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Policy considerations for scaling up access to HIV pre-exposure prophylaxis for adolescent girls and young women: Examples from Kenya, South Africa, and Uganda

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Abstract

Adolescent girls and young women (aged 15–24 years; AGYW) continue to carry a disproportionate burden of HIV in sub-Saharan Africa. Pre-exposure prophylaxis (PrEP) helps reduce the risk of acquiring HIV for persons at substantial risk, including AGYW. As countries plan for the rollout of PrEP across sub-Saharan Africa, PrEP policies and programs could address the unique needs of AGYW. The purpose of this analysis was to identify policy considerations to improve AGYW access to PrEP. After reviewing the literature, we identified 13 policy considerations that policymakers and stakeholders could evaluate when developing or reviewing PrEP-related policies. We sorted these considerations into five categories, which together comprise an AGYW Access to PrEP Framework: AGYW-friendly delivery systems, clinical eligibility and adherence support, legal barriers and facilitators, affordability, and community and AGYW outreach. We also reviewed policies in three countries (Kenya, South Africa, and Uganda) to explore how PrEP-related policies addressed these considerations. Some of these policies addressed some of the 13 policy considerations, but none of the policies directly addressed the unique needs of AGYW for accessing PrEP. To improve access to PrEP for AGYW, country policies could include specific components that address these 13 considerations. To reach AGYW effectively, each country could use the 13 considerations we have identified to analyze current policies to identify existing programmatic barriers to AGYW accessing HIV services and address these barriers in PrEP-related policies.

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CONFLICT OF INTEREST STATEMENT

The authors have no conflicts of interest to declare.

ETHICS STATEMENT

The findings and conclusions in this manuscript are those of the authors and do not necessarily represent the official position of the funding agencies.

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Keywords

adolescent girls and young women; adolescent health; health policy; HIV and AIDS; pre-exposure prophylaxis; PrEP; prevention

1 | BACKGROUND

Over the last decade, the world has made significant progress in the global fight against HIV and AIDS, with dramatic reductions in mortality and morbidity, but adolescent girls and young women (AGYW) have not benefited equally from this progress. Epidemiological data is often not stratified for AGYW specifically, but some estimates of the HIV burden in AGYW are available. For example, UNICEF estimated in 2013 that from 2005 to 2012, AIDS-related deaths among adolescents (i.e., persons aged 10–19 years) increased by 50%, whereas other population groups experienced a 30% decrease.[1] In 2017 UNAIDS estimated that every week, around 7000 AGYW aged 15–24 years became infected with HIV; in sub-Saharan Africa, three in four new infections among adolescents aged 15–19 years were in girls; and young AGYW aged 15–24 years were twice as likely to be living with HIV than men.[2]

Adolescents and young adults are at increased HIV risk due to biological, social, and psychological transitions unique to this stage of development.[3–5] Adolescent transitions drive increases in new, high-risk behaviours that increase exposure and susceptibility to HIV infection (e.g., sexual and drug/alcohol experimentation and age-disparate relationships).[5] Interpersonal and structural factors, such as peer relationships, poverty, gender norms, gender-based violence, and rape, also influence adolescent HIV risk.[3,5] AGYW are less likely to use non-adolescent-centred health facilities and often desire privacy about sexual activity, which can undermine treatment and prevention efforts.[5,6] Inadequate adolescent-focused prevention and treatment efforts have contributed to stark disparities between adolescents and the adult population in access to HIV treatment and prevention services. According to data from recent Population-based HIV Impact Assessment surveys in seven countries, less than half (46.3%) of HIV-positive AGYW were aware of their HIV-positive status.[7]

UNAIDS estimates that 130,000 (range, 88,000–190 000) new HIV infections occurred in 2015 among adolescents aged 10–19 years, and adolescent girls are estimated to account for 100,000 (range, 67,000–140 000) of those infections.[8] Adolescents (aged 15–19 years) in sub-Saharan Africa account for 1.3 million (62%) of the 2.1 million HIV-positive adolescents globally.[3] Among young people in sub-Saharan countries, women aged 15 to 19 years are at three to six times higher risk of HIV acquisition compared to men of the same age.[9] These statistics are even more alarming in the context of population growth-the number of young people aged 15–24 years in the African region is expected to double by 2030.[8,10,11] The persistent challenge in reaching AGYW has led HIV experts to call urgent attention to this issue and advocate for an adolescent “prevention revolution.”[4,5]

