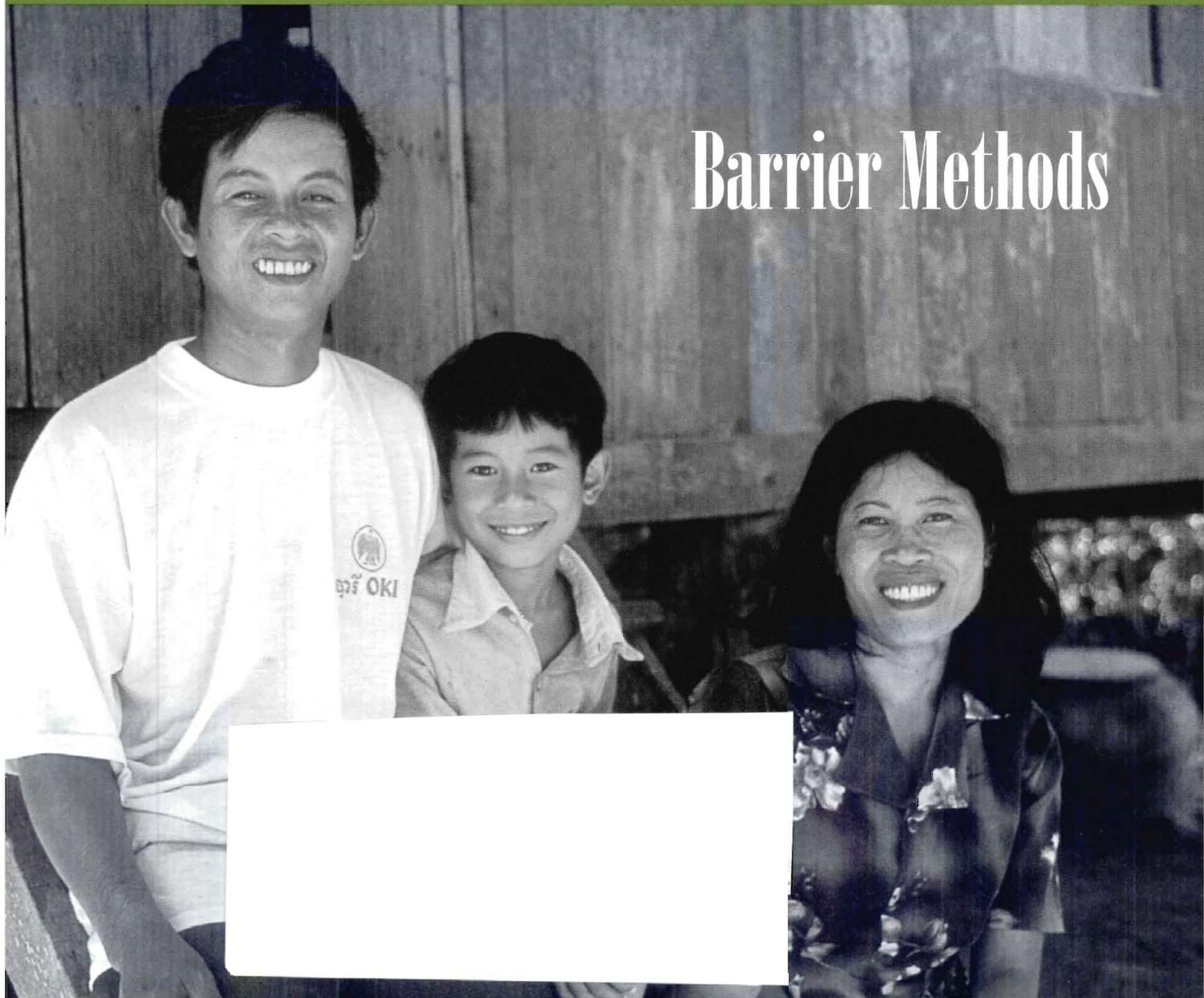


Network

FAMILY HEALTH INTERNATIONAL, VOLUME 22 NUMBER 4, 2003

Barrier Methods



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Barrier methods are just one of many contraceptive options from which couples can choose. A family from Banan District, Cambodia, enjoys a quiet moment, in the cover photograph by Richard Lord.

Network is published quarterly in English, Spanish, and French by Family Health International and is distributed without charge. Periodicals postage is paid at Durham, NC and additional mailing offices. POSTMASTER: Send requests, queries, and address corrections to:

Network

Family Health International
P.O. Box 13950
Research Triangle Park, NC 27709 USA

To obtain a free subscription, please write to the Publications Coordinator at the above address.

Phone: (919) 544-7040
Fax: (919) 544-7261
Web site: <http://www.fhi.org>

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Family Health International is a nonprofit research and technical assistance organization dedicated to contraceptive development, family planning, reproductive health, and AIDS prevention around the world.

Network is supported in part by the U.S. Agency for International Development. The contents do not necessarily reflect FHI or USAID policy.



ISSN 0270-3637
USPS 696-610

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Printed on recycled paper

The “ABC to Z” Approach

Condoms are one element in a comprehensive approach to HIV/STI prevention.

By Willard Cates, Jr., MD, MPH
President, Institute for Family Health, Family Health International

Male condoms — when used consistently and correctly — are an effective means of preventing HIV infection, gonorrhea (in men), and unplanned pregnancy among people who are sexually active and need to protect themselves. Both a consensus report issued by the U.S. National Institutes of Health (NIH) in 2001 and a fact sheet released by the U.S. Centers for Disease Control and Prevention (CDC) in 2002 have recognized these facts.¹

Nonetheless, some observers continue to question the inherent effectiveness of male condoms.² Others downplay condoms as an HIV prevention strategy by exaggerating “condom failure,” as measured by breakage and slippage rates. Because the most important factor affecting condom failure is non-use³ — not breakage or slippage — this negative interpretation might discourage condom use and thus enhance the spread of sexually transmitted infections (STIs).

Amidst these polarized views, we can craft a constructive middle ground to answer two basic questions:

- Are condoms effective against STIs?
- If so, what is the appropriate role of condoms in strategies to prevent HIV and other STIs?

The first question involves generating a common interpretation of data on condom effectiveness. The NIH consensus report and the CDC fact sheet are clear in

this regard: If used consistently and correctly, male condoms provide protection against HIV (the most serious STI), gonorrhea (the most easily transmitted STI), and unintended pregnancy. Depending on the meta-analysis or model used to study condom effectiveness, consistent use reduces HIV incidence by at least 80 percent and perhaps as much as 97 percent.⁴ For protection against unintended pregnancy, condoms are 86 percent to 97 percent effective, depending on whether use is typical or ideal, respectively.⁵ The scientific evidence to support these conclusions is not complete, but it is strong and consistent enough to produce the solid public health recommendation that *condoms work*. Most HIV/STI transmission or pregnancy risks likely occur because of condom non-use or inconsistent use.⁶ To maximize the consistent use of condoms in sexually active populations with a high prevalence of HIV/STIs, public health messages must reinforce and communicate in an unequivocal way the positive news on condom effectiveness, especially for dual protection (against both pregnancy and STIs).

Do we need to conduct more research to clarify condom effectiveness against STIs other than HIV? I would argue “no.” The simple fact that condoms are effective against unplanned pregnancy and HIV infection will remain the most compelling reason to use them, regardless of any additional protection they may provide. Meanwhile, it is important to recognize

that the *absence of evidence* that condoms provide such additional protection is not *evidence of absence* of protection. Given the physical properties of male latex condoms, it is reasonable to assume that they can be effective against any STI spread by the exchange of body fluids.

Having established that condoms are effective in reducing unplanned pregnancy and HIV infection, we must also acknowledge that they do not work perfectly. What then is the appropriate role of an imperfect prevention method, like condoms, among strategies to reduce HIV spread? Those using various approaches to preventing HIV, as well as other health conditions, recognize that incremental, partially effective steps work best to produce collectively effective (but not perfect) prevention programs.⁷ Controlling the spread of STIs will require different, mutually reinforcing techniques.

Although these combined prevention strategies can dramatically affect HIV spread,⁸ they need to be carefully designed and implemented. Accurate messages about condoms must build on (and not substitute for) a wide range of HIV/STI risk avoidance and risk reduction approaches.⁹ These approaches include delayed initiation of sexual intercourse, mutual faithfulness, and selection of low-risk partners. In Uganda, these approaches, together with condoms, have been labeled the “ABC strategy”: abstinence, be faithful to one partner, or — if “A” or “B” cannot be achieved — use



GETTY IMAGES

CONDOM USE BY SEXUALLY ACTIVE INDIVIDUALS HELPS PROTECT AGAINST SEXUALLY TRANSMITTED INFECTIONS BUT IS JUST ONE OF SEVERAL APPROACHES TO PREVENTION. ANOTHER APPROACH THAT IS APPROPRIATE FOR MANY COUPLES IS ABSTINENCE AND, LATER, FAITHFULNESS TO ONE PARTNER IN A MONOGAMOUS RELATIONSHIP.

condoms. This ABC approach defines an appropriate role for condoms as an essential part of a larger armamentarium for HIV prevention. Notably, the components of the ABC approach need to be balanced. For example, neither an AAAAbc approach (which overemphasizes abstinence) nor a CCCCab approach (which overemphasizes condom use) would have an optimal public health impact.

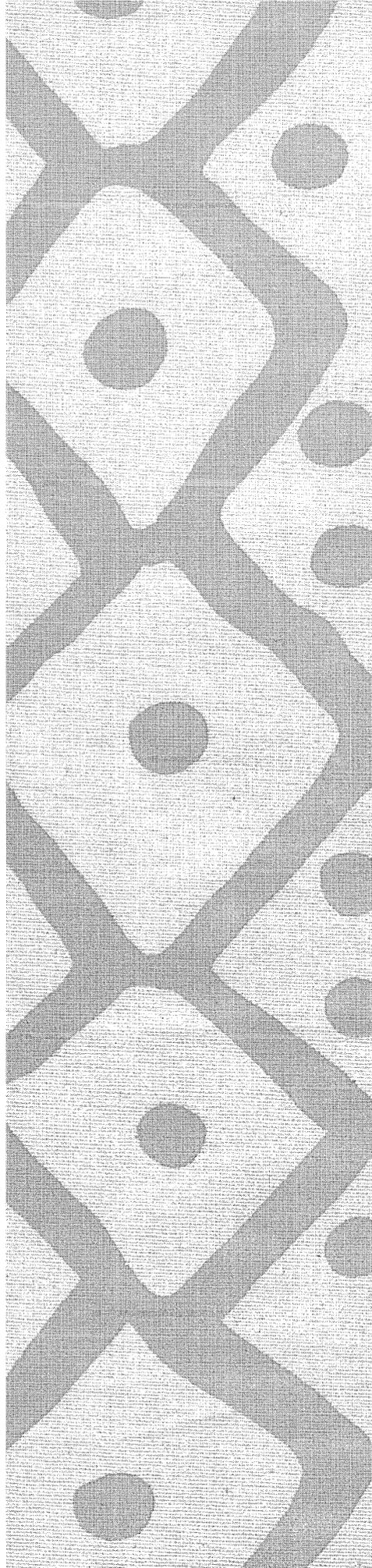
Moreover, our collection of weapons against HIV goes well beyond the ABC strategy, including potentially effective interventions such as screening and treatment for other STIs, male circumcision,

use of antiretrovirals for prevention, various approaches to prevention of mother-to-child transmission (by reducing viral load), screening of blood products, and needle-exchange programs. The future may also give us topical microbicides and HIV vaccines, which may not provide complete protection but can enhance our HIV prevention arsenal. Thus, rather than the limited ABC message, we should use a broader "ABC to Z" model to convey the full spectrum of prevention opportunities, of which consistent use of condoms is only one.

