## Study: Partner Violence Screening Not Effective

BY MARY ANN MOON

reening all women at primary care visits for intimate partner violence does not appear to be beneficial, according to one study.

Such screening did not appear to cause any harm, but neither did it prompt affected women to access services or otherwise deter intimate partner violence (IPV), said Dr. Harriet L. MacMillan of McMaster University, Hamilton, Ont., and her associates.

Some medical organizations, including the American Medical Association and the American College of Obstetricians and Gynecologists, recommend such screening of all women, "despite the lack of evidence that it is effective." Others-including the U.S. Preventive Services Task Force and the Canadian Task Force on Preventive Health Care—say that there isn't sufficient evidence either for or against such screening.

Dr. MacMillan and her colleagues conducted a study to assess whether IPV screening reduced subsequent violence or improved womens' quality of life. They randomly assigned 6,743 women to be screened or not screened at primary care visits, then followed them for 18 months to determine whether intimate violence decreased (JAMA 2009;302:493-501).

The study subjects were aged 18-64 years and were recruited when they attended 12 primary care sites, 11 emergency departments, and 3 ob.gyn. clinics in Ontario in 2005-2006. They completed the Woman Abuse Screening Tool, an eight-item self-report instrument that measures physical, sexual, and emotional abuse in the preceding year, before consulting the clinician.

Any discussion of positive findings on the screen and referral for further treatment was left to the discretion of the treating clinician. Overall, 44% of the women who were screened for IPV reported discussing violence with the clinician, compared with 8% of those who were not screened.

The women also were assessed for depressive symptoms, posttraumatic stress disorder, alcohol abuse/dependency, and global mental and physical well-being. All were given an information card listing available resources for women exposed to violence.

A subset of 347 screened women and 360 unscreened were included in the data analysis for this study. The proportion of these subjects who were lost to follow-up was high: 43% of those who were screened for IPV and 41% of those who were not screened.

No significant differences were foundbetween the two groups in IPV recurrence, and only a weak, nonsignificant benefit in depression and quality of life scores with screening, Dr. MacMillan and her colleagues said.,

"If there were an effective intervention to which women could have been referred once identified as exposed to IPV, it is possible that the results of this trial would have been more positive," Dr. MacMillan and her associates noted.

Some experts have raised concerns about possible harmful effects of routine IPV screening, "including reprisal violence, psychological distress, family disruption, and risk of a child being removed from a mother's care following child protective services involvement,' the investigators added. Their study showed no evidence of a harmful effect on either abused or nonabused women.

In an accompanying editorial, Kathryn E. Moracco, Ph.D., of the University of North Carolina, Chapel Hill, and Dr. Thomas B. Cole, contributing editor of the JAMA, noted that universal screening for IPV must be distinguished from specifically assessing abuse in women who are at increased risk. In the latter case, screening "may not only detect violence but may also lead to more accurate diagnosis and treatment of co-occurring health problems," they said (JAMA 2009;302:568-9). "The results of the study by MacMillan et al. should dispel any illusions that universal screening with passive referrals to community services is an adequate response to violence in intimate relationships," they

Neither the investigators nor the editorial writers reported financial disclosures. The study was funded by the former Ontario Women's Health Council.

## Mirena®

(levonorgestrel-releasing intrauterine system)

BRIEF SUMMARY
CONSULT PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION

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

- AINDICATIONS
  is contraindicated when one or more of the following conditions exist:
- Pregnancy or suspicion of pregnancy.
   Congenital or acquired uterine anomaly including fibroids if they distort the
- Le conjenian la acquient uterine arionary inducing injunious in largification the uterine cavity inflammatory disease or a history of pelvis inflammatory disease united by the largification of the past 3 months.

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  Known or suspected uterine or central neoplasia or unresolved, abnormal Pap smear.

  Senital baceling of unknown ethology.

  Intracted acute cervicitis or vaginitis, including bacterial vaginosis or other lower genital tract infections is controlled.

  Acute liver disease or liver tumor (benign or malignant).

  Occiditions associated with increased susceptibility to pelvic infections.

  A previously inserted IUD that has not been removed.

  Hypersensitivity to any component of this product.

