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CONTRACEPTIVE TECHNOLOGY

U P D A T E

A Monthly Newsletter for Health Professionals

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First contraceptive patch offers once-a-week dosing

FDA approves Ortho Evra transdermal contraceptive

Women soon will have another option in birth control: the Ortho Evra transdermal contraceptive. Look for the contraceptive patch to be available in the first half of 2002, according to Raritan, NJ-based Ortho-McNeil Pharmaceutical, which will market the drug.

Ortho Evra is worn for one week at a time and is replaced on the same day of the week for three consecutive weeks. The fourth week, which is patch-free, allows a woman to have her menstrual period — similar to the regimen for birth control pills. Women can wear the patch on one of four areas of the body: the buttocks, abdomen, upper torso (front and back, excluding the breasts), or upper outer arm. Women who are candidates for the Pill also may be considered for the patch; those with contraindications to hormonal contraception should seek another method. **(See cautions on p. 3)**

The contraceptive patch offers a convenient, effective form of birth control for women, especially for those who may struggle with daily pill-taking, 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

EXECUTIVE SUMMARY

The Food and Drug Administration has approved the first transdermal contraceptive: the Ortho Evra contraceptive patch (Ortho-McNeil Pharmaceutical, Raritan, NJ). The patch will be available in the first half of 2002.

- Results from clinical trials show that the patch provides effective contraception and cycle control and is well tolerated.
- While the price for the contraceptive patch has not yet been established, it will be comparable in cost to birth control pills. It will be available only in one color, beige; other colors, including a clear patch, are being evaluated for future development.

nurse practitioner training program at Harbor-UCLA Medical Center in Torrance.

"We participated in the clinical trials and were very pleased to see how well-accepted this [method] was," says Nelson. **(Contraceptive Technology Update has reported on the patch in three articles: October 1999, p. 113, "Another option? Contraceptive patches are now under research"; March 2001, p. 29, "Patch now under regulatory review"; and August 2001, p. 88, "Contraceptive patch, ring: In U.S. by 2001?" Past CTU articles are available on the web site www.contraceptiveupdate.com. Click on "archives.")**

While the price for the contraceptive patch has not yet been established, it will be comparable to that of birth control pills, Ortho-McNeil says. It will be available only in one color, beige; other colors, including a clear patch, are being evaluated for future development. The company has established a web site, www.orthoevra.com, and toll-free telephone number, (877) 227-2824 [(877) BC-PATCH], to provide information on the new contraceptive.

Review the results

Just-released data from the drug's clinical trials shows that the patch provides effective contraception and cycle control and is well tolerated by women who use it.¹ The patch was developed by R. W. Johnson Pharmaceutical Research Institute in Raritan; it and Ortho-McNeil are members of the New Brunswick, NJ-based Johnson & Johnson corporate family.

The results of the open-label, 73-center study were based on the experiences of 1,171 women who used the patch for six cycles and 501 women who used the method for 13 cycles. The treatment regimen for each cycle consisted of three consecutive seven-day patches (21 days) followed by one patch-free week.

The 20 cm³ patch used in the trial consisted of three layers: an outer protective layer of polyester; a medicated, adhesive middle layer; and a clear polyester release liner, removed before patch

application. Each patch contained 150 mcg of the progestin norelgestromin and 20 mcg of the estrogen ethinyl estradiol. Women applied the patch to one of four anatomic sites: buttocks, upper outer arm, lower abdomen, or upper torso, excluding the breasts. New patches could be placed close to, but not on, the previous application site.

The life table estimates of the probability of overall and method-failure pregnancy through 13 cycles were 0.7% and 0.4%, respectively. Five method-failure pregnancies and one user-failure pregnancy occurred among 1,664 women treated for 10,994 cycles. The overall Pearl index was 0.71, and the method-failure Pearl index was 0.59. In a separate paper, researchers found the contraceptive patch comparable to a combination pill in terms of contraceptive efficacy and cycle control.²

Adverse events associated with patch use were typical of hormonal contraception, and most were mild-to-moderate in severity and not treatment limiting, the investigators state. The most common adverse events resulting in discontinuation were application site reactions (1.9%), nausea (1.8%), emotional lability (1.5%), headache (1.1%), and breast discomfort (1%).

Incidence of breakthrough bleeding was low throughout the study. Perfect compliance (defined as 21 consecutive days of dosing, followed by a seven-day drug-free interval; no patch could be worn for more than seven days) was achieved in 90% of subject cycles; only 1.9% of patches detached completely, according to the study results.

Watch the weight

In clinical trials, the product appeared to be less effective in women weighing more than 198 pounds (90 kg). Of the six pregnancies that occurred in the study, four were among women who weighed 198 pounds or more. Although this finding may suggest that the occurrence of pregnancy is associated with increased body weight, a separate meta-analysis of all patch studies will be published to offer more conclusive results.

