.[3] The analysis examined data from the 2006-2008 cycle of the National Survey of Family Growth, a nationally representative household survey. (Contraceptive Technology Update *reported on the analysis. See "Too few young women get tested for chlamydia," June 2012, p. 65.)*

Public health officials also are keeping an eye on increasing rates of gonorrhea. A total of 321,849 cases were reported in 2011. This number corresponds to a rate of 104.2 per 100,000 people, reflecting a 4% increase since 2010. While infection rates remain at near-historic lows, CDC analysts note this is the second consecutive year of increases for the disease. A total of 62% of gonorrhea cases reported in 2011 were in those ages 24 and younger.[1]

Trend data reported for the first time this year

EXECUTIVE SUMMARY

A total of 1.4 million new cases of chlamydia were reported in the United States in 2011, according to a new analysis of national sexually transmitted infection surveillance data. This number corresponds to a rate of 457.6 cases per 100,000 population, an increase of 8% compared with the 2010 rate of 423.6. The rise is most likely due to increased screening, expanded use of more sensitive tests, and more complete national reporting.

- Gonorrhea rates also are increasing. A total of 321,849 cases were reported in 2011. This number corresponds to a rate of 104.2 per 100,000 people, reflecting a 4% increase since 2010.
- While gonorrhea infection rates remain at near-historic lows, analysts note this is the second consecutive year of increases for the disease.

Statement of Financial Disclosure: 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.

Check CDC screening STI recommendations

• Annual chlamydia screening for all sexually active women age 25 and under, as well as older women with risk factors such as new or multiple sex partners.

• Yearly gonorrhea screening for at-risk sexually active women (e.g. those with new or multiple sex partners, and women who live in communities with a high burden of disease).

• Syphilis, HIV, chlamydia, and hepatitis B screening for all pregnant women, and gonorrhea screening for at-risk pregnant women at the first prenatal visit, to protect the health of mothers and their infants.

• Screening at least once a year for syphilis, chlamydia, gonorrhea, and HIV for all sexually active gay men, bisexual men, and other men who have sex with men (MSM). MSM who have multiple or anonymous partners should be screened more frequently for sexually transmitted infections (STIs) (i.e., at three- to six-month intervals). In addition, MSM who have sex in conjunction with illicit drug use (particularly methamphetamine use) or whose sex partners participate in these activities should be screened more frequently. ■

Source: Centers for Disease Control and Prevention. Sexually transmitted diseases treatment guidelines, 2010. *MMWR* 2010; 59(No. RR-12).

show that primary and secondary (P&S) syphilis rates are increasing among men who have sex with men (MSM), who now account for nearly three-quarters of all infections, while declining among heterosexuals, notes **Hillard Weinstock**, MD, MPH, a CDC medical epidemiologist.

Our `shared responsibility'

To truly address the increasing rates of syphilis among gay and bisexual men, the underlying conditions that place some at greater risk for STIs must be confronted, says Weinstock. "Every American has the ability to protect their own health; however, we also have a shared responsibility to tackle the root causes of these disparities," he notes.

While the data in the current report does not address why such increases are occurring, data from other research indicates that risk behavior alone does not explain the disproportionate levels of infection among gay and bisexual men, says Weinstock. Complex issues such as homophobia and stigma also can make it difficult for gay and bisexual men to seek appropriate care and treatment, he states.

A recent CDC analysis, comparing trends in P&S syphilis among MSM by age group and race/ethnicity, shows that sexual networks and a range of social and economic factors (higher rates of STIs, access to healthcare, etc.) place African American and Latino MSM at increased risk, notes Weinstock.[4] Previous research also finds other factors, such as poverty, language, and legal barriers, might also play a role, he states.

An average of four in 10 men who have sex with men who are infected with syphilis also are infected with HIV, national surveillance data indicates.[1] Syphilis infection can place a person at increased risk for HIV infection, or increase an HIV-infected person's viral load, according to the CDC. Given the high prevalence of HIV in the MSM community, increasing syphilis infections among men who have sex with men are particularly troubling, the agency notes.

