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1999 pill survey enclosed in this issue

INSIDE

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1999 Annual Pill Survey

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American Health Consultants® is A Medical Economics Company

Get ready: Women to have more options for preventing disease

Partnership is key to getting products into market

(Editor's note: This is the second of a two-part series. In last month's issue, Contraceptive Technology Update *presented an overview of vaginal microbicides. This month,* CTU *discusses the efforts to provide female-controlled protection and focuses on products being researched.)*

Expanding the options for preventing HIV and other sexually transmitted diseases (STDs) is more urgent than ever due to the increase in heterosexual HIV transmission. Women now account for 19% of all adult AIDS patients in the United States.[1] The rise of STDs, termed "the hidden epidemic" by leading U.S. health experts, represents a deep concern for women because complications of STDs are greater and more frequent among women than men.[2]

Vaginal microbicides offer women a self-controlled method of protection that does not require partner knowledge or cooperation. Microbicides may or may not have spermicidal properties. A microbicide that is

Free issue of *Alternative Therapies in Women's Health*

As a bonus for our readers, we are enclosing a complimentary copy of *Alternative Therapies in Women's Health,* also published by American Health Consultants. This monthly publication is a source of news and assessment of herbs, dietary supplements, and alternative therapies for women. Topics in the enclosed issue include soybean intake and bone density; chocolate addiction; a review of a textbook on herbs, *Rational Phytotherapy;* a label review of *The Essential Woman;* and clinical abstracts on candy, calcium and PMS, and chronic vaginal symptoms.

CTU readers will receive a $10 discount. You may use the order form included with the issue, or contact American Health Consultants, Customer Service, P.O. Box 71266, Chicago, IL 60691-9986. Phone: (800) 688-2421. Fax: (800) 850-1232. E-mail: customerservice@ahcpub.com. ■

EXECUTIVE SUMMARY

With the rise of the incidence of AIDS in U.S. women, there is a clear need for more options in female-controlled protection. Vaginal microbicides represent an important resource in the fight against HIV and other sexually transmitted diseases.

- Companies, scientists, and activists are joining together in the Alliance for Microbicide Development, a Takoma Park, MD-based organization designed to move microbicide products through research stages and onto market shelves more quickly.
- Research is ongoing in developing products that offer dual protection against disease and pregnancy. Formulations also are being investigated for disease prevention alone.

not also a spermicide may prevent disease but not pregnancy.[3]

While there are several promising leads in the research and development pipeline, no one product has yet made it to the market shelves. Several companies, scientists, and advocates have banded together to form a consortium, the Alliance for Microbicide Development, based in Takoma Park, MD. The group is focused on improving the efficiency of pre-clinical development processes, tracking product progress through research and development, providing information to the public and policy groups, and fostering the building of a funding base to support combination and comparative studies.

Some 27 biopharmaceutical companies, 10 research entities, eight advocacy groups, and several consultants have joined the alliance, reports its director, **Polly Harrison**, PhD. "We want to get the pipeline unblocked," she says. "There is a serious need for these products."

The term "microbicides" serves as an umbrella for a wide variety of products. By definition, microbicides are substances that destroy or incapacitate infection-causing organisms, including bacteria, viruses, and parasites. Some preparations are combining spermicides such as nonoxynol-9 (N-9) or octoxynol-9 in carriers such as a gel, foam, cream, film, or suppository. Others represent novel approaches such as an acid-buffering gel or viral inhibitors.

Researchers are examining use of these products as both a spermicide and microbicide, offering dual prevention against both pregnancy and disease. Investigation also is focusing on use of these products as stand-alone microbicides for women who need disease protection but desire to have children, or for men who have sex with men.

Following is an overview of some of the products in the pipeline, with a focus on those that may offer prevention against both pregnancy and HIV / STD:

❑ **Buffer for protection**

BufferGel is a polymeric gel developed by three Baltimore-based Johns Hopkins University researchers who formed ReProtect LLC to bring the product to market. An extensive Phase I safety trial has been successfully completed in Providence, RI, reports **Richard Cone**, PhD, professor of biophysics at Johns Hopkins and managing director of ReProtect. The trial was sponsored and performed by HIVNET, the HIV Network for Prevention Trials coordinated through the National Institutes of Health in Bethesda, MD.

HIVNET is now pursuing additional Phase I tests of BufferGel at four international sites, says Cone. If the product is found safe for women to use at these international sites, HIVNET will decide whether to pursue Phase II tests of BufferGel for preventing common STDs. If BufferGel is shown to be effective in Phase II trial, HIVNET might proceed to the much larger trials needed to test whether BufferGel is effective against HIV infections.

