

CBAS Newsletter: Volume 4, Number 2

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FEATURED RESEARCH

Acceptance and Use of the Female Condom Among Women With Incomplete Abortion in Rural Tanzania

Rasch V, Yambesi F, Kipingili R. *Contraception.* 2007; 75(1): 66-70.

Background: This study describes the outcome of a postabortion care intervention aimed at introducing the female condom as a means of preventing women from having unwanted pregnancies and sexually transmitted infections (STIs)/HIV.

Methods: Postabortion contraceptive counseling and services were offered to 548 women admitted to the Kagera Regional Hospital for incomplete abortion. The counseling included information about STI/ HIV and the use of the male or female condom. In total, 521 (95%) women accepted contraception.



The female condom.

months after abortion among 475 (91%) women. The female condom was accepted by 201 of 521 (39%) and was used by 158 of 521 (30%). Women who had experienced an unsafe abortion, had attended secondary school or earned an income were more likely to accept the female condom. The 158 women who used the female condom were generally satisfied with the method, and the majority of them intended to use it again.

Conclusion: Postabortion care programs provide an excellent entry

point for introducing the female condom as a contraceptive method for the prevention of both repeat unwanted pregnancies and STI/HIV infection.

Results: Contraceptive use was assessed 3

Microbicide Applicators: Understanding Design Preferences Among Women in the Dominican Republic and South Africa

Cohen JA, Steele MS, Urena FIC. Sexually Transmitted Diseases. 2007; 34(1); 15-19.

Objectives: The objectives of this study were to prioritize applicator design attributes among women in the Dominican Republic and South Africa, and to determine how preferences differed based on sociodemographic variables.

Goal: The goal was to identify acceptable microbicide applicator designs in 2 low-resource settings.

Study Design: A total of 895 women, randomly sampled from clinics in the Dominican Republic (n=449) and South Africa (n=446), were surveyed with questions on sociodemographics, applicator attribute preferences, and price/design tradeoffs.

Result: Single-use design was the most valued attribute, and reusable design and low price were the least valued attributes in both populations. Preference for single-use design was associated with concern about reusable applicators spreading germs, secondary or higher education, older age, having children, and perception of moderate to high HIV risk.

Conclusions: Acceptability factors related to microbicide delivery mechanisms should continue to be evaluated among potential microbicide users to directly inform product development and introduction of microbicides.

More Information on the Brazilian Algae Candidate

On January 16, BBC News Online reported that Brazilian researchers had found a candidate microbicide that was 95% effective in laboratory tests. The report then noted that, "First-generation microbicides now being tested are expected...to be 50—60% effective. However, preliminary tests of the Brazil gel suggest it could be substantially more effective."

While news of any new microbicide candidate is exciting, this report may have implied a bigger breakthrough than actually occurred. Pre-clinical (laboratory) testing is a first step in product development and candidates are not advanced to the next steps unless they show strong indications of potential effectiveness. However, a compound must clear many more tests before it enters human trials as a candidate microbicide.

The Today Sponge is Back!

Synova Healthcare has announced plans to begin a campaign to market the female contraceptive Today Sponge. The Today Sponge, which is constructed of soft polyurethane foam and contains spermicide to prevent pregnancy, is inserted into the vagina for up to 24 hours and provides barrier protection. The device is 89% to 91% effective in preventing pregnancy but does not protect against sexually transmitted infections. The sponge was introduced in 1983, but sale of the product was discontinued in 1995 because its manufacturer, Wyeth, did not want to invest in the equipment upgrades necessary to maintain FDA approval. In 2000, Allendale Pharmaceuticals Inc. purchased the manufacturing rights to the sponge, and the FDA approved it in April 2005. The Today Sponge had sales of about 250 million from 1983 through 1995. According to Synova, the product costs



\$7.99 for a three-pack. Synova plans to begin an aggressive marketing campaign to inform consumers that "the back," sponge is Synova CEO Stephen King said. "The first 120 days of the campaign will focus on public relations and advertise-Internet ments and will be followed by television, radio and print advertisements in Mav 2007," King said.

Dr. Luiz Castello Branco, an immunologist at the well-regarded Oswoldo Cruz Instutute in Rio de Janeiro and Principal Investigator of this compound, shared the following information with our colleagues at the Alliance for Microbicide The compound Development. is dolabellane diterpene isolated from the marine algae Dictyota pfafii. In the test tube, it appears to inhibit HIV-1 reverse transcriptase and HIV-1 replication at a post-transcriptional step.

