

PrEPared-Registered Nurse: Nurse-Led, Community-Based Pre-exposure Prophylaxis Delivery Among Diverse Populations in South Florida: A Quasi-Experimental Study

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Abstract

Pre-exposure prophylaxis (PrEP) coverage remains low among populations most affected by HIV, and U.S. implementation outcomes for nurse-led PrEP delivery under standing orders (physician-authorized protocols permitting registered nurses to perform specified clinical actions) remain minimal. This quasi-experimental study evaluated nurse-led PrEP delivery ($N = 197$; April 2023–October 2024) across five South Florida sites, using a historical provider-led cohort ($N = 561$) for context. Female enrollment increased from 12.3% to 24.9%, and heterosexual enrollment from 16.9% to 32.5% (both $p < .001$). Same-day initiation occurred in 97.0% of encounters; 47.7% persisted on PrEP 6 months or longer, and 56.7% demonstrated adherence. Hispanic/Latino participants showed higher completion than non-Hispanic participants (56.2% vs. 37.0%, $p = .011$), whereas Black/African American participants showed lower engagement across all outcomes ($p < .001$) despite comparable enrollment. Findings suggest the model was associated with expanded reach into some underserved populations, alongside disparities requiring targeted engagement.

Key words: health equity, HIV prevention, nurse-led care, pre-exposure prophylaxis, quasi-experimental implementation study

HIV incidence continues to impose a disproportionate burden on specific geographic and demographic communities in the United States, despite the availability of highly effective biomedical prevention strategies (Butts et al., 2023; Centers for Disease Control and Prevention [CDC], 2024). South Florida, encompassing Miami-Dade, Broward, and Palm Beach counties, consistently ranks among the highest regions nationally for new HIV diagnoses, with rates substantially exceeding national averages (Butts et al., 2023). Pre-exposure prophylaxis (PrEP) has demonstrated efficacy exceeding 90% in preventing HIV acquisition through sexual transmission when taken as prescribed (Landovitz et al., 2021), yet uptake remains critically low among populations most affected by the epidemic.

National surveillance data reveal stark and persistent disparities in PrEP access and utilization. Although 94% of

White individuals for whom PrEP is clinically indicated receive prescriptions, coverage drops to 13% among Black individuals and 24% among Hispanic/Latino individuals (CDC, 2024). These disparities reflect the compounding effects of structural determinants including limited geographic access, inflexible clinic hours, insufficient provider cultural competency, HIV-related stigma, and medical mistrust rooted in historical health care discrimination (Hagiwara et al., 2024; Hull et al., 2021).

Traditional clinic-based PrEP delivery models presuppose sustained health care engagement that may not align with the lived experiences of individuals at elevated HIV risk. Populations most affected by HIV often face transportation barriers, health care workforce shortages, concerns about confidentiality, and previous negative health care encounters that create institutional distrust (Hagiwara et al., 2024; Hull et al., 2021). These structural deterrents limit the reach of clinic-based prevention services, fueling ongoing cycles of new infections among communities already disproportionately affected.

Task-shifting, the systematic delegation of defined clinical tasks from physicians to trained nurses or other health care workers within established protocols, has emerged internationally as an effective and scalable strategy for expanding access to HIV prevention and treatment services (World Health Organization [WHO], 2022). Nurse-led PrEP delivery models have demonstrated feasibility and acceptability in Canadian settings, where registered nurses

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(RNs) provide comprehensive PrEP services under medical directives, achieve strong patient satisfaction and linkage to care, and are often reported by patients as more comfortable to discuss sexual health and risk behaviors with than physicians (Orser et al., 2023). Active-offer approaches, in which nurses proactively discuss PrEP candidacy during encounters rather than waiting for patients to initiate prevention conversations, have substantially increased PrEP uptake (Kroch et al., 2023).

Community-centered PrEP delivery models that embed prevention services within trusted settings have demonstrated promise in reducing structural barriers and increasing engagement among underserved populations (Butts et al., 2023; Li et al., 2022). Decentralized delivery through community-based organizations, mobile health units, and faith-based settings increases geographic accessibility and reduces HIV stigma by offering services in environments where individuals already gather (WHO, 2022). In the United States, published literature on non-physician providers in PrEP care has largely examined nurse practitioners, physician assistants, and pharmacists, describing their roles in prescribing, uptake, and provider-level barriers (Zhang et al., 2020). Clinic-based models integrating PrEP into primary care and women's health settings have also reported increases in provider prescribing and patient enrollment following structured implementation programs (Casey et al., 2023). RN-led models operating under standing delegation orders, in which RNs independently conduct the full PrEP encounter rather than supporting physician- or APRN-led prescribing, remain comparatively less represented in this literature (Butts et al., 2023; Zhang et al., 2020). To our knowledge, implementation outcomes specific to this type of RN-led, standing-order model within the U.S. health system remain limited and may warrant further investigation.

The PrEPared-RN initiative was developed to address this narrower evidence gap by implementing and evaluating a RN-led PrEP delivery model combining standing delegation orders, community-based service delivery, active outreach, and culturally responsive care within a multisite nonprofit health system in South Florida. Primary implementation outcomes include health equity reach, engagement, medication adherence, PrEP persistence, and identification of demographic and clinical predictors of sustained PrEP engagement.

Methods

Study Design and Setting

The PrEPared-RN study used an implementation research approach, focusing on the systematic uptake of an

evidence-based PrEP delivery model into routine clinical practice (Eccles & Mittman, 2006). Because PrEP efficacy is established through prior clinical trials, our study addresses the gap between what is known to work and how to deliver it equitably at scale, using a quasi-experimental cohort design within a framework guided by the Reach, Effectiveness, Adoption, Implementation, Maintenance (RE-AIM) framework (Glasgow et al., 1999, 2019). The PrEPared-RN intervention cohort (enrolled April 2023–October 2024; $N = 197$) was compared with a historical baseline cohort comprising all patients prescribed PrEP through traditional provider-led services at the same CAN Community Health sites during the 12-month period immediately preceding program implementation (April 10, 2022–April 9, 2023; $N = 561$). The baseline cohort was identified through electronic medical record query using the same five South Florida clinic sites, restricted to patients with an active PrEP prescription during the observation window. Demographic variables were extracted using identical fields across both cohorts: race, ethnicity, birth sex, sexual orientation, and age. The quasi-experimental approach was appropriate given the real-world practice setting where randomization was not feasible because the intervention represented an organizational practice change affecting workflow and service delivery patterns across multiple sites. This design enabled a descriptive comparison of demographic reach into priority populations between the pre-implementation and post-implementation periods, while acknowledging the inherent limitations in causal inference associated with nonrandomized designs. The historical baseline cohort included both newly initiated and previously established PrEP patients, whereas the PrEPared-RN cohort comprised exclusively new enrollees; this difference in cohort construction is a limitation discussed further below, and comparisons between cohorts are presented as descriptive context rather than as evidence of a program effect. Study reporting followed the Strengthening the Reporting of Observational Studies in Epidemiology guidelines; the completed Strengthening the Reporting of Observational Studies in Epidemiology checklist is provided as Supplementary File 1, <https://links.lww.com/JNC/A142>.

