

RESEARCH ARTICLE



A Cross-Sectional Study of Differences in Pre-Exposure Prophylaxis Uptake in Kenya

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Abstract: Sub-Saharan Africa bears a disproportionate burden of human immunodeficiency virus acquisition, with young people facing acute exposure risks. Pre-exposure prophylaxis represents a cornerstone of biomedical prevention; however, population-level disparities across demographic and geographic subgroups remain inadequately characterized. A cross-sectional secondary analysis of the Kenya National AIDS and STI Control Programme National Data Warehouse evaluated pre-exposure prophylaxis utilization among 675,277 HIV-negative individuals aged 15 years and older seeking clinical prevention services during 2021. The cohort comprised 31,764 active pre-exposure prophylaxis users and 643,513 non-users. Multivariable logistic regression quantified crude odds ratios, adjusted odds ratios, and multiplicative interaction terms across age, gender, and geographic classifications. Overall prophylaxis utilization reached 4.70% (31,764/675,277). Individuals aged 15–29 years exhibited significantly reduced odds of uptake compared to adults aged 30 years and older (4.38% vs. 5.15%; adjusted odds ratio: 0.84, 95% confidence interval: 0.82–0.85). Male individuals showed lower utilization than females (4.40% vs. 4.88%; adjusted odds ratio: 0.88, 95% confidence interval: 0.86–0.90). Prophylaxis uptake across broad urban versus rural designations appeared identical in main-effect modeling (adjusted odds ratio: 1.00, 95% confidence interval: 0.97–1.03); however, geographic classification modified the association between age and utilization (Wald test statistic: 79.64, $p < 0.0001$). The age-related deficit was markedly amplified in urban areas (adjusted odds ratio: 0.71, 95% confidence interval: 0.68–0.74) compared to rural environments (adjusted odds ratio: 0.89, 95% confidence interval: 0.87–0.91). Targeted biomedical prevention initiatives must address the persistent deficits affecting young urban individuals and men through dedicated, differentiated, youth-centered delivery mechanisms.

Keywords: Pre-exposure prophylaxis; Kenya; HIV prevention; Sub-Saharan Africa; Youth health services.

1. Introduction

Human immunodeficiency virus (HIV) is a persistent global health concern, with Eastern and Southern Africa remaining the epicenters of transmission despite tremendous progress in biomedical interventions [1, 2]. Kenya has positioned itself as an international benchmark in epidemic response, achieving sweeping reductions in transmission via the scale-up of voluntary medical male circumcision, prevention of mother-to-child transmission, and rapid universal antiretroviral therapy rollout [3, 4]. Programmatic analysis indicate that Kenya has approximated the UNAIDS 95-95-95 targets, achieving elevated rates of status awareness, treatment coverage, and viral load suppression among people living with HIV [4, 5].

Nevertheless, national indicators mask substantial epidemiological variation across key geographic zones and demographic strata [3, 6]. Epidemiologic transmission clusters disproportionately within specific high-burden counties, including Nairobi, Kisumu, Homa Bay, Migori, Siaya, Kiambu, and Mombasa, which together account for roughly half of the country's prevalent HIV burden [3]. Similarly, young people particularly adolescent girls and young women aged 15 to 24 years bear an elevated incidence footprint compared to older cohorts or age-matched male peers [6, 7]. Biological vulnerabilities, pronounced power imbalances in age-disparate partnerships, economic dependence, transactional sex, and pervasive social stigma intersect to elevate vulnerability within this cohort [7, 8].

To interrupt incident transmissions among populations experiencing substantial ongoing risk, Kenya was among the first countries in sub-Saharan Africa to grant regulatory approval for daily oral pre-exposure prophylaxis (PrEP) containing tenofovir disoproxil fumarate and emtricitabine (TDF/FTC) in 2015, integrating it within the 2016 national clinical guidelines [9, 10]. Delivered within an integrated public health framework that incorporates regular antibody screening, sexually transmitted infection management, barrier contraception, and adherence counseling, PrEP provides a client-controlled biomedical prevention modality [9, 11].

