CONTRACEPTIVE TECHNOLOGY UPDATE®
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IN THIS ISSUE

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New data released underscores safety of dedicated continuous-use pill

Prepare to counsel women on continuous-use oral contraceptive

New research released on Lybrel, the first dedicated continuous use oral contraceptive (OC) (Wyeth Pharmaceuticals; Collegeville, PA), underscores the safety of the new drug.[1,2] Now on U.S. pharmacy shelves, a four-week supply of 28 tablets costs about $57 at CVS and Wal-Mart, similar to the cost of other birth control pills.[3] The pill was approved by the Food and Drug Administration in May 2007.

What is the status of insurance coverage for Lybrel? Wyeth has been working with the major health care plans and pharmacy benefit management companies to ensure access for the pill, says company spokeswoman **Danielle Halstrom**. At this time, most health care plans and pharmacy benefit management companies are providing access to Lybrel as an option for their participants, she reports.

Other contraceptive pill regimens have placebo or pill-free intervals lasting four to seven days that stimulate a menstrual cycle. Lybrel is designed to be taken without the placebo or pill-free time interval.

EXECUTIVE SUMMARY

New research released on Lybrel, the first dedicated continuous use oral contraceptive, underscores the safety of the new drug. While other contraceptive pill regimens have placebo or pill-free intervals lasting four to seven days that stimulate a menstrual cycle, Lybrel is designed to be taken without the placebo or pill-free time interval.

- Findings from a substudy designed to evaluate the effect of the continuous daily regimen pill on endometrial histology indicate the pill has a good endometrial safety profile.
- Results from a new study indicate that most women who use the drug return to their regular bleeding pattern after they stop use of the pill.

While the concept of using pills in a continuous manner is not a new concept for family planners, Lybrel represents the first dedicated product in that category.

For many years, the progestin-containing pill, also called the mini-pill, has been used on a daily continuous basis as an oral contraceptive, points out **Julia Johnson**, MD, professor and vice chair of gynecology in the Division of Reproductive Endocrinology and Infertility in the Department of Obstetrics and Gynecology at the University of Vermont College of Medicine in Burlington. The newest continuous pill differs in that it also contains a low dose of estrogen (20 mcg ethinyl estradiol) in addition to a commonly used contraceptive progestin (90 mcg levonorgestrel), says Johnson.

Johnson and other researchers performed a substudy of Lybrel's Phase III trial to evaluate the effect of Lybrel on endometrial histology. Findings of the substudy, designed to evaluate the effect of the continuous daily regimen pill on endometrial histology, indicate the pill has a good endometrial safety profile.[1]

The safety of continuous contraceptives, with or without adding a small amount of estrogen, is well established, says Johnson. The impact on the endometrial lining with any progestin-containing contraceptive is thinning and atrophy of the endometrium, she notes. Women are reassured when they learn that the lack of menses is not because the lining cannot shed, but because there is no lining to shed. Johnson says this effect on the endometrium is expected by all progestin contraceptives: oral, injectable, implant, or intrauterine systems.

"The advantage of having an inactive endometrium is the suppression of menses for women with dysmenorrhea or menorrhagia; in addition, the estrogen component of these pills also suppresses the ovary and prevents functional cyst formation, as seen with progestin-only contraceptives," says Johnson. "Future studies are needed, but continuous oral contraceptives may also improve other common gynecologic disorders, such as premenstrual syndrome."

Will periods return?

Women who are interested in using Lybrel will want to know about the ability to menstruate and become pregnant after discontinuation of the pill. Results from a new study indicate that most women who use the drug return to their regular bleeding pattern after they stop use of the pill. Of the 187 women who completed the study, 185 (98.9%) returned to spontaneous menses (181) or became pregnant[2] within 90 days after pill use. For the two women who did not experience menses during the study interval, one reported

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Editorial Questions

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menses on Day 124 and the other at approximately two months after the study ended.[2]

To perform the observational study, researchers enrolled women ages 18-49 with a history of regular menstrual cycles who had participated for at least six months in an open-label trial of the drug. The median time to return to menses in the women who completed the study was 32 days, and the incidence of spontaneous menses or pregnancy at day ≤ 90 was 98.9%. Researchers report that the duration of amenorrhea during drug use before stopping treatment was unrelated to the time to the return to menses.