Our study was conducted at CAN Community Health, a multistate nonprofit health care system serving diverse communities with high HIV prevalence and substantial unmet need for prevention services. The intervention was implemented across five service sites in South Florida, spanning Miami-Dade, Broward, and Palm Beach counties, geographic areas with among the highest HIV diagnosis rates in the United States. Our

study received institutional review board approval from the Advarra Central Institutional Review Board (Columbia, Maryland), conducted in accordance with the Declaration of Helsinki. All participants provided written informed consent before enrollment. Per protocol, safety events were collected from nursing phone interviews and laboratory reports and reported to the Medical Director; Medical Directors, serving as sub-investigators, monitored safety events, which were defined per protocol as Grade 3 or 4 toxicities, liver function test results exceeding three times the upper limit of normal, any event triggering dismissal from care, or any unwanted or undesirable medication effect. A study safety committee provided oversight, and the protocol specified that our study could be terminated prematurely in the event of a pattern of adverse events. In addition to the escalation process described below, every PrEP-RN encounter, whether it required escalation, was assigned to a supervising provider who reviewed and signed off on the encounter, with further consultation available as indicated.

Intervention Description

The PrEPared-RN intervention comprised several integrated components. Central to the model was a comprehensive standing delegation order developed collaboratively by physicians, nurse practitioners, nursing leadership, and research faculty. This order authorized RNs to conduct complete PrEP encounters, including: (a) structured risk assessment and detailed patient history; (b) HIV and sexually transmitted infection (STI) testing with pre-test and post-test counseling; (c) physical examination focused on STI signs and symptoms; (d) laboratory ordering and result interpretation within defined parameters; (e) short-term PrEP prescription initiation; and (f) follow-up care coordination. The standing order specified clear parameters for nursing practice within the standing delegation order scope while defining clinical situations requiring immediate physician consultation, ensuring appropriate oversight while enabling nurses to practice to the full extent of their licensure within a structured, collaborative framework.

Medication options included emtricitabine/tenofovir alafenamide (emtricitabine [FTC]/tenofovir alafenamide [TAF]) and emtricitabine/tenofovir disoproxil fumarate (FTC/tenofovir disoproxil fumarate [TDF]), prescribed by standing order after confirmed negative HIV status. FTC/TAF was designated for individuals assigned male at birth without injection drug use risk factors; FTC/TDF was designated for individuals assigned female at birth

or those who inject drugs, in accordance with U.S. Food and Drug Administration approval at the time of study.

Participating nurses completed standardized training encompassing: Collaborative Institutional Training Initiative Good Clinical Practice certification; the National HIV Curriculum Prevention of HIV course (University of Washington); comprehensive Centers for Disease Control and Prevention (CDC) PrEP guideline review; protocol-specific training on PrEPared-RN clinical procedures; and cultural competency education emphasizing LGBTQ+-affirming care and services for communities of color. Competency was documented through a structured checklist maintained in personnel files. Some participating nurses were bilingual in English, Spanish, and Haitian Creole, and virtual interpretation services were available during all clinical encounters to support participants with limited English proficiency.

Services were delivered through multiple access modalities: (a) scheduled clinic-based appointments at CAN Community Health sites; (b) mobile outreach units deployed to community events, nightlife venues, and festivals; and (c) community-embedded services within faith-based organizations and community-based organizations serving priority populations, including houses of worship, community health fairs, LGBTQ+ social events, community centers, barbershops and beauty salons serving communities of color, and street-based outreach in high-prevalence neighborhoods. This multimodal approach recognized that different individuals face distinct structural barriers and that service delivery flexibility enhances overall program reach. Active case finding was integrated through partnership with CAN Community Health community engagement and prevention teams, whose outreach workers linked HIV-tested individuals to nursing appointments.

A protocol modification was implemented during our study period to satisfy external grant funding reporting requirements: brief health care provider visits were added to the clinical workflow to document provider involvement. This modification did not alter the core nurse-led delivery model because nurses continued to conduct comprehensive PrEP encounters including risk assessment, testing, counseling, and prescription initiation. Study medications were available through the Gilead Sciences investigator-initiated grant supporting our study (Protocol Number IN-US-412-6439), which reduced pharmacy access barriers for participants during our study period; this level of medication access may not be replicable in nonresearch settings without comparable pharmaceutical support. The sponsor had no role in our study design; the collection, analysis, or

interpretation of the data; or the preparation, review, or approval of the manuscript. Dissemination of findings was expected under the funding agreement, but the sponsor exercised no control over the content of the manuscript or the selection of publication venue. Consistent with our study protocol, adverse events were reported to the sponsor's designated medical monitor. To support participation and reduce logistical barriers to study visit attendance, participants received a \$25 gift card per completed study visit.

Participants and Recruitment

Inclusion criteria required participants to be 18 years of age or older, consistent with the adult patient population served by the implementing organization, meet clinical eligibility criteria for PrEP per CDC guidelines (confirmed negative HIV status), and express willingness to engage with nurse-led care. Consistent with CDC guidance that individuals seeking PrEP should be initiated regardless of specific risk factor identification during assessment, all individuals requesting PrEP services were considered eligible. Exclusion criteria included persons living with HIV, clinical contraindications to PrEP medications (FTC/TDF or FTC/TAF), current pregnancy or breastfeeding (note: this exclusion criterion was applied consistent with practice norms at study initiation; 2021 CDC PrEP guidelines address PrEP use during pregnancy and breastfeeding), and presence of complex comorbidities (e.g., chronic hepatitis B virus infection, renal dysfunction with eGFR below 60 mL/min for TDF/FTC candidates, advanced chronic kidney disease with eGFR below 30 mL/min for TAF/FTC candidates, or use of contraindicated medications) requiring immediate physician management.

Recruitment occurred through multiple channels: (a) outreach workers and PrEPared RNs conducting HIV testing and PrEP education at community events, directly linking interested individuals to nursing appointments; (b) internal referrals from CAN Community Health providers and program specialists through warm handoffs; (c) self-referrals following word-of-mouth, social media, or community marketing; and (d) transition from nonoccupational postexposure prophylaxis (nPEP) to PrEP on treatment completion.

