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Impact of the Early COVID-19 Pandemic on the Number of HIV Pre-Exposure Prophylaxis (PrEP) Uses and the Proportion of PrEP users receiving STI Testing Services

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Abstract

Background: With potential impact of the COVID-19 pandemic on HIV PrEP care management, we assessed the number of PrEP users and STI-testing-eligible PrEP users, STI testing rates and prevalence between pre-pandemic (01/01/2018–03/31/2020) and early-pandemic (04/01/2020–09/30/2020) periods.

Methods: In this retrospective cohort study, a PrEP user for a given quarter is defined as either a previous PrEP user or a PrEP initiator who has at least one day coverage of TDF/FTC in the given quarter. The STI-testing-eligible PrEP users for a given quarter were defined as those persons whose *runout* date (previous dispense date + days of TDF/FTC supply) was in the given quarter.

Results: The quarterly number of PrEP users increased from the 1st quarter of 2018 to the 1st quarter of 2020 and then decreased in the 2nd and 3rd quarter of 2020. Among STI-testing-eligible PrEP users who had ≤14 days between runout and next refill date, gonorrhea and chlamydia screening testing rates were 95.1% for pre-pandemic and 93.4% for early-pandemic (p=0.1011). Among all STI-testing-eligible PrEP users who were tested for gonorrhea and chlamydia, gonorrhea prevalence was 6.7% for pre-pandemic and 5.7% for early-pandemic (p=0.3096) and chlamydia prevalence was 7.0% for pre-pandemic and 5.8% for early-pandemic (p=0.2158).

Conclusions: Although the early COVID-19 pandemic resulted in lower numbers of PrEP users and PrEP initiators, individuals who remained continuous users of PrEP maintained extremely high rates of bacterial STI screening. With high STI prevalence among PrEP users, assessments of PrEP care management are continuously needed.

Summary:

Quarterly numbers of PrEP users and PrEP initiators were decreased, but STI testing and STI prevalence among PrEP users were similar during early-pandemic, compared to pre-pandemic.

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Keywords

STI; HIV PrEP; gonorrhea and chlamydia testing; STI prevalence; telehealth

HIV Pre-Exposure Prophylaxis (PrEP) is an extremely effective tool in the prevention of HIV acquisition among high-risk individuals and is considered as one of the key strategies in *Ending the HIV Epidemic in the United States* (EHE).(1, 2) When implemented as recommended, PrEP clinical management requires regular engagement by PrEP users with the health care delivery system through laboratory testing for, among other things, bacterial sexually-transmitted infections (STI) around the time of PrEP prescription refill – usually every 90 days.(3, 4)

In March 2020, the World Health Organization declared the onset of a pandemic caused by the SARS-CoV-2 virus or COVID-19. In response to this public health threat, governments implemented public health measures aimed at mitigating the effect of the COVID-19 pandemic, including stay-at-home orders.(5) Utilization of in-person health care services declined beginning in March and April, 2020, relative to 2019 and January / February, 2020. (6, 7) Health care delivery systems also implemented and expanded practices to increase virtual care, telehealth, or telemedicine to provide medical services and/or increase their capacity to care for COVID-19 patients, often by shifting resources from other health care services.(8, 9)

Despite this continued availability of services, the COVID-19 pandemic and related response measures may have impacted the decision of individuals to either initiate or continually receive PrEP, including laboratory testing services at the time of refill of PrEP prescription, during this period. A recent study showed a 22.0% reduction (95% CI: 19.1%−24.8%) in PrEP prescriptions after the emergency declaration.(10) Another study also stated that number of PrEP encounters decreased although patients were still able to access PrEP clinical services during the COVID-19 pandemic.(11) From survey studies, the reasons for reduction of PrEP prescriptions might be due to the fact that many patients stopped taking their PrEP entirely, started selectively skipping doses, and/or changed their sexual behaviors, such as having no new sex partners, reducing sexual activity, or reducing anal sex with new or unknown sex partners.(12) (13, 14) Two previous studies also have shown the COVID-19 pandemic impact on chlamydia and gonorrhea testing: weekly test volume declined, but test positivity increased. (15, 16) Using an interrupted time-series analysis, a recent study also showed that PrEP monthly prescriptions were not much different 2 year before and 1 year after the COVID19 outbreak.(17) However, no study has been published examining chlamydia and gonorrhea testing among PrEP users before and after the start of the COVID-19 pandemic in the United States.

