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Update on emergency contraception: Has status change increased access?

Client Confidentiality Card may help women overcome barriers

A year after the Food and Drug Administration (FDA) approved behind-the-counter status for the emergency contraceptive (EC) pill Plan B (Barr Pharmaceuticals; Pomona, NY) is the drug more available to women? While the company says sales have increased from about $40 million annually to an expected $80 million for 2007, availability is mixed, according to reports around the country.[1]

For example, in New York City, results of a recent survey indicate that 94% of contacted pharmacies carry the drug since shipments of the dual-status drug began in November 2006.[2] The figure represents an increase from just more than 50% in the last five years, say city officials.

Krista Anders, MD, obstetrics and gynecology resident at the University of Florida (UF) College of Medicine — Jacksonville, performed a telephone survey of Northeast Florida pharmacies in the Duval County/Jacksonville area. Her survey revealed that prior to behind-the-counter status, approximately one-half of pharmacies carried Plan B, says **Andrew Kaunitz**, MD, professor and assistant chair in the Obstetrics and Gynecology Department at UF College of Medicine — Jacksonville. Following the FDA approval of

EXECUTIVE SUMMARY

A year after the Food and Drug Administration approved behind-the-counter status for the emergency contraceptive pill Plan B, reports indicate that the status is mixed when it comes to drug availability.

- While some areas, such as New York City, report increased access, others are seeing no expansion in availability of emergency contraception (EC). For example, a 2007 survey of North Carolina pharmacies shows that 40% do not stock Plan B.
- The Pharmacy Access Partnership and the Pacific Institute for Women's Health have developed the Client Confidentiality Card to help women of all ages access EC in a discreet, confidential manner.

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dual status, about three-quarters of pharmacies now stock Plan B, says Kaunitz. However, pharmacies in low-income areas were less likely to stock Plan B, he reports.

Contrast these overall gains in access against the numbers amassed through a recent survey of North Carolina pharmacies conducted by NARAL Pro-Choice North Carolina. The survey, conducted among some 600 pharmacies across the state, shows about 40% do not stock the drug, with more than 30% of that figure refusing to order it.[3] The numbers are especially troubling for victims of sexual assault, given that a 2004 survey conducted by NC Women United, Planned Parenthood, NC Coalition Against Sexual Assault, and NARAL found that about 25% of hospitals do not provide EC. Many of those hospitals who did not provide EC onsite said they offered a prescription for the drug, says **Melissa Reed**, executive director of the state NARAL organization. The new survey shows that many of the pharmacies that don't stock EC are located in rural areas, similar to hospitals that do not provide EC on site, she notes.

"It is really a double jeopardy for women in rural communities," says Reed.

Impact of state laws?

Availability of EC in the United States may vary with differences in state laws, according to a survey presented at the recent American College of Obstetricians and Gynecologists (ACOG) annual clinical meeting.[4] The survey, performed in 2005 prior to the FDA approval of dual-label status, looked at more than a thousand pharmacies in Atlanta, Philadelphia, and Boston. Overall, 23% were unable to fill a prescription for EC within 24 hours. About one-third of Atlanta pharmacies (35%), 23% of Philadelphia sites, and 4% of Boston facilities were unable to meet the 24-hour deadline. Researchers also report that 9% of the pharmacists in Atlanta and 5% of pharmacists in Philadelphia said they would refuse to dispense the drug.

Subtle differences in state law may affect EC availability. In Georgia, pharmacists can elect not to carry Plan B, while in Massachusetts, state laws require that pharmacies stock the drug if there is a demand for it. In Pennsylvania, no laws have been enacted regarding whether the drug should be stocked.[5]

The FDA's approval of dual status for Plan B may well change the numbers, says **Rebekah Gee**, MD, MPH, Robert Wood Johnson clinical scholar at the University of Pennsylvania, who presented the survey results at the ACOG meeting. She is performing a similar study of pharmacies and says refusals to carry the drug are "much lower" now.

"I think that the FDA decision raised awareness

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about Plan B and helped to define the drug more as a mainstream medication," states Gee.

Up access with 'C-Cards'

Plan B's dual status means that the drug is available "behind the counter," but without a prescription, to consumers 18 years of age and older. It remains prescription-only for women 17 and younger. ***(Contraceptive Technology Update* reported on the FDA approval in its article, "Finally! Emergency contraception given approval by FDA for nonprescription sale," October 2006, p. 109.)** Nine states — Alaska, California, Hawaii, New Mexico, Maine, Massachusetts, New Hampshire, Vermont, and Washington — have pharmacy access programs that enable women to get Plan B directly from specially trained pharmacists without going to a prescriber first for a prescription. Women younger than 18 in those states are able to access Plan B directly from a certified pharmacist; those younger than 14 in Hawaii need parental consent to get Plan B through a pharmacist.

Some women, especially those of younger age, may feel inhibited to ask for EC in the pharmacy setting, where there often is little privacy to discuss personal health care issues with the pharmacist. Research conducted by the Pharmacy Access Partnership and the Pacific Institute for Women's Health shows that young women would be more likely to seek such services if there were a way to have a private conversation with a pharmacist in a crowded pharmacy, says **Belle Taylor-McGhee**, the partnership's executive director. The two groups have developed the Client Confidentiality Card, or the "C-Card," to help women of all ages access EC in a discreet, confidential manner.

The top half of the C Card contains basic information about EC and how it works. The bottom half has a message for pharmacists that can be torn off and used to request EC nonverbally in a discreet manner in a crowded pharmacy. The bottom half of the C-Card states: "Dear Pharmacist, I would like to obtain emergency contraception. Please help me learn about this important backup birth control method in a confidential way. Thank you." The idea is that the pharmacist will then find a private way to discuss with and provide EC to the woman, out of earshot of other pharmacy patrons.

The Pharmacy Access Partnership has been contacting pharmacy associations and organizations around the country to spread the word about the card's availability, says Taylor-McGhee. Public health departments, as well as pharmacists, are interested in distributing the cards, she says. **(See the resource box, above, for ordering information.)**

RESOURCE

To obtain Client Confidentiality Cards, visit the Pharmacy Access Partnership's web site, www.PharmacyAccess.org. Click on the link under "Client Confidentiality Card" for ordering information. Cards are $10 per 100 (including shipping and handling) and may be ordered online, by telephone at (510) 272-0150, or e-mail to info@pharmacyaccess.org.

