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Longitudinal trends in HIV non-occupational post-exposure prophylaxis (NPEP) use at a Boston community health center between 1997 and 2013

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Abstract

Secular trends in non-occupational post-exposure prophylaxis (NPEP) use have not been well-characterized. We performed a retrospective longitudinal study of 894 electronic medical records of NPEP users, mostly men who have sex with men, at a Boston community health center who presented between July, 1997 and August, 2013. NPEP use and condomless sexual exposures increased over time; 19.4% had multiple NPEP courses. Having an HIV-infected partner was associated with increased odds of regimen completion, and three-drug regimens were associated with decreased odds of completion. Targeted adherence and risk-reduction counseling are warranted for select NPEP users at this center.

Keywords

PEP; NPEP; post exposure prophylaxis; HIV; biomedical prevention

INTRODUCTION

Despite an increasing number of interventions to prevent HIV transmission,¹⁻⁷ approximately 50,000 new HIV infections occur in the United States each year,⁸ HIV non-occupational post-exposure prophylaxis (NPEP) entails a 28-day course of antiretroviral medication administered to HIV-uninfected individuals within 72 hours after a potential sexual or intravenous drug needle exposure to HIV, which the CDC has recommended by since 2005.⁹ Although NPEP efficacy trials have not been performed, its effectiveness is

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Conflicts of Interest

For the remaining authors none were declared.

supported by macaque models¹⁰⁻¹¹ and a large retrospective case-control study of occupational PEP.¹²

While the frequency of unprotected anal intercourse increased from 48% to 57% from 2005 to 2011 in men who have sex with men (MSM) who are HIV-uninfected or had unknown status,¹³ several studies have reported that awareness of NPEP among high-risk MSM has remained low.¹⁴⁻¹⁹ In addition, subsequent HIV acquisition rates have been high among MSM PEP users in several series.^{15,20-23} Multiple centers have reported that newer PEP regimens have improved tolerability and fewer drug-drug interactions²⁴⁻²⁸ compared to earlier regimens.²⁹⁻³¹ However, the factors associated with NPEP completion and non-completion have not been well-described, as few studies have examined long-term trends of NPEP use within the past 10 years.^{15,23,32-33} In order to understand the specific behaviors, patterns, and outcomes of NPEP users to guide future prevention interventions, we examined the characteristics of NPEP users and circumstances of exposures, frequency of NPEP use, and trends in prescriptions and tolerability of NPEP regimens among persons who used NPEP since 1997 at the largest NPEP provider in New England.

METHODS

Patients and Procedures

This study is a retrospective longitudinal review of NPEP users at a large urban community health center in Boston, MA, who presented between July 1, 1997 and August 1, 2013. Any HIV-negative patient who had a prescription for antiretroviral medication in their electronic medical record during this time period was screened for study eligibility. Inclusion criteria included: 1) age 18 years or older at NPEP enrollment; 2) sexual or intravenous drug needle exposure; and 3) negative baseline HIV test at the time of NPEP presentation. Patients were excluded if they had confirmatory positive HIV testing within 30 days of antiretroviral treatment, were prescribed NPEP after reporting an exposure by phone but did not follow up in person, were prescribed antiretrovirals for anything other than NPEP, had occupational exposures, or were enrolled in an NPEP clinical trial.

Extracted demographic information for each NPEP course included: date of birth, date of initial encounter at the health center, date of last encounter or HIV test, gender identity, race, gender preferences of sexual partner, and insurance status. Each patient could have had multiple NPEP courses over the study period. The following data were extracted: date of NPEP enrollment, nature of exposure, and partner's reported HIV status. Providers used a standardized intake form containing this information. Prescribed antiretroviral regimen, regimen completion, reasons for documented non-completion or modifying the regimen, adverse effects, and follow-up at 1, 3, and 6 month intervals after the exposure were recorded. Any HIV testing, including a rapid whole blood fingerstick assay or a serum antibody and/or plasma viral load, was required to count as having followed up at 3 and 6 months. Each provider chose the NPEP regimen on a case-by-case basis after a rapid HIV test was confirmed to be negative and did not follow a specific center-specific protocol.

Statistical Methods

Proportions for categorical variables and means and standard deviations for continuous variables were calculated for descriptive characteristics of the sample. NPEP regimens were tabulated by specific drug regimen, and comparisons were made between 2 versus 3-drug regimens, and azidothymidine-versus tenofovir-based regimens. Logistic generalized estimation equation (GEE) models were used to assess trends in NPEP prescriptions over time, including reason for seeking NPEP (i.e. condomless versus protected consensual exposure with condom failure) and drug regimen (i.e. tenofovir- versus azidothymidine-based regimen). Time was modeled as a continuous variable by calendar year of NPEP prescription.

