Unintended Pregnancies Put Mothers, Babies at Risk

BY NANCY WALSH New York Bureau

MINNEAPOLIS — Data from a surveillance system in Maryland show that the burden of unintended pregnancy remains large, with multiple potential risks for both mothers and infants, according to Dr. Diana Cheng of the Maryland Department of Health and Mental Hygiene,

The Maryland Pregnancy Risk Assess-

ment Monitoring System (PRAMS) was established by the Centers for Disease Control and Prevention with the goal of obtaining information about maternal behaviors and experiences that may be associated with adverse pregnancy outcomes.

Between 2001 and 2005, a random sample of 7,381 mothers completed the PRAMS survey from 2 to 6 months after

The survey included the following question: Thinking back to just before you got pregnant, how did you feel about becoming pregnant?

Available answers were "I wanted to be pregnant sooner," "I wanted to be pregnant later," "I wanted to be pregnant then," or "I didn't want to be pregnant then or at any time in the future.'

Pregnancies were classified as intended if the mothers had wanted them then or sooner and as unintended if they said they wanted them later or not at all.

Analysis of the survey responses deter-

mined that 58% of the pregnancies were intended, while 42% were unintended, Dr. Cheng reported at the annual meeting of the Association of Reproductive Health

Among women with intended pregnancies, 16% said they wanted their pregnancy sooner and 42% said they wanted their pregnancy then.

Among women with unintended pregnancies, 31% said they wanted their pregnancies later and 11% said they didn't want to be pregnant then or ever.

"We also looked at maternal behaviors and risk factors, and the group whose pregnancies were unwanted really fared

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much worse," Dr. Cheng said. A total of 86% of the mothers whose pregnancies were unwanted did not take folic acid daily, 44% initiated prenatal care after the first trimester, and about 24% smoked during pregnancy.

Post partum,

37% did not breast-feed, 30% smoked, 27% reported depression, and 50% did not place their babies on their backs to

Moreover, 11% of women in this group reported a history of physical abuse.

In contrast, significantly lower percentages of women with intended pregnancies reported unhealthy behaviors. For example, among mothers in this group, 87% initiated prenatal care during the first trimester, 81% breast-fed, and 69% placed their babies on their backs for sleep.

A total of 10% of babies born to mothers whose pregnancies were unwanted were low birth weight, as were 7% of babies born to mothers whose pregnancies were intended.

The survey also found that 43% of the women were using birth control at the time they became pregnant.

"Discouragingly, the fact that this many women were using birth control and became pregnant anyway suggests inconsistent or improper use of contraceptives," Dr. Cheng noted.

Among the women who did not use birth control, most said they did not think they could get pregnant at that time. Other reasons for failure to use contraceptives included cost and difficulties in obtaining birth control supplies, she noted.

Improving women's access to education about contraception will help couples better plan pregnancies and increase the rates of intended pregnancies, and counseling, particularly with the inclusion of the partner, can help clarify common misconceptions about birth control, she said.

Unwanted and mistimed births remain a huge educational challenge and opportunity for family planning organizations and specialists, Dr. Cheng con-

PATIENTS SHOULD BE COUNSELED THAT THIS PRODUCT DOES NOT PROTECT AGAINST HIV INFECTION (AIDS) AND OTHER SEXUALLY TRANSMITTED DISEASES

INDICATIONS AND USAGE: MIRENA® is indicated for intrauterine contraception for up to 5 years. Thereafter, if continued contraception is desired, the system should be replaced. RECOMMENDED PATIENT PROFILE: MIRENA® is recommended for women who have had at least one child, are in a stable, mutually monogamous relationship, have no history of pelvic inflammatory disease, and have no history of ectopic pregnancy or condition that would predispose to ectopic pregnancy.

CONTRAINDICATIONS: MIRENA® insertion is contraindicated when one or more of the following conditions exist: 1. Pregnancy CONTRAINDICATIONS: MIRENA® insertion is contraindicated when one or more of the following conditions exist: 1. Pregnancy or suspicion of pregnancy. 2. Congenital or acquired uterine anomaly including fibroids if they distort the uterine cavity. 3. Acute pelvic inflammatory disease or a history of pelvic inflammatory disease unless there has been a subsequent intrauterine pregnancy. 4. Postpartum endometritis or infected abortion in the past 3 months. 5. Known or suspected uterine or cervical neoplasia or unresolved, abnormal Pap smear. 6. Genital bleeding of unknown etiology. 7. Untreated acute cervicits or vaginitis, including bacterial vaginosis or other lower genital tract infections until infection is controlled. 8. Acute liver disease or liver tumor (benign or malignant). 9. Woman or her partner has multiple sexual partners. 10. Conditions associated with increased susceptibility to infections with micro-organisms. Such conditions include, but are not limited to, leukemia, acquired immune deficiency syndrome (AIDS), and I.V. drug abuse. 11. Genital actinomycosis (See WARNINGS) 12. A previously inserted IUD that has not been removed. 13. Hypersensitivity to any component of this product. 14. Known or suspected carcinoma of the breast. 15. History of ectopic pregnancy or condition that would predispose to ectopic pregnancy.