Women need to know

More effort will be needed to increase access to emergency contraception. The American Medical Association has just adopted a new policy requesting that pharmacies use their web site or other means to let patients know whether they stock and dispense EC and if a prescription is required. If a pharmacy doesn't dispense EC, pharmacies should indicate where it can be obtained in their region, the policy states.[6]

NARAL Pro-Choice North Carolina says it will continue to work with pharmacists to increase their knowledge of EC, as well as with the state hospital association to boost the number of facilities that stock EC. The group lobbied for legislation this year to require hospitals and urgent care facilities to stock the drug, says Reed. While the bill did not pass, women's health advocates will push for approval in the following session, she reports. The NC organization also will work to boost community awareness of EC availability to increase access to the drug, she adds.

The Pharmacy Access Partnership is working with several pharmacy associations around the country to survey pharmacists about their experience with EC in the dual-status environment, reports Taylor-McGhee. While the analysis is ongoing, preliminary results appear "mixed," she states. In states such as California, which offered pharmacist access prior to the label change, access to EC appears less cumbersome, she notes. Education is a key part of EC access, Taylor-McGhee notes.

"I think the challenge will continue to be to educate women about emergency contraception

availability and emergency contraception use, and also to encourage pharmacists to provide the kind of environment that is conducive to women accessing it without intimidation, without barriers," she states.

Telling women about EC is a key piece in the access puzzle, says Gee. "I tell all my patients of reproductive age about Plan B, especially if they are on a birth control method that has higher failure rates or lower compliance like withdrawal, the rhythm method, the condom, or the pill," she states.

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What do young women know about IUDs?

EXECUTIVE SUMMARY

Results of a recent cross-sectional survey indicate that more than half of women between the ages of 14 and 24 had never heard of an intrauterine device (IUD), and 97% had never used one. Eighty-four percent of the women had been sexually active; about 25% of those sexually active had been pregnant.

- Patients' lack of knowledge may stem from providers who may not discuss the method during contraceptive counseling.
- Young women are open to hearing messages on intrauterine contraception, survey results indicate. Following a two-minute presentation on the method, 65% of survey participants said they liked the idea of an IUD for themselves.

The next patient in your exam room is an 18-year-old female. What do you think she knows about intrauterine contraception?

Not much, according to results of a recent cross-sectional survey.[1] More than half of women between the ages of 14 and 24 who participated in the survey said they had never heard of an intrauterine device (IUD), and 97% had never used one. Eighty-four percent of the women had been sexually active; about 25% of those sexually active had been pregnant.[1]

This lack of knowledge may stem from providers who may not discuss the method during contraceptive counseling, says **Lisa Johnson**, MD, who presented results of the survey at the recent North American Society for Pediatric and Adolescent Gynecology annual meeting in Atlanta. Johnson, now an adolescent medicine physician with the Nassau (Bahamas) Department of Public Health, worked with researchers from Chicago and Pittsburgh during her fellowship at the Children's Hospital of Pittsburgh's Division of Adolescent Medicine.

Health care providers do not offer IUDs as a routine method of contraception to adolescents because of their own misinformation about the safety of the method, observes **Melanie Gold**, DO, an associate professor in the Department of Pediatrics at the University of Pittsburgh School of Medicine and in the Department of Behavioral and Community Health Sciences at the Graduate School of Public Health. Teens also get misinformation from their mothers and grandmothers about the "dangers" of IUDs, says Gold, a co-author of the paper. Some have been told IUD use leads to infertility or causes infections, she notes.

Check the survey

In performing the survey, researchers looked to determine:

- What do young women know about intrauterine contraception, and how do they feel about it?
- How much do they like the idea of an IUD for themselves after they are informed about intrauterine contraception?
- What IUD characteristics are appealing to this group?

• What participant characteristics are associated with a positive view of IUDs?

Participants were given a 20-minute, 44-item semi-structured interview assessing demographics, sexual history, contraceptive use and attitudes, and IUD knowledge and attitudes if they had heard of the method. Researchers provided a two-minute description and demonstration of IUDs followed by a test of knowledge for all participants.

Most (80% and above) of participants agreed or strongly agreed they would consider a birth control method where they would experience less painful and lighter periods, as well as one they could initiate and stop. About 60% said they would be willing or very willing to use a birth control method that causes irregular vaginal bleeding if it were to deliver a high effectiveness rate. However, only 30% of the respondents said they would consider a birth control method that involved placing a small plastic object in the uterus, and only 27% said they would be interested in a device that had to be placed and removed by a health care provider.

Following the two-minute presentation, 65% of survey participants said they liked the idea of an IUD for themselves; most of those who answered in this manner were sexually active. What were the most appealing characteristics of the IUD? The most popular survey responses included: "It does not affect ability to have children in the future" (81%), "It is not necessary to use every day" (71%), and "It is not necessary to remember with each sex act"(67%).

Take the time

Two intrauterine contraceptives are available in the United States: the Mirena levonorgestrel intrauterine system (Mirena LNG IUS; Bayer HealthCare Pharmaceuticals; Wayne, NJ) and the Copper T 380A intrauterine device (ParaGard IUD; Barr Pharmaceuticals, NY). The ParaGard IUD is approved for 10 years of contraception; the Mirena is approved for five years of birth control.

The World Health Organization eligibility criteria classes use of IUDs in young women ages 20 and younger, as well as for nulliparous women, as a "2" — for a situation in which the advantages of using the method generally outweigh the theoretical or proven risks.[2] The ParaGard IUD is now approved for use for nulliparous women in stable relationships from ages 16 through menopause. **(*Contraceptive Technology Update* reported on the labeling change in the article "Intrauterine method sees upswing in use," November 2005, p. 131.)** Women with a history of sexually transmitted diseases or pelvic inflammatory disease (PID) are no longer contraindicated for use of ParaGard, unless a patient currently has acute PID or engages in sexual behavior suggesting a high risk for the disease, the labeling states.

