Understanding HIV pre-exposure prophylaxis use in the United States and the potential impact of community pharmacies

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Abstract

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The US HIV epidemic is characterized by notable geographic, racial, and socioeconomic disparities and substantial health and economic burden. Pre-exposure prophylaxis (PrEP) is a safe, effective therapy to prevent the acquisition of HIV, but uptake remains low, partly due to inadequate access to PrEP providers. Community pharmacies are well-positioned to expand access for populations disproportionately impacted by the HIV epidemic. This dissertation leverages several modeling methods to examine population-level factors driving PrEP utilization and the potential impact of community pharmacies for expanding PrEP access nationwide.

First, I trained a robust set of machine learning models to explore population-level characteristics and social determinants of health that were most predictive of county-level PrEP use across the US. The best performing model highlighted the importance of county HIV prevalence and testing rates, access to healthcare facilities and providers, healthy lifestyle indicators (e.g., access to exercise facilities, obesity rates), and sociodemographic factors (e.g., racial composition, income, education). This exploratory, ecological analysis sets the stage for further investigations into the relationships between identified

predictors and PrEP utilization, ultimately informing potential population-level strategies or policies to promote PrEP uptake.

Furthermore, prompted by recent state legislation permitting community pharmacy-based PrEP, my second and third aims assessed the potential impact of a hypothetical federal policy empowering pharmacists to initiate PrEP for eligible individuals. My nationwide examination of geospatial access to PrEP providers and community pharmacies in 2022 demonstrated that community pharmacies could expand access in 78.2% to 94.3% of census tracts that currently lack PrEP access, potentially benefitting 34.7 to 41.0 million US residents and alleviating geographic and racial disparities in PrEP access. Lastly, I adapted an infectious disease model to simulate plausible pharmacy-based PrEP scenarios in the Atlanta metropolitan area, a region with high HIV burden. I concluded that community pharmacy-based PrEP could substantially improve health outcomes in terms of quality-adjusted life-years gained and HIV cases averted and would be cost-saving or cost-effective over a 50-year time horizon. Overall, the work presented in this dissertation provides insight into predictors of PrEP utilization in the US and the potential impact and value of community pharmacies for bridging gaps in PrEP access.

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CHAPTER 1. Introduction

The US HIV epidemic

Human immunodeficiency virus/ acquired immunodeficiency syndrome (HIV/AIDS) continues to be a public health crisis in the US and globally despite the availability of effective treatments and prevention medications. The US Centers for Disease Control (CDC) estimated that HIV prevalence has grown to over 1.2 million people living with HIV (PLWH), with over 37,500 new HIV cases in 2022.[1] The US HIV epidemic is characterized by stark disparities, with the greatest proportions of new HIV cases in 2022 among black and Hispanic individuals, men who have sex with men (MSM), and residents in the south. Moreover, a recent CDC study estimated that the lifetime HIV risk among was 1 in 27 for black males, 1 in 50 for Hispanic males, and 1 in 171 for white males.[2] The HIV epidemic also has substantial economic implications, as the US federal domestic discretionary funding of HIV totaled over $30.0 billion the last four years for HIV prevention, awareness, treatment, and research, with $7.75 billion included in President Biden's Fiscal Year (FY) 2025 budget request.[3] Two national efforts, Ending the HIV Epidemic (EHE) and the National HIV/AIDS Strategy (NHAS), have the common goal of reducing new HIV infections by 90% by the year 2030.[4,5]

Pre-exposure prophylaxis

A key component of these national efforts is HIV prevention with pre-exposure prophylaxis (PrEP), a safe and effective drug therapy taken to prevent the acquisition of HIV.[6–9] PrEP is currently available as a once-daily oral tenofovir disoproxil fumarate/emtricitabine (TDF/FTC) , once-daily oral tenofovir alafenamide /emtricitabine (TAF/FTC), and bi-monthly, long-acting injectable cabotegravir (CAB-LA).[6,7,10] In 2023, the US Preventative Services Task Force's recommended offering PrEP therapy to any individual at risk of HIV acquisition, including: MSM and heterosexually active individuals with a sex partner with HV, inconsistent condom usage, or recent history of sexually transmitted infections (STIs) such as syphilis, gonorrhea, and chlamydia, and people who inject drugs (PWID) who have an injection partner with HIV, share equipment, or are at sexual risk.[11] Despite its effectiveness and cost-effectiveness, PrEP scale-up in the US has been slow, and the CDC estimated that only 36.0% of the 1.21 million eligible individuals in the US were on PrEP therapy in 2022.[1,12–17]

Table 1: New HIV diagnoses and PrEP use in 2022 by race/ethnicity

	HIV diagnoses, N (%)	PrEP users, N (%)
Black/African American	14,570 (38.8)	60,048 (13.7)
Hispanic/Latinx	11,733 (31.3)	76,249 (17.4)
White	9,126 (24.3)	282,041 (64.5)
Other	2,092 (5.5)	19,088 (4.4)
Total	**37,521**	**437,425**

CDC HIV Surveillance Tables Vol 4 No 4

Disparities and barriers to PrEP

Prior modeling studies have demonstrated the potential benefits of PrEP to reduce HIV disparities,[18,19] but these inequities are also observed in PrEP. Black and Hispanic individuals accounted for 70.1% of new HIV diagnoses, but only 31.1% of PrEP users in 2022 (Table 1).[1] Studies have also reported that black and Latinx individuals had lower PrEP awareness and PrEP discussions with healthcare providers compared to white MSM, which was particularly magnified in the South.[20,21]

Numerous prior studies have highlighted social, cultural, structural, and practical barriers to PrEP.[20,22–26] They range from mistrust of the healthcare system, stigma and discrimination from healthcare providers, insurance coverage and costs, and concerns about adverse effects.[24–32] Barriers also include limited access to providers able and willing to prescribe PrEP, particularly in rural and/or Southern areas.[32–37] An estimated 13% of PrEP-eligible MSM lived more than 30 minutes to a registered PrEP prescriber in 2017, and areas with more black MSM, poverty, and uninsurance were disproportionately impacted.[38] Although additional training and certification is not needed for primary care providers to prescribe PrEP, many have limited experience, training, and comfort with discussing and prescribing PrEP. [26,29,31,39,40] Healthcare access deserts and longer travel times have been associated with poorer adherence and outcomes.[41–43]

Role of pharmacists in PrEP care

PrEP delivery through nontraditional approaches such as non-physician healthcare providers are needed to promote PrEP uptake. The scope of practice of pharmacists has been expanding the last several decades, and the COVID-19 pandemic further highlighted the important role and potential of these highly accessible healthcare professionals.[44–46] Prior studies have shown the clinical and economic benefits of pharmacy-based HIV interventions and PrEP programs,[47–50] and the Kelley-Ross Pharmacy Group, which established the first community pharmacy-based PrEP program in 2015, demonstrated its long-term feasibility and sustainability.[51] Healthcare access is multidimensional and goes beyond geographical access,[52] and pharmacy-based PrEP programs can also address barriers through PrEP navigation (e.g., insurance, patient assistance programs), refill reminders, telemedicine, linkage to care, and accessibility outside of standard business hours.[31,51,53 9,54–57] California was the first state to pass legislation permitting community pharmacists to dispense PrEP and PEP without a prescription,[58] and 16 additional states have passed similar policies as of Fall 2023, each with varying scopes of practice.[59] An early assessment found an increase in PrEP prescriptions in states with pharmacy-based PrEP policies,[60] but the full effects of these policies have yet to be observed.

The first aim of this dissertation seeks to explore population-level factors associated with county PrEP utilization rates to prompt future studies to better understand potential causal relationships and targets, ultimately informing future strategies and policy decisions. Due to the novelty of community pharmacy-based PrEP, the impact of scaled pharmacy-based PrEP interventions and policies are unknown. The second aim of this dissertation identifies and characterizes the areas in which community pharmacies could expand access to PrEP services, and the third aim examines the potential long-term health and economic impacts in the Atlanta metropolitan area, which has one of the highest HIV incidence in the US.

CHAPTER 2. Population-level predictors of US county pre-exposure prophylaxis utilization rates

Abstract

Background

Pre-exposure prophylaxis (PrEP) is a key strategy in US efforts to reduce HIV incidence and end the HIV epidemic, but its uptake remains suboptimal despite its proven effectiveness. Our study leverages regression and machine learning models to explore population-level factors that are predictive of county-level PrEP utilization rates to prompt future research and inform potential policies promoting PrEP use.