The goal of this work was to assess the potential impact of the COVID-19 pandemic on HIV PrEP care management within a clinical setting. Specifically, we aimed to describe changes in the number of individuals using PrEP before and after the onset of the COVID-19 pandemic and assess the proportion of PrEP users receiving recommended screening for gonorrhea and chlamydia and prevalence of gonorrhea and chlamydia around the time of PrEP prescription refill.

Methods

We conducted this retrospective cohort study using data from Kaiser Permanente Northwest (KPNW), an integrated health care delivery system serving over 600,000 members located in Northwest Oregon and Southwest Washington. As described previously, KPNW maintains a centralized approach to PrEP care management, whereby all prescriptions and laboratory orders related to PrEP are managed by specialized providers in one clinical department.(18) Following the U.S. Preventive Services Task Force (USPSTF) guide on PrEP management, the centralized clinic has telehealth as an option to serve PrEP users, has standing laboratory orders to allow the PrEP users to get PrEP-related tests every three months, and has standing prescription orders for refills. The PrEP users have the option to go to any KPNW laboratory facility in any medical office building across the service area for laboratory testing. The pharmacy is required to dispense PrEP medication only after the laboratory testing has been done. As an option for routine PrEP management, telehealth was already available prior to the COVID19 pandemic in the centralized PrEP clinic.

Like the previous KPNW study, we electronically abstracted data for this study from the KPNW electronic health record (EHR) system, including medical utilization, relevant diagnostic codes, laboratory testing and results, and internal prescription drug fill data.(18) Our retrospective cohort population included adult (aged ≥18 years) members of KPNW receiving PrEP prior to January 1, 2018, and adult members newly initiating PrEP from January 1, 2018 through September 30, 2020. PrEP initiation has been defined previously. (18) In general, we defined PrEP initiation as having received at least one, ≥30-day supply of Tenofovir/emtricitabine (TDF/FTC) and no evidence of prior HIV infection (defined as negative HIV laboratory results and/or an absence of HIV-related diagnostic diagnoses recorded within the entire history of the member's EHR). We defined the date of the first pharmacy fill as the date of PrEP initiation. A PrEP user for a given quarter (three calendar months) was defined as the person who was either a previous PrEP user (who was initiated with PrEP prescription before the given quarter) or a PrEP initiator and who had at least one day coverage of TDF/FTC in the given quarter. To assess STI (gonorrhea and chlamydia) testing at the time of PrEP prescription refill for a given quarter, the PrEP users were limited to those persons whose PrEP medication *runout* date (previous dispense date + days of TDF/FTC supply) was in the given quarter. We called those PrEP users who had a runout date in the given quarter as "STI-testing-eligible PrEP users" in that quarter. Of STI-testing-eligible PrEP users in the given quarter, we further classified them into two subgroups, according to their next prescription refill status and the date. We defined *continuous users* as those with a gap of ≤14 days between the runout date and the next refill date; and *discontinuers* as those with a gap of >14 days or those without evidence of a subsequent PrEP refill. Of STI-testing-eligible PrEP users in the given quarter, we evaluated laboratory records to determine whether individuals had evidence of a combined gonorrhea and chlamydia screening test performed within +/−45 days from the *runout* date in the given quarter (if there were >1 runout dates in the given quarter, the last one was selected). Although we defined our study period as January 1, 2018 through September 30, 2020, we included an additional two-months, through November 30, 2020, to appropriately further classify STI-eligible PrEP users into 2 subgroups (*continuous users* and *discontinuers*) and

apply laboratory screening metrics at the end of the study period. Where we compared time periods, we defined the *pre-pandemic* period as January 1, 2018 through March 31, 2020 (a total of 9 quarters) and the *early-pandemic* period as April 1, 2020 through September 30, 2020 (a total of 2 quarters), although the COVID-19 pandemic started at the middle of March, 2020 in the United States.