Nelson believes that the research will indicate that the patch is most effective for women who

COMING IN FUTURE MONTHS

■ TV ad campaign promotes EC

■ Take Charge program extends services

■ How to treat abnormal Pap smears

■ Answering your contraceptive injectable questions

■ Clinic safety: Update your emergency plan

Who should not use Ortho Evra?

Some women should not use the Ortho Evra contraceptive patch. Check for any of the following conditions:

- A history of heart attack or stroke
- Blood clots in the legs (thrombophlebitis), lungs (pulmonary embolism), or eyes
- A history of blood clots in the deep veins of the legs
- Chest pain (angina pectoris)
- Known or suspected breast cancer or cancer of the lining of the uterus, cervix, or vagina
- Unexplained vaginal bleeding
- Hepatitis or yellowing of the whites of the eyes or of the skin (jaundice), during pregnancy or during previous use of hormonal contraceptives
- Liver tumor (benign or cancerous)
- Known or suspected pregnancy
- Severe high blood pressure
- Diabetes with complications of the kidneys, eyes, nerves, or blood vessels
- Headaches with neurological symptoms
- Use of oral contraceptives
- Disease of heart valves with complications
- Need for a prolonged period of bed rest following major surgery
- An allergic reaction to any of the components of Ortho Evra

Source: U.S. prescribing information for Ortho Evra, Ortho-McNeil Pharmaceutical, Raritan, NJ.

weigh less than 198 pounds. Since oral contraceptives share similar doses of estrogen and progestin, it may well be time to re-examine the role of weight vs. efficacy in pills as well, Nelson observes.

Adhesion is good

The high rate of adhesion for the patch may well play a role in its efficacy, researchers point out in the new study. Based on experiences in the clinical trial, how hard is it to remove the patch at the end of its useful cycle?

A pending study will include data on the ease of removing the patch (“peel-force”) after wearing the patch under normal conditions, says **Kellie McLaughlin**, Johnson & Johnson spokeswoman. The study also will examine adhesion during

exercising and assess whether extreme conditions affect adhesion.

Will women wear it?

Women who participated in the trial enjoyed wearing the patch, says Nelson. Some even displayed it on the upper arm, kind of a “badge of courage,” she notes. Clinicians had to instruct women not to apply decals or other decorative markings on the patches.

While several different patch colors, including a clear model, were evaluated in the clinical trials, beige was selected because it maintained its appearance best over the seven-day wear period. The manufacturer continues to examine development of other color options.

For those who want total privacy with their birth control decision, the patch may not be the right option since it must be worn, says Nelson. But for those who have trouble with daily pills, what some term the “pill in a patch” may offer an effective option.

“There is a lot of anxiety about [pill-taking],” she states. “I think the patch will make it easier for women to use it.”

References

1. Smallwood GH, Meador ML, Lenihan JP, et al. Efficacy and safety of a transdermal contraceptive system. *Obstet Gynecol* 2001; 98:799-805.
2. Audet MC, Moreau M, Koltun WD, et al. Evaluation of contraceptive efficacy and cycle control of a transdermal contraceptive patch vs. an oral contraceptive: A randomized controlled trial. *JAMA* 2001; 285:2,347-2,354. ■

Research eyes extending the menstrual cycle

Would women miss having monthly menstruation if given the choice? In Europe and Australia, many women already manipulate their oral contraceptive (OC) pill packs to reduce monthly periods,¹ and U.S. providers routinely prescribe extended OC use for problems such as menstrual migraines. To date, however, there are no products approved or packaged for extended OC use in the United States.

“Menstruation can be optional, and certainly will be in the coming years with the large number of approaches to menstruation suppression that

EXECUTIVE SUMMARY

Research is focusing on development of an extended cycle oral contraceptive (OC) as more women examine foregoing their monthly periods.

- Recent studies indicate that by extending the use of active pills, women had a 49-day menstrual cycle with fewer bleeding days and no increase in breakthrough bleeding. Women on the 49-day cycle reported fewer symptoms and spent about half as much on menstrual products.
- Menstrual suppression may offer reduction in anemia, lessened risk for certain cancers, and relief of menstrual symptoms. More research could determine the proper formulation.

will be available to women,” says **Sheldon Segal**, PhD, distinguished scientist at the Population Council and an adjunct professor of clinical pharmacology at Cornell Medical School, both based in New York City. Segal is co-author of *Is Menstruation Obsolete?* a book that examines the advantages of menstrual suppression.²

U.S. women and their clinicians are increasingly recognizing advantages associated with experiencing less frequent uterine bleeding, says **Andrew Kaunitz**, MD, professor and assistant chair in the obstetrics and gynecology department at the University of Florida Health Science Center/Jacksonville. For some women, dysmenorrhea, menorrhagia, or other specific health issues motivate the desire for fewer menstrual periods, while other women may prefer fewer or no menses simply to avoid the inconvenience and/or unpleasantness of monthly bleeding episodes, he observes.