BufferGel is formulated at pH 4, the same mild acidity as the healthy vagina, explains Cone. It has sufficient buffer capacity to acidify semen, thus helping to maintain the protective acidity of the vagina. Mild acidity rapidly kills sperm, syphilis, and white blood cells, which may be motile vectors for transmitting HIV and other STDs, says Cone. The same acidity more slowly kills STD pathogens, including HIV, herpes simplex virus, chlamydia, and gonorrhea.

COMING IN FUTURE MONTHS

- ■ Vaginal vitamin for disease protection
- ■ Examining a four-periods-per-year pill
- ■ Natural family planning makes its mark
- ■ Tailoring HRT to your patients
- ■ Monitoring DMPA discontinuation rates

BufferGel is being evaluated as a stand-alone product, as well as serving as a pre-coating to a disposable barrier device, such as a diaphragm or cervical cap, for further protection enhancement.

❑ **Surfactants in review**

BioSyn, a Philadelphia-based company, is working with its C31G technology in looking at HIV, STD, and pregnancy prevention. The company's technology rests on a family of molecules that attaches to the surface of bacteria, yeast, and enveloped viruses such as HIV and rapidly inactivates them, says **Daniel Malamud**, PhD, professor of biochemistry at the University of Pennsylvania and BioSyn's vice president of research and development.

The C31G technology is in two Phase I human clinical tests: one a safety and efficacy trial, and the other an irritation study to ensure there are no untoward effects on mucosal tissues, Malamud says. Because the C31G material is active against a variety of pathogens, BioSyn plans to evaluate it against a series of STDs, including HIV, says Malamud.

❑ **Inhibiting viral entry**

PRO 2000 Gel is a synthetic colorless, odorless polymer with high thermal stability developed by Procept, based in Cambridge, MA. Company vice president **Al Profy**, PhD, says PRO 2000 coats HIV and prevents it from infecting susceptible cells. It also seems to coat the head of the sperm and prevent fusion with the egg, he notes.

Pre-clinical in vitro studies have shown that PRO 2000 can block infection by HIV, herpes simplex virus type 2 (HSV-2), and chlamydia. During in vivo studies, PRO 2000 Gel was shown to provide complete protection against vaginal HSV-2 infection in mice.

Two Phase I clinical trials were conducted at the Institute of Tropical Medicine in Antwerp, Belgium, and at St. Mary's Hospital in London, with funding from the British Medical Research Council. Those trials showed that daily use of PRO 2000 Gel was safe and well-tolerated, Profy says, and participants found the product aesthetically acceptable. A study funded by the National Institutes of Health to assess all potential uses of the product, including STD prevention and contraception, is slated to begin this year, he says.

❑ **An 'invisible condom'**

The Infectious Diseases Research Center at Canada's Laval University in Sainte Foy, Quebec, has developed a nontoxic polymer-based liquid that solidifies into a gel when applied to the body. Dubbed the "invisible condom," the gel, which forms a waterproof film, reduced transmission of HIV and the HSV-2 in laboratory and animal tests.

Plans are to study the material for protection against STDs and pregnancy, says **Michel Bergeron**, MD, FRCP, director of the Laval University's division of microbiology and the Infectious Diseases Research Center. Clinical research should begin in the fall, with approval sought in worldwide markets. The center is negotiating with major companies to bring the product to market, Bergeron says.

❑ **Novel compounds eyed**

The Hughes Institute in Roseville, MN, has received funding from the National Institutes of Health to develop two novel compounds in products that will provide HIV and pregnancy prevention. The two compounds, aryl phosphate derivatives of bromo-methoxy-azidothymidine, show powerful spermicidal and microbicidal effects when tested in hamsters and mice.[4] Researchers say the compounds may be useful as dual-function vaginal contraceptives for women who are at high risk for contracting HIV. (Research is examining the use of spermicides such as nonoxynol-9 in new carrier agents**. Read more about these products on p. 40.**)

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RESOURCE

For more information on the Alliance for Microbicide Development, contact:

Polly Harrison, PhD, Director, or **Gretchen Kidder**, Research Associate, Alliance for Microbicide Development, 6930 Carroll Ave., Suite 830, Takoma Park, MD 20912. Telephone: (301) 270-5924 or 5925. Fax: (301) 270-5926. E-mail: pharriso@aol.com or ggkidder@aol.com.

