



# InterPrEP (II): A study of internet-based pre-exposure prophylaxis (PrEP) with generic tenofovir DF/emtricitabine (TDF/FTC) in London Analysis of Safety and Outcomes 56 Dean Street Chelsea and Westminster Hospital NHS Foundation Trust



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## Introduction

The PROUD and IPERGAY PrEP trials demonstrated an 86% reduction in new HIV diagnoses in high risk men who have sex with men (MSM). Although PrEP is not available on the National Health Service (NHS) in England, people are buying generic versions of TDF/FTC on the internet, a practice that is legal under UK import laws. One month's supply of generic TDF/FTC as PrEP can be purchased online for £30 - £40/month, versus the commercial price of over £400/month for branded Truvada from Gilead. From February 2016, we began offering users of generic PrEP visiting our clinic regular tests for HIV sexually transmitted infections (STIs) as well as for hepatitis B and C. We also monitored their renal function and measured antiretroviral drug concentrations. Here, we describe the characteristics and outcomes of individuals purchasing online PrEP attending our service.

## Methods

HIV-negative individuals attending our clinic between February 2016 and February 2017, who reported purchasing generic PrEP online were given risk reduction advice and evaluated for HIV, hepatitis B and C, renal function and STIs (gonorrhoea, chlamydia and syphilis) at first visit. They were offered regular follow-up visits every three months. Plasma Therapeutic Drug Monitoring for tenofovir (TFV) and FTC was also offered. Drug concentrations were measured by ultra-performance liquid chromatography, coupled with UV detection with a linear range of 25 to 10,000 ng/mL.

## Results

Over 700 individuals accessed the service during 2016 – 2017; data was available for 371 patients attending at least one follow-up visit. Median time on generic PrEP in 371 individuals was 17.2 months (223 total patient-years of follow up). >99% were Male, 82% were White, 90% took PrEP daily and 10% event-driven; 97% (214/221) were on generic TDF/FTC from Cipla Ltd. Adequate drug levels were seen in 88% of patients on first sample; drug concentrations were adequate in all repeat samples. Baseline eGFR (>60ml/min) and/or urinalysis was normal in 96% (288/301) of individuals. Renal function deteriorated in <1% (1/136) of individuals seen at follow-up; however this patient has a pre-existing chronic kidney condition. 44% of patients (112/253) reported using "chems" in the 12 months before starting PrEP, and 30% (77/255) reported this whilst taking PrEP. During follow-up on PrEP, 35% (129/348) of patients were diagnosed with an STI at one or more follow-up visits. In 223 person-years of follow up, there were no cases of HIV infection (0%, 95% C.I. 0-1.6%). There were no new cases of hepatitis B and two new cases of hepatitis C.

## Discussion

While PrEP remains unavailable on the NHS, and branded Truvada is unaffordable to the majority of people, high risk MSM are using the internet to obtain generic PrEP for £30 to £40 per month. Our analyses did not uncover any counterfeit examples of generic PrEP. Concentrations of TFV and FTC in blood samples of generic PrEP users were similar to those in healthy volunteers on branded Truvada from Gilead. We observed no new cases of HIV in 371 individuals on generic PrEP for median 17.2 months. Interestingly, over the 15 months from November 2015 to February 2017, we have recorded a 42% reduction in new HIV diagnoses at our clinic. We believe that our support for individuals taking generic PrEP has contributed to this fall. 18% (58/316) of individuals had one or more STIs at baseline and 35% (129/348) at follow-up. Strategies to reduce STIs remain crucial including the continued promotion of condom use where possible and regular testing for, and rapid treatment of STIs.