More providers need education on intrauterine contraception, says **Allan Rosenfield**, MD, dean of the Mailman School of Public Health at the New York City-based Columbia University. Several obstetrics and gynecology residencies fail to include IUD insertion/removal training, yet the Copper T 380A and the Mirena are probably the most effective, reversible methods of contraception available, he notes.

"The IUD should be much more highly recommended as a major contraceptive in family

Conferences highlight intrauterine contraception

To obtain up-to-the-minute education on intrauterine contraception, attend *A Clinical Update on Intrauterine Contraception* continuing medical education program organized by the Association of Reproductive Health Professionals (ARHP). The goal of the program is to help make intrauterine contraception a more utilized birth control method in the United States.

ARHP is providing logistical support, honoraria, and travel expenses to faculty lecturers for the project. It is funded through an unrestricted educational grant from Bayer HealthCare Pharmaceuticals.

The ARHP annual meeting, scheduled for Sept. 26-29 at the Hilton Minneapolis, will feature an IUD training session during a Sept. 26 pre-conference. Cost for the pre-conference session is $200. Registration information is available online at www.arhp.org/rh2007.

The Nov. 1-3 *Contraceptive Technology*: Quest for Excellence conference at the Sheraton Atlanta Hotel also will have a pre-conference IUD training session. Pre-conference fee is $105 on or before Sept. 20, and $135 after that date. Visit the Contemporary Forums web site, www.contemporaryforums.com, and click on the conference title for registration information.

To schedule an ARHP lecture, contact the ARHP education staff at (202) 466-3825, or visit the organization's visiting faculty program web site at www.arhp.org/cme. ■

planning programs and most particularly by OB-GYNs," states Rosenfield.

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Start spreading the news: NYC Condom unwrapped

EXECUTIVE SUMMARY

The New York City Department of Health and Mental Hygiene has expanded its condom distribution program with the introduction of its own private label NYC Condom. Since its debut on Valentine's Day 2007, some 10 million condoms have been distributed throughout the city.

- The condoms are available free from several community resources. Health care and social service organizations make up 44% of condom orders. Schools and universities, community and senior centers, and businesses also are placing orders for the condoms.
- Posters, radio advertisements, and a dedicated web site communicate the city's message of "We've got you covered."

Think about your condom distribution program. Does it consist of a basket of condoms at the clinic admission desk?

Take that vision and expand it a thousandfold, as evidenced by the New York City Department of Health and Mental Hygiene's new NYC Condom. Since its debut on Valentine's Day 2007, some 10 million condoms with the distinctive black "NYC Condom" plastic wrapper have been distributed throughout the city, according to **Monica Sweeney**, MD, MPH, assistant commissioner of the city's Bureau of HIV Prevention and Control.

Condom distribution is nothing new for the city public health department, which has operated such a program since 1971, says Sweeney. But the decision to develop the private-label condoms and to distribute them free of charge represents an important effort in HIV prevention, says **Allan Rosenfield**, MD, dean of the Mailman School of Public Health at the New York City-based Columbia University. New York is the first city to embark on such a campaign, and it may well serve as a model for others, says Rosenfield.

In June 2005, New York City launched an Internet-based Free Condom Initiative to provide community and social service organizations with condoms. Since that program's inception, distribution of condoms grew from 300,000 to 1.5 million per month. City health officials decided to develop a private-label brand to further boost the numbers, says Sweeney.

The tactic apparently is working. Some 5 million NYC Condoms were distributed during the program's first month of operation, with 3.7 million dispersed in the second month. Some 1,600 local organizations have received free condoms by ordering online at www.nyccondom.org or by calling 311, the city's information hotline.

Half are new customers

According to health department statistics, half of the 1,600 establishments that have received NYC Condoms are new customers. One in every three NYC Condoms went to organizations in Central Brooklyn, Central/East Harlem, and the South Bronx, where the health department operates satellite health offices, says Sweeney. An additional 800,000 condoms have been distributed in Manhattan's Chelsea and Clinton neighborhoods.

Who is ordering the condoms? Health care and social service organizations accounted for 44% of condom orders, say health department officials. Community and senior centers accounted for 7% of deliveries, and schools and universities received 9% of orders. Businesses also are participating in the program: 4% of orders were placed by bars and clubs, 5% by event planners, and 1% from beauty parlors, health clubs, and movie theaters.

Does the health department charge any fee for distribution? Absolutely not, says Sweeney. "We want to make condoms available to anyone who wants to use them," she states. "Whether you're using them for contraception alone, or for both contraception and prevention of sexually transmitted diseases, including HIV, we don't want anyone not to use them for lack of having them available."

The city has made a commitment to continue to distribute the condoms free of charge as long as the demand is present, says Sweeney. As more condoms are needed, the department issues a request

for proposal (RFP) invitation to condom manufacturers to submit bids for the product. "We go with the company that can guarantee us the best price while maintaining the highest quality," Sweeney says.

'We've got you covered'

A key to the condom program's success has been its consumer awareness campaign. Colorful posters are in subways, on bus stop kiosks, and distributed throughout the city, says Sweeney. Radio ads, as well as the web site, www.nyccondom.org, get the word out about the availability of the product.

While getting condoms out is an important message, health officials also are focusing on educating users on the importance of correct and consistent usage, says Sweeney. For example, during Gay Pride parade events, packets with condoms, lubricants, and educational material were distributed, she notes. City health officials will conduct a survey later this year to gauge the program's impact on prevention efforts, says Sweeney.

The consumer awareness program is very direct in its approach to condoms, says Sweeney. Juxtapose the frankness of the official poster of a condom with the tagline "We've Got You Covered" with the recent rejection of a Trojan condom advertisement by CBS and FOX networks. The commercial features a bar scene with women and pigs. When one pig goes to the restroom and returns with a condom purchased from a vending machine, he is transformed into an attractive man. The commercial closes with the message: "Evolve: Use a condom every time." In a written response to Trojan, FOX said that it had rejected the spot because "contraceptive advertising must stress health-related uses rather than the prevention of pregnancy," while in its rejection, CBS wrote, "While we understand and appreciate the humor . . . we do not find it appropriate for our network even with late night-only restrictions."[1]

"We're not saying, 'Here's a condom; go have sex,'" says Sweeney of the NYC Condom program. "But for those people who are sexually active, use a condom."