Methods

We compiled a dataset with county PrEP utilization rates (users per 100,000 of the population), county- and state-level variables related to HIV (e.g., HIV prevalence, PrEP provider density), and a comprehensive set of social determinants of health (SDOH) such as social vulnerability, healthcare access, affordable housing, and HIV criminalization laws. We employed multiple regression and machine learning models including linear regression, regularized regression, decision trees, and XGBoost to identify the most predictive factors of PrEP use. We used ten-fold cross-validation to tune hyperparameters and evaluate model performance with root mean square error as the performance metric. SHapley Additive exPlanations (SHAP) values were calculated to better understand the relationships between key variables and the outcome.

Results

Our best performing model was XGBoost. We not only confirmed the importance of HIV-related variables like prevalence and testing, but our findings also revealed the predictive importance of access to healthcare facilities, healthcare providers, and exercise facilities. Furthermore, factors

such as racial distribution, income, education levels, and health behaviors like smoking and obesity emerged as highly predictive of county-level PrEP utilization rates.

Conclusion

Our study emphasizes the complex combination of HIV-related and SDOH factors that may impact county-level PrEP utilization rates. It lays the groundwork for future research to further evaluate the mechanistic and potentially causal relationships between identified key predictors and PrEP use. These studies could inform population-level interventions and policies to promote PrEP uptake, reduce new HIV cases, and contribute to ending the HIV epidemic.

Background

The US HIV epidemic continues to pose a public health concern despite the availability of effective treatment and preventative therapies, and Centers for Disease Control (CDC) reported over 37,500 new HIV diagnoses in 2022.[1] The Ending the HIV Epidemic (EHE) initiative aims to reduce new HIV cases by 90% by the year 2030,[4] and its HIV prevention strategy centers around pre-exposure prophylaxis (PrEP), a highly effective medication to prevent the acquisition of HIV. However, with over a decade since PrEP was first approved and despite its effectiveness and limited adverse effects, PrEP remains underutilized, as only 36.0% of the estimated 1.21 million eligible individuals were on therapy in 2022.[1,61] Individuals eligible for PrEP include those who have: a sex partner with HIV, recent diagnoses of sexually transmitted infections (STIs), inconsistent condom usage with partners of unknown HIV status, transactional sex, or injection drug use with shared equipment.[62]

The challenges to PrEP uptake are complex and multifaceted[63] and require a multi-pronged approach that both addresses individual- and population-level barriers and promotes facilitators. Key patient-level barriers include lack of awareness of PrEP or personal HIV risk, mistrust of the healthcare system exacerbated by stigma, discrimination, and racial disparities, and obstacles such as uninsurance, high out-of-pocket costs, and fear of potential adverse effects.[9,24,25,27,28,31,32,63] Past studies have also identified patient-level predictors and social determinants of health (SDOH) related to PrEP use, including lower rates of higher education, high-risk sexual behavior, younger age, higher income levels, histories of STIs, and recreational drug use,[64–68] and this body of research has informed the development of innovative, targeted delivery programs.[69–71]

Complementing these targeted interventions are several state and federal efforts to promote PrEP access and use. Notably, the US Preventative Services Task Force's (USPSTF) 2019 grade A recommendation requires all non-grandfathered commercial insurance plans to cover

PrEP medication and related services.[62] Substantial federal funding through the EHE, CDC, and Ryan White HIV/AIDS Program has been allocated to expand PrEP services at the state and local health departments and health centers.[3] Additionally, several state policies have worked towards expanding access to PrEP by permitting and/or reimbursing for PrEP initiation through telemedicine, community health workers, and non-physician providers such as community pharmacists, advanced nurse practitioners, and physician assistants.[59,72,73]

Despite these efforts, the persistently low uptake of PrEP highlights the need to expand our understanding of population-level factors that may be impacting its use and non-use. Current studies have largely focused on limited factors and SDOHs including HIV prevalence, Medicaid expansion, PrEP drug assistance programs (PrEP-DAP), state discrimination laws, racial distribution, education level, and median income.[74–78] With potential initiatives such as President Biden's proposed $9.8 billion national Mandatory PrEP Delivery program,[79] it is crucial to consider a broader range of population-level and environmental factors such as healthcare access, social vulnerability, and affordable housing to better understand these population-level factors before investing more money to enhance access and coverage. This study leveraged several machine learning methods to assess a broad spectrum of population-level predictors across the US. By identifying important factors, we aimed to inform future research that will guide policy decisions and structural interventions at county, state, and federal levels, ultimately enhancing strategies to end the US HIV epidemic.

Methods

An ensemble of machine learning models were developed to identify population-level features (or predictors) related to PrEP use in all US counties with available 2022 outcome data. We incorporated a wide range of factors using the most recent data available (Table 2), and data were merged using Federal Information Processing Standard (FIPS) codes or by county and state name, when necessary.

Data sources

Our outcome of interest was county PrEP utilization rate in 2022, defined as the number of PrEP users per 100,000 of the county's population. The data was sourced from Emory University's AIDSVu,[80,81] which estimates PrEP rates using IQVIA prescription records linked to a claims database and an algorithm to determine prescription indication for PrEP.[82] PrEP rates were suppressed if the number of users in a county was greater than zero and less than five or if a county population less was than 100, to maintain confidentiality. AIDSVu also provided data on county-level HIV prevalence rate (number of people living with HIV [PLWH] per 100,000 of the county's population) and adhered to each county's or state's data suppression requirements.[80] Additionally, we utilized the CDC's AtlasPlus database for estimates of percentage of PLWH who received HIV care and rates of chlamydia, gonorrhea, early or non-secondary syphilis, primary or secondary syphilis.[80,83]

Our analysis included features from each SDOH domain: economic context (e.g., median household income, households living below the poverty line), education access and quality (e.g., educational attainment, adult literacy), healthcare access and quality (e.g., density of healthcare facilities and providers), neighborhood and built environment (e.g., air pollution, availability of healthy food), and social and community context (e.g., racial distribution, social vulnerability index).[84] For measures not available at the county-level, we incorporated state-level data such as polices impacting PrEP health insurance coverage, HIV deaths and testing rates, and HIV criminalization and discrimination laws. The SDOH and state-level predictors were drawn from a wide range of sources that are detailed in Table 2 and Appendix A1.

Table 2: Features and data sources

Features	**Year**	**Unit of analysis**	**Sources**
Outcome: PrEP user rate (per 100,000 of population)	2022	County	80
HIV prevalence rate (per 100,000 of population)	2021	County	80
Percent of people living with HIV who were virally suppressed	2021	County	80
Total population, gender, race	2020	County	85
Median household income, poverty level, Gini index, public assistance	2022	County	86,87
Means of transportation to work, household make up, owner, veteran population, life expectancy, vehicle access	2022	County	86
Insurance coverage: none, private, Medicaid, Medicare, Tricare, VA	2022	County	86
State policies for Medicaid and HIV indicators	2020	State	88–94
State PrEP drug assistance programs	2022	State	95
Sexually transmitted infections rates: gonorrhea, syphilis, chlamydia	2022	County	83
Unemployment rate	2022	County	96
PrEP provider density (per 100,000 of the population)	2022	County	85,97
Community pharmacy density (per 100,000 of the population)	2022	County	98
Health professional shortage area, medically underserved area	2022	County	99
Ryan White recipients and subrecipients	2021	County	100
HIV criminalization laws	2022	State	101,102
Adult literacy and numeracy	2017	County	103
Vacant housing, public transportation, broadband access, severe housing problems	2022	County	86,87
Educational attainment, school segregation, school funding	2022	County	86,87
Social deprivation index	2022	County	104
Healthy food environment, childcare centers and costs	2022	County	86,87
Area deprivation index	2022	County	104
Social vulnerability index	2020	County	105
LGBTQ state advocacy category	2022	State	106
Historic redlining	2020	Census tract	107
Metropolitan area	2020	County	108
Density of primary care, dental, mental health providers	2022	County	87
Drug overdose deaths	2020	County	87
Adult smokers, obesity, with exercise access, excessive drinking, mammography screenings, diabetes	2022	County	87
Low birthweight, teen births,	2022	County	87
Deaths related to alcohol-impaired driving, injury, firearms, suicide	2022	County	87
Air pollution, drinking water violations	2022	County	87
Gender pay gap	2022	County	87
Drug overdose deaths	2020	County	109
Densities of physician assistants, nurse practitioners, Indian Health Services facilities, Federally Qualified Health Centers, rural health clinics, rehabilitation facilities, emergency departments, hepatitis C testing facilities, HIV testing facilities	2020	County	109

Data Analysis and Model Selection

First, we assessed the outcome and features for completeness and excluded all counties without 2022 estimates for PrEP utilization rate. We characterized features with missing values through descriptive statistics and visualized patterns of missingness with maps. We excluded features with high proportions of missingness or potentially biased in their missingness such as missing not completely at random. The remaining features values were imputed using R package *MissRanger*, which iteratively fits chained random forest models until the average out-of-bag (OOB) prediction error no longer improves. We did not impute values for data suppressed due to low counts (e.g., HIV cases < 5, county population < 100, or other restrictions based on local, state, or CDC agreements). The relationships between PrEP prevalence and all features were examined using Pearson's correlation coefficient and other descriptive statistics. We then split the dataset into 75% training and 25% test sets and scaled all predictors. We used multiple machine learning approaches to train the models for feature selection and used 10-fold cross-validation with grid search to select optimal tuning parameters and evaluate predictive performance in the training set. Model performance was evaluated with root mean square error (RMSE).