To account for the fact that patients could have multiple PEP courses, bivariate and multivariable logistic GEE models were used to assess factors associated with completing NPEP regimen. Factors included age, race/ethnicity, gender identity (categorized as MSM versus other identity for modeling purposes due to small numbers of individuals reporting non-MSM identities), insurance versus no insurance, consensual versus non-consensual exposure, partner HIV status, three-drug versus two-drug regimen, and tenofovir versus azidothymidine-based NPEP regimen. Completion analyses were restricted to patients who had documentation of regimen completion or non-completion. All analyses were conducted in Stata version 12.1 (StataCorp, College Station, TX). All study procedures were approved by the Fenway Health Institutional Review Board.

RESULTS

Of 1084 unique medical records initially identified, 894 patients prescribed 1,244 NPEP courses met the inclusion criteria. Of the 894 patients, 19.4% presented for NPEP multiple times (range 2 to 15, mean:1.4; median:1, IQR:1 to 1). Most common reasons for 190 patients being excluded from the study were: no documentation of PEP corresponding to date of antiretroviral prescription (21.1%), antiretrovirals prescribed for pre-exposure prophylaxis (PrEP) (21.6%) or Hepatitis B (11.1%), patient requested a privacy alert that requires any provider to enter a medical reason before accessing their record (21.6%), and occupational exposures (12.6%).

Of the 894 patients in this analysis, median age at first NPEP course was 32.3 years (IQR: 26.3 to 40.2; Table 1). Most (88.1%) were MSM, 56.2% had private insurance, and 71.5% were non-Latino white. Reasons for seeking NPEP included consensual condomless sex (61.3%), condom failure/removal (31.4%), non-consensual sex (5.3%), and injection drug use (1.1%; Table 1).

Consensual condomless exposures included receptive oral (21.3%), insertive anal (36.6%), receptive anal (56.6%), insertive vaginal (1.2%), and receptive vaginal sex (2.5%). Patients may have reported more than one exposure at a given NPEP visit. The HIV serostatus of the partner was unknown for 62.1%. Among those who reported a known HIV-infected source, the treatment status was unknown for 17.2%, 4.1% thought the source was not on treatment, and 13% thought the source was on treatment. Among consensual sexual exposures, the

proportion of reported condomless exposures increased by year (OR=1.05 per year, 95%CI: 1.01-1.08, P=0.004).

Consensual sexual exposure in which there was a condom failure occurred in 29.9% of NPEP courses. Among these exposures, 67.7% were with partners of unknown HIV status, 13.7% known HIV-infected but unknown treatment status, 3.8% known HIV-infected and not on treatment, and 14.8% known HIV-infected and on treatment.

Non-consensual exposures included receptive oral (7.8%), insertive anal (3.0%), receptive anal (56.1%), and receptive vaginal sex (43.9%). Most (92.4%) partners were of unknown HIV status; 6.1% were known HIV-infected but treatment status unknown, and 1.5% were known HIV-infected and known to be on treatment. Fourteen (1.1%) patients presented for NPEP due to recreational injection drug exposure.

Figure 1A shows the distribution of NPEP prescriptions by year. Overall there was an increasing trend in number of NPEP prescriptions per year. The most commonly-prescribed regimens contained tenofovir, which began in 2005 and increased over time ($P<0.001$). Nearly half (47.6%) of regimens consisted of three drugs, and there was a decrease in three-drug regimens over time, with two-drug regimens becoming increasingly prevalent ($P<0.001$).

Among the 540 patients (43.4% of the sample) with documented completion status, 85.7% completed their NPEP regimen. Among the 77 (14.3%) who did not complete their regimen, reasons included medication intolerance (48.1%) due to nausea (43.2%), diarrhea (13.5%), and rash (13.5%), and learning that one's partner was HIV-negative (9.1%), but for almost half (45.5%), the reasons were not specified. A substantial proportion of patients (10.5%) did not return for any follow-up after the initial NPEP visit. Among those with documented completion status, having an HIV-infected partner (AOR 1.90, 95%CI: 1.05-3.45, $P=0.03$) was associated with increased odds of completion of regimen, and a three-drug regimen (versus two-drug, AOR 0.45, 95%CI: 0.25-0.78, $P=0.005$) was associated with decreased odds of completion. The year of NPEP enrollment (AOR 1.12; 95%CI: 1.06-1.18; $P<0.001$) and tenofovir-based regimens (versus azidothymidine-based regimens; AOR 2.80; 95%CI: 1.69-4.63; $P<0.001$) were strongly associated with completion in the bivariate analysis but dropped out in the multivariable analysis (Table 2).