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Research eyes HPV vaccine effectiveness

Results from a new international meta-analysis study of Gardasil (Merck & Co.; Whitehouse Station, NJ), the cervical cancer vaccine, indicate the shot is nearly 100% effective against the two types of the human papillomavirus (HPV) responsible for most cases of cervical cancer.[1]

To perform the meta-analysis, researchers combined and analyzed data from four randomized trials that involved 20,583 women ages 15 to 26 from more than two dozen countries across Europe, North America, Latin America, and Asia. Participants were randomly assigned to receive the HPV vaccine or placebo and followed for an average of three years. Results of the analysis indicate that prophylactic administration of the vaccine was highly effective in preventing premalignant changes of the cervix.

3.1 million abnormal Pap smears

There are about 50 million to 60 million Pap smears performed each year in the United States, and an estimated 3.1 million are read as abnormal,[2] says **Kevin Ault**, MD, associate professor of obstetrics and gynecology at Emory University School of Medicine and lead author of the meta-analysis. By preventing precancerous growth, not

EXECUTIVE SUMMARY

Results from a meta-analysis study of Gardasil, the cervical cancer vaccine, indicate the shot is nearly 100% effective against the two types of the human papillomavirus (HPV) responsible for most cases of cervical cancer.

- Scientists now have evidence that HPV causes some throat cancers. According to the research, oral HPV infection is the strongest risk factor for the disease, regardless of tobacco and alcohol use, and having multiple oral sex partners tops the list of sex practices that boost risk for the HPV-linked cancer.
- Results of Phase III data on the HPV vaccine candidate Cervarix show that at 18 months after the first of a three-dose regimen, 100% of women up to age 55 vaccinated with the candidate vaccine had antibodies present against the two most common cancer-causing HPV types.

only will cervical cancer cases be reduced, but the number of abnormal Pap smears will be lessened as well, he notes.

Researchers at the Johns Hopkins University's Kimmel Cancer Center now have conclusive evidence that HPV causes some throat cancers in men and women. According to new research, oral HPV infection is the strongest risk factor for the disease, regardless of tobacco and alcohol use, and having multiple oral sex partners tops the list of sex practices that boost risk for the HPV-linked cancer.[3]

Study author and cancer virus expert **Maura Gillison**, MD, PhD, first reported the connection between HPV and specific throat cancers in 2000, which supported previous work by other investigators.[4] In the current study, researchers looked at 100 men and women newly diagnosed with oropharyngeal cancer. Those who had evidence of prior HPV infection were 32 times more likely to develop the cancer, much higher than the rate increase for smokers and drinkers. Study participants who reported having more than six oral sex partners in their lifetime were 8.6 times more likely to develop the HPV-linked cancer, data show.[3]

HPV-linked oral cancers have been on the rise since 1973, and Gillison expects the trend to continue to a point when HPV-associated cancers will outpace those caused by tobacco and alcohol use. They currently account for 60% of oropharyngeal cancers and about one-third of all oral cavity and pharynx cancers in the United States.[5]

With the HPV link now established, what is the next step in research when it comes to use of HPV vaccines in prevention of oral HPV infection? Gillison says randomized, placebo controlled clinical trials are needed to evaluate whether vaccination will prevent oral HPV infection.

Check data on Cervarix

New research continues to emerge on GlaxoSmithKline's experimental HPV vaccine, Cervarix. Results of Phase III data show that at 18 months after the first of a three-dose regimen, 100% of women up to age 55 vaccinated with the candidate vaccine had antibodies present against the two most common cancer-causing HPV types: 16 and 18.[6] The company awaits FDA approval of the vaccine. Its application was submitted in March 2007. **(*Contraceptive Technology Update* reported on Cervarix's filing in the article "What is next on the HPV vaccine horizon?" June 2007, p. 65.)**

The new study looked at healthy women from Germany and Poland, ages 15 to 55. Immunogenicity and safety were assessed at 18 months after the first dose of a three-dose vaccination regimen.

While prevalence of oncogenic HPV infection is highest in women younger than age 25, incident infection is estimated to occur in 5%-10% of women ages 25-55, state researchers in the new study. New infections decrease with age, but the proportion that persists is higher; therefore, women older than age 25 also may benefit from HPV vaccination, they conclude. **[Editor's note: Access HPV vaccine patient handouts developed by the Centers for Disease Control and Prevention in the online version of *Contraceptive Technology Update*. If you're accessing your online account for the first time, go to www.ahcmedia.com. Click on the "Activate Your Subscription" tab in the left-hand column. Then follow the easy steps under "Account Activation." If you already have an online subscription, go to www.ahcmedia.com. Select the tab labeled "Subscriber Direct Connect to Online Newsletters. Please select an archive." Choose "*Contraceptive Technology Update*," and then click "Sign on" from the left-hand column to log in. Once you're signed in, select "2007" and then select the September 2007 issue. For assistance, call Customer Service at (800) 688-2421.]**

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Pain: Chief complaint during heavy periods

Results of a new survey indicate that in women experiencing heavy periods, pain is the most commonly reported problem.[1] What are some clinical strategies to help ease these symptoms?

Before suggesting treatments, it is important to understand the etiology of excessive uterine bleeding. Consider the causes, suggest authors of *Contraceptive Technology*:

- **Obstetrical:** pregnancy or pregnancy complications;
- **Medication:** phenytoin, anticoagulants, digitalis, unopposed estrogen, or copper intrauterine device;
- **Systemic:** coagulation disorders, endocrinopathies such as thyroid or adrenal disorders, hepatic or renal failure, or trauma;
- **Cervical abnormalities:** infection, polyp, cancer, or trauma;
- **Abnormalities:** fibroids, infections, hyperplasia, polyp, cancer, or adenomyosis;
- **Dysfunctional uterine bleeding:** diagnosis of exclusion.[2]

Women experiencing heavy periods with pain warrant vaginal ultrasonography, which may reveal the presence of such conditions as adenomyosis or uterine fibroids, says **Andrew Kaunitz**, MD, professor and assistant chair in the Obstetrics and Gynecology Department at the University of Florida College of Medicine — Jacksonville.

Another diagnostic possibility in this setting is endometriosis.

