Title: Demonstrating the effective delivery of oral HIV pre-exposure prophylaxis (PrEP) as part of an HIV combination prevention intervention (IPCP-Kenya)

The Kenya Ministry of Health reported HIV prevalence to be 5.6% in 2015. However, within key and priority populations, the HIV burden is greater – 15% for both female sex workers (FSW) and men who have sex with men (MSM) and as high as 30% amongst adolescent girls and young women (AGYW) population group. Kenya has scaled up various HIV prevention interventions including HIV testing and counselling, condom promotion and distribution, voluntary medical male circumcision, ART for people living with HIV, and behaviour change programmes for most at risk populations. Additionally, HIV pre-exposure prophylaxis (PrEP), an ARV drug taken to protect an uninfected individual from acquiring HIV has been recognized as among the most effective drugs for HIV prevention, within approval by FDA granted and randomised clinical trials reporting an efficacy rate of over 80% for individuals who are at a substantial continuous risk of HIV acquisition and take oral PrEP daily as recommended. Though shown to be effective, it is not yet clear what effect introducing this drug into HIV prevention programs will have on the behaviour of those who use it. There are also questions on what is needed at health infrastructure, human resource, demand creation, community engagement and end-user support level to deliver PrEP to those who need it and have them use it effectively for HIV prevention, and most importantly integration in the already robust Kenya HIV Prevention programs.

This LVCT Health led demonstration project aims to generate evidence on how daily oral HIV PrEP can be delivered alongside other available prevention methods to MSM, FSW and young women at high HIV risk (YW) in real life settings. Justification to carry out the demonstration project was gained from results of a feasibility study conducted in October to December 2013 which demonstrated high willingness to take PrEP among KP and PPs, and support for the introduction of PrEP as part of combination prevention packages among policy makers and health providers. The data also suggested the need for exploring optimal adherence interventions and a better understanding of risk and self-risk perceptions, factors influencing adherence to HIV Prevention, including PrEP for those most in need of it.

Participant Enrolment and Follow Up

Six public (2) and private (4) health facilities were selected for implementing this PrEP demonstration project from August 2016 with an expected completion date of October 2017. A total of 1,626 eligible participants were enrolled from August 2015 to October 2016: 546 FSW, 637 YW and 443 MSM across the 6 demonstration sites. Follow up period for all initiated on PrEP was 12 months from their point of enrolment, during which they are offered daily oral PrEP and qualitative and quantitative data collected from them.

After initiation on PrEP, clients were expected to return to the facilities and obtain a refill of their PrEP, as well as receive adherence counselling by a trained health service provider on the importance of sustaining the use of the medication during periods of risk. All were monitored for any side effects. To promote uptake of HIV prevention and oral HIV PrEP, the following measures were taken: use of peer educators for FSW and MSM for PrEP demand creation amongst the MSM, FSW groups, community health volunteers for YW; enrolment of all on PrEP into weekly support group; peer tracing and follow up for those with low appointment attendance rates.

Findings

Emerging lessons from the IPCP demonstration project thus far include:

- ✓ Stigma against PrEP users exists as well as numerous myths and misconceptions around its use which acted as a barrier to PrEP access and effective. Effective PrEP communication should emphasize the positive aspects of PrEP use and communication materials are best developed together with end users
- ✓ PrEP initiation and follow up procedures will need to be simplified to avoid potentially increasing the burden of work for health service providers but also to make it easier for end users to access PrEP services.
- ✓ There might be need to adjust timings of PrEP service provision centres to cater for the needs and preferences of different target populations
- ✓ PrEP use could potentially result in social harm. Mitigation measures will be needed including putting in place mechanisms to support PrEP users to disclose PrEP use if deemed necessary.
- ✓ Key populations in Kenya are very mobile and there might be need to consider networking PrEP services so as to allow them easy access to PrEP whenever they need it

These lessons learnt helped inform the development of the 2016 Kenya National PrEP Implementation Framework. Following dissemination of the guidelines, PrEP was officially rolled out in Kenya by the Ministry of Health in March 2017, for individuals at substantial ongoing risk of HIV.

What next?

There is need for implementation science research on how to better PrEP delivery, maximising uptake of all its users during scale up. Pertinent issues that need to be addressed in ensuring effective delivery of PrEP to those who need it most include to:

1. Test PrEP adherence and retention strategies for AGYW (compare different strategies in different sites and compare effectiveness)
2. Approaches to ensure rapid/immediate PrEP initiation e.g. point of care creatinine and Hep B testing
3. Test different integrated models for delivery of PrEP for different populations e.g. delivery in ANC clinics, CCCs, VCTs, FP clinics, as well as community based service delivery e.g. at youth friendly centers, DiCEs
4. Measure feasibility and effectiveness of different models that are less involving to the health service provider e.g. only counsel those who miss appointments or self-reported adherence challenges, integrate self-testing among users of PrEP
5. Understand end-user decision making (particularly AGYW) and develop innovative interventions to motivate uptake for ARV based prevention
6. Study social harms alongside the implementation and scale up of ARV based prevention
7. Test communication messages and demand creation strategies for different populations-develop standard toolkits for addressing opposition to ARV based prevention

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