ACCEPTABILITY OF MICROARRAY PATCHES FOR DELIVERY OF HIV PRE-EXPOSURE PROPHYLAXIS (PrEP) AMONG WOMEN AND HEALTH CARE PROVIDERS IN SOUTH AFRICA

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VALUE-ADDED TECHNOLOGY

Issues of user compliance with daily antiretroviral (ARV)-based dosing regimens highlight the need for a long-acting delivery method for HIV pre-exposure prophylaxis (PrEP) that can be discreetly self-administered and thus help improve product access and use by people—especially women—at risk of HIV infection in low-resource settings.

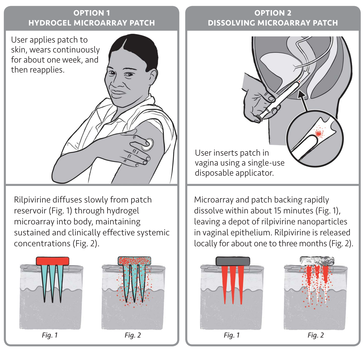
Currently in development, microarray patches that are designed for self-administration and formulated with ARV drugs (e.g., rilpivirine) for sustained, long-acting release hold promise for increasing adherence to PrEP regimens among women at risk of HIV infection who are challenged by daily drug regimens and may have limited access to the tools and trained personnel required for safe 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 1. Two potential delivery options.



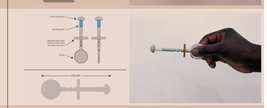
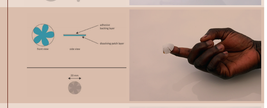
APPLICATOR PROTOTYPES

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 2. Adhesive skin patch.

Concept description	Prototype image
Adhesive skin patch	

Figure 3. Vaginal patch applicator.

Concept description	Prototype image
Balloon applicator	
Tong applicator	
Tampon applicator	
Wand applicator	
Digitally applied with finger cap	
Digitally applied with finger cot	

PATH/Claire Suni

Microarray patches designed for self-administration and formulated with ARV drugs for sustained, long-acting release could someday offer a discreet and effective form of PrEP protection for women at risk of HIV infection.

METHODS

A total of eight focus groups with six women each were conducted in Johannesburg and the KwaZulu-Natal regions. Participants represented both urban and rural locations, a range of ages (18–40 years old), and varying socioeconomic levels. We focused on groups at greatest risk of HIV infection, and with the highest incidence of HIV in South Africa.

In-depth interviews were conducted with six health care providers (four nurses and two community health clinic practitioners).

In addition, 20 physicians representing five key provinces were interviewed over the phone and through an online forum.

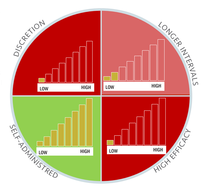
RESULTS

The vaginal patch was particularly well-received among the focus group participants—many of whom mentioned that a vaginally-inserted patch would empower women and provide the utmost discretion for delivery of HIV PrEP. Vaginal insertion of other types of health care products, such as tampons and pessaries, was a familiar concept to participants, who also noted that this mode of delivery inspired confidence in the efficacy of the product. Among the vaginal applicator prototypes evaluated, participants were most comfortable with digitally applied patches and tampon-like applicators.

The skin patch was less favored by focus group participants, who questioned the product's efficacy given its site of administration. Participants also doubted their ability to wear the patch continuously and discreetly.

Skin patch results

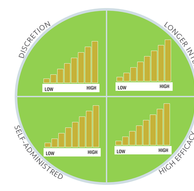
- Nude colour makes the patch obvious and visible.
- Lack of breathability would leave marks on the body.
- Seven-day applications means the patch would constantly need to be worn.
- The patch was easy enough to use without a health care professional's assistance and provided a quick and easy stick-on solution.



- A weekly application was too frequent for most women, especially those on two-month+ contraceptives.
- Those on the pill were more understanding.
- Efficacy was questioned as consumers were unable to understand how the active medication would pass through their skin.

Vaginal patch results

- It dissolves quickly, leaving no trace behind.
- The woman doesn't need any health professionals help to administer the product.



- Re-application every 3 months matches current contraceptive choice pattern.
- Inserted at the site where infection occurs raised efficacy levels.

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

- Second-generation designs of the finger cot and wand/tampon applicator concepts are in development.
- Dissolving microarray patches and applicators will soon 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.

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