Outcome Measures

Primary implementation outcomes were assessed per the RE-AIM framework (reach, effectiveness, adoption, implementation, and maintenance) and included (a) health equity reach (reach domain), the proportion of

enrollees from populations experiencing documented PrEP disparities, compared with national PrEP coverage benchmarks (CDC, 2024); (b) access effectiveness (reach and adoption domains), the pattern of PrEP enrollment following expansion of service modalities across clinic-based, mobile, and community-embedded settings; (c) medication adherence (effectiveness domain), documented as compliant with prescribed PrEP at available follow-up; (d) study completion (effectiveness domain), completion of the 6-month study protocol; and (e) PrEP persistence (effectiveness and maintenance domains), duration of continuous PrEP engagement, defined as ≥ 6 months of documented participation. Implementation fidelity, a component of the implementation domain, was assessed through completion rates for protocol-mandated laboratory testing, Patient Health Questionnaire-2 (PHQ-2) screening, and the proportion of encounters managed by nurses independently within standing order parameters. Adoption and organizational maintenance were evaluated qualitatively through implementation observations rather than as primary quantitative outcomes and are described in the discussion section. Medication adherence was operationalized as nurse-documented adherence status recorded in the electronic medical record at each follow-up visit, based on patient self-report during clinical encounters; objective adherence measures such as pharmacy refill data or antiretroviral drug-level testing were not part of our study protocol.

Demographic data collected at enrollment included self-reported race and ethnicity, sexual orientation and gender identity, age, county of residence, substance use history, prior PrEP and nPEP use, prior STI history, number of sexual partners, and depression screening using the PHQ-2. Consistent with Sex and Gender Equity in Research reporting recommendations, birth sex, gender identity, and sexual orientation were collected and analyzed as distinct variables for different purposes: birth sex was used to determine medication eligibility (FTC/TAF vs. FTC/TDF) consistent with U.S. Food and Drug Administration labeling at the time of study conduct; gender identity was used to demographically describe the cohort; and sexual orientation and LGBTQ+ status were used to characterize behavioral risk networks relevant to PrEP engagement. These variables were not treated as interchangeable in analysis. STI status at enrollment was documented from point-of-care testing and laboratory results obtained at the initiation visit.

Statistical Analysis

Categorical variables were compared using chi-square or Fisher exact tests as appropriate, with odds ratios

(ORs) and 95% confidence intervals (CIs) calculated for categorical outcomes. Pre-implementation to post-implementation demographic comparisons between the historical baseline cohort ($N = 561$) and the PrEPared-RN intervention cohort ($N = 197$) were conducted using chi-square tests for all categorical demographic variables, with OR and 95% CI calculated to quantify the magnitude of difference in demographic composition. Continuous and ordinal variables were analyzed using Mann–Whitney U or Kruskal–Wallis tests. Three multivariate logistic regression models were constructed to identify independent predictors of study completion, medication adherence, and PrEP persistence ≥ 6 months. Variables were selected for inclusion based on their theoretical relevance to PrEP engagement as specified in our study protocol and consistent with our study's focus on priority populations (i.e., race, ethnicity, and LGBTQ+ identity, given our study's health equity focus) and on significant or clinically plausible bivariate associations with the primary outcomes (i.e., prior PrEP use, STI at enrollment, PHQ-2 score, prior nPEP use, alcohol use, tobacco use, and illicit drug use); variables with high multicollinearity were excluded and complete case analysis was used ($n = 162$; 82.2% of cohort). A formal a priori power calculation was not conducted because this implementation study enrolled all eligible participants during our study period rather than a prespecified sample size. A post hoc power calculation for the primary racial disparity comparison (study completion, Black/African American $n = 55$ vs. White $n = 134$) indicated that this sample size provided approximately 99% power to detect the observed difference (21.8 vs. 56.7%) at $\alpha = .05$, and approximately 80% power to detect a smaller difference of approximately 22 percentage points at these same subgroup sizes. Smaller subgroup comparisons, such as those involving Hispanic/Latino ethnicity in the multivariate models, had correspondingly lower power to detect an effect of a given size, and confidence interval widths, which are narrower for larger subgroup comparisons and wider for smaller subgroups, should be considered when interpreting statistically nonsignificant findings because these may reflect limited precision rather than the absence of a true association. All tests were two-tailed; significance was set at $p < .05$.

Results

Sample Characteristics

Between April 2023 and October 2024, PrEPared-RN enrolled 197 participants across five South Florida service sites. Demographic characteristics are presented in

Table 1. The majority of participants were assigned male sex at birth (75.1%; $n = 148$), with 24.9% ($n = 49$) female. By gender identity, 142 (72.1%) identified as cisgender male, 47 (23.9%) as cisgender female, 5 (2.5%) as transgender female, 1 (0.5%) as transgender male, and 2 (1.0%) as nonbinary or genderqueer. Racial distribution included 68.0% ($n = 134$) White, 27.9% ($n = 55$) Black/African American, 2.0% ($n = 4$) Asian, and 2.0% ($n = 4$) other/unknown. Ethnically, 45.2% ($n = 89$) identified as Hispanic/Latino and 54.8% ($n = 108$) as non-Hispanic. Sexual orientation data indicated that 32.5% ($n = 64$) identified as heterosexual, and 67.0% ($n = 132$) identified as lesbian, gay, bisexual, transgender, queer/questioning, and other sexual and gender minorities (LGBTQ+), comprising men who have sex with men (MSM; 50.3%, $n = 99$), bisexual individuals (15.7%, $n = 31$), and pansexual individuals (0.5%, $n = 1$). Notably, MSM represented the largest single LGBTQ+ subgroup, whereas heterosexual participants comprised 32.5% of the cohort, substantially exceeding their approximate 10% representation in national PrEP programs. Prior PrEP use was reported by 22.0% ($n = 42$) of participants, and 5.2% ($n = 10$) had prior nPEP use, reflecting the program's intentional pathway for nPEP-to-PrEP transition. Enrollment screening identified an STI in 30.8% ($n = 60/195$) of participants; among those with a positive STI, 44.8% had two or more concurrent infections, with gonorrhea (23.0%), chlamydia (21.8%), and syphilis (10.3%) as the most common organisms identified.

Demographic Comparison: Historical Baseline and Intervention Cohorts

The historical baseline cohort comprised 561 patients prescribed PrEP through traditional provider-led services across the same five South Florida sites during the 12-month pre-implementation period (April 10, 2022–April 9, 2023). Baseline demographic characteristics are presented alongside intervention cohort data in Table 1, as descriptive context rather than a controlled comparison. The baseline cohort was predominantly male at birth (87.5%; $n = 491$) compared with 75.1% ($n = 148$) in the intervention cohort; female representation was significantly higher in the intervention cohort (12.3 vs. 24.9%; $\chi^2(1) = 16.59$, $p < .001$; OR = 2.36, 95% CI [1.56–3.55]). Racial composition did not differ significantly between cohorts: White participants comprised 60.4% ($n = 339$) at baseline versus 68.0% ($n = 134$) in the intervention cohort ($p = .071$), and Black/African American participants comprised 22.6% ($n = 127$) versus 27.9% ($n = 55$), respectively ($p = .163$).