Newly published information offers more information about the safety of extended use of active OC tablets. In the research, investigators found that by extending the use of active pills, women had a 49-day menstrual cycle instead of the usual 28-day cycle, resulting in fewer bleeding days and no increase in breakthrough bleeding days.³ Women on the 49-day cycle reported fewer symptoms such as headaches and spent about half as much on menstrual products than those on the 28-day cycle.

Drug companies are eyeing the development of an extended-cycle OC. Barr Laboratories of Pomona, NY, is seeking Food and Drug Administration (FDA) approval for its four-periods-per-year pill, Seasonale, which uses a patented 84-day dosing regimen. If the drug is approved, it may be

available in 2003, according to company sources. (See the May 1999 CTU article, “4-periods-a-year pill eyed for use in U.S.,” p. 51, for more information on Seasonale. Past CTU articles are available on the web site: www.contraceptiveupdate.com.)

The just-published OC research involved the use of Lo/Ovral-28, a 30 mcg ethinyl estradiol/0.3 mg norgestrel pill. Its manufacturer, Wyeth-Ayerst Laboratories of Philadelphia, declined to state if it is considering FDA approval for an extended-cycle pill.

Pursuit of a dedicated product is high on the list for **Leslie Miller**, MD, assistant professor of obstetrics and gynecology at the University of Washington and family planning medical director at Public Health — Seattle and King County, both in Seattle. Miller served as co-author for the study and has launched an informational web site on menstrual suppression, www.noperiod.com.

“Overall, my hope is that someday there will be an FDA-approved, labeled, low-dose OC pill packaged in a large volume, and just as with [hormone replacement therapy], women will come to realize taking a week off the pill only induces bleeding, cyclic symptoms, irregular bleeding, and pill failure,” states Miller.

Review the history

Historically, women without access to contraception could have as few as 50 menstrual cycles in a lifetime, due to multiple pregnancies and a shorter life span than that of women today. In contrast, the modern woman can have up to 450 cycles.³

The current OC regimen of 21 active pills and seven placebo pills was designed to mimic the normal menstrual cycle, even though it is unnecessary for contraceptive efficacy.⁴ Pill users experience a withdrawal bleed for one week out of each 28 days, when the hormonal pills are not taken.

The pill-free interval brings its own set of symptoms. A study designed to measure the timing, frequency, and severity of hormone-related symptoms in OC users compared symptoms in active-pill and hormone-free intervals.⁵ Almost all symptoms were significantly worse during the seven-day hormone-free interval than during the 21 days of hormone-containing pills.

Segal sees the main advantage of menstrual suppression in its positive effect on a variety of health issues. Evidence shows a strong correlation between the number of menstrual cycles and the risk of ovarian, endometrial, and breast

cancer; the lower the number of cycles, the lower the risk, or greater the protective effect, says Segal. In the case of ovarian cancer, the risk is reduced by 40% in OC users in comparison to nonusers⁶, Segal observes. In addition, menstruation-related problems, such as premenstrual syndrome, dysmenorrhea, and menorrhagia, are relieved through menstrual suppression.

“However, the most important benefit for women around the world is [the reduction of] anemia,” says Segal. “A very large percentage of women in developing countries are anemic to begin with, so losing another 60-70 cc of blood a month is just irreplaceable iron loss.”

Further research is needed on the proper pill formulation for suppression, since not all pills are suited for the task, says Miller.

“Phasic preparations, with weekly dosing amount variation, would destabilize the endometrium, and it is possible the extra week of estrogen could produce a higher estrogen effect if higher than 20 mcg ethinyl estradiol doses are used,” she notes.

While the Pill is one of the most studied drugs in terms of safety and efficacy, the body of research is focused on the 21/7 regimen, Segal observes. He supports further research on the effects of menstrual suppression with current OC formulations.

“There should be some additional attention as to what are the health effects or possible side effects of continuous administration,” states Segal. “I think we have some presumptive evidence, but we need some empirical evidence.”

References

1. Den Tonkelaar I, Oddens BJ. Preferred frequency and characteristics of menstrual bleeding in relation to reproductive status, oral contraceptive use, and hormone replacement therapy use. *Contraception* 1999; 59:357-362.

2. Coutinho EM, Segal SJ. *Is Menstruation Obsolete?* New York: Oxford University Press; 1999. Updated and translated from an earlier work in Portuguese by EM Coutinho titled *Menstruação, a Sangria Inútil*. Sao Paolo: Editora Gente; 1996.

3. Miller L, Notter KM. Menstrual reduction with extended use of combination oral contraceptive pills: Randomized controlled trial. *Obstet Gynecol* 2001; 98:771-778.

4. Thomas SL, Ellertson C. Nuisance or natural and healthy: Should monthly menstruation be optional for women? *Lancet* 2000; 355:922-924.

