

Pre-exposure prophylaxis (PrEP) prescriptions among individuals at high risk for HIV in the United States, 2012-2018

Mo Zhou¹; Yan Song¹; Emily Gao¹; Yohance Whiteside²; Emma Billmyer¹; James Signorovitch¹

¹Analysis Group, Inc., Boston, MA, USA; ²Merck & Co., Inc., Kenilworth, NJ, USA

Introduction

- Pre-exposure prophylaxis (PrEP) for HIV infection can reduce the risk of contracting HIV up to 99% via sexual contact and approximately 74% via intravenous drug injection¹
- Despite the known benefits associated with PrEP, the CDC reports that 4 out of 5 individuals who could benefit from PrEP therapy are still not taking it^{2,3}
- There is a need to gain insights on the characteristics of high-risk individuals who do use PrEP vs those who do not use PrEP in the real world
- Such insight will help healthcare stakeholders identify the populations with unmet need in PrEP service and, ultimately, target efforts to reduce new HIV infections

Objectives

- To describe the demographic and behavioral characteristics of high-risk individuals who do vs do not use emtricitabine/tenofovir disoproxil fumarate (FTC/TDF) as PrEP
- To describe the overall trends in the uptake of FTC/TDF as PrEP in 2012-2018 in the US

Methods

Data source

- This study first conducted interviews with providers of different specialties who treat individuals at high risk for HIV as well as a medical coder to understand the use of ICD codes for identifying and documenting individuals who are at high risk for HIV. The results of these interviews informed the identification of individuals at high risk for HIV in the subsequent database analyses
- A retrospective observational study was conducted using two IBM MarketScan[®] claims databases, including Commercial Claims and Encounters (CCA) Database (2011-2019) and Multi-State Medicaid Database (2011-2018)

Sample selection

- The retrospective database analyses identified individuals who were at high risk for HIV using ICD codes indicating high-risk sexual behavior or rectal/repeated bacterial STI (syphilis, chlamydia, gonorrhea) based on the interviews with healthcare providers
 - The index date was defined as the earliest of:
 - The first claim with a high-risk sexual behavior code
 - The first claim with a rectal bacterial STI code, or
 - The claim that identifies a second nonrectal bacterial STI within 12 months (ie, a second type of STI or a reinfection of the same STI)
- Individuals were excluded if they had acute or established HIV infection prior to or within 30 days after the index date, were prescribed antiretroviral medication for HIV treatment (including FTC/TDF) prior to or within 30 days after FTC/TDF PrEP initiation/index date, or had evidence of hepatitis B or abnormal renal function 12 months prior to or within 30 days after the index date
- Individuals were required to be at least 15 years of age on the index date

Statistical analyses

- Individuals were considered PrEP users if they had at least one FTC/TDF PrEP prescription within 12 months of the index date
- The uptake of FTC/TDF PrEP was reported as the proportion of individuals at high risk of HIV prescribed FTC/TDF PrEP for each calendar year and stratified by gender and age groups
- Demographic and behavioral characteristics were described and compared for individuals who used vs did not use FTC/TDF PrEP using the chi-square test for categorical variables and *t* test for continuous variables

Table 1. Characteristics of people at high risk for HIV who do vs do not use FTC/TDF PrEP during the follow-up period^a

