

# 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

EVIDENCE BRIEF  
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## Background

Adolescent girls and young women (AGYW) in eastern and southern Africa bear a disproportionate burden of two co-occurring epidemics in the region: HIV and violence. In South Africa, HIV prevalence among 20 to 24 year-old women is three times higher (15.6 %) than among men the same age (4.8 %);<sup>1</sup> this gender disparity is also apparent in Tanzania, where AGYW have a three-fold higher HIV prevalence than young males (3% vs. 1%).<sup>2</sup> Key factors contributing to young women's elevated risk of HIV acquisition are gender inequality, harmful gender norms and the high prevalence of gender based violence (GBV), including intimate-partner violence (IPV).<sup>3-5</sup> In Johannesburg, South Africa, more than a third (36.6%) of adolescent girls interviewed in a multi-country study of violence reported either physical or sexual IPV in the past year.<sup>6</sup> And in Tanzania, a recent cross-sectional study found that as many as 61% of women reported lifetime experience of physical and/or sexual IPV; 27% in the past 12 months.<sup>7</sup>

Globally, the association between IPV and HIV is now well-established, having been confirmed by at least two prospective studies, which estimate the population attributable fraction of HIV due to IPV to be between 12% and 22%.<sup>4, 8</sup> Importantly, research increasingly shows that there are multiple pathways by which partner violence – including physical, sexual and emotional violence – increases young women's HIV risk. One pathway that is becoming more apparent to researchers in this field involves the influence of partner violence on women's ability to consistently use HIV prevention technologies (See Box 1).

In the case of oral pre-exposure prophylaxis (PrEP), consistent use is critical, as trials have shown that its efficacy depends on it being used. Women in particular need high levels of consistent use to achieve protective concentrations of tenofovir/ emtricitabine.<sup>9</sup>

## Box 1: HIV prevention trials in east and southern Africa in the context of IPV

### MIRA: Condom and diaphragm (South Africa & Zimbabwe)

- 55% of participants reported recent IPV, including fear of violence (41%), emotional abuse (38%), being physically assaulted (16%) and forced sex (15%) by their regular male partner
- IPV was associated with both condom and diaphragm non-adherence<sup>18</sup>

### MDP 301: Microbicide gel (South Africa, Tanzania, Uganda & Zambia)

- Participants in the Johannesburg site described their partners as authoritarian, controlling and suspicious; they were also often perpetrators of IPV<sup>19</sup>
- In Mwanza, Tanzania, women developed tactics to avoid angry or violent partners, and worked hard to conceal gel use if partners opposed its use<sup>20</sup>

### FACTS 001: Oral PrEP (South Africa)

- An estimated 10% of the enrolled cohort experienced at least one social harm during the 27 months of the trial, most of which was attributed to partner conflict or violence<sup>21</sup>

### PARTNERS Demonstration Project: Oral PrEP (Kenya & Uganda)

- PrEP interruption was significantly associated with IPV, with a greater than 2-fold higher risk of non-adherence when violence was reported (AOR = 2.6, 95% CI 1.2 to 6.0)<sup>22</sup>

### CHARISMA: Vaginal ring (South Africa)

- Ring use and study participation exacerbated IPV, and for some couples, was even a rationale for additional abuse
- As a result, women felt powerless and fearful of conflict, and some chose to stop using the product<sup>23</sup>

When adherence is high, risk of HIV infection may be reduced by as much as 70%<sup>10</sup> – and for this reason, PrEP has been viewed by many as a potentially empowering technology for young women.

Given the mounting evidence that even the fear of violence or rejection may lead to non-uptake of PrEP, as well as PrEP concealment and subsequent low use, programmes to deliver these products to young women need to address this risk at the outset. In particular, innovative approaches are needed to counter the negative impact of partner violence in shaping young women's decisions to use PrEP.

It is this need that led to the development of the EMPOWER Study, which asked:

**Is it feasible, acceptable and safe to integrate responses to gender-based violence and harmful norms into an HIV prevention programme offering PrEP for AGYW aged 16-24 years?**

## Why this study is important

HIV is not inevitable and nor is violence. A number of promising interventions to address violence and harmful gender norms in low- and middle-income countries (LMICs) have been identified, including: group-based participatory activities for women and men; community mobilisation; empowerment training for women; and economic interventions.<sup>11</sup>

Although not routinely recommended, studies have shown that GBV screening is acceptable to women and able to identify those at risk of violence.<sup>12</sup> How to implement such screening in the context of PrEP delivery, however, is less clear. Despite the growing evidence base for HIV, GBV and stigma prevention interventions,<sup>11, 13</sup> there are far fewer data on how these approaches could be combined and integrated into biomedical HIV prevention programmes. PrEP demonstration projects offer an ideal opportunity for developing and testing combined approaches.

