It dissolves quickly,

Figure 1. Two potential delivery options.

• A user acceptability study was conducted with limited access to the tools and trained personnel challenged by daily drug regimens and may have for sustained, long-acting release hold promise formulated with ARV drugs (e.g., rilpivirine) Currently in development, microarray patches that are designed for self-administration and formulated with ARV drugs (e.g., cilastatin) for sustained, long-acting release hold promise for increasing adherence to PrEP regimens among women at risk of HIV infection who are challenged by daily drug regimens and may have limited access to the tools and trained personnel required for self injections.

BUILDING THE EVIDENCE BASE

A user acceptability study was conducted with women and health care providers in South Africa to gather initial feedback on two types of long-acting, self-administered microarray patches for HIV PrEP:

• An adhesive skin patch for sustained, systemic delivery of an ARV drug (Figure 1, option 1.)
• A dissolvable vaginal patch for local delivery of a long acting formulation of an ARV drug. (Figure 1, option 2.)

Figure 2. Adhesive skin patch.

APPLICATOR PROTOTYPES

Focus group participants were asked for their thoughts and perceptions on the concept of a skin patch (Figure 2) and vaginal patch for HIV PrEP, as well as on six vaginal patch applicator prototypes (Figure 3).

Figure 3. Vaginal patch applicator.

PRIMARY CONCERNS

• Focus group participants wanted reassurance that the patch would not increase vaginal lubrication or produce discharge, both of which were described as undesirable. Key questions from the participants included the amount of time required for the patch to be absorbed and what activities might impact the efficacy of the product (e.g., vaginal cleansing, menstruation, concomitant infections, and/or pregnancy).
• Health care providers wanted reassurance that the patch would be highly effective and available only by prescription to prevent use of the patch by people who are already HIV positive, which could lead to drug resistance.

KEY CONCLUSIONS

• According to focus group participants and health care providers, an ideal HIV PrEP solution would be discreet, long-acting (three to six months), highly effective, and self-administered.
• Focus group participants also expressed interest in a product that protects them not only against HIV, but also against other sexually transmitted infections and pregnancy.
• Overall, study findings indicated ease of access will be key to product uptake and use by women, especially among those who currently receive contraceptives and other sexual health care free-of-charge from government clinics and hospitals.

MOVING FORWARD

• Several generations of the finger cot and wand/tampon applicator concepts are in development.
• Dissolving microarray patches and applicators will also be tested in a vaginal model.
• An alternative dissolving skin patch design that could provide long-acting protection after a short wear time is being assessed.

ACKNOWLEDGMENTS

Support for this project is made possible by the generous support of the American people through the United States Agency for International Development (USAID) under the terms of the HealthTech Cooperative Agreement # AID-OAA-A-11-00051. The contents are the responsibility of PATH and do not necessarily reflect the views of USAID or the US Government.