Characteristic	Commercially insured high-risk individuals			Medicaid-insured high-risk individuals		
	FTC/TDF PrEP within 12 months of index N = 4,257	No FTC/TDF PrEP within 12 months after index N = 130,825	P value	FTC/TDF PrEP within 12 months of index N = 231	No FTC/TDF PrEP within 12 months after index N = 102,752	P value
Age at index date, n (%)						
Mean ± SD	36.7 ± 11.1	29.6 ± 12.1	<0.01	31.8 ± 11.6	25.2 ± 11.0	<0.01
Age groups			<0.01			<0.01
16-17 y	7 (0.2%)	8,530 (6.5%)		8 (3.5%)	24,913 (24.2%)	
18-24 y	657 (15.4%)	54,585 (41.7%)		67 (29.0%)	29,282 (28.5%)	
25-34 y	1,388 (32.6%)	27,740 (21.2%)		74 (32.0%)	22,008 (21.4%)	
35-44 y	1,088 (25.6%)	19,364 (14.8%)		41 (17.7%)	10,677 (10.4%)	
45-54 y	790 (18.6%)	12,244 (9.4%)		25 (10.8%)	5,116 (5.0%)	
55-64 y	309 (7.3%)	5,710 (4.4%)		14 (6.1%)	2,373 (2.3%)	
≥65 y	18 (0.4%)	743 (0.6%)		0 (0.0%)	381 (0.4%)	
Sex, n (%)			<0.01			<0.01
Male	4,197 (98.6%)	48,489 (37.1%)		178 (77.1%)	22,617 (22.0%)	
Female	60 (1.4%)	82,336 (62.9%)		53 (22.9%)	80,135 (78.0%)	
Race/ethnicity, n (%)						<0.01
White	-	-	-	99 (42.9%)	40,661 (39.6%)	
Black	-	-	-	93 (40.3%)	50,461 (49.1%)	
Hispanic	-	-	-	4 (1.7%)	3,793 (3.7%)	
Other	-	-	-	35 (15.2%)	7,837 (7.6%)	
Region, n (%)			<0.01			
Northeast	1,044 (24.5%)	27,839 (21.3%)		-	-	-
Midwest	648 (15.2%)	24,846 (19.0%)		-	-	-
South	1,636 (38.4%)	62,039 (47.4%)		-	-	-
West	925 (21.7%)	15,485 (11.8%)		-	-	-
Unknown	4 (0.1%)	616 (0.5%)		-	-	-
Health plan type,^b n (%)			<0.01			<0.01
Restrictive	650 (15.3%)	15,679 (12.0%)		175 (75.8%)	67,253 (65.5%)	
Broad	2,669 (62.7%)	83,734 (64.0%)		1 (0.4%)	1,859 (1.8%)	
Consumer-driven	832 (19.5%)	26,595 (20.3%)		0 (0.0%)	0 (0.0%)	
Fee-for-service	65 (1.5%)	4,067 (3.1%)		55 (23.8%)	33,639 (32.7%)	
Unknown	41 (1.0%)	750 (0.6%)		0 (0.0%)	1 (0.0%)	
High-risk sexual behaviors,^c n (%)	3,913 (91.9%)	122,390 (93.6%)	<0.01	215 (93.1%)	95,560 (93.0%)	0.97
Heterosexual	1,871 (44.0%)	59,328 (45.3%)	0.07	158 (68.4%)	51,189 (49.8%)	<0.01
Homosexual	1,984 (46.6%)	1,897 (1.5%)	<0.01	68 (29.4%)	642 (0.6%)	<0.01
Bisexual	166 (3.9%)	1,088 (0.8%)	<0.01	9 (3.9%)	1,126 (1.1%)	<0.01
Unspecified	671 (15.8%)	61,582 (47.1%)	<0.01	22 (9.5%)	44,434 (43.2%)	<0.01
Bacterial STI,^d n (%)	993 (23.3%)	14,636 (11.2%)	<0.01	50 (21.6%)	15,177 (14.8%)	<0.01
Modified Charlson Comorbidity Index,^e mean ± SD	0.2 ± 0.6	0.2 ± 0.5	0.10	0.5 ± 1.0	0.3 ± 0.7	<0.01

FTC/TDF, tenofovir disoproxil fumarate/emtricitabine; PrEP, pre-exposure prophylaxis; SD, standard deviation; STI, sexually transmitted infection.

^aThe follow-up period was defined as the 1-year period following the index date.

^bHealth plan type categories were defined as follows: restrictive: HMO and EPO; broad: PPO and POS; consumer-driven: HDHP and CDHP.

