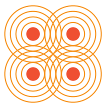

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EVIDENCE FOR HIV PREVENTION IN SOUTHERN AFRICA

The EMPOWER study: An evaluation of a combination HIV intervention that includes oral PrEP for adolescent girls and young women in South Africa and Tanzania (findings from Tanzania)

EVIDENCE BRIEF
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What have we learned?

The EMPOWER study in South Africa and Tanzania aimed to assess the feasibility, acceptability and safety of offering oral pre-exposure prophylaxis (PrEP) as part of a combination HIV prevention package addressing gender-based violence (GBV) and stigma in adolescent girls and young women. The impact of empowerment clubs, incorporating a four-session empowerment curriculum, on retention in care and adherence to PrEP, was also assessed.

In Tanzania, the study population was adolescent girls and young women working in bars, restaurants and other food and alcohol outlets in Mwanza city. Among women who were screened for eligibility to take part in the study, prevalence of HIV was high – 9.5%.

Risk factors for HIV were highly prevalent:

- Among the women screened for eligibility to take part, more than one third (35%) had experienced GBV. Sexual violence and psychological abuse were the most common forms of violence – around one in five (22%) women reported experiencing either form of violence.
- More than half (59%) of women enrolled were diagnosed with at least one sexually transmitted infection at the start of the study. However, very few women reported experiencing any symptoms.

During study information meetings with young women, there was considerable interest in oral PrEP. All women who enrolled into the study started PrEP immediately. Consistent use of PrEP was challenging for some women – around one third of women did not have a consistent supply of PrEP to enable them to take a pill every day. During clinic visits, common reasons reported for not taking PrEP consistently were forgetting to take pills, not bringing pills when they travelled and losing pills.

Ensuring that women had regular access to HIV prevention services, including PrEP adherence support/care, was challenging. Half the women missed one or more of three scheduled clinic visits over the six-month study period. Furthermore, attendance at the empowerment clubs was very low. Just over a quarter of women attended all four curriculum sessions and around one third (31%) did not attend any sessions. However, women who attended the clubs were very positive about the curriculum.

Lack of economic security seemed to be a major barrier to women accessing HIV prevention services. Delivery of sexual reproductive health services needs to be flexible and responsive to the needs of this and similar populations of adolescent girls and young women. It is vital that services include screening for GBV with appropriate referral for ongoing support. Further research is needed to explore and better understand the lives of these young women, in particular, where HIV prevention fits in relation to other priorities in their day-to-day lives.

"... Aah it's because in the community there is gender-based violence, a man wants to have everything he wants. For example; there is HIV, but how the man sees it is that you're his lover, maybe he doesn't want to use condoms, or he doesn't want to get tested. But this clinic helps you to know that even if he won't put on condoms, there is a medication to protect you from being infected with HIV."

(study participant, indepth interview)

What is the issue?

In Tanzania, the overall prevalence of HIV among people age 15-49 years is estimated to be around 5%. Prevalence is higher among women compared with men (5.8% vs. 3.6%), particularly in the younger age groups.[1] For example, women age 23-24 are more than twice as likely to be infected with HIV than men of the same age (6.6% vs. 2.8%).[2] A range of factors contribute to young women's vulnerability to HIV in Tanzania, including younger age at sexual debut than boys, older partners,[3] cultural norms that include subordination of women to men, and lack of female-controlled HIV prevention options.

Pre-exposure prophylaxis (PrEP) offers a promising female-controlled HIV prevention option for women. A systematic review of eighteen studies concluded that PrEP is effective in reducing HIV infection across types of sexual exposure, sexes, and PrEP regimen and dosing. Furthermore, the effectiveness of PrEP in reducing HIV infection is greater with higher adherence.[4] The findings of this review led the World Health Organization to announce in September 2015 that tenofovir-based oral PrEP should be offered to those at substantial risk of HIV infection. However, despite the evidence that oral PrEP is effective when taken, there are concerns about its benefits for adolescent girls and young women, mainly because of poor adherence. Two trials of oral PrEP that enrolled women from eastern and southern Africa were unable to detect efficacy because of low adherence, particularly among younger women.[5, 6]

PrEP is not currently licensed in Tanzania but is being introduced into settings with similarly high background rates of violence. Studies of populations in Tanzania indicate around a third of women have experienced past-year physical and/or sexual violence from an intimate partner.[7, 8] Violence, in all its forms – physical, sexual and psychological – increases a woman's risk of HIV infection.[9, 10] Examples of pathways that appear to be significant are[9]:

- sexual abuse in childhood has possible developmental and psychological consequences that can lead to a range of risk behaviours, such as abusing alcohol and other substances, and multiple sexual partners,
- violent and abusive men are more likely to engage in a range of higher risk behaviours and therefore more likely to be HIV positive, which in turn increases the risk of HIV acquisition among their partners,
- the biological effect of violence and trauma on a woman's immune system and hormonal functioning may mean that she is more susceptible to becoming infected with HIV and, once infected, more rapid progression of the disease.

