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INTERNAL/FEMALE CONDOM RESEARCH

Hsu R, Tavrow P, Uysal J, Alterman AE. Seeking the female (internal) condom in retail pharmacies: Experiences of adolescent mystery callers. Contraception. 2020 Feb;101(2):117-121. View the article here.

BACKGROUND: Female (internal) condoms could be viable alternatives to male (external) condoms. Our objective was to describe barriers that adolescent mystery callers encountered when trying to access female condoms in US pharmacies.

METHODS: In mid-2016, university students seeking "condoms for girls" called retail pharmacies in Arizona, California, New Mexico and Utah. We evaluated differences in product availability and callers' experiences by pharmacy type.

RESULTS: Of our final sample (n=1475), only eight outlets (0.5%), all national chains, definitely stocked female condoms. Of those not (or probably not) stocking female condoms, 11% tried to be helpful (e.g., offered to special order), 59% made no substantive comment, and 30% were unhelpful (e.g., dismissive, rude, gave wrong information). National chain employees were significantly more unhelpful (34% vs 22%, p< .01).

CONCLUSION: Almost no pharmacies in four southwestern states stocked female condoms in mid-2016. Pharmacy staff frequently were unhelpful, which could deter adolescent use of female condoms even if new types become available.

Walsh TL, Snead MC, St Claire BJ, Schwartz JL, Mauck CK, Frezieres RG, Blithe DL, Archer DF, Barnhart KT, Jensen JT, Nelson AL, Thomas MA, Wan LS, Weaver MA. Comparison of self-reported female condom failure and biomarker-confirmed semen exposure. Contraception. 2019 Nov;100(5):406-412. View the article here.

OBJECTIVE: To investigate whether rates of self-reported Woman's Condom (WC) clinical failure and semen exposure from a functionality study are comparable to results from a contraceptive efficacy substudy.

STUDY DESIGN: We structured our comparative analysis to assess whether functionality studies might credibly supplant contraceptive efficacy studies when evaluating new female condom products. Couples not at risk of pregnancy in the functionality (breakage/slippage/invagination/penile misdirection) study and women in the contraceptive efficacy study completed condom self-reports and collected precoital and postcoital vaginal samples for up to four uses of the WC. Both studies used nearly identical self-report questions and the same self-sampling procedures and laboratory for prostatic specific antigen (PSA), a well-studied semen biomarker. We compared condom failure and semen exposure proportions using generalized estimating equations methods accounting for within-couple correlation.

RESULTS: Ninety-five (95) efficacy substudy participants used 334 WC and 408 functionality participants used 1572 WC. Based on self-report, 19.2% WC (64 condoms) clinically failed in the efficacy substudy compared to 12.3% WC (194 condoms) in the functionality study (p=.03). Of the 207 WC efficacy uses with evaluable postcoital PSA levels, 14.5% (30 uses) resulted in semen exposure compared to 14.2% (184 uses) of the 1293 evaluable WC functionality study uses.

CONCLUSIONS: When evaluating the ability of an experimental condom to prevent semen exposure, the rate of clinical condom failure reported by participants risking pregnancy in an efficacy substudy was significantly higher than the rate reported by participants not risking pregnancy in a functionality study. The rate of semen exposure, assessed by an objective biomarker was nearly identical for the two studies.

IMPLICATIONS: Our results suggest that an objective marker of semen exposure in functionality studies could provide a reasonable alternative to contraceptive efficacy studies in evaluating risk of unintended pregnancy and inferring protection from sexually transmitted infection than condom failure rates based on self-report.

BARRIER METHODS UPDATE

In February 2020, ReWire.News published an in-depth piece on barrier methods of contraception, specifically highlighting Ovaprene, a non-hormonal barrier contraceptive method developed by Daré Bioscience. The device consists of a plastic vaginal ring and polymer mesh that, in conjunction with ferrous gluconate, acts to prevent sperm from entering the cervix. In contrast to other available barrier methods that require removal after sexual activity, Ovaprene is designed for monthly use.

An initial multi-site study of the device was completed in November 2019 in collaboration with an Idaho Falls, ID community clinic, as well as CONRAD, Oregon Health & Science University, and the University of Pennsylvania. Thirty-eight sexually active women, aged 18-50 who had undergone tubal sterilization and thus not at risk for pregnancy, enrolled in the study launched in May 2018. The research team utilized a postcoital test to measure sperm in mid-cycle cervical mucus after sexual activity across multiple menstrual cycles. Twenty-three study participants reportedly attended 21 visits each for postcoital testing. Although the full results of the study have not yet been published, topline findings reported by Daré in a recent press release indicate that sperm was effectively blocked from entering the cervical canal across all participants in all cycles of use. In addition, they report that 90% of participants would recommend the device to others. Daré plans to apply for investigational device exemption from the United States Food and Drug Administration (FDA), the regulatory agency that reviews and provides approval for medical devices in the United States, and will conduct additional testing of the device in support of an application for pre-market approval.

As reported in Xconomy.com in January 2020, Daré has entered into an agreement with Bayer Pharmaceuticals to license Ovaprene for entry into the US market, pending the outcome of the pivotal clinical trial of the device and approval by the FDA. At the time of that announcement, they anticipated entry of the product into the US market as early as 2023.

ABOUT US

Mission of CBAS
Established in 2004, the Cervical Barrier Advancement Society (CBAS) aims to raise the profile of cervical barrier methods, including diaphragms, caps, female condoms, and other devices, and to share the latest news and resources related to these methods.

CBAS contact information
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