We first trained a set of linear regression models: a saturated model containing all predictors as well as models using forward, backward, and a hybrid of forward and backward stepwise selection. To further reduce features, we employed recursive feature elimination (RFE) for linear regression with 10-fold cross-validation, repeated five times. Features that exhibited p-values less than 0.05 were considered significant predictors. We then trained penalized regression models of lasso and elastic net regression, with 10-fold cross-validation to tune the regularization parameter λ.

Next, we trained a series of tree-based models that can potentially capture nonlinear relationships. We began with an overgrown regression tree and applied cost complexity pruning, utilizing the optimal tuning parameter α determined through 10-fold cross-validation. Additionally, we trained two sets of random forest models. We used 1,000 bootstrapped datasets from the training set to train regression trees, using the OOB observations to estimate the average model performance. Furthermore, we implemented RFE for random forest model, again using 10-fold cross-validation, repeated five times.

Lastly, we applied extreme gradient boosting (XGBoost), which iteratively builds trees based on the errors of previous trees. We applied 10-fold cross-validation to tune hyperparameters of: learning rate, maximum depth of a tree, minimum sum of instance weight needed in a child, subsample ratio of the training instance, and maximum number of boosting iterations. To discern the most influential features, we applied a gain threshold of 0.01.

Utilizing our best performing model as determined by test RMSE, we calculated SHapley Additive exPlanations (SHAP) values for each observation and predictor in our test set to better understand feature importance and explain outputs of our prediction model.[110] SHAP values are based on game theory and quantify the magnitude and direction of each feature's impact on the predicted PrEP utilization rate relative to the average predicted rate. For each observation (i.e., county) in our test set, we can observe how each feature affected the prediction relative to the average. Features with SHAP values of 0 indicate that the feature did not have any impact on the predicted PrEP rate relative to the average. Those with positive SHAP values increased the predicted outcome and those with negative decrease the predicted PrEP rate. We generated SHAP summary, dependence, and force plots to examine local and global insights into feature impacts on predictions.

All analyses were conducted using R version 4.2 with packages including *tidyverse, tidycensus, tigris, glmnet, tree, caret, boot, randomForest, xgboost,* and *SHAPforxgboost.*

Results

Table 3 displays the key characteristics of 2,227 counties included in our final dataset after excluding those with suppressed or unavailable PrEP rates and those in Connecticut due to the changes in the 2022 ACS's reporting of the state's "county-equivalents.[111] Utilizing Pearson's correlation coefficient (Appendix A2), we found many features positively correlated with PrEP rate, including number of Ryan White recipients, HIV prevalence, PrEP DAP medical coverage, urban status, income, HIV testing rates, STI rates, and PrEP provider density. Conversely, factors such as lower education, smoking rates, home ownership, and lack of internet access showed a negative correlation with PrEP use.

Our trained models identified 11 to 109 important features, and the best performing model was XGBoost, with a test RMSE of 64.42 (Appendix A3, Appendix A4). The final model contained 100 features, and 14 exceeded our gain threshold (Table 4, Appendix A5). Based on the gain metric, the most important predictor was HIV prevalence, followed by the density of primary care and mental health providers. The 14 important predictors included four related directly to HIV or STIs and others distributed across the SDOH domains of social and community context (five features), healthcare context (three features), and neighborhood and built environment (two features.

Table 3: County characteristics

	Overall (N=2,227)
PrEP rate[1], Median (Min - Max)	67.0 (0 - 1,850)
HIV prevalence rate[1], Median (Min - Max)	139 (0 - 2,380)
Population, Median (Min - Max)	43,000 (216 - 9,940,000)
Census Region, N (%)	
Midwest	633 (28.4%)
Northeast	202 (9.1%)
South	1,099 (49.3%)
West	293 (13.2%)
% Female, Median (Min - Max)	50.6 (34.5 - 57.7)
Age (years) - Female, Median (Min - Max)	42.0 (20.4 - 68.9)
Age (years) - Male, Median (Min - Max)	39.5 (22.5 - 67.7)
% Race - White, Median (Min - Max)	80.3 (3.26 - 97.4)
% Race - Black, Median (Min - Max)	3.73 (0 - 87.5)
% Race - Asian, Median (Min - Max)	0.75 (0 - 43.0)
% Race - American Indian and Alaskan Native, Median (Min - Max)	0.44 (0 - 93.8)
% Race - Pacific Islander, Median (Min - Max)	0.038 (0 - 14.0)
% Ethnicity - Hispanic, Median (Min - Max)	5.20 (0.501 - 97.7)
% Households living below poverty, Median (Min - Max)	13.4 (1.72 - 55.8)
Family income (USD), Median (Min - Max)	62,400 (28,800 - 170,000)
Unemployment rate[1], Median (Min - Max)	3.50 (0.900 - 14.7)
Gini coefficient[2], Median (Min - Max)	0.447 (0.348 - 0.604)
% Household - Single occupant, Median (Min - Max)	14.8 (1.21 - 29.2)
% Without internet, Median (Min - Max)	12.3 (0 - 49.8)
Overall social vulnerability index percentile[3], Median (Min - Max)	0.536 (0.0003 - 0.999)
% Education - Less than high school, Median (Min, Max)	10.5 (1.79 - 42.4)
PrEP provider rate[1], Median (Min - Max)	0 (0 - 38.0)
Primary or secondary syphilis rate[1], Median (Min - Max)	6.50 (0 - 267)
Chlamydia rate[1], Median (Min - Max)	334 (0 - 2,790)
Early, non-secondary syphilis rate [1], Median (Min - Max)	4.40 (0 - 221)
Gonorrhea rate[1], Median (Min - Max)	114 (0 - 2,300)
State with Medicaid expansion, N (%)	1,511 (67.8%)
State with PrEP DAP copay coverage, N (%)	593 (26.6%)
State with PrEP DAP medication coverage, N (%)	534 (24.0%)

PrEP, pre-exposure prophylaxis; PrEP DAP, PrEP drug assistance program; USD, US dollars
[1]Rates are reported as per 100,000 of the county population.
[2]The Gini index is a measure of income inequality ranging from 0 to 1, with higher values representing greater inequality.
[3]The overall social vulnerability index percentile is based on numerous census variables and captures the county's j

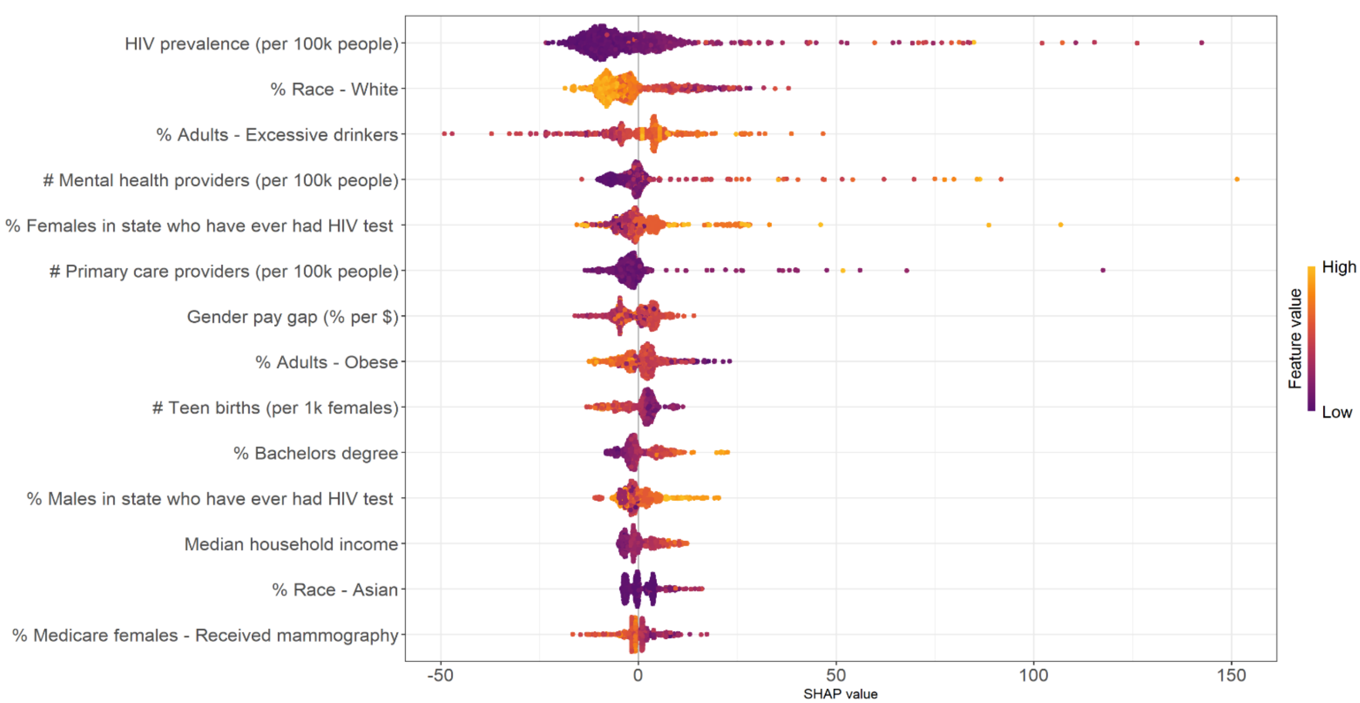
Table 4: Important features identified by XGBoost and SHAP

