



POLICY & PRACTICE

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CDC Eliminates HIV Exclusion

People seeking to immigrate to the United States will no longer be required to undergo HIV testing, under a final rule issued by the Centers for Disease Control and Prevention. "While HIV infection is a serious health condition, it is not a communicable disease that is a significant public health risk for introduction, transmission, and spread to the U.S. population through casual contact," CDC officials wrote in the Federal Register in November. The rule goes into effect on Jan. 4. Until now, CDC policy has been that individuals with HIV who are living outside the United States are not eligible to receive a visa for admission to the country. The CDC proposed the change earlier this year and received more than 20,000 public comments on it, the majority of which (about 19,500) supported removing HIV from the list of communicable diseases of public health significance, agency officials said.

Court Rejects Defamation Claim

A California appeals court has thrown out the defamation case against Dr. Bruce Flamm, a clinical professor of ob.gyn. at the University of California, Irvine. He was sued for making critical statements about the authors of a 2001 study published in the *Journal of Reproductive Medicine*. The heavily criticized study purported to show that prayer increased the success rates of in vitro fertilization. Dr. Flamm wrote in *OB.GYN. NEWS* on March 15, 2007, that one of the authors of the study, Dr. Kwang Cha, had been guilty of plagiarizing a later study. In 2007, Dr. Cha sued Dr. Flamm for defamation, saying that the opinion piece implied that he had been found guilty of plagiarism in a court or other official body. The lawsuit was rejected by the Los Angeles Superior Court, but Dr. Cha appealed to the California Appellate Court. That court has now affirmed the lower court's ruling. In a statement, Dr. Flamm called the ruling a victory for evidence-based medicine and said that scientists must be allowed to question "bizarre claims." "Physicians should debate their opinions in medical journals, not in courts of law," he said. Dr. Flamm serves on the editorial advisory board for *OB.GYN. NEWS*.

Teen Parents Not Stereotypical

While many Americans assume that teenaged parents come from impoverished, single-parent homes, teen pregnancy happens across the socioeconomic spectrum, according to a new analysis. Surveys of middle- and high-school students show that 39% of teens who had ever given

birth to or fathered a child as a teenager were living with two biological or adoptive parents before the birth, the National Campaign to Prevent Teen and Unplanned Pregnancy reported. Another 19% of these teens said that they were living with one biological parent and one stepparent. About 72% of teens who had either fathered a child or given birth as a teenager were living in households that were above the federal poverty level. In fact, most of that group was living in households with incomes at or above 200% of poverty. "Despite what many may believe, teen childbearing is not limited to a particular income group or family structure, which means that prevention efforts must be broad in their design and reach," Sarah Brown, CEO of the National Campaign to Prevent Teen and Unintended Pregnancy, said in a statement. The findings are based on an analysis of the National Longitudinal Study of Adolescent Health and a public opinion poll of more than 1,000 adults.

Embryo Donation Training

The nonprofit group called RESOLVE: The National Infertility Association is developing a series of training programs to help the medical teams at fertility clinics better understand the issues surrounding embryo donation. RESOLVE, which usually focuses on consumer education, will use a grant from the U.S. Health and Human Services Department to create training modules for health care providers, so they in turn can provide information to their patients. As part of the program, clinic staff will assess their knowledge and current practices related to informing patients about the option to donate embryos. The group RESOLVE also plans to develop online programs for continuing education credit and to offer social networking opportunities.

Pipeline Is Full of Treatments

Pharmaceutical and biotechnology companies have nearly 1,000 medications and vaccines in the pipeline to treat diseases that disproportionately affect women, according to a report released by the Pharmaceutical Research and Manufacturers of America. The 969 medicines are either in clinical trials or under review by the Food and Drug Administration. For example, treatments in the pipeline include 112 for breast cancer, 86 for obstetric/gynecologic conditions, 76 for asthma, 155 for diabetes, 131 for arthritis, and 80 for Alzheimer's disease, according to PhRMA.