Cyclical, but particularly extended or continuous use of oral contraceptives, may reduce flow and pain, says Kaunitz. Use of depot medroxyprogesterone acetate (DMPA; Depo Provera, Pfizer, New York City) as well as the levonorgestrel intrauterine system (Mirena LNG IUS, Bayer HealthCare Pharmaceuticals; Wayne, NJ) represent two effective and underutilized options in women with heavy flow and cramps, Kaunitz observes. In his practice, these medical, office-based therapeutic strategies are proactively offered to patients with heavy flow/pain before considering surgical management, he states.

EXECUTIVE SUMMARY

Results of a new survey indicate that in women experiencing heavy periods, pain is the most commonly reported problem.

- Obstetrical conditions, medications, systemic conditions, cervical abnormalities, and other abnormalities may cause excessive uterine bleeding. Dysfunctional uterine bleeding is a diagnosis of exclusion.
- For women with acute, prolonged, but less significant bleeding, those who are hemodynamically stable with no other identified problems may benefit from use of oral contraceptives. Women who opt not to take oral contraceptives may look at use of nonsteroidal anti-inflammatory drugs for pain relief.

What's the problem?

For the current survey, researchers performed a cross-sectional postal survey along with qualitative interviews of Scottish women. Of the 2,833 women who were surveyed, 906 women ages 25 to 44 reported heavy or very heavy periods. Further analysis was performed on this subset, with a portion of the women participating in qualitative interviews.

The new research was spurred by previous work regarding referrals to hospital clinics for menstrual problems,[3] says **Miriam Santer**, MD, a research fellow in the University of Edinburgh Medical School's Division of Community Health Sciences and lead author of the current paper. As a family practitioner, Santer says she has seen several women with heavy menstrual bleeding, many of whom seemed frustrated with their symptoms and care.

When asked what bothered them the most about their periods, the women who indicated a history of heavy bleeding reported pain most frequently, followed by heaviness, moodiness or tiredness, irregularity, and other timing problems,

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such as unpredictable duration and spotting. The type of work women did played a major role in how problematic heavy menstruation was for them, researchers note.

"I think one of the main implications of this paper is how important it is for women experiencing heavy menstrual bleeding to fully understand the range of treatments available," observes Santer. "Because other menstrual symptoms, such as pain, influence the impact of heavy menstrual bleeding, women need to discuss their symptom profile with their health care provider and come to a decision about the best treatment for them."

To evaluate excessive uterine bleeding, take a complete menstrual history, with a focus on the last several months, advise *Contraceptive Technology* authors. The age of the patient and the pattern of her bleeding guide the evaluation.[2]

For women with acute, prolonged but less significant bleeding, women who are hemodynamically stable with no other identified problems may benefit from use of oral contraceptives.[2] Women who opt not to take contraceptive may look at use of nonsteroidal anti-inflammatory drugs (NSAIDs), which may help to alleviate pain, Santer notes.

Options for NSAID doses and schedules for menorrhagia treatment include:

- ibuprofen, 800 mg three times daily;
- naproxen sodium, 550 mg three times daily;
- mefenamic acid 500 mg three times daily; or
- meclofenamate sodium, 100 mg three times daily.

Initiate therapy immediately prior to or on the first day of menses, with recommended dose maintained for three to five days.[4]

An individual approach is important in addressing patients' needs when it comes to treatment, Santer says. "For instance, although the LNG-IUS is a very effective treatment for many women, especially those requiring contraception, this might be less helpful for someone whose main concern is irregularity of bleeding," Santer notes.

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Sexual behavior: Review national survey details

Understanding sexual behavior is an important piece of the family planning puzzle, and a new national report provides insights on current sexual practices.[1]

Researchers with the Centers for Disease Control and Prevention's National Center for Health Statistics (NCHS) have issued the report, which uses data collected over a four-year period from the National Health and Nutrition Examination Survey (NHANES). The long-running survey is a program of studies designed to assess the health status of adults and children in the United States.

Results of the survey may have special significance for the study of sexual behavior, because information on sexual behavior and drug use for adults ages 20-59 was collected using the Audio Computer-Assisted Self-Interview (ACASI) method. The ACASI method, used for the first time in the NHANES survey, allows respondents to answer questions in complete privacy about socially sensitive questions related to drug use and sexual behavior.

Before 1999, many sexual behavior and drug use questions were asked in face-to-face private interviews. Studies have shown that more private methods of interviewing yield higher reporting of

EXECUTIVE SUMMARY

Sexual behavior trends are highlighted in the recent release of information from the National Health and Nutrition Examination Survey (NHANES). Compiled by researchers with the Centers for Disease Control and Prevention's National Center for Health Statistics.

- Of the 6,237 adults, ages 20 to 59, who participated in the survey, approximately 96% had had sex.
- Sixteen percent of adults first had sex before age 15, while 15% abstained from sex until at least age 21. Males were more likely than females to have had sex before the age of 15.

socially sensitive behaviors than with face-to-face interviews,[2-5] says **Cheryl Fryar**, MSPH, an associate service fellow at NCHS and lead author of the report. "Survey planners attempted to minimize response errors by implementing ACASI for the socially sensitive behavior questions asked in the survey," says Fryar. The NHANES ACASI was conducted in a private room of a mobile examination center in English or Spanish.

What did they find?

The new report uses data collected over a four-year period (1999-2002) from the NHANES survey. A total of 6,237 adults, ages 20 to 59, provided information in the survey.

Here's what researchers found:

- Approximately 96% of U.S. adults have had sex.
- Sixteen percent of adults first had sex before age 15, while 15% abstained from sex until at least age 21.
- Males were more likely than females to have had sex before the age of 15.
- The proportion of adults who first had sex before age 15 was highest for non-Hispanic blacks (28%), compared to 14% for Mexican-Americans and non-Hispanic whites.
- Six percent of blacks abstained from sex until age 21 or older, compared to 17% of Mexican-Americans and 15% of non-Hispanic whites.
- One-quarter of all women and 17% of men reported having no more than one partner of the other sex in their lifetime.
- Seventeen percent of all men and 10% of women reported having two or more sexual partners in the past year.
- Black men (46%) and women (13%) were more likely to report having 15 or more partners in a lifetime than other racial or ethnic groups.

Substance use can be intricately connected with sexual risk taking, according to the authors of *Contraceptive Technology*.[6] Asking questions about drug use can aid clinicians in assessing risks in family planning patients.