We calculated the proportion of STI-testing-eligible PrEP users who had chlamydia/gonorrhea testing for a given quarter by dividing the number of individuals having chlamydia/gonorrhea testing, regardless of the number of tests for each person, within each of the respective 90-day observation windows by the total number of STI-testing-eligible PrEP users in each subpopulation. We calculated the prevalence of chlamydia and gonorrhea as the number of persons with positive tests, regardless of the number of positive tests for each person, for the respective infection divided by the number of persons with combined chlamydia/gonorrhea testing during each of the respective 90-day observation windows for a given quarter. In this study, we did not distinguish the chlamydia and gonorrhea tests by anatomical site, although some PrEP users might have multiple specimens from multiple anatomical sites for each encounter or multiple specimens from multiple encounters during the given 90-day period.

Of PrEP users for a given quarter, we also assessed the number of medical visits or encounters to the centralized PrEP management clinic. The number of those encounters were based on the date of the PrEP management visit, which might be different from the prescription date or specimen collection date. The type of encounter was classified as either in-clinic (face-to-face) or virtual (telehealth).

We compared the quarterly number of PrEP initiators between pre-pandemic and early-pandemic by a t-test and estimated proportions between pre-pandemic and early-pandemic by the χ^2 test. We compiled and analyzed all data for this study using SAS v. 9.4 M4 (Maintenance Pack #4) [SAS Institute, Inc.; Cary, NC]. Our research was reviewed and approved by the KPNW Institutional Review Board (FWA# 00002344).

Results

During the study period January 1, 2018 through September 30, 2020, 625 KPNW members initiated HIV PrEP: 95.7% were male; 68.2% and 12.8% were non-Hispanic White and Hispanic; 38.7% and 26.9% were aged 25–34 years and 35–44 years; and 85.6% were insured with commercial plans (Table 1). The quarterly number of PrEP initiators after COVID-19 pandemic was smaller than that prior to COVID-19 pandemic (with mean of 61.6 (standard error (SE)=3.9) during pre-pandemic vs. 35.5 (SE=1.5) during early-pandemic, t-value=6.21 and p=0.0218).

During the study period, the quarterly number of PrEP initiators varied broadly; and the quarterly number of PrEP initiators during the early COVID-19 pandemic was lower than that prior to COVID-19 pandemic (Figure 1). The quarterly number of all PrEP users increased from the 1st quarter of 2018 to the 1st quarter of 2020 and then decreased in the 2nd and 3rd quarters of 2020 (Figure 2).

PrEP users and STI-testing-eligible PrEP users also changed during the study period and the proportion of PrEP users who were STI-testing-eligible PrEP users ranged from 81.3% to 91.1% during the pre-pandemic period and 70.5%−81.4% during the early-pandemic period (Table 2). The proportion of PrEP users who were STI-testing-eligible PrEP users were 92.6% during the pre-pandemic period and 90.2% during the early-pandemic period (χ^2=6.2978 and p=0.0121). The proportion of STI-testing-eligible PrEP users who were continuous PrEP users was 73.7% during the pre-pandemic period, compared to 61.9% during the early-pandemic period (χ2=47.8768 and p<.0001).

Among PrEP users who were eligible for STI testing, gonorrhea and chlamydia screening testing near the date of running out of medication was 85.9% for pre-pandemic period and 75.3% for early-pandemic period (χ2=58.7502 and p<0.0001) (Table 2). Among all PrEP users who were eligible for STI testing and who were tested for gonorrhea and chlamydia, the prevalence of gonorrhea was 6.7% for pre-pandemic period and 5.7% for early-pandemic period (χ2=1.0324 and p=0.3096) and the prevalence of chlamydia was 7.0% for pre-pandemic period and 5.8% for early-pandemic period (χ2=1.5321 and p=0.2158).

Among the subgroup who were eligible for STI testing and who were defined as *continuous* PrEP users, gonorrhea and chlamydia screening testing around the runout date was 95.1% for pre-pandemic period and 93.4% for early-pandemic period (χ2=2.6881 and p=0.1011) (Table 2).

