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INSIDE

Inserted in this issue:
— Information and enrollment form for the Vasectomy Information Line
— 2001 Salary Survey

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Estrogen and ovarian cancer linked? Get perspective on new research

Stay the course with current standard of care, experts advise

It's a familiar scenario: News stories give a quick sound bite linking estrogen use with increased risk for ovarian cancer, and calls pour into clinicians' offices from worried women who are using some form of hormone replacement therapy (HRT) for menopausal symptoms. What do you tell your patients?

"Neither the Rodriguez study[1] nor our work brings with it the need to change the current standard of care," states **James Lacey Jr.**, MPH, PhD, an epidemiologist in the Division of Cancer Epidemiology and Genetics at the National Cancer Institute in Rockville, MD, who is researching the possible link between ovarian cancer and HRT. "Women should be encouraged to discuss all of the potential risks and benefits of HRT with their health care providers before making an individual decision about whether to use HRT."

Initial concerns were raised with the recent release of research from the Cancer Prevention Study II. The study, coordinated by the American Cancer Society (ACS) in Atlanta, recruited 1.2 million people in 1982 and followed them through 1996. Researchers periodically obtained information from death certificates and tabulated cancer deaths among the participants.

EXECUTIVE SUMMARY

While recent research indicates a possible link between hormone replacement therapy (HRT) and increased risk of ovarian cancer, there is no indication to change current medical practice regarding use of the drug therapy.

- While a just-published study from the American Cancer Society indicates a possible link between HRT and ovarian cancer, the overall risk for the disease is small.
- The researchers did not identify the dose of estrogen used by women in the study. Current therapy generally involves a lower dose of estrogen, combined with the hormone progestin, than the women in the study are estimated to have used.

The paper has just been published in the *Journal of the American Medical Association* by **Carmen Rodriguez**, MD, MPH, senior epidemiologist in the Epidemiology and Surveillance Research division of the ACS, and colleagues at the society. The report looked at 211,581 postmenopausal women who completed a baseline questionnaire in 1982 and had no history of cancer, hysterectomy, or ovarian surgery at enrollment. The main outcome measure was ovarian cancer mortality, compared among never-users, users at baseline, and former users as well as by total years of use of estrogen replacement therapy (ERT).

A total of 944 ovarian cancer deaths were recorded in 14 years of follow-up. Among the 46,260 women who in 1982 reported having taken estrogen at some point, 255 women had died of ovarian cancer by 1996, compared with 689 of 165,321 nonestrogen-takers also in the study.

Duration of use was associated with increased risk in baseline and former users, according to the researchers' analysis. Baseline users with 10 or more years of use had a relative risk of 2.20 (95% confidence interval, 1.53-3.17), while former users with 10 or more years of use had a relative risk of 1.59 (95% confidence interval, 1.13-2.25). Scientists concluded that among this study population, postmenopausal estrogen use for 10 or more years was associated with increased risk of ovarian cancer mortality that persisted up to 29 years after cessation of use.

Research eyes HRT link

Look for further evidence to come from the Rockville, MD-based National Cancer Institute, which also is reviewing data on the use of combined hormonal therapy and the risk of ovarian cancer.

"Our findings are generally consistent with the Rodriguez, et al. paper [that] reported that long-term use of estrogen replacement therapy was significantly associated with an increased risk of death due to ovarian cancer," states Lacey, who presented preliminary findings at the recent American Association for Cancer Research conference in New Orleans.[2] "Our data suggested that long-term use of estrogen replacement therapy was significantly associated with an increased risk of incident ovarian cancer; however, our data also suggest that use of the combined estrogen-progestin replacement therapy [an issue that was not addressed in the Rodriguez et al. paper] was not associated with ovarian cancer incidence, although we cannot rule out a slight increase in risk associated with the combined estrogen-progestin therapy."

More research is needed on the complex relationships between menopausal estrogens, menopausal progestins, and ovarian cancer, states Lacey.

It is important to understand the differences in current medical practice and those observed during the time of the ACS study's data collection, says Rodriguez. Today, women who have uterus and ovaries intact use combined HRT with estrogen and progestin. In the 1970s and 1980s, HRT consisted of administration of conjugated estrogens in high dosages and without added progestins.

The ACS study also did not examine the dose of hormones used, says **David Archer**, MD, professor of obstetrics and gynecology and director of the Clinical Research Center at the Eastern Virginia Medical School in Norfolk. Current therapy generally employs a lower dose of estrogen.

According to the ACS, about 23,100 new cases

Possible Symptoms of Ovarian Cancer

- Swelling of the abdomen
- Problems such as gas, bloating, long-term stomach pain, or indigestion
- Bleeding between periods or after menopause
- Pelvic pain
- Feeling of pressure in the pelvis
- Leg pain

Source: American Cancer Society, Atlanta.