Lybrel is similar to other oral contraceptive pills in that when women stop taking them, they are at risk of pregnancy, says the paper's lead author, **Anne Davis**, MD, MPH, FACOG, assistant professor of clinical obstetrics and gynecology at Columbia Presbyterian Medical Center in New York City. There is no delayed return to fertility. In contrast, in a study of return to fertility among users of DMPA conducted in Thailand, women conceived nine months on average after the last injection, or 5.5 months after discontinuing, which the researchers assumed to be 15 weeks after the last injection.[4]

All of the women in the current study had regular menstrual periods prior to taking Lybrel, Davis points out. For women who have irregular cycles, use of Lybrel will not "correct" the cycle, she notes. Women will return to their previous mode of menstruation when they stop taking the drug, says Davis.

Data back safety

As clinicians more frequently prescribe extended/continuous OCs and other hormonal contraceptives, some clinicians and women may be concerned that extended/continuous exposure to the sex steroids in the contraceptives may be associated with delayed return to fertility and/or endometrial disease, observes **Andrew Kaunitz**, MD, professor and associate chair in the Obstetrics and Gynecology Department at the University of Florida College of Medicine — Jacksonville. Research indicates this is not the case, he notes.

Kaunitz points to a study of continuous OC use conducted in Oregon, where one woman conceived within one week of stopping pills after six months of continuous use.[5] The findings of a separate study provide similar data. In a study of 30 women who discontinued a one-year Phase III trial of continuous-use pills in order to conceive, 57% had become pregnant by three months, and 81% had become pregnant by 12 months. The overall pregnancy rate at 13 months was 86%.[6]

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Use counseling tips for continuous-use pill

Your next patient says she is interested in using Lybrel, the new continuous-use oral contraceptive (OC). What should you tell her about this form of birth control?

In many ways, Lybrel is no different from other combined oral contraceptives, says **Anne Davis**, MD, MPH, FACOG, assistant professor of clinical obstetrics and gynecology at Columbia Presbyterian Medical Center in New York City. It contains the same estrogen and progestin as similar low-dose OCs, and it comes in a monthly dispenser.

"What is different about it is the way you take it, not what is in it," says Davis. "There is no scheduled withdrawal bleeding with placebo pills; there is the same pill, every day, and you take one pill every day until you don't need it any more."

The advantage of having an inactive endometrium is the suppression of menses for women with dysmenorrhea or menorrhagia, points out **Julia Johnson**, MD, professor and vice chair of gynecology in the Division of Reproductive Endocrinology and Infertility in the Department of Obstetrics and Gynecology at the University of Vermont College of

Medicine in Burlington. The disadvantage of the lack of endometrial development? Unpredictable spotting and bleeding, says Johnson, who has participated in research of the drug.

"Although the majority of women find that the bleeding resolves with continued use of a daily oral contraceptive, it is important for women to be aware of this side effect," says Johnson. "The bleeding and spotting is not a sign of a serious adverse event, but this can be bothersome to women and is a most common reason to stop this form of contraceptive."

While breakthrough bleeding and spotting on Lybrel may decrease over time, some women will continue to have such episodes. One-fifth (21%) of women in the clinical trial had uterine bleeding by Pill Pack 13, with a median of four days of bleeding and three days of spotting per 28-day pill pack. More than three-quarters (77%) of women who experienced bleeding on Pill Pack 13 reported they were satisfied with the method, with 7% as neutral and 16% as dissatisfied.[1]

"If women are counseled regarding this side effect, they can often tolerate the bleeding and spotting as an expected early effect of this form of contraceptive," observes Johnson.

Weigh the facts

For Davis, who also has participated in Lybrel's research, counseling on unscheduled bleeding is an important component in determining success with the method.

"The pattern of bleeding is completely unpredictable," she notes. "Overall, when you look at the clinical data over time, there was a slight decrease in the amount of bleeding and spotting days over time, but that is as a group."

Some women may bleed a little in the beginning of pill use and will have no bleeding later on, while other women may not experience bleeding at pill initiation, but develop bleeding in subsequent pill packs.

Women who choose Lybrel should be accepting of unscheduled bleeding before they begin the method, says Davis. Counsel on having a minipad available for such bleeding, and also stress that such bleeding does not indicate sign of infection or illness, she notes.

Advise women to continue taking their pills, even when they experience unscheduled bleeding. If the bleeding or spotting lasts for more than seven consecutive days, women should call their health care provider, the drug packaging states.

There is no determination as to who will experience such episodes, notes Davis.

