EVIDENCE UPDATE

Pre-Exposure Prophylaxis and Adolescent Girls and Young Women in Eastern and Southern Africa: The latest insights

July 2024

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Background

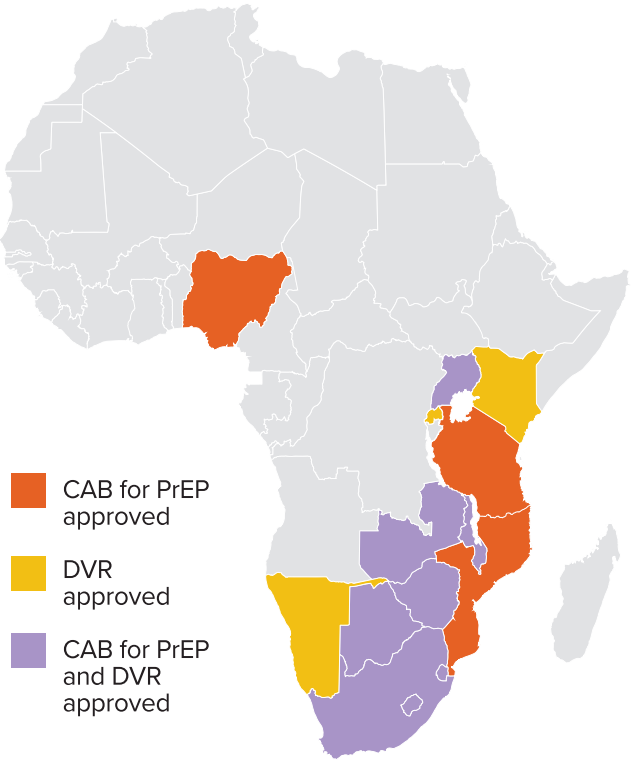
Eastern and southern Africa (ESA) is the world's most heavily HIV-impacted region with nearly 21 million people, 53% of the global total, living with HIV, and 500,000 new infections in 2022[1]. Within the region, adolescent girls and young women (AGYW) are disproportionately affected, accounting for 76% of new infections amongst people aged 15-24 and 26% of new infections overall[2]. Pre-exposure prophylaxis (PrEP) is a safe and effective means of HIV prevention currently available in nearly every country in ESA[3], though PrEP is still not reaching all who could benefit. To support the scale-up of PrEP amongst AGYW in ESA, in September 2021 UNICEF, together with partners*, released the implementation brief "Improving the Quality of Pre-Exposure Prophylaxis Implementation for Adolescent Girls and Young Women in Eastern and Southern Africa," which highlighted considerations to help improve the quality and coverage of AGYW PrEP programming[4].

The PrEP landscape has evolved significantly in the three years since the original brief was released, both in scale and variety. Global PrEP provision has grown rapidly, from fewer than two million cumulative PrEP initiations to over 6.5 million[5]. In addition, in several countries across ESA, AGYW now have a choice of two or more PrEP options, including tenofovir disoproxil fumarate-based daily oral PrEP (TDF combined with either emtricitabine (FTC) or lamivudine), the monthly dapivirine vaginal ring (DVR), and two-month injectable cabotegravir (CAB) for PrEP (see Figure 1). Additional options, including six-month injectable lenacapavir (LEN), the dual prevention pill (DPP) which combines oral PrEP and oral contraception, tenofovir alafenamide-based oral PrEP (FTC/TAF), and a three-month DVR, are also in late-stage development and may become available as early as 2025 (see Figure 2).

Considering these developments, this updated brief summarises the most recent evidence on AGYW PrEP provision, serving as a supplement to the original 2021 implementation brief. Evidence was drawn from a review of over 40 resources published in 2022-2024, including academic literature as well as briefs and tools developed by implementers.