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Translating clinical trial efficacy into population-level epidemic control demands equitable, frictionless initiation and persistence across the prevention cascade [11, 12]. Prior regional investigations have established that structural, social, and logistical impediments systematically undermine PrEP delivery [13, 14]. While women have indicated elevated clinical engagement due to reproductive, maternal, and family planning touchpoints, young individuals and men experience systematic estrangement from healthcare environments [13–15]. Disparities in healthcare facility distribution, staffing competencies, long distances, and persistent community-level stigma further compromise rural prevention infrastructure [12, 16].

Despite massive programmatic rollout across Kenya's decentralized healthcare infrastructure, robust population-based empirical evidence evaluating demographic and geographic utilization dynamics remains fragmented. Clarifying how age and gender interact with rural and urban service environments is vital for informing differentiated healthcare delivery models. Therefore, this investigation analyzes population-level programmatic data from Kenya's National AIDS and STI Control Programme (NASCOP) to evaluate differences in PrEP uptake between young individuals aged 15–29 years and older adults aged 30 years and older, while assessing the influence and interaction of gender and geographic residence.

2. Materials and Methods

2.1. Study Design and Data Source

A population-based, cross-sectional secondary analysis was conducted using centralized programmatic health records extracted for calendar year 2021 from the Kenya National AIDS and STI Control Programme (NASCOP) National Data Warehouse (NDW) PrEP Dashboard. The NDW serves as the central electronic repository capturing routine clinical service delivery encounters from public, private, and faith-based healthcare facilities across all 47 counties of Kenya. Clinical encounters originate across diverse entry points, including voluntary HIV testing and counseling sites, outpatient departments, antiretroviral therapy clinics, maternal and child health centers, family planning units, and specialized youth-friendly clinical centers.

Across the reporting facilities during the 2021 monitoring cycle, 714,002 individuals were registered in the clinical prevention and testing databases. Programmatic records corresponding to 38,725 individuals who tested HIV-positive upon initial clinical evaluation were excluded, as PrEP indication is restricted to HIV-uninfected persons. The resultant nationwide analytic cohort comprised 675,277 HIV-negative individuals aged 15 years and older presenting for routine prevention or testing services. Because data within the central dashboard are aggregated by facility-level and county-level contingency matrices, an individual-level pseudo-record dataset was systematically reconstructed from the multidimensional cross-tabulations. For every county, stratified contingency cells classified patients across specific age brackets, binary sex assignments, screening results, and documented clinical prophylaxis utilization categories. Individual electronic records were expanded from these cross-tabulations, matching the precise demographic profile, geographic location, and clinical prophylaxis classification of each recorded encounter across all 47 counties. Figure 1 shows the sample derivation and exclusion cascade from the centralized National Data Warehouse to arrive at the final analytic cohort of 675,277 HIV-negative individuals

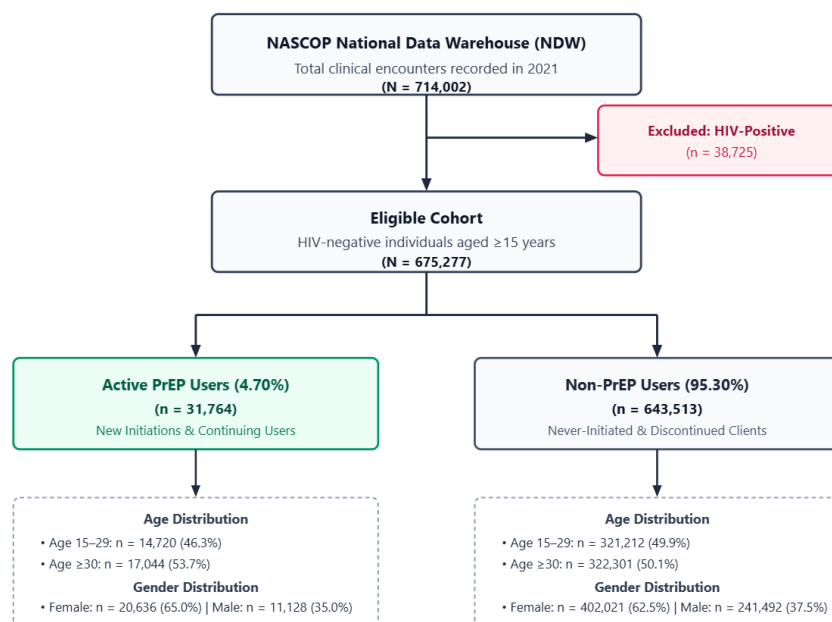


Figure 1. Selection of Cohort and Data Extraction

2.2. Outcome Definition and Operational Classification

The primary outcome of interest was active PrEP utilization during the 2021 calendar year. Within the NDW data infrastructure, individual client status is classified under three functional designations: newly initiated on PrEP, continuing PrEP maintenance, or discontinued PrEP.