Figure 1: New HIV diagnoses at 56 Dean Street; Jan 2015 to March 2017 (MSM)

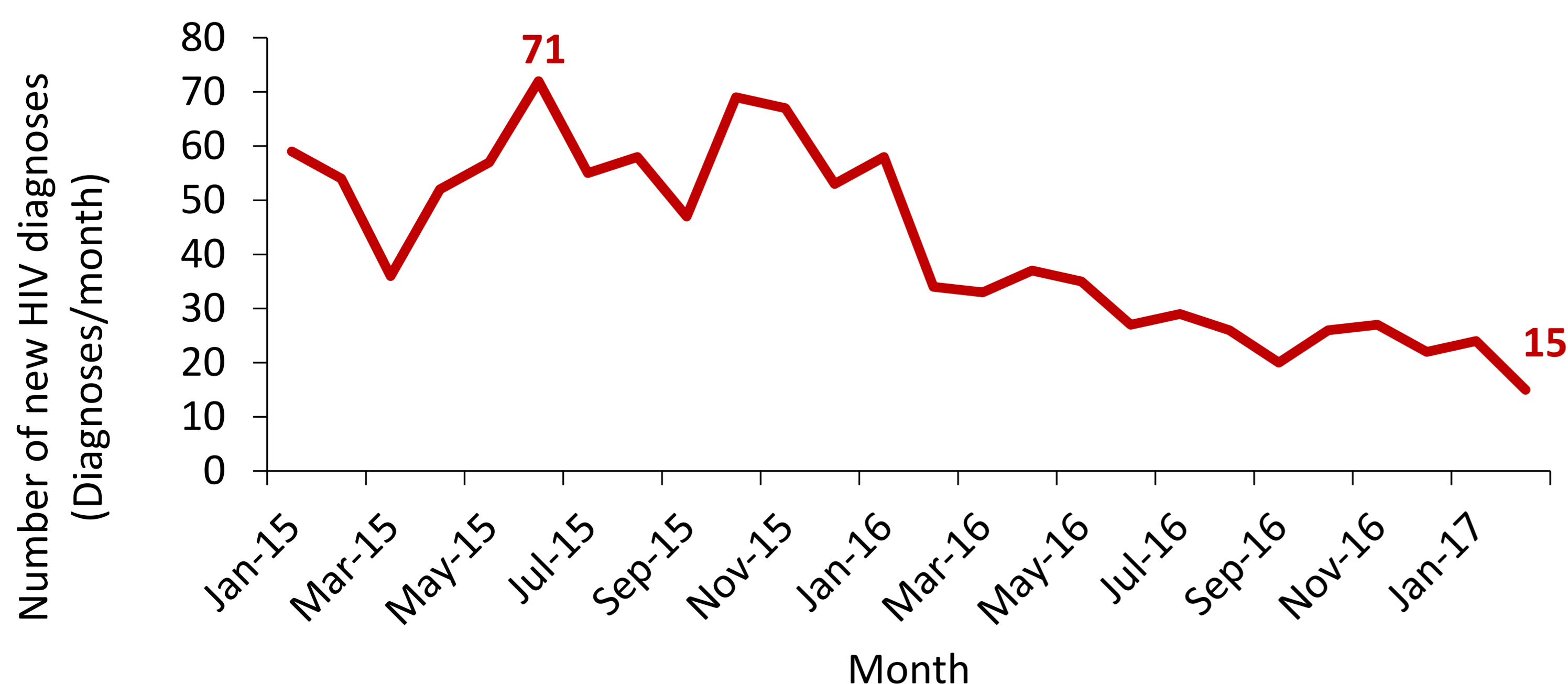


Table 1: InterPrEP Baseline Characteristics compared with recent studies

Characteristic	56 Dean Street (n=371)	IPERGAY <sup>1</sup> (N=199)	PROUD <sup>2</sup> (n=273)	San Francisco Kaiser Permanente <sup>3</sup> (n=972)
MSM (%)	100%	100%	100%	98%
Median age (years) (IQR)	37 (30-43)	35 (29-43)	35 (30-43)	37 (18-68)
Ethnicity White (%)	82%	94%	81%	65%
Chemsex (%)	44%	43%	43%	-
PrEP dosing schedule	Daily & Event-driven	Event driven	Daily	Daily

Table 2: STIs at baseline and during follow-up

STI	STI at baseline	STI during follow-up
Chlamydia	9% (30/316)	26% (92/348)
Gonorrhoea	7% (23/316)	23% (79/348)
Syphilis	3% (9/316)	3% (11/348)
Hepatitis C	<1% (1/316)	1% (3/348)