Table 1. Demographic and Clinical Characteristics: Historical Baseline and PrEPared-RN Cohorts

Variable	Category	Historical Baseline <i>n</i> = 561	PrEPared-RN <i>n</i> = 197	<i>p</i> -Value
Demographics				
Age (years)	<i>M</i> (<i>SD</i>)	42.8 (12.9)	34.7 (9.7)	<.001
	Median (IQR)	40 (33–52)	34 (27–40)	
	Range	22–89	20–61	
Birth sex	Male	491 (87.5%)	148 (75.1%)	<.001
	Female	69 (12.3%)	49 (24.9%)	
	Unknown	1 (0.2%)	N/A	
Gender identity ^a	Male	465 (82.9%)	142 (72.1%)	—
	Female	55 (9.8%)	47 (23.9%)	
	Transgender female	19 (3.4%)	5 (2.5%)	
	Transgender male	10 (1.8%)	1 (0.5%)	
	Other/genderqueer	10 (1.8%)	2 (1.0%)	—
	Choose not to disclose	2 (0.4%)	N/A	—
Race	White	339 (60.4%)	134 (68.0%)	.071
	Black/African American	127 (22.6%)	55 (27.9%)	.163
	Asian	15 (2.7%)	4 (2.0%)	
	Other/unknown/declined	80 (14.3%)	4 (2.0%)	
Ethnicity	Hispanic/Latino	233 (41.5%)	89 (45.2%)	.420
	Non-Hispanic	265 (47.2%)	108 (54.8%)	
	Unknown/declined	63 (11.2%)	N/A	
Sexual orientation	Gay/Lesbian/Other (MSM proxy)	356 (63.5%)	99 (50.3%)	.002
	Heterosexual	95 (16.9%)	64 (32.5%)	<.001
	Bisexual	60 (10.7%)	31 (15.7%)	.081
	Pansexual	N/A	1 (0.5%)	
	Other/unknown/declined	50 (8.9%)	N/A	
LGBTQ+ (aggregate) ^b	Yes	416 (74.2%)	132 (67.0%)	.060
	No	145 (25.8%)	65 (33.0%)	
Enrollment site				
Site ^c	South Beach	198 (35.3%)	77 (39.1%)	—
	Lake Worth	149 (26.6%)	53 (26.9%)	
	Broward Central	91 (16.2%)	10 (5.1%)	
	North Miami	79 (14.1%)	32 (16.2%)	
	Broward West	44 (7.8%)	25 (12.7%)	

(continued on next page)

Table 1. (continued)

Variable	Category	Historical Baseline <i>n</i> = 561	PrEPared-RN <i>n</i> = 197	<i>p</i> -Value
Clinical characteristics (PrEPared-RN cohort only)				
Prior PrEP use	Yes	N/A	42/191 (22.0%)	—
	No		149/191 (78.0%)	
Prior nPEP use	Yes	N/A	10/191 (5.2%)	
STI at enrollment	Positive	N/A	60/195 (30.8%)	
	Gonorrhea		23.0%	
	Chlamydia		21.8%	
	Syphilis		10.3%	
Medication prescribed	Descovy (FTC/TAF)	N/A	146 (74.1%)	
	Truvada (FTC/TDF)		51 (25.9%)	
PHQ-2 screening	0 (No concern)	N/A	178/189 (94.2%)	
	≥3 (Clinical threshold)		2/189 (1.1%)	

Note. Baseline cohort: *N* = 561, April 10, 2022–April 9, 2023, provider-led PrEP services, same 5 South Florida sites. PrEPared-RN cohort: *N* = 197, April 2023–October 2024, nurse-led delivery. *p*-values are from chi-square tests for categorical variables and from the Mann–Whitney *U* test for age; cells marked N/A indicate variable not available in that cohort. Clinical characteristics (prior PrEP use, STI at enrollment, medication prescribed, PHQ-2 screening) were not systematically extractable for the historical baseline cohort from routine electronic medical record fields and are reported for the PrEPared-RN cohort only. National PrEP coverage benchmarks for race and ethnicity are sourced from the CDC (Centers for Disease Control and Prevention, 2024); the national PrEP coverage figure for women (9%) is sourced from AIDSvu, 2024 PrEP use data. An LGBTQ+ national benchmark was not available for direct comparison. Denominators vary where data were incompletely recorded: prior PrEP and prior nPEP use were documented for 191 participants, PHQ-2 numeric scores were available for 189, and STI status was evaluable for 195. FTC/TAF = emtricitabine/tenofovir alafenamide; FTC/TDF = emtricitabine/tenofovir disoproxil fumarate; MSM = men who have sex with men; nPEP = nonoccupational post-exposure prophylaxis; PHQ-2 = Patient Health Questionnaire-2; STI = sexually transmitted infection.

^a Gender identity data are presented for both cohorts using the same categorical breakdown. Intervention cohort transgender identities (transgender female *n* = 5, transgender male *n* = 1) were identified by cross-referencing gender identification against birth sex. Nonbinary/genderqueer *n* = 2. Baseline cohort gender identity includes full categorical breakdown.

^b Baseline LGBTQ+ aggregate includes gay, lesbian, and bisexual identities only; transgender and other gender identities are reported separately under gender identity.

^c Intervention cohort site-level distribution derived from participant subject number codes in our study database.

Hispanic/Latino enrollment was 41.5% (*n* = 233) at baseline versus 45.2% (*n* = 89) in the intervention cohort (*p* = .420), a difference that was not statistically significant. Heterosexual representation was significantly higher in the intervention cohort than at baseline (16.9% [*n* = 95] vs. 32.5% [*n* = 64]; $\chi^2(1) = 20.35, p < .001$; OR = 2.36, 95% CI [1.63–3.42]), whereas the proportion identifying as gay or lesbian (MSM proxy) was significantly lower (63.5 vs. 50.3%; $\chi^2(1) = 10.05, p = .002$; OR = 0.58, 95% CI [0.42–0.81]). Bisexual enrollment trended upward (10.7 vs. 15.7%; *p* = .081) without reaching statistical significance. The *M* age of the baseline cohort was 42.8 years (*SD* = 12.9; median = 40, IQR: 33–52); the intervention cohort was

significantly younger (*M* age 34.7 years, *SD* = 9.7; median = 34, IQR: 27–40; range: 20–61) than the baseline cohort (*M* difference: 8.1 years, *p* < .001). Because the baseline cohort included both newly initiated and previously established patients, whereas the intervention cohort comprised only new enrollees, these demographic differences should be interpreted as descriptive rather than attributable to the intervention.