Note: Dr. Cates is an epidemiologist whose public health career has focused on the interface of contraceptive choice and HIV/STI prevention. Before joining FHI in 1994, he headed the Division of STD/HIV Prevention at the CDC for a decade. Dr. Cates delivered the plenary speech at a recent workshop sponsored by the U.S. National Institute of Child Health & Human Development about the design of studies of condom effectiveness and the prevention of STIs.

REFERENCES

1. U.S. National Institute of Allergy and Infectious Diseases (NIAID). *Scientific Evidence on Condom Effectiveness for Sexually Transmitted Disease (STD) Prevention* [workshop summary], NIAID, Herndon, VA, June 12-13, 2000. Available: <http://www.niaid.nih.gov/dmid/stds/condomreport.pdf>; Cates W Jr. The NIH condom report: the glass is 90% full. *Fam Plann Perspect* 2001;33(5):231-33; U.S. Centers for Disease Control and Prevention. *Fact Sheet for Public Health Personnel: Male Latex Condoms and Sexually Transmitted Diseases*. Available: <http://www.cdc.gov/biv/pubs/facts/condoms.pdf>.
2. Coburn T. CDC's deadly "safe sex" program and suppression of landmark condom report [news conference press release], Washington, DC, July 24, 2001.
3. Steiner MJ, Cates W Jr, Warner L. The real problem with male condoms is nonuse. *Sex Transm Dis* 1999;26(8):459-62.
4. Weller S, Davis K. Condom effectiveness in reducing heterosexual HIV transmission (Cochrane Review). In *The Cochrane Library, Issue 1*. Oxford, UK: Update Software, 2002; Mann J, Stine C, Vessey J. The role of disease-specific infectivity and number of disease exposures on long-term effectiveness of the latex condom. *Sex Transm Dis* 2002;29(6):344-49.
5. Trussell J, Kowal D. The essentials of contraception. In Hatcher RA, Trussell J, Stewart F, et al., eds. *Contraceptive Technology, Seventeenth Revised Edition*. (New York: Ardent Media, Inc., 1998)216.
6. Steiner.
7. Cates W Jr, Hinman AR. AIDS and absolutism — the demand for perfection in prevention. *N Engl J Med* 1992;327(7):492-94.
8. Garnett GP, Anderson RM. Strategies for limiting the spread of HIV in developing countries: conclusions based on studies of the transmission dynamics of the virus. *J Acquir Immune Defic Syndr Hum Retroviral* 1995; 9(5):500-13.
9. Adams MB. Effect of condoms on reducing genital herpes transmission. *JAMA* 2001; 286(17):2095. □



Targeting Populations at Increased Infection Risk

Condom promotion remains an important HIV prevention measure.

Traditionally, efforts to prevent HIV infection by promoting condom use — as part of a comprehensive array of risk-reduction approaches — have targeted individuals at increased risk of infection. One such targeted population is sex workers based in brothel establishments, as well as those based in non-brothel establishments (where condom use often is low). The second is men, since they often make the final decisions on condom use in sexual relations.

Sex work in non-brothel establishments such as restaurants, bars, and massage parlors is so common in many settings that a variety of interventions are attempting to reach these populations with condom use messages. (Notably, while it is recognized that many social, cultural, and economic conditions foster commercial sex work, FHI and similar organizations are unable to eliminate these conditions. Rather, FHI intervenes to help such women protect themselves from acquiring or transmitting HIV/STIs and prevent unplanned pregnancy.)

A Dominican Republic condom promotion intervention highlighted in this issue (see article, page 9) involves sex workers employed in both brothel and non-brothel establishments. Meanwhile, FHI is conducting an intervention targeting female employees of two Asian-based breweries who supplement their income with sex work.

“Female beer promoters, who serve beer to customers in restaurants, are paid little and are under constant pressure to either meet sales targets or lose income,” says Michael Merrigan, senior program officer in FHI’s Cambodia office. “They are in close contact with customers, and many supplement their meager income by having sex with customers after hours.” To help these women protect themselves against HIV/STIs, FHI offers a comprehensive prevention approach that includes peer education, building relationships with establishment owners to facilitate women’s access to HIV/STI education and services, STI services delivered at beer promoters’ homes, as well as condom promotion.

FHI’s work with female beer promoters is part of a larger program that regularly targets both brothel-based and non-brothel-based sex workers in Cambodia for HIV/STI outreach education. FHI’s HIV/STI prevention and care activities with non-brothel-based sex workers also focus on women working in such establishments associated with commercial sex as karaoke beer gardens, massage parlors, and guest houses/hotels. FHI-supported interventions include outreach and peer education to provide information and behavior change messages about HIV/STI prevention, provision of and referral to STI treatment services, and condom promotion. And, as more sex workers have learned

their HIV status, FHI has begun to address care, treatment, and support issues for this group.

GREATER EMPHASIS ON MEN

Use of a wide array of HIV/STI prevention strategies holds the most promise for reducing the spread of these infections. FHI both promotes and implements what it calls an “ABC to Z” model: abstinence, be faithful to one partner, or — if “A” or “B” cannot be achieved — use condoms. These three strategies can be further complemented by a number of other effective HIV prevention approaches; that is, the “to Z” component of the “ABC to Z” model. (See article, page 3.) Although condom use is an important element of this comprehensive approach, men often express a dislike for condoms and are particularly likely to abandon condom use with regular partners, whom they assume are not infected with HIV/STIs. In Thailand, young men are decreasing their patronage of brothel-based sex establishments,¹ but they are increasingly engaging in unprotected sexual relationships with female peers.² A 2001 study found that two-thirds of 5,646 young men inducted into the Royal Thai Army in May 1999 had sex with a girlfriend within the past year, but just 13 percent used a condom.³ Research also indicates that some young men continue to buy sex in informal venues while concurrently having unprotected sex with female peers.⁴ This puts

their presumably low-risk, regular partners at high risk of infection.

The vulnerability to HIV infection of presumably low-risk individuals is also illustrated in a modeling exercise, conducted in Cambodia with assistance from FHI. In 2002, the Cambodia Working Group on HIV/AIDS Projection estimated that almost half of new infections in the country that year were transmitted between husbands and wives.⁵

Given that men often make the final decision on condom use in sexual relations, attempting to increase their condom use is a challenge that reproductive health workers continue to address.

In Harare, Zimbabwe, FHI researchers and in-country collaborators began to explore in 2002 whether partners of 344 women (who had been through a two-month condom promotion intervention) felt more comfortable learning about condom use in all-male group sessions or in couple sessions with their regular partners. Preliminary results from this randomized trial show that a similar and unexpectedly high proportion of men (about 40 percent) attended condom promotion sessions when invited, regardless of type of session.

“That level of male involvement is much higher than expected and is encouraging in terms of getting males involved in condom promotion activities via their regular partners,” says Dr. Markus Steiner, an FHI senior epidemiologist who helped

design the study. “We think our results show that, in a country like Zimbabwe where there is a very good existing family planning infrastructure, it is possible to get men more involved in a family planning setting.”

Meanwhile, a review of operations research in 13 countries found that having men promote condoms through community-based distribution (CBD) programs can increase not only the total number of condoms that programs distribute, but also the number dispensed to male clients.⁶ The report highlighted research in Peru that found that male CBD workers with the Promoción de Labores Educativas y Asistenciales en Favor de la Salud (PROFAMILIA) CBD program in Lima sold twice as many condoms per month as did female CBD workers: a median of 49 condoms and 24 condoms per month, respectively. The Peruvian study found similar performance patterns among workers in the Centro NorPeruano de Capacitación y Promoción Familiar (CEN-PROF) CBD program in Trujillo,⁷ as did a 1995 study among CBD volunteers in the Kilifi district of Coast Province, Kenya. Fifteen male CBD volunteers in the Kilifi district each distributed approximately 9,550 condoms during the 18-month study period, while 15 female CBD volunteers in the same district each distributed approximately 3,523 condoms.⁸ Both studies adjusted for other factors that could influence worker performance, including education, occupation, marital status, training, length of time in the program, and CBD post location.

Having men promote condoms through CBD programs may require adjustments in attitudes, recruitment methods, and training schedules. The Peruvian study found that female program managers never fully accepted men in the CBD program



GISELE WULFSOHN/PANOS PICTURES

CONDOM UPTAKE CAN INCREASE WHEN MEN DISTRIBUTE CONDOMS. HERE, THE MALE NARRATOR OF AN AIDS PREVENTION SHOW HANDS OUT CONDOMS TO MEMBERS OF HIS AUDIENCE IN SOWETO, JOHANNESBURG, SOUTH AFRICA.

CAMPAIGNS WITH UNIFORMED SERVICES CHANGE BEHAVIORS

In Thailand, HIV prevalence has declined markedly over the past decade. This has been attributed to various condom promotion campaigns, including a 100 percent condom use program implemented in 1991 that mandated consistent condom use in all brothels. The decline in HIV prevalence has been especially notable among Thai military inductees.¹ A 2002 study of some 7,000 men inducted into the Royal Thai Army found that HIV prevalence fell from 11 percent among those inducted in 1991 to 2 percent among those inducted in 1998.²

Although not uniform throughout the country, Thailand's 100 percent condom program generally enforces condom use by requiring that sex workers be examined monthly for sexually transmitted infections (STIs) and by gathering information about specific brothel use from men attending governmental clinics for STI treatment. Some brothels regularly associated with STIs have been closed.