Among all virtual or face-to-face medical visits during the study period, virtual visits were the main type of PrEP encounters for PrEP users (96.6%) and ranged from 93.4% to 99.6% (Table 3). The proportion of PrEP-related encounters that were virtual or telehealth visits was 96.3% for pre-pandemic period and 98.8% for early-pandemic period (χ2=5.7403 and p=0.0166).

Discussion

The onset of the COVID-19 pandemic has been associated with significant impacts on the healthcare delivery system, STI testing, PrEP utilization, and people's sexual behaviors., (8, 9,, 14)(11, 15) Although we, too, observed a lower number of individuals initiating PrEP during the initial stages of the COVID-19 pandemic, our study might be the first study found extremely high rates (>93%) of routine chlamydia and gonorrhea testing among continuous PrEP users. The high chlamydia and gonorrhea testing rates in this study may be largely due to the nature of the clinical setting (i.e., an integrated health care delivery system) and mandated laboratory testing prior to PrEP medication. Our study highlights the importance of a centralized clinic and the use of telehealth for PrEP care management.

In our study, we observed an approximate 42.7% decrease in the quarterly number of PrEP initiators between the pre-pandemic and early pandemic periods (from 61.6 to 35.5). This decrease is not surprising, as the PrEP initiation cascade typically begins upon risk screening and/or a request for PrEP in the primary care setting, leading to a referral to the centralized care management clinic. The widespread closure of health care services during

the initial phase of the pandemic led to a dramatic decrease in primary care visits, leading to fewer referrals for PrEP initiation. Our results indicated that the COVID-19 pandemic also had a negative impact on the number of individuals continuing PrEP use. Among STI-testing-eligible PrEP users, the proportion of them who were classified as continuous users decreased to 57.6% in the 2nd quarter (April-June) and 67.4% in the 3rd quarter (July-September) of 2020, compared to the quarterly rates (70.9%−79.1%) prior to the COVID-19 pandemic. These changes show that assessments of the number of PrEP initiators and the number of continuous PrEP users are continuously needed.

Encouragingly, however, we found extremely high rates of routine STI testing among continuous PrEP users, even during the initial stages of the pandemic, in contrast to other reports.(10, 11) The main reason for this might be due to having a centralized PrEP care management program, including telehealth, that had been used in this system before the COVID-19 pandemic began in the United States. Other studies have described adaptions made by providers during the initial stages of the pandemic, such as allowing PrEP refills without requiring the usual 3-month follow-up testing, offering home-collected laboratory samples for PrEP users, having telephone or web-based visits, and prescribing a 90-day supply of PrEP medication (rather than a 30-day supply with two refills) or an alternative prescription strategy, such as an on-demand option (2–1–1). (4, 11, 19) The on-demand option (2–1–1) is the dosing schedule of 2 pills in the 2–24 hours before sex, 1 pill 24 hours after the initial two-pill dose, and 1 pill 48 hours after the initial two-pill dose, and this option is designed and tested primarily to meet the needs of men who had infrequent sex and thus for whom daily dosing might not be necessary. This option is not approved by the FDA and is not recommended by CDC. Many of these adaptions had already been incorporated as standard practice within the KPNW HIV PrEP care management clinic, including having standing orders for laboratory testing and prescription refills, providing a 90-day supply of medication, and the use of telehealth visits. Consequently, fewer adaptations were required in order to maintain continuity in HIV PrEP care within this health care system. For instance, our data have shown that the number of medical visits or encounters for all PrEP users combined in a given quarter was smaller than the number of STI-testing-eligible PrEP users who had gonorrhea and chlamydia testing. This likely indicates the impact of standing laboratory orders, allowing PrEP users to obtain necessary laboratory testing at the appropriate time, in some cases without clinician visits.