"You can't look at a woman and say you're going to be the one who's going to have it, because you don't know," she says. "There are no predictors."

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New microbicide for HIV prevention now in trials

Researchers have launched a clinical safety trial of VivaGel (SPL7013), a topical vaginal microbicide, for potential use in preventing the sexual transmission of HIV. The trial is being conducted in two sites, the University of South Florida in Tampa and the University of Puerto Rico in San Juan and it is supported by funding from the Division of AIDS at the National Institute of Allergy and Infectious Diseases and the National Institute of Child Health and Human Development.

Starpharma Pty. Ltd., of Melbourne, Australia, is looking at VivaGel as a candidate microbicide for the prevention of HIV/AIDS and genital herpes. The gel's active ingredient belongs to a class of compounds known as dendrimers, large molecular structures that incorporate multiple units of an active component on their surfaces. Each dendrimer in VivaGel incorporates 32 copies of the active component. Researchers believe the gel's unique molecular structure may hamper the ability of HIV to

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- The trial is being conducted in two sites, the University of South Florida in Tampa and the University of Puerto Rico in San Juan.
- The gel's manufacturer, Starpharma Pty. Ltd., of Melbourne, Australia, is looking at VivaGel as a candidate microbicide for the prevention of HIV/AIDS and genital herpes. It also is looking at the use of the compound as a condom coating, as well as its potential as a contraceptive.

attach to and infect healthy cells.

Starpharma recently announced trial results that showed VivaGel was well tolerated and safe for continued development following topical penile application in men, says **Jackie Farley**, MBA, the company's chief executive officer. Acceptability was a secondary endpoint in this study, and interviews indicated that VivaGel would be acceptable to participants if shown to be protective against sexually transmitted infections, she notes.[1] Findings from an earlier unpublished Phase I study of VivaGel in sexually abstinent women ages 18-43 indicate no safety concerns. Women were randomly assigned to receive different doses of the gel and closely examined during a seven-day inpatient stay in a clinical research unit.

Two sites eye drug

Screening of potential candidates for the trial began in July 2007. The trial, which will include 40 women, ages 18 to 24, who are sexually active and HIV-negative, is designed as a randomized placebo-controlled Phase I safety and acceptability trial with two treatment arms. Participants will be randomly assigned to one of two study groups, with one group applying VivaGel twice a day for two weeks, with participants in the other group using a placebo gel. All women in the study will be given condoms for use during each sexual interaction. Participation in the study is scheduled for three weeks, which will include the two-week period that gels are used.

If trial results prove satisfactory in terms of the safety profile and the acceptability, then the next step likely will be an extended safety study, where the study group may include a larger group of women who will use the product for a longer period of time, typically six months, says **Ian McGowan**, MD, PhD, visiting professor of medicine at the University of Pittsburgh School of Medicine and Magee-Womens Research Institute. McGowan is co-principal investigator of the Microbicide Trials Network and protocol chair for the current study of VivaGel.

The VivaGel study is the first of three trials expected to be launched this year by the Microbicide Trials Network (MTN). MTN is an HIV/AIDS clinical trials network established in 2006 by the Division of AIDS, National Institute of Allergy and Infectious Diseases (NIAID), part of the U.S. National Institutes of Health.

The active ingredient in VivaGel, SPL7013, is a fourth-generation polylysine dendrimer. Thirty-two naphthalene disulfonate moieties, attached by amide linkages, are found on the molecule's surface. The structure prevents HIV infections by binding to the gp120 glycoprotein receptors on the virus's surface, an interaction which in turn stops HIV from attaching to receptors on T cells in the body.[2] Given VivaGel's potential for infection prevention, Starpharma is looking at use of the product as a coating for condoms.

"The potential for VivaGel to be used as a condom coating reflects some of the growing momentum building to bring an effective preventative measure for HIV and STIs to market," notes Farley. "Starpharma has already signed an agreement with a leading manufacturer of condoms, which will include a program of evaluation and development and also commercialization rights covering condoms with VivaGel costing within a specific geographical region."

Preclinical animal studies on VivaGel have provided early evidence that VivaGel may serve as an effective contraceptive, says Farley. Further studies on the contraceptive ability of VivaGel are already under way, she notes.

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New review boosts knowledge of implants

Your next patient is a young mother of three who is looking for long-term, effective contraception. She says she is not ready to consider tubal sterilization. What methods can you offer her?