In Cambodia, similar condom promotion campaigns — including a 100 percent condom use policy initiated in 1998 and expanded to all provinces in 2001 — also have been highly effective. A recent report issued by the Cambodia Working Group on HIV/AIDS Projection found that some 35,000 new HIV infections a year were due to sex work in the mid-1990s. In contrast, by 2002, fewer than 2,000 infections a year were attributable to sex work.³

HIV prevalence for Cambodian police — a traditionally high-risk population — has also decreased, dropping from 6 percent in 1998 to 3 percent in 2000, according to HIV Sentinel Surveillance (HSS) reports.⁴ And policemen's reported consistent condom use with sex workers rose from 65 percent to 85 percent between 1997 and 2001, according to Behavioral Surveillance Survey (BSS) data. Although HIV sentinel data for the Cambodian military — another traditionally high-risk population — has not been collected since 1997, BSS condom-use data showed that military personnel's reported consistent condom use with sex workers doubled from a traditional low of 43 percent in 1997 to 87 percent in 2001. During that same period, the percentage of military men reporting sex with female sex workers over the month before the survey decreased from 51 percent to 20 percent.⁵

"What Cambodia has done is remarkable," says Anthony Bennett, deputy director of the care and treatment division of FHI's Institute for HIV/AIDS and, between 1995 and 1998, senior technical officer in FHI's Asia regional office.

One factor that may be contributing to the rising rates of condom use within these populations is the implementation in 1998 of a uniformed services peer education program developed by FHI's Implementing AIDS Prevention and Care (IMPACT) project and conducted in collaboration with the Cambodian Ministry of National Defense, the Cambodian Ministry of the Interior, and the Cambodian Red Cross. The program is one of several that FHI is conducting with military and police in selected countries in Asia and Africa to help them integrate HIV/AIDS prevention activities into their systems. As part of a comprehensive approach to HIV/STI prevention, the program provides STI services and counseling and addresses various high-risk behaviors such as substance abuse. (Recognizing that use of various, mutually reinforcing

techniques holds the most promise for reducing the spread of HIV/STIs, FHI both promotes and implements what it calls an "ABC to Z" model: abstinence, be faithful to one partner, or — if "A" or "B" cannot be achieved — use condoms. These three strategies can be further complemented by a number of other effective HIV prevention approaches; that is, the "to Z" component of the "ABC to Z" model. [See article, page 3.]

"An estimated 78 percent or more of Cambodia's military and 23 percent of the country's police will have been reached with condom promotion and other HIV prevention messages by the end of 2003," says Michael Merrigan, senior program officer in FHI's Cambodia office. "Peer education networks are now operating in four out of five Cambodian military regions."

Condoms are promoted in a number of ways:

- Remote military bases have FHI-supplied condom boxes that men can access confidentially.
- Peer educators demonstrate correct condom use with penis models.
- Peer educators counsel that condom use is one of many HIV risk-reduction strategies. Other counseling messages are that peers should reduce their number of sexual partners and avoid heavy alcohol consumption or social situations that could lead to use of commercial sex establishments.
- Peer educators emphasize that using condoms can help one protect oneself and one's family from HIV infection.
- Peer education drama teams promote condoms during theatrical productions.

"During conversations with servicemen, peer educators also try to address and correct the many common misconceptions about condoms and HIV infection that exist," Merrigan says.

— Emily J. Smith

REFERENCES

1. Nelson KE, Celentano DD, Eiumtrakol S, et al. Changes in sexual behavior and a decline in HIV infection among young men in Thailand. *N Engl J Med* 1996;335(5):297-303; Celentano DD, Nelson KE, Lyles CM, et al. Decreasing incidence of HIV and sexually transmitted diseases in young Thai men: evidence for success of the HIV/AIDS control and prevention program. *AIDS* 1998;12(5):F29-F36.
2. Nelson KE, Eiumtrakol S, Celentano DD, et al. HIV infection in young men in northern Thailand, 1991-1998: increasing role of injection drug use. *J Acquir Immune Defic Syndr* 2002;29(1):62-68.
3. The Cambodia Working Group on HIV/AIDS Projection. *Projections for HIV/AIDS in Cambodia: 2000-2010*. Phnom Penh, Cambodia: National Center for HIV/AIDS, Dermatology and STDs, 2002.
4. Ministry of Health. National Center for HIV/AIDS, Dermatology and STDs. *Report on HIV Sentinel Surveillance in Cambodia*. Phnom Penh, Cambodia: Ministry of Health. National Center for HIV/AIDS, Dermatology and STDs, 2000.
5. Sopheab H, Gorbach P, Bunleng H. *Cambodia's Behavioral Surveillance Survey, 1997-1999 (BSS I-III)*. Phnom Penh, Cambodia: National Center for HIV/AIDS, Dermatology and STDs; Ministry of Health, Cambodia; San Diego State University/Family Health International, 2001; National Center for HIV/AIDS, Dermatology and STDs. *Behavioral Surveillance Survey 2001, Cambodia*. Phnom Penh, Cambodia: National Center for HIV/AIDS, Dermatology and STDs, in press. ■

and that, in spite of male CBD workers' high productivity, female managers continued to have doubts about the men's work. "Men have less free time to do the work," one manager observed. Another commented, "Men produce less." Such attitudes may have contributed to the fact that female CBD workers replaced male counterparts who left the program.⁹ Research in Tanzania found that men in some communities initially had reservations about male CBD workers distributing condoms and other contraceptives to their wives, although they changed their views after becoming more familiar with the program.¹⁰

While recruiting men into CBD programs can be difficult, research has found that CBD training curricula do not need to be markedly altered to accommodate male workers.¹¹ Only the timing of sessions may need to be changed. In Peru, both the PROFAMILIA and CENPROF CBD programs scheduled training on weekends to accommodate men's work schedules.¹²

OFFERING A CHOICE

In the effort to encourage condom use among men, researchers are studying whether offering them a choice of male condoms increases rates of use and decreases STI rates. FHI researchers are conducting randomized controlled trials in Jamaica, Ghana, Kenya, and South Africa to explore this idea.¹³

In Kingston, Jamaica, FHI is studying condom preferences of 1,000 men attending the capital's largest STI clinic for treatment of urethral discharge. Half of the men will be offered only the standard condoms distributed at the clinic. The other group will be offered Rough Rider condoms, designed with ribbed "pleasure bumps"; Inspiral condoms, which have a loose-fitting shape to enhance sensation; standard condoms issued by the U.S. Agency for International Development (USAID); and standard clinic condoms. At study enrollment, the men are being screened and treated for gonorrhea, trichomoniasis, and chlamydial infection. Screening for these STIs will continue at regular intervals during this six-month study. Structured individual interviews are being conducted at each study visit to learn

about condom use and selection. Data collection is expected to be complete in July 2004.

"If we find that providing a choice of condoms has no impact on self-reported use and STI incidence, then programs should just provide the least expensive condom available and not spend resources providing slightly more expensive condoms with fancy packaging or features to enhance pleasure, such as ribs or a looser fit," says FHI's Dr. Steiner, the study's principal investigator. "However, if we find that choice increases condom use and decreases STI rates, then providing a choice is an intervention that could be easily replicated elsewhere."

FHI's condom choice trials in Ghana, Kenya, and South Africa are similar to the trial in Jamaica, except that only self-reported condom use data are being collected. In all three sites, men assigned to a "choice" group are being given their selection of four condoms: Rough Rider, Inspiral, USAID-issued, or each country's socially marketed condom. Men in a "no-choice" group are being offered only the USAID condom.

The studies in Ghana and South Africa are yielding interesting early findings. FHI researchers have noted that study participants are selecting the Rough Rider as their first choice and the Inspiral and the socially marketed condoms as their second choices. "The interesting thing is that in both countries, the socially marketed condoms are essentially the same as the USAID condoms — they are just packaged differently," says Carol Joanis, an FHI associate director and the principal investigator of the studies in Ghana, Kenya, and South Africa. Joanis plans to conduct focus groups with study participants to find out reasons for their condom selections.

"We need to know why participants like particular condoms," Joanis says. "Do they prefer condom attributes, like the bumps and ridges? Are they attracted to a condom based on the way it was promoted? Or, do they simply like the color of the packaging?"

— Emily J. Smith

REFERENCES

1. Nelson KE, Eiumtrakol S, Celentano DD, et al. HIV infection in young men in northern Thailand, 1991-1998: increasing role of injection drug use. *J Acquir Immune Defic Syndr* 2002;29(1):62-68; Nelson KE, Celentano DD, Eiumtrakol S, et al. Changes in sexual behavior and a decline in HIV infection among young men in Thailand. *N Engl J Med* 1996; 335(5):297-303.
2. VanLandingham M, Trujillo L. Recent changes in heterosexual attitudes, norms and behaviors among unmarried Thai men: a qualitative analysis. *Int Fam Plann Perspect* 2002; 28(1):6-15; Saengdidtha B, Ungchusak K. Sexual behaviours and sexually transmitted diseases among young Thai men in 1999. *Venerology* 2001;14(4):157-59.
3. Saengdidtha.
4. VanLandingham.
5. The Cambodia Working Group on HIV/AIDS Projection. *Projections for HIV/AIDS in Cambodia: 2000-2010*. Phnom Penh, Cambodia: National Center for HIV/AIDS, Dermatology and STDs, 2002.
6. Population Council. *Program Brief No. 2. Using Men as Community-Based Distributors of Condoms*. Washington, DC: Frontiers in Reproductive Health, Population Council, 2002.
7. Foreit JR, Garate MR, Brazzoduro A, et al. A comparison of the performance of male and female CBD distributors in Peru. *Stud Fam Plann* 1992;23(1):58-62; Population Council.
8. Family Planning Association of Kenya and Population Council/Africa OR/TA Project. *Increasing Male Involvement in the Family Planning Association of Kenya (FPAK) Family Planning Program*. Nairobi, Kenya: Population Council, 1995.
9. Foreit.
10. Chege J, Rutenberg N, Janowitz B, et al. *Factors Affecting the Outputs and Costs of Community-Based Distribution of Family Planning Services in Tanzania*. Nairobi, Kenya: Population Council, 1998; Population Council.
11. Family Planning Association of Kenya and Population Council/Africa OR/TA Project; Foreit.
12. Foreit.
13. Steiner M. Update — condom choice initiative. Annual meeting of the FHI Technical Advisory Committee, Contraceptive Technology and Family Planning Research, Chapel Hill, NC, May 2, 2002. ■

PUBLIC HEALTH INITIATIVE NEARLY HALVES STI RATES

A 40 percent decline in rates of sexually transmitted infections (STIs) occurred among a sample of 400 female sex workers who participated in a recent initiative to promote 100 percent condom use in 68 commercial sex establishments in two Dominican Republic cities.

Conducted over a year, the initiative — supported by the Horizons Program of the Population Council, the Johns Hopkins School of Public Health, and the AcciónSIDA project of the Academy for Educational Development (AED) — involved two condom promotion approaches. The first, carried out at 34 sex establishments in Santo Domingo, encouraged solidarity among female sex workers, sex establishment owners and managers, and other employees (such as disc jockeys, bartenders, and doormen) to commit to consistent condom use in the establishments. The second approach, carried out at 34 sex establishments in Puerto Plata, was similar but also applied a regional governmental 100 percent condom use policy and a graduated sanction system directed at sex establishment owners. Both approaches were conducted not only in brothels, but also in other establishments (such as bars and discos) where sex work may occur.