1.1 | Potential of PrEP

In 2014, the World Health Organization (WHO) issued guidance calling for PrEP to be considered as part of a package of prevention services for men who have sex with men.[12] WHO published new guidelines on the use of ART for the prevention and early treatment of HIV infection that recommended people with a 'substantial risk' of HIV infection be provided with daily PrEP as part of a combined HIV prevention strategy.[13,14] WHO defined *substantial risk* as a population group with an HIV incidence greater than 3 per 100 person-years in the absence of PrEP.[14] In 2016, the WHO issued guidelines recommending daily HIV PrEP for all people at substantial risk of acquiring HIV[13] and in 2018 published the adolescents and young adults module for their HIV PrEP implementation tool. In 2016 UNAIDS published guidance on HIV Prevention among Adolescent Girls and Young Women that identified PrEP as a component of core HIV prevention programs for AGYW.[15] It also identified a number of implementation questions and issues that should be considered as part of offering PrEP to AGYW. Some of these issues identified were ensuring informed consent, community awareness, delivery models, stigma, and gender based violence. PrEP could prove to be transformative in protecting AGYW from HIV infection, and PrEP policies could help ensure that this vulnerable population equitably benefits from PrEP. PrEP, as part of a combination prevention package, could serve as a bridge to protect adolescents during a period of time in which they are at substantial risk of HIV-exposure.[3,4] PrEP is unlike any other prevention strategy currently available for young women, because it is user-driven, efficacious, discreet, and has the potential to empower women at high risk of HIV to have significant control over their risk of HIV acquisition.[5] We selected three sub-Saharan African countries with high prevalence and incidence rates of HIV to review policies relating to PrEP: Kenya, South Africa, and Uganda. Each country has conducted PrEP trials and demonstration projects, their laws and policies are available in English, and all three countries were participating in the Determined, Resilient, Empowered, AIDS-free, Mentored, and Safe (DREAMS) initiative.[16] In Kenya, UNAIDS 2018 estimates show 1,500,000 [ranges, 1,300,000-1,800,000] children and adults living with HIV; HIV prevalence for young women of 2.6% [1.4%-3.9%] compared to 1.3% [0.8%-1.9%] for young men; and 53,291 people enrolled on PrEP.[17] In Uganda, UNAIDS 2018 estimates show 1.3 million children and adults living with HIV [1.3-1.4 million]; HIV prevalence for young women of 2.9% [1.3%-4.2%] compared to 1.0% [0.4%-1.5%] for young men; and 1969 people enrolled on PrEP.[18] In South Africa, UNAIDS 2018 estimates show 7.2 million [6.6 million-7.9 million] children and adults living with HIV; HIV prevalence among young women of 10.2% [4.6%-14.8%] compared to 3.9% [1.4%-6.0%] for young men; and 3189 people receiving PrEP.[19]

2 | METHODS

To identify considerations for establishing policies that improve AGYW access to PrEP, we conducted two separate literature searches in February 2017 with different search term combinations. The searches resulted in 68 unique responsive articles. The search methodology, including search terms, hits, and initial and secondary inclusion criteria are summarized in Table 1.

We reviewed these 68 articles to identify issues that may be important considerations for low- and middle-income countries scaling up PrEP for AGYW. Data were extracted from these articles into an Excel spreadsheet with the following fields: authors; title; source; response to search [enter 1 or 2]; geographic population; keywords; key findings; and lessons learned. Potential considerations were identified throughout the literature review with 42 considerations initially identified. An additional field was added to the Excel spreadsheet to identify the number of the consideration(s) supported by each article. At the end of the literature analysis, the considerations were reviewed and thematically organized. Some closely related considerations were combined, and considerations that were not unique to AGYW were removed (e.g., policy calls for on-going HIV testing and counselling while on PrEP). This analysis reduced the number of considerations to 13.

After completing the literature review and identifying the 13 policy considerations affecting AGWY access to PrEP, we conducted an online search for governmental PrEP-related policies from Kenya, South Africa, and Uganda. For our purposes, “PrEP-related policy” refers to a normative document issued by the government, whether compliance is required (e.g., policy) or recommended (e.g., guidance). We searched Ministry of Health and other governmental websites as well as websites of non-governmental organizations. Other policies were provided to us via e-mail from subject matter experts who reviewed our initial findings. The 13 policy considerations were compared to the PrEP policies identified in Kenya, South Africa, and Uganda to analyse the extent to which they were reflected in the current policies.

3 | RESULTS

Our literature review and analysis yielded 13 policy considerations for access to and scale-up of PrEP for AGYW in low- and middle-income countries. These considerations should not be interpreted as exclusive or sufficient by themselves, but rather as important issues for policymakers and stakeholders when analysing how to scale-up access to PrEP for AGYW. The 13 policy considerations are listed in Table 2 with the literature references supporting each consideration.

The extent to which the 13 policy considerations are reflected in the PrEP policies of Kenya, South Africa, and Uganda varies as discussed in further detail below. Table 3 lists the policies from Kenya, South Africa, and Uganda that we identified as explicitly referencing PrEP.

Various frameworks have been used to describe the elements of effective health systems, such as the WHO Health Systems Framework and its system building blocks: leadership/governance, health care financing, health workforce, medical products and technologies, information and research, and service delivery.[76] The WHO has also published Global Standards for Quality Health-Care Services for Adolescents consisting of the following standards: adolescent health literacy, community support, appropriate package of services, providers’ competencies, facility characteristics, equity and non-discrimination, data and quality improvement, and adolescents’ participation. These frameworks provide helpful background for analysing adolescent health systems, but these frameworks did not

adequately address the 13 unique considerations we identified for AGYW access to PrEP. We organized the 13 considerations identified in our literature review into five categories that comprise an AGYW Access to PrEP Framework (Figure 1): AGYW-friendly delivery systems, clinical eligibility and adherence support, legal barriers and facilitators, affordability mechanisms, and community and AGYW outreach.

This framework incorporates both adequate supply and demand-creation that will improve reliable access to PrEP initiation and follow-up services for AGYW. The AGYW Access to PrEP Framework includes several supply considerations, such as delivery systems for PrEP initiation (Consideration 1) and provider training (Consideration 2). Demand-creation is equally important to improve uptake of PrEP. Demand creation can be especially challenging with adolescents who may lack understanding of their legal rights, financial resources, or knowledge to seek out necessary health care services. The AGYW Access to PrEP Framework therefore includes several demand-creation considerations, such as affordability mechanisms(Consideration 12) and health information privacy laws (Consideration 11).