DISCUSSION

While NPEP is generally underutilized,³⁴ this study noted a rise in number of NPEP courses and consensual condomless sex over a 16-year period, with 56.6% of all consensual sexual exposures involving condomless anal receptive intercourse. The frequency of recurrent NPEP coincides with the 9-28% range as reported in other settings.^{20,32,35-36} Our data are also consistent with other studies which demonstrated that many MSM who received NPEP continued to practice high-risk behaviors and remained at elevated risk for HIV acquisition.^{15,23} While NPEP users are typically self-selected patients that may be more knowledgeable about biomedical prevention, the recurrent use of NPEP for condomless anal sex represents a lack of uptake of or ineffective risk-reduction counseling provided during

NPEP. These data suggest the need to anticipate that many NPEP users remain at increased risk for HIV acquisition after NPEP and may be good candidates for PrEP and other evidence-based biobehavioral interventions.³⁷

Regarding NPEP prescriptions, there was a shift from azidothymidine to tenofovir-based regimens after the approval of tenofovir/emtricitabine for HIV treatment in 2004. Since then, there has been a steady rise in NPEP prescriptions at this health center using tenofovir/emtricitabine alone or in combination with lopinavir/ritonavir, efavirenz, or raltegravir. Furthermore, tenofovir-based regimens tended to be associated with increased NPEP completion rates, which reinforces that providers should favor tenofovir-based regimens for NPEP. This finding also has important implications for pre-exposure prophylaxis (PrEP), for which the current U.S. Food and Drug Administration has approved tenofovir-emtricitabine.³⁸ Further studies are required to assess the association between NPEP completion with a tenofovir-based regimen and PrEP tolerability.

The fact that an HIV-infected partner was associated with better completion rates may reflect a higher self-perceived HIV risk compared to those who have partners with unknown status. The decreased completion while on 3-drug regimens as compared to 2-drug regimens is likely to be related to the regimen factors, namely dosing, pill burden, and adverse effects. Although it has not been feasible to do a head-to-head study of 2- versus 3-drug regimens, a decision analysis by Bassett and colleagues suggested that a 2-drug regimen might be preferable because better tolerability might lead to increased completion rates.³⁹ However, newer regimens containing tenofovir and using integrase inhibitors may enable patients assigned to a 3-drug regimen to experience fewer side effects and lower pill burdens compared to earlier regimens that relied on azidothymidine-based combinations and ritonavir-boosted protease inhibitors.

This study has several limitations, particularly the retrospective design. Adverse effects and completion of NPEP regimens were inconsistently reported, including circumstances when patients returned for follow-up at the appropriate interval. Documentation of regimen completion was unavailable for 56.6% of NPEP courses, and nearly 20% of patients did not follow up after completion of their regimen. Whether these patients differed substantially from those who returned for follow-up is unknown.

There may have been outstanding factors that influenced the selection of NPEP regimens, such as co-morbid conditions, duration and aggressiveness of sexual contact, report of visible blood at the site of exposure, and whether or not the insertive source partner ejaculated inside the exposed patient. While victims of sexual assault represented a small proportion of this sample, it is possible that many sought NPEP at local emergency departments, which may explain the predominance of consensual exposures here.

This study demonstrates that NPEP is an increasingly utilized method of biomedical prevention of HIV at this large urban community health center and that NPEP users demonstrated recurrent high-risk behavior. These findings reinforce that earlier, targeted HIV risk-reduction and PrEP counseling may be warranted for a select group of NPEP users. It will also be critical to engage groups such as high-risk MSM of color, who are

underrepresented in this study and are likely to be underutilizing NPEP, despite being disproportionately affected by HIV.

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Figure 1.

NPEP trends by number of each regimen prescribed per year*

AZT: Azidothymidine; 3TC: Lamivudine; TDF: Tenofovir; FTC: Emtricitabine. Data illustrated for 2013 represents NPEP visits through August 1. Logistic generalized estimating equations were used to analyze trends over time.