STI data collected among 200 sex workers at each site before and immediately after the interventions showed at both sites comparable declines in the prevalence of one or more of three STIs (chlamydial infection, gonorrhea, and trichomoniasis). In Santo Domingo, rates declined from 25 percent to 16 percent, while those in Puerto Plata declined slightly more, from 29 percent to 16 percent.

The initiative measured condom use with new clients and with regular paying and regular nonpaying partners at both sites. Self-reported consistent condom use increased significantly in both cities. Notably, consistent condom use with new clients increased from 75 percent to 94 percent in Santo Domingo, while in Puerto Plata it more than doubled (from 13 percent to 29 percent) with regular paying and regular nonpaying partners. Additionally, observed rates of sex workers' verbal rejection of unsafe sex with clients increased significantly (from 50 percent to 80 percent) in Puerto Plata only.

"The combined community-based solidarity/governmental policy and sanction model implemented in Puerto Plata produced much higher rates of compliance with key intervention components than the solidarity-only model implemented in Santo Domingo," says Dr. Deanna Kerrigan, assistant research professor with Johns Hopkins University's Department of International Health in Baltimore, MD, USA, and a principal investigator in the study. "However, given that relatively few sanctions were levied during the intervention in Puerto Plata, the governmental policy and perhaps the threat of sanctions — rather than sanctions themselves — appear to have made this critical difference."

Creating a norm and a governmental policy endorsing consistent condom use, Dr. Kerrigan says, involved fostering relationships among members of three key groups:

- Community members, including sex workers, owners, managers, and other employees of female commercial sex establishments;

- Governmental employees, such as health inspectors, STI clinic physicians, and policy-makers affiliated with the country's national HIV/AIDS/STI control program and regional health departments; and
- Nongovernmental organizations such as the Centro de Promoción y Solidaridad Humana (CEPROSH) in Puerto Plata and Centro de Orientación e Investigación Integral (COIN) in Santo Domingo, both of which have conducted peer education and HIV prevention activities with sex workers in the country for more than 15 years. The national organization of sex workers, Movimiento de Mujeres Unidas-MODEMU, also participated.

The forging of such alliances generated innovative collaborations that allowed for a more comprehensive approach to HIV/STI prevention. In the case of sex workers, a comprehensive approach and messages centered around condom use, STI services, and creating an environment that encouraged safe sex practices. As part of the Dominican Republic initiative, sex worker peer educators provided pre- and post-STI counseling at governmental STI clinics. Governmental health inspectors and employees of the nongovernmental organizations visited sex establishments to reinforce the importance of complying with monthly STI exams. Nongovernmental employees collaborated with sex worker peer educators to train governmental health inspectors and STI clinic physicians to provide guidance on improving sex workers' health care service quality.

Educational materials geared toward female sex workers, sex establishment owners and managers, employees, and clients were also developed. Solidarity among these groups was nurtured during workshops that stressed that condom use is a team effort. These activities resulted in such changes as disc jockeys routinely promoting condoms over public announcement systems at participating sex establishments in both sites.

Participatory workshops gave sex workers an opportunity to role-play how to negotiate condom use with different types of sexual partners. They focused on sex workers' condom use with both regular paying and regular nonpaying partners, with whom condom use in the Dominican Republic has been observed to be much lower than with new clients.¹ Such efforts seek to develop a norm of safer sex among a critically important group at risk for HIV/STIs.

— Emily J. Smith

REFERENCE

1. Kerrigan D, Moreno L, Rosario S, et al. Adapting the Thai 100% condom programme: developing a culturally appropriate model for the Dominican Republic. *Cult Health Sex* 2001;3(2):221-40; Kerrigan D, Moreno L, Rosario S, et al. The impact of two 100% condom use models in reducing HIV-related risk among female sex workers in the Dominican Republic. Unpublished paper. Horizons Program, 2002. Available: <http://www.popcouncil.org/horizons/horizonpublications.html>; Kerrigan D, Ellen JM, Moreno L, et al. Environmental-structural factors significantly associated with consistent condom use among female sex workers in the Dominican Republic. *AIDS* 2003;17(3):415-23. ■

MEASURING CONDOM USE BETTER

Among sexually active individuals at risk for HIV infection, consistent and correct condom use remains the best protection against HIV. Because some people who report that they use condoms consistently still become infected with HIV,¹ doubts have been raised about condom effectiveness. But growing awareness that self-reports of consistent condom use may be inaccurate has led researchers to seek ways to measure more accurately the consistency of condom use.

"Research documenting transmission of HIV/STIs among individuals self-reporting consistent condom use has cast doubt on the inherent effectiveness of condoms among some people," says Dr. Markus Steiner, an FHI senior epidemiologist and coauthor of a recent editorial on the subject of measuring condom efficacy.² "Instead, it should prompt recognition of the difficulty of determining true consistency of condom use." Furthermore, Dr. Steiner and his coauthors emphasize, the misdirected debate over condom effectiveness can undermine overall condom use because potential users may lose confidence in the method.

Scientists have increasingly questioned the validity of self-reported consistent condom use.³ Individuals queried about condom use may fail to fully understand interviewers' questions. They may be unable to recall whether they always used condoms. Most importantly, wishing to please interviewers, they may change their answers to ones they perceive as being more acceptable.

"There is a lot of bias in self-reports of condom use, but researchers can also do a lot to reduce that bias," notes Dr. Cynthia Waszak Geary, an FHI senior scientist who has researched ways of increasing the validity of data on self-reported condom use.

Asking more focused questions can reduce some reporting bias, Dr. Waszak says, as can "creating a bias toward telling the truth. This can be done by explaining to study participants that it is more important that the researchers know the truth about condom use than it is for researchers to know that participants have used condoms all the time. Respectful interviewers may also be more likely to gather unbiased information."

The question of whether self-reports of condom use are valid has implications for providers: Clients who say they use condoms consistently may, for a variety of reasons, exaggerate their condom use. Also, providers wishing to promote honest dialogue with clients about condom use should remain nonjudgmental.

OTHER CONDOM USE MEASURES

Seeking more reliable ways to measure the consistency of condom use, FHI researchers have begun to study the use of biological markers of semen exposure in the vagina.

Cervical and vaginal swab samples are being collected from approximately 400 sex workers in Madagascar who are participating in an FHI study comparing two condom promotion initiatives. The samples will be examined in U.S. laboratories for prostate-specific antigen (an antibody found in semen) and Y chromosomes (normally found only in men, but present in women exposed to semen). Lab results will be compared with self-reports of condom use. Detection of prostate-specific antigen (possible from 24 to 48 hours after exposure to semen, depending upon semen quantity) or Y chromosome fragments (possible up to 14 days after exposure) would indicate either condom failure (breakage or slippage) or condom non-use. While exposure to semen sometimes occurs because condoms break, slip, or are used incorrectly, most exposure is due to condom non-use.⁴

"Biological markers of semen exposure may provide an alternative for measuring condom use and supply evidence for assessing the validity of traditional condom use measurements," says María Gallo, an FHI research associate who is coordinating this biological marker investigation, which should yield results in 2004.⁵ Similar FHI research initiatives using biological markers will begin this year in Tanzania and Kenya.

— Emily J. Smith

BERYL GOLDBERG



BEING NONJUDGMENTAL IS LIKELY TO PROMOTE HONEST DIALOGUE WITH CLIENTS ABOUT CONDOM USE, AS WELL AS OTHER HEALTH ISSUES. HERE, A PATIENT CONSULTS WITH HER DOCTOR IN MEXICO CITY, MEXICO.

REFERENCES

1. Saracco A, Musicco M, Nicolosi A, et al. Man-to-woman sexual transmission of HIV: longitudinal study of 343 steady partners of infected men. *J Acquir Immune Defic Syndr Hum Retroviral* 1993;6(5):497-502.
2. Steiner M, Feldblum P, Padian N. Invited commentary: condom effectiveness — will prostate-specific antigen shed new light on this perplexing problem? *Am J Epidemiol* 2003;157(4):298-300.
3. Weir S, Roddy R, Zekeng L, et al. Association between condom use and HIV infection: a randomized study of self reported condom use measures. *J Epidemiol Community Health* 1999;53(7):417-22.
4. Steiner MJ, Cates W Jr, Warner L. The real problem with male condoms is nonuse. *Sex Transm Dis* 1999;26(8):459-62.
5. Macaluso M, Lawson L, Akers R, et al. Prostate-specific antigen in vaginal fluid as a biologic marker of condom failure. *Contraception* 1999;59(3):195-201; Lawson L, Macaluso M, Bloom A, et al. Objective markers of condom failure. *Sex Transm Dis* 1998;25(8):427-32. ■

Female Condom Reuse Issues Explored

For female condom users, use of a new female condom for every act of sexual intercourse continues to be recommended by the World Health Organization (WHO).¹ Likewise, the female condom (a potential alternative for the male condom) is approved only for one-time use by the U.S. Food and Drug Administration. Such positions by public health experts reflect, in part, concerns that women may be unable to clean the device adequately to make its reuse safe.

However, female condom reuse has been reported in a number of settings, likely because many women cannot afford to buy multiple female condoms. Recognition that reuse is occurring — and may be acceptable, feasible, and safe in some circumstances — led WHO to declare in July 2002 that “the final decision on whether or not to support reuse of the female condom must ultimately be taken locally.”²

This declaration came six months after WHO released a female condom cleaning and handling draft protocol based on two expert meetings to discuss the reuse issue.³ The protocol, which outlines steps for preparing female condoms for reuse, stated that a single female condom may be used up to five times as long as it is:

- Disinfected by soaking it, as soon as possible after use, for one minute in a 1-to-20 dilution of sodium hypochlorite (liquid household bleach) in water; and
- Washed, dried, stored, and relubricated — following protocol procedures — before being used again.

WHO recommends that, on the local level, program managers not recommend female condom reuse until they have adapted the protocol (retaining all the procedural steps) to local conditions and then tested the protocol’s feasibility, efficacy, and usefulness in their settings.⁴ WHO will provide guidance for program managers on programmatic implications of reuse. This protocol only applies to the polyurethane female condom manufactured by the Female Health Company.

The product’s brand names include FC Female Condom, Reality, Femidom, Dominique, Femy, Myfemy, Protectiv’, and Care.

WHO does not promote female condom reuse, in part because the female condom cleaning and handling protocol has not been extensively studied for safety or evaluated for efficacy in humans. But WHO-funded research is under way in South Africa to explore the structural integrity of female condoms disinfected, washed, and reused in accordance with the protocol, as well as users’ ability to follow the protocol correctly.

