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Old myth debunked: Data show IUD is safe birth control option for teens

Teens' rates of complications from IUDs no higher than for adults

Intrauterine devices (IUDs) are as safe for adolescents, including those who have never given birth, as they are for adults, according to just-published research.[1]

Researchers from the University of Texas Medical Branch at Galveston looked at private insurance claims from about 90,000 IUD users ages 15-44 to examine complications, failures, and discontinuation rates associated with device use. Results were compared by age and type of IUD used, which include the levonorgestrel IUD (LNG IUD, Mirena, Bayer HealthCare Pharmaceuticals, Wayne, NJ) and the copper T 380A IUD (ParaGard, Teva North America, North Wales, PA) Investigators examined whether adolescent IUD users were more likely to experience complications such as dysmenorrhea, amenorrhea, or IUD failure. Data analysis suggests the following:

- Serious complications resulting from IUD use, including ectopic pregnancy and pelvic inflammatory disease (PID), occurred in less than 1% of women regardless of age.
- Early discontinuation didn't differ between adolescents and older women, indicating that the IUD was not associated with greater complications among this age group.

EXECUTIVE SUMMARY

Intrauterine devices (IUDs) are as safe for teens, including those who have never given birth, as they are for adults, according to an analysis of private insurance claims of IUD users ages 15-44.

- Analysis indicated that serious complications resulting from IUD use, including ectopic pregnancy and PID, occurred in less than 1% of women regardless of age.
- Early discontinuation didn't differ between teens and older women, indicating that the IUD wasn't associated with greater complications among teens.
- Use of the levonorgestrel IUD was tied to fewer complications and lower rates of discontinuation than the copper T 380A IUD for all ages.

• Use of the LNG IUD was associated with fewer complications and lower rates of discontinuation than the copper T 380A IUD in all age groups.[1]

What prompted the research team to look at private insurance claims to gain understanding of intrauterine contraception among adolescents and other reproductive-age women? Using such information allowed investigators to examine the outcomes of a large number of young women, according to **Abbey Berenson**, MD, director of the Center for Interdisciplinary Research in Women's Health at the university. "This large sample size allowed us to examine outcomes in a more expedient and cost-effective manner than would have been possible with a prospective study," states Berenson, who served as lead author of the research paper. "Moreover, we felt that examining billing codes for serious consequences, such as ectopic pregnancy, would be more accurate than a study which relied solely on interview data."

Because this was a retrospective study, the findings should be confirmed by a prospective trial on IUD use in adolescents, Berenson adds.

IUDs safe for teen use

In 2012, the American College of Obstetricians and Gynecologists (ACOG) issued a committee opinion stating that long-acting reversible contraceptives such as the IUD and the contraceptive implant are safe, effective, and appropriate options for adolescents.[2] *(To read more about the opinion, see the* Contraceptive Technology Update *article, "Long-acting methods safe for teens: include options in your counseling," December 2012, p. 133.)*

The U.S. Medical Eligibility Guidelines For Contraceptive Use (US MEC) ranks use of the Copper T-380A and the levonorgestrel IUDs as a "Category 2" (a condition for which the advantages of using the method generally outweigh the theoretical or proven risks) for women under age 20, with the same rating for nulliparous women.[3] With the ACOG US MEC guidance in hand, clinicians can make evidence-based decisions in safely using the contraceptive method in adolescents.

Assess potential pain

Fear of pain has been cited as a barrier to IUD use, so talk with prospective users about this possibility.[4] Intrauterine device insertion has been variably described by nulliparous women as ranging from "period pain" (62%) to "severe abdominal pain" (14%).[5] In a study of nulliparous women age 25 or younger, 13.8% reported no pain at insertion, 65.9% reported mild to moderate pain, and 21.3% noted severe pain.[6]

Providers might underestimate patient pain levels: in a recent secondary analysis of a randomized placebo-controlled trial of 200 women that looked intracervical lidocaine gel as an analgesic during IUD insertion, data indicates a wide expanse between providers' and patients' perceptions. On a 100-point visual analog

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scale, patients' mean perceived pain score was 63.8, registering moderate pain, while the providers' assessment of their patients' pain level was recorded at a mean of 35.3, registering as mild pain.[7]

In talking about intrauterine contraception, tell women that some patients experience dizziness and/or cramps after insertion.[8] Such pain is normal. If they want to take medication to alleviate the pain, products that contain ibuprofen or naproxen are best.[8]

Prescribing information for the Mirena LNG-IUD continues to recommend that the device be used in women who have had at least one child. When the ParaGard copper-releasing IUD was first marketed in the United States in 1988, the prescribing information contained a "recommended patient profile," which included a history of childbearing; in 2005, the labeling was amended so it no longer discourages use by nulliparous women.

In January 2013, the Food and Drug Administration approved Skyla, a new IUD from Bayer HealthCare Pharmaceuticals. Skyla is smaller in size 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; Mirena is labeled for up to five years of use. Skyla's product labeling 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. *(To read more about the device see "FDA approves smaller levonorgestrel intrauterine system — a 'mini Mirena,'" CTU, March 2013, p. 25.)*

Although it is possible to insert the larger Mirena IUD in most young women, never-pregnant women, and nulliparous women, to avoid potential insertion pain, Skyla might be a good fit for young nulliparous women, observes **Robert Hatcher**, MD, MPH, professor emeritus of gynecology and obstetrics at Emory University School of Medicine in Atlanta. The fact that the device is labeled for three years' use might appeal to younger women who might not want to commit to the LNG or Copper T380A intrauterine contraceptives, both which have longer labeled efficacy rates, he notes.

