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New guidance uses best evidence to direct family planning services

Guidance aims for improved reproductive health outcomes for women, men

The Centers for Disease Control and Prevention (CDC) and the Office of Population Affairs (OPA) of the U.S. Department of Health and Human Services have just issued new guidance to improve the quality of family planning services. The *Providing Quality Family Planning Services — Recommendations of CDC and the U.S. Office of Population Affairs* (QFP) define what services should be offered in a family planning visit and gives providers the information they need to improve family planning services.

The recommendations were developed collaboratively by the two agencies and were based on a rigorous systematic review of the available evidence and extensive input from a broad range of clinical experts. *(Read the guidance online at http://1.usa.gov/1jX4SOp.)*

Why is the new guidance needed? The United States continues to face challenges to improving the reproductive health of the population, say public health officials. Nearly 50% of all pregnancies are unintended, with more than 700,000 adolescents ages 15-19 becoming pregnant each year and more than 300,000 giving birth. One of eight pregnancies in the United States

EXECUTIVE SUMMARY

The Centers for Disease Control and Prevention and the Office of Population Affairs of the U.S. Department of Health and Human Services have issued new guidance to improve family planning services. The guidance titled *Providing Quality Family Planning Services — Recommendations of CDC and the U.S. Office of Population Affairs* defines what services should be offered in a family planning visit and gives providers the information they need to improve.

- For the first time, the two agencies encourage using the family planning visit to provide essential preventive services such as breast and cervical cancer screening.
- The guidance also addresses the needs of male clients, includes a special section on serving adolescents, and it provides detailed guidance on educating clients about the effectiveness of long-acting reversible contraception (LARC).

results in preterm birth, and infant mortality rates remain high, compared with those of other developed countries.[1]

For the first time, CDC and OPA encourage using the family planning visit to provide essential preventive services such as breast and cervical cancer screening, in accordance with recommendations for women issued by the Institute of Medicine.[2]

The new guidance also addresses the needs of male clients, includes a special section on serving adolescents, and it provide detailed guidance on educating clients about the effectiveness of long-acting reversible contraception (LARC). Overall, the new recommendations integrate and fill gaps in other guidelines for the family planning setting, including those developed for contraception, achievement of pregnancy, preconception, and sexually transmitted infections (STIs), including HIV.

The recommendations cover the following:

- Describe what services should be offered in a family planning visit: contraceptive services, pregnancy testing and counseling, advice for achieving pregnancy, as well as information on basic infertility, preconception health, and STI services. They also describe how these services should be provided.
- Address the needs of female and male clients, describe how to provide services to special populations such as adolescents, provide detailed guidance on how to provide contraceptive services, and encourage providers to discuss contraceptive effectiveness with clients seeking to prevent pregnancy.
- Encourage using the family planning visit to provide other essential preventive health services, such as blood pressure screening and breast and cervical cancer screening.

Follow the steps

The QFP recommendations are designed to help reduce negative health outcomes and to increase the number of women and men who are able to achieve their desired number and spacing of healthy children, said **Susan Moskosky**, MS, WHNP-BC, acting director of the OPA, who participated in a webinar announcing the guidance's release. *(A link to the webinar transcript, as well as other QFP materials, is available at http://1.usa.gov/1s9dry7, under "May 8, 2014.")*

Providing quality counseling is an essential component of client-centered care, and counseling is defined as a process that enables clients to make and follow through on decisions, said Moskosky. Education is an integral component of the counseling process that helps clients to make informed decisions. Use the five key principles of quality counseling to get your information across:

- establishing and maintaining rapport with the client;
- assessing the client's needs;
- working with the client interactively to establish a plan;
- providing information that can be understood and retained by the client;

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• confirming client understanding.

While these principles initially were developed specific to the provision of contraceptive counseling, they can be applied to a variety of family planning services, said Moskosky. Clinicians also should establish the following steps in providing contraceptive services:

• establishing and maintaining rapport with the client;

• obtaining clinical and social information from the client;

• working with the client interactively to select the most effective and appropriate contraceptive method for him or her;

• conducting a physical assessment related to the contraceptive use when warranted;

• providing the contraceptive method along with instructions about consistent and correct use;

• helping the client to develop a plan for using that selected method and for follow up and documenting client understanding. *[Use the* Family Planning and Related Preventive Health Services Checklists for Women and Men *developed by the Family Planning National Training Centers. They are included with the online issue of* Contraceptive Technology Update. *Go to www.ahcmedia.com. On the right side of the page, see "Access Your Newsletters. Sign In." You'll need your subscriber number from your newsletter envelope or your invoice. If you need help accessing the online document, contact customer service at (800) 688-2421 or customerservice@ahcmedia.com.]*

Get out the word

The CDC and OPA are planning numerous activities designed to disseminate and support implementation of the new guidance in family planning and other primary care settings, says **Lorrie Gavin**, MPH, PhD, senior health scientist in the CDC's Division of Reproductive Health.

Presentations about the guidance are being made at several national reproductive health conferences, Gavin reports. (*The presentation at the recent meeting of the National Family Planning and Reproductive Health Association is available for viewing at http://bit.ly/1oYi9ch.)*

Numerous papers about the new guidance are scheduled to be released in peer-reviewed journal articles throughout the year, says Gavin. Just released is an article in the August 2014 issue of *Journal of Women's Health*, she notes.