Meanwhile, female condom reuse issues have been explored in numerous studies, many of which have been conducted by FHI with funding from the U.S. Agency for International Development (USAID). Research has found that the female condom remains structurally sound after repeated cycles of bleach disinfection and washing.⁵ A USAID-supported study by FHI found that couples who disinfected, washed, dried, relubricated, and reused the same female condom five times experienced no more adverse effects in the vagina, on the cervix, or on the penis than did couples who used five female condoms one time each.⁶ And a WHO-supported study of the effect of disinfection on common STIs found that the female condom must be soaked at least one minute in a 1-to-20 dilution of bleach in water to kill the organisms that cause gonorrhea, chlamydial, herpes, and HIV infections.⁷ Since some women may not have access to bleach, research is under way to assess the safety and feasibility of cleaning used devices with only detergent and water. This USAID-supported study, to be conducted by FHI and completed by July 2003, will test the effect of Sunlight- and Omo-brand detergents on the organisms that cause gonorrhea, chlamydial, herpes, and HIV infections.

“These products were chosen for their widespread availability,” says Carol Joanis, an FHI associate director and the study’s

principal investigator. “Sunlight dishwashing liquid is available worldwide, and Omo is available in most developing countries, except for certain parts of Latin America and Asia. Notably, where Omo is unavailable, Surf detergent — which is identical in formulation — is commonly offered.”

— Emily J. Smith

REFERENCES

1. World Health Organization. WHO information update: considerations regarding reuse of the female condom. Unpublished paper. World Health Organization, 2002. Available: <http://www.who.int/reproductive-health/rtis/reuse.en.html>.
2. World Health Organization.
3. World Health Organization. The safety and feasibility of female condom reuse: report of a WHO consultation. Unpublished paper. World Health Organization, 2002. Available: http://www.who.int/reproductive-health/rtis/report_reuse.doc.
4. World Health Organization. WHO information update: considerations regarding reuse of the female condom.
5. Potter B, Gerofi J, Pope M, et al. Structural integrity of the polyurethane female condom after multiple cycles of disinfection, washing, drying and relubrication. *Contraception* 2003;67(1):65-72; Joanis C, Latka M, Glover LH, et al. Structural integrity of the female condom after a single use, washing, and disinfection. *Contraception* 2000;62(2):63-72.
6. Joanis C, Ballagh S. Female condom reuse: in vivo safety. WHO consultation on re-use of the female condom. Geneva, Switzerland, January 28, 2002; Ballagh S, Joanis C. Reuse of Reality female condom: colposcopy and adverse events. WHO consultation on re-use of the female condom. Geneva, Switzerland, January 28, 2002.
7. Ballard R, Fehler G, Htun Y, et al. Re-use of the female condom — effectiveness of disinfection procedures. WHO consultation on re-use of the female condom. Geneva, Switzerland, January 28, 2002. ■

Dual Protection

Best approach to recommend may vary.

Continuing research and discussion on the two major strategies for dual protection against both unplanned pregnancy and sexually transmitted infections (STIs) indicate that each strategy has distinct advantages and disadvantages (see table, page 14) and that appropriate dual protection messages may differ according to individual situations.

“Whether a condom-only or dual method approach to dual protection is appropriate and feasible depends on the individuals involved and the settings in which an approach is offered,” says Dr. Jason Smith, a senior scientist in FHI’s behavioral and social science research group.

Various strategies offer dual protection. For example, abstinence provides dual protection. So, too, does being in a monogamous relationship in which both partners are free of STIs (and at least one partner is using effective contraception). Furthermore, avoiding all forms of penetrative sex affords dual protection. But for many sexually active men and women, one major way to

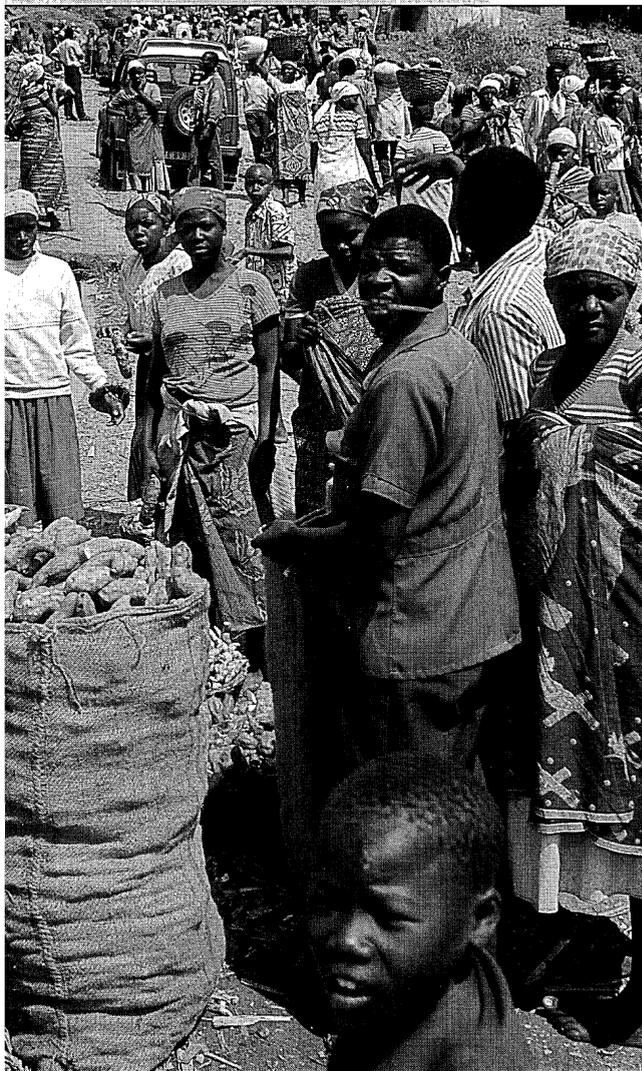
achieve dual protection is to use simply condoms to protect against both pregnancy and STIs. Another major option is dual method use: using one method to protect against unplanned pregnancy (often a hormonal method or other highly effective noncoitally dependent contraceptive) and a second method to protect against STIs (a male or female condom).

No large randomized trials have been conducted to compare these two approaches. And, results of observational research on dual method use are limited and inconsistent.¹ But experts recognize that determining appropriate dual protection messages depends on assessing individuals’ separate risks of unplanned pregnancy and HIV/STIs and then determining how effectively various contraceptive methods reduce those risks.

ASSESSING RISKS

Hormonal implants and injectables, intrauterine devices (IUDs), or sterilization provide the greatest protection against pregnancy, but condoms (male and female) are the only method known to provide protection against HIV, other STIs, and pregnancy. Thus, the primary goal of dual protection — whether to prevent pregnancy, infection, or both — will influence what dual protection strategy is adopted, say Dr. Markus Steiner, an FHI senior epidemiologist, and Dr. Willard Cates Jr., president of FHI’s Institute for

BETTY PRESS/PANOS PICTURES



A VARIETY OF PEOPLE SHOP AT A MARKET IN CYABINGO, RWANDA. DETERMINING APPROPRIATE DUAL PROTECTION MESSAGES TAKES INTO ACCOUNT DIFFERENCES AMONG INDIVIDUALS AND SETTINGS.

EMPHASIZING DUAL PROTECTION MESSAGES

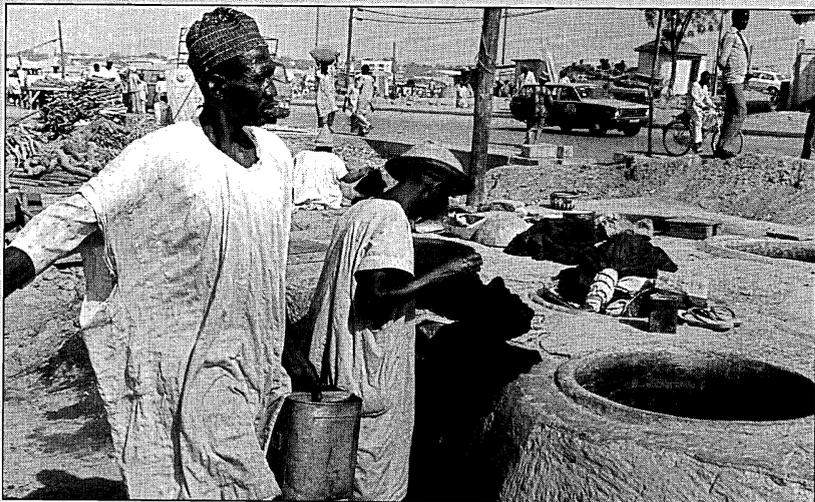
Dual protection messages are being integrated into family planning counseling services, and providers are embracing the new messages, research from Nigeria shows.

Between 1999 and 2001, the nongovernmental Association for Reproductive and Family Health (ARFH) in Ibadan, Nigeria, and U.S. collaborators completed the first phase of a project to integrate HIV and sexually transmitted infection (STI) prevention into family planning services by promoting dual protection counseling among new clients in six family planning clinics.¹ ARFH conducted participatory training with 15 family planning providers on topics such as helping clients recognize their risk of HIV and other STIs, emphasizing the role of condoms in dual protection, and tailoring counseling messages to meet clients' individual needs. Providers were also encouraged to use a dual protection flip chart during counseling sessions, offer clients both female and male condoms, and distribute brochures on dual protection and male and female condom use.

Structured observations of provider-client interactions, conducted among 325 female clients before provider training and 289 female clients after training, showed that the percentage of new clients counseled on various components of dual protection increased significantly after training. Some of the most notable increases occurred in discussions on how dual protection can be achieved using either one or two methods (from 5 percent to 75 percent), how effectively various family planning methods prevent HIV and other STIs (from 7 percent to 42 percent), and how clients might convince their partners to use condoms (from 0 percent to 18 percent).

According to client exit interviews, the percentage of clients aware of the concept of dual protection also increased, from 8 percent before provider training to 50 percent after training. And while only 2 percent of family planning clients who visited the clinics in 1999 left with condoms as their only method of contraception, 6 percent who visited in 2000 left with condoms as their only method.

BERYL GOLDBERG



A WORKER CARRIES DYE TO ONE OF SEVERAL PITS IN KANO, NIGERIA.