Talk it up

Researchers at the University of Texas Medical Branch at Galveston reported "significant" growth in the frequency of teenagers using an IUD for contraception in their current study.[1] However, many teenagers received their device after delivery of an infant, which suggests that IUDs might not be prescribed as often to nulliparous teenagers. Educational programs might be needed to communicate the safety of IUD use in adolescents who have not given birth, they note.

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Review risks, benefits of sterilization option

Sterilization remains the most popular form of contraception in the United States; 30.2% of couples rely on tubal sterilization for birth control, while 18.6% use oral contraceptives.[1] What are some of the reasons why female sterilization continues as a leading contraceptive method in the United States?

There are many reasons why women chose a particular contraceptive method, including how well it prevents pregnancy, safety, side effects, their desire for more children, cost, and accessibility, says **Alison Edelman**, MD, MPH, associate professor and co-director, family planning fellowship in the Department of Obstetrics and Gynecology at Oregon Health & Science University in Portland. Edelman served as a co-author of a new practice bulletin from the American

EXECUTIVE SUMMARY

Sterilization remains the most popular form of contraception in the United States; 30.2% of couples rely on tubal sterilization for birth control, while 18.6% use oral contraceptives.

- A new practice bulletin from the American College of Obstetricians and Gynecologists gives clinicians updated information on the risks and benefits of sterilization.
- In the United States, more than 50% of all tubal sterilizations are performed in the early postpartum period, with sterilization procedures performed after 8-9% of all hospital deliveries. Postpartum permanent contraception requires counseling and informed consent prior to labor and delivery. Providers should counsel on postpartum options during prenatal care, when the patient can make a considered decision, review the risks and benefits of sterilization, and consider alternative contraceptives.

College of Obstetricians and Gynecologists (ACOG) which looks at the risks and benefits of sterilization.[2]

"Permanent contraception or female sterilization is an extremely safe and effective method for those women who are done with childbearing," notes Edelman. "Additionally, permanent contraception is often more accessible to women because the costs are typically covered by insurance, especially immediately following a pregnancy, which has not been the case for many other contraceptive methods."

Sterilization for women blocks fertilization by cutting or occluding the fallopian tubes to prevent the sperm and egg from uniting.[3] Analysis of data from the U.S. Collaborative Review of Sterilization (CREST), a large, prospective, multicenter observational study, found a five-year cumulative failure rate of 13 per 1,000 for aggregated sterilization methods (including laparoscopy and laparotomy).[4] The risk of pregnancy persisted for years after the sterilization procedure and varies by occlusion technique and age of the woman, the ACOG bulletin notes. The five-year cumulative failure rate is 14 per 1,000 procedures for the copper T 380A intrauterine device (IUD),[5] while the five-year cumulative pregnancy rate for the levonorgestrel-releasing IUD ranges from five to 11 per 1,000 procedures.[6-8]

Annual failure rates of intrauterine contraception are 0.8% for the copper T380A and 0.2% for the levonorgestrel-releasing IUD. The etonogestrel implant has a 0.05% reported failure rate, the lowest of any contraceptive method.[9]

Women's options for extremely safe and effective methods, such as long-acting reversible contraceptive (LARC) methods such as the IUD or subdermal implant, are increasing and becoming more acceptable to women and providers, notes Edelman. Women who are considering permanent contraception also should be counseled regarding these options, as well as vasectomy, as they can achieve similar rates of pregnancy protection, she states. *(See box item on p. 77 for components of presterilization counseling.)*

"In fact, rates of female permanent contraception have started to decline in a cohort of women studied in Newcastle [in the United Kingdom] as the rates of IUD use have increased,"[10] says Edelman. "I think as women learn more these great choices and as more women use these methods — because women talk to other women about their likes and dislikes — we will see U.S. rates of permanent contraception decline as well."

Talk before postpartum

In the United States, more than 50% of all tubal sterilizations are performed in the early postpartum period, with sterilization procedures performed after 8-9% of all hospital deliveries.[11]

Postpartum permanent contraception requires counseling and informed consent prior to labor and delivery. Providers should counsel on postpartum options during prenatal care, when the patient can make a considered decision, review the risks and benefits of sterilization, and consider alternative contraceptive methods. Research indicates that such obstacles as young age and concern for patient regret, the consent process, lack of available operating rooms and anesthesia, and receiving care in a religiously affiliated hospital prevent as many as 50% of women who request postpartum sterilization during their prenatal care from undergoing the procedure before discharge after delivery.[12] Risk of repeat, unintended pregnancy within one year of delivery has been reported to be as high as 46.7% for women who requested but did not receive postpartum sterilization.[12]

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, says, "I think this highlights our responsibilities to these women. If we cannot provide them tubal ligation, we should place an implant before she leaves the hospital; by the time we discover we can't do her procedure, it is generally too late to place an IUD."

While many women who choose sterilization for contraception do not regret their decision, clinicians must provide thorough and effective counseling in reducing the possibility of regret. Younger women are at greater risk; a meta-analysis of studies of post-sterilization regret concluded that women who underwent sterilization at age 30 or younger were twice as

Check Pre-sterilization Counseling Components

- Permanent nature of the procedure
- Alternative methods of contraception available (reversible methods, as well as male sterilization)
- Reasons for choosing sterilization
- Screening for risk indictors for regret
- Details of the procedure, including risks and benefits of anesthesia
- The possibility of failure, including ectopic pregnancy
- The need to use condoms for protection against sexually transmitted diseases, including HIV infection
- Need for post-procedure confirmation following transcervical sterilization methods
- Federal and state Medicaid regulations regarding informed consent, including age of the client, circumstances in which consent is obtained, and interval from time of consent to procedure.