COMING IN FUTURE MONTHS

- Check new incentives for STD testing
- Medical abortion: Progress report
- Tips on reaching Hispanic teens
- Dispel common myths about the Pill
- Use the web for family planning education

of ovarian cancer were estimated to occur in the United States in 2000, which makes it the sixth most common cancer in women.

"The risk of ovarian cancer, the baseline risk, is very low," remarks Rodriguez. "So even if it doubles, we don't get into a very high likelihood of having the disease."

Susan Wysocki, RNC, NP, president and CEO of the Washington, DC-based National Association of Nurse Practitioners in Women's Health, agrees that the risk is low. Along with that point, keep the following three in mind, she suggests:

- Even when the risk is increased, the risk remains low.
- The ACS study looked at regimens of HRT that are no longer used today.
- No change in prescribing has been recommended as a result of the research.

Some patients may express concern about use of combined oral contraceptives (OCs) because they also contain estrogen, states **Robert Hatcher**, MD, MPH, professor of gynecology and obstetrics at Emory University School of Medicine in Atlanta. Remind them that OCs make women less likely to develop ovarian cancer.

"In no way does this study suggest that our current advice to women initiating use of combined oral contraceptives is incorrect, when we say that combined pills have a dramatic protective effect against ovarian cancer," states Hatcher.

Be aware of symptoms

Even though the risk for ovarian cancer is low, it is still important for women and clinicians to be aware of its signs and symptoms, clinicians warn.

Early cancers of the ovary often have no symptoms. Since tumors on the ovary cannot usually be found through a Pap test, only one-fourth of ovarian cancers is found at an early stage, state ACS statistics.

"For ovarian cancer, there's not a screening [modality] right now," observes Rodriguez. "People have to be very aware of the symptoms, and it can be a very silent kind of disease."

Teach patients about the possible symptoms. **(See symptoms, p. 62.)** While they often may be caused by other disorders than cancer, it is wise to have them checked out by a health care provider.

Imaging studies, such as computed tomography, magnetic resonance imaging scans, and ultrasound can show whether there is a mass in the pelvis. However, a biopsy must be performed to confirm if the mass contains cancerous cells.

SOURCES

For more information on hormone replacement therapy and ovarian cancer risk, contact:

- **Carmen Rodriguez**, MD, MPH, American Cancer Society, Epidemiology and Surveillance Research Division, 1599 Clifton Road N.E., Atlanta, GA 30329.
- **David Archer**, MD, Clinical Research Center, Eastern Virginia Medical School, Norfolk, VA. E-mail: archerdf@evms.edu.
- **Susan Wysocki**, RNC, NP, National Association of Nurse Practitioners in Women's Health, 503 Capitol Court N.E., Suite 300, Washington, DC 20002. E-mail: NPWHDC@aol.com.

The ACS researchers now are looking at a smaller group of the Cancer Prevention Study II women, those who used a combination of estrogen and progestin for HRT. The data will be examined to see if combination HRT increases the risk for ovarian cancer, as well as if the risk increased for those women who switched from estrogen-only to a combination HRT regimen, says Rodriguez.

Effect on breast cancer?

The scientists also are reviewing the impact of estrogen and combination therapy, as well as the effect of body mass, on the risk for breast cancer, states Rodriguez. The group already released results on the effect of body mass on the association between ERT and mortality among postmenopausal women, in which an analysis examined the association between postmenopausal estrogen use and different causes of death.[3] After 12 years of follow-up, analysis results reveal that all-cause death rates were lower among baseline estrogen users than never-users.

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2. Lacey JV. Ovarian cancer and hormone replacement therapy in a prospective cohort study. Presented at the American Association for Cancer Research. New Orleans; March 25, 2001.
3. Rodriguez C, Calle EE, Patel AV, et al. Effect of body mass on the association between estrogen replacement therapy and mortality among elderly U.S. women. *Am J Epidemiol* 2001; 153:145-152. ■

Norplant implant deemed safe, effective

No news available on suspect lots

While a post-marketing study of the Norplant contraceptive adds to the body of positive evidence on its use, American providers continue to wait for results of product stability tests for suspect lots of the implant.

The just-released post-marketing surveillance marks the first of three publications from the large-scale international investigation.[1] Researchers used controlled cohort methodology to compare the experiences of women using Norplant against those who chose two other forms of long-term birth control: the intrauterine device (IUD) and surgical sterilization. The study confirms the safety with respect to serious disease and the high contraceptive efficacy of Norplant, copper IUD, and sterilization.

While the post-marketing surveillance gives providers further understanding of the use of the contraceptive implant in international settings, American family planners look to product stability tests from Wyeth-Ayerst Pharmaceuticals of Philadelphia on certain suspect lots of the product.

The company issued an advisory in August 2000 which alerted providers that routine shelf-life stability laboratory tests indicated product from certain specified lots might not release enough levonorgestrel to deliver effective, ongoing contraception. **(See *Contraceptive Technology Update* October 2000, p. 117, and November 2000, p. 129, for complete information on the suspect lots.)** Some 22,000 kits were contained in the suspect lots, according to company estimates.

