

## Microbicides Research in Kenya: *What is going on?*

The microbicides field is relatively new to many Kenyans and there are few actors involved to date. Various research sponsors, international organizations, and local institutions and organizations are engaging in microbicides-related activities in the country. Most of the research activities thus far are cross-sectional surveys measuring HIV incidence among different populations of women and exploring the sexual behaviours and related practices among these populations.

The key organizations involved in microbicides related research in Kenya are: Family Health International (FHI), the International Centre for Reproductive Health (ICRH), the International Partnership for Microbicides (IPM), the Kenya Medical Research Institute (KEMRI) in collaboration with the University of California, San Francisco (UCSF) and the University of Washington (UW), the University of Nairobi (UoN) in collaboration with Emory University (Emory) and the Urban Research and Development Centre for Africa (URADCA).

The impact of HIV/AIDS varies widely across the country, e.g. some areas of Nyanza province such as Homa Bay and Suba are estimated to have a general prevalence rate greater than 20%, considerably higher than the national prevalence rate of 6.1% (NACC, 2005)<sup>1</sup>. Studies are underway to establish the actual incidence of HIV in these highly impacted areas and to assess their suitability for hosting microbicide trials.

The table below summarizes the various microbicide-related ethnographic/incidence, acceptability, safety and efficacy studies currently being conducted in Kenya.

Study Name	Description	Target Population	Site(s)	Research Institution	Sponsor / Funder	Study Status
Adolescent Sexual Health Formative Study	This study seeks to explore knowledge and beliefs about STI/HIV risk among adolescent girls. It also explores the acceptability of participation in microbicide trials by adolescent girls and the acceptance of parents to consent to participation by their daughters.	Adolescent girls and their parents	Kisumu	KEMRI and UCSF	KEMRI/UCSF	Completed. Data analysis is on-going
Ethnographic Study of Sexual Behaviour of a Cohort of Female Sex Workers in Nairobi	A comparative ethnographic study of the sexual and reproductive health-seeking behaviour of two populations of women: female sex workers and low-risk women in monogamous relationships.	24 female sex workers and 24 married women in monogamous relationships	Nairobi (Kibera and Mukuru slums)	UoN in collaboration with Emory	Emory	Completed. Data analysis is on-going.



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Nairobi HIV Cross-Sectional Incidence Study	A cross-sectional study to determine the incidence of new HIV-1 infections among women in four sites in Kenya. The study enrolls women for a one-time contact at selected voluntary counseling and testing (VCT) sites in the study area.	4,000 HIV and STI negative women (1,000 women per site)	Meru, Naivasha, Nandi Hills, Thika	KEMRI, with technical support from FHI	IPM through FHI	Completed. Data analysis is on-going.
Mombasa HIV Cross-Sectional Incidence Study	The aim of this cross-sectional study is to estimate the rate of new HIV-1 infections.	800 high-risk women	Mombasa (Chaani and Kisauni)	ICRH	IPM	Completed. Data analysis is on-going.
Mombasa HIV Incidence Cohort Study	The aim of this cohort study is to (1) estimate the annual incidence of HIV-1 among high-risk women, (2) assess the ability to accrue and retain women in the study for 12 months, and (3) establish the ability of the site to conduct studies according to Good Clinical Practice guidelines.	400 HIV- uninfected high-risk women	Mombasa (Chaani and Kisauni)	ICRH	IPM	Enrollment completed. Full study expected to be complete by mid-September 2007.
Product Attribute Study	Market research study to assess consumer preference of three placebo gels.	550 sexually active women, aged 18-30	Nairobi and Nakuru; Cape Town, Durban, and Johannesburg, South Africa; Kitwe and Lusaka, Zambia	MR Solutions and Research IQ (market research firms)	IPM	Completed. Results expected 2007.
Safety and Acceptability Study of a Placebo Intravaginal Ring	An international multi-centre trial to assess the safety and acceptability of an intravaginal ring for the delivery of microbicides.	200 (50 per site) HIV uninfected women on reliable contraception	Mombasa; Durban and Johannesburg, SA; and Moshi, Tanzania	ICRH	IPM	Began enrollment in Johannesburg April 07. Mombasa began enrolling May-June 07.

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Study Name	Description	Target Population	Site(s)	Research Institution	Sponsor / Funder	Study Status
Male Microbicide Study	A Phase I randomised double-blinded placebo-controlled microbicide study to determine the safety and acceptability of a topical microbicide, 62% ethanol alcohol in an emollient gel, among men.	1,050 men at risk of STIs	Kisumu	KEMRI and UW	National Institutes of Health (NIH)	Pre-clinical evaluations including an estimation of STI/HIV prevalence has been completed.  Phase I trial is to be initiated in early 2007.
VivaGel™ Study	An expanded Phase I randomized placebo-controlled trial to determine the safety and tolerability of VivaGel™, a topical microbicide, when applied vaginally twice daily for 14 days in HIV negative and STI-free young women.	60 young women aged 18-24 (30 women per site)	Kisumu and San Francisco (USA)	KEMRI and UCSF	NIH	Enrollment and follow-up on-going.

<sup>i</sup> Kenya HIV/AIDS Data Booklet 2005: [http://www.nacc.or.ke/downloads/aids\\_booklet\\_2005.pdf](http://www.nacc.or.ke/downloads/aids_booklet_2005.pdf).

GCM is a diverse network of advocates and nongovernmental organisations (NGOs) working to expand HIV prevention options and encourage ethical research that involves civil society.

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