1. Ectopic Pregnancy
Evaluate women who become pregnant while using Mirena for ectopic pregnancy. Up
to half of pregnancies that occur with Mirena in place are ectopic. The incidence of
ectopic pregnancy in clinical trials that excluded women with risk factors for ectopic
pregnancy was about 1 ectopic pregnancy per 1000 users per year.
Tell women who choose Mirena about the risks of ectopic pregnancy, including the loss
of fertility. Teach them to recognize and report to their physician promptly any symptoms
of ectopic pregnancy. Women with a previous history of ectopic pregnancy, tubal
surgery or pelvic infection carry a higher risk of ectopic pregnancy. The risk of ectopic pregnancy and use
Mirena is unknown. Clinical trials of Mirena excluded women with a history of ectopic
pregnancy.

- Septic abortion In patients becoming pregnant with an IUD in place, septic abortion—with septicemia septic shock, and death—may occur. Continuation of pregnancy
- ptic shock, and death—may occur. intinuation of pregnancy intinuation of pregnancy in woman becomes pregnant with Mirena in place and if Mirena cannot be removed woman chooses not to have it removed, she should be warned that failure to remove rena increases the risk of miscarriage, sepsis, premature labor and premature livery. She should be followed closely and advised to report immediately any flu-like interpretations, fever, chills, cramping, pain, bleeding, vaginal discharge or leakage of fluid. Incatem affects and congenital acompalies.
- elevery. She should be followed closely and advised to report immediately any flu-tiles symptoms, fever, chills, cramping, pain, bleeding, seginal discharge or leakage of fluid. Long-term effects and congenital anomalies. When pregnancy continues with Mirena in place, long-term effects on the offspring are unknown. As of September 2006, 390 line births out of an estimated 9.9 million are unknown. As of September 2006, 390 line births out of an estimated 9.9 million for the continues of the cont

- 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 infrequently can necessitate hysterectormy, or 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 tendermess, dyspareunia, chilis, and fever.

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, Guidelines for PID treatment are available from the Centlers for Disease Control (CDC), Atlanta, Georgia. Actionnycosis has been associated with IUDs. Symptomatic women with IUDs should have the IUD removed and should receive antibiotics. However, the management of the asymptomatic carrier is controversial because actinomyceles can be found normally in the genital tract cultures in healthy women without IUDs. False positive findings of actionnycosis on Pap Smears can be a problem. When possible, confirm the Pap smear diagnosis with cultures.

findings of actinomycousts on ray series as the ready series of the Pap series diagnosis with cultures.

5. Irregular Bleeding and Amenorrhea Mirera can after the bleeding pattern and result in spotting, irregular bleeding, heavy bleeding, oligomenorrhea and amenorrhea. During the first three to six months of Mirera can also the formation of bleeding and spotting days may be irregular. Thereafter the number of bleeding and spotting days usually decreases but bleeding may remain irregular. Thereafter the number of bleeding and spotting days usually decreases but bleeding may remain irregular. The bleeding irregularies develop during prolonged treatment, appropriate diagnostic measures should be taken to rule out endometrial pathology. Amenorrhea develops in approximately 20% of Mirena users by one year. The possibility of regnancy should be considered if menstruation does not occur within six veeks of the onset of previous menstruation. Once pregnancy has been excluded, repeated pregnancy estad and previous menstruation of the province of

Expulsion rial or complete expulsion of Mirena may occur (see PRECAUTIONS, Continuation of Removal).

7 days of a menstrual perion airus preginating massionem.

9. Ovarian Cysts
Since the contraceptive effect of Mirena is mainly due to its local effect, outlatory cycles with follicular rupture usually occur in women of fertile age using Mirena. Sometimes aires did the follicle is delayed and the follicle may continue to grove. Enlarged follicles have been diagnosed in about 12% of the subjects using Mirena. Whost of these follicles are asymptomatic, although some may be accompanied by pelvic pain or dyspereuria. In most cases the enlarged follicles disappear sportaneously during two to three months observation. Persistent enlarged follicles should be evaluated. Surgical intervention is not usually required.