Wyeth continues to conduct additional testing and analysis of the lots in question and has submitted results of these analyses to the Food and Drug Administration (FDA), reports **Audrey Ashby**, company spokeswoman.

"We are working with the FDA to evaluate this information and are making every effort to provide additional information about the contraceptive efficacy of Norplant from the specified lots," says Ashby. "Women who began using Norplant before Oct. 20, 1999, are not affected, and the Norplant System remains an effective long-term contraceptive."

EXECUTIVE SUMMARY

Post-marketing surveillance on the Norplant contraceptive implants adds to the body of evidence confirming the safety and effectiveness of the method.

- There have been no other large-scale studies of Norplant with a parallel, comparable control group of women using nonhormonal methods.
- American providers continue to wait for results of shelf-life stability laboratory tests of certain suspect lots of Norplant implants.

Look at the study

The post-marketing surveillance is unique since there have been no other large-scale studies of Norplant with a parallel, comparable control group of women using nonhormonal methods, explains **Tim Farley**, PhD, co-author of the study and a scientist in epidemiology and evaluation in the Geneva-based World Health Organization's Special Programme of Research, Development, and Research Training in Human Reproduction, Department of Reproductive Health and Research.

"This allows us to compare the effectiveness and safety of the method and to assess the incidence of minor side effects with the incidence among women using nonhormonal methods of contraception," he notes.

Altogether, 7,977 women initiated Norplant, with 6,625 choosing the IUD, and 1,419 selecting sterilization. A total of 32 family planning clinics in eight developing countries participated in the research. Participants were interviewed and examined at semiannual visits and followed for five years, regardless of change of contraceptive methods. Incidence rate ratios of health events were estimated for initial and current method use.

The overall follow-up rate was 94.6%, with 78,323 woman-years of observation accumulated. Pregnancy rates for Norplant, copper IUD, and sterilization each averaged less than one per 100 woman-years, further evidence of the long-term effectiveness of the three methods.

With two exceptions, no significant excess risk of serious morbidity was detected for Norplant users compared with controls, the study reveals. The incidence of gallbladder disease was higher in women who initiated Norplant use than in controls, as was the incidence of hypertension and borderline hypertension in current implant users.

It is difficult to know what to add about the

SOURCE

For more information on the Norplant post-marketing surveillance research, contact:
- **Irving Sivin**, Center for Biomedical Research, The Population Council, 1230 York Ave., New York, NY 10021.

reported higher incidence of hypertension/borderline hypertension in the Norplant users compared with the control women, Farley says. Such a finding has not been reported previously for Norplant users; however, assessment of blood pressure was more frequent among the Norplant users compared with the women in the control group, he states.

"If the observed increased incidence is true and of the actual magnitude observed, it would theoretically result in one more case of hypertension per annum in 3,000 Norplant users than in a similar number of IUD users," says Farley.

Further examination of the comparative data between the Norplant and IUD groups might yield more information, says **Irving Sivin**, study co-author and senior scientist with The Population Council in New York City. Implants were removed at the end of five years, but many women retained their IUD, and that practice might have resulted in the elevated blood pressure readings, he hypothesizes.

Look for more information to come from the post-marketing surveillance, says Farley. The current paper serves as a summary of key findings; two papers that provide extensive details on contraceptive efficacy and reproductive health, and another on nonreproductive health, are in press with the journal *Contraception*, he reports.

Reference

1. Meirik O, Farley TM, Sivin I. Safety and efficacy of levonorgestrel implant, intrauterine device, and sterilization. *Obstet Gynecol* 2001; 97:539-547. ■

Program seeks to expand vasectomy service

For counties in Florida that offer vasectomies funded through federal Title X family planning monies, there is access to male sterilization for low-income men. But what happens for those men who live in counties that have not established such services and cannot afford to pay for private care?

Enter the Clearwater-based Vasectomy Support Foundation Inc. (VSF), a not-for-profit organization that promotes and helps pay for vasectomy services for qualified-income level men who desire such services, are content with the number of children that they have, and possess no medical coverage through Title X, Medicaid, or private insurance funds.

EXECUTIVE SUMMARY

Many men might be interested in vasectomy as means of permanent contraception, but they might not have access to publicly funded vasectomies.
- In Florida, a foundation promotes and helps pay for vasectomies for qualified-income level men who are content with the number of children they have and possess no medical insurance.
- The nonprofit organization demonstrates the need for local publicly funded vasectomies and provides information through a telephone service and Internet site.

The foundation is the brainchild of Tampa urologist **Douglas Stein**, MD, who has been active in providing vasectomies through contracts with area county health departments and Planned Parenthood clinics since 1996, as well as through his own private practice.