CDC and OPA officials have convened numerous regional webinars with the Title X community, states Gavin. Electronic list-servs and eblasts have been used to announce the release of the guidance and targeted national organizations engaged in family planning, professional medical associations, maternal/child health providers, and others, she says.

Supporting implementation

Organizers also are working on several activities that they hope will support actual implementation by providers, reports Gavin. OPA-funded national training centers are developing training materials that will give providers the knowledge and skills needed to deliver services in accordance with QFP recommendations. The materials will include job aids, patient education materials, and suggestions for ways to modify the clinic environment to facilitate the delivery of recommended services. Materials will be available to all providers; visit www.fpntc.org.

Organizers are exploring the role that performance measurement and quality improvement can play in supporting implementation of QFP recommendations and in improving the quality of care, says Gavin. "For example, we plan to submit two performance measures of contraceptive services to the National Quality Forum for their endorsement, and they will be integrated into the Title X program after endorsement," says Gavin. "We also are discussing adoption of these measures with representatives from other health systems, such as Medicaid, Maternal and Child Health Bureau program staff, and community health centers."

Organizers are exploring the role that clinical decision support tools can play in facilitating the delivery of family planning services, notes Gavin. For example, organizers are exploring tools that: automatically prompt the provider to ask about pregnancy intention at least once/year and to document in the medical record the client's intention and contraceptive method selected at the end of the visit; identify the preconception, STI, and related preventive health screening services that should be offered to a client, given the client's characteristics; and identify the contraceptive methods that are safe (per the *U.S. Medical Eligibility Criteria for Contraceptive Use*) for a client, given her characteristics, states Gavin.

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Research eyes safety of same-day IUD insertion

Concerns about asymptomatic sexually transmitted infections (STIs) in women at high risk for disease might deter clinicians from same-day placement of intrauterine contraception. However, results from two recent studies indicate such delays are unnecessary.[1,2] Both studies were presented at the 2014 annual clinical meeting of the American College of Obstetricians and Gynecologists (ACOG).

In the first study, researchers at a Title X Pittsburgh clinic offered same-day testing for STIs and intrauterine device (IUD) placement from September 2011 to May 2013 to all women seeking emergency contraception or pregnancy testing who had no cervicitis on examination and wanted to avoid pregnancy for six or more months. Participants in the study completed surveys on the day of their clinic visit and three months later regarding contraceptive use and STI testing, diagnosis, and treatment.

Of 947 eligible women, 366 (39%) completed surveys. Of those who completed surveys, 28 women had chosen same-day intrauterine contraceptive insertion. Rates of pelvic inflammatory disease within three months of visiting the study clinic were similar with same-day IUD placement (3.6%, 95% confidence interval [CI] 0-10.4%) or without same-day intrauterine contraceptive placement (5.3%, 95% CI 3.0-8.5%, P = .82). Most women (82%) who opted for same-day intrauterine contraceptive placement reported still using the IUD three months later. Pregnancy within three months of visiting the study clinic was reported by 3.6% (95% CI 0-19.2%) of women who opted for same-day intrauterine contraceptive placement compared with 10.7% (95% CI 7.4-15.3%) of others.[1]

"The women in our study were seeking either emergency contraception or pregnancy testing. When they saw that [same-day IUD insertion] was offered, they chose it," said **Eleanor Bimla Schwarz**, MD, MS, director of the women's health services research unit at the Center for Research on Health Care in the Pitt School of Medicine in Pittsburgh. "Same-day insertion increases the convenience of the method."

In the second study, researchers at the Baylor College of Medicine in Houston sought to identify the incidence of gonorrhea and chlamydia in women presenting for intrauterine device insertion in People's Community Health Center, a Houston academic community clinic, to evaluate the current "two-visit" practice for IUD insertion. The scientists performed a retrospective chart review from 2009 to 2010. They identified study participants from a list of all patients who had gonorrhea and chlamydia testing as those who presented for IUD insertion. Subsequent encounters were reviewed to identify participants who presented for IUD placement, were lost to follow-up, or presented with a pregnancy.

A total of 720 patients met inclusion criteria. The average age was 30.3 years, with average gravidity at 2.89 and parity at 2.5 (SD 1.2-3.8). The incidence of gonorrhea was 0.56%, and the incidence of chlamydia was 2.5%.

Just 69.74% of patients returned for the second visit for IUD placement, according to a chart review. Those who tested positive for gonorrhea or chlamydia were less likely to return (odds ratio, 4.68), and the rate of pregnancy was significantly higher in those who did not return (32.4% vs. 1.9%).

"Like previously reported studies in other populations, the incidence of gonorrhea and chlamydia in our patients is low; however, rates of failure to return and pregnancy are high," the researchers conclude. "Current 'two-visit' protocols should be amended to allow for immediate placement of IUDs in similar populations to prevent delay in contraceptive services and unintended pregnancy."

EXECUTIVE SUMMARY

Concerns about asymptomatic sexually transmitted infections in women at high risk for disease might deter clinicians from same-day placement of intrauterine devices (IUDs). However, results from two studies presented at a national meeting indicate such delays are unnecessary.