CE/CME instructions

Physicians and nurses participate in this continuing medical education/continuing education program by reading the articles, using the provided references for further research, and studying the questions at the end of the issue. Participants should select what they believe to be the correct answers and refer to the list of correct answers to test their knowledge. To clarify confusion surrounding any questions answered incorrectly, please consult the source material. After completing this activity with the **December** issue, you must complete the evaluation form provided and return it in the reply envelope provided in that issue to receive a certificate of completion. When your evaluation is received, a certificate will be mailed to you. ■

CE/CME Questions

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

- **identify** clinical, legal, or scientific issues related to development and provisions of contraceptive technology or other reproductive services.
- **describe** how those issues affect services and patient care.
- **integrate** practical solutions to problems and information into daily practices, according to advice from nationally recognized family planning experts.

9. What is the name of the card developed by the Pharmacy Access Partnership and the Pacific Institute for Women's Health to increase access to emergency contraception?

A. Client Confidentiality Card
B. Informed Consent Card
C. Go 2 EC Card
D. Got EC? Card

10. The ParaGard intrauterine device is approved for use for nulliparous women in stable relationships from:

A. ages 14 through menopause.
B. ages 16 through menopause.
C. ages 21 through menopause.
D. ages 25 through menopause.

11. Out of about 50 to 60 million Pap smears performed each year in the United States, approximately how many are read as abnormal?

A. 1.1 million
B. 2.1 million
C. 3.1 million
D. 4.1 million

12. Which nonsteroidal anti-inflammatory drugs may help to alleviate menstrual pain?

A. Ibuprofen, meclofenamate sodium, naproxen sodium, and erythromycin
B. Ibuprofen, meclofenamate sodium, doxycycline, and mefenamic acid
C. Ibuprofen, clotrimazole, naproxen sodium, and mefenamic acid
D. Ibuprofen, meclofenamate sodium, naproxen sodium, and mefenamic acid

Answers: 9. A; 10. B; 11. C; 12. D.

Here's what the new survey results found about drug use:

- Twenty-one percent of adults 20-59 years old have tried cocaine or street drugs at some time in their lives.
- Five and one-half percent of adults said they used cocaine or street drugs within the past 12 months.
- Past year use of cocaine or street drugs increased as the age group became younger, with the youngest age group (20-29 years) having the highest prevalence.
- Men (26%) were more likely to have ever tried cocaine or street drugs than women (17%).

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HPV Vaccine Questions & Answers

In June 2006, the Advisory Committee on Immunization Practices (ACIP) voted to recommend the first vaccine developed to prevent cervical cancer and other diseases in females caused by certain types of genital human papillomavirus (HPV). The vaccine, Gardasil®, protects against four HPV types, which together cause 70% of cervical cancers and 90% of genital warts.

The Food and Drug Administration (FDA) recently licensed this vaccine for use in girls/women, ages 9-26 years. The vaccine is given through a series of three shots over a six-month period.

WHO SHOULD GET THIS VACCINE

The HPV vaccine is recommended for 11-12 year-old girls, and can be given to girls as young as 9. The vaccine is also recommended for 13-26 year-old girls/women who have not yet received or completed the vaccine series.

These recommendations have been proposed by the ACIP—a national group of experts that advises the Centers for Disease Control and Prevention (CDC) on vaccine issues. These recommendations are now being considered by CDC.

Why is the HPV vaccine recommended for such young girls?

Ideally, females should get the vaccine before they are sexually active. This is because the vaccine is most effective in girls/women who have *not* yet acquired any of the four HPV types covered by the vaccine. Girls/women who have not been infected with any of those four HPV types will get the full benefits of the vaccine.

Will sexually active females benefit from the vaccine?

Females who are sexually active may also benefit from the vaccine. But they may get less benefit from the vaccine since they may have already acquired one or more HPV type(s) covered by the vaccine. Few young women are infected with all four of these HPV types. So they would still get protection from those types they have not acquired. Currently, there is no test available to tell if a girl/woman has had any or all of these four HPV types.

Why is the HPV vaccine only recommended for girls/women ages 9 to 26?

The vaccine has been widely tested in 9-to-26 year-old girls/women. But research on the vaccine's safety and efficacy has only recently begun with women older than 26 years of age. The FDA will consider licensing the vaccine for these women when there is research to show that it is safe and effective for them.

What about vaccinating boys?

We do not yet know if the vaccine is effective in boys or men. It is possible that vaccinating males will have health benefits for them by preventing genital warts and rare cancers, such as penile and anal cancer. It is also possible that vaccinating boys/men will have indirect health benefits for girls/women. Studies are now being done to find out if the vaccine works to prevent HPV infection and disease in males. When more information is available, this vaccine may be licensed and recommended for boys/men as well.

Should pregnant women get the vaccine?

The vaccine is not recommended for pregnant women. There has been limited research looking at vaccine safety for pregnant women and their unborn babies. So far, studies suggest that the vaccine has *not* caused health problems during pregnancy, nor has it caused health problems for the infant-- but more research is still needed. For now, pregnant women should complete their pregnancy before getting the vaccine. If a woman finds out she is pregnant after she has started getting the vaccine series, she should complete her pregnancy before finishing the three-dose series.

EFFICACY OF THE HPV VACCINE

Studies have found the vaccine to be almost 100% effective in preventing diseases caused by the four HPV types covered by the vaccine– including precancers of the cervix, vulva and vagina, and genital warts. The vaccine has mainly been studied in young women who had not been exposed to any of the four HPV types in the vaccine.

The vaccine was less effective in young women who had already been exposed to one of the HPV types covered by the vaccine.

This vaccine does not treat existing HPV infections, genital warts, precancers or cancers.

How long does vaccine protection last? Will a booster shot be needed?

The length of vaccine protection (immunity) is usually not known when a vaccine is first introduced. So far, studies have followed women for five years and found that women are still protected. More research is being done to find out how long protection will last, and if a booster vaccine is needed years later.

What does the vaccine *not* protect against?