Other ongoing interventions to provide training that emphasizes dual protection messages include the following:

- New York-based EngenderHealth and FHI are collaborating to implement and evaluate comprehensive dual protection training in Ethiopia. EngenderHealth has developed and field-tested a training protocol — covering sexuality and gender, HIV and STI prevention, dual protection, and integrated counseling skills — and is using it to train staff at primary health care facilities in three regions of Ethiopia. FHI will soon assess the training's impact on providers' and clients' knowledge and attitudes, providers' counseling practices, and clients' use of dual protection strategies.
- With technical assistance from FHI, the Reproductive Health Research Unit (RHRU) in South Africa is implementing the National Dual Protection Strategies Program, which includes a South Africa Department of Health program to introduce the female condom into the country.² Training materials on dual protection, barrier methods, and how to integrate these topics into family planning counseling have been developed and used to train service delivery providers in nine provinces. The RHRU and FHI will continue to revise the training materials, supervise training, and monitor provider performance related to the new curriculum.
- In Kenya, FHI and other organizations are collaborating to train youth counselors to promote male condoms among their peers, using either a standard STI protection message or a dual protection message. Over 60 counselors have been trained in western Kenya. Using pre- and post-training surveys, FHI is assessing counselors' knowledge and attitudes about condom use, STIs, and consequences of unplanned pregnancy and STIs; whether the standard STI protection message is distinct from the dual protection message; and how well counselors are remembering the messages. (Of note, FHI views such condom promotion efforts as just one component of a more comprehensive approach to HIV/STI prevention. FHI promotes and implements what it

calls an "ABC to Z" model: abstinence, be faithful to one partner, or — if "A" or "B" cannot be achieved — use condoms. These three strategies can be further complemented by a number of other effective HIV prevention approaches; that is, the "to Z" component of the "ABC to Z" model. [See article, page 3.]

— Kerry L. Wright

REFERENCES

1. Adeokun L, Mantell JE, Weiss E, et al. Promoting dual protection in family planning clinics in Ibadan, Nigeria. *Int Fam Plann Perspect* 2002;28(2):87-95.
2. Family Health International. *Expanding Barrier Method Strategies Program. Process Data Report*. Research Triangle Park, NC: Family Health International, 2002. ■

Family Health, in a recent commentary.² They also emphasize that “to achieve dual protection under typical circumstances, trade-offs must be made.”

Promoting only condoms (which are often used inconsistently) among family planning clients at low risk of HIV, says Dr. Steiner, could increase a client’s pregnancy risk. In those cases, providers might want to offer a hormonal method or an IUD to ensure effective pregnancy prevention but also suggest condoms to be used in situations in which there is increased risk of infection (such as with new partners, partners who are not monogamous, or partners who have not been tested for STIs).

“If, on the other hand, one works in a clinic where 40 percent of clients are HIV positive, the equation is very different,” says Dr. Steiner. Since HIV prevention is likely the primary goal in this setting, condoms alone may be a more appropriate option. This is because some clients who use effective noncoitally dependent contraceptives are less likely to use a second method, such as condoms, to prevent STIs.³ If emergency contraceptive pills are available, they might be offered as backup to condoms to provide occasional extra protection against pregnancy if a condom is not used or fails (breaks or slips).

SOCIAL CONTEXTS

Understanding the full social context in which individuals are making decisions about dual protection also helps to clarify which strategy to implement, says Dr. Smith, who has conducted qualitative research on dual method use in the United States.

Social context involves both individual and community factors. Individual factors include partner attitudes about different methods, how often a person has sexual intercourse, and a person’s own perceptions of risk and the consequences of pregnancy or STIs. Community factors include the

social acceptability of contraception, access to and availability of different methods, attitudes toward sexual intercourse, and gender-related power differentials.⁴

Gender-related power differentials may be especially influential. For example, the fact that men often control the use of condoms in relationships can leave women powerless to make decisions or afraid to ask their partners to use condoms. “The condom itself may be a risk to these women,” says Dr. Smith. “It could represent risk of a beating, loss of status, or perhaps worse: loss of trust in a relationship that gives meaning to their lives or that they depend on for survival.”

To explore such barriers to dual protection, particularly dual method use, 11 focus group discussions were recently conducted among 47 in-school adolescents, 14 out-of-school adolescents, and 19 teachers and former teachers in Ghana.⁵ Results confirmed earlier findings that issues of mistrust make condom negotiation within long-term relationships difficult.⁶ Most men said they would react with anger or

suspicion if their partners suggested using condoms in addition to another contraceptive method. “I will think that she does not trust me,” said one male student. “If she mistrusts me, I have to end the relationship.” Similarly, said a female teacher, “If you tell him you are using a birth control method but you still want him to use a condom, he will be furious because he will feel like you don’t trust him.” (Negotiating condom use for pregnancy prevention — rather than for HIV/STI prevention — can destigmatize condoms and facilitate their acceptance.)

In the study in Ghana, both men and women admitted to having multiple partners. Yet, couples rarely discussed risks of pregnancy and STIs, and men were unwilling to acknowledge that women might have more than one partner, further demonstrating the complexity of relationships and of negotiating dual protection within them.

Given all these factors, dual protection messages may differ for men versus women, just as they may differ for sex

DUAL PROTECTION STRATEGIES

ADVANTAGES

DISADVANTAGES

USE OF CONDOMS ONLY

- | | |
|---|---|
| <ul style="list-style-type: none"> ◆ Destigmatizes condoms, which — in this case — are promoted for a dual purpose ◆ Low-tech and relatively affordable | <ul style="list-style-type: none"> ◆ Not the most effective means of preventing pregnancy ◆ Rates of incorrect and inconsistent use are high ◆ May be difficult for some to negotiate use within relationships |
|---|---|

DUAL METHOD USE

- | | |
|---|--|
| <ul style="list-style-type: none"> ◆ Best protection against pregnancy ◆ Most effective dual protection if both methods are used consistently | <ul style="list-style-type: none"> ◆ May be unrealistic for people to be motivated to use two methods ◆ May decrease consistent use of one of the methods ◆ Could stigmatize condoms, which — in this case — are promoted for STI prevention only ◆ May be financially or logistically difficult |
|---|--|

workers versus low-risk married women, educated versus uneducated individuals, and youth versus adults. "Their lives are different, their situations are different, their risks are different," says Dr. Smith. "So we need to better define these differences and then try to tailor sensible messages to individuals' particular needs."

— Kerry L. Wright

REFERENCES

1. Cates W Jr, Steiner MJ. Dual protection against unintended pregnancy and sexually transmitted infections. What is the best contraceptive approach? *Sex Transm Dis* 2002;29(3):168-74.
2. Cates, Steiner.
3. Cates W Jr. Contraception, unintended pregnancies, and sexually transmitted diseases: why isn't a simple solution possible? *Am J Epidemiol* 1996;143(4):311-18.

4. Cates W Jr, Spieler J. Contraception, unintended pregnancies, and sexually transmitted infections. Still no simple solutions. *Sex Transm Dis* 2001;28(9):552-54.

5. Goparaju L, Afenyadu D, Benton A, et al. *Gender, Power and Multi-Partner Sex: Implications for Dual Method Use in Ghana*. Washington, DC: Centre for Development and Population Activities (CEDPA), 2002.

6. Woodsong C, Koo HP. Two good reasons: women's and men's perspectives on dual contraceptive use. *Soc Sci Med* 1999;49(5):567-80. ■

DUAL PROTECTION AND CONSISTENCY OF CONDOM USE

Results from a recent, cross-sectional observational study from Zimbabwe suggest that dual method users do not use condoms as consistently as those who use only condoms for dual protection against pregnancy and sexually transmitted infections.¹ But this does not necessarily mean that providers should recommend a condom-only, rather than a dual method, approach to dual protection, says Dr. Markus Steiner, an FHI senior epidemiologist and coauthor of the study.

"Almost certainly, those people using condoms alone are different from the people using them in conjunction with other methods," he says. This suggests that consistency of condom use may depend at least as much on individual characteristics (such as background, lifestyle, and motivations for behavior) as on whether a condom-only or a dual method approach to dual protection is used.

Research from Ethiopia illustrates this point. Results of a cross-sectional survey of some 370 sex workers in Addis Ababa showed that sex workers who used condoms consistently (with at least 95 percent of their clients) had several unique characteristics: generally, they were at least 30 years old, had been counseled by peer educators, had very few clients each day, refused sex unless their clients used condoms, and had used condoms for contraception in the previous five years. Of note, 65 percent of 145 sex workers who had used condoms for contraception used them consistently in the study, compared with only 24 percent of 224 sex workers who had not previously used them for contraception.

(Women in the former group also were less likely to be HIV-infected.) Furthermore, those sex workers motivated to use condoms for contraception were more likely to refuse sex with clients who would not use a condom (54 percent versus 10 percent).²

In the study conducted in Zimbabwe, researchers sought to determine the prevalence and consistency of condom use, alone or in conjunction with another contraceptive method, among nearly 900 family planning clients. Preliminary results of structured questionnaires showed that about one-third of the women were using two methods and 5 percent were using condoms alone. But those using only condoms used them more consistently than did those using condoms plus another method.

"The most striking finding was the low level of condom use in a place of such high HIV prevalence," notes former FHI fellow Dr. Thulani Magwali, a lecturer at the University of Zimbabwe and lead author of the study. This may have been at least partly due to difficulties women have negotiating condom use within their relationships, he speculates.

— Kerry L. Wright

REFERENCES

1. Magwali TL, Steiner MJ, Brown JM, et al. Dual method and dual purpose use among family planning clients at three family planning clinics in Zimbabwe. Unpublished paper. Family Health International, 2002.
2. Aklilu M, Messele T, Tsegaye A, et al. Factors associated with HIV-1 infection among sex workers of Addis Ababa, Ethiopia. *AIDS* 2001;15(1):87-96. ■

After N-9, What Next?

Several potential microbicides are poised to be tested for effectiveness in humans.

Now that the spermicide nonoxynol-9 (N-9) has been ruled out as a microbicide¹ (see article, page 18), attention has shifted to other substances that might be used topically as a protective barrier against HIV and other sexually transmitted infections (STIs). An effective vaginal microbicide would offer a desperately needed option for women at risk of HIV who cannot persuade their partners to use condoms.

More than 50 agents are being studied for their microbicide potential, and about one-third are in clinical (human) trials.² While a microbicide is unlikely to reach the market until after 2010, six microbicide products are expected to enter effectiveness trials — the most advanced stages of testing in humans — in 2003 and 2004, says Dr. Zeda Rosenberg, chief executive officer of the International Partnership for Microbicides (IPM) and former FHI scientific director for the HIV Prevention Trials Network (HPTN), a worldwide collaborative research program that evaluates HIV prevention interventions. The IPM was founded in 2002 to accelerate microbicide research, development, and access and has attracted nearly \$100 million in support, including a \$60 million grant from the Bill and Melinda Gates Foundation.

Those products nearing effectiveness trials act in different ways to prevent HIV and other STI pathogens from infecting cells. Four of them — Carraguard (carageenan, derived from red seaweed), dextrin-2-sulfate, cellulose sulfate, and PRO 2000 — are sulfated or sulphonated polymers with large, negatively charged

molecules that bind to pathogens or to potential host target cells, forming a protective coating.

The other two microbicide candidates poised to enter effectiveness trials kill or inactivate pathogens. C31G, like N-9, damages bacterial membranes and viral envelopes. BufferGel destroys pathogens by maintaining the natural acidity of the vagina in the presence of alkaline semen.

All six compounds have shown some ability to block HIV and other sexually transmitted pathogens in test tubes or in animals.³ Four of them may also offer protection against pregnancy. The two that do not appear to be contraceptive are Carraguard and dextrin-2-sulfate.