For the primary analytical framework, PrEP utilization was operationalized as a binary categorical measure. Active users comprised individuals documented as either initiating PrEP for the first time during 2021 or maintaining ongoing PrEP therapy throughout the assessment period. The unexposed comparison group comprised individuals who were not taking PrEP during 2021, uniting never-initiators and individuals who had previously discontinued therapy.

Grouping discontinued users with never-users reflects active person-time protection against HIV transmission at the point of clinical cross-sectional evaluation, isolating individuals receiving prophylactic pharmaceutical coverage from those unprotected by active antiretroviral regimens. Programmatic data in secondary reporting dashboards do not reliably capture exact discontinuation intervals, cessation reasons, or clinical re-initiation timelines, which precludes longitudinal modeling of adherence or persistence trajectories.

2.3. Primary Exposure and Covariate Definitions

The primary exposure variable was patient age, categorized into a dichotomous classification: young individuals aged 15 to 29 years versus older adults aged 30 years and older. This age cutoff reflects priority youth cohorts in regional and national adolescent health strategies while preserving statistical power across sub-analyses.

Secondary demographic and structural covariates included gender and geographic location:

2.3.1. Gender

Gender was captured from routine clinical registration logs as a binary variable (male vs. female). Biological sex and gender classifications are recorded during clinical registration and triage in Kenyan healthcare facilities according to national reporting guidelines.

2.3.2. Geographic Classification and Regional Administrative Zones

Geographic location was operationalized at two distinct administrative tiers. First, the 47 administrative counties were classified into eight standard regional administrative zones matching Kenya's historical provincial structure: Central, Coast, Eastern, Nairobi, Nyanza, Rift Valley, Western, and Northern (North Eastern). Second, counties were categorized into a binary urban versus rural designation based on established infrastructural, urbanization, and service density criteria [17, 18]. Consistent with urban accessibility classifications by Macharia et al. [18], the counties of Nairobi, Mombasa, Kiambu, Kisumu, and Uasin Gishu were categorized as urban environments, characterized by dense public transportation networks, commercial development, and elevated health facility densities. The remaining 42 counties were categorized as rural environments.

2.4. Statistical Analysis

Summary demographic statistics were computed for the total study sample and stratified by active PrEP utilization status. Categorical distributions and proportional differences across strata were evaluated using two-sided Pearson chi-square (χ^2) tests of independence.

Univariable and multivariable logistic regression models were developed to quantify the relationship between patient characteristics and active PrEP utilization. The primary association between age category (referent: ≥ 30 years) and prophylaxis utilization was examined crude and after simultaneous adjustment for gender (referent: female) and geographic classification (referent: urban). Crude odds ratios (CORs), adjusted odds ratios (AORs), and corresponding 95% confidence intervals (CIs) were estimated using maximum likelihood techniques.

To investigate potential effect modification, two separate multiplicative interaction terms were independently incorporated into multivariable models: age group $\times$ gender, and age group $\times$ geographic location. Statistical significance of interaction terms was evaluated using Wald χ^2 tests. Where significant effect modification was indicated ($p < 0.05$), stratified sub-analyses were conducted to estimate stratum-specific adjusted odds ratios. All statistical analyses were executed using SAS software (Version 9.4, SAS Institute Inc., Cary, NC, USA) using the PROC LOGISTIC procedure.

2.5. Ethical Considerations

This study involved secondary analysis of fully anonymized, aggregated programmatic health data extracted from the Kenya Ministry of Health NASCOP National Data Warehouse. The original source datasets consist of de-identified routine clinical monitoring registers, devoid of individual personal identifiers, medical record numbers, or biometric variables. In accordance with national ethical guidelines and international regulatory standards for secondary health data research, the protocol received formal institutional review board approval from the College of Health Institutional Review Board at Oregon State University (Protocol ID: IRB-2023-1492) and was determined to be exempt from formal informed consent requirements due to the exclusive utilization of secondary, de-identified public health monitoring data.

