

Preexposure Prophylaxis Use History in People With Antiretroviral Resistance at Human Immunodeficiency Virus (HIV) Diagnosis: Findings From New York City HIV Surveillance and Partner Services, 2015–2022

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Background. Drug resistance may be acquired in people starting human immunodeficiency virus (HIV) preexposure prophylaxis (PrEP) during undiagnosed infection. Population-based estimates of PrEP-related resistance are lacking.

Methods. We used New York City surveillance and partner services data to measure the effect of PrEP use (tenofovir disoproxil fumarate/tenofovir alafenamide fumarate with emtricitabine) history on the baseline prevalence of M184I/V mutations in people with HIV diagnosed in 2015–2022. PrEP use was categorized as “recent” (defined as PrEP stopped ≤ 90 days before diagnosis), “past” (PrEP stopped > 90 days before diagnosis), or “no known use.” Resistance-associated mutations were determined using the Stanford algorithm. We used log binomial regression to generate the adjusted relative risk (aRR) of M184I/V by PrEP use history in people with or without acute HIV infection (AHI).

Results. Of 4246 people with newly diagnosed HIV and a genotype obtained within ≤ 30 days of diagnosis, 560 (13%) had AHI; 136 (3%) reported recent and 124 (35%) past PrEP use; and 98 (2%) harbored M184I/V. In people with AHI, recent PrEP use was associated with a 6 times greater risk of M184I/V than no known use (aRR, 5.86 [95% confidence interval, 2.49–13.77]). Among people without AHI, the risk of M184I/V in recent users was 7 times that in people with no known use (aRR, 7.26 [95% confidence interval, 3.98–13.24]), and in past users, it was 4 times that in those with no known use (4.46 [2.15–9.24]).

Conclusions. PrEP use was strongly associated with baseline M184I/V in New York City, regardless of AHI status. Ordering a nucleic acid test when indicated after assessment of exposure, antiretroviral history, and AHI symptoms can decrease PrEP initiation in people with undetected infection.

Keywords. HIV; preexposure prophylaxis; drug resistance; resistance associated mutations; United States.

Preexposure prophylaxis (PrEP) using tenofovir disoproxil fumarate (TDF) or tenofovir alafenamide fumarate (TAF) in combination with emtricitabine (FTC) is a highly effective human immunodeficiency virus (HIV) prevention strategy [1–5]. However, there are concerns about acquired drug resistance (ADR) from PrEP initiation in individuals with undiagnosed HIV, or transmitted drug resistance (TDR) from infection with drug-resistant virus once PrEP has begun, and the resulting impact on treatment outcomes [6–9]. Multiple studies indicate that while antiretroviral (ARV) resistance from PrEP is rare

(<0.1%), it can occur with relative frequency in individuals who initiate PrEP during unrecognized acute HIV infection (AHI) and that even short duration and low levels of PrEP may be sufficient to induce FTC-selected M184I/V mutations [7, 10, 11].

Meta-analysis of data from several trials found that 41% of subjects with undetected incubating infection who started PrEP had mutations associated with TDF/FTC, compared with 3% of those who were infected after PrEP was begun [7, 11]. A case series showed that M184I/V developed in 23% of San Francisco sexual health clinic patients who started PrEP or postexposure prophylaxis during undiagnosed AHI [12]. M184I/V is more commonly reported across studies of drug resistance associated with PrEP use than TDF-selected K65R [7]. The elevated risk of developing drug resistance mutations associated with PrEP during AHI has potential implications for the success of first-line treatment regimens and for the possible persistence of minority variants, increasing the risk of future virologic failure [6, 13].

Findings on PrEP-related drug resistance have emerged largely from PrEP efficacy studies, case reports and clinic-based

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cohorts. One report using partner notification data showed a 53% prevalence of ≥ 1 nucleoside reverse-transcriptase inhibitor resistance mutation among 15 men who were on PrEP when HIV was diagnosed. M184I/V was found alone or combined with K65R, A62V, M41L, or T215E in all 8 men with nucleoside reverse-transcriptase inhibitor resistance, and K65R was combined with the other mutations in 3 [14]. We used New York City (NYC) HIV surveillance and partner services data to quantify the phenomenon at the population level in the years following the expansion of PrEP programming. We reported the baseline prevalence of M184I/V and K65R mutations and measured the association of PrEP use (daily or event-driven TDF/TAF with FTC) and timing before HIV diagnosis with the baseline prevalence of M184I/V in people with diagnosis between 2015 and 2022. We examined whether the effect of PrEP use history on this association was modified by diagnosis with AHI.