Spermicides examined in microbicide research

Spermicides such as nonoxynol-9 (N-9) are being examined as researchers explore development of vaginal microbicides. A nonionic detergent, N-9 is familiar to family planners in its use in over-the-counter spermicide preparations. Used as a contraceptive for decades, N-9 was grandfathered into federal Food and Drug Administration regulations under the monograph process.

Questions continue to swirl around N-9 use, and the push is on for definitive answers. Epithelial disruption could be affected by the dose, delivery system, or frequency of use of N-9.[1] In the laboratory, N-9 is lethal to organisms that cause gonorrhea, genital herpes, trichomoniasis, syphilis, and HIV.[2] However, findings from human studies have been inconsistent, say authors of the chapter on vaginal spermicides in *Contraceptive Technology*.[3]

Research disappointment and hopes

The most recent study reported that the use of an N-9 vaginal film (manufactured by Apothecus Pharmaceutical Corp. of Oyster Bay, NY) did not reduce the rate of new HIV, gonorrhea, or chlamydia infection in a group of sex workers who used condoms and received treatment for sexually transmitted diseases.[4] The double-blind, placebo-controlled study included 1,292 HIV-negative female sex workers in Cameroon who were randomly assigned to use a film containing 70 mg of N-9 or a placebo film, inserted into the vagina before intercourse. Participants also were offered condoms.

As pointed out in *Contraceptive Technology Update*'s lead article last month, the definitive answer on N-9 has yet to appear. In different formulations or different strengths, the spermicide may provide the level of safe, effective protection needed in a vaginal microbicide. In the meantime, researchers are exploring its use, along with other spermicides, as an effective female-controlled protection product.

Novavax, with offices in Columbia and Rockville, MD, has developed a chemical delivery system that give its products the look and feel of cosmetics rather than gel, says **Craig Wright**, MD, an infectious disease specialist and founder of the company. Novavax is examining the use of its non-phospholipid lipisome technology with several different types of spermicides and microbicides, says Wright. The National Institutes of Health (NIH) in Bethesda is funding Phase I research of two products: one with a 4% concentration of N-9, and a second with a combination of octoxynol-9 and tributyl phosphate.

New use for familiar substance

The Center for Biomedical Research at the Population Council in New York City has performed lab tests on a compound derived from red seaweed, combined with N-9, an effort to develop a spermicide that will protect against HIV and pregnancy. The compound, carrageenan, is used in such food products as ice cream and soup. It does not kill microbes, but it averts infection by binding to the surface of such viruses as HIV and prevents the microbes from adhering to cells.

Population Council researchers have developed a carrageenan gel that is effective over a wide pH range, retains its properties at high temperatures, and remains effective for hours in the vagina. It is not absorbed by the body, so researchers say it should not cause any systemic effects. The council's researchers have tested the carrageenan / N-9 formulation vaginally in mice against herpes simplex virus-2. They also have examined carrageenan alone and in tandem with N-9 in rectal studies in mice.

Combining spermicides

A novel gel formulation containing low amounts of two spermicides, octoxynol-9 and benzalkonium chloride, is being evaluated for contraceptive and STD protection. According to **Stephen Hayter**, president / CEO of Empyrean Bioscience in Phoenix, in vitro studies show the formulation to be effective in killing HIV, herpes, hepatitis B, syphilis, gonorrhea, chlamydia, and trichomoniasis. In vivo safety studies also show the product will not cause vaginal or urethral irritation.

The ingredients act in synergy to attack HIV, an enveloped virus, explains Hayter. Octoxynol-9 attacks the envelope itself, reduces the surface tension, and allows the benzalkonium chloride to enter and destroy the virus.

He says the product, called Preventx, is scheduled to enter a Phase III trial funded and conducted by the National Institutes of Health's National Institute of Allergy and Infectious

Diseases. The first part of the trial will determine the product's effectiveness in stopping pregnancy and halting the transmission of chlamydia and gonorrhea, with the second portion to focus specifically on HIV and other STDs.

The Advantage-S bioadhesive contraceptive gel, developed by Columbia Laboratories of Miami, consists of a patented bioadhesive carrier system and 52.5 mg of N-9. Family planners may remember this product as Advantage-24. **(See *CTU,* April 1995, p. 45.)** A Phase III clinical study sponsored by UNAIDS began in May 1996 to test the Advantage-S formulation in the prevention of HIV and STDs in about 2,000 women. The NIH is performing similar testing in Africa.