Source: Roncari D, Hou, MY. Female and male sterilization. In: Hatcher RA, Trussell J, Nelson AL, et al. Contraceptive Technology: 20th revised edition. New York: Ardent Media; 2011. ■

likely to express regret as women older than age 30 at the time of the procedure.[13] Because of the regret issue, LARC methods should be strongly considered if the patient is young, says **Robert Hatcher**, MD, MPH, professor emeritus of gynecology and obstetrics at Emory University School of Medicine in Atlanta.

"In this age of rapidly increasing use of long acting reversible contraceptives, it may be wise for a woman to use one of the reversible contraceptives for several years if there is any chance at all that she might change her mind and want to become pregnant in the future, because all of the LARC methods are fully reversible quickly," notes Hatcher. "Tubal sterilization reversal is extremely expensive and involves a complicated process to reverse."

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Mammography rates stay steady after guidance

More than three years after new guidelines rejected routine annual mammograms for most women, women in all age groups continue to get yearly screenings, new research indicates.[1]

In 2009, the United States Preventive Services Task Force (USPSTF) recommended against routine mammogram screening for women between ages 40 and 49.[2] *(To review the guidance, see the* Contraceptive Technology Update *article, "Check the new screening guidance for cervical cancer and breast cancer," January 2010, p. 1.)*

In a study conducted by Boston-based Brigham and Women's Hospital researchers, data indicates that

EXECUTIVE SUMMARY

More than three years after new guidelines rejected routine annual mammograms for most women, women in all age groups continue to get yearly screenings, new research indicates.

- In 2009, the United States Preventive Services Task Force recommended against routine mammogram screening for women between ages 40-49.
- In 2011, the American College of Obstetricians and Gynecologists issued new breast cancer screening guidelines that recommend mammography screening be offered annually to women beginning at age 40.
- The five-year survival rate is 98% for women whose breast cancer tumors are discovered at their earliest stage, before they are palpable and when they are small and confined to the breast.

mammogram rates in the United States have not declined in the 40-49 age group, or any other age group. "If the USPSTF recommendations had been widely adopted, we would have expected to see a significant decline in mammography rates among women in their 40s," said the study's lead author, **Lydia Pace**, MD, MPH, a global women's health fellow in the hospital's Division of Women's Health. "However, this study demonstrates that younger women are continuing to get mammograms."

To perform the study, researchers examined data from nearly 28,000 women who were asked about their mammography use during the 2005, 2008, and 2011 National Health Interview Survey, which has monitored the health of the nation since 1957. Their analysis indicates that among all women, mammography rates rose at a slight but statistically non-significant rate between 2008 and 2011 from 51.9% to 53.6%. Among women ages 40-49, mammography rates also rose at a slight but statistically non-significant rate between 2008 and 2011 from 46.1% to 47.5%.

The current research does not explain the reasons why mammography rates did not decline. It is worth noting, however, that several prominent professional and advocacy organizations continue to recommend mammography screening for women between the ages of 40 and 49, said Pace in a statement accompanying the paper's publication. "Providers may disagree with the USPSTF recommendations or they may not have the time or the tools needed for discussions with patients about the relative benefits and harms of mammography," observed Pace. "Patients may also disagree with the recommendations and may still be requesting annual mammograms or self-referring to mammography facilities."

ACOG guidance differs

In 2011, the American College of Obstetricians and Gynecologists (ACOG) issued new breast cancer screening guidelines that recommend mammography screening be offered annually to women beginning at age 40.[3] *(*CTU *reported on the move; see "New guidance issued for breast screening," October 2011, p. 116.)*

What led to ACOG's change for clinical practice? Three factors came into play:

- the incidence of breast cancer;
- the sojourn time for breast cancer growth;
- the potential to reduce the number of deaths from it.

The period between when a breast cancer might be detected by a mammogram while it is very small and before it grows big enough to become symptomatic is known as sojourn time. While the sojourn time of individual cancers can vary, the greatest predictor is age, the practice bulletin notes. Women ages 40-49 have the shortest average sojourn time (2-2.4 years), while women ages 70-74 have the longest average sojourn time (4-4.1 years).[4]

The five-year survival rate is 98% for women whose breast cancer tumors are discovered at their earliest stage, before they are palpable and when they are small and confined to the breast.

The largest and longest running breast cancer screening studies in history re-confirm that regular mammography screening cut breast cancer deaths by roughly one-third in all women ages 40 and over, including women ages 40-49,[5,6], says a statement from the American College of Radiology and Society of Breast Imaging.[7] "These data directly refute the USPSTF claim that mammography reduced deaths by 15% and show that the USPSTF calculations were understated by half," the statement reads. "Doing so resulted in a doubling of the USPSTF estimate of the number of women needed to be invited to screen in order to save one life."

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Appeal filed to delay unrestricted EC sales

Unrestricted access to emergency contraceptive pills (ECPs) remains blocked. The U.S. Department of Justice (DOJ) filed an appeal May 13, 2013, to delay the sale of ECPs to women of any age without a prescription.