Stein is an advocate of the no-scalpel vasectomy (NSV) technique, which was pioneered in the United States in 1988 by New York City-based AVSC International (now EngenderHealth). Developed by Chinese surgeon Li Shunqiang, the NSV technique is less invasive, less painful, heals more quickly, and has fewer complications than the traditional vasectomy procedure. **(To learn more about NSV, check out *Contraceptive Technology Update*, May 2000, p. 56.)** Stein underwent AVSC's NSV training in 1990 and quickly incorporated the procedure into his practice.

Raising public awareness

Stein sees the foundation as a way to move vasectomy out of its current "Catch-22" situation. He explains it in this manner:

In Florida, each county may or may not have a contract with a provider for vasectomy services. These services can be provided in the provider's

office or in the county health department facility. The vasectomies are paid for by federal Title X funds, which are administered through the state to individual counties, which then make payment to the provider. **(Some counties might have in-house providers trained through AVSC's program. See *CTU,* March 1998, p. 29.)**

Public assistance isn't well known

What happens when there are no publicly funded vasectomy programs? Because men are unaware that there might be public assistance for vasectomy services, they don't ask for them, says Stein. Since there appears to be no public demand, health departments do not establish vasectomy services with Title X funding. Men then have to resort to contacting private providers, and many stumble at the barrier of private-pay charges.

"I've heard a hundred times, 'Doc, I've called around, and one guy wanted $600, one guy wanted $800, and I can't afford that kind of money,'" Stein observes. "When I say, 'Do you know you could get it through the county?' they say, "That would be a great idea.'"

Stein began to brainstorm. What if vasectomy services could be offered to all men, regardless of whether they live in a county that provides publicly funded procedures, with a nonprofit organization paying the costs? The nonprofit organization would not only underwrite the vasectomy services, but would demonstrate the need for establishing local publicly funded vasectomy services.

The VSF was founded in 2000 with the following goals:

- Educate the public about the ease and advantages of vasectomy as long-term contraception for those couples whose families are complete.
- Educate referral sources, such as health departments, Planned Parenthood clinics, and private health care offices, about government-funded and VSF supplemental programs through personal visits, direct mailings, and brochures.
- Educate vasectomy services providers (primarily urologists) as to how they may become registered VSF providers.

The VSF has established a web site, www.vasectomysupport.com, to serve as an information clearinghouse for information about low-income vasectomy funding throughout the Florida region.

Advertisements are run in local large-circulation weekly newspapers. While their format might differ, the message remains the same: no scalpel, nothing removed, 15 minutes, and $0-$290, depending on income. The ads and the $290 price do much to pull in clients, says **Cynthia Street**, RN, MS, senior community health nursing supervisor at the Pasco County Health Department, New Port Richey clinic. The health department contracts with Stein to deliver its Title X vasectomy services.

The department previously contracted with another urologist who performed hospital-based vasectomies, says Street. With the NSV technique, men can come directly to the clinic in the morning and be out by noon. A mail-in process verifies the sperm count, which eliminates the need for a return visit. Street reports the clinic is seeing a broad cross-section of the population, who cite the convenience and price as motivation for making the family planning decision.

Vasectomy seems to be not only dependable, but a simple, long-term arrangement for many men, says Stein.

"We're not trying to tell people how many kids they should have. We're only trying to say that vasectomy is a good option, if you feel comfortable with the number of children you already have," states Stein. "Finances should be no barrier." ■

SOURCE

For more information on the Vasectomy Support Foundation, contact:

- **Douglas Stein**, MD, Vasectomy Support Foundation Inc., P.O. Box 3851, Clearwater, FL 33767-8851. Telephone: (727) 827-4636. E-mail: douglas_stein@vasectomysupport.com.

Add public sites to national hotline

As reported in the May 2001 issue of *Contraceptive Technology Update*, New York City-based EngenderHealth (formerly AVSC International) has established a national toll-free Vasectomy Information Line, (888) VASEC-4-U [827-3248]. This first-of-its-kind information line not only provides the caller with information about vasectomy and answers to frequently asked questions, but it also automatically links the caller to the nearest vasectomy service.

Now EngenderHealth is expanding the line to include public sector sites across the country that

provide vasectomy services, says **Daria Teutonico**, program manager at EngenderHealth. There is no charge for this service; EngenderHealth will cover the costs of adding new sites to the line and all costs associated with use of the toll-free line, she says.

"The only request is that the person who is responsible for answering the phone at the facility, to which the 1-888 line is forwarded, is aware of the vasectomy services or knows to whom to refer such calls," says Teutonico.

(Editor's note: See the enclosed insert in this issue for more information on the Vasectomy Information Line, and use the enclosed form to sign up your clinic for a free listing.) ■

EC on the Internet: Programs go on-line

Two innovative Planned Parenthood affiliates are pushing past their brick-and-mortar clinic walls into the virtual reality of cyberspace by offering on-line medical assessments for emergency contraceptive pill (ECP) prescriptions.