Protectaid, marketed in Canada by Axcan Pharma in Mont-Saint-Hilaire, Quebec, Canada, is being considered as a vaginal microbicide. The product is a vaginal sponge containing low levels of N-9 and benzalkonium chloride. Researchers also are looking at pre-coating such barrier devices as diaphragms and cervical cap with spermicide for use in female-controlled STD protection.

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FDA approval sought for frameless, flexible IUD

The options for intrauterine devices (IUDs) in the United States may be expanded as a Belgian company plans to seek federal Food and Drug Administration (FDA) approval of a frameless, flexible IUD.

Contrel, based in Knokke-Heist, Belgium, is preparing an Investigational New Drug application to initiate studies for FDA approval of its GyneFix IUD, according to **Dirk Wildemeersch**, MD, Contrel's founder and chairman. The GyneFix is available in Austria, Belgium, France, Hungary, the Netherlands, People's Republic of China, Spain, Switzerland, and the United Kingdom.

Other IUDs already on U.S. market

Two IUDs are now available to U.S. women: the ParaGard TCu 380A from Ortho-McNeil Pharmaceutical of Raritan, NJ, and the Progestasert from Alza Pharmaceuticals of Palo Alto, CA.

The ParaGard is a T-shaped IUD with copper bands wrapped around the arms and copper thread wound around its stem. The Progestasert, also a T-shaped device, releases small amounts of progesterone from its built-in reservoir.

The design of the GyneFix differs from the ParaGard and the Progestasert in design and implantation. The device consists of six copper sleeves on a non-biodegradable surgical nylon thread. A knot in the upper extremity of the thread serves as an anchor. It's implanted into the fundal myometrium with a specially designed insertion instrument. By suspending the copper sleeves on suture material, the Gynefix device is designed to reduce the problems with expulsion and removal for pain or bleeding that have been associated with the plastic frame of conventional IUDs.

The clinical development of GyneFix began in the 1980s by gynecologists working at the University of Ghent, Belgium. The group, led by Wildemeersch, published preliminary results on the device (then known as the Copper-Fix or Cu-Fix IUD) in 1988.[1] The Special Programme of Research, Development, and Research Training

EXECUTIVE SUMMARY

Manufacturers of the GyneFix frameless, flexible intrauterine device (IUD) are seeking federal Food and Drug Administration approval of the device.

- GyneFix consists of six copper sleeves on a non-biodegradable surgical nylon thread. A knot in the upper extremity of the thread serves as an anchor. It is implanted into the fundal myometrium with a specially designed insertion instrument.
- Failed insertions due to shortcomings of the IUD's inserter have been noted in earlier studies. The inserter now has been modified to eliminate such problems, according to the manufacturer. As with all IUDs, proper training is essential for proper placement.

in Human Reproduction of Geneva, Switzerland, initiated a multicenter randomized comparative trial of the Cu-Fix (FlexiGard) and the TCu 380A in 1989.

Interim results from the multinational trial were published in 1995.[2] The three-year pregnancy rates for the two devices were similar (1.6 and 1.9 per 100 women, respectively), but the FlexiGard's three-year expulsion rate was 7.4 women per 100, compared with the TCu 380A's rate of 4.4 per 100 women.

There were 2,184 successful insertions of the TCu 380A, and 2,102 of the FlexiGard, but researchers reported 53 insertion failures for the FlexiGard and only one for the TCu 380A. If the FlexiGard's nylon thread was not properly implanted in the fundal myometrium, it could be inadvertently removed when providers withdrew the inserter tube or expulsed a few weeks after implantation, researchers surmised.

Comparing effectiveness

A separate randomized international two-year clinical trial also compared the TCu 380A and the Cu-Fix.[3] It found that while both IUDs provide highly effective protection against pregnancy, the TCu 380A had a lower expulsion rate.

Wildemeersch and his colleagues modified the insertion technique and inserter tube and reported an improved rate: two insertion failures in 527 attempts (0.4%) in a multicenter trial, compared with the 2.5% rate in the HRP trial.[4]

While the GyneFix implant is the same as the Cu-Fix and the FlexiGard, its insertion system has been enhanced for easier use and greater reliability, thereby reducing the number of failed insertion rates, says Wildemeersch. "Failed insertion due to shortcomings of the FlexiGard inserter was a major problem in the FlexiGard studies. This problem is now solved."