* UNICEF; The Global Fund for AIDS, Tuberculosis, and Malaria; World Health Organisation Regional Office for Africa, and the Joint UN 2gether 4SRHR Programme

Figure 1- New PrEP Product Approvals in Africa, July 2024



Country	Products approved
Botswana	CAB for PrEP and DVR
Eswatini	CAB for PrEP and DVR
Kenya	DVR
Lesotho	CAB for PrEP and DVR
Malawi	CAB for PrEP and DVR
Mozambique	CAB for PrEP
Namibia	DVR
Nigeria	CAB for PrEP
Rwanda	DVR
South Africa	CAB for PrEP and DVR
Tanzania	CAB for PrEP
Uganda	CAB for PrEP and DVR
Zambia	CAB for PrEP and DVR
Zimbabwe	CAB for PrEP and DVR

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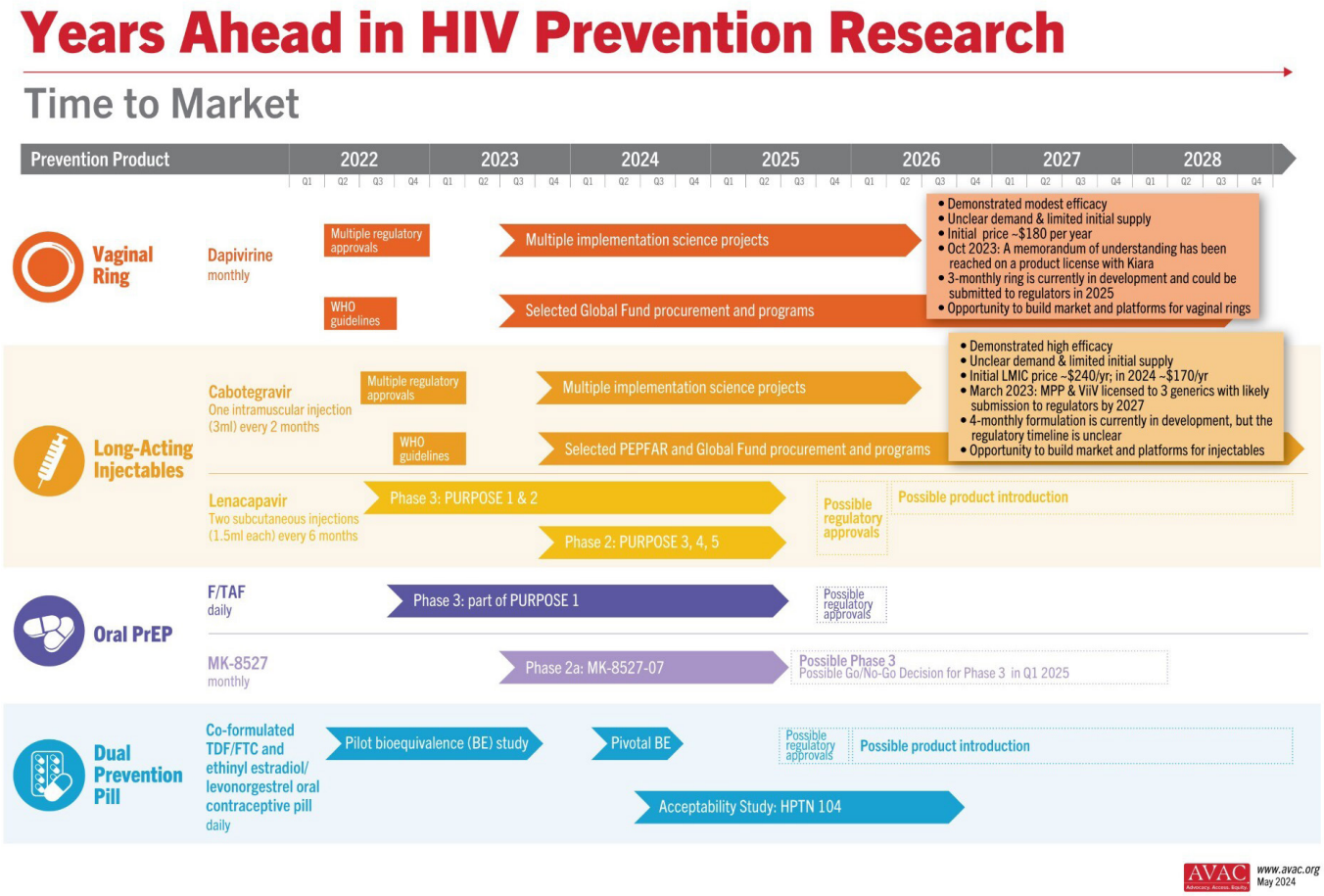
Figure 2- The PrEP Product Pipeline



AGYW and PrEP: The latest insights

Scale-up of PrEP since 2021 has allowed implementers and researchers to generate significant new evidence on opportunities and challenges for reaching AGYW in ESA with PrEP services- these insights are summarised below.