## Approach

We developed a scalable health sector intervention, incorporating several novel components within the context of adolescent and youth friendly services, and tested its feasibility, acceptance and safety. Specifically, the intervention was designed to address the heightened vulnerability of AGYW to HIV and violence in South Africa and Tanzania.

Targeting AGYW aged 16-24 years who were at substantial risk of infection, we identified young women through community and clinic-based outreach activities. We then offered them combination HIV prevention in the form of a

standard uptake and adherence package that included:

- Provision of daily oral PrEP to HIV negative AGYW within the context of a comprehensive sexual and reproductive health package, which included condoms, contraception and treatment for sexually transmitted infections (STIs)
- Integrated screening and linkage-to-care (within HIV counselling and testing) for AGYW who had experienced lifetime GBV and stigma – a novel intervention in the context of PrEP delivery
- Supportive interventions such as counselling, SMS visit reminders, and community and partner mobilisation.

The study compared this package with an enhanced support package, in which half the cohort were randomised to attend monthly clubs that followed an empowerment curriculum (See Box 2). These clubs were designed to offer women additional adherence support and build resilience to stigma, IPV and relationship conflict, and were modelled on adherence clubs used successfully to support ART.<sup>14, 15</sup>

### Box 2: EMPOWER clubs

- Monthly sessions in a non-clinic venue, lasting around 2 hours
- Group-based, participatory methods led by a trained peer facilitator
- Modelled on the experience of ART clubs
- Followed a four-session curriculum addressing:
  - Gender roles and social norms
  - Sexual and reproductive health
  - Power and control
  - Empowerment

The EMPOWER Consortium was led by Wits RHI at the University of the Witwatersrand in South Africa, in partnership with the Mwanza Intervention Trials Unit (MITU) in Tanzania, the London School of Hygiene and Tropical Medicine in the UK, and the US-based International Center for Research on Women (ICRW).

The study enrolled 431 sexually active AGYW in inner-city Johannesburg, South Africa and Mwanza, Tanzania, and followed them for 6-15 months. PrEP continuation was evaluated at 6 months (our primary outcome). Qualitative, in-depth interviews were also conducted with 25 participants in Johannesburg and 14 in Mwanza three months after accepting PrEP. A smaller sub-set completed additional serial interviews at the 6-month visit (both sites) and at the 12-month visit (Johannesburg only). Interviews were also held with healthcare providers in study clinics and with community stakeholders in both sites.

## What did we find?

### 1. A sizeable portion of EMPOWER participants reported a lifetime experience of GBV

- Around one third of the young women screened at enrolment had experienced at least one form of GBV (physical, sexual, or psychological violence) in their lifetime: 33% in South Africa and 35% in Tanzania
- While most were assessed as not being at immediate risk of harm, many required referrals to mental health or other support services

### 2. GBV screening was novel but acceptable to participants

- Despite very high levels of GBV, nearly all AGYW interviewed reported that this was the first time they had ever been asked about their GBV experiences by a health provider
- Both the AGYW and healthcare providers interviewed in the study found the integration of GBV screening into HCT to be feasible and acceptable
- Healthcare providers appreciated the regular supervision and support they received during the study, while participants welcomed the non-judgemental and confidential approach

### 3. PrEP uptake was very high

- Of the AGYW enrolled at baseline, 100% in Mwanza and 94% in Johannesburg accepted PrEP. This exceeded our expectations and reflects the huge interest in alternative female-controlled methods of HIV prevention in this at-risk population
- Medical reasons for exclusion from the programme were low (<6%)

### 4. AGYW who enrolled in the study and accepted PrEP were at high risk of HIV

- Most of the cohort described themselves as single (90%); nearly one-third of Johannesburg participants reported having more than one partner in the last 6 months (29%), compared to 40% in Mwanza
- Consistent condom use in the past 6 months varied from 20% (Johannesburg) to 31% (Mwanza)
- More Johannesburg participants reported having a known HIV positive partner or partner of unknown status (38%) than those in Mwanza (23%)
- The burden of curable STIs was high: 30% of PrEP acceptors in Johannesburg screened positive for Chlamydia and 29% of Mwanza participants for trichomonas
- A greater proportion of PrEP acceptors than decliners were dependent on their partner for income

### 5. PrEP continuation rates were comparable to rates in other PrEP studies with adolescents<sup>16,17</sup>

- 60% of AGYW were still using PrEP at Month 6
- Participants were significantly less likely to continue on PrEP if they were: married or living with a partner; had two or more children; did not think PrEP would prevent HIV infection; or if their partner was their source of income
- Women who continued on PrEP appear to have been motivated by an accurate awareness of their HIV risk, a belief that PrEP is effective, and a desire to take control of their health. This was balanced against the practical realities of managing daily pill-taking and regular clinic visits with minimal social support