METHODS

Study Population and Data Sources

We included people with HIV newly diagnosed between 2015 and 2022, assigned for partner services, for whom a genotype obtained within 30 days of diagnosis was available in the NYC HIV Surveillance Registry (henceforth, Registry). Disease investigation specialists attempt to interview everyone with newly diagnosed HIV to facilitate linkage to care, elicit sex and needle-sharing partners and capture sociodemographics, HIV risk, and PrEP and postexposure prophylaxis use [15–17].

PrEP use has been systematically documented since 2015. In addition to client self-report, information is extracted from medical record review, provider interview, the Registry and laboratory databases, provider report form (a mechanism for providers to report new HIV diagnoses to the health department), and NYC surveillance case investigation records. Data are recorded on an electronic case investigation form and managed on a secure server, compliant with confidentiality and data security protocols. HIV-related laboratory results (CD4 cell count, HIV viral load [VL], and HIV-1 genotype sequences [Sanger or consensus sequences when next-generation sequencing is conducted]) are reported to the health department and stored in the Registry and laboratory databases. Resistance associated mutations were determined using the Stanford algorithm [18].

Study Design and Variables

We described PrEP use history, AHI, and the prevalence of M184I/V and K65R mutations in a retrospective cohort of people with newly diagnosed HIV in 2015–2022. We measured the association of PrEP use history and timing with the presence of M184I/V at their baseline genotype obtained within 30 days of diagnosis, in people with or without AHI respectively.

The primary exposure, PrEP use history and timing relative to HIV diagnosis, was categorized as (1) “recent PrEP use”

(defined as PrEP stop or start date in the 0–90 days before diagnosis or a missing stop date where the reasons for discontinuing PrEP included “HIV diagnosis” or “tested positive for HIV”; in these instances the stop date was set as the HIV diagnosis date); (2) “past PrEP use” (PrEP stop date >90 days before diagnosis or a missing stop date where the reasons for discontinuing PrEP did not include “HIV diagnosis” or “tested positive for HIV”); or (3) “no known PrEP use.” We used client self-report, provider report and medical record review to determine PrEP use, stop and start dates, and reasons for discontinuing the most recent PrEP course before diagnosis. PrEP start and stop dates were used to calculate the duration in days of PrEP use. We assessed for PrEP using TDF/TAF with FTC and did not differentiate between daily or event-driven dosing. Long-acting cabotegravir was not included in our PrEP ascertainment.

M184I, M184V, M184IV, and M184MV mutations were collapsed into a single variable for any M184I/V mutation. AHI and prediagnosis negative results for the nucleic acid test (NAT) were ascertained through the Registry. AHI is defined by either a provider-documented diagnosis based on symptoms present at intake and/or a test history or a spectrum of laboratory test results consistent with AHI [19–21].

Statistical Analyses

We compared sociodemographic characteristics, namely, age group (<30 vs ≥ 30 years), gender (cisgender men, cisgender women, or transgender people), race and ethnicity (black, Hispanic, white, of other [Asian/Pacific Islander, Native American, or unknown—grouped owing to small numbers]), and HIV transmission category (men who have sex with men [MSM], heterosexual contact, transgender people with sexual contact, or injection drug use) of people with varying PrEP use histories, using χ^2 /Fisher exact test of significance to assess differences in proportions ($P < .05$). We reported univariate statistics on the duration of PrEP use in days for people with start and stop dates and the number of PrEP users with a negative NAT result in the 0–15 days before their PrEP start date and in the 14 days after it, an indication that the test may have informed PrEP eligibility [22].

We used log binomial regression to generate stratum-specific (AHI vs no AHI) adjusted relative risk (aRR) and 95% confidence intervals (CIs) for the effect of PrEP use on M184I/V mutations. Effect modification by AHI on the association between PrEP use and the emergence of M184I/V is supported by evidence on the reversion of M184I/V to wild type in the absence of PrEP drugs (1.5–9 months for ADR and 6–60 months for TDR) [8, 11] suggesting that the mutation is more likely to be detected in people with HIV diagnosed earlier in the infection.