Community and AGYW Engagement

Harmful gender norms can limit AGYW autonomy and should be addressed as an integral part of any programme offering PrEP. Many AGYW feel they live in a patriarchal "man's world" and require parental or partner permission to use PrEP[6]. Their PrEP use can be negatively impacted by the fact that while many parents want to see their daughters remain HIV-negative, some may struggle to reconcile this with "traditional 'good-girl' notions" that stigmatise pre-marital sex[7,8]. Male partners of AGYW may also display discomfort with their PrEP use due to common misconceptions, including that PrEP is a contraceptive, can negatively impact foetal development, is an HIV treatment drug, or is only used by sex workers[9]. These structural factors can lead to internalised shame around PrEP, which has been shown to reduce PrEP uptake[10].

Community norms may lead some adolescent girls to believe they are too young to use PrEP. PrEP use is associated with sexual activity, and many adolescents in particular fear the judgement of their community if they are perceived to be sexually active. This fear can be a barrier to PrEP uptake[11]. Lowered age of consent policies for HIV testing and treatment are associated with increased PrEP uptake generally[12] and may help overcome these barriers by normalising use of HIV services by young people.

Provider Attitudes and Behaviour

Provider stigma can be a significant barrier to AGYW accessing PrEP services. AGYW fear providers may gossip about them to others, which can discourage them from being open about behaviours which may expose them to HIV[13,14]. Some providers have reported feeling concerned that providing PrEP will encourage AGYW to become more sexually active and discourage condom use; some also report the need to be harsh or lecture AGYW seeking sexual and reproductive health services as they feel a need to act in the role of the client's "mother"[13,15]. Other providers have reported a willingness to deliver PrEP to AGYW, but have concerns over whether adolescent girls are capable of consistently taking oral PrEP daily, especially if they are concealing it from their parents and/or partner[16]. New, longer-acting methods may help overcome some of these concerns. Recent evidence from Kenya has shown that the quality of PrEP provision to AGYW, including provider communication, was significantly improved by offering providers a two-day training in adolescent health, PrEP guidelines, values clarification, and communication skills followed by role playing with trained actors[17], and represents an opportunity to scale up similar interventions

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to facilitate provider behaviour change. As with clinical skills, continuous mentoring and supportive supervision are important to reinforce these learnings and identify areas for further capacity building[18].

Service Delivery Considerations

HIV self-testing (HIVST) services provide an entry point to engage AGYW in PrEP decision-making. In July 2023 HIVST was recommended by WHO for use in oral PrEP and DVR initiation and continuation[19]—providing AGYW with a confidential and private testing option which they may find more acceptable. HIVST can also increase awareness of male partner HIV status[20].

Providers should facilitate AGYW understanding of their own potential exposures to HIV and offer PrEP to those who ask for it. AGYW PrEP uptake correlates with high risk perception[11] and condomless sex[10], demonstrating that AGYW PrEP use often coincides with known periods of risk. Formal risk assessments may miss AGYW who do not feel comfortable disclosing certain risk behaviours to providers. In addition, not all AGYW who engage in transactional sex identify as sex workers[21] and could subsequently be missed on an assessment if such identification is conditional to PrEP provision. Self or provider driven assessments of behaviours that might expose someone to HIV may help AGYW identify their own HIV prevention needs but they should not be used to exclude anyone from PrEP access.

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Confidentiality is paramount for AGYW and should be a top consideration when designing service delivery models. For many AGYW, who may perceive themselves as "daughters" of their entire community, PrEP use is synonymous with sexual activity, and can involve social risks which may outweigh its benefits[14]. Therefore, AGYW fear being seen accessing PrEP in a health facility, and may prefer to visit at idle times[22,6,14,23,13]. Arranging special opening hours dedicated to AGYW, packaging PrEP within integrated service delivery, or offering telehealth options where permitted may support increased PrEP uptake by promoting discretion.