3.1 | AGYW friendly delivery systems

3.1.1 | Consideration 1. Will PrEP services be offered using AGYW-friendly delivery systems?—

A key policy consideration for promoting the availability of PrEP for AGYW is ensuring that it is provided at youth-friendly locations and through appropriate mechanisms for AGYW.[20,31,59,60,70] This consideration includes treatment initiation by a health care provider legally authorised to prescribe PrEP, locations where patients obtain PrEP refills, and locations where patients undergo required HIV testing and counselling.[60] Limiting any of these sites to only HIV-specific facilities may lead some AGYW to avoid seeking PrEP services out of fear that others in her social network may see her visiting the HIV clinic and speculate she is HIV positive.[43] Additionally, AGYW may have limited transportation options, and HIV clinics and other health facilities may not be conveniently located for AGYW. Making PrEP initiation and follow-up services (e.g., on-going HIV testing and counselling and refill pickups) available at youth-friendly sites may be one strategy for improving availability of PrEP for AGYW. WHO has published guidance on “Developing national quality standards for adolescent friendly health services,” which may be a helpful resource for designing and monitoring the quality of adolescent-friendly delivery systems.[77] Adolescent-friendly health services are there defined as those which are, “accessible, acceptable, equitable, appropriate, and effective …”

Policymakers could consider reviewing whether these interventions are provided using models that address the needs of AGYW. For example, South Africa’s PrEP and Test and Treat (T&T) Guidelines called for PrEP to be provided as part of the following comprehensive package: “condoms, lubricants, STI management, screening and management of intimate partner violence, sexual and reproductive health services, and HIV services, including counselling and testing, HIV management, ART, PEP, and PrEP.”[78]

None of the policies that we reviewed from Kenya, South Africa, or Uganda discussed AGYW or youth-friendly service delivery models in depth, but the Kenya ART Guidelines, Kenya PrEP Implementation Framework, and South Africa PrEP and T&T National Policy touched on this issue. The Kenya ART Guidelines stated that PrEP could be made available

in a range of settings, including youth-friendly outlets.[79] The Kenya ART Guidelines further stated PrEP implementation can be integrated in any setting that meets the conditions for initial evaluation and initiation including "Integrated prevention centres and youth friendly outlets…[and that] Resupply of PrEP can be done in both community and facility settings."[79] The Kenya PrEP Implementation Framework also discussed AGYW-friendly delivery mechanisms for PrEP, stating, "PrEP will be delivered using community-based and facility-based delivery models" and expressly referencing "youth-friendly centres" as part of demand/awareness creation, provision of PrEP, and monitoring and follow-up.[80]

The South Africa PrEP and T&T Policy addressed the importance of making PrEP services available in clinics that are not focused solely on HIV, stating, "Ideally, PrEP and T&T should be fully integrated into the primary healthcare package at all the entry points of the public health system… This will mitigate against stigmatisation when trying to obtain HTS and PrEP services."[81] The policy did not explicitly discuss or identify facilities that would cater to AGYW.

Uganda was still in the early stages of PrEP at the time of our review, and the Uganda Consolidated HIV Guidelines stated that PrEP should only be offered in funded demonstration project sites and "is not to be rolled out in all public health facilities yet."[82] Nevertheless, the Ugandan Technical PrEP Guidance discussed PrEP service delivery and stated that "PrEP will be given at sites accredited to provide ART through specialized PrEP service delivery points and other sites which may include ANC Clinics, Reproductive health/family planning clinics, STI treatment centers, youth friendly clinics, etc."[83]

3.1.2 | Consideration 2. What type of training/education will health care providers undergo to provide PrEP services to AGYW?—

Training to assess AGYW's risk and to guide patients to identify their own risk would help enable health care workers to provide PrEP for AGYW. If PrEP is provided in primary care settings or other health care settings, provider sensitization may also be helpful to reduce provider-initiated stigma and discrimination against AGYW seeking PrEP.

The Quality of Care section of South Africa's PrEP and T&T National Policy acknowledged the importance of training providers to reach priority populations, including AGYW.[81] The South Africa PrEP and T&T Policy also stated that providers should be supplied with job aids and tools, disseminated as part of a PrEP Implementation Pack, to support PrEP services.

The Kenya ART Guidelines acknowledged the importance of training, stating that PrEP may only be prescribed by "a healthcare professional who has completed training on the national guidelines for the use of ARVs as PrEP."[84] The Kenyan PrEP Implementation Framework stated, "PrEP will be prescribed and dispensed by trained health care providers, including doctors, clinical officers, nurses, pharmacists, pharmaceutical technologists."[80] Kenya's Task Sharing Policy Guidelines 2017–2030[85] expressly authorized PrEP service provision through medical officers, nurses, midwives, clinical officers, and pharmacists and cites WHO's "Treat, Train, Retain: Task Shifting Global Recommendations and Guidelines, 2008," in support of this approach.[86]

Uganda's PrEP Technical Guidance recognized that "PrEP service needs trained, non-stigmatizing, non-judgmental staff to provide high-quality HIV testing in order to identify people who are HIV-negative, at substantial risk of HIV and ready to have ongoing follow-up and regular HIV testing."[83] This guidance also called for data monitoring of the "proportion of staff receiving an annual PrEP and sensitivity training."[83]

