

POLICY & PRACTICE

Cesarean Rate Jumps 38% in U.S.

The number of babies delivered by cesarean section at U.S. community hospitals increased 38% between 1997 and 2003, according to a report from the Agency for Healthcare Research and Quality. More than one-quarter of the 4 million births that occurred in U.S. hospitals in 2003 were by cesarean section, compared with about one-fifth in 1997. The proportion of cesarean sections that are elective also is increasing, according to the report, which relied on data from the Healthcare Cost and Utilization Project. National charges as-

sociated with cesarean births were more than \$14.5 billion in 2003, with 53% of the bill going to private payers and 41% being charged to Medicaid. The charges for an uncomplicated cesarean delivery averaged about \$11,500, about \$5,000 more than a routine vaginal delivery. The report also noted that vaginal birth after cesarean (VBAC) decreased by more than 60% from 1997 to 2003. The rate of VBAC was 35.3 per 100 women who had a previous cesarean in 1997 and dropped to 13.7 per 100 women in 2003. During the same period, the use of episiotomies and forceps during

vaginal birth also dropped. The full analysis is available online at www.hcup-us.ahrq.gov/reports/statbriefs/sb11.pdf.

Oral Contraceptives' Clinic Prices Cut

After an initial decision to raise prices of oral contraceptives earlier this summer, Ortho-McNeil has agreed to lower prices for the products for federally funded health clinics across the country. The company raised prices in July for various oral contraceptive products, inciting "widespread panic" among public health clinics, according to Marilyn Keefe, interim CEO of the National Family Planning and Reproductive Health Association. After hear-

ing about the impact the price hike would have on the approximately 4,500 public health clinics nationwide, Ortho-McNeil announced at the end of August that it would drop its prices. "While the company has consistently followed a mandated formula to public health services as a result of participation in the federal government's Medicaid program, the organization has decided to further lower pricing to meet the needs of women and insure access to contraceptive choices and work with underfunded public health services," Ortho-McNeil said in a statement. The new prices are 92%-94% discounted from the list price of the drugs, Ms. Keefe said.

ParaGard[®] T 380A[®]

intrauterine copper contraceptive

Brief Summary

(See package brochure for full prescribing information)

Patients should be counseled that this product does not protect against HIV infection (AIDS) and other sexually transmitted diseases.

ParaGard[®] T 380A Intrauterine Copper Contraceptive should be placed and removed only by healthcare professionals who are experienced with these procedures.

INDICATIONS AND USAGE

ParaGard[®] is indicated for intrauterine contraception for up to 10 years. The pregnancy rate in clinical studies has been less than 1 pregnancy per 100 women each year.

CONTRAINDICATIONS

ParaGard[®] should not be placed when one or more of the following conditions exist:

1. Pregnancy or suspicion of pregnancy
2. Abnormalities of the uterus resulting in distortion of the uterine cavity
3. Acute pelvic inflammatory disease, or current behavior suggesting a high risk for pelvic inflammatory disease
4. Postpartum endometritis or postabortal endometritis in the past 3 months
5. Known or suspected uterine or cervical malignancy
6. Genital bleeding of unknown etiology
7. Mucopurulent cervicitis
8. Wilson's disease
9. Allergy to any component of ParaGard[®]
10. A previously placed IUD that has not been removed

WARNINGS**1. Intrauterine Pregnancy**

If intrauterine pregnancy occurs with ParaGard[®] in place and the string is visible, ParaGard[®] should be removed because of the risk of spontaneous abortion, premature delivery, sepsis, septic shock, and, rarely, death. Removal may be followed by pregnancy loss.

If the string is not visible, and the woman decides to continue her pregnancy, check if the ParaGard[®] is in her uterus (for example, by ultrasound). If ParaGard[®] is in her uterus, warn her that there is an increased risk of spontaneous abortion and sepsis, septic shock, and, rarely, death. In addition, the risk of premature labor and delivery is increased.

Human data about risk of birth defects from copper exposure are limited. However, studies have not detected a pattern of abnormalities, and published reports do not suggest a risk that is higher than the baseline risk for birth defects.

2. Ectopic Pregnancy

Women who become pregnant while using ParaGard[®] should be evaluated for ectopic pregnancy. A pregnancy that occurs with ParaGard[®] in place is more likely to be ectopic than a pregnancy in the general population. However, because ParaGard[®] prevents most pregnancies, women who use ParaGard[®] have a lower risk of an ectopic pregnancy than sexually active women who do not use any contraception.

3. Pelvic Infection

Although pelvic inflammatory disease (PID) in women using IUDs is uncommon, IUDs may be associated with an increased relative risk of PID compared to other forms of contraception and to no contraception. The highest incidence of PID occurs within 20 days following insertion. Therefore, the visit following the first post-insertion menstrual period is an opportunity to assess the patient for infection, as well as to check that the IUD is in place. Since pelvic infection is most frequently associated with sexually transmitted organisms, IUDs are not recommended for women at high risk for sexual infection. Prophylactic antibiotics at the time of insertion do not appear to lower the incidence of PID.