WARNINGS: 1. Ectopic Pregnancy: In large clinical trials of MIRENA®, half of all pregnancies detected during the studies were WARNINGS: 1. Ectopic Pregnancy: In large clinical trials of MIRENA*, half of all pregnancies detected during the studies were catopic. The per-year incidence of ectopic pregnancy in the clinical trials was approximately 1 ectopic pregnancy per 1000 users per year. The rate of ectopic pregnancy and pregnancy and trials was approximately 1 ectopic pregnancy. The rate of ectopic pregnancy is associated with MIRENA* use is not significantly different than the rate for sexually active women not using any contraceopilon. Clinical trials of MIRENA* excluded women with a history of ectopic pregnancy or conditions that increase the risk of ectopic pregnancy. Women who choose MIRENA* must be warmed about the risks of ectopic pregnancy. They should be taught to recognize and report to their physician promptly any symptoms of ectopic pregnancy. Women should also be informed that ectopic pregnancy has been associated with complications leading to loss of fertility. 2. Intrauterine Pregnancy: In the event of an intrauterine pregnancy with MIRENA* should be removed. Removal or manipulation of MIRENA* may result in pregnancy loss. MIRENA* in place, MIRENA* should be removed. Removal or manipulation of MIRENA* and ye result in pregnancy loss. Di Continuation of pregnancy; It a woman becomes pregnant with MIRENA* in place and if MIRENA* cannot be removed or the woman chooses not to have it removed, she should be warmed that failure to remove MIRENA* increases the risk of miscarriage, essis, premature labor and premature delivery. She should be followed closely and advised to record immediately any full-like woman chooses not to have it emoved, site should be warned that failure to remove MiRENA" increases the risk of miscarriage, sepsis, premature labor and premature delivery. She should be followed closely and advised to report immediately any fluid-symptom, propriately any fluid should be followed closely and advised to report immediately any fluid symptoms, fever, chills, cramping, pain, bleeding, vaginal discharge or leakage of fluid. c) Long-term effects and congenital anomalies: When pregnancy continues with MIRENA" in place, long-term effects on the offspring are unknown. Because of the trautaterine administration of levonorpestral and local exposure to the hormone, the possibility of teratopenics following exposure to MIRENA" cannot be completely excluded. Clinical experience with the outcomes of pregnancies is limited due to the small number of reported pregnancies following exposure to MIRENA" congenital anomalies have occurred infrequently when MIRENA" has been in place during pregnancy. In these cases the role of MIRENA" in the development of the congenital anomalies is unknown. As of September 1999, 32 live births following exposure to MIRENA" were reported retrospectively. All but 2 of the infants were healthy at birth. One infant had pulmonary artery hypoplasia and another infant had cystic hypoplastic kidneys. (A sibling of this infant had renal agenesis with no MIRENA" exposure.) 3. Sepsis: As of 1999, four cases of Group at streptococcal sepsis (GAS) out of an estimated 1.3 million MIRENA" were were reported. All four women experienced the symptom of severe pain within hours of insertion, and this was followed by sepsis within a few days (of insertion). All recovered with treatment. Since death from GAS is more tilkely if treatment is delayed, it is important to be aware of these rat but serious infections. Aseptic technique during MIRENA" insertion is essential. (GAS sepsis can also occur postpartum, after minor surgery, in wounds and in association with other Illus). 4. Petic Inflammanory Disea usually within the first 20 days thereafter) (see **Insertion Precautions**). A decision to use **MIRENA**® must include consideration of the risks of PID. a) Women at increased risk for PID: PID is often associated with a sexually transmitted disease, and

MIRENA® does not protect against sexually transmitted disease. The risk of PID is greater for women who have multiple sexual partners, and also for women whose sexual partner(s) have multiple sexual partners. Women