We examined the association of age, gender, race and ethnicity, and HIV transmission category with PrEP use history and with the appearance of M184I/V to assess for confounding, and

Table 1. Sociodemographic Characteristics of People With Newly Diagnosed Human Immunodeficiency Virus, Assigned for Partner Services and With an Available Genotype Within ≤30 Days of Diagnosis, by Preexposure Prophylaxis Use History—New York City, 2015–2022

Characteristic	Recent PrEP Use (≤90 d) (n = 136)		Past PrEP Use (>90 d) (n = 124)		No Known PrEP Use (n = 3986)		Total (n = 4246)		P Value (χ ² Test)
	No.	%	No.	%	No.	%	No.	%	
Acute HIV infection	41	30	24	19	495	12	560	13	<.001
Age group									<.001
<30 y	68	50	74	60	1492	37	1634	38	
≥30 y	68	50	50	40	2494	63	2612	62	
Race and ethnicity									.01
Black	41	30	40	32	1652	41	1733	41	
Hispanic	53	39	47	38	1447	36	1547	36	
White	32	24	30	24	602	15	664	16	
Other ^a	10	7	7	6	285	7	302	7	
Gender									<.001
Cisgender men	125	92	116	94	3131	79	3372	79	
Cisgender women	2	1	0	0	738	19	740	17	
Transgender people	9	7	8	6	117	3	134	3	
HIV transmission category									<.001
MSM	116	85	115	93	2356	59	2587	61	
Transgender with sexual contact	9	7	6	5	127	3	142	3	
Other ^b	11	8	3	2	1503	38	1517	36	
Interviewed by DIS	127	93	124	100	3494	88	3745	88	<.001

Abbreviations: DIS, disease investigation specialist; HIV, human immunodeficiency virus; MSM, men who have sex with men; PrEP, preexposure prophylaxis.

^a“Other” includes Asian/Pacific Islander, Native American, and unknown.

^b“Other” includes heterosexual contact, injection drug use, and unknown risk.

we included the transmission category (dichotomized as MSM vs other categories collapsed owing to small numbers) in the final model. Statistical analyses were conducted using SAS 9.4 software (SAS Institute).

RESULTS

Descriptive Analysis

Of 10 356 people with a new HIV diagnosis assigned for partner services in this time period, a total of 4246 (40%) had an available genotype obtained within 30 days of diagnosis and comprised our analytic population. Among them, 560 (13%) had AHI diagnosed, 98 (2%) had the M184I/V mutation, 5 (0.1%) had the K65R mutation, and 2 (<0.1%) had both. Any PrEP use was reported by 260 (6%), recent PrEP use by 136 (3%), and past PrEP use by 124 (3%). The average duration of PrEP use was 326 days (median, 123 days, interquartile range, 31–487 days).

There were significant differences among the 3 groups based on PrEP use history and timing. Recent PrEP users had the highest proportion of AHI compared with past users and those with no known use (30%, 19%, and 12%, respectively). Recent and past users were more likely to be non-Hispanic white than people with no known use (24%, 24%, and 15%, respectively) and more likely to be cisgender men (92%, 94% and 79%). A greater proportion of recent and past PrEP users had transmission category reported as MSM compared with those with no known use (85%, 93%, and 59%, respectively) (Table 1).

The prevalence of M184I/V was almost twice as high in people with recent PrEP use than those with past use, and 7 times higher than in people with no known use (14% vs 8% vs 2%, respectively). People with diagnosed AHI had twice the prevalence of M184I/V of those without AHI (4% vs 2%, respectively). These differences were statistically significant. There were no differences in prevalence of the mutation in terms of age, race and ethnicity, or gender (Table 2). Of the 260 PrEP users, 5 (2%) had a negative NAT result in the 0–4 days and 3 (1%) in the 10–15 days preceding PrEP start, and 3 (1%) had a negative NAT result in the 2–11 days following PrEP start.

Log Binomial Regression Models Stratified by AHI Status

AHI Diagnosis

Among those with AHI, people with recent PrEP use, compared with those with no reported PrEP use, had 6 times the risk of having M184I/V at their baseline genotype (aRR, 5.86 [95% CI, 2.49–13.77]). The risk of having the mutation among past users was almost 3 times as high as that in people with no known PrEP use (aRR, 2.77 [95% CI, .66–11.64]), although this difference was not statistically significant (Table 3).

No AHI Diagnosis

Among people without AHI, those with recent PrEP use had 7 times the risk of having M184I/V of those who had no known PrEP use (aRR, 7.26 [95% CI, 3.98–13.24]). The risk of

Table 2. Differences in Baseline Prevalence of M184I/V by Preexposure Prophylaxis use History and Other Factors in People With Newly Diagnosed Human Immunodeficiency Virus and Assigned for Partner Services—New York City, 2015–2022

Characteristic	M184I/V Mutation Present At Baseline Genotype		Total No.	P Value (χ^2 Test)
	No.	%		
All	98	2	4246	...
PrEP use history				<.001
Recent PrEP use	19	14	136	
Past PrEP use	10	8	124	
No known PrEP use	69	2	3986	
Age group				.08
<30 y	46	3	1634	
≥30 y	52	2	2612	
Race and ethnicity				.80
Black	40	2	1733	
Hispanic	38	2	1547	
White	17	3	664	
Other ^a	3	1	302	
Gender				.30
Cisgender men	84	2	3372	
Cisgender women	13	2	740	
Transgender people	1	1	134	
HIV transmission category				.002
MSM	74	3	2587	
Other ^b	24	1	1659	
Acute HIV infection				.02
Yes	23	4	560	
No	75	2	3686	

Abbreviations: HIV, human immunodeficiency virus; MSM, men who have sex with men; PrEP, preexposure prophylaxis.