- Findings from a study of women who were offered same-day insertion of intrauterine contraception indicate rates of pelvic inflammatory disease within three months were similar in those who opted for and against same-day insertion.
- In a study to identify the incidence of gonorrhea and chlamydia in women presenting for intrauterine device insertion in a clinic with a "two-visit" insertion policy, statistics show just 69.74% of patients returned for the second visit for IUD placement.

Why the hesitation?

Clinicians have in hand guidance asserting the safety of same-day insertion of intrauterine contraception.

In 2009, ACOG issued a recommendation to adopt same-day insertion protocols for the IUD and the contraceptive implant, both of which are methods of long-acting reversible contraception (LARC).[3] ACOG's clinical recommendations specifically state that LARCs can be inserted at any time during the menstrual cycle as long as pregnancy is reasonably excluded and that routine STI screening is not required unless the client is at high risk of STIs. If this situation is the case, screening and insertion can occur on the same day or when the test results are available.[3]

Previous research also backs this practice. According to a 2012 joint study of nearly 60,000 women by researchers at the University of California, San Francisco and Kaiser Permanente Northern California in Oakland, the risk of developing pelvic inflammatory disease following insertion of an IUD is very low, whether or not women have been screened for gonorrhea and chlamydia.[4] (Contraceptive Technology Update *reported on the research. See "Put myths to bed: Study shows IUD insertions don't cause PID in women," February 2013, p. 13.)*

To understand clinicians' attitudes about LARC same-day insertions, researchers surveyed staff members at family planning agencies in Colorado and Iowa regarding their LARC provision practices and their attitudes. Just 18% of agencies typically offered an IUD, and 36% typically offered an implant, in one visit.[5]

Barriers must be overcome for more women to receive IUDs without the extra burden of multiple visits. Often, the option of delivering same-day placement of IUDs is out of the clinician's hands; there are often issues regarding payment authorization, 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. Also, some clinics might not have IUDs in stock due to cost considerations, she notes.

"When possible, offering IUDs the same day of an appointment can mean that the woman's next visit isn't for a pregnancy test," says Wysocki. "It's important to recognize any time lag for providing an effective method of contraception can make a difference for preventing an unintended pregnancy."

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New guidelines focus on PrEP use against HIV

The Centers for Disease Control and Prevention (CDC) has issued clinical guidance for use of anti-HIV drugs in uninfected patients who are at substantial risk of infection.[1,2] Research indicates that pre-exposure prophylaxis (PrEP) can reduce HIV infection rates; when taken daily as directed, PrEP can reduce the risk of HIV infection by more than 90%.[3]

The guidelines solidify interim PrEP guidance issued in 2012 by the CDC and the 2012 approval by the Food and Drug Administration of 300 mg tenofovir disoproxil fumarate and 200 mg emtricitabine for use as PrEP in combination with safer sex practices. *(*Contraceptive Technology Update *reported on both events. See "Check interim guidance for PrEP in men, women," October 2012, p. 113.)*

"HIV infection is preventable, yet every year we see some 50,000 new HIV infections in the United States," said CDC Director **Tom Frieden**, MD, MPH, in a statement accompanying the guidance release. "PrEP, used along with other prevention strategies, has the potential to help at-risk individuals protect themselves and reduce new HIV infections in the U.S."

According to the CDC guidance, PrEP should be

considered for HIV-uninfected patients with any of the following indications:

- anyone who is in an ongoing sexual relationship with an HIV-infected partner;
- a gay or bisexual man who has had sex without a condom or has been diagnosed with a sexually transmitted infection within the past six months, and is not in a mutually monogamous relationship with a partner who recently tested HIV-negative;
- a heterosexual man or woman who does not always use condoms when having sex with partners known to be at risk for HIV (for example, injecting drug users or bisexual male partners of unknown HIV status) and is not in a mutually-monogamous relationship with a partner who recently tested HIV-negative;
- anyone who has, within the past six months, injected illicit drugs and shared equipment or been in a treatment program for injection drug use.[1]

CDC expands uptake

PrEP has the potential to alter the course of the epidemic in the United States, if targeted to the right populations, for use in the right way and in the right circumstances, says **Dawn Smith**, MD, MPH, a CDC medical epidemiologist who led the development of the guidelines. To realize the promise of PrEP in the United States, public health officials must expand uptake and address practical implementation issues, she notes.

The CDC is leading efforts on multiple fronts to support PrEP uptake and address critical issues for its delivery in community settings, according to Smith. As part of those efforts, the agency is conducting an implementation pilot study to examine the practical requirements, costs, and impact of PrEP at four federally qualified health centers in Houston, Philadelphia, Newark, and Chicago. The pilot will look specifically into services provided by health centers that serve adults at substantial risk of acquiring HIV infection, such as gay and bisexual men, heterosexual women and men, and people who inject drugs, states Smith.

How can you integrate PrEP into your practice? Visit the CDC web site, http://1.usa.gov/1fzbtkI, for a variety of online resources. At this site, clinicians can download the current guidance, as well as a supplement that includes checklists and interview guides to assist with PrEP prescribing and counseling. *(Click on the publication's title under the heading* "Pre-exposure Prophylaxis."*)*

Consistent with FDA labeling, the guidelines emphasize the importance of HIV testing before PrEP is prescribed, as well as at three-month intervals during patient use. Such testing ensures that anyone on PrEP who becomes infected with HIV can discontinue PrEP use to minimize the risk that the virus could become resistant to the drugs. Such patients then can begin receiving HIV treatment.