One option is the contraceptive implant Implanon (Organon USA; Roseland, NJ). A small, thin, hormonal contraceptive that is effective for up to three years, Implanon was approved in July 2006 by the U.S. Food and Drug Administration**.** The device, made of a soft medical polymer, contains 68 mg of the progestin etonogestrel. Implanted in the inner side of a woman's upper arm during an in-office procedure, the matchstick-sized device releases the

drug in a low, steady dose.

A just-published review provides an overview of the effectiveness and tolerability of subdermal contraceptives.[1] The review includes information on Implanon, as well as Jadelle, a two-rod implant developed by the Population Council in New York City, and Norplant, a six-rod implant formerly manufactured by Wyeth Pharmaceuticals in Madison, NJ. Norplant has been unavailable in the United States since 2000; Jadelle has not been introduced in the United States. (Wyeth Pharmaceuticals suspended shipment of Norplant implants in August 2000 when concerns arose about efficacy of suspect lots. While the lots were found effective in July 2002, the manufacturer chose not to reintroduce the product in the United States.)

What do implants offer?

The new review was designed to assess the effectiveness and tolerability of subdermal implantable contraceptives compared to other reversible methods of contraception. Researchers used database searches and reference lists, and they interviewed individuals and organizations working in the contraceptive field to identify all randomized and controlled trials comparing subdermal implants with other forms of reversible contraceptives.

The researchers found that all studied implants were good at preventing pregnancy. No one subdermal implant was found to be any more or less effective than the others in preventing unwanted pregnancies.[1]

Most women who use contraceptive implants chose to continue with the method long term, the new report states. More than 80% of women still were using the implant method at two years, researchers found. Women in developed country studies were less likely to continue with these methods when compared to women in developing country studies.[1]

Device removal was quicker for Implanon and Jadelle than for Norplant, according to the new report. Mean time for Implanon insertions was 1.1 minutes; removal time was 2.6 minutes.[1] Insertion problems were rare with any of the implants; problems during removal were uncommon, but they were significantly more likely to occur in Norplant users than Implanon users.[1]

Counsel on bleeding

When counseling women about the advantages and risks of using Implanon, providers must educate prospective patients about bleeding issues, says **Jo Power**, MRCOG, MFFP, a researcher at Margaret Pyke Center in London and lead author of the review.

"I think it is important that women choosing this method understand that their bleeding patterns may be unpredictable," notes Power. "Bleeding patterns vary from woman to woman and may also change with time for any individual woman; patterns may include no bleeding, infrequent, frequent, or prolonged bleeding."

According to the Implanon patient package insert, the most common side effect of the method is a change in menstrual periods. Women should expect their menstrual periods to be irregular and unpredictable throughout the time they are using the method. Women may have more bleeding, less bleeding, or no bleeding, advises the insert. The time between periods may vary, and spotting may occur in between periods.

Menstrual bleeding patterns in Implanon were similar to Norplant in comparative trials; however, amenorrhea occurred more with Implanon, said **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 programs at Harbor — UCLA Medical Center in Torrance.[2] Normal menses returned within three months in almost all women following removal.[3]

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COMING IN FUTURE MONTHS

- Review nonhormonal contraceptive options
- What do women know about uterine fibroids?
- What's next for breast cancer prevention drugs?
- Counsel women on safety of HPV vaccine
- DMPA — Safe to use in women with sickle cell anemia

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Uninsured women are not getting Pap smears

How many women in your family planning facility may be missing a needed Pap smear? Check your numbers: One-fourth of uninsured U.S. women between the ages of 18-64 report not having had a Pap smear within the last three years of a government-issued survey.[1]

The numbers are twice the 11% rate for women with private insurance and higher than the 15% rate for women covered by Medicaid or any other public insurance. The U.S. Preventive Services Task Force (USPSTF) recommends that women from ages 21-64 receive a Pap smear screening at least every three years to detect cervical cancer and abnormal cells that can develop into cancer.[2]

More than 17 million women are uninsured, according to figures from the Kaiser Family Foundation (KFF).[3] According to a 2004 KFF national survey, 40% of uninsured women said they had not had a Pap smear in the previous two years, compared to 20% of insured women.[3]

The figures for the current government report come from the 2005 cycle of the Medical Expenditure Panel Survey, which gives a detailed glimpse of health services used by Americans and their frequency of use, as well as their costs and

CE/CME Instructions

Physicians and nurses participate in this continuing medical education/continuing education program by reading the articles, using the provided references for further research, and studying the questions at the end of the issue. Participants should select what they believe to be the correct answers and refer to the list of correct answers to test their knowledge. To clarify confusion surrounding any questions answered incorrectly, please consult the source material. After completing this activity with the **December** issue, you must complete the evaluation form provided and return it in the reply envelope provided in that issue to receive a certificate of completion. When your evaluation is received, a certificate will be mailed to you. ■

CE/CME Questions

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.
- **describe** how those issues affect services and patient care.
- **integrate** practical solutions to problems and information into daily practices, according to advice from nationally recognized family planning experts.