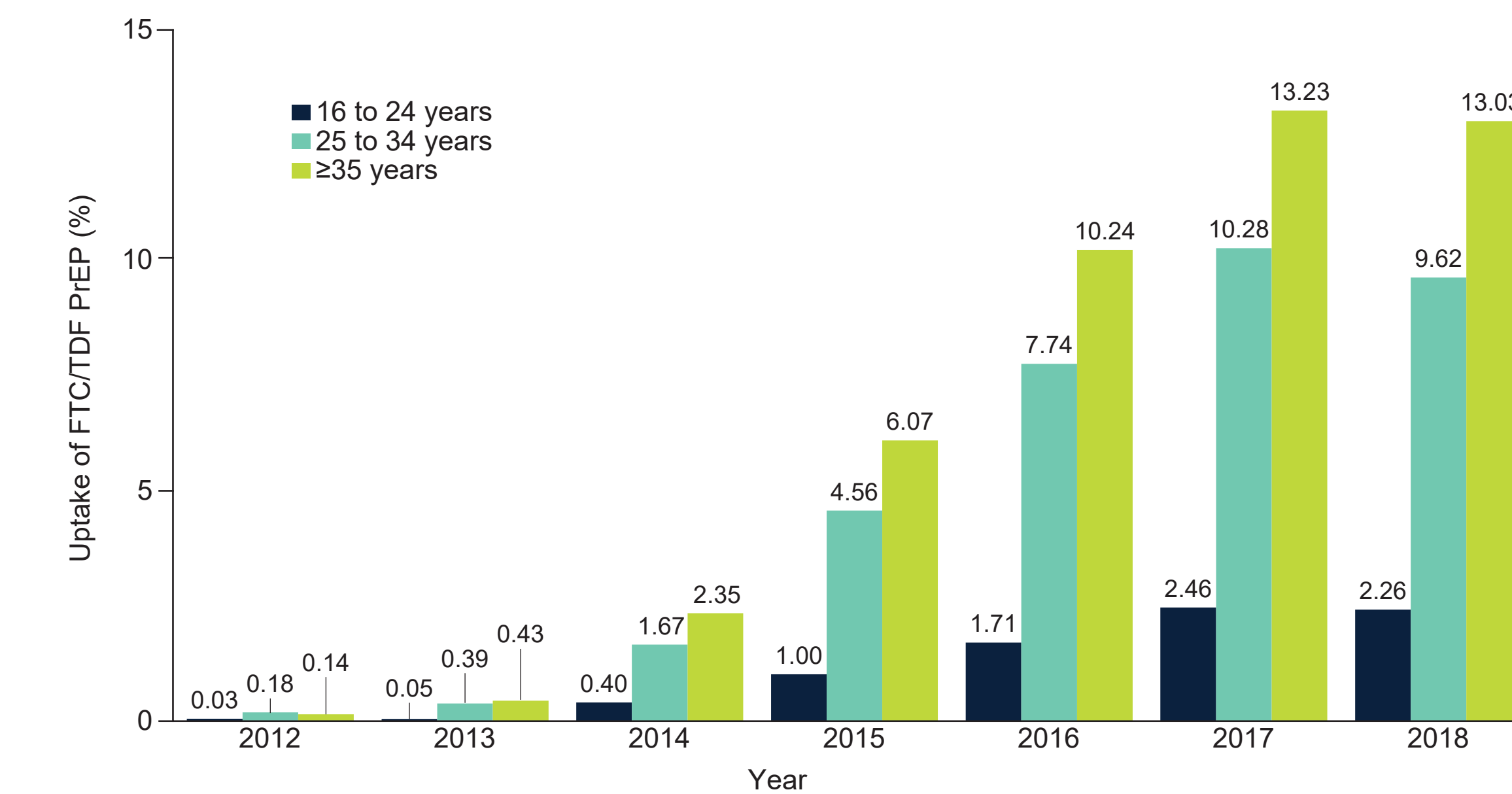
^cICD-10 codes for high-risk sexual behavior specify heterosexual, homosexual, and bisexual, while ICD-9 codes do not. ICD-10 codes took effect on October 1, 2015.

^dBacterial STIs included chlamydia, gonorrhea, and syphilis.

^eModified Charlson Comorbidity Index excluded AIDS/HIV.

Figure 1. Uptake of FTC/TDF PrEP among people at high risk for HIV by age and year