5. Sulak PJ, Scow RD, Preece C, et al. Hormone withdrawal symptoms in oral contraceptive users. *Obstet Gynecol* 2000; 95:261-266.

6. Speroff L, Darney PD. *A Clinical Guide for Contraception*. Baltimore: Williams & Wilkins; 1992. ■

Progress under way on the microbicide front

Canadian scientists are now in clinical trials with the “invisible condom,” a topical microbicide that may offer women a female-controlled form of protection against HIV and other sexually transmitted diseases (STDs.)

The “invisible condom” consists of an active ingredient, sodium lauryl sulfate, and a carrier, a thermoreversible gel formulation that has the unique property to be fluid at room temperature and a gel at body temperature. The phase transition temperature at which the formulation changes from liquid to gel can be adjusted as necessary. The gel formulation, when applied with a specially designed applicator, covers not only the cervix area, but the vaginal mucosa as well. **(For more information, see *Contraceptive Technology Update*, April 1999, p. 37, “Get ready: Women to have more options for preventing disease.” Past CTU articles are available on the web site: www.contraceptiveupdate.com.)**

Researchers at the Infectious Diseases Research Centre of Laval University in Quebec City, led by Michel Bergeron, MD, FRCP, have shown that sodium lauryl sulfate is a potent inactivator of HIV-1 infectivity to cultured cells.¹ Previous studies from the Canadian laboratory have demonstrated that sodium lauryl sulfate inactivates different strains of herpes simplex virus type 1 and type 2 (HSV-1, HSV-2) in vitro.² The team’s most recently published research shows that the gel formulation prevents infection of susceptible cells by HIV-1 and HSV-2.³

The move into clinical testing represents an

EXECUTIVE SUMMARY

Clinical trials are under way in Canada on a microbicide, the “invisible condom,” that may offer female-controlled protection against HIV and other diseases.

- The microbicide consists of an active ingredient, sodium lauryl sulfate, and a carrier, a thermoreversible gel formulation that is a fluid at room temperature and a gel at body temperature. The gel, applied with a special applicator, covers the cervix area and vaginal mucosa.
- Progress on microbicide protection will be reported at Microbicides 2002, set for May 12-15 in Belgium.

exciting advance, says **Rabeya Omar**, PhD, a member of the research team. The Canadian government has provided \$350,000 to help fund the Phase 1 clinical testing.

"We hope to have a safe and effective microbicide for all women," says Omar. "We hope that people will think about this as a potential option for women all over the world."

How does it work?

The name "invisible condom" has been trademarked, and the gel formulation and the unique applicator have been patented, says Omar. But how does the "invisible condom" work?

The Canadian scientists theorize that the gel formulation can be inserted into the vagina well in advance of intercourse. When it is delivered through the specially designed applicator, the formulation can cover the smallest vaginal folds and forms a semisolid physical barrier to infective agents. This adhering capability is seen as a potential advantage of the gel formulation over other carriers, such as creams, which may leak from the vagina and prove unpleasant for use, says Omar.

A second layer of protection, a chemical barrier, is afforded through the active agent, sodium lauryl sulfate, which disrupts viral membranes. The sodium lauryl sulfate gel formulation has been shown not to be toxic to the vaginal mucosa of rabbits. In addition to protection against HIV and HSV-2, sodium lauryl sulfate, which has protein denaturant potency, also may prove effective against human papillomavirus, a nonenveloped virus, of which certain types have been causally linked to cervical cancer.⁴

The "invisible condom" research is just one of the advances being recorded on the microbicide front, says **Polly Harrison**, PhD, director of the Silver Spring, MD-based Alliance for Microbicide Development.

"Several products are moving into advanced clinical trials, with another half-dozen in Phase One," states Harrison. "And there are whole new categories of compounds that we are seeing for the first time in active development."

Progress on the protection front will be reported at Microbicides 2002, set for May 12-15, 2002, in Belgium. The three-day conference will be divided into three tracks: basic science; clinical science; and behavioral science, public health, and the microbicide marketplace. It will include scientific overviews; workshops to review issues unique to microbicides, such as trial design, outcome

measures, and ethical issues in clinical trials; and poster sessions. (Readers can check out the conference's web site at www.itg.be/micro2002.)

Harrison, who is serving on the conference organizing committee, says that there is increased interest in microbicide development, which may bode well for the actual delivery of a product.

"There are new requests for proposals that the National Institutes of Health has put out for development teams, and we are seeing people who have never been involved in microbicides coming from the first ranks of science to start working in this arena," she states. "It is thrilling!"