"We think on-line prescribing provides a very unique opportunity to provide access to women with a very unique medication, and that is emergency contraception," says **Steve Trombley**, president and CEO of Planned Parenthood — Chicago Area. "Given that emergency contraception has no contraindications that would prevent it from being prescribed, it is uniquely suited to being delivered on-line."

Women are quickly finding out about the Emergency Contraception EC4U service, which just went on-line in late 2000, says Trombley. With no formal marketing, the program already has written more than 300 prescriptions, he reports. **(The service is available on the Planned Parenthood — Chicago Area's web site, www.ppca.org, as well as www.EC4U.org.)**

A comprehensive marketing program was set to kick off as of *Contraceptive Technology Update*'s press time, and Trombley says he expects the program will write 300 prescriptions per month when the campaign swings into gear.

Planned Parenthood of Georgia in Atlanta expanded its EC Connection toll-free prescribing hotline to include on-line medical assessments about a year ago, says **Kay Scott**, the affiliate's president and CEO. **(Editor's note: Access the web site through www.ecconnection.org or Planned Parenthood of Georgia's site, www.ppga.org.)**The program recently was recognized for its success at the Planned Parenthood Federation of America (PPFA) leadership conference held in Dallas. **(The EC Connection toll-free telephone program was highlighted in *CTU*, June 1999, p. 64.)**

The Georgia program continues to offer access to ECPs through its toll-free telephone connection, says Scott. However, because most of the women who want EC can access a computer, more requests are coming from the Web site. About three-fourths of the requests for the EC Connection come over the Internet, she estimates.

Get information on-line

Due to state prescribing laws, both the Georgia and Chicago Area EC programs are available only to their respective state's residents. Both programs charge $40, payable by credit card, for the medical assessment. Cost of the prescriptions, which are filled at local pharmacies or picked up at Planned Parenthood clinics, are separate.

To request ECPs through the Georgia program, women must first read an on-line consent form and an instruction sheet. The information subsequently is electronically transmitted to a Planned Parenthood nurse practitioner. Once the information is received, a Planned Parenthood employee makes telephone contact with the patient to review it, and a prescription is called into the patient's preferred pharmacy, or if she desires, may be picked up at a local Planned Parenthood clinic. The Georgia EC Center operates from Monday to Friday, 8 a.m. to 4:30 p.m.; Saturday, 9 a.m. to 12:30 p.m.; and Sunday, 1-4:30 p.m. If requests are

EXECUTIVE SUMMARY

Women in Georgia and Illinois can obtain on-line medical assessments for emergency contraceptive pill (ECP) prescriptions, thanks to innovative programs by two Planned Parenthood affiliates.

- The on-line assessments break down the geographic barriers often faced by women who don't have ready access to ECP providers' offices. Once the assessments are reviewed, Planned Parenthood providers call in prescriptions to women's chosen pharmacies.
- Cost of the medical assessment is $40 for each program and are payable by credit card. Prescription costs are separate.

RESOURCES

- For more information on the Planned Parenthood — Chicago Area EC4U program, contact its director, Chris Williams, at chrisw@ppca.org.
- For more information on the Planned Parenthood of Georgia EC Connection program, contact its vice president for marketing and communication, Leola Reis, at l.reis@mindspring.com.

submitted on-line when the center is closed, with patients' permission, someone will contact them as soon as possible the following day.

"What is frustrating about our 1-800 service is that it is about a 20-minute phone conversation where you go through a medical history form," says Scott. "We decided that writing a program and offering an option on-line would save the frustration and probably get so much better information."

The Chicago Area's EC4U program is similar to the Georgia program; however, it does not entail a separate telephone call from the program. Women review EC information, give consent, and submit a short medical assessment online. The information is reviewed by a health care professional, who sends an e-mail confirmation when the prescription is ready. Instructions are included on how to take EC, as well as information about long-term birth control methods.

The EC4U service hours are Monday, 9 a.m. to 5 p.m.; Tuesday, 8:30 a.m. to 4 p.m.; Wednesday, 10:30 a.m. to 6 p.m.; Thursday 10 a.m. to 5:30 p.m.; Friday 8:30 a.m. to 1:30 p.m.; and Saturday, 9:30 a.m. to 1:30 p.m. On-line assessments submitted outside of the operating hours listed do not receive a prescription confirmation until the following morning; if an assessment is submitted after operating hours on Saturday, confirmation is not transmitted until Monday morning.

Planned Parenthood — Chicago Area has budgeted about $200,000 for its comprehensive marketing program for the EC4U program, says Trombley. The first phase kicks off with an advertising component, placing posters and wallet-sized pamphlets in women's bathrooms in more than 150 Chicago bars and nightclubs. The eye-catching posters feature illustrations of a sperm and a computer mouse, dubbed "Sammy the Sperm" and "Mack the Mouse," with the caption, "The Race is On." The pamphlets give details about emergency contraception and the EC4U service.