Among those tested, we found high positive testing rates of chlamydia and gonorrhea. This confirms that patients taking PrEP remain at risk of acquiring an STI and further supports the importance of follow-up HIV/STI testing during HIV PrEP management. The high chlamydia and gonorrhea prevalence among persons tested during the COVID-19 pandemic period also indicates that, regardless of whether the PrEP users might have changed their sexual behaviors during the COVID-19 pandemic, compared to the pre-pandemic period, PrEP users remained at risk from chlamydia and gonorrhea infections and timely testing was needed during the COVID-19 pandemic.

There were several limitations to this study. First, KPNW membership may provide limited generalizability to the US population. The centralized approach to PrEP care management within this integrated health care delivery system, especially with the prior adoption

of telemedicine, may also result in differences in chlamydia and gonorrhea testing and prevalence compared to other commercial and Medicaid clinical settings. Second, without a survey of PrEP users, we could not identify the reasons that persons discontinuously used PrEP or switched to different PrEP options, such as the on-demand option. Third, without information on sexual behavior in this study, we were not able to assess the association between high STI prevalence and changes in sexual behavior during the PrEP management period, especially during the COVID-19 pandemic period. Fourth, because the quarterly numbers of positive gonorrhea or chlamydia testing results for STI-testing eligible PrEP users were discontinuous users, the estimated positivity may be not reliable. Therefore, the estimated positivity was not reported in this study. Fifth, our early-pandemic period is only 2 quarters which is a very brief time for the COVID-19 pandemic period, compared to the overall length of the pandemic is now at 2 ½ years. Sixth, testing for syphilis, serum creatinine, and hepatitis B virus during the study period were not able to be assessed, although they are also recommended routine medical services for HIV PrEP. Finally, the decreased number of PrEP users during the early COVID19 pandemic might be due to the change in the numbers of members in the KPNW from 2019 to 2020. Although we did not assess the recent change in the number of members in the KPNW, the overall number of members was 12.2, 12.4, 12.5, and 12.6 million in 2018, 2019, 2020, and 2021, respectively, in KP.(20)

Our study suggests that the early stages of the COVID-19 pandemic resulted in lower numbers of individuals initiating PrEP and changes in PrEP use. Previous studies have shown that the volume of chlamydia and gonorrhea testing declined broadly in early 2020 as COVID-19-related health care disruptions took effect.(15, 16, 21) The positivity of tests conducted, however, increased in previous studies, suggesting that a shift to diagnostic testing may have occurred. Although risk assessment is challenging in a telemedicine environment, patients may benefit if clinicians proactively engage with patients who are diagnosed with a bacterial STI and thus may meet criteria for PrEP.(4, 22) With updated guidelines on HIV PrEP management, such as cabotegravir (CAB) injections as PrEP for sexually active adults and emtricitabine with tenofovir alafenamide (F/TAF) as additional oral PrEP option for sexually active men and transgender women, or the implementation of rapid HIV laboratory testing for patients who are starting PrEP on the same day, health care providers will have more options prescribing HIV PrEP medicines and increasing PrEP use by people who could benefit from it.(4) Although PrEP users who remained continuous users of PrEP maintained extremely high rates of bacterial STI screening, the updated guidelines on CAB injection, given every two months, may impact the current STI testing schedule. Therefore, future assessment of STI testing among PrEP users might need to be modified based on updated PrEP management guidelines.

Disclaimer:

The findings and conclusions in this study are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