Because no prevention strategy for sexually active people is 100% effective, the CDC guidance encourages patients taking PrEP to use other effective prevention strategies to further reduce their risk, including:

- using condoms consistently and correctly;
- getting HIV testing with partners;
- choosing less risky sexual behaviors, such as oral sex;
- for people who inject drugs, getting into drug treatment programs and using sterile equipment.

While a vaccine or cure might one day end the HIV epidemic, PrEP is a powerful tool that has the potential to alter the course of the U.S. HIV epidemic today, stated **Jonathan Mermin**, MD, MPH, director of CDC's National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention in a statement accompanying the guidance release.

"These guidelines represent an important step toward fully realizing the promise of PrEP," said Mermin. "We should add to this momentum, working to ensure that PrEP is used by the right people, in the right way, in the right circumstances."

EXECUTIVE SUMMARY

The Centers for Disease Control and Prevention (CDC) has issued clinical guidance for use of anti-HIV drugs in uninfected patients who are at substantial risk of infection. Research indicates that pre-exposure prophylaxis (PrEP) can reduce HIV infection rates. When taken daily as directed, PrEP can reduce the risk of HIV infection by more than 90%.

- The guidelines solidify interim PrEP guidance issued in 2012 by CDC and the 2012 approval by the Food and Drug Administration of 300 mg tenofovir disoproxil fumarate and 200 mg emtricitabine for use as PrEP with safer sex practices.
- The guidelines emphasize HIV testing before PrEP is prescribed, as well as at three-month intervals during use.

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Time to look at LARC use in postpartum teens

Postpartum placement of long-acting reversible contraception (LARC) might be an effective way to address unplanned pregnancies in adolescents. Efficacy is key in preventing rapid repeat pregnancy; 20% of adolescent mothers give birth again within two years.[1]

Insertion of an intrauterine device (IUD) or contraceptive implant immediately postpartum ensures reliable contraception for teens when they are highly motivated to prevent pregnancy and are already in the healthcare system, according to a committee opinion from the American College of Obstetricians and Gynecologists.[2]

The *U.S. Medical Eligibility Guidelines for Contraceptive Use* ranks use of the Copper T-380A IUD as a "Category 1" (no restrictions) for insertion less than 10 minutes after delivery of the placenta, and levonorgestrel IUDs as a "Category 2" (a condition for which the advantages of using the method generally outweigh the theoretical or proven risks) for the same scenario.[3] For insertion after 10 minutes past delivery of placenta to up to four weeks postpartum, both IUDs and the implant are rated as Category 2.[3]

Findings from a new study indicate postpartum LARC use decreases rapid repeat pregnancy among first-time adolescent mothers.[4] To help perform the retrospective cohort study, researchers looked at 340 first-time adolescent mothers age 19 or below at an urban teaching hospital. They examined the rate of repeat pregnancy in two years.

Researchers recorded a repeat pregnancy rate of 35% among the 340 first-time adolescent mothers with documented follow-up time. Logistic regression analysis comparing adolescents with and without repeat pregnancy revealed that leaving the hospital postpartum without initiating any contraception was associated with significant increase risk of repeat pregnancy (odds ratio [OR] = 2.447, 95% confidence interval [CI] 1.326-4.515). Follow up within eight weeks postpartum was associated with lower chance of repeat pregnancy (OR = 0.322, 95% CI 0.172-0.603). Initiation of a LARC method (either an intrauterine device or subdermal implant) by eight weeks postpartum also was associated with decreased chance of rapid repeat pregnancy (OR=0.118, 95% CI 0.035-0.397).

"Adolescent mothers who initiate a LARC method within eight weeks of delivery are less likely to have a repeat pregnancy within two years than those who choose other methods or no method," note researchers. "First-time adolescent mothers should be counseled about this advantage of using LARC."

Use of LARC methods offer the most effective rates against unplanned pregnancy, says **Veronica Gomez-Lobo,** MD, director of pediatric and adolescent obstetrics and gynecology at MedStar Washington Hospital Center and Children's National Medical Center, both in Washington, DC. When patients get busy and don't return for the first postpartum visit at six weeks, immediate postpartum initiation provides protection, notes Gomez-Lobo, a coauthor of the current paper. Women usually ovulate at four weeks if they are not breastfeeding; again, immediate LARC placement provides protection before the first six-week visit, she adds.

EXECUTIVE SUMMARY

Postpartum placement of long-acting reversible contraception (LARC) might be an effective way to address unplanned pregnancies in adolescents. Efficacy is key in preventing rapid repeat pregnancy; 20% of adolescent mothers give birth again within two years.

- Insertion of an intrauterine device or contraceptive implant immediately postpartum ensures reliable contraception for teens when they are highly motivated to prevent pregnancy and are already in the healthcare system, according to a committee opinion from the American College of Obstetricians and Gynecologists.
- Findings from a new study indicate postpartum LARC use decreases rapid repeat pregnancy among first-time adolescent mothers.