An e-mail campaign will follow, which will allow targeted recipients to get information about the program, as well as pass it along to their friends. Planned Parenthood — Chicago Area also will be working with college sororities and campus women's groups to promote events around emergency contraception.

The campaign will wrap up in the fall of 2001 with a large-scale event featuring Drew Pinsky, MD, from the MTV *Loveline* television program. The affair will be co-hosted by a local radio station, which is offering information about the EC4U program on its own web site.

"Our agency and our board of directors are 100% behind making emergency contraception more available to our clients, the women who need it," says Trombley. "We think this is the most cost-effective way to do it." ■

The IUD and PID: What are the risks?

With the addition of the Mirena intrauterine system (IUS) [Berlex Laboratories, Montville, NJ] on the U.S. market, more women are taking a fresh look at the contraceptive method. What should you know about the intrauterine device (IUD) and the risk of pelvic inflammatory disease (PID) as you discuss the array of available birth control options?

Pelvic inflammatory disease is a broad term

EXECUTIVE SUMMARY

Intrauterine devices (IUD) represent safe, effective, long-term contraception. However, consider the risks of pelvic inflammatory disease (PID) when counseling.

- While IUD users are more likely to develop PID than nonusers, it is uncommon. The greatest risk occurs during the weeks following insertion; strict asepsis at insertion and leaving the IUD in place for its life span can reduce the risk.
- The recommended patient profile includes parous women in stable mutually monogamous relationships with no history of PID. However, nulliparous women at low risk for sexually transmitted diseases might be candidates. Women with a history of PID might be candidates if they are in stable mutually monogamous relationships and have had a pregnancy since the PID episode.

for any infection that ascends from the cervix into the uterus, fallopian tubes, and ovaries.[1] Among American women of reproductive age, one in seven reports having received treatment for PID.[2] Possible complications from the disease include ectopic pregnancy, pelvic abscess, and involuntary infertility.[2]

Epidemiologic research in the 1970s and 1980s tended to overestimate the risk of pelvic infection from IUD use.[1] More recent research indicates that while IUD users are more likely to develop PID than nonusers, it is still an uncommon complication.[1] The greatest risk of PID occurs during the first few weeks following insertion; strict asepsis at insertion and leaving the IUD in place for its life span can reduce the chance of developing PID.[2]

However, the myth persists that IUDs increase the long-term risk of developing PID.[2] The fact is that in properly selected patients, the IUD does not increase PID risk in the long term. The small risk immediately following insertion disappears at about 20 days.[2]

According to *A Pocket Guide to Managing Contraception*, the recommended patient profile for IUD candidacy includes parous women in stable mutually monogamous relationships (at low risk for sexually transmitted diseases) with no history of PID.[3] However, nulliparous women at low risk for sexually transmitted diseases also might be candidates. Women with a history of PID might be candidates if they are in stable mutually monogamous relationships and have had a pregnancy since the PID episode.[3]

Apprehension about PID, especially in areas such as Africa where the sexually transmitted disease (STD) rate might be high, might cause patients, providers, and program managers to avoid IUDs. But what is the actual risk? This question is the basis of a recent review published by **James Shelton**, MD, senior medical scientist at the U.S. Agency for International Development in Washington, DC.[4]

On the basis of the data and possible difficulties presented, fully symptomatic PID attributable to IUD use is quite uncommon, even with high STD prevalence, Shelton concludes. Low STD prevalence favors the use of IUD even more, he states.

Shelton used existing data to calculate the risk of PID. His model of the risk of clinical pelvic inflammatory disease shows that the estimated risk is low (0.15%), even with a high STD prevalence. This estimated risk argues for making the IUDs more available, he states.

SOURCES

For more information on intrauterine devices and pelvic inflammatory disease, contact:

- **James Shelton**, MD, U.S. Agency for International Development. E-mail: JShelton@USAID.gov.
- **Charles Morrison**, PhD, Family Health International. E-mail: cmorrison@fhi.org.

Sexually transmitted diseases are an important contraindication for IUD insertion. Since laboratory testing for STDs might not be possible in some developing countries, researchers are looking at the use of algorithms, a list of simple questions, to assess risk of infections.[5]

Scientists at Family Health International (FHI) in Research Triangle Park, NC, are planning to evaluate the use of risk assessment algorithms, developed to predict STD and subsequent IUD-related complications among IUD candidates, on some existing data sets of family planning populations, says **Charles Morrison**, PhD, senior epidemiologist in FHI's clinical research division.

Morrison and other FHI researchers originally looked at the use of algorithms in examining the safety and complications related to IUD use among HIV-infected women in Kenya.[6] By further researching the algorithms, the scientists hope to develop criteria that, rather than screening out women, will screen in the majority of women for whom there should be no barrier to IUD insertion, states Morrison.

