

Microbicides

Microbicides show promise in protecting people from HIV and sexually transmitted infections (STIs). Since 2000, RTI International has contributed to microbicide research by applying a holistic, multidisciplinary approach to studying the many issues associated with microbicide development and future use.

Microbicides could offer protection against HIV and STIs for individuals who have difficulty using condoms correctly and consistently. In summer 2010, the first successful trial of a vaginal microbicide was announced, showing that the antiretroviral gel Tenofovir significantly reduced South African women's risk of HIV acquisition.¹ RTI investigators are currently involved in a second trial, examining the same gel in a daily dosage form in Uganda, Zimbabwe, and South Africa.

RTI's expertise in social, behavioral, and epidemiological sciences, as well as biomedical and laboratory services, allows us to explore the wide array of research directly and indirectly associated with microbicide development.

Social and Behavioral Sciences. RTI is at the forefront of developing new instruments and technologies to improve the measurement of health status and health-related behaviors associated with HIV/AIDS and STI prevention. RTI investigators have developed and used a variety of tools and technologies to measure product acceptability and adherence, including face-to-face interviews, audio computer-assisted self-interviewing, logs and diaries, interactive voice response, and qualitative methods such as in-depth interviews and focus group discussions. Our survey designers are experts in statistics, cognitive psychology, psychometrics, and survey methodology.

Biomarker and Adherence Measurement Research. In addition to the use of traditional tools for self-reported behavioral data, RTI investigators study biomarkers of sexual behavior (such as prostate-specific antigen, or PSA) and objective markers of product use, involving



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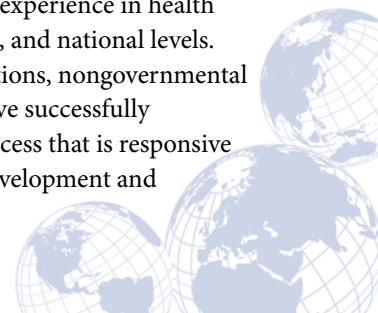
partnerships with small businesses and other research organizations in the development of new technologies for objective assessment of vaginal product adherence.

Clinical Trials and Intervention Studies. RTI investigators have extensive experience in the design and management of acceptability and feasibility research and preclinical and clinical trials of female-initiated methods for HIV/STI prevention. RTI works collaboratively with national and international partners to conduct the research and actively participates in multinational research networks.

Drug Development. RTI's laboratory operations support a wide range of drug development activities, including lead compound identification, preclinical support, and clinical trials sample analysis. Our preclinical services include manufacturing support, comprehensive reproductive and general toxicology studies, and candidate drug characterization support. RTI's clinical trials experience includes analysis of biological samples using state-of-the-science systems. RTI also provides various services for drug development, including medical monitoring, consumer preferences research, conjoint analysis, and coordination of clinical trials.

Health Policy. RTI brings extensive experience in health policy research at the local, regional, and national levels. Working with governmental institutions, nongovernmental and grassroots organizations, we have successfully promoted a participatory policy process that is responsive to client needs and allows for the development and

¹ Q. A. Karim, et al. (2010). Effectiveness and safety of Tenofovir Gel, an antiretroviral microbicide, for the prevention of HIV infection in women. *Science* (329):1168–1174.



Selected Research Activities

International research

RTI staff conducted a safety and acceptability study of the Duet™ device as a possible delivery mode for vaginal microbicide gels. Conducted in Zimbabwe, this study focused on learning about women's and men's perspectives on this diaphragm-like device as a reusable microbicide delivery mechanism and their preferences for the timing of product insertion. It also evaluated the safety of the device in this study population.

U.S.-based research

With funding from the National Institutes of Health (NIH), RTI conducted the Acceptability of Vaginal Microbicides Across Risk Groups and Time study among non-Hispanic blacks and whites; immigrant Hispanic adults; and teens, individuals, and couples recruited from STI and family planning clinics. Participants were given over-the-counter lubricants, serving as proxies for microbicides, to use during sex. They were then interviewed about their experiences and preferences for future products.

Collaborative development of microbicide technology

Important microbicide development activities are being conducted by NIH-funded multinational networks of research groups, such as the Microbicide

Trials Network (MTN). RTI staff serve in leadership roles on the MTN and have previously served with the HIV Prevention Trials Network and STI Clinical Trials Group. These networks have active microbicide studies in the field, ranging from early safety studies to advanced studies of efficacy. RTI investigators are currently part of the Behavioral Research Working Group of the MTN and serve as protocol team members for phases I, II, and III microbicide and pre-exposure prophylaxis (PrEP) trials.

A critical component of microbicide clinical trials is investigational product adherence. RTI, in collaboration with U.S. and South African partners, is managing a sub-study to "VOICE," an MTN phase IIB microbicide and PrEP trial to explore household and community-level factors that influence women's ability to adhere to gel and tablet use.



Candidate microbicide delivery applicators.
[Photo: Cynthia Woodsong]

Also in support of adherence research, RTI, in collaboration with colleagues in industry and at the University of Florida, is conducting a pilot study to evaluate the ability of a breath-based detection system to identify the presence of a taggant in vaginal gels or condoms.

Technical assistance and research support

RTI is providing a variety of services to the International Partnership for Microbicides (IPM) in support of its efforts to accelerate the development and availability of microbicides. Current work supports the IPM study of safety and acceptability of a vaginal ring for delivery of microbicides, advisory services to multiple research protocols, and support for analysis and documentation of study findings for quantitative behavioral, acceptability, and adherence data and for qualitative data.

Ethics support for microbicides research

RTI staff have participated in numerous consultative ethics meetings, led the development of an array of materials supporting the informed consent process, and consulted on development of microbicide video materials. We have also contributed to ethics training materials and conducted ethics training for all staff levels, including researchers, community leaders, and peer recruiters.

implementation of effective policies and programs for HIV/AIDS and reproductive health.

Multisite Coordination. RTI offers long-standing experienced operating multisite data coordinating centers for worldwide projects, many with an HIV/AIDS focus. We provide support services such as study operations, training, regulatory oversight, administrative support, and data coordination, management, and analysis.

Medical Writing. RTI medical writers are experienced in preparing investigational new drug applications, clinical

development (phases I–III) protocols, new drug applications, and post-marketing reports.

See www.rti.org/microbicides for more on these projects and related publications and presentations.

More Information

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