^a“Other” includes Asian/Pacific Islander, Native American, and unknown.

^b“Other” includes heterosexual contact, injection drug use, and unknown risk.

mutation in people with past use was 4 times as high as that in those with no known PrEP use (aRR, 4.46 [95% CI, 2.15–9.24]) (Table 3).

DISCUSSION

We used NYC HIV surveillance and partner services data to establish the relationship between PrEP use history and timing and the development of mutations associated with resistance to TDF/TAF or FTC, the components of PrEP, in people with newly diagnosed HIV in 2015–2022 and with an available baseline genotype within 30 days of diagnosis. We examined effect modification by AHI on this association.

The M184I/V mutation, conferring resistance to FTC, was found in 2% of our population. However, among recent PrEP users the prevalence was 10 times higher than in people with no reported history of PrEP use. Past PrEP use, even when not recent, was associated with a 4 times higher prevalence of M184I/V. In contrast, the prevalence of the signature TDF mutation, K65R was negligible, with none of the 5 people with

Table 3. Adjusted Relative Risk of Resistance Associated Mutations M184I/V at Baseline Genotype by Preexposure Prophylaxis Use History, in People With or Without Acute HIV Infection—New York City, 2015–2022

PrEP Use History	aRR (95% CI) ^a	
	AHI	No AHI
Recent PrEP use	5.86 (2.49–13.77)	7.26 (3.98–13.24)
Past PrEP use	2.77 (.66–11.64)	4.46 (2.15–9.24)
No known PrEP use	1.00 (Reference)	1.00 (Reference)

Abbreviations: AHI, acute human immunodeficiency virus infection; aRR, adjusted relative risk; CI, confidence interval; PrEP, preexposure prophylaxis.

^aAdjusted for transmission category: men who have sex with men versus other (heterosexual, contact, injection drug use, transgender with sexual contact, unknown risk).

K65R reporting any PrEP use. Large differences in the distribution of M184I/V by PrEP use in the 90 days before diagnosis (30% in PrEP users vs 1% in the nonusers) were also reported in a UK clinic-based study [23]. In our analysis, MSM were more likely than those in other transmission categories to present with M184I/V at baseline. This association may be partially explained by PrEP use history, given that the majority of PrEP users in our population were MSM. Some part of this association may be attributed to transmitted resistance in sexual networks [24, 25].

AHI was significantly more frequent in both recent and past PrEP users than in people with no known PrEP use. While only a small subset of our population was on PrEP at the time of HIV diagnosis, continuation of PrEP prescriptions by providers is usually contingent on HIV testing at 3-month intervals and therefore more likely to lead to diagnosis of infection in the acute phase. Early diagnosis among individuals with a history of PrEP use may be attributable either to greater access to sexual health services and regular HIV testing or to differential healthcare-seeking behavior. Further, disparities in PrEP uptake tend to align with socioeconomic disparities that present barriers to HIV testing [17, 26, 27].

Evidence from the literature indicating that M184I/V tends to decay and revert to wild type over time in the absence of ARVs led us to examine whether the effect of PrEP on presence of the mutation was modified by early diagnosis, here defined by AHI. This was supported by the strong association of PrEP use with AHI in our data. Given the possibility of reversion of resistance and of ADR resulting from suboptimal ARV therapy (ART), we considered timing of the baseline genotype as an additional factor in whether M184I/V would be observed, restricting our pool of genotypes to those obtained within 30 days of diagnosis [8, 11].

Our data show that PrEP use, particularly recent use, is strongly associated with the presence of M184I/V mutation at the baseline genotype in both strata of AHI. Recency of PrEP use may, in some cases, suggest delayed seroconversion, diagnostic failure, and continued selective pressure [23]. In a population where a proportion of baseline genotypes are delayed,

AHI or early diagnosis could have the potential to constitute a distinct pathway between PrEP use and the manifestation of M184I/V owing to the role of temporality and the increased likelihood that reversion of resistance may not have occurred. However, our findings, based on genotypes obtained within 30 days of diagnosis, suggest that AHI does not amplify the effect of PrEP use on the presence of M184I/V. Prior PrEP use might be linked to ADR if PrEP was initiated during undiagnosed infection and continued thereafter, to either TDR or ADR if PrEP adherence was suboptimal or if PrEP was used intermittently, and to TDR owing to infection with HIV that is resistant to TDF/TAF/FTC. Distinguishing TDR from ADR with certainty in the context of PrEP use exceeds the scope of our data.

