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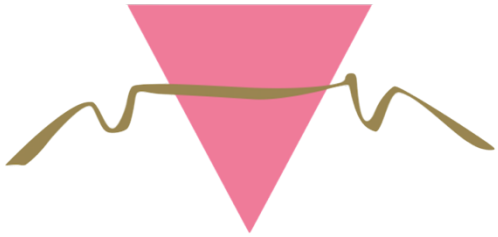

HIV ARV-BASED PREVENTATIVE MEASURES

February 2016[1]

PrEP

"PrEP" stands for Pre-Exposure Prophylaxis. PrEP is a way for people who don't have HIV but who are at very high risk of getting it to prevent HIV infection by taking a pill every day. The only PrEP available in South Africa is Truvada, a pill that contains two HIV medications (tenofovir and emtricitabine). These medicines work by blocking entrance into the cell OR blocking HIV from using the cell to replicate itself once inside by inhibiting production steps.. If you take PrEP regularly and correctly and are exposed to HIV through sex, injection drug use or another method, these medicines can work to keep the virus from taking hold in your body. Truvada® is approved by the U.S. Food and Drug Administration (FDA) and the SA Medicines Control Council (MCC) for daily use as PrEP for people at very high risk of getting HIV infection.

PrEP is a powerful HIV prevention tool and can be combined with condoms and other prevention methods to provide even greater protection than when used alone. But people who use PrEP must commit to taking the drug every day and seeing their health care provider for follow-ups every 3 months. Truvada for PrEP provides 92%-99% reduction in HIV risk for HIV-negative individuals who take the pills every day as directed. If a daily dose is missed, the level of HIV protection may decrease. People who use PrEP correctly and consistently have higher levels of protection against HIV. The iPrEx study found PrEP to be have an estimated level of protection of 99%, 96% and 76% for people taking 7, 4 and 2 PrEP pills per week respectively. When starting PrEP, it takes at least seven days to reach high levels of protection against HIV and when stopping PrEP, individuals should continue using PrEP for four weeks after the last significant exposure and discuss with their with doctor regarding changes in sexual behaviours and alternative preventative methods. Highest level of protection against rectal and vaginal exposure to HIV is achieved and maintained after 7 and 20 daily doses of Truvada respectively.

Importantly, PrEP can only be used by those whose status is definitively known to be negative, as it can have detrimental effects if used by HIV-positive persons. PrEP is a prophylaxis, meaning it is a treatment to prevent infection and not treat the infection itself. PrEP is not a treatment for HIV. HIV drug resistance refers to the ability of viruses to continue multiplying despite the presence of drugs that usually kill them. As HIV multiplies it sometimes changes form and produces different versions of itself. These different versions can develop whilst taking different HIV medicines and some of the versions may be drug resistant. This resistance can cause HIV treatments to fail. There is a concern that taking preventative methods can lead to drug resistant HIV. However, PrEP is only for people who are HIV negative and resistance cannot develop in HIV negative persons as there are no cells replicating themselves to mutate/develop alternate strains. This is why ongoing HIV testing is necessary to ensure such drug resistance does not develop should the person become HIV positive. The two ARVs contained in Truvada are not sufficient for treating HIV on its own. Treatment of HIV

[1] Compiled by Emma Jones-Phillipson, Policy Intern, and Matthew Clayton, Research, Advocacy & Policy Manager

usually requires 3 or more anti-HIV drugs used in combination. Studies show no resistance in people who test HIV negative and take PrEP correctly and consistently. Truvada has minor side effects that tend to subside after a few weeks (nausea, headache, weight loss or gain, stomach upset, minor changes in bone health and kidney function).

PrEP is designed for those identified to be at risk for contracting HIV. In South Africa, the National Strategic Plan on HIV, STIs and TB identified the following populations as "most-at-risk" for contracting HIV and accessing HIV services: young women between the ages of 15 and 24 years; people living close to national roads and in informal settlements; young people not attending school; people with the lowest socio-economic status; uncircumcised men; people with disabilities; sex workers and their clients; people who abuse alcohol and illegal substances; men who have sex with men; and transgender persons. Given the different nature of the HIV and AIDS epidemic in South Africa, being an economic as well as a social issue, the list of vulnerable populations (and those who could stand to benefit from PrEP) is broader than those referred to in studies or designations from more developed countries like the US. These "first world" lists tend to be limited to MSM; drug users; heterosexual men or women who do not regularly use condoms during sex with partners of unknown HIV status who are at substantial risk of HIV infection; gay and bisexual men diagnosed with STIs in the previous 6 months. PrEP is also a potential option for women who are considering getting pregnant where their partner is HIV-positive as it may provide an option to protect both the mother and baby from transmission i.e. HIV negative women in sero-discordant relationships[2].