Furthermore, violence and threats of violence can be a barrier to women accessing information and may undermine their ability to initiate and use HIV prevention services, resulting in decreased use of and adherence to HIV prevention options and services.[9]

HIV prevention strategies that address the different forms of violence against women are urgently needed.

The EMPOWER study

The EMPOWER study was conducted to assess the feasibility, acceptability and safety of offering oral PrEP as part of a combination HIV prevention package that addresses gender-based violence (GBV) and stigma in adolescent girls and young women, aged 16-24 years, at substantial risk for HIV infection. The study was conducted at two sites – Johannesburg, South Africa and Mwanza city, Tanzania.

In Tanzania, the study population was adolescent girls and young women working in bars, restaurants and other food and alcohol outlets in Mwanza city. Women who were HIV negative, not pregnant and interested in taking oral PrEP were enrolled into the study following informed consent procedures. Study participants were offered oral PrEP at enrolment and followed up for six months. At each clinic visit, women underwent:

- HIV testing and counselling with integrated screening for GBV and stigma (using a tool developed by the study team),
- comprehensive sexual and reproductive health care.

Intervention

As part of the study, an enhanced adherence/care package was evaluated for its impact on retaining women in care and supporting continued use of oral PrEP. Women enrolled into the study were randomly allocated to either:

- standard adherence/care package; or
- standard adherence/care package plus empowerment clubs.

The standard adherence/care package comprised comprehensive sexual and reproductive health care with counselling and SMS reminders for oral PrEP users. The empowerment clubs incorporated a four-session gender empowerment curriculum as follows:

- Gender Roles & Social Norms
- Sexual Reproductive Health
- Power and Control
- Empowerment

The curriculum was designed to be participatory and reflective with the aim of empowering young women by building good communication and conflict resolution skills and supporting safe introduction of HIV prevention methods, including PrEP, within intimate relationships. Trained female facilitators facilitated the sessions, following detailed guidance on each session in the Strive to Empower manual.

Evaluation

In Mwanza, the study team worked with local community leaders and owners of bars, restaurants and other food and alcohol outlets, to organise study information meetings for female employees. Women who were interested in taking part in the study were invited to meet with a member of the team to go through the EMPOWER information sheet. Those who were eligible to take part and who provided informed consent were enrolled into the study.

Among 90 women screened for eligibility, 52 were enrolled into the study. Of these, 26 women were allocated to receive the standard adherence/care package plus empowerment clubs, while 26 women were allocated to receive the standard adherence/care package only. Participants in both groups were followed up at three time points over a six-month period.

Members of the EMPOWER study team in Tanzania

EMPOWER study findings in Tanzania

1 Risk factors for HIV were highly prevalent among women taking part in the study

Among women who took part in the EMPOWER study in Tanzania, there were high rates of GBV and sexually transmitted infections (STIs).

Of the 84 women who underwent counselling and testing for HIV as part of eligibility screening for the study, 9.5% women were HIV positive. This is almost twice the national prevalence of HIV in Tanzania, which is around 5%.[11]

High rates of gender-based violence

Screening for GBV as part of HIV testing and counselling was feasible and acceptable to women. Among 82 women who underwent screening for GBV as part of eligibility screening for the study, 35% reported experiencing violence. The most frequent forms of GBV reported were:

- sexual violence – around one in five women (22%), and
- psychological abuse – around one in five (22%) women.

Physical violence was reported by 12% of women. The rates of GBV were similar when restricted to the 52 women who were subsequently enrolled into the study, although a higher proportion (17%) of these women reported physical violence. GBV reported by women had frequently been perpetrated by a partner. Although, around a third (30%) of women who reported psychological abuse, reported that the abuse had been perpetrated by someone other than a partner

Following enrolment, new episodes of GBV were reported by two participants. One woman reported controlling behaviour by her partner who took her PrEP pills from her, forbidding her to use them. She tested positive for HIV and started antiretroviral therapy, and did not report any new episodes of violence during the study period. The second participant reported a new episode of physical violence from her partner, which was unrelated to her participation in the study or taking PrEP.