The legal paperwork asked the Second U.S. Circuit Court of Appeals in Manhattan to postpone U.S. District Court Judge Edward Korman's April 5 ruling that eliminated age limits on the drug while the government appeals that overall decision. On May 6, 2013, Korman denied the DOJ's request to postpone his ruling while the government appealed, but he gave them until May 13 to appeal again. *[*Contraceptive Technology Update *issued separate e-bulletins on the judge's actions. To receive breaking news as it occurs, provide your email address to AHC Media customer service at customerservice@ahcmedia.com or (800) 688-2421.]*

The April 5 ruling by Korman, if had been enacted, would have the Food and Drug Administration (FDA) make all levonorgestrel-based emergency contraception available without a prescription and without point-of-sale or age restrictions. The judge's April 5 ruling came in response to the New York City-based Center for Reproductive Rights' renewed lawsuit against the FDA to expand over-the counter EC access to women of all ages.

"Women who urgently need emergency contraception have been delayed in getting it or denied access entirely for more than a decade because of the political maneuverings of the last two presidential administrations," said **Nancy Northup**, president and CEO of the center. "The federal court has made clear that these stalling tactics were based purely on politics, not science."

According to Center spokesperson **Kate Bernyk**, it expects the Second Circuit to be fully briefed on the stay motion by the end of May and rule some time after that. "Because Korman granted the government a temporary stay of his order so they could have time to ask the Second Circuit if they could delay compliance pending their overall appeal of his decision, the FDA does not have to yet take action to move all levonorgestrel EC over the counter," states Bernyk.

Plan B One-Step gets nod

In separate action April 30, the FDA announced its approval of an amended application submitted by North Wales, PA-based Teva Women's Health to market its ECP, Plan B One-Step, for use without a prescription by women age 15 and older.

With the FDA's action, only Plan B One-Step will be available for non-prescription sale to those age 15 and above. Other brands of levonorgestrel ECPs are not included in the FDA's April 30 approval. The ulipristal acetate ECP, ella, also remains prescription-only.

"Plan B One-Step will be available in retail outlets with an onsite pharmacy, where it generally will be available in the family planning or female health aisles to consumers 15 years of age and older within a few months," states **Denise Bradley**, vice president, corporate communications of Americas Teva Pharmaceuticals.

While Plan B One-Step now will be shelved on the counter with other family planning products, it will be clearly be labeled "not for sale to those

EXECUTIVE SUMMARY

Unrestricted access to emergency contraceptive pills (ECPs) remains blocked. The U.S. Department of Justice filed an appeal May 13, 2013, to delay the sale of ECPs to women of any age without a prescription.

- The action postpones an April 5 ruling by U.S. District Court Judge Edward Korman that would have made all levonorgestrel-based emergency contraception available without a prescription and without point-of-sale or age restrictions.
- In separate action April 30, the FDA announced approval of Plan B One-Step, for use without a prescription by women age 15 and older. While the drug will now be stocked alongside other over-the-counter family planning products, women must be able to provide proof of age before purchasing the product.

under 15 years of age *proof of age required* not for sale where age cannot be verified." The drug also will be packaged with a product code prompting a cashier to request and verify the customer's age. Customers who cannot provide age verification will not be able to purchase the product. In addition, Teva has arranged to have a security tag placed on all product cartons to prevent theft.

According to the FDA, Teva has indicated that it plans to educate consumers, pharmacy staff, and healthcare professionals about the product's new status. The company also has indicated it will conduct an audit of the age verification practices after the product is approved to ensure that the age limitation is being followed, the FDA states.

The Association of Reproductive Health Professionals registered its disappointment in what it terms as "conditional" approval of access to Plan B One-Step emergency contraception for women 15 and older. "The proof-of-age requirement places an undue burden on the many women who do not have this type of identification," reads a statement from the organization. "We encourage the FDA to approve EC for unrestricted over-the-counter access."

Although the FDA's action improves the accessibility of EC, the American College of Obstetricians and Gynecologists (ACOG) has reaffirmed its position that EC should be available over-the-counter (OTC) without any age restriction. Additionally, it is unclear how 15-year-olds will be able to prove age without a government identification, ACOG noted in a May 1 statement.

"The medical evidence demonstrates that EC is safe and effective in preventing pregnancy for all reproductive-age females," the statement reads. "The College strongly encourages the FDA to reaffirm its earlier decision to approve EC for unrestricted OTC access." ■

Genital wart cases drop after program launched

Five years after Australia launched a national human papillomavirus (HPV) vaccination program in young women, data indicates that genital wart cases have dropped not only among women, but heterosexual men as well.[1]

Australia implemented its initial quadrivalent vaccine national immunization program in 2007, first targeting girls ages 12-13, with catch-up programs launched from 2007-2009 for girls 13-18 and young women ages 18-26. In 2010 the vaccination coverage rates in the school-based program were reported to be 83% for the first dose, 80% for the second dose, and 73% for the third dose in those age 12-13, with coverage rates decreasing with increasing age.

To perform the current study, investigators from the University of New South Wales in Sydney and Melbourne Sexual Health Centre analyzed the ongoing population effect of the vaccination program five years after it was established. Data were taken from eight sexual health clinics; Australian-born patients who attended any of the clinics for the first time between January 2004 and December 2011 were included in the analysis.

The study period was divided into the pre-vaccination period (2004-2007) and the vaccination period (2007-2011). Researchers looked at three age groups: those under 21, those age 21-30, and those 30 and older.

Between 2004 and 2011, 85,770 patients were seen for the first time. Of these, 7,686 (9%) were diagnosed with genital warts. Overall, data indicate the proportion of women diagnosed with genital warts increased during the pre-vaccination period from 9% in 2004 to 10% in 2007, then decreased in the vaccination period to 3%. In men, the proportion remained relatively stable in the pre-vaccination period from 13% in 2004 to 12% in 2007, and then decreased during the vaccination period to 7%.