Training important step

Training is an important component of proper insertion of the GyneFix, observes **Michael Rosenberg**, MD, MPH, clinical professor of obstetrics/gynecology and epidemiology at the University of North Carolina and president of Health Decisions, a private medical research firm, both in Chapel Hill. He served as head of the second multinational study of the device. Just as women who use oral contraceptives well have considerably better success with the method than women who do not, individuals well-trained in the insertion and anchoring of the GyneFix can do much better with training than those who are not, Rosenberg says.

Providers at the Margaret Pyke Family Planning Centre in London have been inserting GyneFix for about 18 months, reports its medical director, **John Guillebaud**, MA, FRCSE, FRCOG, MFFP. He also sees training as an important component to proper insertion of the device.

Guillebaud says the GyneFix seems to share practically all the strengths of the TCu 380 PLUS, and it offers a reduced expulsion rate. It removes the possibility of frame-related pain and reduces the risk of malpositioning within the uterus, he says. Good training is essential, however, for proper placement of the device, he says.

Contrel continues to work with designers in further modifying the inserter, which should further reduce the learning curve for providers, Wildemeersch says.

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RESOURCES

For more on intrauterine devices (IUDs), contact:

Contrel (Gynefix IUD) in Belgium. E-mail: Gynefix @innet.be. World Wide Web: http://www.gynefix.com.

Ortho Pharmaceutical Corp. (ParaGard T380A IUD), Medical Affairs, P.O. Box 300, Raritan, NJ 08869. Telephone: (800) 682-6532. World Wide Web: http://www.ortho-mcneil.com.

Alza Pharmaceuticals (Progestasert IUD), Medical Information, 950 Page Mill Road, P.O. Box 10950, Palo Alto, CA 94303-0802. Telephone: (800) 634-8977. World Wide Web: http://www.alza.com.

Further insight gained on impact of OC use

A cohort study of 46,000 British women, half of whom were using oral contraceptives (OCs), gives family planners further insight into the long-term effects of pill use.[1] The study shows that OCs seem to have their main effect on mortality while they are being used and in the 10 years after stopping use.

Ten or more years after stopping use, mortality rates were similar in past users and never-users. There is little evidence to suggest any persistent adverse effect 10 or more years after women stop OC use, researchers conclude.

Robert Hatcher, MD, MPH, professor of OB/GYN at Emory University in Atlanta and lead author of *Contraceptive Technology*, terms the findings "good news."

"The study showed that there were no causes of death that were increased in women who quit pills more than 10 years ago, which is great," he notes.

Implications of the study

Although this study provides confidence that long-term OC use does not increase mortality, further investigation is needed in regard to pill use and cause-specific mortality, notes **Andrew Kaunitz**, MD, professor and assistant chair of the department of obstetrics and gynecology at the University of Florida Health Sciences Center in Jacksonville.

The study is a 25-year follow up of women enrolled in the Manchester, England-based Royal College of General Practitioners' OC study. Set up in 1968 to monitor the health of OC users, the study recruited 23,000 women who were using the Pill and a similar number of never-users. General practitioners were asked to provide information on the type of OC prescribed, pregnancies, new illness, or death for each woman every six months. Most of the women who used the Pill used combined OCs with 50 mcg estrogen.

By December 1993, the cohort had been followed for 25 years, and the median age of the women was 49. During that period, 1,599 deaths were reported, with 945 deaths occurring in those women who had ever used OCs and 654 in never-users. Over the entire period, the risk of death from all causes was similar in women who had used the Pill and those who never had, and the risk of death for most specific causes did not differ significantly between the two groups.

Looking at risks

Among current users and recent users (those who had used within 10 years), the relative risk of death from ovarian cancer was 0.2; from cervical cancer, 2.5; and from cerebrovascular disease, 1.9. For women who had stopped using the Pill 10 or more years previously, there were no significant excesses or deficits either overall or for any specific cause of death, the researchers report.

"My concern with this study it does not have the statistical power to analyze cause-specific mortality," notes Kaunitz. "For instance, there were not enough cases of fatal ovarian or cervical cancer to draw meaningful inferences [regarding] the impact of OC use on fatalities from these two malignancies."

When family planners look to determine the impact of OCs on certain conditions such as malignancies, epidemiologic case-control studies that include large numbers of incident cases of a given malignancy offer a better understanding, Kaunitz suggests.

