

Study Brief

Assessing Physical Delivery of PrEP in Support of Proof of Deliverability: Results from South Africa

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MatCH
Maternal, Adolescent and Child Health
Department of Obstetrics and Gynaecology
Faculty of Health Sciences
University of the Witwatersrand



Mixed results from recent PrEP and microbicide trials have triggered international funders, governments and researchers to consider whether and how ARV-based products could successfully be used for HIV prevention. Key issues to consider include: what at-risk populations are best suited for these products, what formulations could most successfully be used, how to ensure services are acceptable to users in order to support adherence and how to provide these products in real-life service delivery settings. This study focused on physical delivery of ARV-based prevention products by (1) identifying the most acceptable channels for the delivery of PrEP and microbicides based on potential users' and key informants' preferences, (2) evaluating the potential impact of integrating these new products on service quality in existing channels and (3) determining the additional capacity and support needed to integrate these products into existing services. Additionally, potential users' and key informants' interest in ARV-based prevention and their preferences for product formulation were explored. The findings add valuable information to the ongoing discussions about whether and how to implement PrEP and microbicides for HIV prevention. This study was funded by the Bill & Melinda Gates Foundation and was conducted at sites in South Africa and Kenya. This brief describes the results from South Africa.

This research focused on daily-oral PrEP, monthly injectable PrEP and coitally dependent vaginal gels. Groups deemed likely to be early beneficiaries of an available PrEP product were identified as study populations. These were: adolescent women ages 14 - 17 and young women ages 18 – 24 in KwaZulu-Natal (KZN), South Africa.

Qualitative research was conducted in each country; focus group discussions were held with potential user populations and in-depth interviews were held with policy makers, program managers and service providers. Quantitative facility assessments were conducted in both countries. A costing exercise was also undertaken to measure the costs of resources used to strengthen service delivery channels in order to provide PrEP to specific target groups.

Public sector primary health care including family planning, antenatal care and STI clinics, HIV services, NGOs, outreach and community-based services, educational settings and youth-focused programs were investigated as potential delivery channels

Adolescents, young women and key informants did not express a clear preference for a particular PrEP formulation but noted some benefits and limitations associated with each specific formulation. Regulatory requirements, the existing South African healthcare system, and participant perspectives led to the identification of **public primary health care clinics** as the primary PrEP delivery channel for adolescents and young women. Given the extensive existing programs for ARV provision, the provision of PrEP in these accredited facilities was viewed as the most viable and cost effective option for PrEP provision. Additionally, primary health care services offer providers with the capacity to provide ARVs and existing procurement and tracking systems. Concerns include stigma, heavy provider workload, and the need for equipment and supplies. Although the recommendation for actual PrEP service provision is limited to accredited facilities, extensive information, sensitization, and mobilization for PrEP should occur in multiple locations, including youth centers, schools and malls, as well as and primary care settings.

In South Africa, the total start-up costs for PrEP provision are estimated at US\$ 2.2 million and are dominated by training costs. Costs of activating the channels are low in relation to the annual costs of service delivery with costs driven by the product cost. High annual costs could be reduced if a low-cost generic formulation of oral Truvada were available. Additionally, costs would vary depending on product formulation and dosing regimen and acceptance and uptake of PrEP.

Additionally, **family planning services** within primary health clinics are recommended as a delivery channel for young women. Family planning use is high among young women in KZN and clinics are widely available and accessible. Providing PrEP through a basic primary health care setting reduces potential stigma associated with PrEP provision, provides a convenient opportunity for integrated health care and takes advantage of existing staff, facilities and client management systems.

Potential user groups and key informants stressed the importance of having PrEP products available in multiple settings in order to increase access, support adherence and address concerns over privacy, convenience and quality of care. Potential users and key informants identified several categories of inputs necessary for PrEP provision; given that resources are limited; these issues must be prioritized with a focus on effective combinations of prevention and treatment options that maximize the impact of limited resources. Donors and implementing governments must consider the amount of funding that could be allocated for PrEP provision and whether PrEP provision provides an acceptable return on investment. Study results provide valuable information for funders and implementing governments to use when considering PrEP roll-out; however, the process of identifying target populations and delivery channels for PrEP will require sustained discussions between policy makers, civil society, service providers and user populations. Demand creation and motivations for potential users to adhere to the products will also need to be addressed.

Successful PrEP delivery must address several key factors which generally varied little by potential delivery channel. The inputs identified as necessary for PrEP provision include:

- *Position-specific staff training* for existing and new providers, including training on side effects, counseling including continued condom promotion and promoting and monitoring adherence. This need varies by provider and service type—ARV providers have considerable relevant training whereas FP providers would need more training.
- *Improvements to counseling*, including additional training and counselors, are also needed to strengthen HIV testing.
- In government facilities, extensive *sensitization* for providers will also be needed to reduce stigma towards adolescent and young women and potentially other high-risk user groups.
- *Client education on PrEP*, including outreach activities to introduce the product, create demand, and promote adherence, will be essential for successful PrEP delivery.
- *Additional staff* may be needed for counseling given that PrEP counseling may be time consuming. Increased staffing is also necessary to decrease client wait time and provider workload. This reflects the overall sense of understaffing in many facilities and may not be directly related to the provision of PrEP.
- *Adding physical space in facilities* for exam rooms, counseling, and potentially pharmacy supply storage may be necessary.
- *Stock forecasting systems* may need to be improved to avoid stock outs in ARVs needed for HIV prevention as well as treatment, particularly within the government and family planning channels.
- *PrEP client tracking and recordkeeping systems* to monitor PrEP use and adherence and to forecast the need for PrEP products will be required. This may include hiring more staff for recordkeeping, upgrading or creating a recordkeeping system, and training staff to compile and manage data.
- *Ensuring adequate laboratory referral systems* for facilities not equipped to conduct liver and kidney function testing will be important.
- Systems to ensure *sufficient commodities* will be needed for HIV testing and lab testing, including HIV testing kits, gloves, syringes, and supplies for liver and kidney function tests.
- *Improvements to client flow* in clinics will be needed to shorten wait time, including separating ARV and PrEP services but integrating PrEP with other services within HIV treatment services.
- Changes to facility operating times, including *extending working hours* during weekdays and weekends to increase clients' access to services, will be important.
- *Integrating PrEP with other services*, including ARV provision, family planning, and combination prevention efforts/services will also be important to provide services that both maximize existing resources and that ensure users' interactions with the health system are as efficient as possible.
- *Sufficient funding* is needed to ensure free or low cost products and services, as well as increased staffing.

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