In women under age 21, results showed that 9% were diagnosed with genital warts in 2004 and

EXECUTIVE SUMMARY

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11% in 2007. During the vaccination period, the proportion declined dramatically to 0.85% (13 cases). In 2011, none of the vaccinated women under age 21 were diagnosed with genital warts. In the same year, 7% of unvaccinated women under age 21 (out of 161) were diagnosed with genital warts. Significant declines in genital warts also were seen in women ages 21-30, and heterosexual men under age 21 and ages 21-30, during the vaccination period.[1]

Shot makes mark

What are some of the reasons the HPV vaccine has been so well-received in Australia?

Acceptance of the HPV vaccine stems from its universally offered school-based program and its marketing as a cancer vaccine, says the study's lead author, **Basil Donovan**, MD, professor and head of the Sexual Health Program at The Kirby Institute at the University of New South Wales, Sydney, Australia,.

"The influence of religious extremists is minimal in Australia, as is the influence of the general anti-vaccination lobby," says Donovan. "As a background issue, the virus-like-particle that forms the basis of the vaccine was an Australian invention, and the inventor, Professor Ian Fraser, is a national hero. Perhaps this gives Australians some sense of ownership."

Australia's success with HPV vaccine uptake has made an impact on other European countries. According to **Colm O'Mahony**, MD a consultant in genito-urinary medicine at the Countess of Chester Hospital in Chester, England, and co-author of an accompanying editorial to the current research, vaccine uptake in the United Kingdom has been "very good — around 80%."

What about young males?

How about immunization in young males? In 2013, the Australian government began a publicly funded HPV vaccination program for boys ages 12-13, with a catch-up for boys ages 14-15. No national program has yet been implemented in the United Kingdom, says O'Mahony.

"The Joint Committee on Vaccination and Immunization is aware of the benefit of vaccinating boys, but no decision has been made yet," he notes. "In the current financial meltdown of the National Health Service, we are not hopeful of getting a male vaccination program."

Where is the United States in HPV vaccine uptake? According to a 2013 report, 32% (95% confidence interval [CI] = 30.3% to 33.6%) of girls ages 13-17 in 2010 had received three doses of the HPV vaccine.[2] Coverage was statistically significantly lower among the uninsured (14.1%, 95% CI = 9.4% to 20.6%) and in some Southern states, such as in Alabama (20.0% [95% CI = 13.9% to 27.9%]) and Mississippi [95% CI = 13.8% to 28.2%]), where cervical cancer rates were highest and recent Pap testing prevalence was the lowest.[2]

HPV vaccines are given as three shots to protect against HPV infection and HPV-related diseases. There are two approved vaccines. Cervarix is a bivalent vaccine that protects against HPV types 16 and 18. Gardasil, a quadrivalent vaccine, guards against HPV types 16 and 18, which are associated with most HPV-related cancers, as well as HPV types 6 and 11, which are associated with the occurrence of anal and genital warts. Both vaccines have been approved to protect against cervical cancers in women; Gardasil also is approved to guard against genital warts, as well as cancers of the anus, vagina, and vulva. Both vaccines are available for females; Gardasil is available for males.

Current recommendations by the Centers for Disease Control and Prevention and the Advisory Committee on Immunization Practices call for preteen girls and boys to receive the vaccine at ages 11 or 12. The HPV vaccines are recommended for all teen girls and women up to age 26 who did not get all three doses of the vaccine when they were younger, and for all teen boys and men through age 21 who did not get all three doses of the vaccine when they were younger. It is also recommended for gay and bisexual men or any men who have sex with men, as well as men with compromised immune systems, including HIV infection, through age 26.[3]

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Healthcare is at issue in immigration reform

New bill is best hope for reform

By **Adam Sonfield**
Senior Public Policy Associate
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In the wake of the 2012 elections, President Obama and members of Congress from both political parties declared immigration reform a top legislative priority. A "Gang of Eight" Senators, four Democrats and four Republicans, introduced a purportedly comprehensive bill in April 2013 that is widely viewed as the best hope for reform.

If enacted, the legislation would grant provisional status and a path to citizenship, including a 10-year waiting period prior to receiving a green card, to millions of undocumented immigrants in the United States. Yet, as introduced, that bill is far from comprehensive when it comes to integrating immigrants into the U.S. healthcare system. It leaves in place two decades' worth of legal barriers to immigrants' access to affordable health insurance coverage, including coverage for sexual and reproductive health care.

For public health insurance, including Medicaid and the Children's Health Insurance Program (CHIP), the most notable restriction dates to 1996, when Congress established a five-year waiting period for lawfully present immigrants before they are deemed eligible to enroll. In the years since, that waiting period has been lifted only in limited circumstance — only in states that have taken up options to exempt children or pregnant women. Beyond those options, Medicaid will only pay for emergency care, including labor and delivery, to individuals regardless of immigration status.

The Affordable Care Act of 2010 was a missed opportunity to repeal the five-year ban. The law does allow lawfully present immigrants, regardless of their length of residency in the United States, to purchase private coverage through the health insurance "exchanges" starting in 2014 and to receive federal subsidies to make this coverage affordable. But even with those subsidies, the coverage will be less affordable than Medicaid. Undocumented immigrants, by contrast, are not only ineligible for subsidies but are even barred from purchasing coverage through the exchanges at full cost.