HIV- or PrEP-related	Social and community context	Healthcare context	Economic context	Neighborhood and built environment	Education access and quality
HIV prevalence (per 100k of population) % Females who have ever had HIV test % Males who have ever had HIV test # Ryan White recipients or subrecipients	% Race - White % Race - Asian % Adults - Excessive drinkers % Adults – Obese % Race – American Indian or Alaskan Native	# Mental health providers (per 100k of population) # Primary care providers (per 100k of population) # Federally qualified health centers (per 1k of population) Teen births (per 100k females) % Medicare Females received mammogram	Gender pay gap Median household income	% Households with at least 1 child % Population with access to exercise facilities	Bachelor's degree

Features colored in blue were considered the most important by XGBoost only, those in red by SHAP only, and those in purple by both.

Further insights from the SHAP values revealed several interesting trends (shown in Figure 2, Appendix A7). First, while SHAP identified many of the same important features as XGBoost, we also found features related to socioeconomic status and educational attainment to be important predictors. Generally, counties with higher percentages of bachelor's degrees and higher median household income had higher SHAP values, which indicate higher predicted PrEP usage. Aligning with XGBoost, access to healthcare providers or facilities also emerged as important features, with many, but not all, higher density counties having higher SHAP values. Conversely, higher values of adult obesity, teen births, and mammography rates tended to decrease the predicted outcome. We also noted several nonlinear PrEP rate trends related to HIV testing, excessive drinking, and high school education. For example, higher percentages of males or females in a state who ever received an HIV test were not always linked with higher SHAP values. We observed that counties with high HIV testing rates (in yellow in Figure 2) had either the highest or lowest SHAP values, and counties with low to moderate testing rates accounted for the middle of the SHAP value distribution (Appendix A7).

Figure 1: SHAP values for the most important predictors identified by SHAP



Discussion

Because of the ongoing US HIV epidemic and consistently low uptake of PrEP, it is essential to identify and understand the factors that potentially influence PrEP utilization in order to develop policies to effectively promote its use. Our study leveraged multiple machine learning models to explore important population-level factors predictive of county PrEP utilization rate. This work provides a foundation for further research into key variables that could inform the development of population-level interventions or policies aimed at increasing PrEP uptake or overcoming barriers to its adoption. Our best performing model identified 23 key features that are predictive of county-level PrEP utilization, and our computed SHAP values offered deeper insight into both the local and global effects of these factors on predicted PrEP rates. In this discussion, we highlight several important population-level predictors that merit further exploration to better understand their relationship with PrEP uptake.

A primary theme that emerged from our analysis was the impact of healthcare access. Our model considered several to be drivers of PrEP use such as the densities of primary care providers, mental health services, Federally Qualified Health Centers (FQHCs), and Ryan White recipients. Previous research has shown that greater access to PrEP providers was associated with higher PrEP use,[112,113] but the impact of broader healthcare access is less understood. Because a wide range of providers may prescribe PrEP, not solely PrEP-trained providers, it is pertinent to explore the effects of access to various healthcare provider and facility types on PrEP utilization since these relationships are likely multifaceted. A recent study concluded that areas with high densities of FQHCs saw improved HIV outcomes such as linkage to care and viral suppression.[114] However, they also noted higher rates of new HIV diagnoses in the same areas. While these facilities' enhanced engagement with at-risk populations could be identifying more HIV cases, there are likely additional factors at play. The complex relationships between healthcare access, PrEP use, and overall health outcomes necessitate deeper investigation in order to potentially integrate PrEP services more effectively.

We observed strong positive predictive relationships between PrEP utilization and the prevalence of HIV and HIV testing. This finding is not surprising, as areas with higher HIV prevalence pose heighted transmission risk to individuals without HIV and also potentially more awareness of PrEP.[1,74,75] However, the SHAP dependence plots for the percentages of males and females in the state who have ever had HIV testing revealed nonlinear relationships between testing and PrEP utilization, as the SHAP values did not always increase with higher testing rates. Because quarterly HIV testing is recommended during PrEP therapy and could reflect patients' perception HIV risk, our finding that higher state HIV testing rates were predictive of lower PrEP use for some counties was perplexing.[62] However, this may be attributed to heterogeneity of HIV testing and PrEP use within states, and future research could estimate the county-level testing rates and further evaluate its relationship with PrEP utilization.

One theme that emerged in our analysis and not previously noted in literature was related to health behaviors or lifestyles. First, the percentage of the county population with access to exercise locations surfaced as one of the most important predictors in our model. While this finding could suggest a direct relationship between exercise access and PrEP use, this predictor may also be serving as a proxy for broader access to healthier lifestyles and resources. Further, counties with higher rates of obesity and lower mammography rates tended to have lower SHAP values, potentially linking poorer health behaviors and lower preventative care to lower PrEP utilization. We also identified heavy drinking as a strong predictor of PrEP use. Prior research at the patient-level has linked heavy alcohol consumption and cannabis use to riskier sexual behaviors, potentially warranting PrEP intervention.[115,116] However, it remains unclear whether the relationship between heavy drinking and PrEP utilization rate is due to these related risk behaviors or other underlying factors. Further research is required to better understand how various health behaviors and habits relate to PrEP uptake.

Our model also highlighted several key economic and educational factors predictive of PrEP use. We found that counties with lower median household incomes generally displayed lower SHAP values, which point to economic-related disparities in PrEP usage.[77,87] Interestingly, counties with larger gender pay gaps had higher SHAP values, suggesting potential economic disparities between genders within the counties. We also found that counties with higher percentages of individuals with a bachelor's degree had higher SHAP value, but associations of education and PrEP use have been inconsistent across studies, revealing another field for further investigation.[76,78]

Many counties with higher percentages of white residents had lower SHAP values, and those with higher percentages of Asian residents tended to have higher SHAP values. Because the majority of PrEP users are white, this finding suggests complex relationships between PrEP and racial distribution. Because the majority of PrEP users are white,[1] this finding suggests complex relationships between PrEP and racial distribution. This complexity is echoed in prior research, which presents conflicting findings on how race and ethnicity are associated with PrEP use, and highlights the need for further detailed assessment.[76,77] Additionally, our best performing model did not corroborate several policy-related factors previously identified as to be significant. Prior studies have concluded that counties in states with Medicaid expansion, PrEP-DAP, HIV non-criminalization laws, sexual/minority nondiscrimination laws, and robust LGBTQ+ protections were associated with higher PrEP utilization.[76–78] However, our model did not identify these policies to be important predictors, and additional research would be valuable to further understand any potential impacts of these policies on PrEP use.

Our analysis had several notable strengths. First, we built upon prior population-level studies of PrEP use by considering additional county or state-level features previously omitted such as access to various healthcare resources and STI prevalence. We also incorporated a wide range of SDOHs not previously captured, including social vulnerability, health behaviors, and environmental factors. To ensure the rigor of our analysis, we employed multiple machine learning methods including linear and penalized regressions and more advanced statistical model like XGBoost, which can account for nonlinear relationships between predictors and outcomes. Because XGBoost was our best performing model, our findings suggest nonlinear relationships between predictors and our outcomes. Furthermore, by conducting our analysis at the county-level, we were able to use population-level factors at a unit of analysis that captured heterogeneity within states while remaining relevant from a policy implementation standpoint.

However, we also note several study limitations. As an exploratory and predictive analysis, we did not establish causal relationships between the population-level predictors and PrEP prevalence. Although we employed robust statistical models, the features identified to be predictive do not necessarily represent mechanisms by which PrEP use is increased in real world settings. Additionally, county-level findings from our ecological study cannot be directly applied to individual-level predictors or PrEP utilization, and several of our state-level features, such as percentages of people who have ever tested for HIV, may also introduce ecological fallacy. Our analyses also faced notable data constraints such as substantial data suppression that prevented us from generalizing conclusions to counties excluded in our analysis. Moreover, the outcome measure of PrEP utilization rate did not account for need or demand for PrEP in each county. Although PrEP-to-need ratios would provide better insights, there was substantial data suppression associated with new HIV diagnosis counts for 2022, and the counties with available outcome data would have decreased substantially.