Take a look at implant

Offering the contraceptive implant to adolescent mothers immediately postpartum is cost-effective, according to results from a recently released study.[5] Previous investigation of adolescents enrolled in a Colorado prenatal-postnatal program indicated that rapid repeat pregnancy was significantly decreased compared with control participants, with excellent continuation of device use one year after delivery.[6] However, at the time, implants offered this way were not covered by payers, including Medicaid, says **Leo Han**, MD, fourth-year resident in the Department of Obstetrics and Gynecology at the University of Colorado School of Medicine in Aurora.

Researchers wanted to perform the cost-effectiveness study not only to demonstrate it would be cost-effective, but to put a dollar/savings figure on offering implants postpartum, explains Han, lead author of the current paper. To conduct the study, 171 participants in the Colorado adolescent prenatal-postnatal program were enrolled in a prospective observational study of implant insertion, with 225 women enrolled in the standard contraceptive initiation arm for comparison. Researchers looked at implant discontinuation, repeat pregnancies and pregnancy outcomes, and compared the anticipated public expenditures for implant recipients and comparisons at six, 12, 24, and 36 months postpartum using actual outcomes of the cohort and Colorado Medicaid reimbursement estimates. Costs were normalized to 1,000 adolescents in each arm and included one year of well-baby care for delivered pregnancies.

At six months, the expenditures of the implant group exceeded the comparison group by $73,000, statistics indicate. However, at 12, 24, and 36 months, researchers found that publicly funded implants would result in a savings of more than $550,000, $2.5 million, and $4.5 million, respectively. For every dollar spent on the implant program, $0.79, $3.54, and $6.50 would be saved at 12, 24, and 36 months. Expenditures between the implant and comparison groups would be equal if the comparison group pregnancy rate was 3.8%, 18.6%, and 30.5% at 12, 24, and 36 months; actual rates were 20.1%, 46.5%, and 83.7%.

Good news: Shortly after the initial presentation of this data, Colorado Medicaid began reimbursing for immediate postpartum implant placements, says Han.

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Research targets new condom technology

Eleven research teams have received funding from the Bill and Melinda Gates Foundation of Seattle to pursue new condom designs that could help increase condom use by improving sexual sensation and other aspects of user experience.

Boosting condom use is important, especially among at-risk adolescents. Of teens who had sex in the past month, almost one in four males and almost four in 10 females did not use a condom, 2011 statistics indicate.[1]

The $100,000 Phase I grants are designed to "foster and accelerate innovative ideas that can improve, and even save, people's lives," said **Chris Wilson,** MD, director of Global Health Discovery & Translational Sciences at the Gates Foundation, in a release accompanying the grants announcement.

11 research funding recipients named

Researchers in the United States receiving grants for condom research from the Gates Foundation include the following:

- **Shengxi Chen**, PhD, of Arizona State University in Tempe will produce a male condom using a material to mimic the surface of the skin for a more natural feel, coupled with a chemical to activate erection.
- Mahua Choudhury, PhD, and scientists at Texas A&M University in Kingsville, TX, will pursue development of low-cost male condoms from a strong and highly elastic three-dimensional hydropolymer embedded with an antioxidant to enhance sexual experience and help prevent HIV transmission.
- Charles Chung and researchers from UbIQ World in San Francisco plan to engineer the surface of male condoms using nanofabrication technology to mimic human skin, thereby enhancing sensation and encouraging use.
- **Debby Herbenick**, PhD, MPH, of Indiana

University in Bloomington, IN, and researchers will design a new female condom with a more natural elliptical opening as opposed to the more conventional round one. The condom will be ribbed on one side to provide directed internal stimulation for the female.

• Daniel Resnic and colleagues at Origami Healthcare Products in Los Angeles are refining an internal condom made of soft, pliant silicone for tests in a small, randomized crossover controlled trial.

• Mache Siebel, MD, and researchers at HealthRock in Newton, VA, will test a female condom that is inflated and positioned using air pressure.

• Steve Strauss and scientists at Ultimate Medical Products in Rockville, NY, will refine a presently designed condom applicator that is quick and easy to use, can be applied with one hand, and ensures the condom is correctly fitted,

• Wei Zhang and researchers at QX-System in Milpitas, CA, will design a sliding tampon applicator, a flexible tube surrounded by a soft balloon, which is positioned inside a female condom that can be inserted like a regular tampon. Once the condom is in position, the applicator can be removed and reused.

Goal: more condom use

As a method of birth control, condoms have many advantages including being low-cost, being easy to use, and providing protection against numerous sexually transmitted infections (STIs), says Chen, assistant professor of research at Arizona State University's Biodesign Institute. However, the drawbacks to more universal and consistent use of condoms are their tendencies to decrease pleasure and/or induce the loss of erection, he notes.

"The reason for these obstacles is that condoms are made from hydrophobic materials, such as latex, polyurethane, and polyisoprene, which are excluded from the human physiological environment, such as the surface of the skin," states Chen. "Thus, currently used condoms always cause the foreign body sensation to decrease pleasure and/or induce the loss of erection."

The Arizona researchers are proposing to design and prepare a skin-like condom, which mimics the membrane of living cells to increase pleasure and enhance erection, says Chen.

Herbenick and her team are developing a new female condom that is attentive to women's genital anatomy and is designed to enhance sexual pleasure.