Women at risk

These legal restrictions have made it difficult for many immigrants to find health coverage they can afford. In fact, among women of reproductive age (15-44), 45% of the 6.6 million noncitizen immigrants were uninsured in 2011, compared with 24% of naturalized citizens and 18% of U.S.-born women.[1] Those figures are just as striking among poor women in that age-group: 60% percent of noncitizen immigrant women were uninsured, compared with 34% of U.S.-born women. The Medicaid waiting period is particularly salient for this group: Only 26% of poor noncitizen immigrant women of reproductive age had Medicaid coverage, compared with 44% of those who are U.S. born.

The political difficulty of reversing restrictions on immigrants' access to health insurance was driven home in 2012, when President Obama took an initial, unilateral step toward immigration reform by establishing the Deferred Action for Childhood Arrivals (DACA) program. That program allows young people who immigrated without documentation as children and who are in school or working to remain in the country for renewable two-year periods. Yet, the program bars young people granted DACA status from almost every form of public and private health coverage. Essentially, immigrants granted DACA status are treated as undocumented when it comes to health coverage.

The Gang of Eight's bill starts from the same position of barring immigrants granted provisional status from many safety-net programs, despite being required to pay federal taxes. The five-year waiting period for Medicaid and CHIP would remain and would kick in only after an immigrant receives her green card, which would typically be 10 years down the line, resulting effectively in a wait of roughly 15 years. Immigrants with provisional status likewise would be barred from receiving federal subsidies to purchase private insurance through the exchanges. Unlike undocumented immigrants, they would be allowed to purchase unsubsidized coverage on the exchanges, but such coverage is unlikely to be affordable for lower income women and families.

Advocates for immigrants' access to health coverage, including advocates focused on sexual and

reproductive health, are working with members of Congress to move away from this harmful starting point. They have a strong case to make for why blocking immigrants' access to health coverage is bad for women, families, and society. Immigrant women, and especially undocumented immigrants, have higher birthrates than U.S.-born women.[2,3] They also are particularly likely to be young, low-income and women of color, which are demographic characteristics linked to an elevated risk of unintended pregnancy and STIs.[3-5] Ensuring they have coverage for services such as maternity care, contraception, cervical cancer screening, and STI testing and treatment would benefit their health and the health of their partners and children.

One promising sign is that, according to a February 2013 poll, most Americans believe immigrants granted provisional status should be able to qualify for Medicaid (63%) and for subsidies to buy insurance on the exchanges (59%).[6]

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COMING IN FUTURE MONTHS

- ■ Ovarian cancer prevention — What works?
- ■ Many women see pregnancy safer than contraception
- ■ Contraceptive counseling welcomed at well-baby visit
- ■ Case study: refugee clinic enhances reproductive health

CNE/CME OBJECTIVES & INSTRUCTIONS

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

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

CNE/CME QUESTIONS

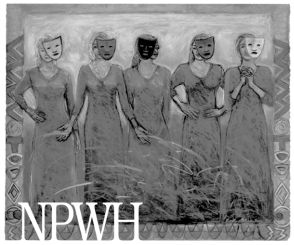
1. What is the U.S. Medical Eligibility Guidelines For Contraceptive Use rating for intrauterine contraceptive use in nulliparous women?
   A. Category 1: no restriction on use
   B. Category 2: advantages of using method outweigh theoretical or proven risks
   C. Category 3: theoretical or proven risks usually outweigh advantages of using method
   D. Category 4: unacceptable health risk if method is used

2. What is the most popular form of contraception in the United States?
   A. Combined hormonal pills
   B. Male condoms
   C. Sterilization
   D. Intrauterine contraception

3. According to 2011 breast cancer screening guidelines issued by the American College of Obstetricians and Gynecologists, mammography screening should be offered annually to women beginning at what age?
   A. 40
   B. 45
   C. 50
   D. 55

4. According to an April 30, 2013, ruling by the Food and Drug Administration, which emergency contraceptive pill can be sold with age verification to women age 15 and above, and stocked on drugstore shelves along with other over-the-counter family planning products?
   A. Plan B
   B. Ella
   C. Plan B One-Step
   D. Next Choice

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.



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QUARTERLY

U.S. HIV vaccine trial halts shots — What is the next step in research?

Shot unsuccessful at preventing healthy subjects from contracting HIV

The National Institute of Allergy and Infectious Diseases (NIAID) is halting the administration of injections in the clinical trial of an investigational HIV vaccine regimen after a scheduled interim review data indicated the regimen did not prevent HIV infection, nor did it reduce viral load among vaccine recipients who became infected with HIV. *[On April 26, 2013,* Contraceptive Technology Update *issued an e-bulletin on the study shutting down. To receive breaking news as it occurs, provide your email address to AHC Media customer service at customerservice@ahcmedia.com or (800) 688-2421.]*

The study began testing in 2009 the prime-boost vaccine regimen developed by NIAID's Vaccine Research Center. Conducted by the NIAID-funded HIV Vaccine Trials Network (HVTN), the Phase IIb study, known as HVTN 505, was designed to determine whether the vaccine regimen could prevent HIV infection and/or reduce the amount of virus in the blood of vaccine recipients who became infected with HIV. *(To read more about the trial, see "Initiative for HIV vaccine research funded — Quest for a shot persists,"* STI Quarterly *supplement, December 2012, p. 1, and "New research may boost AIDS vaccine research,"* CTU, *October 2010, p. 118.)*

The trial was looking at the safety and efficacy of a two-part HIV vaccine regimen consisting of one vaccine designed to prime the immune system, followed by another vaccine designed to boost the immune response. Investigators had enrolled 2,504 HIV-negative men who have sex with men and transgender people who have sex with men at 21 sites in 19 U.S. cities to conduct the study.