13. What is the dosage of ethinyl estradiol in each tablet of Lybrel?
A. 30 mcg
B. 20 mcg
C. 15 mcg
D. 10 mcg

14. The microbicidal candidate VivaGel contains molecules known as:
A. macrocycles.
B. fullerenes.
C. dendrimers.
D. micelles.

15. Which women would NOT be good candidates for the contraceptive implant Implanon?
A. Recently postpartum women.
B. Mothers who are exclusively breast-feeding.
C. Smokers older than age 35.
D. Women who have had breast cancer.

16. According to guidance from the American College of Obstetricians and Gynecologists, when should the first Pap smear be performed?
A. About three years after first sexual intercourse or by age 21, whichever comes first.
B. At age 14.
C. At age 16.
D. At age 18.

Answers: 13. B; 14. C; 15. D; 16. A.

method of payment. The current Pap smear figures are similar to those found in 2004 and 2003, says **Anita Soni**, PhD, a survey analyst/statistician at the Agency for Healthcare Research and Quality and author of the report.

What does the new report reveal about the frequency of Pap smears? Take a look at the numbers:

- In the overall picture, 14% of women ages 18-64, regardless of insurance status, did not receive a Pap smear within the last three years.
- Asian women were more than twice as likely (21.5%) to have not received a Pap smear in the last three years than African-American women (10%). These numbers compare to 13.5% in white women and 16% in Hispanic women.
- Single (never married) women were nearly twice as likely not to have received the Pap test within the last three years as compared with those who were married.[1]

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New research indicates circumcision does not affect women's STD risk

More investigation needed to determine circumcision's impact on women

With findings suggesting that male circumcision reduces risk of HIV acquisition for men, researchers now are turning attention on circumcision's impact on acquisition of sexually transmitted disease (STD) for women. Findings presented at the recent International Society for Sexually Transmitted Diseases Research in Seattle indicate that the protective effect of male circumcision may not transfer to STD risk reduction in female sexual partners.[1]

An international expert consultation was convened in March 2007 by the World Health Organization (WHO) and the UNAIDS Secretariat, with a recommendation issued that male circumcision be recognized as an additional important intervention to reduce the risk of heterosexually acquired HIV infection in men. The consultation was held following publication of evidence from three randomized controlled trials undertaken in Kisumu, Kenya; Rakai District, Uganda; and Orange Farm, South Africa, that male circumcision reduces the risk of heterosexually acquired HIV infection in men by about 60%.[2-4] **(*Contraceptive Technology Update* reported on the data in the articles "New recommendations out on HIV and circumcision," June 2007, p. 67, "Adult male circumcision reduces risk for HIV," March 2007, p. 30, and "Male circumcision and HIV prevention: Method can dramatically reduce risk, study says," *STD Quarterly*, October 2005, supplement p. 1.)**

In contrast to HIV, the effects of circumcision on other sexually transmitted infections have been studied much less, states **William Miller**, MD, PhD, MPH, associate professor of medicine and epidemiology at the University of North Carolina at Chapel Hill. Miller and fellow researchers analyzed data from a prospective cohort study on

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Findings presented at the recent International Society for Sexually Transmitted Diseases Research indicate that the protective effect of male circumcision may not transfer to STD risk reduction in female sexual partners. More research is under way to look at the issue.

- The report's findings indicate that male circumcision was not associated with women's risk of acquisition of gonococcal or trichomonal infections.
- Circumcision had no effect on chlamydia when all participants were considered together. However, when analysis was restricted to monogamous women, those with circumcised partners appeared to have increased risk for chlamydial infection.

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hormonal contraception and incident HIV and STDs conducted among women from Uganda, Zimbabwe, and Thailand for the report presented at the Seattle conference.