—Mary Ellen Schneider

- Inform patient of the risks of leaving Mirena in place or removing it during pregnancy and of the lack of data on long-term effects on the offspring of women who have had Mirena in place during conception or gestation [see *Warnings and Precautions (5.2)*].
- If possible, Mirena should be removed after the patient has been warned of the risks of removal. If removal is difficult, the patient should be counseled and offered pregnancy termination.
- If Mirena is left in place, the patient's course should be followed closely.

In the event of a sexually transmitted disease during Mirena use:

Should the patient's relationship cease to be mutually monogamous, or should her partner become HIV positive, or acquire a sexually transmitted disease, she should be instructed to report this change to her clinician immediately. The use of a barrier method as a partial protection against acquiring sexually transmitted diseases should be strongly recommended. Removal of Mirena should be considered.

Mirena should be removed for the following medical reasons:

- New onset menorrhagia and/or metrorrhagia producing anemia
- Sexually transmitted disease
- Pelvic infection; endometritis
- Symptomatic genital actinomycosis
- Intractable pelvic pain
- Severe dyspareunia
- Pregnancy
- Endometrial or cervical malignancy
- Uterine or cervical perforation.

Removal of the system should also be considered if any of the following conditions arise for the first time:

- Migraine, focal migraine with asymmetrical visual loss or other symptoms indicating transient cerebral ischemia
 - Exceptionally severe headache
 - Jaundice
 - Marked increase of blood pressure
 - Severe arterial disease such as stroke or myocardial infarction.
- Removal may be associated with some pain and/or bleeding or neurovascular episodes.

5.14 Glucose Tolerance

Levonorgestrel may affect glucose tolerance, and the blood glucose concentration should be monitored in diabetic users of Mirena.

6 ADVERSE REACTIONS

The following most serious adverse reactions associated with the use of Mirena are discussed in greater detail in the *Warnings and Precautions section (5)*:

- Ectopic Pregnancy [see *Warnings and Precautions (5.1)*]
- Intrauterine Pregnancy [see *Warnings and Precautions (5.2)*]
- Group A streptococcal sepsis (GAS) [see *Warnings and Precautions (5.3)*]
- Pelvic Inflammatory Disease [see *Warnings and Precautions (5.4)*]
- Embedment [see *Warnings and Precautions (5.6)*]
- Perforation [see *Warnings and Precautions (5.7)*]
- Breast Cancer [see *Warnings and Precautions (5.10)*]

6.1 Clinical Trial Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The data provided reflect the experience with the use of Mirena in the adequate and well-controlled studies for contraception (n=2,339) and heavy menstrual bleeding (n=80). For the contraception indication, Mirena was compared to a copper IUD (n=1,855), to another formulation of levonorgestrel intrauterine system (n=390) and to a combined oral contraceptive (n=94) in women 18 to 35 years old. The data cover more than 92,000 woman-months of exposure. For the treatment of heavy menstrual bleeding indication (n=80), the subjects included women aged 26 to 50 with confirmed heavy bleeding and exposed for a median of 183 treatment days of Mirena (range 7 to 295 days). The frequencies of reported adverse drug reactions represent crude incidences.

The adverse reactions seen across the 2 indications overlapped, and are reported using the frequencies from the contraception studies.

The most common adverse reactions (≥5% users) are uterine/vaginal bleeding alterations (51.9%), amenorrhea (23.9%), intermenstrual bleeding and spotting (23.4%), abdominal/pelvic pain (12.8%), ovarian cysts (12%), headache/migraine (7.7%), acne (7.2%), depressed/altered mood (6.4%), menorrhagia (6.3%), breast tenderness/pain (4.9%), vaginal discharge (4.9%) and IUD expulsion (4.9%).

Other relevant adverse reactions occurring in <5% of subjects include nausea, nervousness, vulvovaginitis, dysmenorrhea, back pain, weight increase, decreased libido, cervicitis/Papanicolaou smear normal/class II, hypertension, dyspareunia, anemia, alopecia, skin disorders including eczema, pruritus, rash and urticaria, abdominal distention, hirsutism and edema.

6.2 Postmarketing Experience

The following adverse reactions have been identified during post approval use of Mirena: device breakage and angioedema. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.



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