

Paper Microbicide Applicators

A low-cost solution to increase access to HIV prevention methods

In the midst of the AIDS pandemic, microbicides could provide urgently needed options for women and men seeking protection from HIV. Tenofovir (TFV) gel, a topical antiretroviral microbicide, is the leading microbicide in development. Previous clinical research has suggested that it is safe, acceptable, and effective in reducing the risk of HIV and HSV-2 infection.¹⁻³ Researchers for CAPRISA 004, a Phase 3 clinical trial of TFV gel, demonstrated that when used before and after sex, TFV reduced HIV infection by an estimated 39 percent overall and by 54 percent in women who used the gel most frequently.¹

Most microbicide gels, including TFV, are being tested in clinical trials with prefilled, single-use, plastic applicators. However, the plastic applicator is the most expensive component of the TFV product.⁴

INCREASING ACCESS TO MICROBICIDES FOR POPULATIONS IN LOW-RESOURCE SETTINGS

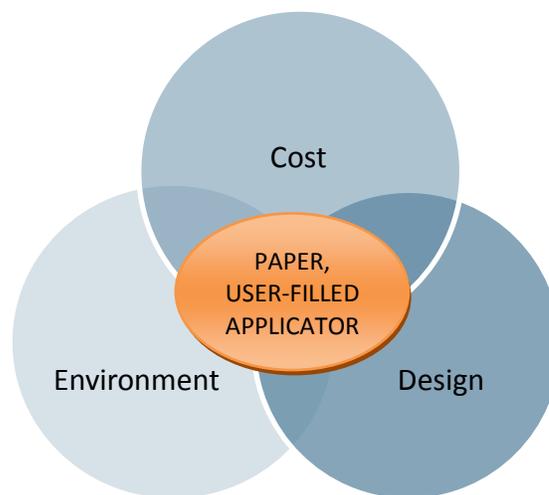
Since 2003, PATH has conducted a wide range of activities to inform and advance the development of novel microbicide delivery methods that are safe, acceptable, affordable, and appropriate for use in low-resource settings.⁵⁻⁷

Through PATH's microbicide delivery activities, we identified a paper, user-filled applicator, manufactured by



Tekpak, Inc. (Marion, AL), as an important practical option that could help reduce cost per dose, thereby improving access to microbicide products in impoverished regions most affected by HIV. Benefits of paper applicators include:

- Cost: it is less expensive than the prefilled applicator.
- Design: its single-use design is a desired attribute among women who have articulated concerns about reusing vaginal applicators.
- Environment: it provides a green disposal option, especially important in settings where burning is a common disposal method.



To help ensure that this affordable option could be made available for microbicide delivery in low-resource settings at the same time that the leading drug, TFV gel, is approved and ready for introduction, PATH, Profamilia, and CONRAD conducted a bridging study to evaluate and compare the paper applicator to the prefilled, plastic applicator. Results indicated that the paper applicator was equally safe, equally comfortable and easy to use, and delivered accurate and precise gel doses.

NEXT STEPS FOR TENOFOVIR DELIVERY

PATH is working with the key sponsors and stakeholders responsible for TFV introduction to help ensure that the paper applicator is part of the TFV introduction strategy for South Africa and other low-resource settings. All partners agree that having a lower-cost applicator for delivery of TFV gel can help reduce overall product costs and improve access to TFV, especially in resource-limited settings heavily impacted by HIV.

MORE OPTIONS MEANS GREATER ACCEPTABILITY

It will take a range of microbicide products and delivery options to address the needs of women and men throughout the different stages of their life. PATH will continue to advocate for the development and use of a variety of affordable, appropriate microbicide delivery methods for low-resource settings to ensure that people can successfully access and use microbicide products to protect themselves from HIV.



PRODUCT INQUIRES

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