Because the vaccine does not protect against *all* types of HPV, it will not prevent all cases of cervical cancer or genital warts. About 30% of cervical cancers will *not* be prevented by the vaccine, so it will be important for women to continue getting screened for cervical cancer (regular Pap tests). Also, the vaccine does *not* prevent about 10% of genital warts—nor will it prevent other sexually transmitted infections (STIs). So it will still be important for sexually active adults to reduce exposure to HPV and other STIs.

Will girls/women be protected against HPV and related diseases, even if they don't get all three doses?

It is not yet known how much protection girls/women would get from receiving only one or two doses of the vaccine. For this reason, it is very important that girls/women get *all three doses* of the vaccine.

SAFETY OF THE HPV VACCINE

The FDA has licensed the HPV vaccine as safe and effective. This vaccine has been tested in over 11,000 females (ages 9-26 years) around the world. These studies have shown no serious side effects. The most common side effect is soreness at the injection site. CDC, working with the FDA, will continue to monitor the safety of the vaccine after it is in general use.

Does this vaccine contain thimerosal or mercury?

No. There is no thimerosal or mercury in the HPV vaccine. It is made up of proteins from the outer coat of the virus (HPV). There is no infectious material in this vaccine.

COST AND COVERAGE OF THE HPV VACCINE

The retail price of the vaccine is $120 per dose ($360 for full series).

Will the HPV vaccine be covered by insurance plans?

While some insurance companies may cover the vaccine, others may not. Most large insurance plans usually cover the costs of recommended vaccines. However, there is often a short lag-time after a vaccine is recommended, before it is available and covered by health plans.

What kind of government programs may be available to cover HPV vaccine?

Federal health programs such as *Vaccines for Children* (VFC) will cover the HPV vaccine. The VFC program provides free vaccines to children and teens under 19 years of age, who are either uninsured, Medicaid-eligible, American Indian, or Alaska Native. There are over 45,000 sites that provide VFC vaccines, including hospitals, private clinics, and public clinics. The VFC Program also allows children and teens to get VFC vaccines through Federally Qualified Health Centers or Rural Health Centers, if their private health insurance does not cover the vaccine. For more information about the VFC, visit www.cdc.gov/nip/vfc/Default.htm

Some states also provide free or low-cost vaccines at public health department clinics to people without health insurance coverage for vaccines.

WHAT VACCINATED GIRLS/WOMEN NEED TO KNOW

The HPV vaccine is given through a series of three shots over a 6-month period. The second and third doses should be given 2 and 6 months (respectively) after the first dose.

Will girls/women who have been vaccinated still need cervical cancer screening?

Yes. There are three reasons why women will still need regular cervical cancer screening. First, the vaccine will NOT protect against all types of HPV that cause cervical cancer, so vaccinated women will still be at risk for some cancers. Second, some women may not get all required doses of the vaccine (or they may not get them at the right times), so they may not get the vaccine's full benefits. Third, women may not get the full benefit of the vaccine if they receive it after they've already acquired one of the four HPV types.

Should girls/women be screened before getting vaccinated?

No. Girls/women do not need to get an HPV test or Pap test to find out if they should get the vaccine. An HPV test or a Pap test can tell that a woman may have HPV, but these tests cannot tell the specific HPV type(s) that a woman has. Even girls/women with one HPV type could get protection from the other vaccine HPV types they have not yet acquired.

Will girls be required to get vaccinated before they enter school?

There are no federal laws that require children or adolescents to get vaccinated. All school and daycare entry laws are state laws—so they vary from state to state. To find out what vaccines are needed for children or teens to enter school or daycare in your state, check with your state health department or board of education.

THE BASICS ABOUT HPV AND CERVICAL CANCER

Genital HPV is a common virus that is passed on through genital contact, most often during vaginal and anal sex. About 40 types of HPV can infect the genital areas of men and women. While most HPV types cause no symptoms and go away on their own, some types can cause cervical cancer in women. These types also have been linked to other less common genital cancers— including cancers of the anus, vagina, and vulva (area around the opening of the vagina). Other types of HPV can cause warts in the genital areas of men and women, called genital warts.

How is HPV related to cervical cancer?

Some types of HPV can infect a woman's cervix (lower part of the womb) and cause the cells to change. Most of the time, HPV goes away on its own. When HPV is gone, the cervix cells go back to normal. But sometimes, HPV does not go away. Instead, it lingers (persists) and continues to change the cells on a woman's cervix. These cell changes (or "precancers") can lead to cancer over time, if they are not treated.

How common is HPV?

At least 50% of sexually active people will get HPV at some time in their lives. Every year in the United States (U.S.), about 6.2 million people get HPV. HPV is most common in young women and men who are in their late teens and early 20s.

Anyone who has ever had genital contact with another person can get HPV. Both men and women can get it – and pass it on to their sex partners- without even realizing it.

How common is cervical cancer in the U.S.? How many women die from it?

The American Cancer Society estimates that in 2006, over 9,700 women will be diagnosed with cervical cancer and 3,700 women will die from this cancer in the U.S.

How common are Genital Warts?

About 1% of sexually active adults in the U.S. (about 1 million people) have visible genital warts at any point in time.

Is HPV the same thing as HIV or Herpes?

HPV is NOT the same as HIV or Herpes (Herpes simplex virus or HSV). While these are all viruses that can be sexually transmitted—HIV and HSV do not cause the same symptoms or health problems as HPV.

Can HPV and its associated diseases be treated?

There is no treatment for HPV. But there *are* treatments for the health problems that HPV can cause, such as genital warts, cervical cell changes, and cancers of the cervix, vulva, vagina and anus.

OTHER WAYS TO PREVENT CERVICAL CANCER AND HPV

Another HPV vaccine is in the final stages of clinical testing, but it is not yet licensed. This vaccine would protect against the two types of HPV that cause most (70%) cervical cancers.

Are there other ways to prevent cervical cancer?

Regular Pap tests and follow-up can prevent most, but not all, cases of cervical cancer. Pap tests can detect cell changes in the cervix *before* they turn into cancer. Pap tests can also detect most, but not all, cervical cancers at an early, curable stage. Most women diagnosed with cervical cancer in the U.S. have either never had a Pap test, or have not had a Pap test in the last 5 years.

There is also an HPV DNA test available for use with the Pap test, as part of cervical cancer screening. This test is used for women over 30 or for women who get an unclear (borderline) Pap test result. While this test can tell if a woman has HPV on her cervix, it cannot tell *which* types of HPV she has.