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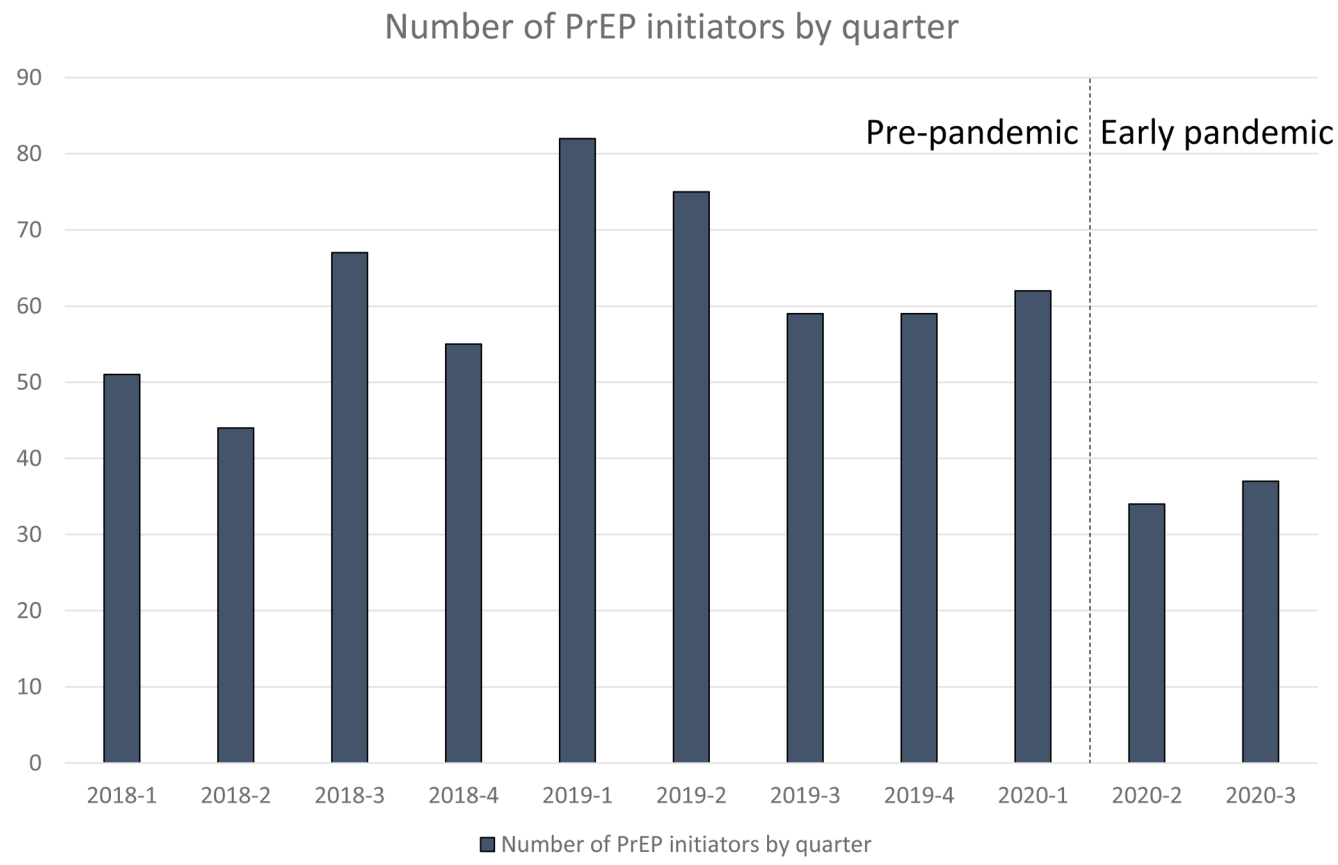

Figure 1:
Quarterly number of PrEP Initiators, January 1, 2018 through September 30, 2020.