PrEP delivery via pharmacies is acceptable to AGYW and sometimes preferred. Even when oral PrEP is available for free in public facilities, many AGYW are willing to pay to access it from a pharmacy as they find it convenient, comfortable, anonymous, fast, less stigmatising, and closer to home. One study in Kenya found much higher PrEP uptake at pharmacies (85%) compared to PrEP demonstration projects in family planning (FP) clinics (4%-22%)[20]. Pharmacies' proximity to home can be a particularly important factor in AGYW PrEP usage—evidence from South Africa and Uganda shows the most commonly reported reason for PrEP discontinuation as excessive distance to a clinic[24,25]. In addition, young people are often highly mobile[18], and pharmacies, due to their ubiquity, can often be easier to locate than health facilities. Several other pharmacy-based models are being trialled, including ones that offer PrEP free of charge, and will generate additional evidence on AGYW access via this channel. Continuity of care for mobile youth across different service delivery points and channels will be important to avoid challenges seen with early PrEP discontinuation amongst AGYW who initiate at mobile clinics[24].

Providers and clients both support service integration, and clients are willing to have longer visits to receive comprehensive services[26]. To ensure successful integration, providers have recommended additional training, increased staffing, having job aids and guidelines, merging FP and PrEP registers, and integrated demand creation[26]. Depending on local guidelines, cadres such as nurses who typically provide FP services may need additional training and certification to provide PrEP[18]. Recommended services for integration include FP[21,27], ante and postnatal care[28], and syndromic screening and management of symptomatic sexually transmitted infections (STIs)[29]. Intimate partner violence (IPV) prevention can also be successfully integrated into PrEP programmes—in a study in Kenya, participants who received an intervention to reduce IPV had approximately two-fold higher PrEP uptake and adherence than control arm participants, with no evidence of increased IPV or social harms[30].

Supporting Effective Use

Effective use continues to be a challenge for many AGYW using oral PrEP, and typical use may not confer adequate protection, though understanding of what these terms mean for cisgender women continues to evolve. AGYW often have lower effective use rates of oral PrEP than older women of reproductive age[25,31]. In one study in Kenya, only three of 50 AGYW participants (6%) showed consistently high effective use of oral PrEP over the study period (defined by the researchers as six pills per week)[30]. Another in Kenya found that only 31% of AGYW who initiated oral PrEP came back for a one month refill, and 13 of 16 seroconversions were due to lack of oral PrEP uptake or uptake of less than four pills per week[32]. Similarly, a study in South Africa amongst AGYW found 69% of participants had discontinued oral PrEP after one month, although 27% returned and restarted later[24]. PrEP cycling is not a concern provided that PrEP use coincides with periods of potential exposure to HIV. Another study in South Africa showed an association between oral contraceptive use and PrEP persistence, suggesting experience with daily pill taking can support oral PrEP usage[32]. While many AGYW could benefit from additional effective use support, such as alarms and phone reminders[11], they may not need to take oral PrEP every day for it to be effective. A recent study with pooled data on oral PrEP use by cisgender women has shown very low HIV incidence amongst individuals with PrEP use as low as four pills per week[33]. Therefore, support for effective use may not need to focus on consistent daily use as was previously prescribed for cisgender women and girls.

Pregnant AGYW have higher rates of effective use of oral PrEP compared to non-pregnant AGYW. This may be due to regular attendance at antenatal clinics. However, typical use may not be coinciding with periods of need—a study amongst pregnant and lactating AGYW in South Africa found high rates of oral PrEP initiation, but only one third of participants continued PrEP use through six months, though AGYW with higher reported rates of condomless sex and STIs were more likely to continue on PrEP through the postpartum period[28]. Research from Kenya has shown that adolescent pregnancy rates can temporarily increase during humanitarian shocks such as the Covid-19 pandemic[34,35], so ensuring that pregnant and postpartum AGYW have consistent access to PrEP during those periods is critical both to prevent HIV during a time when transmission risk is two to three times higher[36], as well as to prevent vertical transmission.

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Emerging Trends in Expanded PrEP Choice amongst AGYW

CAB for PrEP is a safe, longer-acting, and effective new PrEP option for AGYW. A sub-study of HPTN-084, the Phase III CAB for PrEP clinical trial for cisgender women in ESA, investigated adolescent CAB for PrEP and oral PrEP use, and found no HIV infections or serious adverse events. Adherence was excellent, and when given a choice between CAB for PrEP and oral PrEP, 92% chose CAB for PrEP. Participants reported they preferred CAB for PrEP because it is easy, long-acting, and discreet, though some had concerns around injection site pain and side effects[37]. CAB for PrEP is now being rolled out in national PrEP programmes in Malawi, Zambia, and Zimbabwe, and specifically to AGYW in 11 implementation science projects taking place across ESA[38].