Hatcher points to a comprehensive review and re-analysis of 54 studies that represent 90% of the world's data on the subject. The re-analysis showed current OC users at a 24% increased risk for having breast cancer diagnosed. One to four years after discontinuing pills, the risk falls to 16%, and after five to nine years, the risk drops to 7%. More than 10 years out from stopping pill use, women are at no significantly increased risk. **(For further information on the study, see *Contraceptive Technology Update*, December 1996, p. 147.)**

EXECUTIVE SUMMARY

A large 25-year follow up of British women shows that oral contraceptives seem to have their main effect on mortality while they are being used and in the 10 years after stopping use.

- Ten or more years after stopping use, the study showed that mortality was similar in past users and never users.
- There is little evidence to suggest any persistent adverse effect 10 years after women stop taking the Pill.

Use this analogy developed by British family planner John Guillebaud, MA, FRCSE, FRCOG, MFFP, director of the Margaret Pyke Family Planning Centre in London, to explain risks to women, Hatcher suggests:

Imagine two halls, each holding 1,000 women who are age 45. In one hall, none of the women has ever used the Pill. In the other hall, all the women used the pill until age 35, 10 years ago. What would be the risks for breast cancer among the women in the two halls?

In the hall with never-users of OCs, 10 women would be diagnosed with breast cancer. In the other hall, 11 women — just one more — would be diagnosed with the disease. Moreover, the remaining 989 past pill-using women have the same risk for the disease from now on as those who never used the Pill.

"This is reassuring to millions of women who took the pill in the past," write Hatcher and Guillebaud in *Contraceptive Technology*.[3] "In addition, the cancers diagnosed in women who use or who have ever used OCs are less advanced than those who have never used the pill and are less likely to have spread beyond the breast."

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Two programs designed to support condom use

Advertise condoms and increase accessibility

Are you arming your patients with condoms for protection against HIV and other sexually transmitted diseases (STDs)? Providing condoms in the clinical setting is important, but community accessibility to condoms and safer sex information also plays an important role in the fight against what public health experts have termed "the hidden epidemic."

The annual National Symposium on Overcoming Barriers to Condom Use, scheduled this year for June 1-2 in New York City, covers advertising, social marketing, technical advances, testing, and regulation. **(See resource listing, p. 45, for symposium contact information.)** Participants from organizations throughout the world share strategies for increasing condom use in a variety of populations.

Interested in casting a wide net for condom availability? Take a look at how the following two programs participating in the 1998 symposium have worked to make condoms an accepted norm in their communities.

EXECUTIVE SUMMARY

Family planners can examine how two organizations use effective strategies to make condoms available to specific populations.

- The health enhancement services division of the university health service at Northern Illinois University in Dekalb makes condoms easily accessible; their use is an accepted norm on campus.
- ABCD Health Services in Boston expanded its contraceptive availability network in 1997 to include hair salons serving Hispanic women and promotes safer sex messages in in-home "Safety Net" parties.

Northern Illinois University, DeKalb: Condoms go to college

"How do you compare to a typical NIU student?" asks an advertisement developed by the health enhancement services division of the university health service at Northern Illinois University in Dekalb. The ad points out that most students practice healthy behaviors that allow them to be safe in their campus activities. One such behavior? More than half of all students use condoms for STD protection during intercourse.

In 1989, only 30% of Northern Illinois students surveyed indicated they used condoms always or mostly during sex. About 2,500 visits for STDs were logged at the student health center. By 1997, 61% of students reported they used condoms always or mostly during sex. Rates for chlamydia

rates and gonorrhea were down by 50%.

Why such a dramatic drop? "We firmly believe that the increased use of condoms is due almost entirely because of how available we have made condoms, as well as the perception that everybody is using them," says **Michael Haines**, MS, coordinator of health enhancement services at Northern Illinois' university health service. "We think that the availability and the social norm play off of each other."

When condoms were first made available on a large scale at the university, they were distributed through the pharmacy. Condoms now are readily accessible throughout the campus, including the wellness resource center, recreation center, and the three waiting rooms at the health service. Large quantities of condoms are signed out to residence hall advisors, Greek organizations, and other groups, says **Steven Lux**, MS, a health educator. Group leaders must sign a condom policy and accessibility agreement, noting that condoms are not to be distributed but only made available in a free-choice access method along with printed health education information.

A 1996 campus survey contained questions that allowed comparison of students' own condom use with their perception of condom use by other students. Health educators noted a significant positive correlation between student perceptions of other students' condom use and their own condom use, notes Haines.