Only 4% of people in our population with any PrEP use history had evidence of a negative NAT in the 2 weeks before and after PrEP initiation. While our data cannot speak to the overall use of NAT in the context of PrEP screening in NYC, they suggest that in populations at highest risk of HIV infection, complete laboratory testing in conjunction with symptom, exposure, and previous ARV history assessment may not be occurring at optimal levels to rule out AHI before PrEP initiation.

In contrast to previous findings on PrEP-related drug resistance in the setting of AHI that have been obtained from PrEP trials, case reports, and clinical case series, our study draws its conclusions from HIV surveillance and partner services. Owing to surveillance protocols and universal partner services in NYC, everyone with a new HIV diagnosis receives health department investigation, making findings based on these data representative of the local population and providing robust sample sizes to facilitate hypothesis testing. However, these data have limitations. Our analytic sample comprised people with a baseline genotype within 30 days of HIV diagnosis, which represented only 40% of new diagnoses in this time period. Because of potential biases associated with the receipt of a baseline genotype, these findings cannot be said to represent the true prevalence of PrEP-related drug resistance in this population. If PrEP was used close to HIV diagnosis, plasma VLs may have been below the threshold required to conduct resistance testing, potentially leading to an underestimation of drug resistance in PrEP users.

We were lacking reliable data on daily or event-driven dosing, adherence, and prediagnosis HIV-negative tests, which could better inform causal pathways for acquisition of drug resistance. However, while these data could have a role in distinguishing ADR from TDR, their absence does not affect the overall measure of the effect of PrEP use history on the presence of resistance-associated mutations. PrEP use and dates were determined through self-report and medical record review, leading to a potential for recall and information bias, as well as differential misclassification of PrEP use and timing. While true PrEP users were confirmed through robust triangulation of sources and had the highest rates of disease investigation

specialist interviews, some people with no known PrEP use may have been misclassified. Recent PrEP users missing PrEP stop and start dates as well as reasons for stopping PrEP may have been misclassified as past users, leading to underestimation of the effect of recent use on the risk of M184I/V.

In conclusion, we found a strong association between PrEP use and the presence of drug resistance at diagnosis in NYC, a setting of high HIV prevalence, regardless of AHI status. Fewer than half of all people with newly diagnosed HIV had a genotype obtained within 30 days of diagnosis. The reasons for this may include lack of drug resistance testing by providers, low VL at the time of testing, and laboratory reporting failure [28]. The proportion of genotypes conducted within 3 months of diagnosis has declined in NYC, from 72% in 2013 to 46% in 2021 [28, 29]. We found that only 4% of people with PrEP use history had evidence of a negative NAT result in the plausible time frame of PrEP screening, revealing missed opportunities for identifying undiagnosed infection. NAT can more confidently rule out AHI in people who may be reluctant to disclose exposure history, whose illness may be mild, nonspecific or asymptomatic, or whose ARV experience may be uncertain. In situations where RNA testing is not feasible owing to cost or time constraints, repeated HIV antigen/antibody testing in the month following PrEP start can decrease PrEP use during undiagnosed infection and facilitate timely transition to fully suppressive ART [22, 30]. In addition, providers should adhere to guidelines recommending baseline genotype resistance testing for everyone with a new HIV diagnosis and follow-up genotyping for people found to have drug resistance at baseline, to assess short- and long-term treatment options [29–32].

The benefits of PrEP outweigh the risk of ADR. HIV infections averted by PrEP would require long-term ART, entailing an estimated annual risk of drug resistance between 5% and 20% [33, 34]. While some studies show that people with PrEP-related resistance went on to become virally suppressed within 6 months of diagnosis [12, 35] and that dolutegravir-based second-line ART regimens have been successful in limiting the effect of M184I/V on ART efficacy [6], others have found a greater risk of virologic nonsuppression with preexisting M184I/V [6]. Longitudinal assessment of people with PrEP-related drug resistance using population level and surveillance data is warranted.

Notes

Author Contributions. K. M. was responsible for the conception, design, methodology, data analysis, and writing. J. S. H. and L. F. contributed to data preparation. Q. X. contributed to methodology and design, and C. N. U. and L. V. T. provided programmatic and scientific insight.

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