Our study leveraged advanced machine learning techniques to explore the multifaceted predictors of county PrEP utilization across the US, revealing important insights into both known and novel factors. We discovered that features such as healthcare access, socioeconomic status, and health behaviors are predictive of PrEP use at a county-level, and our findings emphasize the complex interplay of SDOHs and the HIV epidemic on PrEP use. By identifying these important predictors, our research contributes to a deeper understanding of PrEP utilization and provides a foundation for further investigation. This future research can potentially inform policy-making to increase PrEP adoption, decrease HIV incidence, and ultimately end the HIV epidemic.

CHAPTER 3. Bridging PrEP access gaps: Mapping geospatial accessibility across the US and leveraging community pharmacies for expansion

Abstract

Background

Pre-exposure prophylaxis (PrEP) is key to ending the US HIV epidemic, but uptake remains low. Federal legislation permitting community pharmacists to initiate PrEP nationwide could expand access to PrEP services.

Objectives

This study aimed to evaluate census tract-level geospatial access to PrEP facilities and community pharmacies across the US and characterize geographic areas and populations where community pharmacies could help bridge the gap in care.

Methods

We identified census tracts with limited or no access (“deserts”) to PrEP facilities and community pharmacies in 2022 using two primary definitions: 1) a tract with no PrEP facilities or pharmacies within a 30-minute drive of the tract centroid; and 2) a tract with low income and low access (no PrEP facilities or pharmacies within one mile of the centroid for low vehicle access tracts, two miles in urban tracts, 10 miles in suburban tracts, 20 miles in rural tract). Tracts with access were “oases,” and PrEP desert, pharmacy oasis tracts represented areas without PrEP facilities where community pharmacies could expand access. We characterized the social determinants of health associated with desert status and conducted sensitivity analyses exploring additional access definitions.

Results

Of the 82,729 census tracts in our dataset, most were classified as dual PrEP and pharmacy oases. We categorized 13.3% as PrEP deserts under the 30-minute threshold, and 94.3% of these PrEP desert tracts were pharmacy oases. Under the low income and low access definition, 17.0% of all tracts were PrEP deserts, 78.2% of which were pharmacy oases. PrEP deserts were predominantly located in the Midwest and South and associated with higher poverty, social vulnerability, and uninsurance.

Conclusion

Our analysis confirmed inequitable access to PrEP facilities across the US. Federal recognition of pharmacists as healthcare providers empowered to initiate PrEP nationwide has the potential to substantially bridge access gaps for underserved communities.

Background

Although HIV incidence has gradually declined in the last two decades, the Centers for Disease Control and Prevention (CDC) reported over 37,500 new HIV diagnoses in the US in 2022.[1] To combat this persistent public health challenge, the US Ending the HIV Epidemic (EHE) initiative's goal is to reduce new HIV infections by 90% by the year 2030. It is crucial to recognize that HIV disproportionally affects historically marginalized populations, and racial and geographic disparities are particularly pronounced in the US HIV epidemic, as over 70% of new HIV diagnoses were among Black and Hispanic individuals and 53% were in the South in 2022.[1]

Pre-exposure prophylaxis (PrEP) offers a highly effective and safe means of preventing HIV for individuals without HIV at higher risk of HIV acquisition such as those with a sexual partner with HIV or unknown status, recent history of condomless sex or sexually transmitted infections, and injection drug use with shared equipment or a partner with HIV.[11] PrEP is currently available as a once-daily oral tablet and bimonthly injection acquisition, and requires proper use and adherence for full effectiveness. [6–9,117,118] However, despite its effectiveness and cost-effectiveness,[6–9,117,118] PrEP scale-up in the US remains slow, nearly a decade after drug approval, particularly among populations at greatest risk. [12–17,119] The CDC estimated that only 36.0% of the 1.2 million eligible individuals were on PrEP therapy in 2022, and only 30.7% were Black or Hispanic.[1]

PrEP has the potential to reduce HIV disparities,[18,19] but inequities persist in PrEP care and PrEP-eligible individuals face many social and structural barriers including lack of awareness of PrEP or perceived HIV risk, uninsurance, high out-of-pocket costs, low education, poverty, and apprehension about side effects, stigma, and discrimination.[9,24–26,28,31,120,121] Prior research has identified inadequate access to providers willing and able to prescribe PrEP as a notable barrier that potentially exacerbates observed disparities, particularly in rural and Southern regions.[32–37]

Health care access deserts are geographic areas with no or low access to particular resources, and prior studies have identified PrEP deserts in the US.[34,38,122] Approximately 13% of PrEP-eligible men who have sex with men (MSM) lived more than 30 minutes from a registered PrEP prescriber in 2017, and PrEP deserts were more prevalent in areas with higher concentrations of black MSM, poverty, and uninsurance.[38] Because past research has linked nonurban PrEP deserts to lower likelihood of PrEP use and higher PrEP clinic density to willingness or use of PrEP,[113,123] it is important to ensure sufficient access to PrEP facilities.

Community (i.e., retail or grocery store) pharmacists gained greater public attention throughout the COVID-19 pandemic as accessible healthcare professionals who could provide care services such as COVID-19 testing, vaccinations, and treatment.[124] With over 90% of US residents living within five miles of a pharmacy and many visiting one at least monthly,[125,126] community pharmacies offer convenient and accessible avenues for PrEP provision, particularly for populations disproportionately impacted by the HIV epidemic. Community pharmacists and pharmacies have been actively involved in PrEP screening and initiation through mechanisms such as collaborative drug therapy agreements, institutional protocols, and more recently, state legislation.[9,49,51,54–57,127] The Kelley-Ross Pharmacy Group, which implemented the first community pharmacy-based PrEP program in 2014, demonstrates the long-term feasibility and effectiveness of these services within the community pharmacy setting.[51]

In 2019, California passed Senate Bill 159 (SB 159) and became the first state to authorize community pharmacists to "furnish", or dispense, PrEP without a prescription from another provider.[58] As of Fall 2023, 16 additional states expanded pharmacists' authority to provide PrEP or post-exposure prophylaxis (PEP) in community settings, and their scopes have ranged from dispensing a short-term supply without a prescription to long-term prescribing.[59] An early analysis of these policies found a 24% increase in annual PrEP prescription fill rates after one year and 110% after two years in states that passed pharmacy-based PrEP legislation compared to those that did not, suggesting promising effects on PrEP uptake.[60] A hypothetical federal policy empowering community pharmacists to initiate PrEP has the potential to improve access to PrEP services and utilization.

Objectives

In this study, we aimed to 1) examine census tract-level access to PrEP facilities using multiple measures of access and 2) characterize areas where community pharmacies could expand access to PrEP services and potentially reduce disparities in HIV prevention efforts.

Methods

Setting

We evaluated census tract-level geospatial access to PrEP facilities and community pharmacies across all 50 US states and Washington, DC in 2022. In instances where data at smaller units were unavailable, we considered county or state-level characteristics. For our analyses using PrEP facility-to-need ratios (defined below), we focused on the 48 US counties, Washington, DC, and seven states designated as the EHE Phase I jurisdictions (Appendix B1).

Data

Service availability and locations of current PrEP facilities, including pharmacies, were accessed through the PrEP Locator, a publicly available national directory of providers who offer HIV prevention and related services. The data are available through CDC's National Prevention Information Network (NPIN) and report any US clinics, clinician offices, and pharmacies that have registered to be in the database.[128] Registered pharmacies, regardless of PrEP accessibility, and characteristics such as addresses, business hours, and languages spoken were derived from the National Council for Prescription Drug Programs' (NCPDP) dataQ database.[98] Information in the database is self-reported by pharmacies or their Prescription

Service Administration Organization. We deemed community pharmacies to be those that could be used by anyone in the general population (i.e., chain, grocery store, or independent) and excluded institutional pharmacies that serve limited populations such as government, military or veteran, or inpatient.