3.2 | Clinical eligibility and adherence support

3.2.1 | Consideration 3. How is clinical eligibility for PrEP defined? Does it allow for individualised assessment of substantial risk?—

WHO defined "substantial risk" as a population group with an HIV incidence greater than 3 per 100 person-years in the absence of PrEP.[14] UNAIDS subnational estimates suggest HIV incidence is greater than 3 per 100 person-years among AGYW in parts of Kenya, South Africa, and Uganda.[87] WHO's 2016 guidelines also acknowledge that "individual risk varies within groups at substantial risk of HIV infection depending on individual behaviour and the characteristics of sexual partners."[14]

Prioritising certain populations for access to PrEP has been discussed as a means to focus limited financial resources on populations that may most benefit from PrEP.[4,20,59,88] However, initially prioritising PrEP for only certain key populations also poses a risk of stigmatising PrEP as appropriate only for certain populations (e.g., sex workers), when the evidence has shown that PrEP is beneficial to anyone who is at substantial risk for acquiring HIV.[3,5,21–24,44,51,61,88] The literature already has identified stigmatisation associated with taking PrEP.[89] Policy makers could consider this evidence when deciding whether to prioritise certain key populations for access to PrEP.

Kenya, South Africa, and Uganda adopted policies that use an individualized risk assessment model. These frameworks help patients, including AGYW, self-identify as high risk for acquiring HIV and facilitate screening patients who engage in high-risk behaviours and who may benefit from PrEP.[90] Table 4 compares the risk eligibility frameworks in each of these countries.

South Africa's PrEP and T&T Guidelines initially prioritised sex workers for access to PrEP but also covered other targeted populations, including MSM, serodiscordant couples, and AGYW. The guidelines stated, "The inclusion of these additional target populations in the PrEP rollout will be at the direction of the [National Department of Health], over time, targeting prioritized populations in phased approaches."[91] As noted in Table 4, the South Africa PrEP and T&T Policy provided greater flexibility to providers to allow self-selected individuals to access PrEP.

Kenya's policies did not expressly prioritize any key populations for PrEP, but Kenya's PrEP Implementation Framework included five scale-up scenarios that prioritize certain counties for PrEP implementation (range, 4–16 counties).[80] Serodiscordant couples, AGYW, and bridging populations were emphasized in each scale-up scenario.

The Ugandan Consolidated HIV Guidelines stated that higher risks for HIV acquisition affect certain populations "such as sex workers, fisher folk, long distance truck drivers, men

who have sex with men (MSM) and, uniformed forces and *adolescents and young women* engaged in transactional sex."(emphasis added).[82] However, the Ugandan Consolidated Guidelines did not expressly prioritize any of these populations for access to PrEP.[82]

3.2.2 | Consideration 4. Are pregnant and breastfeeding women eligible for PrEP?—According to WHO, pregnancy is associated with a higher risk of acquiring HIV, and HIV acquired during pregnancy or breastfeeding is associated with an increased risk of HIV transmission to the infant.[14] AGYW who are at substantial risk of HIV due to exposure from sex without condoms are also vulnerable to becoming pregnant. In settings with high fertility rates, women can spend a significant portion of their lives pregnant or breastfeeding. WHO's 2016 guidance noted studies concluding that adverse pregnancy-related events among women taking PrEP in early pregnancy did not increase while on PrEP and did not identify pregnancy or breastfeeding as contraindications for PrEP.[14,92] WHO's 2017 Technical Brief on Preventing HIV during Pregnancy and Breastfeeding in the Context of PrEP more explicitly stated:

> WHO considers that PrEP should not be discontinued during pregnancy and breastfeeding for women who continue to be at substantial risk of HIV infection. PrEP can also be considered as an additional prevention choice for HIV-negative pregnant women who are at substantial risk of HIV infection, as part of a comprehensive PMTCT package. The choice to start, continue or discontinue PrEP when a woman becomes pregnant should be made by the woman, following discussion of the risks and benefits with her health-care provider.[93]

The Kenya ART Guidelines and Uganda Technical PrEP Guidance stated that PrEP is not contraindicated while pregnant or breastfeeding.[84] However, the South Africa PrEP and T&T Guidelines we reviewed took a different approach: "Oral PrEP is contraindicated for use in pregnancy and breastfeeding by the South Africa MCC [Medicine Control Council]. Therefore, the stance of the NDOH is that PrEP shall not be offered to pregnant or breastfeeding women without further guidance from the MCC."[78]

The South Africa PrEP and T&T Guidelines also presented a summary of existing evidence showing no adverse outcomes from taking PrEP during pregnancy and noted, "There are several ongoing demonstration projects that will allow women to continue PrEP if they fall pregnant, which will provide additional data to inform future recommendations."[91]

3.2.3 | Consideration 5. What types of PrEP adherence education, support mechanisms, and monitoring will be used to improve PrEP adherence amongst AGYW?—Adherence to the daily PrEP regimen is essential to maintaining PrEP effectiveness. WHO's 2016 guidelines found that the level of protection from PrEP was strongly correlated with adherence. The same guidelines also noted, "challenges remain to achieving high levels of adherence among young people" for PrEP.[14] For this reason, policymakers should consider strategies for supporting PrEP adherence among AGYW during periods when an AGYW may be at higher risk of acquiring HIV, known as seasons of risk.