3. Results

3.1. Cohort Characteristics

The analytical cohort under study consisted of 675,277 HIV-negative individuals aged 15 years and older presenting across public and partner clinical testing and prevention centers in Kenya during 2021. Among these individuals, overall PrEP utilization stood at 4.70% (n=31,764), while 95.30% (n=643,513) were not on PrEP.

Bivariate analyses revealed statistically significant demographic and regional disparities in PrEP utilization (Table 1). Female clients exhibited higher prophylaxis uptake than male clients (4.88% vs. 4.41%, $p<0.001$). Adults aged 30 years and older had higher rates of active PrEP use than young individuals aged 15–29 years (5.15% vs. 4.38%, $p<0.001$). In contrast, broad geographic classification showed identical crude uptake proportions between urban and rural cohorts, each recording 4.70% ($p=0.16$).

Substantial heterogeneity emerged across administrative regions ($p<0.001$). The Western region documented the highest proportional PrEP uptake at 15.52% (n=1,489/9,596), followed by Coast at 10.96% (n=3,124/28,498) and Rift Valley at 10.46% (n=1,573/15,037). Intermediate uptake occurred in Nyanza at 5.04% (n=10,190/202,110) and Nairobi at 4.48% (n=3,361/75,019). Regions recording the lowest proportional uptake included Eastern at 3.87% (n=3,028/78,152), Central at 3.60% (n=1,819/50,484), and Northern at 3.32% (n=7,180/216,381). Baseline sociodemographic characteristics of HIV-negative clinical clients according to pre-exposure prophylaxis utilization status in Kenya, 2021 (N=675,277). Reconciled frequency distributions and bivariate associations across gender, age brackets, geographic classifications, and administrative regions are shown in Table 1.

Table 1. Baseline Sociodemographic Characteristics of HIV-Negative Individuals by Pre-Exposure Prophylaxis (PrEP) Use Status in Kenya

Characteristic	PrEP (n=31,764) Users	Non-PrEP (n=643,513) Users	Total (N=675,277)	Utilization (%)	p-value
Gender					
Male	11,128	241,492	252,620	4.41%	<0.001
Female	20,636	402,021	422,657	4.88%	
Age Group (years)					
15–29	14,720	321,212	335,932	4.38%	<0.001
≥30	17,044	322,301	339,345	5.15%	
Geographic Location					
Urban	8,672	176,342	185,014	4.69%	0.160
Rural	23,092	467,171	490,263	4.71%	
Region					
Central	1,819	48,665	50,484	3.60%	<0.001
Coast	3,124	25,374	28,498	10.96%	
Eastern	3,028	75,124	78,152	3.87%	
Nairobi	3,361	71,658	75,019	4.48%	
Nyanza	10,190	191,920	202,110	5.04%	
Rift Valley	1,573	13,464	15,037	10.46%	
Western	1,489	8,107	9,596	15.52%	
Northern	7,180	209,201	216,381	3.32%	

Frequency counts (n) and proportions (%). Pearson χ^2 tests evaluate distributions between active PrEP users and non-PrEP users.

3.2. Multivariable Associations with Prophylaxis Utilization

In unadjusted logistic regression, individuals aged 15–29 years had significantly reduced odds of PrEP utilization relative to adults aged 30 years and older (COR=0.85, 95% CI: 0.83–0.86; Table 2). Following multivariable adjustment for gender and geographic classification, the association persisted with minor attenuation (AOR=0.84, 95% CI: 0.82–0.85). Figure 2 shows the adjusted odds ratios and 95% confidence intervals from the multivariable logistic regression model evaluating independent sociodemographic and geographic correlates of PrEP uptake