Figure 2: Time-dependent plasma TDF concentrations following consumption of oral PrEP

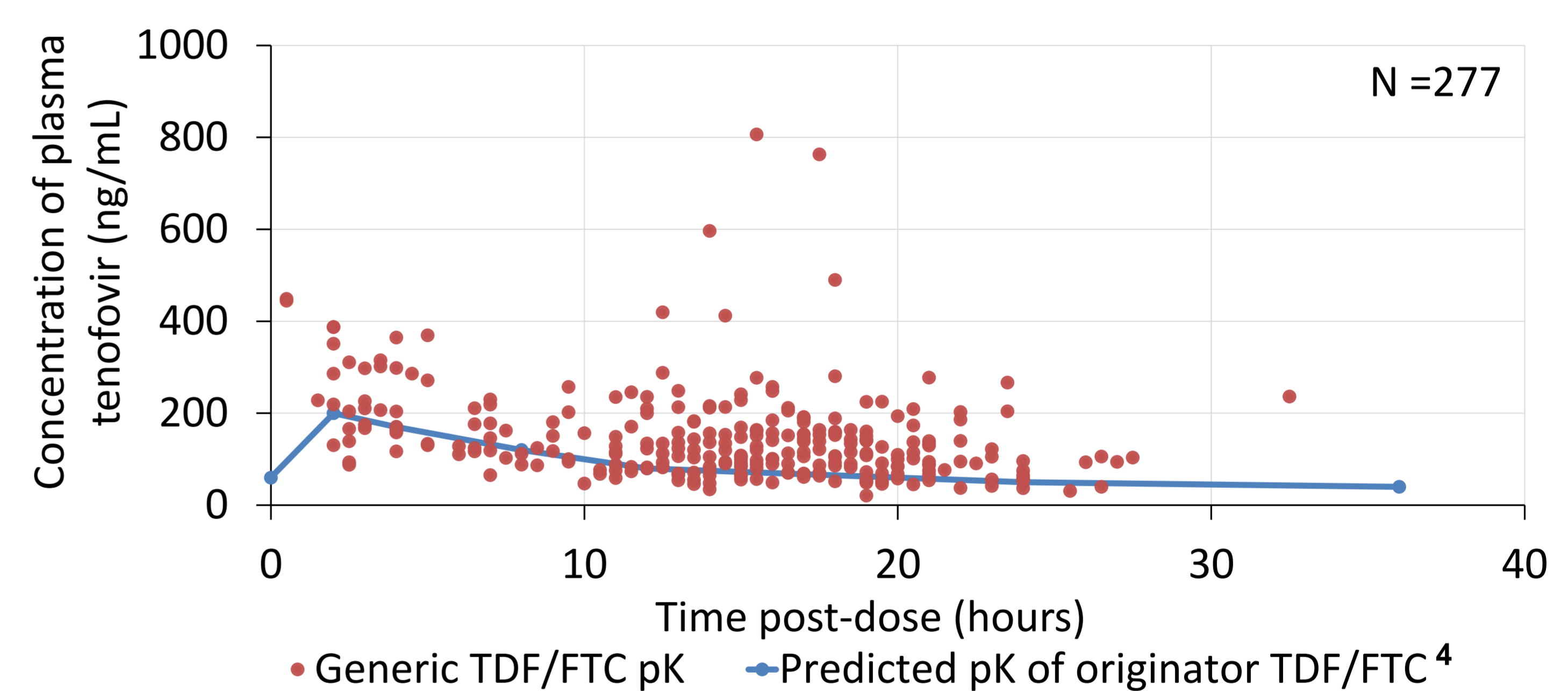


Figure 3: Time-dependent plasma FTC concentrations following consumption of oral PrEP