O. Breast Cancer (Owner) have or have had breast cancer, or have a suspicion of reast cancer, should not use hormonal contraception because breast cancer is a ormone-sensitive tumor, pontaneous reports of breast cancer have been received during postmarketing operance with Mirena. Because spontaneous reports are voluntary and from a population furnoration size, it is not possible to use post-marketing data to reliably estimate the equory or establish causal relationship to drug exposure. I wo observational studies are not provided evidence of an increased risk of breast cancer during the use of Mirena.

Table 1: Annual Number of Birth-Related or Method-Related Deaths Associated with Control of Fertility per 100,000 Nonsterile Women, by Fertility Control Method

AGE GROUP						
METHODS	15–19 years	20-24 years	25–29 years	30–34 years	35–39 years	40-44 years
No Birth Control Method/Term	4.7	5.4	4.8	6.3	11.7	20.6
No Birth Control Method/Abortion	2.1	2.0	1.6	1.9	2.8	5.3
IUD Periodic Abstinence Withdrawal Condom Diaphragm/Cap Spornge Spermicides Oral Contraceptives Implants/Injectables Tubal Sterilization Vasectomy	0.2 1.4 0.9 0.6 0.6 0.8 1.6 0.8 0.2 1.3	0.3 1.3 1.7 1.2 1.1 1.5 1.9 1.3 0.6 1.2 0.1	0.2 0.7 0.9 0.6 0.6 0.8 1.4 1.1 0.5	0.1 1.0 1.3 0.9 0.9 1.1 1.9 1.8 0.8 1.1	0.3 1.0 0.8 0.5 1.6 2.2 1.5 1.0 0.5 1.2	0.6 1.9 1.5 1.0 3.1 4.1 2.7 1.9 0.6 1.3 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

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

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Careful and objective counseling of the patient prior to insertion regarding the expected bleeding pattern, the possible inter-individual variation in changes in bleeding, including amenornhea, and the etiology of the changes may have an effect on the frequency of patient-requested removal.

patient-requested removal. The patient should be informed that some bleeding such as irregular or prolonged bleeding and spottling, and/or cramps may occur during the first few weeks after insertion. If the symptomic continue or are severe she should report them to her healthcare provider. She should also be given instructions on what other symptoms require her to call her healthcare provider. She should be instructed on how to check after her menstrual period to make certain that the threads still protrude from the cervix and catationed not to pull on the threads and displace Mirrens. She should be informed that there is no contraceptive protection if Mirrens is displaced or expelled.

pull on the threads and displace Mirena. She should be informed that there is no northraceptive protection if Mirena is displaced or expelled. Pather Evaluation and Clinical Considerations.

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).

NOTE: Special attention must be given to ascertaining whether the woman is at increased risk of infection (for example, leukemia, acquired immune deficiency syndrome (AIDS), IV. drug abuse), or has a history of PID unless there has been a subsequent intrauterine pregnancy. Mirena is contraindicated in these women. A physical examination a hould include a pelvic examination, a Pay sprear, examination of the breasts, and appropriate tests for any other forms of genital or other sexually transmitted diseases, such as gonorrhea and chlamydia laboratory evaluations, if indicated. Use of Mirena in patients with vaginitis or cervicitis should be postponed until proper treatment has eradicated the infection and until it has been shown that the cervicitis is not due to gnoorrhea or chlamydia (see CONTRAINDICATIONS). Irregular bleeding may mask symptoms and signs of endometrial polyps or cancer. Because irregular bleeding/sporting is common during the first months of Mirena use, exclude endometrial pathology prior to the insertion of Mirena in women with persistent or uncharacteristic bleeding, if funexplained bleeding irregularities develop during the prolinged use of Mirena, appropriate diagnostic measures should be taken. (See WARNINGS, Irregular Bleeding and Amenormea.).

The healthcare 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? Agas of the onset of a menstrual period. Mirena can be regleding and Amenormea.).

Mirena should not be inserted until 6 weeks possipartum or until invol

expuison. Introducins substantiany dealyed, consider warting until 12 weeks postpartum (see WARNINGS, Perforation).