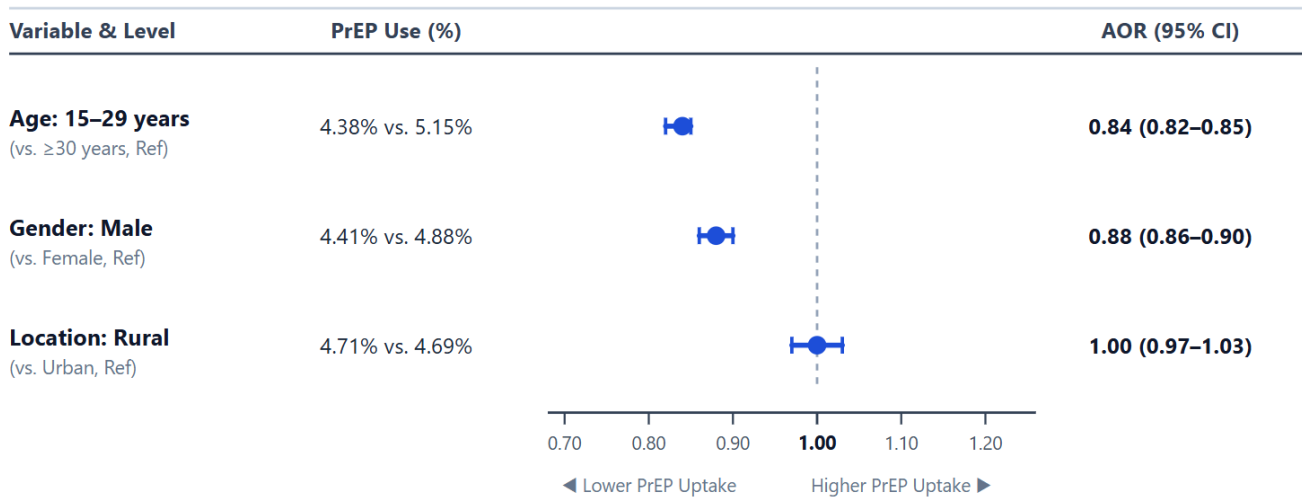


Figure 2. Forest Plot of Adjusted Odds Ratios for Predictors of PrEP Uptake

Gender is found to be as an independent predictor of prophylaxis utilization. Male individuals showed a 10% reduction in crude odds (COR=0.90, 95% CI: 0.88–0.92) and a 12% reduction in adjusted odds (AOR=0.88, 95% CI: 0.86–0.90) relative to female counterparts.

Main-effect modeling indicated that geographic classification was not independently associated with PrEP utilization. Rural clients displayed odds of PrEP use identical to urban residents in crude (COR=1.00, 95% CI: 0.98–1.03) and multivariable models (AOR=1.00, 95% CI: 0.97–1.03). Crude and multivariable logistic regression models evaluating sociodemographic and geographic determinants of pre-exposure prophylaxis utilization among HIV-negative individuals in Kenya, 2021 (N=675,277) are shown in Table 2.

Table 2. Crude and Multivariable Logistic Regression Analyses of Factors Associated with Pre-Exposure Prophylaxis (PrEP) Uptake in Kenya

Characteristic	Crude Odds Ratio (95% CI)	Adjusted Odds Ratio (95% CI)	p-value
Age Group (years)			
15–29	0.85 (0.83–0.86)	0.84 (0.82–0.85)	<0.0001
≥30	1.00 *	1.00 *	
Gender			
Male	0.90 (0.88–0.92)	0.88 (0.86–0.90)	<0.0001
Female	1.00 *	1.00 *	
Geographic Location			
Rural	1.00 (0.98–1.03)	1.00 (0.97–1.03)	0.984
Urban	1.00 *	1.00 *	

*Reference value; CI, confidence interval. Adjusted odds ratios are derived from a multivariable logistic regression model similarly incorporating age category, gender, and binary geographic location. The upper confidence limit for the young age group is reconciled to 0.85 to maintain mathematical alignment with the regression model output.

3.3. Effect Modification

Evaluation of multiplicative interaction terms revealed distinct structural dynamics. The interaction between age group and gender was not statistically significant (Wald $\chi^2=2.20$, $p=0.138$). The degree of youth disparity relative to older adults remained consistent across both male and female clients.

Conversely, the interaction between age group and geographic classification was statistically significant (Wald $\chi^2=79.64$, $p < 0.0001$), indicating that geographic environment modified the relationship between age and PrEP uptake.