"We felt that there was the potential that circumcision could also reduce a woman's risk for acquiring these other STIs," says Miller of the report's genesis. "The mechanism could either be through reducing men's risk, which would secondarily reduce women's risk, or alternatively, there could be reduced transmission associated with circumcision, perhaps through effects on organism burden."

The report's findings indicate that male circumcision was not associated with women's risk of acquisition of gonococcal or trichomonal infections. Circumcision had no effect on chlamydia when all participants were considered together; however, when analysis was restricted to monogamous women, those with circumcised partners appeared to have increased risk for chlamydial infection.[1]

Miller's study was done as a secondary data analysis, he says. "I would think that a study specifically designed to assess this relationship would have a better chance of identifying any protective — or even increased risk — relationship," Miller says. "Furthermore, I think that as programs are developed for circumcision to prevent HIV infection, the potential consequences and/or benefits for women should be carefully monitored."

Review the results

To perform the study on women's risk of chlamydial, gonococcal, and trichomonal infections, scientists looked at 5,925 women from Uganda, Zimbabwe, and Thailand who were seen quarterly for up to two years. The women underwent physical exams with specimen collection and were given face-to-face questionnaires to gather sexual and behavioral data.

Women were asked about the circumcision status of their partners: 18.6% reported a circumcised primary partner at baseline, 70.8% reported an uncircumcised partner, and 9.7% did not know their partner's circumcision status. During follow-up, 411, 307, and 373 participants had a first incident chlamydial, gonococcal, or trichomonal infection, respectively.

In multivariate analysis, after controlling for contraceptive method, age, age at coital debut, and country, the adjusted hazard ratio (HR) comparing women with circumcised partners to those with uncircumcised partners for chlamydia was 1.22 [95% confidence interval (CI): 0.94 to 1.59]; for gonorrhea, adjusted HR: 0.93 (95% CI: 0.70 to 1.24); for trichomoniasis, adjusted HR: 1.05 (95% CI: 0.81 to 1.37), and for all three infections combined, adjusted HR: 1.02 (95% CI: 0.86 to 1.22). Sensitivity analysis excluding women reporting multiple sexual partners had little influence on the estimates for gonorrhea and trichomoniasis; however, for chlamydia, analyses restricted to women with only one sexual partner revealed those with circumcised partners had increased risk of acquisition compared to participants with uncircumcised partners (restricted HR: 1.33, 95% CI: 1.01 to 1.75).[1]

Further research should be aimed at determining male circumcision's potential effects of genital ulcer diseases, such as chancroid, herpes, syphilis, and human papillomavirus (HPV), says **King Holmes**, MD, PhD, director of the Center for AIDS and Sexually Transmitted Diseases at the University of Washington in Seattle. Skin-to-skin transmission routes may be the link to any protective effect, he observes.

For example, earlier research has indicated that women whose male partners were uncircumcised were more likely to acquire/develop cervical cancer,[5] says Holmes. Does this mean that men who don't have a foreskin are more likely to acquire or transmit HPV? Such a hypothesis remains to be fully tested in future studies, he notes.

Hypothesis on circumcision

Results of a meta-analysis presented at the Seattle conference indicate that male circumcision is associated with a reduced risk of symptomatic genital ulcer disease.[6] The report, based on a meta-analysis of observational studies and one randomized trial, hypothesizes that while the protective effect may be due to a reduction in infection with ulcerative STDs, it also is possible that circumcision reduces the frequency and duration of symptoms. This reduction in infection may contribute to reduced acquisition of HIV infection found in circumcised men, the report concludes.[6]

Another area of potential research lies in determining male circumcision's impact on bacterial vaginosis (BV), says Holmes. Scientists have speculated that the bacteria that cause BV can survive under the foreskin of an uncircumcised man, observes Holmes. A man with multiple partners

may be more likely to transmit infection to an uninfected partner by just transporting the bacteria he has acquired from the woman who has the infection, he notes. Findings indicate circumcision may have a protective effect. A statistical review of the past medical files of more than 300 couples in Uganda, where the female partner was HIV-negative and the male was HIV-positive, indicates that male circumcision reduced rates of trichomonas and bacterial vaginosis in female partners.[7]

Does male circumcision extend its protective effect to women when it comes to HIV? Researchers at Johns Hopkins University in Baltimore currently have an ongoing trial to answer that question. The study will not be completed until 2008.