"This trial has provided a clear, swift answer about a specific vaccine strategy," said **Mitchell Warren**, executive director of AVAC, a New York City-based advocacy and education organization. "It's not the answer we hoped for, but the search doesn't end here."

There are other approaches that must be pursued, and the findings from the HVTN 505 trial will help to focus and guide those efforts, said Warren in a statement following the NIAID announcements. "Researchers need to further investigate the data from the HVTN 505 trial to understand more about why this strategy didn't prevent infection," Warren noted.

Take a closer look

The HVTN 505 vaccine regimen involved three immunizations over eight weeks, beginning with a DNA-based vaccine designed to prime the immune system. The DNA priming vaccine was designed with genetic material expressing antigens representing proteins from the surface and internal structures of HIV. Shots of the priming vaccine were followed by a single injection at week 24 with a recombinant vaccine based on a weakened adenovirus type 5 (Ad 5). The adenovirus

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EXECUTIVE SUMMARY

The National Institute of Allergy and Infectious Diseases is halting the administration of injections in the clinical trial of an investigational HIV vaccine regimen after a scheduled interim review data indicated the regimen did not prevent HIV infection, nor did it reduce viral load among vaccine recipients who became infected.

- The study, conducted by the HIV Vaccine Trials Network, was designed to determine whether the regimen could prevent HIV infection and/or reduce the amount of virus in the blood of recipients who became infected.
- The two-part regimen consisted of one vaccine designed to prime the immune system, followed by another vaccine designed to boost the immune response. To conduct the study, investigators enrolled 2,504 HIV-negative men who have sex with men and transgender people who have sex with men in 19 U.S. cities.

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was used as a vector, or carrier, of genetic material expressing a matching set of HIV antigens. Structures from all three major HIV clades, or subtypes, were included.

Safety experts in an April 22, 2013, independent panel review looked at information gathered from 1,250 volunteers who received the investigational vaccine regimen and 1,244 volunteers who received the placebo vaccine. The primary analysis looked at volunteers who were diagnosed with HIV infection after having been in the study a minimum of 28 weeks. This approach allowed enough time for the vaccine regimen to be given and stimulate an immune response.

In the April 22 analysis, data indicated 27 HIV infections occurred among vaccine recipients, and 21 HIV infections were recorded among those receiving the placebo shot. Among volunteers who became HIV-infected during the first 28 weeks of the study, 14 cases of HIV infection occurred among those who received the investigational vaccine regimen, and nine HIV infections were found among those getting the placebo shot. Looking at all data from the day of enrollment through the month 24 study visit, 41 cases of HIV infection occurred in the volunteers who received the investigational vaccine regimen, and 30 cases of HIV infection occurred among the placebo vaccine recipients.

The safety experts also found that the vaccine failed to reduce viral load among volunteers who acquired HIV infection at least 28 weeks after entering the study and who had been followed for at least 20 weeks after diagnosis. The analysis found 30 participants with measurable viral load; 15 were vaccine recipients and 15 received the placebo shot.

Researchers are contacting all participants to inform them of the review board's findings and NIAID's decision to halt injections. Study volunteers are being asked to report to their specific clinic sites over the next few weeks to find out whether they received the investigational vaccines or placebo injections. Researchers will continue following each participant for five years after their enrollment in the trial. Those who became HIV-infected during the trial have been referred to local health services for appropriate care and treatment.

What's the next step?

What is the next step in HIV vaccine research, given this new development?

"I view of the early stopping of the HVTN 505 HIV vaccine trial, it is imperative to better define the immune responses that can protect humans from HIV infection and control infection, and then learn how to design a vaccine that can elicit these responses," says **Timothy Mastro**, MD, FACP, DTM&H, group director of global health, population & nutrition at FHI 360 in Durham, NC. FHI 360 serves as the coordinating and operations center for the HIV Prevention Trials Network.

Science may be yielding new clues on possible HIV vaccine approaches. In an advance for HIV vaccine research, scientists have now determined how both the virus and a resulting strong antibody response co-evolved in one HIV-infected individual.[1] Such findings could help investigators specify which proteins to use to induce antibodies capable of preventing infection from an array of HIV strains. The research team was led by Barton Haynes, MD, director of the Duke Human Vaccine Institute in Durham, NC, and John Mascola, MD, acting director of the National Institutes of Health Vaccine Research Center in Bethesda.

This discovery occurred after scientists identified one of the some 20% of HIV-infected individuals who naturally develop broadly neutralizing antibodies to the virus after several years of infection. The individual was a volunteer in an African study in which participants gave weekly blood samples beginning early in the course of infection. The volunteer joined the study just four weeks after infection and was followed for more than three years.

Because researchers were able to follow the participant from such an early stage, they were able to identify the particular "founder" virus that triggered the immune system to make an immature broadly neutralizing antibody against HIV, as well as the cell from which that antibody emerged. Analyses of the weekly samples also enabled investigators to see the series of changes that the virus

and antibody underwent over 2.5 years until the antibody matured to a form capable of potently neutralizing the virus.[1]

With data in hand, researchers are developing a vaccine that harmlessly mimics the virus at key points in the observed process to generate broadly neutralizing HIV antibodies, first in uninfected animals and then in uninfected people.

"The next step is to use that information to make sequential viral envelopes and test them as experimental vaccines," said Haynes in statement accompanying the publication of research. "This is a process of discovery, and we've come a long way with regard to understanding what the problem has been."