Time to take action

What can clinicians do to stem the tide against rising infection rates? Getting more at-risk patients tested is a first step, say CDC officials. *(See the boxed item above for CDC screening recommendations.)*

"Too many people – including men who have sex with men – are unaware of their infection," says Weinstock. "In addition to disparities among MSM, we also find that youth are particularly affected by STIs and bear the highest rates of gonorrhea and chlamydia."

Clinicians can help bring the "hidden epidemic" of STIs into the spotlight, says Weinstock. Many Americans are reluctant to discuss sexual health issues, though STIs are very common, he notes. Clinicians can aid in bringing these conversations out of the shadows, Weinstock states.

The CDC offers a "Let's Talk About Sexual Health" video to highlight the importance of a healthy dialogue between youth and providers concerning their sexual health. Produced by "Be Smart. Be Well," the video is a joint effort of Blue Cross and Blue Shield of Illinois, Blue Cross and Blue Shield of New Mexico, Blue Cross and

Blue Shield of Oklahoma, and Blue Cross and Blue Shield of Texas. The video features CDC Epidemiologist Elizabeth Torrone, PhD, MSPH. *(Access the video at www.cdc.gov/std. Under "What's New," select "Let's Talk About Sexual Health.")*

Also, providers can take tips from a 2012 CDC podcast offered by **Gail Bolan**, MD, director of the CDC's Division of STD Prevention, to help boost STI awareness among youth. *(To access the podcast, go to www.cdc.gov/std. On the left side of the page, select "Publications & Products," "Videos & Podcasts," then "STD Awareness — Reaching Youth.")* It is important to build and maintain a culture of privacy and confidentiality for your adolescent patients in setting the stage for STI talks, she noted.

Bolan calls for clinicians to discuss the five "Ps" with their patients:

- partners;
- practices;
- protection from STIs;
- past history of STIs;
- pregnancy prevention.

Be sure to encourage STD testing among sexually active young people, says Bolan.

Everyone has a role to play in the fight against STIs, notes Weinstock. Clinicians should talk to their patients about testing and assess their patients' risk for STIs and test them accordingly, while individuals should talk openly with their doctor and partners about STIs and testing, he asserts. MSM who are sexually active should be tested at least annually for STIs and HIV.

Discuss that consistent condom use and mutual monogamy also can decrease risk, says Weinstock. Talk with patients about such web sites as FindSTDTest.org and the CDC's toll-free number, 800-CDC-INFO, to get more information on testing.

"Community leaders can use family-centered approaches ensuring that parents are educated about STDs [sexually transmitted diseases] and are able to talk to their children and teenagers about the facts and STD prevention," Weinstock advocates. "They can also help by speaking out about STDs and fighting stigma."

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FDA approves new test for chlamydia/gonorrhea

The Food and Drug Administration (FDA) has given clearance to Cepheid of Sunnyvale, CA, to market its Xpert CT/NG test. Running on the company's GeneXpert Systems, Xpert CT/NG is a qualitative in vitro molecular diagnostic test for the detection and differentiation of *Chlamydia trachomatis* and *Neisseria gonorrhoeae*. The test began shipping in January 2013, says Jared Tipton, Cepheid's senior director of corporate communications.

The Cepheid Xpert CT/GC test is not like any other point of care (POC) test available in the United States, says Edward Hook, III, MD, professor and director of the Division of Infectious Diseases in the Department of Medicine at the University of Alabama at Birmingham. The test performs as well as the most widely used nucleic acid amplification tests available, says Hook.

"These tests are far, far more accurate than currently available POC tests whose sensitivities compared to nucleic acid amplification tests are in the range of 50% or less," states Hook. "Thus, while the Cepheid test takes a bit longer than most POC tests — about 90 versus 30 minutes to provide results — it is far more accurate."

The Cepheid Xpert CT/GC test is designed so that it can be used in a clinic laboratory, rather than needing to have specimens shipped to a dis-

EXECUTIVE SUMMARY

The Food and Drug Administration (FDA) has given clearance to Cepheid of Sunnyvale, CA, to market its Xpert CT/NG test. Running on the company's GeneXpert Systems, Xpert CT/NG is a qualitative in vitro molecular diagnostic test for the detection and differentiation of *Chlamydia trachomatis* and *Neisseria gonorrhoeae*. The test began shipping in January 2013.