References

1. Bestman-Smith J, Piret J, Desormeaux A, et al. Sodium lauryl sulfate abrogates human immunodeficiency virus infectivity by affecting viral attachment. *Antimicrob Agents Chemother* 2001; 45:2,229-2,237.
2. Piret J, Lamontagne J, Bestman-Smith J, et al. In vitro and in vivo evaluations of sodium lauryl sulfate and dextran sulfate as microbicides against herpes simplex and human immunodeficiency viruses. *J Clin Microbiol* 2000; 38:110-119.
3. Piret J, Gagne N, Perron S, et al. Thermoreversible gel as a candidate barrier to prevent the transmission of HIV-1 and herpes simplex virus type 2. *Sex Transm Dis* 2001; 28:484-491.
4. Howett MK, Neely EB, Christensen ND, et al. A broad-spectrum microbicide with virucidal activity against sexually transmitted viruses. *Antimicrob Agents Chemother* 1999; 43:314-321. ■

Break down barriers to gynecologic care

The doors to your family planning clinic may be open, but many women may not be entering them. Why? While lack of health insurance and cost of care may present barriers, a national survey of African-American, Hispanic and Caucasian women shows that many women avoid gynecologic care due to language and cultural differences between women and their health care professionals, discomfort with a physician, and fear of diagnosis and embarrassment.¹

"Barriers deterring women from their physicians, such as language and cultural differences, can lead to serious long-term health problems," says **Linda Alexander**, PhD, FAAN, executive director and chief executive officer of the Research Triangle Park, NC-based American Social Health Association (ASHA), which released the survey results. "As a leading organization in the field of consumer health

EXECUTIVE SUMMARY

A national survey of African-American, Hispanic, and Caucasian women indicates that many avoid gynecologic care due to language and cultural differences with health care professionals, discomfort with a physician, and fear of diagnosis and embarrassment.

- More than one-half of women surveyed said that at least one of these barriers had interfered with their obtaining gynecologic care.
- One-fourth of women said they had not visited a physician for even a routine gynecologic exam in the past year, and 28% said they do not go for a routine exam.

education, we see these survey results as a call to action for more education and for women to proactively seek gynecologic health care.”

Alexander says the survey was conducted to determine attitudes and behavior toward a number of issues related to gynecological health care, specifically treatment of vaginal yeast infections. The survey results indicate that women may not be addressing important health issues, she notes.

“Many sexually transmitted diseases may appear similar to a yeast infection,” Alexander says. “If women are not seeking care for yeast infections, then it is likely that they are not seeking care for infections that may have more serious health implications.”

Look at the results

According to the telephone survey, conducted among Caucasian, African-American and Hispanic adult women ages 18 and older, the top barriers to seeking gynecologic care are:

- cost (25%, 16%, and 20%, respectively);
- language/cultural differences (21%, 21%, and 20%);
- discomfort with a physician (21%, 17%, and 23%);
- fear of diagnosis (12%, 15%, and 15%);
- embarrassment (9%, 8%, and 18%).

More than one-half (55%) of women surveyed, regardless of ethnicity, said that at least one of these barriers has interfered with their obtaining gynecologic health care. According to the survey responses, 25% of women have not visited a physician for even a routine gynecologic annual examination in the past year, and 28% said they do not go for a routine annual exam.

The Seattle-King County (WA) Department of

Public Health works on many fronts to see that patients receive culturally competent care. According to **Shari Wilson**, coordinator of the department’s Refugee Health Access and Interpretation Program, the agency began to offer interpretation for all services in 1991, and since that time, has seen a continued increase in the number of limited English proficiency clients accessing all of the programs, including family planning.

All Public Health — Seattle and King County Family Planning clinics provide interpreters, and in many cases, bilingual staff, says **Michelle Pennylegion**, MPH, coordinator of the Family Planning Health Education and Outreach Program. Interpreters participate in clinical visits and facilitate scheduling, she notes.

Wilson says the public is made aware of the interpretation program’s services in a variety of ways: word of mouth by its interpreters and clients in the refugee and immigrant communities; its participation in refugee and immigrant community forums and fairs; and the Public Health — Seattle and King County’s web site (www.metrokc.gov/health), outreach materials, signage, and events.

Increasing the number of minority staff members may be helpful in addressing the needs of a diverse population. According to the Department of Health and Human Services, minorities now total more than 25% of the total U.S. population, but are just 10% of the health care work force.

In an effort to increase the number of health professionals who are racial or ethnic minorities, the department awards grants through its Centers of Excellence program to support education programs targeted to racial and ethnic students who are underrepresented in the health professions. Nine such grants totaling \$5.4 million were announced in September 2001. The grants, which were established in 1987, are distributed to qualified schools of medicine, osteopathic medicine, dentistry, and pharmacy. Since that time, more than 250 qualified schools have received grants worth \$153 million to train some 52,000 students.