One journal article on their findings has been published and a second one is in press. Dr. Branco's team believes that the potentially inflated news of their results was generated by the media and may have arisen from a misunderstanding of the original news coverage in Portuguese.

Male Circumcision Update: Women at Increased Risk?

In the January issue of the CBAS newsletter, we highlighted the recent findings from the male circumcision trials which provided further evidence that circumcision could cut men's risk of contracting HIV infection by up to 60%. We also noted that the affects of circumcision on male to female HIV transmission were unknown. However, early results released last month suggest that the period immediately following surgery could be a time during which men may transmit the virus more easily to their female partners. A study undertaken by the Rakai Health Sciences Program and Makerere University in Uganda and Johns Hopkins University tracked 997 HIV-positive men in Uganda, half of whom underwent circumcision. At the start of the trial, the men's female partners were HIVnegative. Of the 70 men who were circumcised, 11 of their female partners became infected, while 4 female partners of the 54 uncircumcised men became infected. Most of the women became infected within the first six months following the procedure. Researchers suspect that men had sex before their surgical wounds had sufficient time (about a month) to heal.

Although, this was a small study and the results are not statistically significant, it means the original hypothesis—women would benefit from circumcision—must be carefully reconsidered. At a minimum, the public health message will have to clearly state that men must refrain from sex during the wound healing period and that women should avoid having sex with recently circumcised men in order to reduce their own risk of infection.

Cellulose Sulfate Trials Close

Family Health International (FHI) announced in January that it halted a Phase III clinical trial of cellulose sulfate (CS)—a potential microbicide being tested for HIV prevention in women—in Nigeria. Simultaneously, CONRAD, a health research organization based in Arlington, Virginia, announced it halted its Phase II clinical trial of CS at sites in Benin, India, South Africa, and Uganda.

Cellulose sulfate was one of four microbicide candidates in Phase III effectiveness trials for prevention of HIV and other sexually transmitted infections. A review of the preliminary results of CON-RAD's CS trial by the study's Data Monitoring Committee (DMC) determined that CS use could lead to an increased risk of HIV infection.

Separately, FHI decided to close its CS study in Nigeria after the DMC also reviewed interim data from the Nigeria study and found no evidence of increased risk of HIV infection.

"In Nigeria, we did not find any evidence of greater risk of HIV infection," said Dr. Vera Halpern, principal investigator of FHI's trial. "But we also found no evidence that the product was effective in preventing HIV. Given the disappointing results from CONRAD's study of the same microbicide candidate in other countries, the responsible course of action was to halt our study."

Cellulose sulfate was assessed in multiple safety trials before entering Phase III HIV prevention trials. The gel, also known as Ushercell, is a cottonbased compound developed by Polydex Pharmaceuticals, based in Toronto, Canada. Prior to the Phase III HIV prevention trials implemented by FHI and CONRAD, CS had been evaluated in 11 rigorous clinical safety and contraceptive trials involving more than a total of 500 participants. Evidence from those early animal and human studies indicated that cellulose sulfate had a strong safety profile with minimum sexually transmitted infections, including HIV.

It is imperative to continue support for ongoing effectiveness trials and for the development of other microbicide candidates in the research pipeline. Microbicides are urgently needed to provide a woman-controlled HIV prevention option because women are socially and biologically more vulnerable than men are to the HIV virus. In Africa, almost 60 percent of new infections are acquired by women and girls.

—Adapted from FHI Press Release

Meeting Focuses on Female-Initiated HIV Prevention Technologies

In light of women and girls' lack of access to resources, and too-often compromised capacity to determine the nature of sexual relations, *a range of* HIV prevention technologies is of the utmost importance.

In December 2006, the International AIDS Vaccine Initiative, in partnership with Ibis Reproductive Health, the Global Campaign for Microbicides and the Center for Health and Gender Equity, sponsored a meeting to explore opportunities for increasing collaboration among a strategic range of stakeholders. The meeting brought together about 25 representatives working in the HIV/AIDS prevention technologies and international women's health advocacy fields to discuss how to promote a range of options, avoid competition for resources and attention, and ensure mutually supportive messages.