PID can have serious consequences, such as tubal damage (leading to ectopic pregnancy or infertility), hysterectomy, sepsis, and, rarely, death. It is therefore important to promptly assess and treat any woman who develops signs or symptoms of PID.

Guidelines for treatment of PID are available from the Centers for Disease Control and Prevention (CDC), Atlanta, Georgia at www.cdc.gov or 1-800-311-3435. Antibiotics are the mainstay of therapy. Most healthcare professionals also remove the IUD.

The significance of actinomycetes-like organisms on Papanicolaou smear in an asymptomatic IUD-user is unknown, and so this finding alone does not always require IUD removal and treatment. However, because pelvic actinomycosis is a serious infection, a woman who has symptoms of pelvic infection possibly due to actinomycetes should be treated and have her IUD removed.

4. Immucocompromise

Women with AIDS should not have IUDs inserted unless they are clinically stable on antiretroviral therapy. Limited data suggest that asymptomatic women infected with human immunodeficiency virus may use intrauterine devices. Little is known about the use of IUDs in women who have illnesses causing serious immunocompromise. Therefore these women should be carefully monitored for infection if they choose to use an IUD. The risk of pregnancy should be weighed against the theoretical risk of infection.

5. Embedment

Partial penetration or embedment of ParaGard[®] in the myometrium can make removal difficult. In some cases, surgical removal may be necessary.

6. Perforation

Partial or total perforation of the uterine wall or cervix may occur rarely during placement, although it may not be detected until later. Spontaneous migration has also been reported. If perforation does occur, remove ParaGard[®] promptly, since the copper can lead to intraperitoneal adhesions. Intestinal perforation, intestinal obstruction, and/or damage to adjacent organs may result if an IUD is left in the peritoneal cavity. Pre-operative imaging followed by laparoscopy or laparotomy is often required to remove an IUD from the peritoneal cavity.

7. Expulsion

Expulsion can occur, usually during the menses and usually in the first few months after insertion. There is an increased risk of expulsion in the nulliparous patient. If unnoticed, an unintended pregnancy could occur.

8. Wilson's Disease

Theoretically, ParaGard[®] can exacerbate Wilson's disease, a rare genetic disease affecting copper excretion.

References: 1. Sivin I, Stern J, Diaz S, et al. Rates and outcomes of planned pregnancy after use of Norplant capsules, Norplant II rods, or levonorgestrel-releasing or copper TCu 380Ag intrauterine contraceptive devices. *Am J Obstet Gynecol.* 1992;166:1208-1213. 2. Vessey MP, Lawless M, McPherson K, Yeates D. Fertility after stopping use of intrauterine contraceptive device. *BMJ.* 1983;286:106. 3. Skjeldestad F, Bratt H. Fertility after complicated and non-complicated use of IUDs: a controlled prospective study. *Adv Contracept.* 1988;4:179-184.

PRECAUTIONS

Patients should be counseled that this product does not protect against HIV infection (AIDS) and other sexually transmitted diseases.

1. Information for patients

Before inserting ParaGard[®] discuss the Patient Package Insert with the patient, and give her time to read the information. Discuss any questions she may have concerning ParaGard[®] as well as other methods of contraception. Instruct her to promptly report symptoms of infection, pregnancy, or missing strings.

2. Insertion precautions, continuing care, and removal.

(See **Package Brochure for INSTRUCTIONS FOR USE.**)

3. Vaginal bleeding

In the 2 largest clinical trials with ParaGard[®] (see **ADVERSE REACTIONS, Table 2**), menstrual changes were the most common medical reason for discontinuation of ParaGard[®]. Discontinuation rates for pain and bleeding combined are highest in the first year of use and diminish thereafter. The percentage of women who discontinued ParaGard[®] because of bleeding problems or pain during these studies ranged from 11.9% in the first year to 2.2% in year 9. Women complaining of heavy vaginal bleeding should be evaluated and treated, and may need to discontinue ParaGard[®]. (See **ADVERSE REACTIONS.**)

4. Vasovagal reactions, including fainting

Some women have vasovagal reactions immediately after insertion. Hence, patients should remain supine until feeling well and should be cautious when getting up.

5. Expulsion following placement after a birth or abortion

ParaGard[®] has been placed immediately after delivery, although risk of expulsion may be higher than when ParaGard[®] is placed at times unrelated to delivery. However, unless done immediately postpartum, insertion should be delayed to the second postpartum month because insertion during the first postpartum month (except for immediately after delivery) has been associated with increased risk of perforation.

ParaGard[®] can be placed immediately after abortion, although immediate placement has a slightly higher risk of expulsion than placement at other times. Placement after second trimester abortion is associated with a higher risk of expulsion than placement after the first trimester abortion.