Demographic, social determinants of health (SDOH), and HIV characteristics were derived from numerous data sources. We extracted demographic and SDOH data from the 2020 Census Demographic and Housing Characteristics file and the 2022 5-year American Community Survey. Annual estimates of county- and state-level HIV-related characteristics were obtained from AIDSVu and CDC EHE surveillance reports and data tables.[80,81,83,119] Social vulnerability index and life expectancy estimates were sourced from the CDC and area deprivation index from Cleveland Clinic's *sociome* R package, which derives the indices from ACS.[104] Using data from the US Health Resources and Services Administration (HRSA), tracts were determined to be medically underserved areas (MUAs) and health professional shortage areas (HPSAs) if it was designated as or located within a MUA or HPSA designated area.[99] Tracts with a MUA designation have limited access to primary care services and HPSA have limited access to primary care, dental, or mental health providers. Regional classification of census tracts were based on US Census, and urbanicity of census tracts were categorized based on population density as defined by the Centers for Medicare and Medicaid services (CMS): less than 1,000 individuals per square mile for rural, 1,000 to 3,000 residents per square mile for suburban, and over 3,000 residents per square mile for urban.[129]

Census tract-level accessibility

In our census tract-level analyses, we excluded any tracts without populations or land and those that were not present in both the 2020 US Census and 2022 ACS data. Because there are no standard access measures for PrEP or healthcare,[130–133] we assessed census tract-level PrEP and pharmacy deserts using two primary measures based on 1) drive time and 2) combination of low income and distance. Population-weighted census tract centroids were used as the origin for all measures because they account for the potential differences in population distributions within a census tract. The US Census Bureau estimated these weights using the population counts of the census blocks within each centroid.[134]

As outlined in Appendix B2, our first primary access measure used a 30-minute drive-time threshold, or isochrone, from each census tract centroid, following the definition used by prior PrEP desert studies.[38,112,122,135] Thus, we considered a census tract to be a PrEP or pharmacy desert if there were no PrEP facilities or pharmacies, respectively, within the 30-minute catchment area, and non-desert tracts were called “oases.” For our second primary access measure, we adapted prior studies’ definitions of pharmacy and food deserts, which are defined by a combination of low income and low access. [136–138] A low income census tract had a poverty rate of 20% or higher or a median family income less than 80% of the state or metropolitan area median income. For low access, we doubled the linear distances used for pharmacy and food deserts and classified census tracts as low access if the nearest resource was over 1 mile from the population-weighted census tract centroid in tracts with low vehicle access (>100 households without vehicles) or if over 500 people or 33% of the tract population were further than 2 miles from the nearest resource in urban areas, 10 miles in suburban areas, and 20 miles in rural areas. We used data from census blocks to estimate the proportion of each census tract population with access. Additional details and the rationale for our two primary measures can be found in the Supplementary Material.

After we determined the PrEP desert status of each census tract, we considered the availability of pharmacies within the same geographic area. A tract was categorized as a "dual desert" if it met the criteria for both PrEP and pharmacy deserts, indicating limited access to both services. We labeled a tract as a "dual oasis" if both PrEP facilities and pharmacies were available within the catchment area, indicating sufficient access to both services. Tracts categorized as "PrEP desert, pharmacy oasis" represented areas with limited access to PrEP facilities but with available pharmacy services, highlighting the potential areas where community pharmacies could expand PrEP access. Conversely, we identified a tract as a "PrEP oasis, pharmacy desert" if it was a pharmacy desert with access to PrEP facilities, emphasizing the need to address pharmacy access gaps in these areas.

Per the University of Washington Human Subjects Research Determination, this study did not involve human subjects and was self-determined to be exempt from IRB review.

Accessibility in EHE jurisdictions

In the EHE Phase I jurisdictions, we examined the potential impact of pharmacies by utilizing the PrEP facility-to-need ratio, a metric established in previous research by Harrington et al and that mirrors the PrEP-to-need ratio.[139,140] This ratio compares the number of PrEP facilities to the estimated need, and the number of new HIV diagnoses within each jurisdiction was used as a proxy for need. We first calculated the ratios with current PrEP facilities alone and a second set considering community pharmacies in addition to current PrEP facilities. Pharmacies that already providing PrEP services and listed in the NPINS database were identified through geocoding and counted only once in our analysis as PrEP facilities because they would not be expanding access.

Statistical analysis

Access deserts and oases were visualized using choropleth maps at the census tract, county, and state levels. We generated descriptive statistics to census tract characteristics such as demographics and SDOH by desert status. Characteristics of PrEP deserts were compared to oases using chi-square tests for categorical variables and t-tests for continuous variables at a significance level of 0.05. ArcGIS Pro was primarily used for geocoding but was supplemented with Google Maps if there were mismatches,[141,142] and Mapbox was used to generate isochrones from each census tract centroid.[143] All mapping and data analyses were conducted in R (version 4.2.1).

Sensitivity analysis

To gauge the impact of the access definitions and thresholds used, we conducted multiple sensitivity analyses and adapted several additional measures from prior studies that evaluated access to PrEP, pharmacies, other healthcare resources, and food (See Appendix B2). Our sensitivity analyses included: 1) additional drive time thresholds (15, 45, and 60 minutes); 2) additional distance thresholds (0.5 miles for low vehicle access, 1 mile for urban areas, 10 miles for suburban, and 20 miles for rural); 3) distance only (without income criterion); 4) convenient access, defined by CMS for Part D network pharmacies; and 5) presence of a facility within the tract. Convenient access followed CMS's definition for Part D network pharmacies: 10% live within 2 miles of the resource for urban areas, 10% live within 5 miles for suburban areas, and 30% live within 15 miles for rural areas.[129]

Results

Data from 82,729 census tracts were included in our analyses. We classified 11,024 (13.3%) census tracts as PrEP deserts using the 30-minute definition. They were concentrated in the Midwest and South and home to approximately 36.1 million people (Figure 3, Table 3, Table 4). We identified over 17,000 community pharmacies in 94% of these PrEP desert tracts, representing 17,000 new potential PrEP access points for 34.7 million residents who currently don't have access. As outlined in Appendix B4, over 55% of these pharmacies were chains, 42.6% were independent, 1.4% operated 24 hours a day, and over 10% offered non-English language services. Only 25.3% of the PrEP desert, pharmacy oasis tracts were located in one of the 17 states with pharmacy-based PrEP legislation. The majority of tracts were dual oases (86.6%), with the few (0.8%) dual deserts were primarily located in the Western US.