Health care providers from all disciplines should become sensitive to the many and varied cultural factors that influence health, according to the Washington, DC-based American College of Obstetricians and Gynecologists, whose Committee on Health Care for Underserved Women addresses the cultural competence issue. The more physicians learn about a patient’s health beliefs and practices, the more likely it is

that culturally appropriate health care will be delivered, positive health outcomes will result, and patient satisfaction will improve, according to the association. **(Check out Internet sources for multicultural information, below.)**

Reference

1. American Social Health Association. Many women avoid routine gynecologic care, national survey says. Press release. Research Triangle Park, NC; Oct. 10, 2001. ■



Reach diverse audiences with appropriate facts

Family planning professionals encounter a broad cross-section of the American population. Check out the following web sites in researching culturally appropriate patient information material:

1. Reproductive Health Outlook. Web: www.rho.org.

The Reproductive Health Outlook web site, published by the Seattle-based Program for Appropriate Technology in Health (PATH), is designed for reproductive health program managers and decision makers working in developing countries and low-resource settings. It provides up-to-date summaries of research findings, program experience, and clinical guidelines related to key reproductive health topics as well as analyses of policy and program implications. It offers in-depth information on reproductive health topics including contraceptive methods, HIV/AIDS, reproductive tract infections, men and reproductive health, adolescent health, family planning program issues, refugee reproductive health, and gender and sexual health.

2. Media/Materials Clearinghouse. Web: www.jhucp.org/mmc/index.stm.

The Media/Materials Clearinghouse is part of the Baltimore-based Johns Hopkins Population Information Program. Funded by the Washington, DC-based U.S. Agency for International Development, it is an international resource for health professionals

who seek samples of pamphlets, posters, videos, and other media/materials designed to promote public health.

Click on the "Health Communication Materials Network" (HCMN) button if you're interested in professionals who specialize in the development of health communication materials, such as pamphlets, posters, video, radio, and training materials. HCMN provides a forum for health communication specialists to share ideas, information, and work samples.

3. ReproLine. Web: www.reproline.jhu.edu/index.htm.

ReproLine is developed by the JHPIEGO, an affiliate of Baltimore-based Johns Hopkins University. JHPIEGO, a nonprofit organization also based in Baltimore, aims its efforts at improving the health of women and families throughout the world by increasing the number of qualified health professionals trained in modern reproductive health care. It offers extensive tools for trainers, and its "Reading Room" offers on-line documents on contraceptive methods, including *The Pocket Guide for Family Planning Service Providers*.

4. Office of Minority Health. Web: www.omhrc.gov.

The Office of Minority Health oversees public health issues affecting American Indians and Alaska Natives, Asian-Americans, native Hawaiians and other Pacific Islanders, Blacks/African-Americans, and Hispanics/Latinos. Click on "Publications" to go to the on-line versions of the agency's newsletters, *Closing the Gap*, which reports on federal, state, and community-based activities related to minority health, and *HIV Impact*, a quarterly newsletter focusing on HIV/AIDS in communities of color.

5. EthnoMed. Web: <http://ethnomed.org/>.

This web site, a joint project of University of Washington Health Sciences Library and the Harborview Medical Center's Community House Calls Program, both based in Seattle, contains medical and cultural information on immigrant and refugee groups. The web site is designed to be used in clinics by care providers in the few minutes before seeing a patient in clinic.

While it offers information specific to groups in the Seattle area, much of the cultural and health material is of interest and applicable in other geographic areas. Ethnic groups currently included in the web site's information base are the Amharic, Cambodian, Chinese, Eritrean, Hispanic, Oromo, Somali, Tigrean, and Vietnamese. Other ethnic groups will be included as materials are written. ■

Teens often misinformed about proper condom use

Your adolescent patients may say they know about condoms, but do they understand how to use them correctly? A recently published study reports that misconceptions about proper condom use are common among teens, even among those who have experience with the method.¹

It is important that providers become aware of the likely discrepancy between adolescents' knowledge about condom use and the actual practices related to their use, says the study's co-author, **Richard Crosby**, PhD, Sexually Transmitted Diseases (STD) Prevention Fellow in Behavioral Science and Health Education in Atlanta-based Emory University's Rollins School of Public Health.

Evidence suggests that misconceptions may be common, says Crosby. Thus, correcting these misconceptions may be a good starting point for motivating and instructing at-risk adolescents to use condoms correctly and consistently, he notes.

In the study, researchers analyzed data from the National Longitudinal Study of Adolescent Health to determine prevalence of misconceptions among 16,677 adolescents ages 15-21. The sample was divided into three groups: sexually experienced teens who had ever used condoms, sexually experienced teens who had never used condoms, and teens with no sexual experience.

Each participant was asked to answer "true," "false," or "I don't know" in response to the following misconceptions regarding condoms:

- When putting on a condom, it is important to have it fit tightly, leaving no space at the tip.

EXECUTIVE SUMMARY

A recent study reports that misconceptions about proper condom use are common among teens, even among those who have experience with the method.

- Teens' perceptions regarding their knowledge of proper condom use did not necessarily correspond to actual knowledge. Teens with condom experience who believed they knew correct use were no more likely to score correctly than those with sexual experience who had never used condoms or those without sexual experience.
- Sexually active adolescents need more information about correct condom use. However, reducing sexual risk behaviors may require other relational skills.