References

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Trojan introduces two new condoms

Encouraging consistent condom use is a daily challenge for family planners. Two new latex condom styles from the makers of Trojan Condoms may help in meeting the needs of certain segments of the patient population.

The Trojan Magnum XL Extra Large and Trojan Extended Pleasure condoms provide solutions to issues facing some sexually active people, says **Dick Kline**, vice president of marketing, Carter Products, a division of manufacturer Carter-Wallace in New York City.

Trojan Magnum XL Extra Large condoms are 30% larger by volume than regular condoms and are sized even larger than original Trojan Magnum condoms. According to company research, an estimated 6% of the male population find currently offered condoms too small and need an extra-large condom, says Kline.

Condom addresses premature ejaculation

The Extended Pleasure condoms also address a special need, states Kline. Almost 30% of men experience premature ejaculation.[1] The Extended Pleasure condoms are the only latex condoms that incorporate a climax control lubricant.

"Use of condoms is the only means by which sexually active individuals can help protect themselves from sexually transmitted diseases," says Kline. "In a continuing effort to encourage increased usage of condoms, the Trojan brand has been a leader in providing new products that will appeal to a greater number of people."

As of *Contraceptive Technology Update* press time, both products were scheduled to reach U.S. market shelves in May. Suggested retail price for a box of 12 Trojan Magnum XL Extra Large condoms is $7.99; a box of 12 Trojan Extended Pleasure condoms is $8.49. To coincide with the May market introduction, consumers can log onto www.trojancondoms.com for more information and to request free samples of the new products.

Advertising for both products will begin in June, states Kline. The successful "Trojan Man" commercials will introduce the new products to consumers. Advertising for Trojan Extended Pleasure condoms will include radio and television commercials, and advertising for Trojan Magnum XL Extra Large condoms will include radio commercials.

Research of other condoms indicates that larger penis circumference and longer penis length can be a risk factor for breakage.[2,3] A larger condom may well translate into less breakage, says **Anita Nelson**, MD, professor in the obstetrics and gynecology department at the University of California in Los Angeles (UCLA) and medical director of the women's health care clinic and nurse practitioner training program at Harbor-UCLA Medical Center in Torrance.

It is important to look at reasons for condom failure. A prospective investigation of men in Mexico, Philippines, and the Dominican Republic showed that those who reported condom failure during the year prior to the study were more likely to experience failures during the study.[4] Counseling can identify persons at increased risk of condom failure who might need more intensive information and attention regarding consistent and correct use. **(Get tips on how to overcome barriers to correct condom use; look at the article and enclosed patient handout in *CTU*, March 1999, p. 31.)**

The new Magnum XL Extra Large condoms are specifically designed to meet the demands of the 6% of men who require an extra large condom. Other men may experience slippage with the Magnum XL Extra Large. As noted in *Contraceptive Technology*, ask clients what does not work about using condoms and offer to help them select a condom most suitable to their needs.[5]

The Trojan Extended Pleasure condoms are the only latex condoms that incorporate a climax control lubricant on a condom. Kline identifies the lubricant as the over-the-counter monographed drug benzocaine. Carter Products has conducted

EXECUTIVE SUMMARY

Men now have more choices in latex condoms, as two new styles from the makers of Trojan Condoms are on drug store shelves. The condoms are manufactured by Carter-Wallace in New York City.

- The Trojan Magnum XL Extra Large condoms are 30% larger by volume than regular condoms and are sized even larger than original Trojan Magnum condoms. According to company research, an estimated 6% of the male population find currently offered condoms too small and need an extra-large condom.
- The Trojan Extended Pleasure condoms are designed for the estimated 30% of men who experience premature ejaculation. The Extended Pleasure condoms are the only latex condoms that incorporate a climax control lubricant.

safety studies of the product, states Kline.

Trojan Extended Pleasure condoms have a reservoir tip for extra safety and are lubricated on the outside for additional sexual comfort.

Until now, an accepted approach to premature ejaculation was for the man to apply anesthetic to the tip of his penis, says Nelson.

"This numbs him out, but it also numbs his partner," explains Nelson. "This [condom] is a local application, which is contained to him."

Many family planners have recommended that men who experience premature ejaculation use a thick, desensitizing condom, says Nelson. Such condoms are getting harder to find due to the current market trend toward super-sensitive, thinner products, she observes.

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CTU UPDATES
News ■ Resources ■ Events

CTU launches web site for readers

As a free service to subscribers of *Contraceptive Technology Update,* we are offering a new web site that will give you access to *OB/GYN Clinical Alert, Contemporary OB/GYN*, and *Physicians' Desk Reference*, among other features.