EXECUTIVE SUMMARY

Eleven research teams have received funding from the Bill and Melinda Gates Foundation of Seattle to pursue new condom designs that could help increase condom use by improving sexual sensation and other aspects of user experience.

• Boosting condom use is important, especially among at-risk adolescents. Of teens who had sex in the past month, almost one in four males and almost four in 10 females did not use a condom, 2011 statistics indicate.

• Of the 11 grants, eight U.S. research teams received $100,000 Phase I grants, designed to foster and accelerate innovative ideas on condom technology.

The design will spring from research and interviews with individuals and couples throughout the world about condom use, HIV/STI prevention, and pleasure.

"Female condom innovation is in its infancy, and we believe that safety and pleasure don't have to be in conflict," Herbenick said in a press statement accompanying the grant award. "We hope to create a product that promotes pleasure while helping to save lives."

What to do now?

It is "terrific" that the Gates Foundation is funding condom innovations, 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.

Design of condoms is important. Even more important is to have the ability to mass produce a condom that is quality controlled, Wysocki notes. If the foundation does find the 'perfect' design, it will have to team up with a manufacturer for production, she states.

What can clinicians do now to encourage condom use? Wysocki encourages clinicians to check out condoms that are on the market.

"Many are innovative, and designed for more pleasurable experiences versus the thick, libido-killing condoms of the past," she notes.

REFERENCE

1. Martinez G, Copen CE, Abma JC. Teenagers in the United States: sexual activity, contraceptive use, and childbearing, 2006-2010 national survey of family growth. *Vital Health Stat* 2011; 1-35. ■

Science gives overview of HPV in healthy adults

69% of Americans have 1 of 109 strains

Research might yield a better understanding of human papillomavirus (HPV) infection.

Results of a new genetic analysis indicate that 69% of healthy American adults are infected with one or more of 109 strains of the virus.[1] Just four of the 103 men and women whose tissue DNA was publicly available through a government database had one of the two HPV types (16 or 18) known to cause most cases of cervical cancer, some throat cancers, and genital warts.[1]

In the two-year study, researchers from New York University (NYU) in New York City, J. Craig Venter Institute in Rockville, MD, and San Diego, Lawrence Berkeley National Laboratory in Berkeley, CA, Gene by Gene Ltd. in Houston, and Vanderbilt University in Nashville analyzed data made publicly available from the National Institutes of Health's Human Microbiome Project, which is gathering information on microorganisms' effects on human health. The study was lead by **Yingfei Ma**, PhD, a research scientist at NYU Langone Medical Center in New York City.

"The HPV 'community' in healthy people is surprisingly more vast and complex than previously thought, and much further monitoring and research is needed to determine how the various non-cancer-causing HPV genotypes interact with the cancer-causing strains, such as genotypes 16 and 18, and what causes these strains to trigger cancer," said Ma in a press release accompanying the study's release.

Tissue samples originally were collected from healthy study volunteers, ages 18 to 80, participating in the microbiome project. The scientists then used shotgun sequencing, which deciphers the genetic code of long strands of DNA in a random firing pattern, until a full picture appeared. The investigators then refined the analysis to only HPV strains by removing all human DNA sequences. Using special bioinformatics software developed at NYU Langone, the researchers compared what was left with known HPV national databases.

With this approach, scientists determined overall HPV prevalence at 68.9%, with specific prevalence as follows: skin, 61.3%; vagina, 41.5%; mouth, 30%; and gut, 17.3%.

Of the 109 HPV types, as well as additional unclassified types detected, most were undetectable by widely used commercial kits targeting the vaginal/cervical HPV types. These HPVs likely represent true HPV infections rather than transitory exposure because of strong organ tropism and persistence of the same HPV types in repeat samples, scientists conclude.[1] In terms of the number of strains:

- Skin samples contained the most varied HPV strains, data shows. Eighty types of HPV were identified, including 40 that were found only in the skin.
- Vaginal tissue had the second most numerous strains, with analysis identifying 43 types of HPV, with 20 strains exclusive to the organ.
- Mouth tissue contained 33 types, of which five were exclusively oral in origin.
- Gut tissue contained six types, all of which were found in other organs.

The researchers are interested in exploring the role of HPV in cancers outside of the uterine cervix, says **Zhiheng Pei,** MD, PhD, FASCP, associate professor of pathology and medicine at NYU School of Medicine.

"The findings that HPV types inhabiting non-cervical body sites are different groups of HPV types pointed out the inadequacy of the cervical HPV detection kits for studies of HPV in other cancers," says Pei, a member of the research team. "We plan to develop a broad range HPV detection kit for use in surveys of HPV distribution in all types of HPV-related diseases throughout the body; the new method will allow assessing whether 'high risk' HPV types could be re-defined according to different organs beyond the cervix."

The Human Microbiome Project (HMP) represents a new approach to understanding the microbial cells that inhabit the human body. Most of the human-associated microbial species have never been successfully isolated in the laboratory. Thanks to

EXECUTIVE SUMMARY

Results of a new genetic analysis indicate that 69% of healthy American adults are infected with one or more of 109 strains of the human papillomavirus (HPV).