The safer image

Condom use now is an accepted norm on the Northern Illinois campus. That message is continually reinforced with media (such as the student newspaper ad) and other forms of education. Health educators have developed "Info-Packs" with educational handouts and condoms for students who wish to do a presentation on preventing STDs or condom use in their speech, health, or women's studies classes. The packs contain a "do-it-yourself" outline that helps students present an educational message to their peers.

RESOURCE

For more information on the National Symposium on Overcoming Barriers to Condom Use, contact:

Pharmacists Planning Service, 101 Lucas Valley Road, Suite 210-E, San Rafael, CA 94903. Telephone: (415) 479-8628. Fax (415) 479-8608. E-mail: PPSI@aol.com.

ABCD Health Services, Boston: Reaching Hispanic women

Want to reach more women with a safer sex message? ABCD Health Services in Boston expanded its contraceptive availability network in 1997 to include hair salons serving Hispanic women.

The hair salons are among many of ABCD's efforts to make condoms more accessible to all segments of the population, says **Irvienne Goldson**, education and training manager. Condoms are distributed at no charge to such diverse businesses as barber shops and auto body shops on a regular basis. By consistently replenishing supplies and providing an assortment of condom selections, community members begin to rely on the businesses as condom resources, with more than 11,000 condoms now distributed each month.

Teaching the message

Education plays a large part in broadcasting the safer sex message. ABCD health educators have made presentations in hair salons as well as at community organizations, and they now take the message home through "Safety Net" parties. State funds have been made available to train community women as facilitators and hostesses for the in-home events.

Safety Net parties cover such issues as substance abuse, female anatomy and physiology, reproductive health, and STDs, all presented in a relaxed atmosphere.

Participants play a variety of games that help convey the safer-sex message. One game, called "high risk / low risk / no risk," uses flashcards with such beliefs as "trust" and "inability to talk to a partner" written on them. In talking about whether a card represents high, low, or no risk, women are able to deal with several issues, says Goldson.

At the end of the party, each participant receives a safer-sex bag, an attractive container with both male and female condoms.

Making presentations in the salons presents challenges because educators must be able to present information without interrupting hair appointments, Goldson says. Educators are evaluating use of a short video that can be shown between weekly presentations, she notes. ■

Expanding the use of no-scalpel vasectomies

The first-ever estimate of the extent of use of no-scalpel vasectomy (NSV) shows that within 10 years of its U.S. introduction, the technique for male sterilization accounts for about 29% of the vasectomies performed nationwide on an annual basis.[1]

No-scalpel vasectomy eliminates the need to make a surgical incision in the scrotum to reach the vas deferens, is less painful, heals more quickly, and has fewer complications. The American introduction of the NSV technique, which was developed in China, was pioneered in 1988 by AVSC International, a New York City-based nonprofit reproductive health care advocacy group. **(For more details, see *Contraceptive Technology Update*, March 1998, p. 29.)**

No-scalpel vasectomies now have become an accepted option in urologic care, according to the national study conducted by AVSC, the School of Public Health and Tropical Medicine at the New Orleans-based Tulane University Medical Center, and the Division for Reproductive Health at the Atlanta-based Centers for Disease Control and Prevention. What has led to this acceptance?

"I think the reasons are due to physicians finding out about it [NSV] and realizing the benefits of it, compared with traditional incisional vasectomy," says **Jeanne Haws**, MPA, senior director at AVSC. "Also, consumer demand helped fuel physician interest, with articles appearing in such varied venues as *McCall's, Men's Health, Playboy,* and *Newsweek* magazines and generating interest."

EXECUTIVE SUMMARY

No-scalpel vasectomies have been rapidly accepted by U.S. providers since their introduction in the nation some 10 years ago. Almost a third of all male sterilization procedures were performed using the technique in 1995, the most recent year for which data are available.

- No-scalpel vasectomy eliminates the need to make a surgical incision in the scrotum to reach the vas deferens, is less painful, heals more quickly, and has fewer complications.
- Advanced practice providers have received training in the method. Ability to integrate the procedure within a provider's scope of practice varies by state.

The study, a retrospective mail survey with telephone follow-up, included 1,800 urology, family practice, and general surgery practices drawn from the Chicago-based American Medical Association's Physician Master File. In 1995, the most recent year for which data are available, about 494,000 vasectomies are estimated to have been performed by 15,800 U.S. physicians. Urologists performed 76% of the vasectomies, with 15% by family practitioners, and 9% by general surgeons.