- Vaseline can be used with condoms, and they will work just as well.

- Natural skin (lambskin) condoms provide better protection against the AIDS virus than latex condoms.

Logistic regression was used to analyze the answers in relation to survey participants' age, race, gender, religious affiliation, sexual experience, experience with condoms, and perceived knowledge of condom use.

Depending on the survey participants' intercourse experience and experience using condoms, 33%-50% believed the first two misconceptions and about one-fifth believed the third one. Misconceptions were less likely among older adolescents, those ever having intercourse, those reporting four or more lifetime intercourse partners, those who had used condoms, females, and those not reporting a religious affiliation.

Teens' perceptions regarding their knowledge of proper condom use did not necessarily correspond to actual knowledge, according to the study analysis' findings. Teens with experience using condoms who believed they knew how to use them correctly were no more likely to score correct responses than those with sexual experience who had never used condoms or those without sexual experience.²

In a separate paper, Crosby et al analyzed responses from a group of sexually active African-American adolescent females.³ Study participants completed a structured interview and provided vaginal swab specimens for STD testing. Subsequent to the interview, teens demonstrated their condom application skills using a penile model. A nine-item scale assessed their perceived self-efficacy to apply condoms.

Approximately 28% of the participants tested positive for at least one STD, and nearly 26% self-reported a history of STDs. Controlled analyses reveal that the teens' self-efficacy for correct condom use was not related to their demonstrated skill. Also, their demonstrated ability was not related to any of the sexual risk behaviors. Recent experience applying condoms to a partner's penis and demonstrated ability were not related to laboratory-diagnosed STDs or their self-reported STD history.

"Adolescents may unknowingly be at risk for HIV and STD infection owing to incorrect condom application," the researchers concluded. "Further, high-demonstrated ability to apply condoms was not related to safer sex or STDs."

Sexually active adolescents need more complete information about correct condom use,

Crosby asserts. However, reducing sexual risk behaviors may require more than enhancing condom application skills; other relational skills may need to be addressed.

School and community-based programs should provide at-risk adolescents with knowledge, motivation, and skills that will lead toward the eventual adoption of condom use, says Crosby. However, there may be local constraints for these programs in teaching teens about condoms, condom use, and pregnancy/STD/HIV prevention, he notes. It is important that such programs be offered across a variety of venues so adolescents will receive education about condoms and condom use at several junctures during their formative years, Crosby states. "The recent Surgeon General's Report⁴ regarding healthy sexuality punctuates the need to provide youth with a substantial sex education program," says Crosby. "Our findings simply suggest that one aspect of these programs should include in-depth education about correct condom use: first, knowledge acquisition, then skill acquisition."

What can you do? Take the time to ask some simple questions of your teen patients, says **Ralph DiClemente**, PhD, professor of public

health and pediatrics at Emory University.

DiClemente has authored several papers on adolescent preventive behavior. **(See the story, right, for some helpful questions in discussing condom use with adolescents.)**

"This should take about two to three minutes, but you can save a life," says DiClemente. "Two or three minutes with a patient now can save you lots of hours down the road."

References

1. Crosby RA, Yarber WL. Perceived versus actual knowledge about correct condom use among U.S. adolescents: Results from a national study. *J Adolesc Health* 2001; 28:415-420.
2. Rosenberg J. Young people in the United States are often misinformed about the proper use of condoms. *Fam Plann Perspect* 2001; 33:235.
3. Crosby R, DiClemente RJ, Wingood GM, et al. Correct condom application among African-American adolescent females: The relationship to perceived self-efficacy and the association to confirmed STDs. *J Adolescent Health* 2001; 29:194-199.
4. Office of the Surgeon General. *The Surgeon General's Call to Action to Promote Sexual Health and Responsible Sexual Behavior*. Rockville, MD; 2001. ■

Ask questions to assess teens' condom knowledge

Teens may be different in many ways, but they share one common thread: They all want to know more when it comes to protecting themselves against sexually transmitted diseases (STDs). Almost a third of sexually active teens polled in a recent national survey say they want to know more about the proper way to use condoms.¹

From a practice standpoint, it might be useful for providers to assess adolescents' knowledge and misconceptions about condom use in regards to pregnancy and STD/HIV prevention, says **Richard Crosby**, PhD, STD Prevention Fellow in Behavioral Science and Health Education in Atlanta-based Emory University's Rollins School of Public Health.

"Subsequently, providers can 1) reinforce accurate knowledge; and 2) dispel any misconceptions that become apparent during this session," he notes.

What can providers do to assess their teen patients' condom knowledge? **Ralph DiClemente**, PhD, professor of public health and pediatrics at Emory University, suggests the following approach:

Ask, "Are you using condoms?" advises DiClemente. If the patient is not using condoms,

and is female, ask what birth control method is being used for pregnancy prevention, he offers.

