Study Brief

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

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 Kenya.

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 included: female sex workers in Nairobi and serodiscordant couples in Nakuru. FHI 360 worked closely with the Ministry of Medical Services and a variety of public, private and NGO facilities working with the target populations.

> Public sector primary health care including family planning, antenatal care and STI clinics, HIV services, NGOs, private sector health services, outreach and community-based services were investigated as potential delivery channels

Qualitative data collection was conducted; 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 also conducted and a meeting with stakeholders was held to validate findings on the viability of potential PrEP delivery channels. 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.

Female sex workers and serodiscordant couples expressed a keen interest in PrEP products and a clear preference for injectable PrEP as a long-lasting and private method. Delivery channels identified for female sex workers included **NGO/research group facilities targeting sex workers** and public sector primary health care, especially family planning services. NGO/research group facilities were prized as high quality, low cost and easily accessible with well-trained, respectful staff. Concerns included limited clinic hours and the potential for the addition of PrEP services to lead to long queues and overwhelmed staff. **Public sector primary health care facilities** were selected as a secondary PrEP delivery channel for their easy accessibility, including free services, expanded working hours and geographical coverage. Additionally, public sector facilities were seen as having the capacity to maximize access, guarantee supply, and ensure safe use. Concerns with public sector facilities included: long wait times, stockouts and concerns with stigma and discrimination against sex workers from staff though the latter was less of a concern with family planning service providers.

If all female sex workers and discordant couples were reached, first-year service delivery costs would be nearly US$ 3.4 million for sex workers and US$ 43.9 million for serodiscordant couples. 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 for oral PrEP 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.

Delivery channels for serodiscordant couples included **Comprehensive Care Centers** (CCCs) within the government system and family planning services. CCCs were identified because of valued existing relationships between the HIV negative individuals and the services and convenience. Additionally, they were seen as providing confidential, high-quality care. Concerns with CCCs included long wait times, poor client flow practices, concerns with stigma associated with HIV-negative individuals receiving care in an HIV treatment facility, and a culture of treatment, rather than prevention, within public sector facilities. Family planning was identified as a secondary channel because of reduced stigma and the capacity to provide confidential services and deliver two services in one visit and location. Concerns with family planning services included waiting time and client flow, staffing shortages, treatment of clients, weaknesses in HIV testing systems and the potential for men to feel uncomfortable accessing services.

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 resources are limited; these issues should be prioritized with a focus on effective combinations of prevention and treatment options that maximize the impact of limited resources. Donors and implementing governments should 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 for PrEP use 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; these 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, promoting and monitoring adherence, and monitoring potential abuse of PrEP. This need varies by provider and service type—ARV providers have considerable relevant training while 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 female sex workers and potentially other high-risk user groups.
- ***Client education on PrEP***, including outreach activities to introduce 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, CCC, 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 clinic will be needed to shorten wait time, including separating ARV and PrEP services but integrating PrEP with other services within CCCs.
- 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 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.

Acknowledgements

- Bill and Melinda Gates Foundation for funding
- APHIA Plus *Nuru ya Jamil*
- Coptic Mission Hospital
- FHOK (Kibera, Nairobi West, Ribeiro sites)
- Key informants
- Langa Langa health center
- Mariakani Cottage Hospital
- Medical Officer of Health, City Council of Nairobi
- Rift Valley Provincial General Hospital
- Provincial Director of Medical Services, Rift Valley
- St. Mary's Mission Hospital
- STI Casino clinic
- SWOP (City clinic and Langata)
- Research Assistants
- Valley Hospital, Nakuru