- The study material came from the National Institutes of Health's Human Microbiome Project, which is gathering information on microorganisms' effects on human health. The project represents a new approach to understanding the microbial cells that inhabit the human body.
- Most of the human-associated microbial species have never been successfully isolated in the laboratory.
- Thanks to advances in DNA sequencing technologies, scientists can conduct comprehensive examination of microbial communities without the need for cultivation.

advances in DNA sequencing technologies, scientists now can conduct comprehensive examination of microbial communities without cultivation.

The National Institutes of Health has awarded a $7.4 million grant to researchers at Virginia Commonwealth University in Richmond to study pregnancy and preterm birth, using the Global Alliance to Prevent Prematurity and Stillbirth (GAPPS) Repository, a novel pregnancy biobank, and other academic institutions for specimens and data. The Multi-Omic Microbiome Study -- Pregnancy Initiative (MOMS-PI) will analyze the maternal and neonatal microbiome to assess its role as a cause of preterm birth. The study is a collaborative project with GAPPS, an initiative of Seattle Children's Research Institute.

REFERENCE

1. Ma Y, Madupu R, Karaoz U, et al. Human papilloma virus community in healthy persons, defined by metagenomics analysis of Human Microbiome Project shotgun sequencing data sets. *J Virol* 2014; 88(9):4,786-4,797. ■

CTU makes move to per-issue testing

Here's a change we know you'll like: From now on, there is no more having to wait until the end of a 6-month semester or calendar year to earn your continuing education credits or to get your credit letter.

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COMING IN FUTURE MONTHS

- Check risk factors for combined hormonal contraceptives
- How you should treat chronic vulvar itching & irritation
- Uptick in syphilis rates: What's behind the increase?
- Look at emerging therapies for bacterial vaginosis

CNE/CME OBJECTIVES & INSTRUCTIONS

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.

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

1. Read and study the activity, using the provided references for further research.
2. Scan the QR code below or log on to www.cmecity.com to take a post-test; tests areto be taken after each issue. First-time users will have to register on the site using the 8-digit subscriber number printed on their mailing label, invoice or renewal notice.
3. Pass the online tests with a score of 100%; you will be allowed to answer the questions as many times as needed to achieve a score of 100%.
4. After successfully completing the test, your browser will be automatically directed to the activity evaluation form, which you will submit online.
5. Once the completed evaluation is received, a credit letter will be emailed to you instantly. ■

CNE/CME QUESTIONS

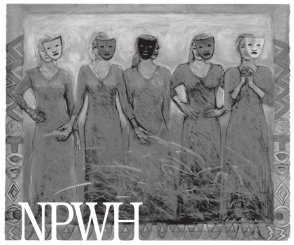
1. According to guidance from the American College of Obstetricians and Gynecologists, when can use of long-acting reversible contraceptives be initiated?
A. At any time during the menstrual cycle as long as pregnancy is reasonably excluded
B. Only during menses
C. Only on cycle days 2 to 5 of menses.
D. Only on the first day of the menstrual cycle

2. Research indicates that pre-exposure prophylaxis (PrEP) can reduce HIV infection rates; when taken daily as directed, PrEP can reduce the risk of HIV infection by what percentage?
A. 50%
B. 75%
C. 80%
D. More than 90%

3. The *U.S. Medical Eligibility Guidelines for Contraceptive Use* lists what category ranking for use of the Copper T-380A intrauterine device for insertion less than 10 minutes after delivery of the placenta?
A. Category 1 -- A condition for which there is no restriction for the use of the contraceptive method.
B. Category 2 -- A condition for which the advantages of using the method generally outweigh the theoretical or proven risks.
C. Category 3 -- A condition for which the theoretical or proven risks usually outweigh the advantages of using the method.
D. Category 4 -- A condition that represents an unacceptable health risk if the contraceptive method is used.

4. Which two types of human papillomavirus (HPV) are known to cause most cases of cervical cancer?
A. 57 and 56
B. 43 and 44
C. 19 and 21
D. 16 and 18

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



Checklist

Family planning and related preventive health services

for women

Family Planning National Training Center
www.fpntc.org

		Family planning services (provide services in accordance with the appropriate clinical recommendation)					
	Screening components	Contraceptive services[1]	Pregnancy testing and counseling	Basic infertility services	Preconception health services	STD services[2]	Related preventive health services
History	Reproductive life plan	✓	✓	✓	✓	✓	
	Medical history	✓	✓	✓	✓	✓	✓
	Current pregnancy status	✓					
	Sexual health assessment	✓		✓	✓	✓	
	Intimate partner violence				✓		
	Alcohol & other drug use				✓		
	Tobacco use	✓ *(combined hormonal methods for clients ≥35 years)*			✓		
	Immunizations				✓	✓[4] *(HPV & HBV)*	
	Depression				✓		
	Folic acid				✓		
Physical examination	Height, weight & BMI	✓ *(hormonal methods)*[3]		✓	✓		
	Blood pressure	✓ *(combined hormonal methods)*			✓[4]		
	Clinical breast exam			✓			✓[4]
	Pelvic exam	✓ *(initiating diaphragm or IUD)*	✓ *(if clinically indicated)*	✓			
	Signs of androgen excess			✓			
	Thyroid exam			✓			
Laboratory testing	Pregnancy test	✓ *(if clinically indicated)*	✓				
	Chlamydia	✓[5]				✓[4]	
	Gonorrhea	✓[5]				✓[4]	
	Syphilis					✓[4]	
	HIV/AIDS					✓[4]	
	Hepatitis C					✓[4]	
	Diabetes				✓[4]		
	Cervical cytology						✓[4]
	Mammography						✓[4]

Source: Centers for Disease Control and Prevention (CDC). (2014, April 25). Providing quality family planning services: Recommendations of CDC and the U.S. Office of Population Affairs. *MMWR. Morbidity and Mortality Weekly Reports.* Retrieved from http://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf

Abbreviations: BMI = body mass index; HBV = hepatitis B virus; HIV/AIDS = human immunodeficiency virus/acquired immunodeficiency syndrome; HPV = human papillomavirus; IUD = intrauterine device; STD = sexually transmitted disease.