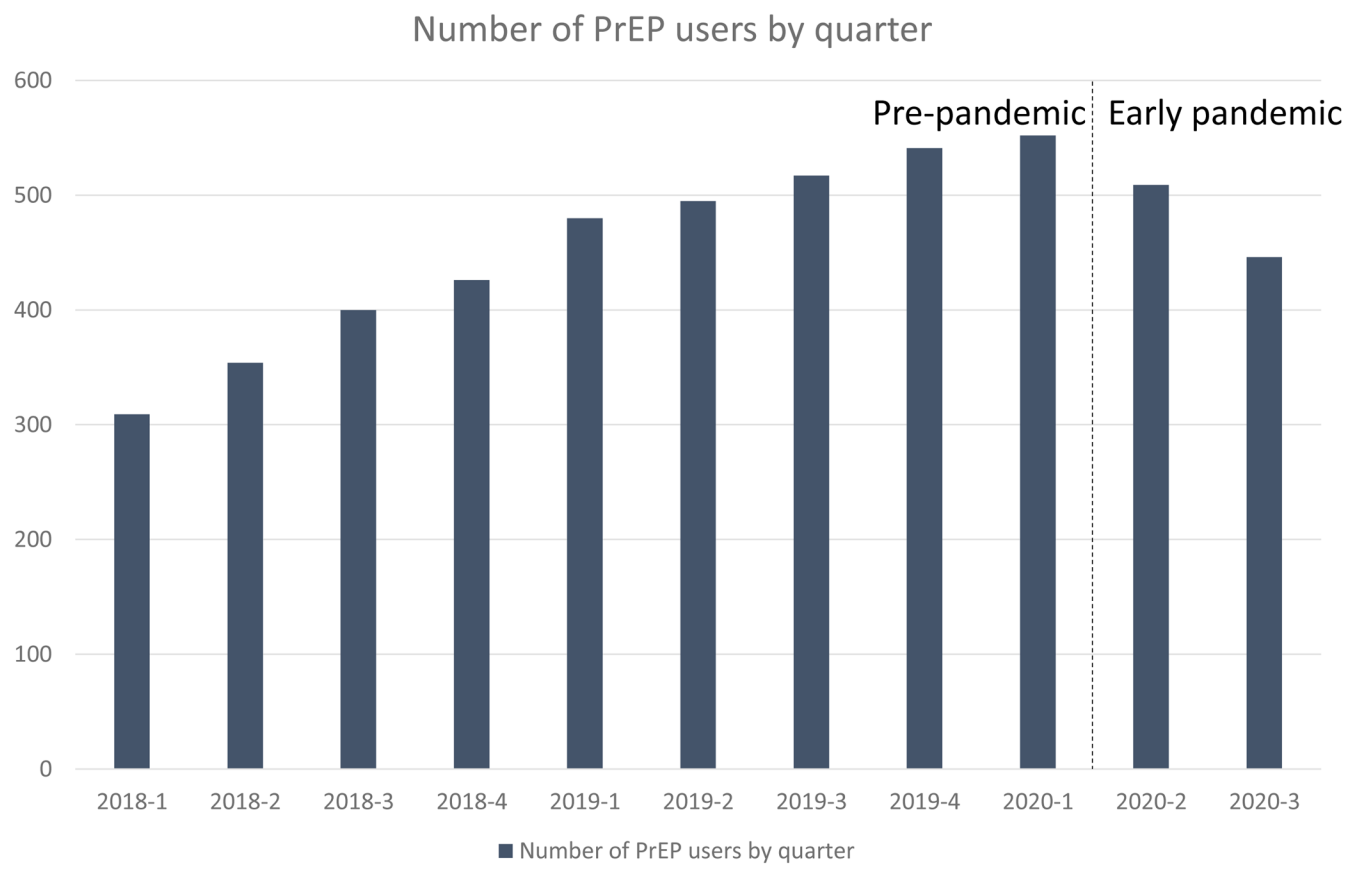

Figure 2:
Quarterly number of PrEP users, January 1, 2018 through September 30, 2020.

Table 1.

The number of PrEP initiators overall and distribution by demographic characteristics during pre-COVID-19 and early-COVID-19 periods, January 2018–September 2020

	Total	Pre-COVID-19‡	Early-COVID-19	Statistic
	N (%)	N (%)	N (%)	
Overall	625	554	71	
Average quarterly number of PrEP initiators (mean)	56.8	61.6	35.5	t-value=6.21 p=0.0218
Sex				
Male	598 (95.7)	531 (95.8)	67 (94.4)	$\chi^2 = 0.3345$
Female/Unknown	27 (4.3)	23 (4.2)	4 (5.6)	p=0.5630
Race/ethnicity				
Hispanic, any	80 (12.8)	71 (12.8)	9 (12.7)	
NH White	426 (68.2)	384 (69.3)	42 (59.2)	$\chi^2 = 4.4599$
Others†	119 (19.1)	99 (17.9)	20 (28.1)	p=0.1075
Age in years				
18–24	78 (12.5)	70 (12.6)	8 (11.3)	
25–34	242 (38.7)	213 (38.4)	29 (40.8)	
35–44	168 (26.9)	151 (27.3)	17 (23.9)	
45–54	80 (12.8)	69 (12.5)	11 (15.5)	$\chi^2 = 0.9378$
55+	57 (9.2)	51 (9.2)	6 (8.5)	p=0.9191
Insurance				
Medicaid/Medicare	90 (14.4)	82 (14.8)	8 (11.3)	$\chi^2 = 0.6376$
Commercial	535 (85.6)	472 (85.2)	63 (88.7)	p=0.4246

†Others: NH Black, NH Asian, NH other, and not specified.