MIRENA® does not protect against sexually transmitted disease. The risk of PID is greater for women who have multiple sexual partners, and also for women whose sexual partner(s) have multiple sexual partners. Women who have ever had PID are at increased risk for a recurrence or re-infection. b) PID warning to MIRENA® users: All women who choose MIRENA® must be informed prior to insertion about the possibility of PID and that PID can cause tubal damage leading to ectopic pregnancy or infertility, or in infrequent cases can necessitate hysterectomy, or can cause death. Patients must be taught to recognize and report to their physician prompty any symptoms of pelvic inflammatory disease. These symptoms include development of menstrual disorders (prolonged or heavy bleeding), unusual vaginal discharge, abdominal or pelvic pain or tenderness, dyspareunia, chills, and fever. c) Asymptomatic PID: PID may be asymptomatic but still result in tubal damage and its sequelae. d) Treatment of PID: Following a diagnosis of PID, or suspected PID, bacteriologic specimens should be obtained and antibiotic therapy should be initiated promptly. Removal of MIRENA® after initiation of antibiotic therapy is usually appropriate. Suidelines for PID treatment are available from the Center for Disease Control (CDC), Altanta, Georgia. Adequate PID treatment requires the application of current standards of therapy prevailing at the time of occurrence of the infection with reference to prescription labeling. Actinomycosis has been associated with IUDs women with IUDs should have the IUD removed and should receive antibiotics. However, the management of the asymptomatic carrier is controversial because actinomycetes can be found normally in the genital tract cultures in healthy women without IUDs. False positive findings of actinomycosis on Pap sense an be a problem. When possible, confirm the Pap semar diagnosis with cultures. 5. Irregular Bleeding and sporting days may be increased and bleeding patterns may be irregular. Thereafter the num be removed and surgery may be required. Adhesions, peritonitis, intestinal perforations, intestinal obstruction, abscesses and erosion of adjacent viscera have been reported with IUDs. It is recommended that postpartum **MIRENA**® insertion be delayed erosion of adjacent viscera have been reported with IÜDs. It is recommended that postpartum MIREMA* insertion be delayed until uterine involution is complete to decrease perforation risk. There is an increased risk of perforation in women who are lactating, Inserting MIREMA* immediately after first trimester abortion is not known to increase the risk of perforation, but insertion after second trimester abortion should be delayed until uterine involution is complete. 8. Ovarian Cysts: Since the contraceptive effect of MIREMA* is mainly due to its local effect, ovulatory cycles with follicular uptine usually occur in women of tertile age using MIREMA*. Sometimes atresia of the follicle is delayed and the follicle may continue to grow. Enlarged follicles have been diagnosed in about 12% of the subjects using MIREMA*. Most of these follicles are asymptomatic, although some may be accompanied by pelvic pain or dyspareunia. In most cases the enlarged follicles disappear spontaneously during two to three months observation. Surgical intervention is not usually required. 9. Breast Cancer: Women who currently have on have had breast cancer should not use hormonal contraception because breast cancer is a hormone-sensitive tumor. 10. Risks of Mortality: The available data from a variety of sources have been analyzed to estimate the risk of death associated with various methods of contraception. The estimates of risk of death include the combined risk of the contraceptive method plats annual. pregnancy or abortion in the event of method failure. The findings of the analysis are shown in the following table: **Annual Number of Birth-Related or Method-Related Deaths Associated with Control of Fertility per 100,000 Nonsterile Women, by**

AGE GROUP						
No Birth Control Method/Term	4.7	5.4	4.8	6.3	11.7	20.6
No Birth Control Method/AB	2.1	2.0	1.6	1.9	2.8	5.3
IUD	0.2	0.3	0.2	0.1	0.3	0.6
Periodic Abstinence	1.4	1.3	0.7	1.0	1.0	1.9
Withdrawal	0.9	1.7	0.9	1.3	0.8	1.5
Condom	0.6	1.2	0.6	0.9	0.5	1.0
Diaphragm/Cap	0.6	1.1	0.6	0.9	1.6	3.1
Sponge	0.8	1.5	8.0	1.1	2.2	4.1
Spermicides	1.6	1.9	1.4	1.9	1.5	2.7
Oral Contraceptives	0.8	1.3	1.1	1.8	1.0	1.9
Implants/Injectables	0.2	0.6	0.5	0.8	0.5	0.6
Tubal Sterilization	1.3	1.2	1.1	1.1	1.2	1.3
Vasertomy	0.1	0.1	0.1	0.1	0.1	0.2

Harlap S. et al., Preventing Pregnancy, protecting health: a new look at birth control choices in the US The Alan Guttmacher Institute 1991: 1-129

PATIENTS SHOULD BE COUNSELED THAT THIS PRODUCT DOES NOT PROTECT AGAINST HIV INFECTION (AIDS) AND OTHER SEXUALLY TRANSMITTED DISEASES.