Implementation Reach: Health Equity

Enrollment in the intervention cohort is summarized here relative to national PrEP coverage benchmarks; the pre/post cohort comparisons themselves are reported

above and are not repeated in detail. Women comprised 24.9% of the intervention cohort, exceeding the national PrEP coverage rate for women (24.9 vs. 9%; AIDSvu, 2024). Heterosexual participants comprised 32.5% of the intervention cohort, and MSM-identified participants comprised 50.3%, compared with 63.5% at baseline. Hispanic/Latino enrollment (45.2%) and Black/African American enrollment (27.9%) each exceeded corresponding national coverage benchmarks (24% and 14%, respectively); both figures were also similar to or higher than the respective baseline-cohort proportions (41.5% and 22.6%), and the pre/post differences for these two groups did not reach statistical significance ($p = .420$ and $p = .163$, respectively). Because both cohorts draw from the same South Florida service area, elevated representation relative to national benchmarks likely reflects the demographic composition of the region rather than a program-specific effect. LGBTQ+ individuals comprised 67.0% of the intervention cohort. These findings are summarized in Table 1.

Access Effectiveness and Service Delivery

Same-day PrEP initiation was achieved in 97.0% ($n = 191/197$) of encounters, with same-day first appointment completion in 98.5% ($n = 194/197$). Program enrollment expanded across our study period after integration of community-based and mobile outreach modalities alongside clinic-based appointments; this growth reflects the cumulative effect of multiple implementation factors and is presented descriptively rather than as a formally analyzed comparative outcome. Implementation observations indicated that approximately 96% of PrEP encounters were managed by nurses independently within standing order parameters; physician consultation was sought in approximately 4% of cases, typically involving medication side effects, complex medical presentations, or STI findings requiring treatment beyond standing order scope.

Pre-exposure prophylaxis Persistence and Study Completion

Overall, 45.7% ($n = 90/197$) of participants completed the 6-month study protocol, and 47.7% ($n = 94/197$) achieved PrEP persistence ≥ 6 months. PrEP persistence data revealed a bimodal distribution: 31.0% ($n = 61$) discontinued at 1 month, whereas 41.6% ($n = 82$) demonstrated persistence beyond the 7-month study observation window. Medication adherence was documented in 56.7% ($n = 110/194$) of participants with

available adherence records. Among participants who discontinued, the predominant reason was loss to follow-up (68.2% of noncompleters), including failed contact attempts (25.2%), inability to reach the participant (21.5%), and no documented follow-up (7.5%). Voluntary withdrawal accounted for 8.4%, relocation for 4.7%, and medication-related concerns (including side effects and difficulty maintaining adherence) for 4.7% of discontinuations. Persistence distributions are presented in Table 2.

Racial and Ethnic Disparities in Engagement Outcomes

Statistically significant and clinically meaningful racial disparities were identified across all three primary engagement outcomes. Black/African American participants demonstrated substantially lower medication adherence (34.0% vs. 66.9%; $\chi^2(1) = 15.52$, $p < .001$; OR = 0.25, 95% CI [0.13–0.50]), study completion (21.8% vs. 56.7%; $\chi^2(1) = 17.71$, $p < .001$; OR = 0.21, 95% CI [0.10–0.44]), and PrEP persistence ≥ 6 months (23.6% vs. 59.0%; $\chi^2(1) = 18.08$, $p < .001$; OR = 0.22, 95% CI [0.11–0.44]) compared with White participants. Median PrEP persistence for Black/African American participants was 1 month (IQR: 1.0–5.0) compared with 7 months (IQR: 2.0–7.0) for White participants (Kruskal–Wallis $H = 23.70$, $p < .001$). These disparities are summarized in Table 3. Because these outcomes were common rather than rare, the ORs reported above overstate the relative difference compared with risk ratios calculated from the same proportions: the risk ratio for medication adherence was 0.51, for study completion was 0.38, and for persistence ≥ 6 months was 0.40 (Black/African American relative to White). The magnitude of disparity remains substantial under either measure. In response to these findings, the program proactively engaged community advisory board members from Black communities, implemented targeted outreach through Black-led faith-based and community organizations, and explored peer navigation models; however, these adaptations occurred during the latter portion of our study period and their impact on engagement outcomes warrants further evaluation.

Intersectional analysis of race and LGBTQ+ identity revealed a pronounced gradient across outcomes. Black/African American non-LGBTQ+ participants had the lowest rates observed in this cohort across all three metrics (study completion: 5.7%; medication adherence: 25.7%; persistence ≥ 6 months: 8.6%), whereas Black/

Table 2. Pre-exposure Prophylaxis Persistence Distribution

Duration on PrEP	<i>n</i>	% of Cohort	Cumulative %
1 month	61	31.0	31.0
2 months	12	6.1	37.1
3 months	3	1.5	38.6
4 months	16	8.1	46.7
5 months	11	5.6	52.3
6 months (study threshold)	12	6.1	58.4
≥7 months (beyond study window)	82	41.6	100
Total ≥6 months (persistence)	94	47.7	

Note. Persistence is defined as duration of documented PrEP continuation in the PrEPared-RN cohort. The distribution is bimodal, with the largest groupings at 1 month (31.0%) and at 7 months or longer (41.6%). Percentages are calculated on the full cohort (*N* = 197).

African American LGBTQ+ participants demonstrated substantially improved outcomes (50.0% across all three metrics). White LGBTQ+ participants demonstrated the highest rates overall (completion: 60.2%; adherence: 73.1%; persistence: 63.0%).

Ethnic Outcomes: Hispanic/Latino Versus Non-Hispanic Participants

In contrast to the racial disparities observed, Hispanic/Latino participants demonstrated study completion and PrEP persistence rates that were comparable with or higher than those of non-Hispanic participants, although medication adherence did not differ significantly between groups. Study completion was significantly higher among Hispanic/Latino participants (56.2% vs. 37.0%; $\chi^2(1) = 6.45$, $p = .011$), as was PrEP persistence ≥6 months (57.3% vs. 39.8%; $\chi^2(1) = 5.30$, $p = .021$) and median persistence duration (7 months [IQR: 2.0–7.0] vs.

4 months [IQR: 1.0–7.0]; Mann–Whitney $U = 5,933$, $p = .003$). Medication adherence was comparable between groups (Hispanic/Latino: 58.6%; non-Hispanic: 55.1%; $p = .733$).