The six candidates have performed well in safety trials designed to detect systemic toxicity or disruption of the epithelial cells that line the vagina.⁴ Such trials usually begin by studying the safety and acceptability of the compound among healthy women. Subsequent study populations represent the range of people who might use a microbicide, including HIV-positive individuals. Recognizing that anal sexual intercourse greatly increases the risk of HIV infection for both men and women, researchers are also beginning to assess the safety of rectal microbicide use.

Two of the compounds, Carraguard and dextrin-2-sulfate, have completed expanded safety trials. Results of the Carraguard trials, involving 565 women in South Africa and Thailand, are expected in May of 2003. Preliminary results of those trials and from the first 35 HIV-negative, sexually active women enrolled in an

expanded safety trial of dextrin-2-sulfate at St. Francis Hospital in Kampala, Uganda, showed no adverse effects.⁵ If the final results of the Uganda trial are equally positive, an effectiveness trial of dextrin-2-sulfate could begin in South Africa, Tanzania, Zambia, and Uganda in 2004. The Population Council hopes to begin an effectiveness trial of Carraguard, involving about 6,000 women in South Africa and Botswana, in 2003.

FHI and the U.S.-based CONRAD Program are also awaiting completion of data analysis — from a recent safety trial involving 54 Cameroonian women — before deciding whether to proceed to an effectiveness trial of cellulose sulfate. CONRAD plans to test the effectiveness of cellulose sulfate in a second trial in Benin, Uganda, and India, and FHI researchers are designing effectiveness trials of another compound, C31G.

HPTN plans to conduct a combined expanded safety and effectiveness trial of BufferGel and PRO 2000. The proposed study design calls for enrollment of more than 3,100 sexually active, HIV-negative women in India, Malawi, South Africa, Tanzania, the United States, Zambia, and Zimbabwe. If this design is approved by a review committee of the U.S. National Institutes of Health (NIH), which is HPTN's sponsor, the trial could begin in 2004. (FHI works with NIH, FHI's Protection of Human Subjects Committee, and local ethical review boards and community groups to ensure that its research is always conducted in compliance with U.S. regulatory requirements and international guidelines designed to protect human research participants and to ensure that study participation is equitable and free of coercion.)

In October 2002, a contraceptive effectiveness trial sponsored by the U.S. National Institute of Child Health and Human Development began enrolling 975 U.S. women who will use a diaphragm with either BufferGel or a conventional spermicide. (Contraceptives do not need to be tested for effectiveness in as many women as do microbicides because the risk of becoming pregnant when one is not using a family planning method is so much greater than the risk of acquiring HIV during each act of unprotected intercourse.) If the

MICROBICIDES APPROACHING EFFECTIVENESS TRIALS: HOW THEY WORK

FORMS PROTECTIVE COATING

Carraguard
Dextrin-2-sulfate
Cellulose sulfate
PRO 2000

KILLS OR INACTIVATES PATHOGENS

C31G
BufferGel

results show that BufferGel offers contraceptive protection equivalent to that of the spermicide, it could be sold as a contraceptive in the United States within two years.

Bringing a substance to market as a microbicide is expected to take much longer, even if any of the first-generation candidates are shown to protect against HIV in humans. Most likely, first-generation microbicides will, at best, be only partially effective.

OTHER CANDIDATES

The six leading microbicide candidates act before HIV invades a host cell. Others are being developed that will interrupt the HIV life cycle after it enters a target cell in the vagina or cervix, by inhibiting either initial replication of HIV or further spread of the infection.

One of these postinfection challengers, a topical formulation of the HIV drug tenofovir disoproxil fumarate (tenofovir DF) called PMPA, is being evaluated in an HPTN safety and acceptability study in the United States. FHI is designing a multinational effectiveness trial to test whether taking a daily tenofovir DF tablet can reduce the risk of HIV infection.

Other promising compounds for second- and third-generation microbicides include monoclonal antibodies and large, artificial molecules called dendrimers. Both inhibit fusion of HIV with targeted cells by binding specific proteins on the surface of the virus.⁶ Research is also under way to test microbicide delivery devices, including the diaphragm (see article, page 19), a vaginal cap, and an intravaginal silicone ring.

The most effective microbicides are likely to be those that combine different or complementary mechanisms of action against HIV, "just as antiretrovirals are much more effective when used in combination than when used alone against HIV," says Dr. Rosenberg.

— Kathleen Henry Shears

REFERENCES

1. World Health Organization (WHO), CONRAD Program. *Safety of Nonoxynol-9 When Used for Contraception: Report from WHO/CONRAD Technical Consultation, October 2001*. Geneva, Switzerland: WHO and CONRAD, 2002. Available: <http://www.who.int/reproductive-health/rtis/nonoxynol9.html>.
2. Harrison PF, Rosenberg Z, Bowcut JC. HIV/AIDS: topical microbicides for disease prevention — status and challenges. Unpublished paper. Alliance for Microbicide Development and International Partnership for Microbicides, 2003.
3. McCormack S, Hughes R, Lacey CJN, et al. Microbicides in HIV prevention. *BMJ* 2001;322(7283):410-13.
4. Mauck C, Creinin M, Barnhart K, et al. A Phase I comparative post-coital testing and safety study of three concentrations of C31G. *Microbicides 2002*, Antwerp, Belgium, May 12-15, 2002; Coggins C, Blanchard K, Alvarez F, et al. Preliminary safety and acceptability of a carageenan gel for possible use as a vaginal microbicide. *Sex Transm Infect* 2000;76(6):480-83; Elias CJ, Coggins C, Alvarez F, et al. Colposcopic evaluation of a vaginal gel formulation of iota-carrageenan. *Contraception* 1997;56(6):387-89; Mauck D, Frezieres R, Walsh T, et al. Single and multiple exposure tolerance study of cellulose sulfate gel: a Phase I safety and colposcopy study. *Contraception* 2001;64(6):383-91; Stafford MK, Cain D, Rosenstein I, et al. A placebo-controlled double-blind prospective study in healthy female volunteers of dextrin sulphate gel: a novel potential intravaginal virucide. *J Acquir*

Immune Defic Syndr Hum Retrovirol 1997;14(3): 213-18; Low-Beer N, Jespers V, McCormack S, et al. A safety study of dextrin sulphate gel as a novel vaginal microbicide: data from HIV negative and positive women. *XIV International AIDS Conference*, Barcelona, Spain, July 7-12, 2002; Van Damme L, Wright A, Depraetere K, et al. A phase I study of a novel potential intravaginal microbicide, PRO 2000, in healthy sexually inactive women. *Sex Transm Infect* 2000; 76(2):126-30; Mayer K, Abdool Karim S, Kelly C, et al. Safety and tolerability of vaginal PRO 2000 gel in sexually active HIV-uninfected and

abstinent HIV-infected women. *AIDS* 2003; 17(3):321-29; Mayer KH, Peipert J, Fleming T, et al. Safety and tolerability of BufferGel, a novel vaginal microbicide, in women in the United States. *Clin Infect Dis* 2001;32(3):476-82; van de Wijgert J, Fullem A, Kelly C, et al. Phase I trial of the topical microbicide BufferGel: safety results from four international sites. *J Acq Immune Defic Syndr* 2001;26(1):21-27.

5. Johnston R. Microbicides 2002: an update. *AIDS Patient Care and STDs* 2002; 16(9):419-30; Bukonya M, Pickering J, Lacey C, et al. A phase II study of the safety of dextrin

sulphate gel in sexually active females in Kampala. *Microbicides 2002*, Antwerp, Belgium, May 12-15, 2002.

6. Harrison; Watanabe M. Topical care of HIV transmission possible. *The Scientist* 2002; 16(22):34; Veazey RS, Shattock RJ, Pope M, et al. Prevention of virus transmission to macaque monkeys by a vaginally applied monoclonal antibody to HIV-1 gp120. *Nature Medicine* 2003; 16(22):34. ■

N-9 NOT FOR WOMEN AT HIGH RISK OF HIV INFECTION

Spermicides containing nonoxynol-9 (N-9) increase the risk of HIV infection when used frequently by women at high risk of infection, but they remain a moderately effective contraceptive option for women at low risk of infection, technical experts convened by the World Health Organization (WHO) and the U.S.-based CONRAD Program have concluded.¹

After reviewing research results about N-9's safety and effectiveness against HIV and other sexually transmitted infections (STIs), the group also agreed that:

- N-9 offers no protection against STIs such as gonorrhea and chlamydial infection.
- Condoms lubricated with N-9 should no longer be promoted because there is no evidence that they are more effective in preventing pregnancy or infection than condoms lubricated with silicone. However, it is better to use a condom lubricated with N-9 than none at all.
- N-9 should not be used rectally.²

In May 2002, the U.S. Centers for Disease Control and Prevention (CDC) published similar recommendations, advising family planning providers to inform women at risk of HIV and other STIs that N-9 spermicides do not protect against these infections.³

The WHO and CDC recommendations are based, in part, on an analysis of 10 randomized clinical trials of the effectiveness of N-9 against HIV or other STIs, involving almost 5,000 women, that included trials conducted by the Joint United Nations Programme on HIV/AIDS (UNAIDS) and FHI.⁴ The analysis, recently published in two parts in the Cochrane Library, confirmed that there was no evidence that N-9 protects against STIs. (The Cochrane Library publishes evidenced-based systematic reviews to provide high-quality information on medical topics.)

Whether N-9 adds contraceptive protection to barrier methods other than condoms is still unknown, although spermicide use with the diaphragm is recommended. Researchers from FHI and Christchurch School of Medicine in New Zealand recently published a Cochrane Review of randomized controlled trials comparing the contraceptive effectiveness, safety, and acceptability of diaphragms with and without spermicide. They were unable to draw any conclusions because they identified only one eligible study, and even that study lacked statistical power. Calling for further research, the review authors wrote that their analysis "provides no evidence to change the commonly recommended practice of using the diaphragm with spermicide."⁵

— Kathleen Henry Shears

REFERENCES

1. World Health Organization(WHO), CONRAD. *Safety of Nonoxynol-9 When Used for Contraception: Report from WHO/CONRAD Technical Consultation, October 2001*. Geneva, Switzerland: WHO and CONRAD, 2002. Available: <http://www.who.int/reproductive-health/rtis/nonoxynol9.html>.
2. World Health Organization.
3. U.S. Centers for Disease Control and Prevention. Sexually transmitted diseases treatment guidelines, 2002. *MMWR* 2002;51(RR-6):1-77. Available: <http://www.cdc.gov/mmwr/PDF/RR/RR5106.pdf>; Nonoxynol-9 spermicide use — United States 1999. *MMWR* 2002;51(18):389-92. Available: <http://www.cdc.gov/mmwr/PDF/wk/mm5118.pdf>.
4. Wilkinson D, Ramjee G, Tholandi M, et al. Nonoxynol-9 for preventing vaginal acquisition of HIV infection by women from men (Cochrane Review). In *The Cochrane Library, Issue 1*. Oxford, UK: Update Software, 2003; Wilkinson D, Ramjee G, Tholandi M, et al. Nonoxynol-9 for preventing vaginal acquisition of sexually transmitted infections by women from men (Cochrane Review). In *The Cochrane Library, Issue 1*. Oxford, UK: Update Software, 2003.
5. Cook L, Nanda K, Grimes D. Diaphragm versus diaphragm with spermicides for contraception (Cochrane Review). In *The Cochrane Library, Issue 1*. Oxford, UK: Update Software, 2003. ■

Will Diaphragms Protect against STIs?