High prevalence of sexually transmitted infections

Among the 46 women who provided a vaginal swab at study enrolment, more than half (59%) were positive for at least one STI:

- 33% had Trichomonas vaginalis,
- 17% had Chlamydia trachomatis,
- 17% had Neisseria gonorrhea,
- 24% had HSV-2.

None of the women tested positive for syphilis. Very few of the women who were diagnosed with an STI had reported any symptoms, which is not uncommon and has been reported elsewhere.[12]

2 High uptake of oral PrEP suggests a desire for HIV prevention options that can be controlled by women

All 52 women enrolled into the study accepted the offer of oral PrEP at enrolment. There were reports from women of mild side-effects within the first month, such as nausea, but these quickly resolved.

By month 6, based on pharmacy refills, 61% of women were still using PrEP.

During clinic visits, some women reported forgetting to take PrEP on some days and others reported losing pills or forgetting to bring them when they travelled.

Aside from the EMPOWER study population, there was considerable interest in oral PrEP. During the study information meetings with women working in bars, restaurants and other food and alcohol outlets, there were a lot of questions about PrEP and how women of all ages can access it in Tanzania. This population of young women are aware of their increased risk of HIV infection – with discussions often focussed on the risk from transactional sex with customers, especially men refusing to use condoms.

3 Participation in HIV prevention support services was challenging for women taking part in the study

Following enrolment, only 50% of participants attended all three of the scheduled clinic visits at one, three and six months. Eight (15%) women did not attend any follow-up clinic visits after enrolment. Women who missed visits did not receive the HIV prevention support services provided as part of the standard adherence/care package, including:

- HIV testing and counselling with screening for GBV and stigma,
- sexual and reproductive health care,
- top-up supplies of oral PrEP.

Of the 26 women who missed one or more clinic visits, six women only missed the last clinic visit at month six and so did receive the full quota of PrEP pills dispensed during the study period.

Attendance at the empowerment clubs was low. Among the 26 women invited to attend the four-session curriculum delivered at the clubs:

- just over a quarter of women attended all four sessions of the curriculum,
- almost one third (31%) did not attend any sessions.

Regular SMS messages were sent to participants reminding them about their clinic appointments and the empowerment clubs. Study team members also visited participants at their work place and/or home, assisting with transport to the clinic if needed. Many women reported work commitments and other income generating activities, as well as personal commitments, as barriers to attending the clinic and the empowerment clubs. Another barrier was frequent travel away from Mwanza, which is typical in this population of young women who often travel for work opportunities.

The women who did attend the clubs were very engaged and interactive. They particularly liked the sessions on sexual and reproductive health, and empowerment. The club facilitators noted that the women asked lots of questions during the sessions, particularly about sexual and reproductive health matters. The women commented that they do not know much about their bodies. Most who took part in the study had not received secondary level education and therefore did not receive even elementary sexual and reproductive health education in school.

What is the impact?

The sample of women in Tanzania was small so any conclusions are very limited. Even so, the high prevalence of risk factors for HIV observed has been reported in other studies of similar populations in Tanzania.[3, 13-15] Oral PrEP for HIV prevention is not currently licensed for use in Tanzania. However, the Tanzanian government has set up a technical working group to assimilate evidence from studies of PrEP within Tanzania. The findings of EMPOWER will be shared with the technical working group. In this population of young women:

- GBV screening integrated into HIV counselling and testing was feasible and acceptable,
- there was high prevalence of GBV and other risk factors for HIV, particularly STIs,
- there was recognition of HIV risk and a desire for female-controlled HIV prevention options,
- consistent engagement with HIV prevention support services was often difficult because of the busy nature of their lives.

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For more about the overall EMPOWER trial in both Tanzania and South Africa, see Delany-Moretlwe, S., Scorgie, F., Harvey S. STRIVE Evidence Brief: The EMPOWER study: An evaluation of a combination HIV prevention intervention including oral PrEP for adolescent girls and young women in South Africa and Tanzania; London School of Hygiene and Tropical Medicine, London, UK; 2019

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STRIVE research consortium
A DFID-funded research programme consortium, STRIVE is led by the London School of Hygiene & Tropical Medicine, with six key research partners in Tanzania, South Africa, India and the USA. STRIVE provides new insights and evidence into how different structural factors – including gender inequality and violence, poor livelihood options, stigma, and problematic alcohol use – influence HIV vulnerability and undermine the effectiveness of the HIV response.