If the teen does identify a particular method, then say, "Do you think that method offers any protection from STDs, including HIV?" If the answer is "yes", then swiftly address this major risk perception, says DiClemente. If your teen patient says condoms are being used during sex, now is the time to gauge their frequency of use, he adds.

Ask, "How frequently do you have condoms when you have sex?" instructs DiClemente. Use such questions as "Do you use condoms every time you have sex? Most of the time? Half of the occasions?" These steps will help gauge the frequency of use and make sure that it is acceptable.

Take the next step by asking, "OK, since you do use condoms, who puts them on?" Follow this question with "Has the condom ever slipped off or broken?"

The indication then may be that condoms are not being used correctly, says DiClemente. Say to the patient: "Let's try doing this. Show me the way you put a condom on this model."

Give the patient a condom, says DiClemente, and allow the patient to open the package and demonstrate on a model, such as a plastic banana or phallic replica. **(Contraceptive Technology**

Update offered a patient handout in its February 2001 issue.)

Reference

1. Kaiser Family Foundation. *National Survey of Teens on HIV/AIDS*. Menlo Park, CA; 2000. ■

STD conference scheduled for March

Make plans now to attend the 2002 National MSTP Prevention Conference March 4-7 in San Diego. The conference is cosponsored by the Atlanta-based Centers for Disease Control and Prevention and the Research Triangle Park, NC-based American Social Health Association.

The biennial conference will feature research findings, lessons learned, and challenges in preventing sexually transmitted diseases. Deadline for pre-registration is Feb. 8. For more information on the conference, accommodations, travel, and exhibits, check out the conference's web site, www.stdconference.org, e-mail queries to info@stdconference.org, or telephone (404) 233-6446. ▼

Conferences coming for *Contraceptive Technology*

Circle your calendar for the upcoming annual *Contraceptive Technology* Conferences. Two locations are provided: the Washington, DC, conference will be held March 13-16 at the Grand Hyatt Hotel, and the San Francisco conference scheduled for March 20-23 at the Hyatt Regency San Francisco.

Preconferences include "Office Gynecology: State of the Art" (Session A), which focuses on current management strategies for common GYN problems and practice guidelines for challenging gynecologic complications; "Back to Basics: The Fundamentals of Contraception" (Session B), which provides information to help patients make informed contraceptive decisions; and "Fine-Tuning Your Breast and Pelvic Exam Skills" (Session C), which features hands-on tips for improving breast and pelvic exam skills.

Conference sessions will address such issues as advances in intrauterine contraception, developments in cervical cancer screening and abnormal Pap smear management, and alternative

therapies in women's health.

The early fee deadline is Feb. 1 for the Washington, DC, conference and Feb. 7 for the San Francisco conference. To register on-line, go to the Contemporary Forums web site, www.cforums.com, click on "Current Conferences," then click on the conference of your choice. Registrants also may call in their registration information to (800) 377-7707, ext. 3, weekdays, 8 a.m.-5 p.m. (PST); fax: (800) 329-9923. ■

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CE/CME Questions

After reading *Contraceptive Technology Update*, the participant will be able to:

- Identify the dosing schedule examined in the clinical trial for the Ortho Evra contraceptive patch.
 - Name the oral contraceptive under research with a patented 84-day dosing regimen.
 - State the active ingredient in the microbicide dubbed the “invisible condom.”
 - Cite a common condom misconception among teens.
1. What is the dosing schedule examined in the clinical trial for the Ortho Evra contraceptive patch?
 - A. four consecutive seven-day patches (28 days) followed by two patch-free days
 - B. three consecutive seven-day patches (21 days) followed by one week of placebo pills
 - C. three consecutive seven-day patches (21 days) followed by one patch-free week
 - D. three consecutive seven-day patches (21 days) followed by one week of a placebo patch
 2. What is the name of the oral contraceptive now in the research pipeline which uses a parented 84-day dosing regimen?
 - A. Alesse
 - B. Lo/Ovral
 - C. Apri
 - D. Seasonale
 3. What is the active ingredient in the microbicide dubbed the “invisible condom”?
 - A. sodium lauryl sulfate
 - B. carrageenan
 - C. *Lactobacillus*
 - D. gossypol
 4. Which of the following is a common condom misconception among teens?
 - A. If you use a water-based lubricant, you may decrease the chance that the condom will break.
 - B. When putting on a condom, it is important to have it fit tightly, leaving no space at the tip.
 - C. Condoms are safe and effective at preventing pregnancy and infection when they are used during each act of intercourse.
 - D. To decrease the chance of the condom slipping down the penis or falling off in the vagina, pull the penis out of the vagina right after ejaculation.

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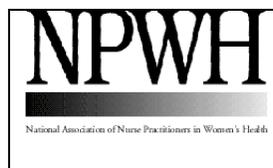
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