Intervention strategies to improve adherence that have been shown to be acceptable to adolescents with chronic health conditions include educational programs for individuals and families, peer counselling, cognitive behavioural therapy, mobile phone text messages for clinic visits and dosing reminders, health worker outreach, and group therapy approaches.[25–27,31,45,53,94]

The Kenya ART Guidelines[84] and Uganda's Consolidated HIV Guidelines[82] called for adherence counselling for PrEP, but did not discuss adherence strategies specifically for AGYW during seasons of risk (i.e., episodes of anticipated higher risk). Adherence mechanisms were discussed in South Africa's PrEP and T&T Guidelines, but AGYW-focused adherence strategies were not expressly discussed in the South Africa policies we reviewed.

3.3 | Legal barriers and facilitators

3.3.1 | Consideration 6. Do age of consent laws permit AGYW at substantial risk of acquiring HIV to self-consent to PrEP services?—

The age of consent for medical care may be a major barrier to the availability of health services for adolescent girls. If an adolescent girl is younger than the age of consent for a particular health service, she must rely on one or more of her parent(s), legal guardian(s), or caregiver(s) to consent on her behalf. Studies have documented that adolescents are often unwilling to communicate with their parents about their sexual activity.[4,27,28,95] Studies have also identified unwillingness on the part of some parents to consent to preventive reproductive health services for their adolescent children.[29,67] Both of these factors can be major barriers for PrEP accessibility for adolescent girls who are at substantial risk of acquiring HIV.

South Africa adopted an age of consent framework in the South African Children's Act 38 of 2005, which allowed mature adolescent girls to self-consent to PrEP as early as 12 years of age. Under Section 129 of the law, a child aged 12 years or older who possesses sufficient maturity and mental capacity to understand the "benefits, risks, social and other implications" of the requested medical treatment can self-consent to medical treatment. HIV treatment and PrEP likely qualify as medical treatment and would apply to AGYW consenting to PrEP.[96] If a child is deemed not to be sufficiently mature by the health worker, the child's "parent, guardian or care-giver" must consent on behalf of the child.[96] Under Section 130 of the South African Children's Act, a child can only consent to an HIV test independently when the child is aged 12 years or older or when the child is younger than 12 years and is of sufficient maturity to understand the benefits, risks, and social implications of such a test. If a child does not satisfy either of the above standards, parent or caregiver consent is required. In practice, it is unclear how often South African health workers find children to be sufficiently mature to consent independently.

In Uganda, the age of consent for medical treatment, including PrEP, appearred to be 18 years. However, Uganda's HIV and AIDS Prevention and Control Act allowed children aged 12 years and older to self-consent to an HIV test.[97] The law did not refer to PrEP or explicitly state the age of consent for initiating ART.

In Kenya, there was no specific statutory age of consent for medical care, but according to the Age of Majority Act of 1974, the age of majority in Kenya was 18 years. In the absence of a specific exception to the Age of Majority Act, the age at which a person can self-consent to medical care in Kenya, including to PrEP, is likely 18. One such statutory exception has been adopted in Kenya for consenting to HIV testing. Kenya's HIV and AIDS Prevention and Control Act (2006) specifically stated that "any child who is pregnant, married, a parent or is engaged in behaviour which puts him or her at risk of contracting HIV may, in writing, directly consent to an HIV test."[98] The Kenya ART Guidelines stated that "adolescents aged 15 years and above and emancipated minors can provide self-consent" to HIV testing but did not mention the age of consent for medical treatment or PrEP.[80]

3.3.2 | Consideration 7. Can caregivers and other non-parental guardians consent to PrEP services on behalf of AGYW who may not legally self-consent to PrEP?—

National laws and associated policies should also consider clarifying who can consent for PrEP or HIV treatment on behalf of adolescent girls younger than the age of consent and on behalf of adolescents without legal guardians.[99,100] Ensuring that the ability of different types of caregivers to consent on behalf of an adolescent is communicated clearly to health care providers can help policy be implemented effectively.

The South African Children's Act provided a useful example of how a country's law can clarify the types of adults that can consent to medical treatment on behalf of an adolescent who is not able to self-consent.[101] It stated that if a child is deemed not to be sufficiently mature to self-consent to medical treatment, the child's "parent, guardian or care-giver" can consent on behalf of the child. The term "caregiver" is defined (in Section 1) as "any person other than a parent or guardian, who factually cares for a child."[101]

The policies and laws we reviewed from Uganda and Kenya did not expressly address whether caregivers can consent to PrEP on behalf of minors.

3.3.3 | Consideration 8. Can AGYW be subject to criminal penalties, either directly or indirectly, for engaging in sex work?—

Sex workers and people who exchange sex for money or non-monetary items face a substantial risk of acquiring HIV due to challenges in negotiating condom use with their clients, sexual encounters with clients with unknown HIV status, and threat of rape and gender-based violence.[102,103] Criminalising sex work, either directly or indirectly, may cause this key population (including sexually exploited minors) to not disclose sex work to health care providers out of fear that they may be reported to police, which may undermine the ability of health care providers to identify women who could benefit from PrEP.