Additional Bivariate Findings

Female sex at birth was significantly associated with lower rates of medication adherence (37.5% vs. 63.0%; $p = .003$), study completion (24.5% vs. 52.7%; $p = .001$), and PrEP persistence ≥6 months (28.6% vs. 54.1%; $p = .003$) compared with male sex at birth. LGBTQ+ identity was the strongest single-variable predictor across all outcomes: LGBTQ+ participants demonstrated substantially higher adherence (69.0% vs. 32.3%; $p < .001$), study completion (58.3% vs. 20.0%; $p < .001$), and persistence ≥6 months (60.6% vs. 21.5%; $p < .001$). Prior PrEP use was significantly associated with higher rates on all three measures (adherence: 80.5% vs. 50.3%, $p = .001$; completion: 76.2%

Table 3. Racial Disparities in Primary Engagement Outcomes: Black/African American Versus White Participants

Outcome	Black/AA	White	$\chi^2(1)$	<i>p</i> -value	OR (95% CI)
Medication adherence	34.0% (18/53)	66.9% (89/133)	15.52	<.001***	0.25 (0.13–0.50)
Study completion	21.8% (12/55)	56.7% (76/134)	17.71	<.001***	0.21 (0.10–0.44)
Persistence ≥6 months	23.6% (13/55)	59.0% (79/134)	18.08	<.001***	0.22 (0.11–0.44)

Note. OR = odds ratio with Black/AA as reference group. *** $p < .001$. Black/African American participants had approximately one-fifth to one-half the likelihood of medication adherence, study completion, and PrEP persistence ≥6 months compared with White participants, depending on whether odds ratios or risk ratios are considered (see Results section). CI = confidence interval; OR = odds ratio.

vs. 37.4%, $p < .001$; persistence: 78.6% vs. 39.4%, $p < .001$). Substance use (alcohol, tobacco, illicit drugs), PHQ-2 depression score, and number of sexual partners were not significantly associated with any engagement outcomes.

Multivariate Analysis

Three multivariate logistic regression models identified independent predictors of each primary outcome. LGBTQ+ identity was the most consistent independent predictor, associated with significantly higher odds of study completion (aOR = 4.16; 95% CI [1.68–10.27]; $p = .002$), medication adherence (aOR = 3.82; 95% CI [1.62–9.05]; $p = .002$), and PrEP persistence ≥ 6 months (aOR = 4.43; 95% CI [1.81–10.85]; $p = .001$). Prior PrEP use independently predicted study completion (aOR = 3.88; 95% CI [1.42–10.62]; $p = .008$) and PrEP persistence (aOR = 4.20; 95% CI [1.48–11.92]; $p = .007$). Black/African American race reached statistical significance as an independent negative predictor of PrEP persistence (aOR = 0.36; 95% CI [0.14–0.96]; $p = .040$) but approached significance for completion (aOR = 0.39; $p = .056$) and adherence (aOR = 0.39; $p = .053$) after adjustment. Full multivariate results are presented in Table 4.

Safety

No safety events, as defined per protocol (i.e., Grade 3 or 4 toxicities, liver function test results exceeding three

times the upper limit of normal, any event triggering dismissal from care, or other unwanted or undesirable medication effects), occurred during our study period. No clinical safety concerns, patient harm events, or concerns regarding nursing clinical decision-making quality were identified through the protocol-defined safety monitoring process described above throughout the 18-month implementation period. In addition to this monitoring process, every encounter was reviewed and signed off by a supervising provider, regardless of whether escalation occurred. Physician escalation is a distinct operational metric describing the proportion of encounters requiring consultation outside the standing delegation order's defined scope rather than a measure of safety events. Approximately 96% of all PrEP encounters were managed to completion by nurses independently within the parameters of the standing delegation order, requiring no physician consultation. Physician escalation occurred in approximately 4% of encounters, and each of these escalations was protocol-driven and deemed clinically appropriate, occurring in two expected categories: medication side effects or tolerability concerns, and medically complex presentations including STI-positive results requiring treatment beyond standing order scope, contraindicated medications, or significant comorbidities requiring physician co-management. These escalations reflect the intended function of the standing delegation order, which specifies clinical circumstances requiring physician involvement, rather than an indication of a safety concern.

Table 4. Multivariate Logistic Regression: Independent Predictors of Primary Outcomes

Variable	Study Completion aOR (95% CI)	Adherence aOR (95% CI)	Persistence ≥ 6 months aOR (95% CI)
Black/AA race	0.39 (0.14–1.03) $p = .056$	0.39 (0.15–1.01) $p = .053$	0.36 (0.14–0.96)* $p = .040$
Hispanic/Latino ethnicity	1.65 (0.75–3.64) $p = .216$	0.77 (0.34–1.78) $p = .546$	1.42 (0.64–3.16) $p = .388$
LGBTQ+ identity	4.16 (1.68–10.27) ** $p = .002$	3.82 (1.62–9.05) ** $p = .002$	4.43 (1.81–10.85) ** $p = .001$
Prior PrEP use	3.88 (1.42–10.62) ** $p = .008$	2.06 (0.72–5.95) $p = .180$	4.20 (1.48–11.92) ** $p = .007$
STI at enrollment	0.79 (0.30–2.09) $p = .632$	0.63 (0.23–1.66) $p = .347$	0.63 (0.24–1.69) $p = .361$
PHQ-2 score	0.67 (0.24–1.89) $p = .445$	0.57 (0.21–1.59) $p = .283$	1.06 (0.39–2.93) $p = .904$
McFadden Pseudo- R^2	0.211	0.182	0.215

Note. aOR = adjusted odds ratio; CI = confidence interval. Models include all variables listed plus prior STI history, prior nPEP use, alcohol use, tobacco use, and any illicit drug use (not shown; all $p > .05$). Complete case analysis $n = 162$ (82.2% of cohort). Female sex at birth excluded because of multicollinearity (VIF > 40). * $p < .05$; ** $p < .01$. After adjustment for other variables in the model, LGBTQ+ identity and prior PrEP use remained independent predictors of higher study completion, adherence, and persistence across all three models; Black/African American race remained an independent negative predictor of persistence and approached significance for study completion and adherence. STI = sexually transmitted infection; VIF = variance inflation factor.

The absence of any identified safety events, adverse medication effects, or inappropriate nursing clinical decisions during our study period is consistent with safe management of routine PrEP care by RNs operating under comprehensive standing delegation orders in a community health setting. This is supported by a defined safety monitoring process, with defined event categories and review by the Medical Director and study safety committee, and by provider review and sign-off of every encounter regardless of escalation status, both described in our methods. However, this process relied on events being identified and reported by clinical staff and providers during routine care rather than on a standardized adverse event severity grading tool applied independently at each visit, so these findings should be interpreted as reassuring rather than as formal safety trial evidence. PHQ-2 depression screening was completed in 95.9% ($n = 189/197$) of participants; 94.2% scored 0 (no concern), with only 1.1% ($n = 2$) scoring at the clinical threshold (≥ 3) for likely depression, indicating low burden of undetected severe depression in this cohort. STI screening was completed in 99.0% ($n = 195/197$) of encounters, with all protocol-mandated laboratory assessments completed at rates exceeding 95%, demonstrating high implementation fidelity to the clinical safety components of the standing delegation order. Comprehensive longitudinal adverse event data are currently undergoing formal validation and will be reported separately.