Are there other ways to prevent HPV?

The only sure way to prevent HPV is to abstain from all sexual activity. Sexually active adults can reduce their risk by being in a mutually faithful relationship with someone who has had no other or few sex partners, or by limiting their number of sex partners. But even persons with only one lifetime sex partner can get HPV, if their partner has had previous partners.

It is not known how much protection condoms provide against HPV, since areas that are not covered by a condom can be exposed to the virus. However, condoms may reduce the risk of genital warts and cervical cancer. They can also reduce the risk of HIV and some other STIs, when used all the time and the right way.

WHERE CAN I GET MORE INFORMATION?

CDC HPV Information - http://www.cdc.gov/std/hpv/
Order Publications at http://www.cdc.gov/std/pubs/

STD information and referrals to STD Clinics
CDC-INFO
1-800-CDC-INFO (800-232-4636)
TTY: 1-888-232-6348
In English, en Español

American Cancer Society (ACS) - http://www.cancer.org

American Social Health Association (ASHA) - www.ashastd.org
P. O. Box 13827
Research Triangle Park, NC 27709-3827
1-800-783-9877

Printable versions of this and other STD fact sheets are available at: www.cdc.gov/std/healthcomm/fact_sheets.htm

CDC
August 2006

HPV (HUMAN PAPILLOMAVIRUS) VACCINE

WHAT YOU NEED TO KNOW

1 What is HPV?

Genital human papillomavirus (HPV) is the most common sexually transmitted virus in the United States.

There are about 40 types of HPV. About 20 million people in the U.S. are infected, and about 6.2 million more get infected each year. HPV is spread through sexual contact.

Most HPV infections don't cause any symptoms, and go away on their own. But HPV is important mainly because it can cause **cervical cancer** in women. Every year in the U.S. about 10,000 women get cervical cancer and 3,700 die from it. It is the 2nd leading cause of cancer deaths among women around the world.

HPV is also associated with several less common types of cancer in both men and women. It can also cause genital warts and warts in the upper respiratory tract.

More than 50% of sexually active men and women are infected with HPV at sometime in their lives.

There is no treatment for HPV infection, but the conditions it causes can be treated.

2 HPV Vaccine - Why get vaccinated?

HPV vaccine is an inactivated (not live) vaccine which protects against 4 major types of HPV.

These include 2 types that cause about 70% of cervical cancer and 2 types that cause about 90% of genital warts. ***HPV vaccine can prevent most genital warts and most cases of cervical cancer.***

Protection from HPV vaccine is expected to be long-lasting. But vaccinated women still need cervical cancer screening because the vaccine does not protect against all HPV types that cause cervical cancer.

3 Who should get HPV vaccine and when?

Routine Vaccination

- HPV vaccine is routinely recommended for girls **11-12 years of age**. Doctors may give it to girls as young as 9 years.

  Why is HPV vaccine given to girls at this age? It is important for girls to get HPV vaccine **before** their first sexual contact – because they have not been exposed to HPV. For these girls, the vaccine can prevent almost 100% of disease caused by the 4 types of HPV targeted by the vaccine.

  However, if a girl or woman is already infected with a type of HPV, the vaccine will not prevent disease from that type.

Catch-Up Vaccination

- The vaccine is also recommended for girls and women **13-26 years of age** who did not receive it when they were younger.

HPV vaccine is given as a 3-dose series:

1st Dose:	Now
2nd Dose:	2 months after Dose 1
3rd Dose:	6 months after Dose 1

Additional (booster) doses are not recommended.

HPV vaccine may be given at the same time as other vaccines.

4 Some girls or women should not get HPV vaccine or should wait

- Anyone who has ever had a life-threatening **allergic reaction** to **yeast**, to **any other component of HPV vaccine**, or to a **previous dose of HPV vaccine** should not get the vaccine. Tell your doctor if the person getting the vaccine has any severe allergies.

HPV Vaccine **2/2/2007**

- **Pregnant women** should not get the vaccine. The vaccine appears to be safe for both the mother and the unborn baby, but it is still being studied. Receiving HPV vaccine when pregnant is **not** a reason to consider terminating the pregnancy. Women who are breast feeding may safely get the vaccine.

> Any woman who learns that she was pregnant when she got HPV vaccine is encouraged to call the **HPV vaccine in pregnancy registry** at 800-986-8999.
>
> Information from this registry will help us learn how pregnant women respond to the vaccine.

- People who are mildly ill when the shot is scheduled can still get HPV vaccine. People with **moderate or severe illnesses** should wait until they recover.

5 What are the risks from HPV vaccine?

HPV vaccine does not appear to cause any serious side effects.

However, a vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. The risk of **any** vaccine causing serious harm, or death, is extremely small.

Several **mild problems** may occur with HPV vaccine:

- Pain at the injection site (about 8 people in 10)
- Redness or swelling at the injection site (about 1 person in 4)
- Mild fever (100°F) (about 1 person in 10)
- Itching at the injection site (about 1 person in 30)
- Moderate fever (102°F) (about 1 person in 65)

These symptoms do not last long and go away on their own.

Life-threatening allergic reactions from vaccines are very rare. If they do occur, it would be within a few minutes to a few hours after the vaccination.

Like all vaccines, HPV vaccine will continue to be monitored for unusual or severe problems.

6 What if there is a severe reaction?

What should I look for?

- Any unusual condition, such as a high fever or behavior changes. Signs of a serious allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

What should I do?

- **Call** a doctor, or get the person to a doctor right away.
- **Tell** your doctor what happened, the date and time it happened, and when the vaccination was given.
- **Ask** your doctor, nurse, or health department to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form.

  Or you can file this report through the VAERS website at www.vaers.hhs.gov, or by calling 1-800-822-7967.

  VAERS does not provide medical advice.

7 How can I learn more?

- Ask your doctor or nurse. They can show you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636 (1-800-CDC-INFO)**
  - Visit CDC's website at **www.cdc.gov/std/hpv** and **www.cdc.gov/nip.**

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
NATIONAL CENTER FOR IMMUNIZATION AND RESPIRATORY DISEASES

Vaccine Information Statement (Interim)
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