Patients with certain types of valvular or congenital heart disease and surgically constructed systemic-plumorary shurts are at increased risk of infective endocarditis. Use of Mirena in these patients may represent a potential source of septic emboli. Patients with known congenital heart disease who may be at increased risk should be treated with appropriate artibiotics at the time of insertion and removal. Patients requiring chronic corticosteroid therapy or insulin for diabetes should be monitored with special care for infection. Mirena should be used with caution in patients who have:

• coagulopathy or are receiving anticoagulants:

• mitgraine, focal mitgraine with asymmetrical visual loss or other symptoms indicating transient cerebral schemia

• exceptionally severe headache

• marked increase of blood pressure

• severe arterial disease such as stroke or myocardial infarction Insertion Precauditions

b. Carefully sound the uterus prior to Mirena insertion to determine the degree of patency of the endocervical canal and the internal os, and the direction and depth of the uterine cavity. In occasional cases, severe cervical stenois may be encountered. Do not use excessive force to overcome this resistance.
 c. Fundal positioning of Mirena is important to prevent expulsion and maximize efficacy. Therefore, follow the instructions for the insertion carefully.
 d. If the patient develops decreased pulse, perspiration, or pallor, have her remain supine until these signs resolve. Insertion may be associated with some pain and/or bleeding. Syncope, bradycardia, or other neurovascular episodes may occur during insertion of Mirena, especially in patients with a predisposition to these conditions or cervical stenoiss.

4. Continuation and Removal

these conditions or cervical stenoiss.

Continuation and Removal

Reexamine and evaluate patients 4 to 12 weeks after insertion and once a year thereafter, or more frequently if clinically indicated.

If the threads are not visible, they may have retracted into the uterus or broken, or Mirena may have broken, perforated the uterus, or been expelled (see WARNINGS, Perforation and Expulsion). If the length of the threads has changed from the length at time of insertion, the system may have become displaced. Pregnancy must be excluded and the location of Mirena verified, for example, by sonography, X-ray, or by gentle exploration of the uterine cavity with a probe. If Mirena is displaced, enrowe it A new Mirena may be inserted at that time or during the next menses if it is certain that conception has not occurred. If Mirena is in place with no evidence of perforation, no intervention is indicated.

Promptly examine users with complaints of pain, odorous discharge, unexplained bleeding (see WARNINGS, Irregular Bleeding and Amenorrhea), fever, gental lessions or sores.

- pregnaricy and of the lack of data on long-term effects on the offspring of women who have had Mirren in place during conception or gestation (see WARNINGS, Intrauterine Pregnancy).

  If possible, Mirren 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 Mirrena is left in place, the patient's course should be followed closely.

  Should the patient's relationship cases 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 lose to the critication 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:

   memorrhagia and/or metorrhagia producing amemia

   acquired immune deficiency syndrome (AIDS)

   sexually transmitted disease

   pelvo infection; entometritis

   pelvo infection; entometritis

   severe dyspareunia

   pregnancy

   undometrial 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 schemia

   exceptionally severe headache

   jaundice

   marked increase of blood pressure

   severe arterial disease such as stroke or myocardial infarction

  Removal may be associated with pain and/or bleeding or neurovascular episodes.

   Glucose Tolerance

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

   Drug Interactions

should be monitored in quadeling users of similar than the monitored in quadeling the monitored in the contraceptive efficacy of Mirena has not been studied. The metabolism of progestogens may be increased by concomitant use of substances known to induce drug-metabolizing liver enzymes, specifically cytochrome P450 enzymes.

8. Pregnancy
Pregnancy Category X (see WARNINGS).

Programy Security Access Profundors,

9. Nursing Mothers
In general, no adverse effects have been found on breastfeeding performance or on the health, growth, or development of the infant. However, isolated post-marketing cases of decreased milk production have been reported. Small amounts of progestins pass into the breast milk of nursing mothers, resulting in detectable steroid levels in infant plasma. Also, see WARNINGS, Perforation.

10. Pediatric Use
Safety and efficacy of Mirena have been established in women of reproductive age. Use of this product before menarche is not indicated.

11. Geriatric Use
Mirena has not been studied in women over age 65 and is not currently approved for

12. Return to Fertility
About 80% of women wishing to become pregnant conceived within 12 months after

abooffinial usersions, wave con-Postmarketing Experience
The following adverse reactions have been identified during post approval use of Mirena:
device brakage 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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