Figure 2: Maps of access desert based on the two primary definitions

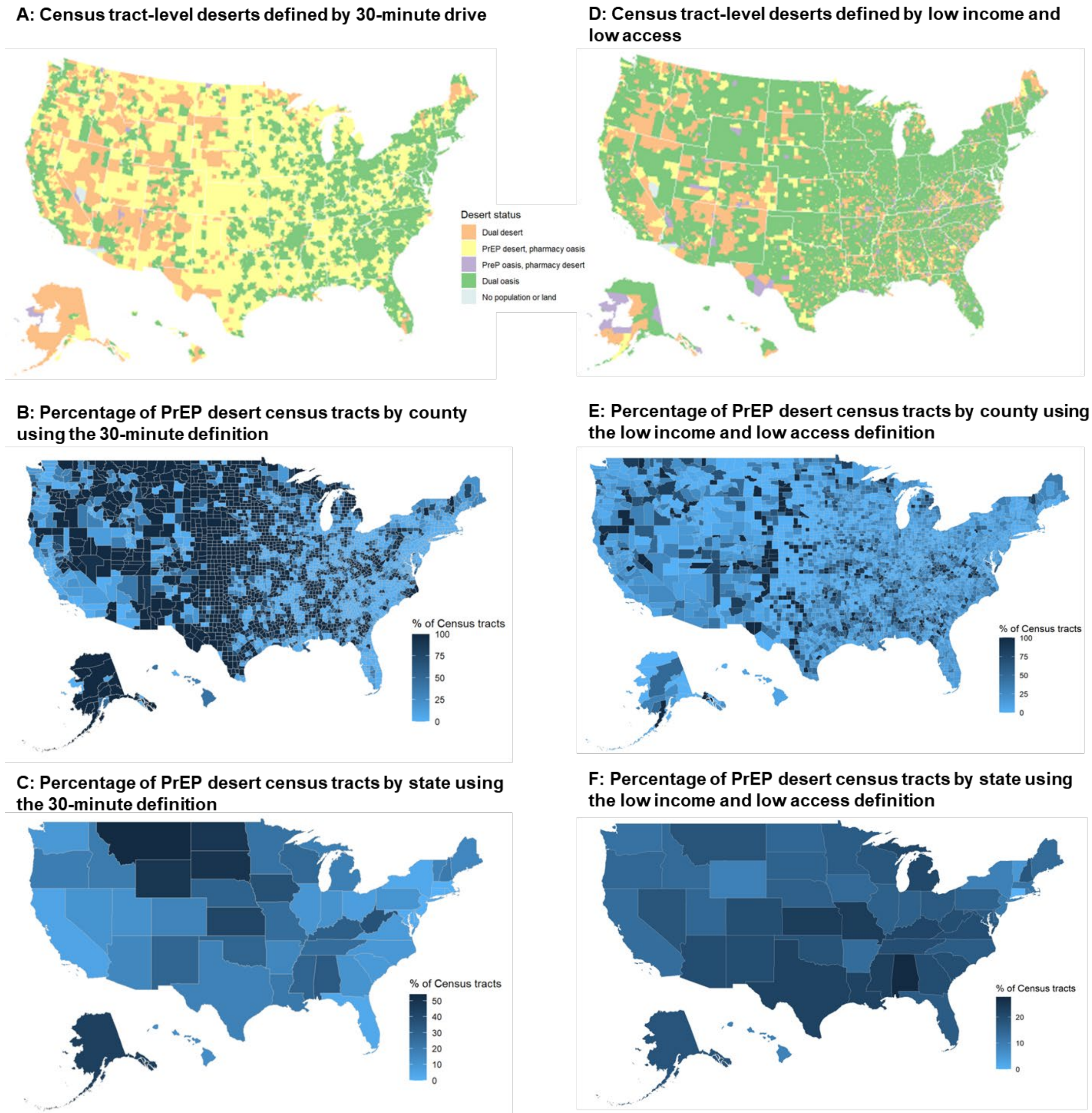


Table 5: Census tract characteristics of PrEP deserts by access measure

Access measure	30-Minute Drive Time			Low Access and Low Income		
	PrEP desert (N = 11,024)	PrEP oasis (N = 71,705)	p-value	PrEP desert (N = 14,043)	PrEP oasis (N = 68,686)	p-value
Total population‡	36,128,476	291,704,941	-	50,948,424	276,884,993	-
Tract mean (SD)	3,280 (1,370)	4,070 (1,700)	< 0.001	3,630 (1,500)	4,030 (1,710)	< 0.001
% Female*	49.6 (4.71)	51.0 (3.54)	< 0.001	51.2 (3.47)	50.8 (3.80)	< 0.001
Median age - Male*	41.9 (8.88)	38.5 (8.40)	< 0.001	36.8 (9.46)	39.4 (8.27)	< 0.001
Median age - Female*	44.0 (8.74)	40.7 (8.80)	< 0.001	39.6 (9.91)	41.5 (8.60)	< 0.001
Race - % White*	78.0 (20.4)	59.6 (26.8)	< 0.001	51.5 (28.9)	64.2 (25.8)	< 0.001
Race - % Black*	6.75 (14.2)	14.3 (21.0)	< 0.001	22.3 (26.8)	11.5 (18.3)	< 0.001
Race - % Other*	15.3 (16.3)	26.0 (20.5)	< 0.001	26.2 (21.9)	24.3 (20.0)	< 0.001
Ethnicity - % Hispanic*	11.2 (18.1)	18.6 (21.5)	< 0.001	21.7 (24.8)	16.8 (20.3)	< 0.001
Median household income*	61,200 (19,500)	83,500 (40,600)	< 0.001	47,300 (13,600)	87,400 (39,300)	< 0.001
% Below poverty*	15.2 (9.81)	13.4 (11.4)	< 0.001	22.4 (11.7)	11.8 (10.2)	< 0.001
% Less than HS education*	12.4 (8.47)	11.3 (10.2)	< 0.001	17.1 (10.8)	10.3 (9.42)	< 0.001
% No insurance*	9.92 (6.96)	8.67 (7.55)	< 0.001	12.6 (8.63)	8.05 (6.98)	< 0.001
% Public insurance*	43.1 (12.0)	36.5 (14.5)	< 0.001	47.2 (13.9)	35.4 (13.6)	< 0.001
Gini index*	0.430 (0.0613)	0.420 (0.0696)	< 0.001	0.445 (0.0655)	0.417 (0.0683)	< 0.001
Area deprivation index*	106 (13.2)	98.7 (20.2)	< 0.001	117 (14.4)	96.1 (18.5)	< 0.001
Social vulnerability index*	0.531 (0.241)	0.496 (0.295)	< 0.001	0.737 (0.198)	0.452 (0.280)	< 0.001
% Unemployment rate*	3.87 (1.44)	3.71 (1.05)	< 0.001	3.89 (1.18)	3.70 (1.09)	< 0.001
Census region‡						
Midwest	3,530 (32.0%)	14,890 (20.8%)	< 0.001	3,345 (23.8%)	15,075 (21.9%)	< 0.001
Northeast	686 (6.2%)	12,987 (18.1%)	< 0.001	1,593 (11.3%)	12,080 (17.6%)	< 0.001
South	4,741 (43.0%)	27,253 (38.0%)	< 0.001	6,352 (45.2%)	25,642 (37.3%)	< 0.001
West	2,067 (18.8%)	16,575 (23.1%)	< 0.001	2,753 (19.6%)	15,889 (23.1%)	< 0.001
Urbanicity‡						
Rural	9,579 (86.9%)	20,336 (28.4%)	< 0.001	4,386 (31.2%)	25,529 (37.2%)	< 0.001
Suburban	932 (8.5%)	16,885 (23.5%)	< 0.001	2,638 (18.8%)	15,179 (22.1%)	< 0.001
Urban	513 (4.7%)	34,484 (48.1%)	< 0.001	7,019 (50.0%)	27,978 (40.7%)	< 0.001
Medically underserved area‡	6,679 (60.6%)	57,446 (80.1%)	< 0.001	11,379 (81.0%)	52,746 (76.8%)	< 0.001
Health professional shortage area‡	3,291 (29.9%)	17,964 (25.1%)	< 0.001	4,081 (29.1%)	17,174 (25.0%)	< 0.001

*Presented as mean (standard deviation)
‡Presented as N (%)

Table 6: Census tract characteristics of by PrEP and pharmacy access measured by 30-minute drive time

	Dual desert	**PrEP desert, Pharmacy oasis**	**PrEP oasis, Pharmacy desert**	**Dual oasis**
Number of tracts (%)	632 (0.8%)	10,392 (12.6%)	21 (0.0%)	71,684 (86.6%)
Total population‡	1,473,085 (0.45)	34,655,391 (10.57)	65,228 (0.02)	291,639,713 (88.96)
Tract mean (SD)	2,330 (1,380)	3,330 (1,350)	3,110 (1,470)	4,070 (1,700)
% Female*	48.1 (5.69)	49.7 (4.62)	48.3 (6.71)	51.0 (3.54)
Median age - Male*	45.7 (10.8)	41.7 (8.69)	38.0 (10.1)	38.5 (8.40)
Median age - Female*	46.6 (10.6)	43.8 (8.59)	40.3 (11.7)	40.7 (8.80)
Race - % White*	68.1 (30.3)	78.6 (19.4)	35.3 (40.2)	59.6 (26.8)
Race - % Black*	2.10 (8.16)	7.03 (14.4)	2.07 (7.35)	14.4 (21.0)
Race - % Other*	29.8 (30.0)	14.4 (14.6)	62.6 (42.0)	26.0 (20.5)
Ethnicity - % Hispanic*	11.5 (16.6)	11.2 (18.2)	7.65 (15.2)	18.6 (21.5)
Median household income*	62,200 (25,600)	61,200 (19,100)	53,800 (22,900)	83,500 (40,600)
% Below poverty*	17.1 (12.2)	15.1 (9.63)	23.9 (13.2)	13.4 (11.4)
% Less than HS education*	11.8 (9.65)	12.4 (8.39)	15.7 (9.06)	11.3 (10.2)
% No insurance*	11.5 (8.50)	9.83 (6.84)	17.0 (11.0)	8.67 (7.55)
% Public insurance*	48.2 (14.3)	42.8 (11.8)	52.2 (14.2)	36.5 (14.5)
Gini index*	0.438 (0.0647)	0.429 (0.0611)	0.455 (0.0538)	0.420 (0.0696)
Area deprivation index*	106 (16.7)	106 (13.0)	119 (18.6)	98.7 (20.2)
Social vulnerability index*	0.543 (0.259)	0.530 (0.240)	0.732 (0.249)	0.496 (0.295)
% Unemployment rate*	4.20 (1.73)	3.85 (1.42)	4.77 (1.78)	3.71 (1.05)
Census region‡				
Midwest	90 (14.2%)	3,440 (33.1%)	3 (14.3%)	14,887 (20.8%)
Northeast	34 (5.4%)	652 (6.3%)	0 (0%)	12,987 (18.1%)
South	94 (14.9%)	4,647 (44.7%)	2 (9.5%)	27,251 (38.0%)
West	414 (65.5%)	1,653 (15.9%)	16 (76.2%)	16,559 (23.1%)
Urbanicity‡				
Rural	625 (98.9%)	8,954 (86.2%)	21 (100%)	20,315 (28.3%)
Suburban	5 (0.8%)	927 (8.9%)	0 (0%)	16,885 (23.6%)
Urban	2 (0.3%)	511 (4.9%)	0 (0%)	34,484 (48.1%)
Medically underserved area‡	467 (73.9%)	6212 (59.8%)	19 (90.5%)	57427 (80.1%)
Health professional shortage area‡	342 (54.1%)	2949 (28.4%)	15 (71.4%)	17949 (25.0%)
State with pharmacy-based PrEP legislation	315 (49.8%)	2,632 (25.3%)	7 (33.3%)	27,912 (38.9%)