1. PATIENT COUNSE/MICE. Prior to insertion, the physician, nurse, or other trained health protessional must provide the patient with the Patient Package Insert. The patient should be given the opportunity to read the information and discuss fully any questions she may have concerning MIREMA" as well as other methods of contraception. Careful and objective counseling of the user prior to insertion reparting the expected beleding patient, the possible interindividual variation in changes in bleeding and the etiology of the changes may have an effect on the frequency of removal due to bleeding problems and amenorhea. The patient should be told that some bleeding such as irregular or prolonged bleeding patient provider. Source over the patient should be told that some bleeding such as irregular or prolonged bleeding and spotting, and/or cramps may occur during the first few weeks after insertion. If the symptoms continue or are severe she should report them to her health care provider. She should be instructed on how to check after her menstrual period to make certain that the thread still protrudes from the cervix and cautioned not to pull on the thread and displace MIREMA. She should be informed that there is no contraceptive protection if MIREFAR is displaced for expeller FEAULIATION AND CLINICAL CONSIDERATIONS. to call her health care provider. She should be instructed on how to check after her menstrual period to make certain that the threat still protrudes from the cervix and cautioned not to pull on the thread and displace MIRENA*. She should be informed that there is no contraceptive protection if MIRENA* is displaced or expelled. EVALUATION AND CLINICAL CONSIDERATIONS:

a) A complete medical and social history, including that of the partner, should be obtained to determine conditions that might influence the selection of an IUD for contraception (see CONTRAINDICATIONS). A physical examination should include a pelvic examination, a Pap smear, and appropriate tests for any other forms of genital disease, such as gonorrhea and chamydia laboratory evaluations, if indicated. Special attention must be given to ascertaining whether the woman is at increased risk of ectopic pregnancy or PID. MIRENA* is contraindicated in these women. b) The health care provider should determine that the patient is not pregnant. The possibility of insertion of MIRENA* in the presence of an existing undetermined pregnancy is reduced if insertion is performed within 7 days of the onset of a menstrual period. MIRENA* can be replaced by a new system at any time in the cycle. MIRENA* can be inserted immediately after first trimester abortion. 9 MIRENA* should not be inserted until 6 weeks postpartum or until involution of the uterus is complete in order to reduce the incidence of perforation and expulsion. d) Patients with certain types of valvular or congenital heart disease and surgically constructed systemic-pulmonary shunts are at increased risk of infective endocarditis. Use of miRENA* is complete in order to reduce the incidence of perforation and expulsion. d) Patients with vention and the sease who may be at increased risk should be treated with appropriate antibiotics at the time of insertion and removal. Patients requiring chronic considerion in patients who have a coaquipotaty or are receiving anticoagulants. f) Use of MIRENA* is co complaints of pair, outputs discribing, needing, need, genial results of softes should be profitipal responsed a dark profits examination recommended. (See WARNINGS regarding amenorthea), b) if examination during visits subsequent to insertion reveals that the length of the threads has changed from the length at time of insertion, and the system is verified as displaced it should be removed. A new system may be inserted at that time or during the next menses if it is certain that conceptior has not occurred. If the threads are not visible, location of the **MIRENA**® should be verified, for example with X-ray has not occurred. If the threads are not visible, location of the MIRENA* should be verified, for example with X-ray, ultrasound, or gentle probing of the uterine cavity. If the MIRENA* is place with no evidence of perforation, no intervention is indicated. If expulsion has occurred, it may be replaced within 7 days of a menstrual period after pregnancy has been ruled out. c) Since MIRENA* may be displaced, patients should be reexamined and evaluated shortly after the first postinsertion menses, but definitely within 3 months after insertion. Symptoms of the partial or complete expusion of any IUD may include bleeding or pain. However, the system can be expelled from the uterine cavity without the woman noticing it. Partial expulsion may decrease the effectiveness of MIRENA*. As menstrual flow usually decreases after the first 3 to 6 months of MIRENA* use, increase of menstrual flow may be indicative of an expulsion. d) in the event a pregnancy is confirmed during MIRENA* in least of the control of the risks of leaving MIRENA* in place or removing it during migregiancy and of the lack of data on long-term effects on the offspring of women who have had MIRENA* in place during onception or gestation (see MARNINGS). If possible MIRENA* should be removed after the patient has been warned of the risks of removal. If removal is is left in place, the patient's course should be followed closely, e) Should the patient's leating the patient's course should be instructed to report this change to read our acquire a sexually transmitted disease, she should be instructed to report this change to