PrEP not designed to be a lifetime solution. Some people have "seasonal" risk where different periods have different levels of risk. It is possible for these people to use PrEP when at higher risk and then stop in favour of another appropriate prevention option. However, only people have seasonal risk, others are at risk because of their very identity, especially if they are at risk because of their vulnerability to being raped or sexually assaulted. People might outgrow being an adolescent or move away from a high risk area, others may not have this privilege i.e. MSM, transgender people. This is a potential field for debate or further inquiry. As PrEP is a fairly new treatment, little is known about long-term side effects. PrEP is only for people who are at ongoing substantial risk of HIV infection. For people who need to prevent HIV after a single high-risk event of potential HIV exposure—such as sex without a condom, needle-sharing injection drug use, or sexual assault—there is another option called post-exposure prophylaxis, or PEP. PEP must begin within 72 hours of exposure, where as PrEP is a daily preventative medication.

CONCERNS RAISED IN QUESTIONS/DISCUSSION:

Does making regular HIV testing (every 3 months) potentially defer people from accessing PrEP as they may be sceptical of whether it works? Important to communicate why testing regularly is important when on PrEP. Important to stress parallel preventative methods (male and female condoms etc) as well. Regular testing does not equate to protection, responsibility must be on prevention. Will people want PrEP? Who would access it if it's available? Will people take a daily medication if they know it prevents HIV? How will sexual practices change for those using PrEP – will they increase risk?[3] Will PrEP be safe in the "real world"? How and where wold it be delivered? Who pays for it, and is it cost-effective? Will the NHI cover PrEP? Will private health schemes? Who will be the gatekeepers of PrEP?

[2] One partner is HIV positive and one partner is HIV negative
[3] Moral Hazard

Potential Answers: Demonstration projects. TB/HIV Care Association will soon be conducting a pilot project on sex workers. Desmond Tutu HIV pilot project on young adolescent and young women in JHB, KZN – DREAMS project[4].

Microbicide Vaginal Ring

Microbicides are medical products designed to protect healthy HIV-negative women from becoming infected with HIV during sex. Unlike PrEP, microbicides can only protect women and can only protect during sexual contact as they are applied topically to the vagina or rectum. Microbicides can take the form of rings, gels, films etc. Where PrEP fights the virus by blocking reproduction through levels of PrEP in the body system, microbicides target the point of entry of the virus in the vaginal canal/rectum. A long-acting dapivirine vaginal ring would provide women with a practical method they can use to protect themselves against HIV for a month at a time (28 days). The monthly ring, which slowly releases the ARV drug Dapivirine over time to protect against HIV, is currently in two Phase III trials, with efficacy results expected in early 2016. The ring is one of the most promising microbicide methods tested thus far. It consists of a silicon ring infused with 25mg of Dapivirine and is placed against cervix, slowly releasing the ARV along vaginal canal until removed and replaced.

Advantages include: One ring could provide protection against HIV for a month or longer; Because the ring is long-acting, it may help women use it consistently and help ensure effectiveness; The ring is convenient and discreet; IPM studies show the ring is highly acceptable to women in Africa, where the need is most urgent; The ring is physically stable, durable and easy to distribute, making it suitable for use in developing countries; The ring delivers the ARV locally where it's needed, with low systemic drug absorption; Dual-purpose rings that combine an ARV with a contraceptive could offer women both HIV protection and contraception in a single product; Combination rings could one day deliver multiple ARV drugs to increase the breadth of protection; and it provides passive agency to women who encounter challenges in negotiating condom use

The ring is not yet available, but there are two current studies (due to be publishing results soon) about the efficacy of the ring in various Southern African countries (including South Africa). These are The Ring Study (SA and Uganda) and the ASPIRE study (SA, Uganda, Malawi and Zimbabwe). The results for the Ring Study are due on 22 February 2016. These studies seek to discover more about acceptability, efficacy, drug interactions, adherence, side effects and so forth.

CONCERNS RAISED IN QUESTIONS/DISCUSSION:

What will the results say? What is the acceptability rate in South Africa? What about issues with foreign objects in vagina – those that are uncomfortable, not culturally receptive, "virgin" etc? How do we target people? If people are cutting out contraceptive implants to smoke the contents and are smoking ARVs, would these rings perhaps become a target for drug abuse? Could this lead to further instances of sexual assault? Will the NHI cover such treatments? Will private health schemes? Who will be the gatekeepers of the ring? Will there be limits? Age limits? Sex limits? What about underage girls? Girls under the age of sexual consent? Will it be made available to vulnerable victims for rape? Who will determine eligibility? Will non-sexually active be eligible? How do we counter instances of moral hazard (reduced use of condoms and other protective measures)?

The issue of female agency - Does promoting passive agency in granting women access to interventions like PrEP and microbicidal rings potentially undermine their ability to exercise their

[4] Additional sites for information: http://www.ipmglobal.org/the-ring-study
http://men.prepfacts.org/the-basics/
https://www.aids.gov/hiv-aids-basics/prevention/reduce-your-risk/post-exposure-prophylaxis/
https://start.truvada.com/?_ga=1.47561380.2050733806.1455195914
http://www.Avac.org/prevention-option/prep
http://www.Prepwatch.org
http://www.cdc.gov/hiv/prevention/research/prep/

active agency in demanding their partners wear condoms? How can we promote both passive and active agency so that women are increasing (and not decreasing) their autonomy in managing their sexual and reproductive health?