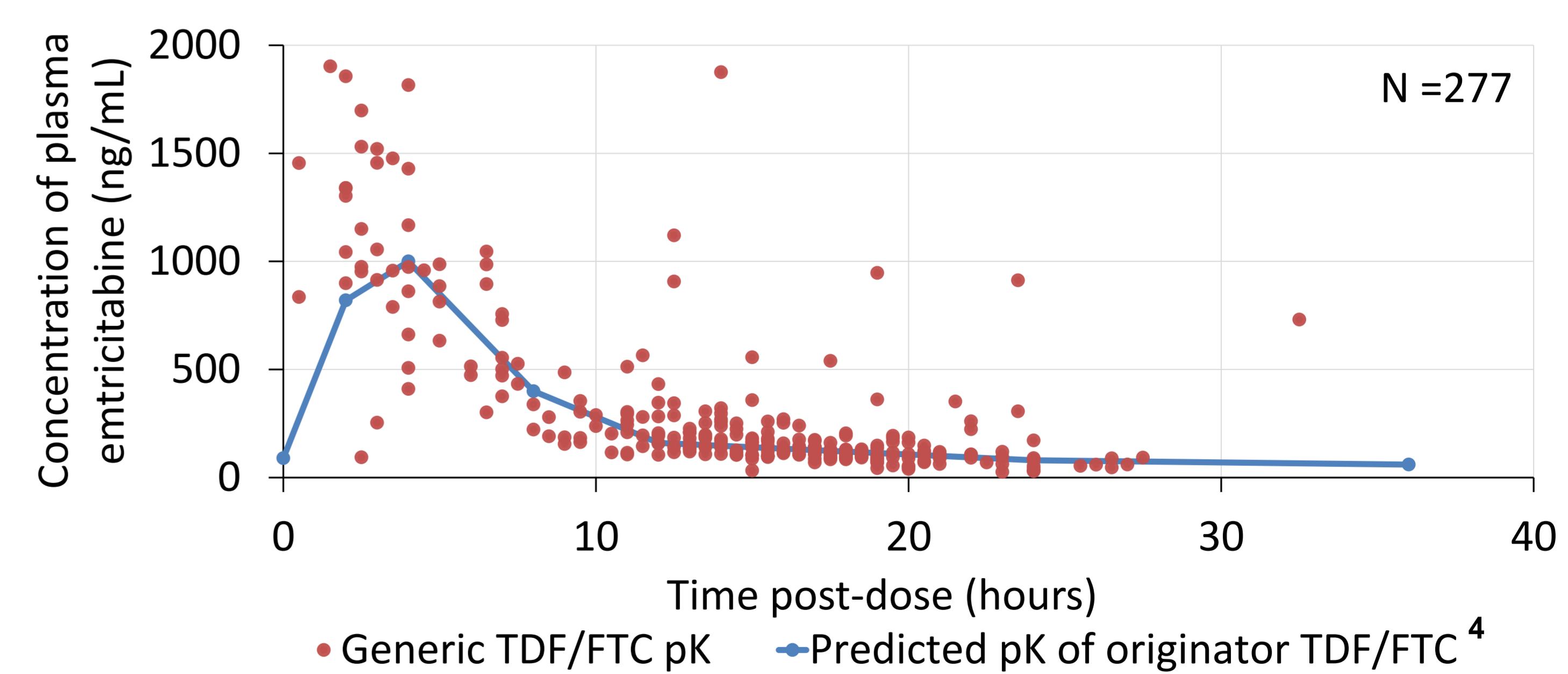


Figure 4: Versions of generic PrEP taken by patients



References: 1. Molina et al. On-Demand Preexposure Prophylaxis in Men at High Risk for HIV-1 Infection. N Engl J Med 2015; 373:2237-2246. 2. McCormack et al. Pre-exposure prophylaxis to prevent the acquisition of HIV-1 infection (PROUD): effectiveness results from the pilot phase of a pragmatic open-label randomised trial. The Lancet, Volume 387, Issue 10013, 53 – 60. 3. Volk et al. No New HIV Infections With Increasing Use of HIV Preexposure Prophylaxis in a Clinical Practice Setting. Clin Infect Dis (2015) 61 (10): 1601-1603. 4. Dickinson et al. Plasma Tenofovir, Emtricitabine, and Rilpivirine and Intracellular Tenofovir Diphosphate and Emtricitabine Triphosphate Pharmacokinetics following Drug Intake Cessation Antimicrob Agents Chemother 59(10): 2015 Oct.