No-scalpel vasectomies represent 29% of the vasectomies performed in 1995. Urologists and family practitioners were equally likely to adopt the technique. Despite admonitions from trainers and others that the technique should be learned from another provider, more than a third of the physicians who used NSV reported they taught themselves the procedure.

AVSC continues to offer training, made possible through a grant from the David and Lucile Packard Foundation of Los Altos, CA, to providers working in state or county health departments or public-sector clinics. (**State health administrators interested in getting training for individuals in their state should check the resource box on p. 47 for more information.** Private-sector physicians or others interested should refer to the AVSC Web site, http://www.avsc.org, for information on providers offering NSV who may be willing to train them in the procedure.)

Advanced-practice use

Advanced-practice providers such as nurse practitioners and physician assistants also have received training in the no-scalpel technique. **John Riley**, PA-C, co-medical director of the Anchorage (AK) Neighborhood Health Center, says he pursued NSV training because he wanted to expand the availability to those lower-income patients who might not otherwise have access to the procedure. Riley has performed about 30 procedures since he received training in 1997. A physician also performs NSV at the Center.

The Health Center is the only Anchorage family practice clinic offering a sliding fee scale, Riley notes. It provides a full range of medical services for men and women, including preventive care, family planning, treatment of sexually transmitted diseases, and care of acute and chronic illness. "We advertise the availability of sliding fee charges for NSV, and a person with income below the federal

poverty level can get the procedure done for as little as $65," he says. "The NSV method has proven to be very popular with patients, and several come in asking for it by name."

Daryl Young, RN, ANP, MS, the director of student health services at the University of Alaska in Anchorage, also has put NSV training into practice. He offers the services at the student health center and the local Planned Parenthood clinic. He has performed 28 procedures since his 1997 training.

Much preparation went into establishing the service. He sought backup from local urologists and made a presentation to the state nursing board to add NSV to his scope of practice. Young says he carefully evaluates each patient who wants to be a NSV candidate and performs post-vasectomy sperm counts to ensure the effectiveness of the procedure.

Both providers received their training through a joint effort coordinated by AVSC, the National Association of Nurse Practitioners in Reproductive Health, based in Washington, DC, and Region X of the U.S. Public Health Service in Seattle. Candidates were screened and evaluated, notes **Chris Knutson**, CRN, ARNP, MN, a nursing care consultant with the Washington public health department in Olympia who worked with the project.

No-scalpel vasectomy definitely is not an entry-level skill, Knutson stresses. Providers who are experienced and procedure-oriented have better success with the technique, she notes.

Reference

1. Haws JM, Morgan GT, Pollack AE, et al. Clinical aspects of vasectomies performed in the United States in 1995. *Urology* 1998; 52:685-691. ■

RESOURCE

For more on no-scalpel vasectomy, contact:

AVSC International, 79 Madison Ave., New York, NY 10016. Telephone: (212) 561-8000. Fax: (212) 779-9439. E-mail: info@avsc.org. Web: www.avsc.org. The Web site offers easy-to-read information on conventional and no-scalpel vasectomy methods and features a state-by-state list of providers who offer no-scalpel vasectomies. If you provide no-scalpel vasectomies and wish to be included on the list, contact Maureen McKenzie, training programs administrator, at (212) 561-8094. E-mail: mmckenzie@avsc.org. Or write to her at the above address.

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NEWS BRIEF

Get women's health info via telephone, Internet

Providers seeking women's health information may be interested in these two Internet sites:

• The U.S. Public Health Service offers the National Women's Health Information Center, a combination Web site and toll-free hotline. The site, www.4woman.gov, has a database and links to more than 1,000 federal agencies, publications, and hundreds of government-screened private sector organizations related to women's health. The bilingual hotline, (800) 994-WOMAN, connects callers to health information specialists and allows them to order fact sheets and brochures.

• Health educators looking for brochures on HIV/STD prevention, abstinence, and other issues should check out www.journeyworks.com, offered by Journeyworks Publishing of Santa Cruz, CA. To request a catalog of brochure titles, visit the Web or contact: Journeyworks Publishing, P.O. Box 8466, Santa Cruz, CA 95061-8466. Telephone: (800) 775-1998 or (831) 423-1400. Fax: (831) 423-8102. ■

CE objectives

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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 story, p. 41.)**

• Describe how those issues affect service delivery and note the benefits or problems created in patient care in the participant's practice area. **(See story, p. 46.)**

• Cite practical solutions to problems and integrate information into daily practices, according to advice from nationally recognized family planning experts. ■

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