- The test performs as well as the most widely used nucleic acid amplification tests available. Current point of care tests take about 30 minutes to deliver results. The Xpert test takes about 90 minutes, yet yields more accurate results.
- The FDA has categorized the Xpert CT/NG test as "moderately complex" under the Clinical Laboratory Improvement Amendments (CLIA).

tant laboratory for processing, observes Hook. "It really represents a potentially major step for getting accurate test results back to patients in a timely fashion," he notes.

Getting faster results might help stem the rising tide of chlamydial and gonorrhea infections. According to newly released information from the Centers of Disease Control and Prevention (CDC), a total of 1.4 million cases of Chlamydia trachomatis infection were reported in 2011, the largest number of cases ever reported to CDC for any condition.[1]

In 2011, gonorrhea rates rose 4.0%, with a total of 321,849 cases of gonorrhea reported in the United States, corresponding to a rate of 104.2 cases per 100,000 population.[2] This upsurge is concerning, as it marks a second year of increases after 2006-2009, when rates reached the lowest level since national reporting began.

Look at the test

How does the new test differ from other available diagnostics in the United States?

The tests are not batch-based, so results are available on-demand, says Tipton. This feature makes it suitable for testing and managing patients in emergency department settings, he notes. It also serves as a valuable tool for evaluation of patients with possible pelvic inflammatory disease (PID), Tipton adds.

The test is designed to avoid false positives, says Tipton. It has received regulatory clearance for all female direct specimens, including urine, self-collected vaginal, and cervical swabs, as well as male urine, states Tipton.

The FDA has categorized the Xpert CT/NG test as "moderately complex" under the Clinical Laboratory Improvement Amendments (CLIA). CLIA regulations are based on the complexity of the test method, Test methods are categorized into three levels of complexity: waived, moderate, and high. To run moderately complex tests, labs must meet requirements for quality control, quality assurance, proficiency testing, and personnel. The molecular CT/NG test is the first of its kind to be categorized as moderately complex, according to Cepheid.

The moderate complexity classification of the Xpert CT/NG test is hailed as a "breakthrough" for sexual health and sexually transmitted disease (STD) prevention, said **Jeffrey Klausner**, MD, MPH, professor of medicine at the University of California, Los Angeles David Geffen School of Medicine, in a statement issued by Cepheid. The large number of moderate complexity point-of-care laboratories that exist in U.S. hospitals and clinics now can offer rapid, highly accurate, and private same-day STD testing, noted Klausner.

"Public health officials need to work with providers to increase the availability of [such] tests," said Klausner. "Faster STD detection and treatment could go a long way in stemming the continued epidemic of STDs in the United States."

Data to emerge

Science also is eyeing the test for use with rectal swabs, as there are no commercially available approved molecular assays for the detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* in rectal swabs.

A recent study looked at using the Cepheid GeneXpert CT/NG assay with the GenProbe Aptima Combo2 assay, using 409 rectal swabs. Using Aptima as the gold standard, the sensitivity, specificity, positive and negative predictive values of GeneXpert for the detection of *C. trachomatis* and *N. gonorrhoeae* were 86%, 99.2%, 92.5%, 98.4% and 91.1%, 100%, 100%, 98.6%, respectively. Despite significantly diluting samples prior to GeneXpert testing, the assay performed well with excellent specificity, researchers note.[2]

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Initiative launched to raise condom awareness

The American Social Health Association (ASHA) in Research Triangle Park, NC, has launched "Condomology," an educational initiative to provide credible, evidence-based information on condom use.

The initiative includes a collection of fact-based content, such as a condom effectiveness scientific dossier, geared toward health professionals, as well as a presentation for consumers, "Making Informed Decisions: Facts About Condoms." Also included are videos on proper condom use and condom manufacturing, as well as a fact sheets on condom effectiveness. To access all Condomology content, visit the American Social Health Association website, www.ashastd.org/condomology.html. ■