You can read stories from the current issue of *CTU*, plus have access to back issues of the newsletter and other publications published by American Health Consultants. The site includes several women's health articles from peer-reviewed journals and patient handouts. Participate in our poll by entering your vote. Also, there's a forum where you can respond to readers' questions and comments or post some of your own. There's also links to several valuable web sites,

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Breast-feeding seminar scheduled in July

Breastfeeding for Health: Looking to the Future, Mindful of the Past is the theme for the 29th Annual Seminar for Physicians, to be held July 5-7 in Chicago. The event is cosponsored by the La Leche League International in Schaumburg, IL, the American College of Obstetricians and Gynecologists in Washington, DC, and the American Academy of Pediatrics in Elk Grove Village, IL.

For more information, visit La Leche League International's web site at www.lalecheleague.org, or contact Carol Kolar, RN, CMP, Director of Education, La Leche League International, P.O. Box 4079, Schaumburg IL 60168-4079. Telephone: (847) 519-7730, extension 218. Fax: (847) 519-0035. E-mail: jcina@llli.org. ■

CE objectives

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. (**See "Estrogen and ovarian cancer linked? Get perspective on new research" in this issue.**)
- Describe how those issues affect service delivery and note the benefits or problems created in patient care in the participant's practice area.
- Cite practical solutions to problems and integrate information into daily practices, according to advice from nationally recognized family planning experts. **(See "The IUD and PID: What are the risks?" and "Trojan introduces two new condoms.")** ■

This continuing education offering is sponsored by American Health Consultants® (AHC), which is accredited as a provider of continuing education in nursing by the American Nurses Credentialing Center's Commission on Accreditation. American Health Consultants® is an approved provider by the California Board of Registered Nursing for approximately 18 contact hours (provider #CEP10864).

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NATIONAL ASSOCIATION NPWH National Association of Nurse Practitioners in Women's Health

A • R • H • P
Association of Reproductive Health Professionals

EngenderHealth's Vasectomy Information Line
1-888-VASEC-4-U

What is the Vasectomy Information Line?

The Vasectomy Information Line is a nationwide toll-free service (1-888-VASEC-4-U) which enables men and women to access pre-recorded information about vasectomy and be automatically connected to the public-sector site (health department clinic, Planned Parenthood affiliate, hospital, community health center) that provides subsidized vasectomy services in their community. The Vasectomy Information Line is confidential, fully automated, and available 24 hours a day in English and Spanish.

What Information Does the Vasectomy Information Line Provide?

Callers to the Vasectomy Information Line are provided with the following information:

- A description of vasectomy
- A rationale for when a vasectomy may make sense for a man and his partner
- Answers to frequently asked questions about vasectomy
- The option to be automatically connected to a public health facility that provides vasectomy

Why has EngenderHealth established this Vasectomy Information Line?

More than half a million men each year undergo vasectomy in the United States. Most of these vasectomies are provided by private physicians and are covered by insurance. Nearly 16,000 private physicians in the United States provide vasectomy. But only 1,600 or 23% of the nation's public-sector sites (health departments, Planned Parenthood affiliates, hospitals, community health centers) provide vasectomy. And although vasectomy is usually covered by 85%-90% of all insurance policies, only 2% of public family planning funds (i.e., funds provided by Title X of the Public Health Service Act or Medicaid) are spent on men. Therefore, vasectomy is often not readily accessible to men who do not have private health insurance.

For the past six years, EngenderHealth has been addressing the poor availability of vasectomy services in the public sector. Through the provision of clinical and counseling training on vasectomy and through extensive social marketing efforts, EngenderHealth has been increasing access to and awareness of low-cost vasectomy services for men and women. As part of this project, EngenderHealth established the Vasectomy Information Line, 1-888-VASEC-4-U.

How Can My Facility Become Part of the Vasectomy Information Line?

If you would like to add your public sector facility to the Vasectomy Information Line, please complete the form on the back.

Sign-up Form for EngenderHealth's Vasectomy Information Line 1-888-VASEC-4-U

Please notify everyone on your staff *(especially those who answer the telephone)* that you provide vasectomy services and that you will be listed on the Vasectomy Information Line.

Facility Information

Facility Name _____

Street Address: _____

_____

City, State, Zip: _____

Telephone number at the facility to which callers to 1-888-VASEC-4-U line will be connected:

_____

Contact information for person supplying information on this form

Name: _____

Telephone: _____

Fax: _____

Email: _____

Vasectomy Procedures (optional, but very helpful to us!)

Average number of vasectomy procedures (traditional and No-Scalpel) performed at this facility each MONTH: _____

Of these vasectomies, approximate number that are No-Scalpel Vasectomy (NSV): _____

Average number of clients that your facility REFERS out for vasectomy (traditional and NSV) each MONTH: _____

Date you submitted this sign-up form to EngenderHealth: _____

Please send this form to EngenderHealth by fax at (212) 561-8067, by email at vasline@engenderhealth.org, or by regular mail at EngenderHealth, 440 Ninth Ave., New York, NY 10001. Thank you!

Source: EngenderHealth, New York City.