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You should screen for HIV from adolescence onward

The U.S. Preventive Services Task Force (USPSTF) has just released its final recommendation statement on screening for HIV, and it recommends that clinicians screen all people ages 15 to 65, as well as younger adolescents and older adults who are at an increased risk for HIV infection, such as those who engage in unprotected vaginal or anal intercourse, use injection drugs, or are men who have sex with men.[1] It also recommends that all pregnant women, including those in labor whose HIV status is unknown, also be screened for HIV.

"HIV is a critical public health problem and, despite recent medical advances, still a devastating diagnosis for the 50,000 people in the United States who contract HIV each year" said **Virginia Moyer**, MD, MPH, chair of the task force and vice president for maintenance of certification and quality with the American Board of Pediatrics in Chapel Hill, NC. "In order to help reduce the suffering of those with HIV and their loved ones, we must continue finding better ways to prevent and treat this disease,"

In 2005, the task force called for HIV screening for adolescents and adults with risk factors, but it expressed concerns about the potential risk of harm associated with routinely screening low-risk individuals. With the new recommendation, the panel acknowledges that about one-quarter of HIV-infected individuals in the United States are unaware of their status. A 2012 report released by the Centers for Disease Control and Prevention (CDC) confirms this fact. It estimates 60% of U.S. youth living with the disease do not know they are infected.[2] *(*Contraceptive Technology Update *reported on the data; see "Time to up HIV testing in U.S. youth ages 13-24," February 2013, p. 18.)*

The task force recommendation falls in line with similar recommendations for HIV screening from the CDC, the American College of Physicians, and the American Academy of Pediatrics. The USPSTF recommends routine screening beginning at age 15, and the CDC recommends routine screening beginning at age 13.

"Primary care clinicians can play an important role in reducing HIV-related disease and death," stated task force member **Douglas Owens**, MD, MS, Henry J. Kaiser, Jr. professor and director of the Center for Health Policy in the Freeman Spogli Institute for International Studies and of the Center for Primary Care and Outcomes Research in the Department of Medicine and School of Medicine at Stanford University. "That is why our recommendation, which closely aligns with the HIV screening guidelines from the CDC[3], encourages clinicians to screen their patients for HIV."

The American Academy of Family Physicians (AAFP) has just released its own guidance on HIV screening. It falls basically in line with the USPSTF guidance; however, it calls for HIV screening to begin at age 18.[4]

The prevalence of HIV infection and rate of new infection among 13-14 year olds and 15-17 year olds are very low, the AAFP guidance states. According to CDC data for the year 2010, there were 529 AIDS cases and 2,200 HIV cases in the age 15-19 group, it notes. Based on the most recent U.S. census, there are close to 4 million adolescents in each cohort year or a total of 20

EXECUTIVE SUMMARY

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- The task force also recommends that all pregnant women, including those in labor whose HIV status is unknown, be screened for HIV.
- About 25% of HIV-infected individuals in the United States are unaware of their status. According to a 2012 report, about 60% of U.S. youth living with the disease do not know they are infected.

million in the age 15-19 group, the guidance points out. "A rough calculation of (2729/ 20 million) provides a rate of 1.3/10,000," the guidance states. "These data are not seroprevalence data, and the actual rates are likely higher."

The CDC case numbers also include children known to be infected at birth and thus not all are infections contracted in the adolescent years, the AAFP guidance notes. In addition the rate calculated is for the five-year group and is likely skewed toward the older ages (18 and 19) and the rates in the 15-17 year olds probably are lower than that calculated, it states.[4]

Screening saves lives

While the best way to reduce HIV-related disease and death is to avoid getting infected, screening is also extremely important, noted Owens in a press statement issued at the publication of the USPSTF guidance.

"Nearly a quarter of people with HIV don't know that they have it, and they're missing out on a chance to take control of their disease," Owens stated. "Universal screening will help identify more people with HIV, allowing them to start combined antiretroviral therapy earlier and live healthier and longer lives."

While there is no cure for HIV infection, treating people with HIV earlier can not only reduce their risk of developing AIDS and delay its onset, but it also decreases the likelihood that they will pass on the infection to someone else, the USPSTF notes. Treating pregnant women also reduces the chances that the virus will be transmitted to their babies, the task force states.

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CTUPDATES
News ■ Resources ■ Events

Get up to speed on HPV with self-study module

The Centers for Disease Control and Prevention (CDC) now offers a free web-based self-study module, "Genital Human Papillomavirus (HPV) Infection," as part of its Self-Study STD Modules for Clinicians series. The module is available at the following web site: http://1.usa.gov/13fMuIB.

The module is a web- based training course designed to guide clinicians in the diagnosis, treatment, and prevention of genital HPV infection. The training module is based on the sexually transmitted disease (STD) curriculum developed by the National Network of STD/HIV Prevention Training Centers.

After completing the course, participants will be able to describe the epidemiology of genital HPV infection in the United States, offer an overview on the pathogenesis of genital HPV, and discuss the clinical manifestations of infection. Participants also will be able to identify methods used to diagnose selected manifestations of genital HPV infections, discuss the CDC-recommended treatment regimens for genital warts, summarize appropriate prevention counseling messages for genital HPV infection, and describe public health measures for the prevention of infection.

The Self-Study STD Module — HPV is intended for nurses, nurse practitioners, nurse midwives, physician assistants, physicians, and other clinicians in primary care settings who desire a basic introduction to STD diagnosis and management. Participants completing the Self-Study STD Module — HPV can earn continuing education in a variety of categories.

Other self-study modules available include chlamydia, gonorrhea, herpes simplex virus, pelvic inflammatory disease, syphilis, and vaginitis. They are available at the following web site: http://1.usa.gov/12fwzys. ■