Discussion

The PrEPared-RN experience is consistent with nurse-led PrEP delivery using standing delegation orders within a multi-modal, community-based service framework being associated with substantial reach into populations experiencing HIV-related health disparities, while maintaining operational feasibility. These findings extend prior U.S.-based work on non-physician providers in PrEP care, including reviews of nurse practitioners, physician assistants, and other nursing staff (Zhang et al., 2020) and clinic-integration models that increased PrEP prescribing and enrollment in primary care and women's health settings (Casey et al., 2023), by describing implementation outcomes specific to a RN-led, standing-order model. Task-shifting, combined with community-embedded service delivery, was associated with a cohort that differed from the historical baseline in ways consistent with reduced barriers to

PrEP access; however, significant racial disparities in engagement outcomes point to structural challenges that remain relevant to equitable PrEP delivery.

Health Equity Reach

The intervention cohort differed from the historical provider-led baseline cohort across several demographic dimensions associated with PrEP access disparities. Female representation was significantly higher in the intervention cohort than at baseline (12.3%–24.9%; OR = 2.36, 95% CI [1.56–3.55], $p < .001$), and heterosexual representation was also significantly higher (16.9%–32.5%; OR = 2.36, 95% CI [1.63–3.42], $p < .001$), alongside a significant proportional decrease in MSM-identified enrollment (63.5%–50.3%; $p = .002$). These differences are consistent with, although do not by themselves establish, a broadening of reach beyond historically MSM-predominant PrEP delivery. Female enrollment in the intervention cohort also exceeded the 9% national PrEP coverage rate for women by a substantial margin (AIDS Vu, 2024); multimodal and mobile delivery may plausibly reduce structural barriers that disproportionately limit women's engagement with traditional HIV prevention clinics (Hull et al., 2021), although our study cannot establish that mechanism directly. Hispanic/Latino enrollment was 45.2% in the intervention cohort versus 41.5% at baseline, a difference that did not reach statistical significance ($p = .420$); both figures substantially exceeded the national PrEP coverage rate of 24% for this population, which likely reflects the demographic composition of the South Florida service area rather than a program-specific effect (Butts et al., 2023). Black/African American enrollment was 27.9% in the intervention cohort versus 22.6% at baseline, also not a statistically significant difference ($p = .163$); both figures exceeded the national coverage rate of 14%, again likely reflecting the regional patient population rather than a program-specific effect. LGBTQ+ individuals comprised 67.0% of the intervention cohort. The intervention cohort was also significantly younger than the baseline cohort (M 34.7 vs. 42.8 years; median 34 vs. 40; $p < .001$). The cohorts differ in composition and period: the intervention cohort comprised exclusively new PrEP initiations, whereas the baseline cohort included both new and established PrEP patients. This compositional difference is a plausible contributor to the observed age difference, which should not be interpreted as a program-specific effect, although it may have practical implications for program design discussed below.

Racial Disparities in Engagement

The most notable finding of our study is the substantial and statistically significant disparity in engagement outcomes among Black/African American participants, who demonstrated approximately one-fifth the odds of achieving medication adherence, study completion, or PrEP persistence ≥ 6 months compared with White participants, despite enrollment rates comparable with the national PrEP disparity gap. This dissociation between comparable enrollment and lower sustained engagement suggests that access alone may be insufficient for equitable HIV prevention outcomes in this population.

Intersectional analysis provides additional context for this finding. Black/African American non-LGBTQ+ participants had the lowest outcomes observed in this cohort (completion: 5.7%; persistence: 8.6%), whereas Black/African American LGBTQ+ participants achieved outcomes comparable with White non-LGBTQ+ participants (50.0% across all metrics). This pattern is consistent with the possibility that LGBTQ+-affirming care environments, peer community networks, and familiarity with HIV prevention services may partially offset broader structural barriers for some participants, whereas Black individuals outside these networks may face additional barriers to engagement; our study cannot establish these mechanisms directly. These patterns are consistent with prior research on medical mistrust, provider-level implicit bias, peer influence dynamics, and underinvestment in Black community health infrastructure (Quinn et al., 2023). Future program iterations could consider evaluating targeted strategies such as peer navigation, community health worker support, and engagement with Black-led organizations and faith communities, although the effectiveness of these specific strategies was not tested in our study.

Predictors of Sustained Engagement and Feasibility

Multivariate analysis identified LGBTQ+ identity (aOR = 4.43; 95% CI [1.81–10.85] for persistence) and prior PrEP experience (aOR = 4.20 for persistence) as the strongest independent predictors of sustained engagement in this cohort. Possible explanations include established behavioral norms, system navigation competency, and familiarity with HIV prevention services among these subgroups, although our study did not directly test these

mechanisms. Substance use, PHQ-2 depression score, and number of sexual partners were not significantly associated with any engagement outcome in this cohort; this finding is consistent with, although does not by itself establish support for, the use of nonrestrictive PrEP eligibility criteria. Whether peer mentorship from experienced PrEP users would improve engagement among individuals initiating PrEP for the first time was not assessed in our study and could be a subject for future research.

Operationally, approximately 96% of encounters were managed by nurses independently within standing order parameters, with same-day PrEP initiation achieved in 97% of encounters. This same-day rate is higher than rates reported for some traditional clinic-based models, where laboratory turnaround and provider scheduling can delay prescription initiation by several days; however, our study did not include a direct, contemporaneous comparison group, and the rate observed here was supported by point-of-care testing and by study medication availability that may not be present in all nonresearch settings. No safety events, as defined per protocol, occurred during the 18-month study period, and no inappropriate clinical decisions or protocol failures were identified through the protocol-defined safety monitoring process described above, which included provider review and sign-off of every encounter regardless of escalation status. These findings are consistent with the observed clinical safety of nurse-led PrEP delivery reported in other settings (Orser et al., 2023). This monitoring relied on clinical staff and providers identifying and reporting events during routine care rather than on a standardized adverse event severity grading tool applied independently at each visit, so these findings should be interpreted as reassuring rather than as formal safety trial evidence. The high completion rates for protocol-mandated STI and depression screening reported in the Results suggest that task-shifting did not come at the cost of clinical thoroughness in this program. Physician escalation, occurring in approximately 4% of encounters, is a separate operational measure of fidelity to the standing delegation order's defined scope rather than a measure of safety; the escalations that did occur were protocol-driven and clinically appropriate, reflecting the intended function of the standing delegation order rather than a safety concern. These findings may be relevant to policymakers and health system leaders considering nurse-led models, alongside more systematic safety data from future work.

Implementation Lessons and Future Directions

Several operational observations emerged during program implementation. These observations reflect program staff experience and administrative records rather than data collected through a formal qualitative research methodology and are reported descriptively rather than as hypothesis generated findings. An initial staffing model that distributed PrEP nursing responsibilities across four 0.5 full-time equivalent positions was associated with nurses being frequently reassigned to other clinical duties. Program staff subsequently reallocated nursing time to two dedicated full-time positions; program leadership reported this change as associated with improved continuity, although it was not evaluated against a comparison metric. Community Advisory Board members contributed to study design, recruitment strategy, outreach messaging, and venue selection. Program staff identified nursing workforce turnover, consistent with broader national nursing workforce shortages, as a challenge to maintaining continuity of participant relationships during our study period; the effect of staff turnover on study outcomes was not formally evaluated.