### 6. Effect of empowerment clubs

- In terms of PrEP uptake and continuation, there was no difference between participants in the standard adherence support arm and those randomized to the empowerment clubs. However, there was a trend towards greater visit attendance in participants who attended more club sessions
- Participants who did attend the club sessions valued them highly, describing them as non-judgmental spaces for exploring their relationships with men. Women also described the life-transforming effect of learning strategies to deal with conflict and how to assert their rights within relationships
- Low participation in the clubs may reflect the busy nature of young women's lives and the challenge of building club cohesion in populations that are essentially healthy and not living with a stigmatised disease

*"I have learned to be strong, to be a strong woman, to believe in myself... to know how to react in different scenarios" (22 yr old Johannesburg student with GBV experience, reflecting on her participation in EMPOWER Clubs)*



## Conclusion

The EMPOWER Study demonstrated that lifetime experience of GBV is already high among adolescent girls and young women in these two countries, and that integrating GBV screening into HIV counselling and testing services is feasible and acceptable to them. The study also demonstrated that it is possible to deliver PrEP to AGYW as part of a scalable combination HIV prevention programme that couches adherence support in an 'empowerment' framework.

While empowerment clubs did not demonstrate any additional benefits for supporting PrEP continuation, participants valued them, describing them as transformative in the context of their lives and relationships. Further analyses will explore the potential benefits of empowerment clubs for improving mental health and contraceptive use outcomes, among others.

Evidence for these novel approaches could inform the development of national PrEP programmes in the region, particularly in Tanzania and other countries where PrEP is not yet licensed. While the onus for preventing violence ultimately rests with perpetrators rather than victims, young women would nonetheless benefit from being equipped with skills and resources that enable them to address or even avoid unhealthy, controlling and violent relationships. Given the multiple points of overlap between the epidemics of HIV and violence in this region, it makes sense from a programmatic and public health point of view to offer violence interventions alongside PrEP delivery. But importantly, it also makes sense to young women themselves, who are acutely aware of their HIV risk and highly motivated to protect their health and their future using new forms of HIV prevention that they may control.