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Older women may not know their risk for HIV

If your practice includes older women, what is your approach in discussing risks for HIV? It's time to address such issues. Results of a new study indicate that older women may not be interested in being tested for HIV, despite having significant risk factors for lifetime exposure.[1]

EXECUTIVE SUMMARY

Results of a new study indicate that older women may not be interested in being tested for HIV, despite having significant risk factors for lifetime exposure.

- Between 11% and 14% of all new HIV diagnoses are reported in Americans older than age 50. Despite the rise in diagnoses, seniors have been largely overlooked by HIV prevention and testing programs and have lower HIV testing rates compared with younger adults.
- Women are at special risk for HIV. The proportion of all HIV cases diagnosed among women and ethnic minorities has risen sharply since the early 1990s. While women represented 6% of all HIV diagnoses in 1984, their numbers climbed to 27% in recent years.

Between 11% and 14% of all new HIV diagnoses are reported in Americans older than age 50.[2-5] Despite the rise in diagnoses, seniors have been largely overlooked by HIV prevention and testing programs and have lower HIV testing rates compared with younger adults.[6-8] Women are at special risk for HIV. The proportion of all HIV cases diagnosed among women and ethnic minorities has risen sharply since the early 1990s. While women represented 6% of all HIV diagnoses in 1984, their numbers climbed to 27% in 2003.[9]

What are some of the chief reasons for lower HIV testing rates among older women? Older women often do not get tested because they believe they are not at risk, says **Aletha Akers**, MD, MPH, assistant professor in the Department of Obstetrics, Gynecology, and Reproductive Sciences at the University of Pittsburgh School of Medicine and lead author of the current study. Older women may believe that they and their partners do not or no longer engage in behaviors that would place them at risk, she observes.

Recommending seniors be tested

Another major reason for lower testing rates is that providers often do not recommend HIV testing to their older patients, says Akers. Providers may assume that older women are not sexually active or, if they are, they may assume that older women are not at risk and therefore do not obtain

a sexual history or offer HIV testing, she notes.

In the current study, researchers underscore the importance of providers to assess current and past risk behaviors among older women who have not been tested for HIV, Akers reports. If a provider only assesses an older woman's current risk behaviors, while ignoring her lifetime risk exposure, he or she may incorrectly assume that an older woman does not need to be tested, she notes.

"Our national HIV education and prevention campaigns have generally ignored older persons," states Akers. "Media campaigns have focused on traditional high-risk groups such as youth, incarcerated individuals, and drug users; this has left older persons with the impression that HIV does not affect them."

Look at the study

To perform the study, researchers analyzed data collected from 514 women ages 50-95, who visited a general internal medicine clinic at a large, inner-city hospital in Atlanta during 2001-2002. Research assistants used a 68-item questionnaire to conduct face-to-face interviews with study participants, most of whom said they were not currently sexually active.

More than 60% of the women had never been tested for HIV, although more than half of them were found to have moderate to high risk for lifetime exposure to the virus based on sexual history and other factors. Less than one-fourth (22%) of the women said they would be interested in HIV testing.

About one-third of women already had been tested. These women were more likely to be younger, sexually active, better educated about HIV, and had received testing at the suggestion of a health care provider, researchers note.

Women with little HIV knowledge and low perceived personal risk were less interested in HIV testing, study findings indicate. Less than 25% of the participants could recall ever receiving counseling to get a test for HIV from a provider, despite their risk factors.[1]

Get the word out

It is important for seniors to be empowered and have the information to make informed decisions about their sexual health and practices, says **Chris Miller**, a spokesman for New York City's Department for the Aging. His department is taking special steps to spread the word about HIV prevention: 32% of people living with HIV/AIDS in New York City are people older than the age of 50, and 16% of all new HIV infections are in people older than 50 in the city.

To affect these numbers, New York City's Department for the Aging is preparing its network of service providers for the "graying" of HIV/AIDS, says Miller. It also is educating seniors who currently use its services, he notes.

In February 2007, the agency met with its community partners and senior health volunteers to educate senior center directors and staff, as well as health promotion volunteers, about basic HIV/AIDS information, says Miller. In June, the agency followed up by sending 81,000 of the city's private-label condoms, NYC Condoms, and HIV/AIDS literature to its senior centers. **(Read more about the NYC condoms; see the article "Start spreading the news: NYC condom unwrapped," *Contraceptive Technology Update* September 2007, p. 102.)**

"We also connected senior centers to local AIDS service organizations for further community-specific education and possible testing," says Miller.

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