Policies from South Africa, Kenya, and Uganda explicitly identify sex workers as key populations for HIV and AIDS prevention, care, and treatment. The South Africa PrEP and T&T Guidelines prioritized the initial rollout of PrEP to sex workers. The Kenya ART Guidelines expressly identified "engaging in transactional sex" as one of the indications of being at substantial risk for acquiring HIV and, thus, potentially eligible for PrEP.[79] Uganda's National HIV and AIDS Strategic Plan identified female sex workers as a key

population for HIV services. However, all three countries criminalized sex work directly or indirectly to varying degrees.[104,105,106] These laws vary based on the source of law (e.g., national, provincial, or municipal law) and may criminalize different types of acts, such as purchasing sex, brokering or profiting from sex work, and/or selling sex, depending on the jurisdiction.

3.3.4 | Consideration 9. Can AGYW be subjected to criminal penalties for engaging in consensual sex with other adolescents?—For adolescent girls to inquire about PrEP, they must feel safe to disclose that they are sexually active. Some countries have laws that criminalize sex between two consenting adolescents, which may discourage adolescent girls from accessing PrEP out of fear of prosecution of themselves or their partners.

In October 2013, the Constitutional Court of South Africa addressed this issue in *Teddy Bear Clinic for Abused Children and Another v. Minister of Justice and Constitutional Development and Others*.[107] In *Teddy Bear Clinic*, the Constitutional Court ruled that Sections 15 and 16 of the Sexual Offences Act were inconsistent with the constitution and invalid. South Africa subsequently amended the law in 2015 to decriminalise consensual sexual relations if both persons are aged 12–15 years (inclusive).[108] The revisions to the law also decriminalised sexual relations between 16 and 17-year-olds with partners under the age of consent, provided they are within 2 years of that age.

The laws and policies we reviewed from Kenya and Uganda did not expressly state whether minors engaging in consensual sex with other minors can be subject to criminal penalties.

3.3.5 | Consideration 10. Is PrEP medication registered by the country's drug regulatory authority for prevention and for use in adolescents?—A key driver for availability of medicines is whether the medicine has been approved for the needed indication by the national drug regulatory authority. In the context of PrEP, the active ingredient (tenofovir/emtricitabine [TDF/FTC]) must be approved not just for HIV treatment but also for HIV prevention. The 2017 WHO Model List of Essential Medicines includes TDF and TDF/FTC and specifically states that TDF is also indicated for pre-exposure prophylaxis. Nevertheless, it can take several months, or even years, for a national drug regulatory authority to approve a medicine for a new indication.[109]

Kenya and South Africa had approved TDF/FTC for prevention at the time of our review.[110,111] In Uganda, a regulatory application had been submitted seeking approval for TDF/FTC for HIV prophylaxis.[112]

3.3.6 | Consideration 11. How will the confidentiality of AGYWs seeking PrEP be protected?—Even if adolescent girls are permitted to self-consent to PrEP, they may fear that the health care provider would disclose their use of PrEP to their parents or that their parents may somehow become aware of their use of PrEP through insurance claim information. Thus, health information confidentiality protections for adolescent patients can be an important facilitator for adolescents seeking preventive reproductive health services, such as PrEP. Additionally, adolescent girls' awareness of these laws and their beliefs about

whether confidentiality rules will be followed could affect the willingness of adolescent girls to seek PrEP.

Under Uganda's HIV Prevention and Control Act, a child aged 12 years or older could self-consent to an HIV test, and the results of her test could not be disclosed without the child's consent, unless an exception applies.[97] The exceptions included disclosure to a parent or guardian of a person of "unsound mind," a legal administrator or guardian (with the consent of the person tested), a person's sexual partner, and medical practitioners. The law did not address confidentiality concerns for adolescents seeking PrEP or ART.

Under the South African Children's Act, if a child was able to consent to an HIV test, the results of the test must be kept confidential, unless an exception applies.[101] Under the same law, a child aged 12 years or older could self-consent to PrEP and ART if she has sufficient maturity and mental capacity to understand the "benefits, risks, social and other implications," but the law did not explicitly address the confidentiality of health information regarding adolescent girls on PrEP or ART. We are aware of no data on health workers' allowance for or disallowance of minor's consent to medical care in South Africa for children aged 12 years or older.

The issue of confidentiality must also be balanced with the importance of encouraging social support networks to encourage PrEP and ART adherence. The 2010 Uganda Testing and Counselling Policy tried to balance these concerns by recommending that providers encourage children and adolescents to disclose results to 'significant persons for support."[113]

The laws and policies we reviewed from Kenya did not expressly discuss confidentiality protections for AGYW using PrEP.

3.4 | Affordability

3.4.1 | Consideration 12. Are mechanisms in place to make PrEP services available for free or at an affordable price for AGYW?—

AGYW may have limited financial resources to pay for on-going PrEP medication and required services (e.g., health care provider visits and quarterly HIV testing). AGYW may be enrolled full-time in school or may not have any personal income. For this reason, it is critical that PrEP policies include mechanisms to facilitate access to PrEP by patients with limited financial resources, including AGYW. For example, PrEP medication and required services could be provided free of charge, or insurance plans could fully cover PrEP and PrEP-required services with no user fees.

Affordability is a relative concept that assesses the extent to which the purchase of a medicine and its associated required services (e.g., required laboratory tests and health care provider visits) would undermine the purchaser's overall financial well-being. Various metrics have been proposed to assess medicine affordability, but one often cited metric by WHO is that a medicine becomes unaffordable when it exceeds 2 days' wages.[114] At least one study has used the wages of the lowest paid government worker as a proxy to measure

medicine affordability at the population level, but many AGYW may have income lower than the lowest government paid worker.[114]

The Kenyan PrEP Implementation Framework noted that the mission of PrEP implementation is "To provide sustainable access to safe, *affordable* and quality PrEP services in combination with other HIV prevention interventions."[80] (emphasis added). None of the policies that we reviewed from Kenya, South Africa, or Uganda discussed affordability for PrEP generally or specifically with respect to AGYW.