6. Magnetic resonance imaging (MRI)

Limited data suggest that MRI at the level of 1.5 Tesla is acceptable in women using ParaGard[®]. One study examined the effect of MRI on the CU-7[®] Intrauterine Copper Contraceptive and Lippes Loop[™] intrauterine devices. Neither device moved under the influence of the magnetic field or heated during the spin-echo sequences usually employed for pelvic imaging. An in vitro study did not detect movement or temperature change when ParaGard[®] was subjected to MRI.

7. Medical diathermy

Theoretically, medical (non-surgical) diathermy (short-wave and microwave heat therapy) in a patient with a metal-containing IUD may cause heat injury to the surrounding tissue. However, a small study of eight women did not detect a significant elevation of intrauterine temperature when diathermy was performed in the presence of a copper IUD.

8. Pregnancy

ParaGard[®] is contraindicated during pregnancy. (See **CONTRAINDICATIONS** and **WARNINGS.**)

9. Nursing mothers

Nursing mothers may use ParaGard[®]. No difference has been detected in concentration of copper in human milk before and after insertion of copper IUDs. The literature is conflicting, but limited data suggest that there may be an increased risk of perforation and expulsion if a woman is lactating.

10. Pediatric use

ParaGard[®] is not indicated before menarche. Safety and efficacy have been established in women over 16 years old.

ADVERSE REACTIONS

The most serious adverse events associated with intrauterine contraception are discussed in **WARNINGS** and **PRECAUTIONS**. These include:

Intrauterine pregnancy	Pelvic infection
Septic abortion	Perforation
Ectopic pregnancy	Embedment

Table 2 shows discontinuation rates from two clinical studies by adverse event and year.

Table 2. Summary of Rates (No. per 100 Subjects) by Year for Adverse Events Causing Discontinuation

Adverse Event	Year									
	1	2	3	4	5	6	7	8	9	10
Pregnancy	0.7	0.3	0.6	0.2	0.3	0.2	0.0	0.4	0.0	0.0
Expulsion	5.7	2.5	1.6	1.2	0.3	0.0	0.6	1.7	0.2	0.4
Bleeding/Pain	11.9	9.8	7.0	3.5	3.7	2.7	3.0	2.5	2.2	3.7
Other Medical Event	2.5	2.1	1.6	1.7	0.1	0.3	1.0	0.4	0.7	0.3
No. of Women at Start of Year	4932	3149	2018	1121	872	621	563	483	423	325

*Rates were calculated by weighting the annual rates by the number of subjects starting each year for each of the Population Council (3,536 subjects) and the World Health Organization (1,396 subjects) trials.

The following adverse events have also been observed. These are listed alphabetically and not by order of frequency or severity.

Anemia	Menstrual flow, prolonged
Backache	Menstrual spotting
Dysmenorrhea	Pain and cramping
Dyspareunia	Urticarial allergic skin reaction
Expulsion, complete or partial	Vaginitis
Leukorrhea	

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U.S. Cancer Deaths Continue to Drop

Overall cancer death rates in the United States are continuing a nearly decade-long decline, according to an annual report on cancer trends released by the American Cancer Society, the National Institutes of Health, and other groups. The findings, which were to be published in the Oct. 15 issue of *Cancer*, included cancer incidence and trend data from 1975 to 2003. The study showed that the overall cancer incidence rates among all races and genders were stable from 1992 to 2003. However, the overall cancer incidence rates for men were stable from 1995 to 2003, while cancer rates in women were on the rise from 1979 through 2003. The report is available online at www.interscience.wiley.com/cancer/report2006.

Scales Influence Smoking Cessation

Pregnant ex-smokers who have confidence in their ability to control their weight are less likely to start smoking again after pregnancy, according to a new study published in the *Annals of Behavioral Medicine*. Researchers found that weight self-efficacy was significantly associated with postpartum motivation not to smoke even after controlling for other factors such as breastfeeding, partner smoking, years of smoking, race, and prepregnancy nicotine dependence. The study included 119 women in their third trimester of pregnancy. All of the participants were not smoking at the time of the study, but had smoked at least eight cigarettes per day for 1 month or more before becoming pregnant. The findings indicate that smoking cessation programs that target women's perceptions about weight gain may be able to improve long-term quitting success, the researchers wrote.

Poll: 70% Unaware of Medicare Cuts

About 70% of Americans recently polled were unaware of scheduled cuts to physician payments under Medicare, according to the American Medical Association. The group commissioned a poll of U.S. adults in an effort to draw attention to the planned 5.1% Medicare payment cut set to take effect in 2007 and additional payment cuts planned over the next several years. The telephone survey, conducted in July, polled more than 1,000 adults in the United States. When told about the scheduled cuts to physician pay, 86% of those surveyed said they were concerned the cuts could affect seniors' access to health care. The AMA is pushing Congress to take action this year to stop the 2007 cut from going into effect.

—Mary Ellen Schneider