The hypothesis that diaphragms might offer women some protection against sexually transmitted infections (STIs), including HIV, will soon be tested in several randomized controlled trials.

One study of the use of diaphragms to prevent transmission of bacterial STIs, funded by the U.S.-based CONRAD Program, is under way in Nairobi, Kenya.¹ Results are expected in about four years. The U.S.-based Population Council plans to begin a similar study involving about 400 sex workers in the Dominican Republic later in 2003. Meanwhile, the first randomized controlled trial of the diaphragm's protective effect against HIV is expected to begin in Zimbabwe, South Africa, and one other country in mid-2003. That trial will be conducted by researchers at the University of California at San Francisco (UCSF), USA, with results expected in three or four years.

Testing the diaphragm's effectiveness against bacterial STIs was logical because gonorrhea and chlamydial infection are clearly acquired in the cervix and not the vagina. And evidence of the diaphragm's potential to protect against these and other STIs has been accumulating.²

If the diaphragm does indeed protect the cervix against STIs, it might indirectly protect against HIV, since HIV infection is facilitated by the presence of other STIs. Meanwhile, "it looks as though the majority of HIV infections probably occur at the cervix, which is more vulnerable than the vagina," says Dr. Nancy Padian, a professor of obstetrics, gynecology, and reproductive sciences at UCSF and principal investigator for the randomized trial.

One reason for this greater susceptibility is that the endocervical lining is thinner and more fragile than the lining of the vagina. It is particularly vulnerable when it extends out onto the face of the cervix, a condition

known as cervical ectopy that is common in adolescents.³ The cervix also seems to be the primary site for a number of HIV receptors, which are proteins on cell surfaces that facilitate attachment and entry of the virus into those cells.⁴

Most studies using animal models of HIV infection have found that the cervix is usually infected first, Dr. Padian notes. When rhesus macaque monkeys were injected with the HIV-like simian immunodeficiency virus (SIV), cervical cells were infected after three days, while vaginal cells were not infected until the twelfth day.⁵ There is, however, some conflicting evidence.⁶ Another study in macaques found SIV-infected cells in both the vagina and the cervix soon after infection, and in one study removal of the cervix in macaques did not decrease the efficiency of SIV transmission.⁷ Moreover, women who have had hysterectomies have acquired HIV infection vaginally.⁸

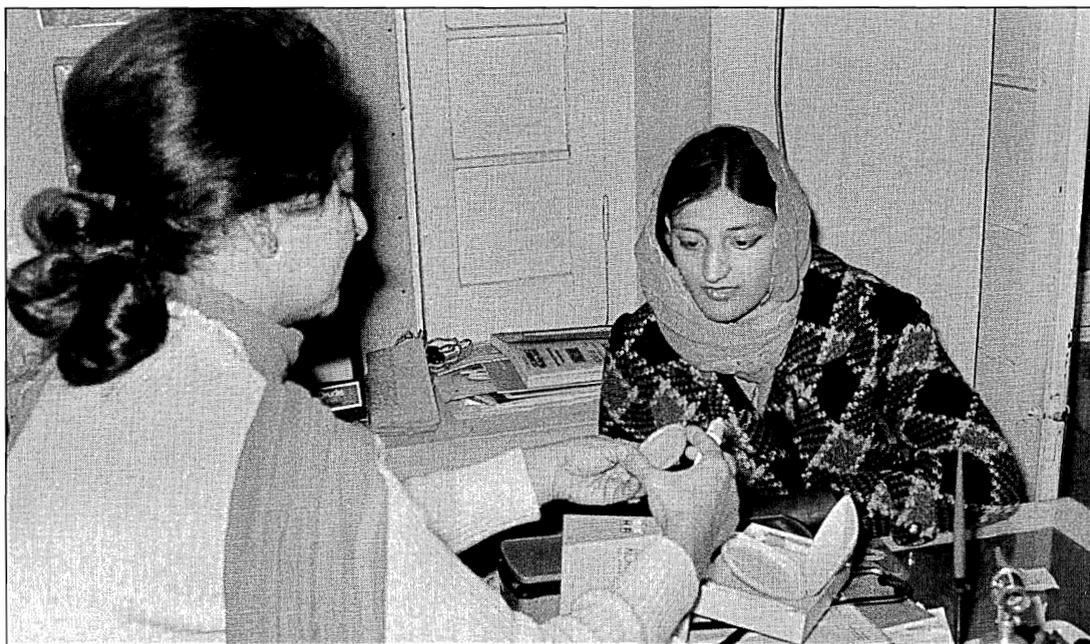
Diaphragms alone are unlikely to provide 100 percent protection against HIV because transmission can occur vaginally,

particularly — but not exclusively — when the epithelial cells on the surface of the vagina are disrupted.⁹ "If there is any physical microtrauma or any inflammatory alteration of the vaginal epithelium, then transmission can very readily take place," says Dr. Robin Shattock, senior lecturer in the Department of Infectious Diseases at St. George's Medical School in London, UK, who has conducted research on the mechanisms of HIV transmission to women. "There's no way to tell what degree of protection diaphragms will provide without conducting trials."

DIAPHRAGMS AND MICROBICIDES

Some researchers think that diaphragms and microbicides may be most effective if used together. Coated on both sides with a microbicide, a diaphragm could block STI pathogens from the cervix and help improve retention of the microbicide in both the cervix and the vagina. To explore the impact of combined use of these methods on STI acquisition, principal

SEAN SPRAGUE/PANOS PICTURES



A FAMILY PLANNING PROVIDER EXPLAINS USE OF THE DIAPHRAGM AS A CONTRACEPTIVE TO A CLIENT IN LAHORE, PAKISTAN.

investigators for the Kenyan diaphragm and STI study — Dr. Craig Cohen of the University of Washington, USA, and Dr. Elizabeth Bukusi of the Centre for Microbiology Research at the Kenya Medical Research Institute — are adding two arms to the trial: one consisting of women who use diaphragms and a microbicide, and one with women who use only a microbicide.

Recognizing that effectiveness will also depend on consistent use, researchers are examining the acceptability of diaphragms among women in Brazil, Kenya, and Zimbabwe. Diaphragms are not a popular contraceptive method now, but that may change if they prove to provide protection against HIV and other STIs. “There is a lot of feeling out there that women will not use a barrier method consistently for a long time,” says Marianne Callahan, clinical director at CONRAD, which is designing studies that will ask

women in South Africa and Zimbabwe to use diaphragms alone or diaphragms with a microbicide. “We would like to show that they will, if they are given a good reason.”

— Kathleen Henry Shears

REFERENCES

1. Cohen C. The diaphragm: a female controlled method to prevent HIV and other sexually transmitted infections? *Microbicides 2002*, Antwerp, Belgium, May 12-15, 2002.
2. Moench TR, Chipato T, Padian NS. Preventing disease by protecting the cervix: the unexplored promise of internal vaginal barrier devices. *AIDS* 2001;15(13):1595-1602.
3. Moench.
4. Moench; Levine WC, Pope V, Ghoomkar A, et al. Increase in endocervical CD4 lymphocytes among women with nonulcerative sexually transmitted disease. *J Infect Dis* 1998;177(1):167-74; Zhang L, He T, Talal A, et al. In vivo distribution of the human immunodeficiency virus/simian immunodeficiency virus

coreceptors: CSCR4, CCR3, and CCR5. *J Virol* 1998;72(6):5035-45.

5. Zhang Z-Q, Schuler T, Zupacic M, et al. Sexual transmission and propagation of SIV and HIV in resting and activated CD4+ cells. *Science* 1999;286(5443):1353-57.

6. Moench; Mingjia M, Short R. How oestrogen or progesterone might change a woman's susceptibility to HIV-1 infection. *Aust NZ J Ob Gyn* 2002;42(5):472-75.

7. Miller CJ. Mucosal transmission of simian immunodeficiency virus. *Curr Top Microbiol Immunol* 1994;188:107-22; Hu J, Gardner MB, Miller CJ. Simian immunodeficiency virus rapidly penetrates the cervicovaginal mucosa after intravaginal inoculation and infects intraepithelial dendritic cells. *J Virol* 2000;74(13):6087-95.

8. Goedert JJ, Eyster ME, Biggar RJ, et al. Heterosexual transmission of human immunodeficiency virus: association with severe depletion of T-helper lymphocytes in men with hemophilia. *AIDS Res Hum Retrovir* 1987;3(4):355-61.

9. Miller CJ, Shattock RJ. Target cells in vaginal HIV transmission. *Microbes and Infection* 2003;5(1):59-67. ■

CONTRACEPTIVE SPONGE RE-ENTERS THE MARKET

The Today contraceptive vaginal sponge has just re-entered the market on a limited basis after an eight-year hiatus. Currently available only in Canada, the sponge is an alternative to the diaphragm that can be obtained without a prescription and used for multiple acts of intercourse within a 24-hour period.

The sponge protects against pregnancy by blocking sperm from entering the cervix and by releasing the spermicide nonoxynol-9. (Notably, potential users of the sponge should be aware that nonoxynol-9 has been shown to increase the risk of HIV infection when used frequently by women at high risk of infection [see article, page 18]). A recent Cochrane Review conducted by FHI shows pregnancy rates during one year of use to be 17 percent to 24 percent for the sponge compared with 11 percent to 13 percent for the diaphragm.¹ With support from the U.S. Agency for International Development (USAID) and the National Institutes of Health, FHI also

conducted the clinical trials that led to the U.S. Food and Drug Administration's (FDA's) original approval of the sponge in 1983. The sponge's original manufacturer took the product off the market in 1995 after problems that would have required a costly upgrade were found at the manufacturing plant. The current manufacturer — New Jersey-based Allendale Pharmaceuticals — must gain a second FDA approval before the sponge can be sold again in the United States. To read more, see <http://www.cnn.com/2003/HEALTH/03/05/sponge.returns.ap/index.html>.

— Kerry L. Wright

REFERENCE

1. Kuyoh MA, Toroitich-Ruto C, Grimes DA, et al. Sponge versus diaphragm for contraception: a Cochrane review. *Contraception* 2003;67(1):15-18. ■