

Microbicide Delivery Device

Health need

In the midst of the growing AIDS pandemic, microbicides could provide urgently needed options for women and men seeking protection from HIV and other sexually transmitted infections. With numerous microbicide products in preclinical or clinical trials, most research has focused on the safety and effectiveness of candidate products, with much less research targeted on devices for delivering these products.

Technology solution

Microbicide delivery devices will be critical in ensuring safe and effective use of microbicide products. The device impacts the product's overall safety (relationship with product purity and stability, avoidance of local trauma associated with insertion or use), efficacy (consistent delivery of the required amount of product in the intended location), and acceptability (comfort, ease of use, disposability). PATH's goal is to ensure that safe, acceptable, and appropriate delivery devices are available for introduction and use with microbicides in low-resource settings. Since 2003, PATH has conducted a wide range of activities to inform and advance the development of new microbicide delivery methods including stakeholder research, clinical and acceptability research, bench testing, commercialization activities, regulatory work, and product development.

Current status and results

In collaboration with microbicide sponsors, researchers, device manufacturers, design companies, and universities, PATH is currently advancing several novel microbicide delivery methods to help reduce cost, ensure microbicide efficacy, and increase user acceptability. Methods include:

- A user-filled paper applicator that is low cost, easily disposed of, and prevents over-filling makes it an important option for microbicide gel delivery in low-resource settings. We evaluated the applicator with Tenofovir 1% gel and are working with key stakeholders in South Africa and elsewhere to advance its use as a delivery option for Tenofovir gel.
- SILCS Diaphragm as a controlled-release microbicide delivery system. We have completed feasibility and proof-of-concept testing for the controlled-release microbicide delivery system. This combination of barrier method and slow-release microbicide could enable prevention of both pregnancy and disease. We are currently looking for additional funding to continue next steps in this development effort.
- SILCS Diaphragm as a reusable delivery system for microbicide gel. We are continuing to build evidence of feasibility, safety, and acceptability. Two studies were recently completed: (1) a feasibility study using MRI to compare gel retention and distribution in the vagina with the SILCS Diaphragm (single-sided and double-sided gel delivery) to a gel delivered by a vaginal applicator, and (2) ease of use and acceptability when couples used these three gel application scenarios during intercourse. CONRAD is planning studies to evaluate the safety and efficacy of the SILCS Diaphragm with Tenofovir gel as a dual-protection device.



PATH/Jesse Schubert

Microbicide in a tube with applicator.

Devices used to deliver microbicide products must be acceptable, affordable, and appropriate for women and men around the world to ensure optimum access and use of microbicides.

Availability

For more information regarding this project, contact Jessica Cohen at jcohen@path.org.

Donor support

Funding for this project has been provided from private foundations and individual donors to the **Health Innovation Portfolio** at PATH, by the **United States Agency for International Development** under PATH's HealthTech program, and from the **Foundation for AIDS Research**.