Closely related to individual affordability is national financing of PrEP programs. The Kenyan PrEP Implementation Framework's analysis of the funding needed to rollout PrEP estimated that Kenya's financial gap in PrEP implementation was more than $300 million USD over 5 years.[80] Strategies mentioned in the framework to address the financial gap include public funding, streamlining existing donor and partner funds aligned to PrEP implementation, providing health insurance coverage (both private and public), and improving efficiency by integrating PrEP prevention into existing programs.

Affordability of PrEP was not expressly discussed in the policies we reviewed from South Africa or Uganda.

3.5 | Community and AGYW outreach

3.5.1 | Consideration 13. How will education and marketing outreach campaigns be used to educate AGYW and the community about PrEP?

—Communication strategies should target media outlets that are designed to reach AGYW,[23,24,42,62] such as targeted social media campaigns, school-based outreach, peer-led activities, and mentor engagement.[115,116]

Social media platforms such as WhatsApp, Facebook, and Twitter have emerged as a promising approach to engage adolescents in health care and have been studied among adolescents for recruitment, retention in care, education, and social support strengthening.[30,31,117] School-based and peer-led strategies have shown beneficial outcomes in studies of HIV-positive adolescents, but it is unclear how to tailor these approaches to HIV-negative adolescent populations at high risk of HIV acquisition.[30,31,46,51,61,115,117,118] Community-based education strategies can help improve acceptability of PrEP by incorporating messaging to decrease PrEP-related stigma.[24,31,42,44,117] However, PrEP marketing activities that target individuals engaging in transactional sex may stigmatise PrEP use by that group–by creating a social construct that PrEP is for people who engage in risky sex[119]–thus decreasing community acceptance of PrEP.[120] This example highlights the importance of using well-tested, tailored messages to help shape positive community perceptions of PrEP.

Kenya's PrEP Implementation Framework included a Focus Area on Communications, Advocacy and Community Engagement, including a high-level communication plan.[80] The objectives of the communication plan were to increase knowledge of PrEP services, create a positive perception and improve the attitude toward PrEP among all stakeholder groups, and increase demand for PrEP among the target audience. The framework specifically addressed

the importance of designing communication strategies for specific populations, including AGYW.

The policies we reviewed from Uganda and South Africa did not expressly discuss community education or marketing outreach campaigns focused on AGYW.

4 | DISCUSSION

If used appropriately and as part of a comprehensive package of prevention, PrEP could be transformative in the global fight against HIV for AGYW who too often lack the power to negotiate sex or face difficulties accessing other prevention methods. Our AGYW Access to PrEP Framework can help governments develop policies that account for the needs of AGYW, including ensuring that PrEP services are provided at AGYW-friendly delivery sites, accounting for AGYW needs in clinical eligibility and adherence support systems, addressing legal barriers and facilitators, improving accessibility and affordability of PrEP services for adolescents, and implementing community and AGYW outreach strategies. A breakdown in any one of these access categories could undermine the potential that PrEP offers for AGYW. Policies in Kenya, South Africa, and Uganda provided useful examples for how to address these considerations in national laws and policies; however, generally, these policies did not have specific strategies to promote and guarantee access to PrEP for AGYW.

Our review has its limitations. For example, this methodology does not include interviews with key stakeholders from our three focus countries. Such data could complement our review.

To realize the potential of PrEP for AGYW, countries could consider including specific sections in PrEP-related policies and laws that explicitly address how they will help ensure access for AGYW. Conducting a situation analysis of existing HIV services for AGYW in each country, including gathering qualitative data from key stakeholder interviews and AGYW and analysing service delivery, health worker capacity, and health outcomes data for AGYW to identify key problems and barriers to AGYW PrEP delivery can help develop effective PrEP policies. The 13 policy considerations we identified can provide a helpful starting point to analyse policy proposals and to build AGYW access frameworks. Engaging civil society and other representatives who focus on outreach to AGYW may help ensure that issues unique to AGYW are considered in relevant policies. Close monitoring of PrEP policy implementation, including developing and implementing a monitoring and evaluation framework, will also help ensure that policies are translated into action and that barriers to implementation are swiftly identified and mitigated.

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DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available in public policies.

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FIGURE 1.
AGYW Access to PrEP Framework

TABLE 1

Literature search results to identify policy considerations for access to HIV PrEP for AGYW in African countries

Date	PubMed search terms	Hits	Initial inclusion criteria	Hits	Secondary inclusion criteria	Hits
02/07/2017	Pre-exposure prophylaxis AND HIV AND [adolescents OR "young women" OR youth]	166	Published between 2006 and 2017, indexed on PubMed, accessible through the University of Washington Library, available in English	164	Article appears to discuss policy relating to PrEP based on title/ abstract	60
02/10/2017	Pre-exposure prophylaxis AND HIV AND policy	73	Published between 2006 and 2017, indexed on PubMed, accessible through the University of Washington Library, available in English	69	Article appears to discuss policies relating to PrEP for adolescent girls and young women in Africa based on title/abstract	16

Note: Total Unique Hits = 68.