Stratum-specific decomposition of the interaction model revealed distinct patterns between urban and rural environments (Table 3). Within urban settings, young people aged 15–29 years exhibited 29% lower adjusted odds of PrEP use compared to older urban adults (AOR=0.71, 95% CI: 0.68–0.74, $p<0.0001$). Within rural settings, this age disparity was attenuated, with young people exhibiting 11% lower odds of PrEP use compared to older rural adults (AOR=0.89, 95% CI: 0.87–0.91, $p<0.0001$).

Evaluating geographic residence stratified by age category further highlighted these divergent relationships. Among older adults aged 30 years and older, rural residence was associated with reduced adjusted odds of PrEP utilization relative to urban residence (AOR=0.89, 95% CI: 0.86–0.92, $p<0.0001$). Conversely, among young people aged 15–29 years, rural residence was associated with higher adjusted odds of PrEP utilization relative to urban residence (AOR=1.12, 95% CI: 1.08–1.16, $p<0.0001$). Category-specific multivariable adjusted odds ratios showing the effect modification between age cohorts and geographic setting on pre-exposure prophylaxis utilization in Kenya, 2021 are shown in Table 3.

Table 3. Gender-Specific Adjusted Odds Ratios (AORs) Demonstrating Effect Modification by Geographic Location on the Association Between Age and PrEP Uptake in Kenya

Stratum	Comparison Group	Adjusted Odds Ratio (95% CI)	p-value
Urban Residents	Age 15–29 vs. ≥ 30 years	0.71 (0.68–0.74)	<0.0001
Rural Residents	Age 15–29 vs. ≥ 30 years	0.89 (0.87–0.91)	<0.0001
Adults Aged ≥ 30 Years	Rural vs. Urban residence	0.89 (0.86–0.92)	<0.0001
Youth Aged 15–29 Years	Rural vs. Urban residence	1.12 (1.08–1.16)	<0.0001

Calculated based on multivariable model incorporating primary terms and the interaction term: Age Group $\times$ Geographic Location (Wald $\chi^2=79.64$, degrees of freedom = 1, $p<0.0001$), controlling for gender.

4. Discussion

This nationwide evaluation of routine clinical prevention records shows persistent age disparities in biomedical HIV prevention in Kenya. HIV-negative young individuals aged 15–29 years had 16% lower odds of PrEP utilization compared to older adults, adjusting for gender and geographic classification. This finding aligns with smaller clinical studies and localized cohort evaluations across sub-Saharan Africa indicating that youth experience lower initiation rates and higher attrition across the prevention cascade [11, 13, 19].

Lower uptake among young individuals is driven by personal, social, and structural barriers. Subjective underestimation of personal HIV risk remains widespread among adolescents and emerging adults, leading individuals facing substantial objective exposure to forgo biomedical prophylaxis [19, 21]. Pervasive community stigma further impedes access, as the daily administration of antiretroviral regimens can lead to social misclassification as living with HIV, inviting judgment from family and peers [11, 13].

Institutional factors within healthcare settings also hinder access. Public healthcare facilities frequently lack adolescent-responsive clinical environments. Young people encountering adult-oriented facilities often report concerns regarding breaches of privacy, provider moralizing, and legal ambiguity surrounding independent consent for sexual and reproductive healthcare [11, 20]. Structural disincentives, including transportation expenses, long clinic wait times, and inflexible scheduling, create acute barriers for youth navigating schooling, unestablished careers, or limited financial autonomy [13, 19].

The analysis confirmed significant gender differences in PrEP utilization, with men having 12% lower adjusted odds of active use relative to women. These findings reflect broader behavioral trends in healthcare engagement across Eastern and Southern Africa [23, 24].

In Kenya, national biomedical HIV prevention programs have strategically prioritized women, particularly adolescent girls and young women, through focused initiatives such as the DREAMS (Determined, Resilient, Empowered, AIDS-free, Mentored, and

Safe) partnership [11, 16]. This targeted prioritization is supported by the routine integration of PrEP counseling into established sexual and reproductive health touchpoints, including antenatal care, post-abortion care, cervical cancer screenings, and maternal-child health clinics [14, 16]. Consequently, women encounter repeated opportunities for HIV status validation and prophylaxis initiation.