After the formal study period, program staff reported that the standing delegation order model was continued within the implementing organization and extended to nurse-led STI treatment protocols; this poststudy development was not part of our study protocol, and its outcomes have not been evaluated. Based on the findings of our study, several directions for future research may be considered. Given the 30.8% rate of STI co-infection observed at enrollment, integration of STI treatment within a nurse-led PrEP framework could be a subject for future evaluation. Current reimbursement structures for nurse-led PrEP encounters were not directly assessed in our study; whether reimbursement policy affects the scalability of nurse-led PrEP delivery is a question for future health services research. Given the bimodal persistence distribution observed, in which a substantial proportion of participants discontinued at 1 month, structured re-engagement approaches during early PrEP initiation may warrant evaluation in the future controlled studies; our study cannot establish whether such approaches would affect persistence.

Limitations

The quasi-experimental design without randomization limits causal inference, as observed outcomes may

reflect temporal trends, concurrent interventions, or selection bias. It is important that, during and after the implementation period, CAN Community Health introduced several concurrent programmatic initiatives including patient navigation services, insurance enrollment and benefits navigation support, same-day PrEP prescription and dispensing services, and patient transportation assistance programs. Because these initiatives occurred concurrently with the nursing model, the observed differences in PrEP enrollment composition cannot be attributed to PrEPared-RN alone, and the available data do not permit estimation of each initiative's independent contribution. In addition, the historical baseline cohort represents patients who received at least one PrEP prescription during the pre-implementation period and includes both newly initiated and previously established patients, whereas the PrEPared-RN cohort comprises exclusively new enrollees; this difference in cohorts may contribute to observed demographic differences and should be interpreted with appropriate caution. A subgroup analysis restricted to newly initiated patients in the baseline period, as suggested during review, was attempted but could not be reliably constructed from routine electronic medical record fields, which do not consistently distinguish new initiations from previously established patients during the pre-implementation window. Data on individuals offered PrEP services who declined enrollment were not systematically captured during either period, precluding analysis of differential uptake rates by demographic group; findings therefore reflect enrollment composition rather than acceptance behavior. Our study was conducted within a single nonprofit health system in South Florida, limiting generalizability to other geographic regions, organizational contexts, and regulatory environments. Demographic data relied on self-report with some missing values. Clinical characteristics available for the PrEPared-RN cohort, including STI status, prior PrEP use, and PHQ-2 screening, were not systematically extractable for the historical baseline cohort and could not be compared between groups. Operational metrics are reported as descriptive, observational data from programmatic records and should not be interpreted as formally validated outcomes. The 97% same-day initiation rate was facilitated by pharmaceutical sample availability through our study grant, and replication without equivalent medication access infrastructure may yield lower rates. The \$25 per-visit incentive may have influenced attendance in ways not fully distinguishable from program effects. Finally, the bimodal

persistence distribution suggests two distinct engagement trajectories not fully captured by summary statistics; future analyses using survival analysis or latent class approaches would yield richer characterization of engagement patterns.

Conclusions

The PrEPared-RN experience is consistent with nurse-led PrEP delivery, using standing delegation orders and multimodal, community-based service frameworks, being associated with expanded reach among some populations experiencing HIV-related health disparities, while operating within a feasible same-day service model. Female and heterosexual representation were significantly higher in the intervention cohort than at baseline, whereas Hispanic/Latino and Black/African American representation, although enrolled at rates exceeding national coverage benchmarks, did not differ significantly from baseline; these patterns should be interpreted as descriptive given the quasi-experimental design and the differences in cohort construction discussed above. At the same time, persistent racial disparities in engagement outcomes among Black/African American participants, particularly pronounced among those outside LGBTQ+ networks, indicate that enrollment reach alone is an insufficient equity metric. Equitable HIV prevention will likely require sustained engagement strategies, such as culturally grounded and peer-supported approaches, in addition to removing barriers to initial access.

These findings offer implementation evidence that may be useful to health care organizations and policymakers considering nurse-led PrEP delivery, including core components such as comprehensive standing delegation orders, systematic nurse training, community-embedded service delivery, and culturally responsive care. The absence of identified safety events during our study period, alongside a low and clinically appropriate physician escalation rate and provider review of every encounter regardless of escalation status, is reassuring. Safety monitoring followed a protocol-defined process with review by the medical director, study safety committee, and supervising providers but did not include a standardized adverse event severity grading tool applied independently at each visit and should not be treated as formal safety trial evidence. Future studies incorporating structured adverse event grading, along with targeted engagement strategies for underserved subgroups, would help clarify the extent to which nurse-led, community-based models can advance equitable PrEP access.

Key Considerations

- No safety events occurred during our study period, consistent with RNs operating under comprehensive standing delegation orders independently managing the full scope of routine PrEP care.
- This program's reach into populations experiencing HIV-related disparities was associated with multimodal, community-embedded service delivery, including mobile units, community-based organization partnerships, and faith-based settings. These modalities may be a relevant consideration for programs seeking to reach individuals who face structural barriers to clinic-based care, although the comparative effectiveness of individual service modalities was not evaluated in our study.
- In this cohort, LGBTQ+ identity and prior PrEP experience were the strongest independent predictors of sustained PrEP engagement.
- Persistent disparities in engagement outcomes among Black/African American participants, despite enrollment rates comparable to those of White participants, indicate that enrollment reach alone did not translate into equitable engagement in this cohort.
- Program staff reported that dedicated full-time nursing roles, in contrast to fractional staffing arrangements, were associated with improved continuity in this program; this observation was not formally evaluated. Reimbursement structures for nurse-led PrEP encounters were not assessed in our study but may be a relevant consideration for organizations planning similar programs.

Disclosures

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Data Accessibility Statement

The study protocol and de-identified datasets analyzed during the current study are available from the corresponding author on reasonable request.

Author Contributions

All authors on this paper meet the four criteria for authorship as identified by the International Committee of Medical Journal Editors (ICMJE); all authors have contributed to the conception and design of the study, drafted or have been involved in reviewing this manuscript, reviewed the final version of this manuscript before submission, and agreed to be accountable for all aspects of the work. Specifically, using the CRediT taxonomy, the contributions of each author are as follows: Conceptualization: K. Wendel; Data curation: K. Wendel; Formal analysis: P. Shukla, M. Wilson; Investigation: K. Wendel; Methodology: K. Wendel, P. Shukla, M. Wilson; Project administration: K. Wendel; Supervision: P. Shukla; Validation: M. Wilson; Writing—original draft: K. Wendel; Writing—review and editing: P. Shukla, M. Wilson.

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