[1] This table presents highlights from CDC's recommendations on contraceptive use. However, providers should consult appropriate guidelines when treating individual patients to obtain more detailed information about specific medical conditions and characteristics (Source: CDC, U.S. medical eligibility criteria for contraceptive use 2010. MMWR 2010;59[No. RR-4]).

[2] STD services also promote preconception health but are listed separately here to highlight their importance in the context of all types of family planning visits. The services listed in this column are for women without symptoms suggestive of an STD.

[3] Weight (BMI) measurement is not needed to determine medical eligibility for any methods of contraception because all methods can be used (US Medical Eligibility Criteria 1) or generally can be used (US Medical Eligibility Criteria 2) among obese women. (Source: CDC. U.S. medical eligibility criteria for contraceptive use 2010. MMWR 2010;59[No. RR-4]). However, measuring weight and calculating BMI at baseline might be helpful for monitoring any changes and counseling women who might be concerned about weight change perceived to be associated with their contraceptive method.

[4] Indicates that screening is suggested only for those persons at highest risk or for a specific subpopulation with high prevalence of an infection or condition.

[5] Most women do not require additional STD screening at the time of IUD insertion if they have already been screened according to CDC's STD Treatment Guidelines (Sources: CDC. STD treatment guidelines. Atlanta, GA: US Department of Health and Human Services, CDC; 2013. Available at http://www.cdc.gov/std/treatment. CDC. Sexually transmitted diseases treatment guidelines, 2010. MMWR 2010;59[No. RR-12]). If a woman has not been screened according to guidelines, screening can be performed at the time of IUD insertion and insertion should not be delayed. Women with purulent cervicitis or current chlamydial infection or gonorrhea should not undergo IUD insertion (U.S. Medical Eligibility Criteria 4). Women who have a very high individual likelihood of STD exposure (e.g., those with a currently infected partner) generally should not undergo IUD insertion (U.S. Medical Eligibility Criteria 3) (Source: CDC. US medical eligibility criteria for contraceptive use 2010. MMWR 2010;59[No. RR-4]). For these women, IUD insertion should be delayed until appropriate testing and treatment occurs.

Checklist

Family planning and related preventive health services

for men

Family Planning National Training Center
www.fpntc.org

		Family planning services (provide services in accordance with the appropriate clinical recommendation)				
	Screening components	Contraceptive services[1]	Basic infertility services	Preconception health services[2]	STD services[3]	Related preventive health services
History	Reproductive life plan	✓	✓	✓	✓	
	Medical history	✓	✓	✓	✓	
	Sexual health assessment	✓	✓	✓	✓	
	Alcohol & other drug use			✓		
	Tobacco use			✓		
	Immunizations			✓	✓ *(HPV & HBV)*[4]	
	Depression			✓		
Physical examination	Height, weight & BMI			✓		
	Blood pressure			✓[4]		
	Genital exam		✓ *(if clinically indicated)*		✓ *(if clinically indicated)*	✓[4]
Laboratory testing	Chlamydia				✓[4]	
	Gonorrhea				✓[4]	
	Syphilis				✓[4]	
	HIV/AIDS				✓[4]	
	Hepatitis C				✓[4]	
	Diabetes			✓[4]		

Source: Centers for Disease Control and Prevention (CDC). (2014, April 25). Providing quality family planning services: Recommendations of CDC and the U.S. Office of Population Affairs. *MMWR. Morbidity and Mortality Weekly Reports*. Retrieved from **http://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf**

Abbreviations: BMI = body mass index; HBV = hepatitis B virus; HIV/AIDS = human immunodeficiency virus/acquired immunodeficiency syndrome; HPV = human papillomavirus; STD = sexually transmitted disease.

[1] No special evaluation needs to be done prior to making condoms available to males. However, when a male client requests advice on pregnancy prevention, he should be provided contraceptive services as described in the section "Provide Contraceptive Services."

[2] The services listed here represent a sub-set of recommended preconception health services for men that were recommended and for which there was a direct link to fertility or infant health outcomes (Source: Frey K, Navarro S, Kotelchuck M, Lu M. The clinical content of preconception care: preconception care for men. Am J Obstet Gynecol 2008;199 [6 Suppl 2]:S389-95).

[3] STD services also promote preconception health, but are listed separately here to highlight their importance in the context of all types of family planning visit. The services listed in this column are for men without symptoms suggestive of an STD.

[4] Indicates that screening is suggested only for individuals at highest risk or for a specific subpopulation with high prevalence of infection or other condition.