## REFERENCES

1. Human Sciences Research Council. The Fifth South African National HIV Prevalence, Incidence, Behaviour and Communication Survey, 2017 Pretoria: HSRC, 2018.
2. Tanzania Commission for AIDS (TACAIDS), ZAC, NBS, OCGS, ICF International. Tanzania HIV/AIDS and Malaria Indicator Survey 2011-12. Dar es Salaam, Tanzania: 2013.
3. Jewkes RD, K.; Nduna, M.; Levin, J.; Jama, N.; Khuzwayo, N.; Koss, M.; Puren, A.; Duvvury, N. Factors associated with HIV sero-status in young rural South African women: connections between intimate partner violence and HIV. *International Journal of Epidemiology*. 2006;35(6):1461-8.
4. Li Y, Marshall C, Rees H, Nunez A., Ezeanolue EE., Ehiri JE. Intimate partner violence and HIV infection among women: a systematic review and meta-analysis. *Journal of the International AIDS Society*. 2014;17:18845.
5. Stockman JKL, Marguerite B.; Campbell, Jacquelyn C. Forced Sexual Initiation, Sexual Intimate Partner Violence and HIV Risk in Women: A Global Review of the Literature. *AIDS and behavior*. 2013;17(3):832-47.
6. Decker MR, Peitzmeier S, Olumide A, Acharya R, Ojengbede O, Covarrubias L, et al. Prevalence and Health Impact of Intimate Partner Violence and Non-partner Sexual Violence Among Female Adolescents Aged 15-19 Years in Vulnerable Urban Environments: A Multi-Country Study. *The Journal of adolescent health : official publication of the Society for Adolescent Medicine*. 2014;55(6 Suppl):S58-67. Epub 2014/12/03.
7. Kapiga S, Harvey S, Muhammad AK, Stockl H, Mshana G, Hashim R, et al. Prevalence of intimate partner violence and abuse and associated factors among women enrolled into a cluster randomised trial in northwestern Tanzania. *BMC Public Health*. 2017;17(1):190. Epub 2017/02/15.
8. Jewkes RKD, K.; Nduna, M.; Shai, N. Intimate partner violence, relationship power inequity, and incidence of HIV infection in young women in South Africa: a cohort study. *Lancet*. 2010;376(9734):41-8. Epub 2010/06/19.
9. Cottrell ML, Yang KH, Prince HM, Sykes C, White N, Malone S, et al. A Translational Pharmacology Approach to Predicting Outcomes of Preexposure Prophylaxis Against HIV in Men and Women Using Tenofovir Disoproxil Fumarate With or Without Emtricitabine. *The Journal of infectious diseases*. 2016;214(1):55-64. Epub 2016/02/27.
10. Fonner VAD, S. L.; Kennedy, C. E.; Baggaley, R.; O'Reilly, K. R.; Koechlin, F. M.; Rodolph, M.; Hodges-Mameletzis, I.; Grant, R. M. Effectiveness and safety of oral HIV preexposure prophylaxis for all populations. *AIDS*. 2016;30(12):1973-83. Epub 2016/05/06.
11. Ellsberg MA, D. J.; Morton, M.; Gennari, F.; Kiplesund, S.; Contreras, M.; Watts, C. Prevention of violence against women and girls: what does the evidence say? *Lancet*. 2015;385(9977):1555-66. Epub 2014/12/04.
12. Christofides N, Jewkes R. Acceptability of universal screening for intimate partner violence in voluntary HIV testing and counseling services in South Africa and service implications. *AIDS care*. 2010;22(3):279-85. Epub 2010/04/15.
13. Bourey C, Williams W, Bernstein EE, Stephenson R. Systematic review of structural interventions for intimate partner violence in low- and middle-income countries: organizing evidence for prevention. *BMC Public Health*. 2015;15:1165. Epub 2015/11/26.
14. Grimsrud A, Lesosky M, Kalombo C, Bekker LG, Myer L. Implementation and Operational Research: Community-Based Adherence Clubs for the Management of Stable Antiretroviral Therapy Patients in Cape Town, South Africa: A Cohort Study. *J Acquir Immune Defic Syndr*. 2016;71(1):e16-23. Epub 2015/10/17.
15. Venables E, Edwards JK, Baert S, Etienne W, Khabala K, Bygrave H. "They just come, pick and go." The Acceptability of Integrated Medication Adherence Clubs for HIV and Non Communicable Disease (NCD) Patients in Kibera, Kenya. *PLoS one*. 2016;11(10):e0164634. Epub 2016/10/21.
16. Hosek SG, Rudy B, Landovitz R, Kapogiannis B, Siberry G, Rutledge B, et al. An HIV Preexposure Prophylaxis Demonstration Project and Safety Study for Young MSM. *J Acquir Immune Defic Syndr*. 2017;74(1):21-9. Epub 2016/09/16.
17. Gill K., Dietrich J., Gray G., Pidwell T., Kayamba F, Bennie T., et al. Pluspills: an open label, safety and feasibility study of oral pre-exposure prophylaxis (PrEP) in 15-19 year old adolescents in two sites in South Africa (Abstract TUAC0207LB). *IAS; Paris 2017*.
18. Kacaneke D, Bostrom A, Montgomery ET, Ramjee G, de Bruyn G, Blanchard K, et al. Intimate partner violence and condom and diaphragm nonadherence among women in an HIV prevention trial in southern Africa. *J Acquir Immune Defic Syndr*. 2013;64(4):400-8. Epub 2013/10/30.
19. Stadler JD-M, S.; Palanee, T.; Rees, H. Hidden harms: women's narratives of intimate partner violence in a microbicide trial, South Africa. *Soc Sci Med*. 2014;110:49-55. Epub 2014/04/12.
20. Lees S. Emergent HIV technology: urban Tanzanian women's narratives of medical research, microbicides and sexuality. *Culture, health & sexuality*. 2015;17(4):412-27. Epub 2014/10/16.
21. Rees H.; Delany-Moretlwe, S.; Lombard, C.; Baron, D.; Panchia, R.; Myer, L.; Schwartz, J.; Doncel, G.; Gray, G. Facts 001 phase III trial of pericoital tenofovir 1% gel for HIV prevention in women. *Conference on Retroviruses and Opportunistic Infections (CROI); Seattle, WA 2015*
22. Cabral A, J MB, Ngunjiri K, Vellozo J, Odoyo J, J EH, et al. Intimate Partner Violence and Self-Reported Pre-exposure Prophylaxis Interruptions Among HIV-Negative Partners in HIV Serodiscordant Couples in Kenya and Uganda. *J Acquir Immune Defic Syndr*. 2018;77(2):154-9. Epub 2017/10/28.
23. Hartmann M, Palanee-Phillips T, O'Rourke S, Adewumi K, Tenza S, Mathebula F, et al. The relationship between vaginal ring use and intimate partner violence and social harms: formative research outcomes from the CHARISMA study in Johannesburg, South Africa. *AIDS care*. 2018;1-7. Epub 2018/10/13.

## STRIVE research consortium

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