Table 1

Descriptive characteristics of individuals accessing NPEP at a large community urban health center, 1997-2013

Characteristic	
Total number of participants	894
Age at NPEP enrollment, years (mean, SD)	33.9 (9.5)
Gender identity	
MSM Male	788 (88.1%)
MSW Male	38 (4.3%)
Female	53 (5.9%)
Transgender/Genderqueer	15 (1.7%)
Race	
White	639 (71.5%)
Latino	97 (10.9%)
African American/Black	63 (7.1%)
Asian	42 (4.7%)
Other/Multiracial	53 (5.9%)
Insurance Status	
No insurance	326 (36.5%)
Private Insurance	502 (56.2%)
Medicaid/Medicare/MassHealth	66 (7.4%)
In primary care at health center	553 (61.9%)
Total number of NPEP courses (range)	1,244 (1 to 15)
Reason for NPEP enrollment	
Unprotected consensual sex	762 (61.3%)
Condom failure/removal	390 (31.4%)
Non-consensual sex/rape	66 (5.3%)
Injection drug use	14 (1.1%)
Partner HIV status	
Known HIV-infected – on treatment	162 (13.0%)
Known HIV-infected – not on treatment	51 (4.1%)
Known HIV-infected – treatment unknown	214 (17.2%)
Unknown	817 (65.7%)
Tenofovir-based treatment regimen	927 (75.7%)
Three-drug treatment regimen	592 (47.6%)

SD: standard deviation; MSM: men who have sex with men; MSW: men who have sex with women

Table 2

Factors associated with documented completion of NPEP regimen

	Regimen completion						
<i>N</i>	Yes	No	OR ¹	<i>P</i>	AOR ²	<i>P</i>	
<i>Age, year (mean, SD)</i>	463 (85.7%)	77 (14.3%)					
<i>MSM vs Other</i>	34.8 (9.4)	32.2 (8.8)	1.03 (1.01 to 1.07)	0.02	1.02 (0.99 to 1.06)	0.14	
<i>Race/Ethnicity</i>	427 (92.2%)	68 (88.3%)	1.55 (0.71 to 3.37)	0.20	1.06 (0.42 to 2.69)	0.90	
White/Caucasian	357 (77.1%)	55 (71.4%)	Ref	**	Ref	**	
Latino	46 (9.9%)	5 (6.5%)	1.38 (0.52 to 3.68)	0.52	1.54 (0.56 to 4.22)	0.40	
African American	20 (4.3%)	7 (9.1%)	0.45 (0.18 to 1.13)	0.09	0.43 (0.16 to 1.15)	0.09	
Asian/Pacific Islander	25 (5.4%)	5 (6.5%)	0.74 (0.27 to 2.06)	0.57	0.80 (0.28 to 2.35)	0.67	
Other	15 (3.2%)	5 (6.5%)	0.44 (0.15 to 1.28)	0.13	0.85 (0.27 to 2.72)	0.78	
<i>Any insurance coverage</i>	326 (70.4%)	50 (64.9%)	1.27 (0.76 to 2.16)	0.36	0.69 (0.38 to 1.25)	0.22	
<i>Non-consensual sexual exposure</i>	17 (3.7%)	5 (6.5%)	0.60 (0.21 to 1.70)	0.33	0.91 (0.26 to 3.19)	0.89	
<i>Partner known to be HIV-infected</i>	180 (38.9%)	22 (28.6%)	1.59 (0.94 to 2.70)	0.09	1.90 (1.05 to 3.45)	0.03	
<i>Three-drug versus two-drug regimen</i>	227 (49.0%)	52 (67.5%)	0.47 (0.29 to 0.79)	0.004	0.45 (0.25 to 0.78)	0.005	
<i>Tenofovir versus AZT-based regimen</i>	330 (72.2%)	35 (47.3%)	2.80 (1.69 to 4.63)	<0.001	1.96 (0.73 to 5.28)	0.18	
<i>Year of NPEP enrollment (median, IQR)</i>	2009 (2004-2011)	2004 (2000-2011)	1.12 (1.06 to 1.18)	<0.001	1.04 (0.94 to 1.16)	0.45	

¹ Odds ratio (RR) estimated with bivariate logistic generalized estimating equation (GEE) model to account for possible multiple NPEP courses per person, an odds ratio of less than 1 indicates reduced odds of non-adherence to regimen and/or follow-up visits;

² Adjusted odds ratio estimated with multivariable logistic GEE model