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 trongly recommended. Removal of MIRENA* should be removed for the following medical reasons: menorrhagia and/or metrorrhagia producing anemia; acquired immune deficiency syndrome (AIDS); sexually transmitted disease; pelvic infection; endometritis; symptomatic orevical perforation. 0) If the retrieval threads are not visible, they may have retracted into the uterus or have been broken, or mitterNa* may have been broken, perforated the uterus, or have been expelled. Location of MIRENA* may be determined by sonography, X-ray, or by gentle exploration of the uterine cavity with a probe. h) 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. 4. Glucose Tolerance: Levonorgestrel may affect plucose belarance, and the blood discose concentration should be monitored in diabetic users of MIRENA* processing, severe arrenar unsease such as stroke or myocardial infarction. 4. Glucose Tolerance: Levonorgestrel may affect glucose tolerance, and the blood glucose concentration should be monitored in diabetic users of MIRENA*.

ament glucose tolerance, and the blood glucose concentration should be monitored in diabetic users of MINENA*.

PRIJG INTERACTIONS: The effect of hormonal contraceptives may be impaired by drugs which induce liver enzymes. The influence of these drugs on the contraceptive efficacy of MINENA* has not been studied. CARCINOGENESIS: Long-term studies in animals to assess the carcinogenic potential of levonorgestrel releasing intrauterine system have not been performed. See "WARNINGS" section. PRESIMANCY Pregnancy Category X. See "WARNINGS" section. NURSING MOTHERS: Levonorgestrel has been identified in small quantities in the breast milk of lactating women using MIRENA*. In a study of 14 breastfeeding women using a MIRENA* prototype during lactation, mean infant serum levels of levonorgestrel were approximately 7% of maternal serum levels. Hormonal contraceptives are not recommended as the contraceptive method of first choice during lactation. PEDIATRIC USE: Safety and efficacy of MIRENA* have been established in women of reproductive are. Les of this conduct before meanageness is not indicated. (See RECOMMENDER PATILTY PROFILE) ERBIATRIC. or first choice during lactation. PEDIATRIC USE: Safety and efficacy of MIRENA* have been established in women of reproductive age. Use of this product before menarche is not indicated. (See RECOMMENDED PATIENT PROFILE) GERIATRIC USE: MIRENA* has not been studied in women over age 65 and is not currently approved for use in this population. INFORMATION FOR THE PATIENT: See Patient Labeling, Patients should also be advised that the prescribing information is available to them at their request. It is recommended that potential users be fully informed about the risks and benefits associated with the use of MIRENA*, with other forms of contraception, and with no contraception at all. Return to fertility; About 80% of women wishing to become pregnant conceived within 12 months after removal of MIRENA*, ADVERSE REACTIONS: The most serious adverse reactions associated with the use of MIRENA* are discussed above in the Warnings section. Others are presented in the Precautions section. Other adverse events reported by 5% or more subjects include: Abdominal pain, Weight increase, Breast pain, Sikin disorder, Acne, Decreased libido. Depression, Abnormal Pap smear, Hypertension, Sinustis Other reported adverse reactions occurring in less than 3% of patients include: failed insertion, migraine, vomitting, anemia, cervicitis, dyspareuria, hair loss, eczema. HOW SUPPLIED: MIRENA* (levonorgestel-releasing intrauterine system), containing a total of 52 mg levonorgestrel, is available in a carton of one sterile unit NDC* 50419-421-01. Each MIRENA* is spelicitied with ethylene oxide. Do not resterilize. For single use only. Do not use if the inner package is damaged or open, insert before the end of the month shown on the label.

STORAGE AND HANDLING: Store at 25°C (7°F); with excursions permitted between 15°-30°C (59-86°F) [See USP

STORAGE AND HANDLING: Store at 25°C (77°F); with excursions permitted between 15°-30°C (59-86°F) [See USP

DIRECTIONS FOR USE: NOTE: Health care providers are advised to become thoroughly familiar with the insertion instructions before attempting insertion of MIRENA®. Manufactured for:



(levonorgestrel-releasing intrauterine system)

Bayer HealthCare Pharmaceuticals

Bayer HealthCare Pharmaceuticals Inc

Manufactured in Finland

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