Commercially insured



Medicaid

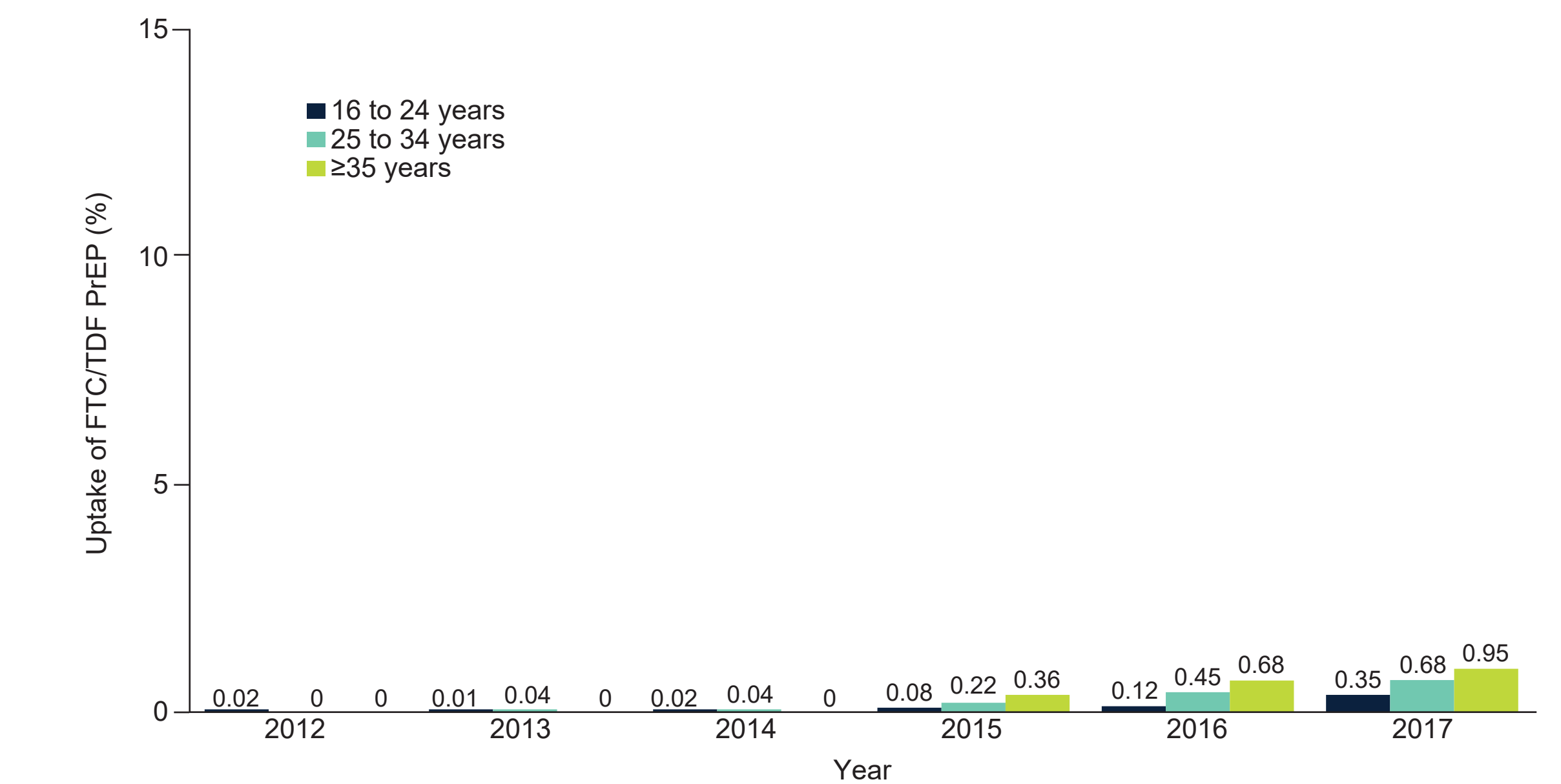