In contrast, men have limited routine interactions with ambulatory healthcare systems, typically presenting only during advanced stages of acute illness [24, 25]. Traditional masculine norms often position medical help-seeking as weakness, while clinical facilities are widely perceived as female-centric spaces [25, 26]. Although voluntary medical male circumcision provides an entry point for adolescent boys, adult men lack equivalent platforms for routine PrEP delivery [26, 29]. Addressing this shortfall requires structural and community-based interventions designed for men. Effective strategies include extended clinic hours, occupational and workplace-based delivery platforms, transport hub clinics, and digital telehealth models coupled with pharmacy pickup or HIV self-testing [24, 27, 28]. Decentralized, community-embedded delivery can mitigate stigma and accommodate working schedules, facilitating greater male engagement with biomedical prevention [25, 27].

A central contribution of this investigation is clarifying the role of geographic location through interaction modeling. Although multivariable main-effect analysis suggested parity between rural and urban uptake overall (AOR=1.00, 95% CI: 0.97-1.03), assessing effect modification revealed pronounced divergence.

The youth deficit was markedly elevated within urban settings, where young individuals faced 29% lower adjusted odds of PrEP use compared to older adults (AOR=0.71). In rural settings, this disparity was attenuated to 11% (AOR=0.89). Correspondingly, rural residence was associated with 12% greater odds of PrEP uptake among youth (AOR=1.12), but 11% lower odds among adults aged 30 years and older (AOR=0.89).

These geographic dynamics reflect structural variations in public health delivery. In rural Kenya, national and donor-supported programs have concentrated extensive community-based outreach platforms, mobile testing units, and specialized youth health projects within high-burden rural counties to counteract distance barriers [14, 16, 22]. These donor-funded interventions often recruit, screen, and support rural young individuals directly within their communities, mitigating clinic-based logistical barriers [14, 21]. Conversely, rural older adults may struggle to access fixed health facilities due to poor road networks and long travel distances, limiting their ongoing PrEP engagement [12, 18].

In urban environments, despite a higher density of health facilities, young people face distinct barriers. Urban centers present heightened social fragmentation, elevated mobility, and intense peer-associated stigma, alongside concerns about encountering acquaintances in crowded urban clinics [18, 22]. Moreover, urban primary care facilities often operate with high patient volumes and limited staffing, restricting provider capacity to offer personalized adolescent counseling. These results indicate that physical proximity to clinical services does not ensure equitable uptake, underscoring the need for tailored urban youth interventions [18, 21]. Several methodological considerations should be evaluated when interpreting these findings. The study utilizes secondary cross-sectional records extracted from routine health information systems, which limits causal inference.

Importantly, the reporting infrastructure lacked detailed metrics for socioeconomic status, educational attainment, transactional sex engagement, marital status, or individual perceived HIV risk. Consequently, residual confounding by unobserved socioeconomic factors may have influenced the observed associations. Additionally, because the reporting system classifies clients into broad categorical cross-tabulations, detailed longitudinal trajectories could not be evaluated. Individuals who discontinued PrEP were grouped with never-users to measure active protective coverage in 2021. However, individuals who discontinue prophylaxis may possess distinct behavioural risk profiles, side-effect experiences, and healthcare interaction patterns compared to individuals who have never initiated therapy [19].

5. Conclusion

This work confirms significant age, gender, and geographic differences in PrEP utilization across Kenya. Despite substantial investments in national rollout, young individuals aged 15–29 years and men remain less likely to use PrEP than older adults and women, with the youth deficit most pronounced in urban environments. Expanding overall facility-based availability is insufficient to ensure equitable access across all priority demographics. Sustained progress toward national epidemic control will require decentralized, male-responsive clinical models, differentiated youth-friendly service platforms, and targeted strategies to reduce structural and stigma-related barriers in urban centers.

Compliance with ethical standards

Conflict of interest statement

The authors declare that they have no competing financial interests, personal relationships, or professional commitments that could have appeared to influence the work reported in this paper.

Statement of ethical approval

This study was conducted in accordance with the Declaration of Helsinki and approved by the Institutional Review Board of Oregon State University (Protocol ID: IRB-2023-1492). The investigation involved secondary analysis of fully anonymized, de-identified routine programmatic data obtained from the Kenya National AIDS and STI Control Programme (NAS COP) National Data Warehouse. The requirement for individual informed consent was formally waived under institutional and federal research exemptions for de-identified secondary data use.

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