‡Pre_COVID-19: January 1, 2018 through March 31, 2020 (a total of 9 quarters) and *early-pandemic* period: April 1, 2020 through September 30, 2020 (a total of 2 quarters).

Table 2.

Number of PrEP users and STI-testing-eligible PrEP users, STI testing rate and prevalence among STI-testing-eligible PrEP users by quarter, January 2018–September 2020

			2018				2019				2020		
			Quarter 1	Quarter 2	Quarter 3	Quarter 4	Quarter 1	Quarter 2	Quarter 3	Quarter 4	Quarter 1	Quarter 2	Quarter 3
PrEP users		N	309	354	400	426	480	495	517	541	552	509	446
Among STI-testing eligible PrEP users	Overall	N	282	340	384	419	427	448	475	506	491	484	377
	People with GC and CT tests	N	257	300	341	366	353	393	406	425	399	341	307
		%	91.1	88.2	88.8	87.4	82.7	87.7	85.5	84.0	81.3	70.5	81.4
	People with a positive gonorrhea	N	18	20	32	30	27	28	29	20	38	26	21
		%	7.0	6.7	9.4	8.2	7.6	7.1	7.1	4.7	9.5	7.6	6.8
	People with a positive chlamydia	N	22	23	26	39	23	26	26	35	35	27	21
		%	8.6	7.7	7.6	10.7	6.5	6.6	6.4	8.2	8.8	7.9	6.8
Among STI-testing eligible PrEP users who were continuous user (gap≤14 days)	Overall	N	223	247	293	318	303	335	355	359	347	279	254
		%	79.1	72.6	76.3	75.9	71.0	74.8	74.7	70.9	70.7	57.6	67.4
	People with GC and CT tests	N	212	237	278	299	289	323	339	336	332	258	240
		%	95.1	96.0	94.9	94.0	95.4	96.4	95.5	93.6	95.7	92.5	94.5
	People with a positive gonorrhea	N	17	16	26	27	25	18	22	18	31	18	18
		%	8.0	6.8	9.4	9.0	8.7	5.6	6.5	5.4	9.3	7.0	7.5
	People with a positive chlamydia	N	19	19	19	31	22	24	19	32	31	17	14
		%	9.0	8.0	6.8	10.4	7.6	7.4	5.6	9.5	9.3	6.6	5.8

GC: gonorrhea; CT: chlamydia

Table 3.

Quarterly number of PrEP-related medical visits or encounters among PrEP users by type of visits in the given quarter during January 2018 through September 2020

	2018				2019				2020			Total
	Quarter 1 N (%)	Quarter 2 N (%)	Quarter 3 N (%)	Quarter 4 N (%)	Quarter 1 N (%)	Quarter 2 N (%)	Quarter 3 N (%)	Quarter 4 N (%)	Quarter 1 N (%)	Quarter 2 N (%)	Quarter 3 N (%)	N (%)
Overall	211	203	254	229	197	201	233	233	238	175	160	2334
Type of encounter for PrEP management												
Face-to-face	14 (6.6)	11 (5.4)	13 (5.1)	9 (3.9)	9 (4.6)	2 (1.0)	11 (4.7)	5 (2.2)	1 (0.4)	1 (0.6)	3 (1.9)	79 (3.4)
Virtual	197 (93.4)	192 (94.6)	241 (94.9)	220 (96.1)	188 (95.4)	199 (99.0)	222 (95.3)	228 (97.8)	237 (99.6)	174 (99.4)	157 (98.1)	2255 (96.6)