Attendees were clinical and behavioral researchers, advocates, program managers and communication professionals working on the range of prevention technologies, including microbicides, cervical barriers, vaccines, and female (and male) condoms. The day began with a brief report on research progress followed by an overview of current advocacy challenges facing each of the current and emerging prevention technologies. Different facilitators then carried the participants through a dialogue designed to: a) identify existing research and advocacy activities; b) highlight current gaps in advocacy that demand focused attention; c) explore opportunities for increasing collaboration among the relevant stakeholders; and d) determine resources required to pursue this work.

The day ended by determining priorities for action. Possible next steps included: hosting regional information sharing sessions at upcoming meetings such as the International Women's Summit in Kenya, the International Congress on AIDS in Asia and the Pacific in Sri Lanka and others; developing 2-page factsheets on each method to support advocacy efforts; and identifying groups, networks and listservs though which the conversation can be expanded in 2007.

-Adapted from meeting report developed by IAVI.

UPCOMING EVENTS

Event: World YWCA Council Date: July 1—11, 2007 Location: Nairobi, Kenya Website: www.worldywca.info/index.php/ywca/ world_council_07

Description: A World YWCA Council is held every four years to set the priorities for the coming years' work, elect the members of the Executive Committee, and set policy through resolutions and recommendations.

Event: International Society for Sexually Transmitted Disease Research (ISSTDR) International Congress

Date: July 29—August 1, 2007

Location: Seattle, WA

Website: www.isstdr.org/

Description: Organized by the <u>International Society</u> for <u>Sexually Transmitted Diseases Research</u> and the <u>International Union against Sexually</u> <u>Transmitted Infections</u>, this conference will address issues surrounding the expansion of HIV and

other STDs. The Seattle meeting will be global in scope and designed to meet the needs of scientists, trainees and students from academia, public health agencies, nongovernmental organizations, and other institutions and agencies.

Event: Association of Reproductive Health Professionals Annual Meeting Date: September 5—7, 2007 Location: Minneapolis, MN Website: www.arhp.org/rh2007/ Description: Attendees of the general sessions

will be able to discuss diagnosis, health care needs, and therapy choice for women with various reproductive health conditions, understand new technologies in family planning, including medications and devices in development for use in the United States, understand latest clinical research, including treatment guidelines for sexually transmitted infections, discuss current social and legal issues that have impacted or are expected to impact the provision of reproductive health services.

CBAS Steering Committee

Marianne Callahan: <u>CONRAD</u> Tsungai Chipato: <u>University of Zimbabwe-</u> <u>University of California San Francisco Collaborative</u> <u>Research Programme in Women's Health</u> Patricia Coffey: <u>PATH</u> Natalya Dinat: <u>Perinatal HIV Research Unit</u> Katy Backes Kozhimannil: Harvard PhD Program in Health Policy Nancy Padian: Women's Global Health Imperative, University of California San Francisco Gita Ramjee: Medical Research Council of South Africa

Helen Rees: <u>Reproductive Health Research Unit</u> Kelley Ryan: <u>Duke Clinical Research Institute</u>

What are cervical barriers?

Most people think of cervical barriers primarily as the diaphragm and cervical cap but a broader definition would encompass Lea's shield, female and male condoms, the sponge and microbicides. For more information about the range of cervical barrier methods, go to <u>http://www.cervicalbarriers.org/information/methods.cfm</u>.

Mission of CBAS

Established in 2004, the Cervical Barrier Advancement Society (CBAS) aims to raise the profile of cervical barrier methods for pregnancy prevention and provide information about research on the potential of cervical barriers to prevent sexually transmitted infections, including HIV.

Membership

CBAS membership is free and open to all who are interested in joining. CBAS's goal is to create an international, professional networking organization including clinical and social science research groups, academic institutions, advocacy groups, trade associations, and pharmaceutical, biotech, and medical device companies. As a member, you will have the opportunity to network and collaborate with other professionals in the field; keep abreast of new research; share information and ideas; and receive a semi-annual newsletter.

CBAS Contact Information: For more information, contact Julia Matthews, CBAS Executive Director at <u>jmatthews@cervicalbarriers.org</u>. CBAS is hosted by Ibis Reproductive Health and based in Cambridge, Massachusetts.

To comment on anything you read in the CBAS newsletter or to contribute a story, event, or news item, please email info@cervicalbarriers.org.