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The DVR is also a preferred option for many adolescents. In the REACH study, where AGYW who had used both oral PrEP and DVR were given a choice to continue with the DVR, oral PrEP, or neither, 65% chose the DVR and 30% chose oral PrEP, with 13% switching products during the product choice period. Those who reported vaginal sex in the three months prior to enrolment were more likely to choose the DVR[39]. Effective use of the DVR was moderately correlated with unstable housing, disclosing DVR use to a male family member, and noting a social benefit from study participation[40]. There are now 14 planned and ongoing DVR implementation science projects across ESA, with ten of these focusing on AGYW[38].

Initial data suggests LEN for PrEP could be a safe and effective option for AGYW in ESA. In June 2024, it was announced that there had been no HIV infections and no significant or new safety concerns in the LEN for PrEP arm of the PURPOSE 1 Phase III clinical trial, being conducted amongst cisgender women aged 16-25 across South Africa and Uganda. PURPOSE 1 will continue as an open-label trial through 2026[41].

The DPP has the potential to simplify combined HIV and pregnancy prevention for AGYW, and facilitate integration. The convenience of taking one pill instead of two may help facilitate effective use, and combining PrEP with oral contraception may help to overcome PrEP stigma[42]. Results are forthcoming on two recently-completed studies with AGYW in Zimbabwe and women aged 16-40 in South Africa to assess preference, adherence, and acceptability of an over-encapsulated version of the DPP versus oral PrEP and oral contraception taken separately[43]. The DPP has recently achieved bioequivalence, and will be submitted for regulatory review by the end of 2024.

Increased choice leads to increased PrEP coverage and lower HIV incidence. The SEARCH SAPPHIRE study in Kenya and Uganda compared PrEP coverage in a dynamic choice model, where participants were offered the choice of oral PrEP, post-exposure prophylaxis (PEP), and CAB for PrEP, and the ability to switch at any time, with a standard of care model where participants were offered a choice of oral PrEP and PEP only. Amongst AGYW, overall PrEP coverage in the dynamic choice group was 71%, compared to 13% in the standard of care model—showing a 58% increase in coverage when CAB for PrEP was added as a prevention option. There were zero cases of HIV infection in the dynamic choice arm, compared to five in the standard of care arm across cisgender women of all ages[44].

AGYW all have different priorities and preferences when choosing a PrEP method- the key is to enable their agency to choose by making options available. In a preferences study in Zambia, asking AGYW to select between CAB for PrEP, the DVR, and oral PrEP, all three options were selected as someone's first choice. The majority of AGYW preferred CAB for PrEP due to its discreet nature, long duration of action, the fact it can be used by both men and women, and that it can protect across a range of exposures (beyond vaginal sex). The smaller number who preferred DVR also cited its discreet nature. A few participants preferred oral PrEP, though others noted the potential difficulty in hiding a pill bottle. All participants agreed on the importance of offering choice[8].

AGYW and PrEP- Looking towards the Future

Though global PrEP initiations scaled up significantly in the period 2021-2024, many AGYW across ESA who could benefit from PrEP are still not using it. This due to a combination of factors- first among them structural factors, such as harmful gender norms and PrEP stigma, which discourage AGYW PrEP usage. AGYW also face challenges with effective use of PrEP, which can be exacerbated by the need or desire to keep PrEP use private. However, the near future brings many opportunities to accelerate PrEP use by AGYW, including expansion of PrEP to new service delivery channels like pharmacies which provide additional layers of discretion and convenience, and new, longer-acting products like CAB for PrEP and the DVR which can facilitate effective use. In addition to this, our understanding of effective use of oral PrEP in cisgender women continues to evolve, and with further research it may be possible to recommend alternative dosing regimens. The challenge the global community must now meet is making these options available in a way that is acceptable and accessible to AGYW.

Resources

- PrEPWatch.org- the one stop shop for PrEP information and tools
- Resources on PrEP and AGYW- all AGYW-related resources in the PrEPWatch resource library
- Getting Rollout Right- insights from a decade of experience with oral PrEP programmes
- Breaking the Cycle of HIV Transmission: A Human Centered Design Approach to Reach Adolescent Girls and Young Women- toolkit designed in consultation with over 3,000 AGYW to support AGYW PrEP use

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