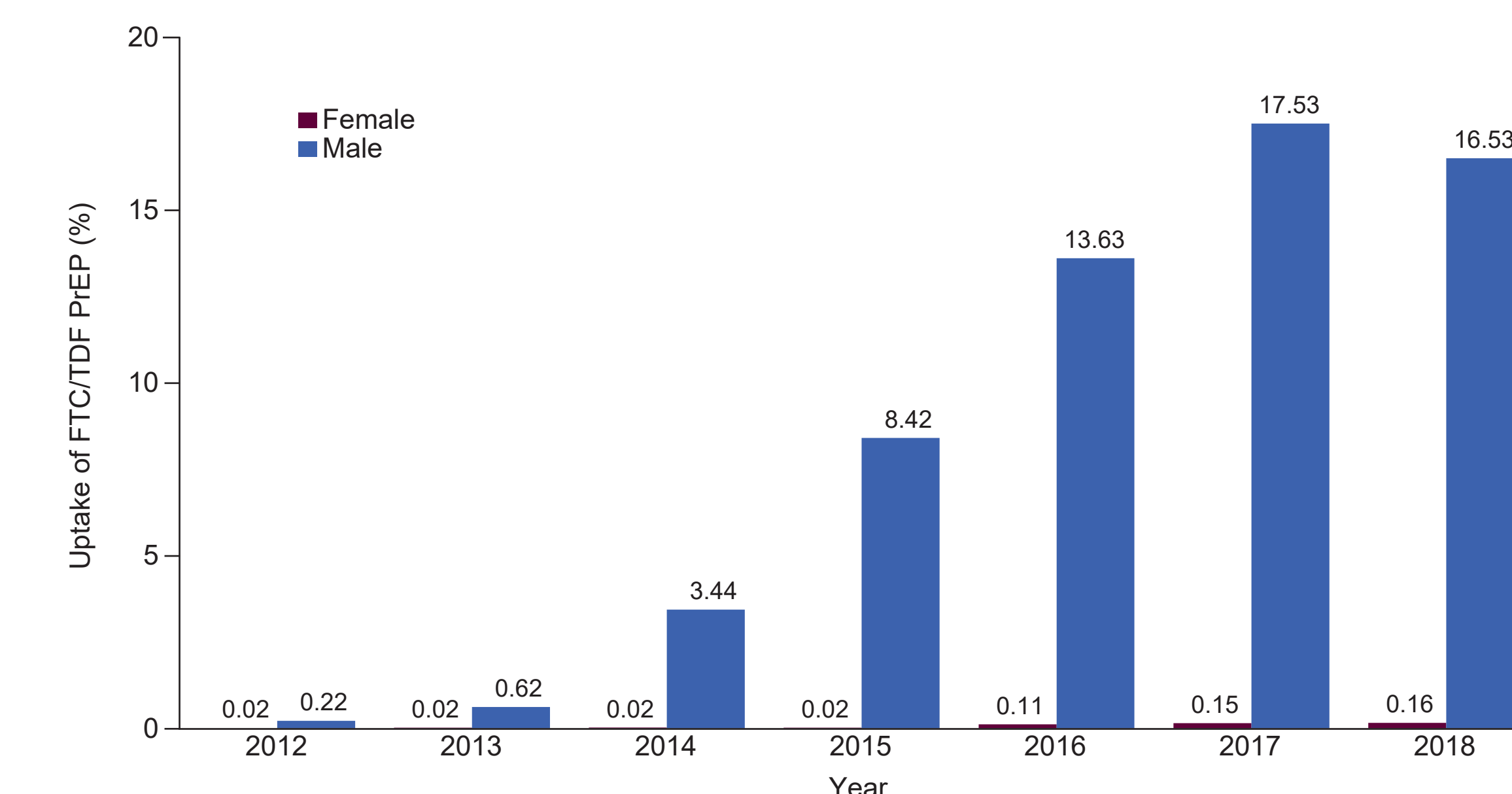
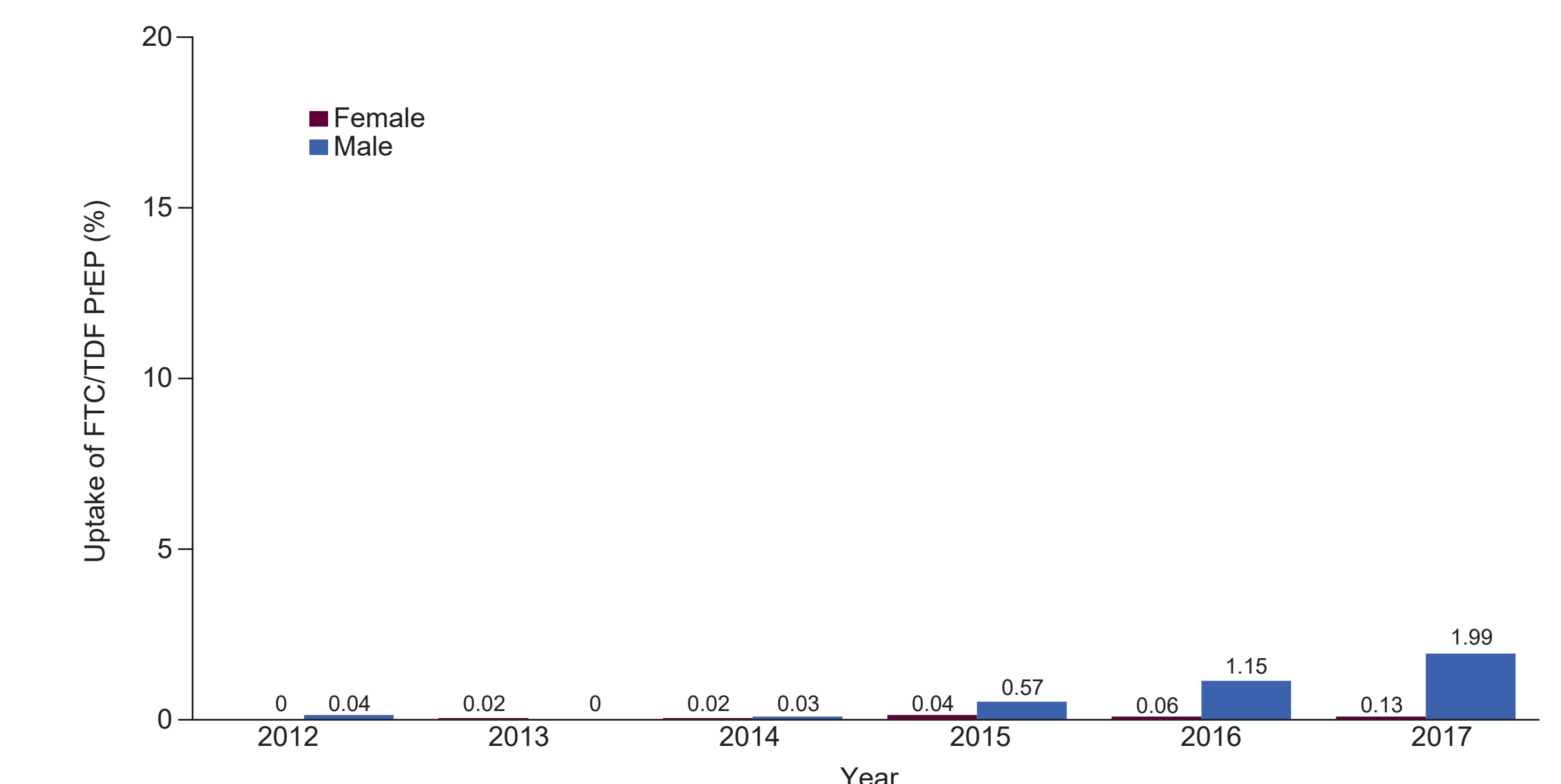