Abbreviations: AGYW, adolescent girls and young women; PrEP, pre-exposure prophylaxis.

TABLE 2

Policy considerations for AGYW Access to PrEP (with references)

No.	Category	Consideration	References
1	AGYW friendly delivery systems	How will PrEP services be offered in locations that cater to AGYW?	5,20–41
2	AGYW friendly delivery systems	What-type of training/education will health care providers undergo on providing PrEP services to AGYW?	25,34,42
3	Clinical eligibility and adherence support	How is clinical eligibility for PrEP defined and does it allow for individualized assessments of substantial risk for AGYW?	5,23,24,28,40,42–50
4	Clinical eligibility and adherence support	Are pregnant and breastfeeding women eligible for PrEP?	43,46,51,52
5	Clinical eligibility and adherence support	What types of PrEP adherence education, support mechanisms and monitoring will be used to improve PrEP adherence amongst AGYW?	5,20,23–25,27,28,30,31,33,34,38,40,42,45–47,51–58
6	Legal barriers and facilitators	Do age of consent laws permit AGYW at substantial risk of acquiring HIV to self-consent to PrEP services?	4,5,21,45,51,54,59–66
7	Legal barriers and facilitators	Can caregivers and other non-parental guardians consent to PrEP services on behalf of AGYW who are not old enough to self-consent to PrEP?	36,60,64,66–68
8	Legal barriers and facilitators	Can AGYW be subject to criminal penalties, either directly or indirectly, for engaging in sex work?	23,24
9	Legal barriers and facilitators	Can AGYW be subjected to criminal penalties for engaging in consensual sex with other adolescents?	66,67
10	Legal barriers and facilitators	Is PrEP medication registered by the country's drug regulatory authority for prevention and for use in adolescents?	5,34,58
11	Legal barriers and facilitators	How will the confidentiality of AGYW seeking PrEP be protected?	28,50,66,67,69
12	Affordability mechanisms	Are mechanisms in place to make PrEP services available for free or at an affordable price for AGYW?	21,28,46,53,70,71
13	Community and AGYW outreach	How will education and marketing outreach campaigns be used to educate AGYW and the community about PrEP?	5,20–27,30,31,35–38,40–42,44,45,51,52,57–59,61,62,65,70,72–75

Abbreviations: AGYW, adolescent girls and young women; PrEP, pre-exposure prophylaxis.

TABLE 3

Policies from Kenya, South Africa, and Uganda explicitly referencing PrEP

Country	Policy title
Kenya	Kenya AIDS strategic framework (KASF) 2014/15–2018/19 HIV prevention revolution road map–countdown to 2030 2016 guidelines on use of antiretroviral drugs for treating and preventing HIV infections Framework for the implementation of pre-exposure prophylaxis of HIV in Kenya Task sharing policy guidelines 2017–2030
South Africa	National policy on HIV pre-exposure prophylaxis and test and treat (8 Dec 2016) (South Africa PrEP and T&T policy) Guidelines for expanding combination prevention and treatment options: Oral pre-exposure prophylaxis and test and treat (8 Feb 2017) (South Africa PrEP and T&T guidelines) South African national sex worker HIV plan 2016–2019 (South Africa national sex worker and HIV plan)
Uganda	National HIV and AIDS strategic plan 2015/2016–2019/2020 Consolidated guidelines for prevention and treatment of HIV in Uganda 2016 Technical guidance on pre-exposure prophylaxis for persons at high risk of HIV in Uganda (Dec 2016)

Abbreviations: PrEP, pre-exposure prophylaxis; T&T, Test and Treat.

TABLE 4

Risk eligibility frameworks for PrEP

Kenya ART guidelines	Must meet at least one of the following risk criteria: • Sexual partner is known to be HIV positive and not on ART or on ART <6 months, or suspected poor adherence to ART, or most recent VL is detectable • Sexual partner(s) are of unknown HIV status and are at high-risk for HIV infection (has multiple sexual partners, has had STIs, engages in transactional sex, injects drugs, from high-HIV burden settings) • Engaging in transactional sex • History of recent sexually transmitted infection • Recurrent use of post-exposure prophylaxis • History of sex whilst under the influence of alcohol or recreational drugs as a habit • Inconsistent or no condom use, or unable to negotiate condom use during intercourse with persons of unknown HIV status • Injection drug use where needles and syringes are shared • Serodiscordant couples trying to conceive
South Africa PrEP and T&T policy	Prioritizes sex workers for PrEP but also states, "Clients who do not meet the target population criteria but who 'self-select' and request PrEP and T&T services should not be turned away. If a client feels they are at substantial risk for HIV infection, proceed with service provision and eligibility testing for PrEP."
Uganda consolidated HIV guidelines	Must meet at least one of the following risk criteria: • Have multiple sexual partners • Engage in transactional sex including sex workers • Use or abuse of injectable drugs and alcohol • Have had more than one episode of an STI within the last 12 months • Are discordant couples, especially if the HIV positive partner is not on ART or has been on ART for less than 6 months • Are recurrent users of PEP (3 consecutive cycles of PEP) • Engage in anal sex • Are part of key populations who are unable and or unwilling to achieve consistent use of condoms

Abbreviations: ART, antiretroviral therapy; PEP, post-exposure prophylaxis; PrEP, pre-exposure prophylaxis; STIs, sexually transmitted infections; T&T, Test and Treat; VL, viral load.