

High prevalence of reproductive tract infection in women screened for a diaphragm and microbicide safety trial in Harare, Zimbabwe

and microbicide safety trial in Harare, Zimbabwe

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Zimbabwe

- Population 12 million
- 25% women age 15-49 yrs
- Shona & Ndebele Ethnic groups
- Life expectancy: 36.5 years
- Most HIV transmission is through heterosexual sex
- 25% Adult HIV Prevalence



Progress to date

- Recruitment completed in April 2005
- 418 women screened and 119 enrolled
- Screen to enrollment ratio was 4:1
- 42 women exited from the study to date
- Estimated date of completion: November 2005

Challenges

- High rate of exclusionary conditions
 - - BV
 - - Candida
 - - Trichomonas
- abnormal pap smears
- Retention
 - - Clinically intensive visits
 - - Participant fatigue
 - - Unreliable transportation
 - - Seasonal travel to rural areas

Background

- The diaphragm is one of the oldest female-controlled contraceptives
- It physically covers the cervix and thus, may decrease exposure to HIV/STI
- It can serve as a delivery mechanism for microbicides
- Combining a physical and chemical barrier may have a synergistic effect for disease prevention
- If proven effective, the diaphragm plus a microbicide may provide a viable female-controlled alternative to male condoms.

Objectives

- - To assess the *safety* of a diaphragm used with the microbicide *Sodium cellulose Sulfate* (CS) or placebo (K-Y® Jelly) when used prior to sexual intercourse for 6 months in sexually active women.
- - To assess the *acceptability* and *compliance* with use of the diaphragm and/or gel prior to vaginal sex for a period of 6 months

DMS study design: a phase I randomized controlled trial

- Sample size: 120
- Three study arms- 40 women per arm
 - Diaphragm and microbicide (CS)
 - Diaphragm and placebo (KY Jelly)
 - Microbicide (CS) alone
- Study site: Spilhaus Clinic, Harare Central Hospital



Diaphragm

Microbicide

Main Eligibility Criteria

- 18-49 years old
- Sexually active
- Not pregnant or breastfeeding
- Using hormonal or long term contraception
- Negative for Bacterial Vaginosis (BV), Candida, Trichomonas, Chlamydia (CT), Gonorrhea (NG), and urinary tract infection (UTI)
- Pap smear cannot show high grade lesion or carcinoma

Laboratory tests at screening

- Pregnancy (HCG urine test)
- Chlamydia/Gonorrhea (cervical PCR)
- BV (wet mount)
- Candida and Trichomonas (wet mount)
- Pap smear
- HIV (2 rapid). *Not an eligibility requirement*

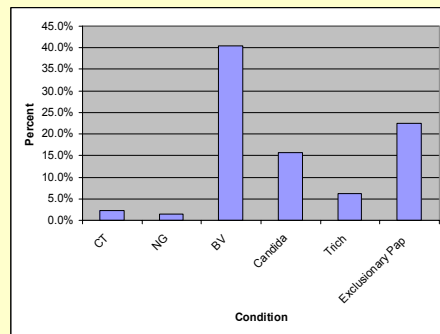
Characteristics of Screening population (N=418)

- Mean age: 30 years (range 18-48)
- Married: 94.5%
- 66% had one lifetime partner
- Mean # of children 2.3 (range 0-9)
- 56% completed secondary education

Diaphragm naïve population

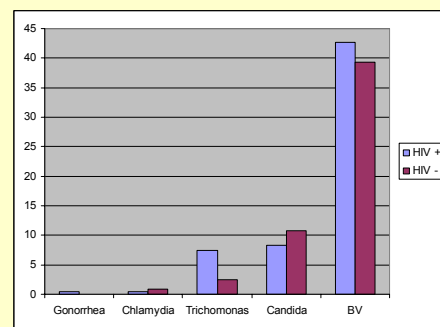
	EVER	NOW
Male condom	57.2%	6.7%
Female condom	6.0%	0.0%
Diaphragm	0.7%	0.0%
Spermicides	0.5%	0.0%
Withdrawal	17.7%	0.0%
Natural/Traditional methods	2.9%	0.0%
Combined Oral contraceptives (COC)	89.7%	65.8%
Injectable hormones	46.2%	18.4%
Sub-dermal implants	7.4%	5.0%
Progestrone-only pills	90.0%	7.9%
Intra-uterine contraceptive device (IUCD)	1.9%	0.7%
Tubal ligation	2.2%	2.2%

Burden of exclusionary conditions



HIV Testing (optional)

- 224 women (54%) elected to receive HIV test
- 36.2% HIV prevalence among those tested



No significant difference in exclusionary conditions between HIV + and HIV- women

Conclusion

Given the high disease burden in this population, enrollment into a safety trial is a challenge. However by recruiting from a truly "at risk" population, we ensure that we target those most likely to directly benefit from these methods, if found effective for disease prevention.