Figure 2. Uptake of FTC/TDF PrEP among people at high risk for HIV by sex and year

Commercially insured



Medicaid



Results

- FTC/TDF PrEP uptake increased from 0.09% to 7.30% among commercially insured individuals in 2012-2018 and from 0.01% to 0.53% among Medicaid insured individuals in 2012-2017
 - High-risk males had larger increases in PrEP uptake than high-risk females in both datasets
 - Individuals ≥35 years old had the largest increase in PrEP uptake, while those 16-24 years old had the smallest increase in both datasets
- The largest proportion of PrEP users across all years were ages 25-34 while the largest proportion of non-PrEP users were ages 18-24
- Compared with PrEP users, a larger proportion of PrEP nonusers were female and Black/African American (*P*<0.05)
- A larger proportion of PrEP users had a risk status of homosexual or bisexual behavior than non-PrEP users (*P*<0.05)
- PrEP users also had higher Charlson Comorbidity Index scores than nonusers among individuals with Medicaid and were less likely to have fee-for-service insurance plans overall (*P*<0.05)

References

- Centers for Disease Control and Prevention. Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2017 Update: A Clinical Practice Guideline. <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf>. Accessed February 18, 2021.
- Sullivan PS, et al. *Curr HIV/AIDS Rep*. 2019;16(4):259-269.
- Centers for Disease Control and Prevention. CDC's HIV Work Saves Lives and Money. <https://www.cdc.gov/nchhstpl/budget/infographics/hiv.html>. Accessed February 18, 2021.

Limitations

- This study uses ICD codes to identify high-risk individuals. ICD codes may be miscoded or missing from medical claims and may not be exhaustive to map directly with the CDC definition of high risk for HIV infection
- Claims for a filled prescription do not guarantee medication consumption by the subject or account for any changes in prescription. Individuals who access PrEP through means other than the insurance coverage would not be captured in the claims data
- The study sample is limited to commercially and Medicaid-insured individuals. The results may not be generalizable to the entire high-risk population in the US
- The current study does not account for change in the therapeutic landscape of PrEP use, as FTC/TDF became generic in September 2020 and new drugs such as emtricitabine/tenofovir alafenamide (FTC/TAF) entered the market; very minimal FTC/TAF claims were observed in the data cut for this study

Conclusions

- Despite an increase in FTC/TDF PrEP initiations, the uptake was low among high-risk individuals, especially among young adults, women, individuals who are heterosexual, and those who are Black/African American. Low initiation rates in these groups may illustrate that FTC/TDF PrEP is not reaching all the individuals at high risk for HIV infection

Downloaded copies of this presentation are for personal use only and may not be reproduced without permission of the authors.

<https://bit.ly/3fXyPDO>