*Presented as mean (standard deviation)
‡Presented as N (%)

Table 7: Census tract characteristics of by PrEP and pharmacy access measured by low access and low income

	Dual desert	**PrEP desert, Pharmacy oasis**	**PrEP oasis, Pharmacy desert**	**Dual oasis**
Number of tracts (%)	3,005 (3.6%)	11,038 (13.3%)	752 (0.9%)	67,934 (82.1%)
Total population‡	9,953,883 (3.04)	40,994,541 (12.5)	2,357,906 (0.72)	274,527,087 (83.7)
Tract mean (SD)	3,310 (1,570)	3,710 (1,470)	3,140 (1,450)	4,040 (1,710)
% Female*	50.1 (3.90)	51.5 (3.27)	49.9 (3.73)	50.8 (3.80)
Median age - Male*	40.6 (10.0)	35.8 (9.04)	41.3 (9.71)	39.4 (8.25)
Median age - Female*	42.9 (9.68)	38.8 (9.78)	43.2 (9.49)	41.4 (8.59)
Race - % White*	63.4 (29.8)	48.3 (27.8)	65.1 (29.4)	64.2 (25.8)
Race - % Black*	17.1 (24.6)	23.7 (27.2)	16.0 (23.9)	11.5 (18.2)
Race - % Other*	19.5 (21.4)	28.0 (21.7)	18.9 (21.8)	24.3 (20.0)
Ethnicity - % Hispanic*	14.0 (20.9)	23.8 (25.3)	14.3 (22.3)	16.8 (20.3)
Median household income*	46,800 (11,700)	47,500 (14,000)	47,200 (12,200)	87,800 (39,300)
% Below poverty*	21.2 (10.6)	22.7 (11.9)	21.2 (10.5)	11.7 (10.2)
% Less than HS education*	16.8 (9.60)	17.2 (11.1)	17.8 (10.3)	10.2 (9.38)
% No insurance*	12.5 (7.92)	12.7 (8.82)	12.0 (7.75)	8.01 (6.96)
% Public insurance*	48.7 (12.3)	46.8 (14.2)	49.2 (12.0)	35.2 (13.6)
Gini index*	0.447 (0.0611)	0.444 (0.0666)	0.452 (0.0609)	0.416 (0.0683)
Area deprivation index*	115 (13.2)	118 (14.7)	115 (13.9)	95.8 (18.4)
Social vulnerability index*	0.667 (0.209)	0.755 (0.191)	0.641 (0.217)	0.450 (0.280)
% Unemployment rate*	4.03 (1.27)	3.85 (1.15)	3.97 (1.21)	3.70 (1.09)
Census region‡				
Midwest	566 (18.8%)	2,779 (25.2%)	93 (12.4%)	14,982 (22.1%)
Northeast	191 (6.4%)	1,402 (12.7%)	69 (9.2%)	12,011 (17.7%)
South	1,679 (55.9%)	4,673 (42.3%)	467 (62.1%)	25,175 (37.1%)
West	569 (18.9%)	2,184 (19.8%)	123 (16.4%)	15,766 (23.2%)
Urbanicity‡				
Rural	2,160 (71.9%)	2,226 (20.2%)	628 (83.5%)	24,901 (36.7%)
Suburban	145 (4.8%)	2,493 (22.6%)	13 (1.7%)	15,166 (22.3%)
Urban	700 (23.3%)	6,319 (57.2%)	111 (14.8%)	27,867 (41.0%)
Medically underserved area‡	2,403 (80.0%)	8,976 (81.3%)	591 (78.6%)	52,155 (76.8%)
Health professional shortage area‡	1,080 (35.9%)	3,001 (27.2%)	264 (35.1%)	16,910 (24.9%)
State with pharmacy-based PrEP legislation	1,042 (34.7%)	3,521 (31.9%)	304 (40.4%)	25,999 (38.27%)

*Presented as mean (standard deviation)

‡Presented as N (%)

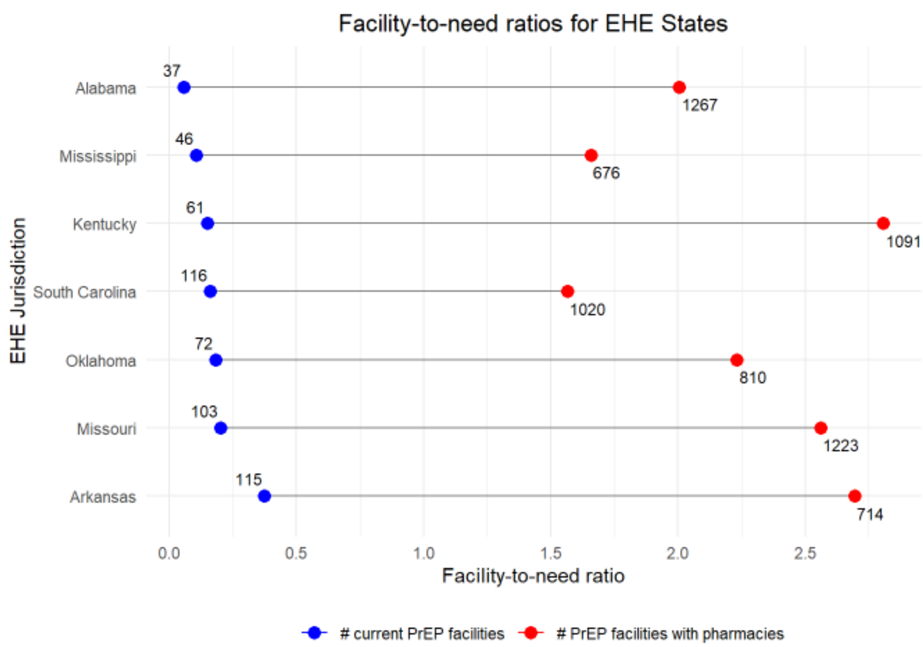
Our analysis using the low income and low access measure yielded similar findings to the first. We classified 14,043 (17.0%) census tracts as PrEP deserts, which were primarily located in the Midwest and South (Figure 3, Table 3, Table 5). Over 35,000 community pharmacies were located in 78.6% of these PrEP desert tracts, equating to 13.3% of tracts that were PrEP deserts, pharmacy oases (Table 5). These pharmacies were mostly chains, 2.7% were open 24 hours, and 17.9% offered non-English language services (Appendix B4). Compared to the 30-minute desert definition, we identified more census tracts as dual deserts (3.6% vs 0.8%), which were distributed across the Southeast and Mid-Atlantic regions (Figure 3).

In Appendix B3, we compare the results from our two primary measures of geospatial access. Approximately 75.5% of census tracts had the same desert classification with both measures, and the majority of discordant results were due to tracts classified as PrEP desert, pharmacy oasis under one definition and dual oasis in the other. Similarly, we observed wide variation in classifications with the additional access definitions in our sensitivity analyses (Appendix B5). Census tracts classified as dual deserts ranged from 0.2% (60-minute definition) to 55.4% (defined by presence within the tracts), and PrEP desert, pharmacy oasis tracts ranged from 3.2% to 38.3%. We found varying degrees of heterogeneity and distributions of desert and oasis tracts across the US, depending on the measure of access used (**Appendix B6**, **B7**, **B8**, **B9**, **B10**, **B11**, **B12**).

We noted several trends when comparing tract-level characteristics by desert status (Table 3, Table 4, Table 5). First, PrEP desert tracts were associated with lower socioeconomic status (e.g., higher poverty, unemployment, uninsurance, area deprivation, and social vulnerability) compared to PrEP oases. Under the low income and low access measure, higher percentages of Black and Hispanic populations lived in PrEP desert tracts compared to PrEP oasis tracts (Table 7), but this racial disparity could potentially with pharmacy-based PrEP (Table 5), as we observed lower percentages of Black and Hispanic residents in dual desert tracts compared to

PrEP desert, pharmacy oasis tracts. Furthermore, most PrEP deserts and dual deserts were in rural areas under the 30-minute definition, but PrEP deserts were concentrated in urban areas under the low income and low access definition. However, because many of these tracts have pharmacy access, the majority of remaining PrEP deserts (“dual deserts”) would shift to rural areas. Lastly, in our analyses of PrEP facility-to-need in EHE Phase I jurisdictions (Figure 4, Figure 5), we estimated that expanding HIV PrEP services via community pharmacies could increase PrEP facility-to-need ratios by 3.5 to 38.6-fold.

Figure 3: Facility-to-need ratios for EHE Phase I states



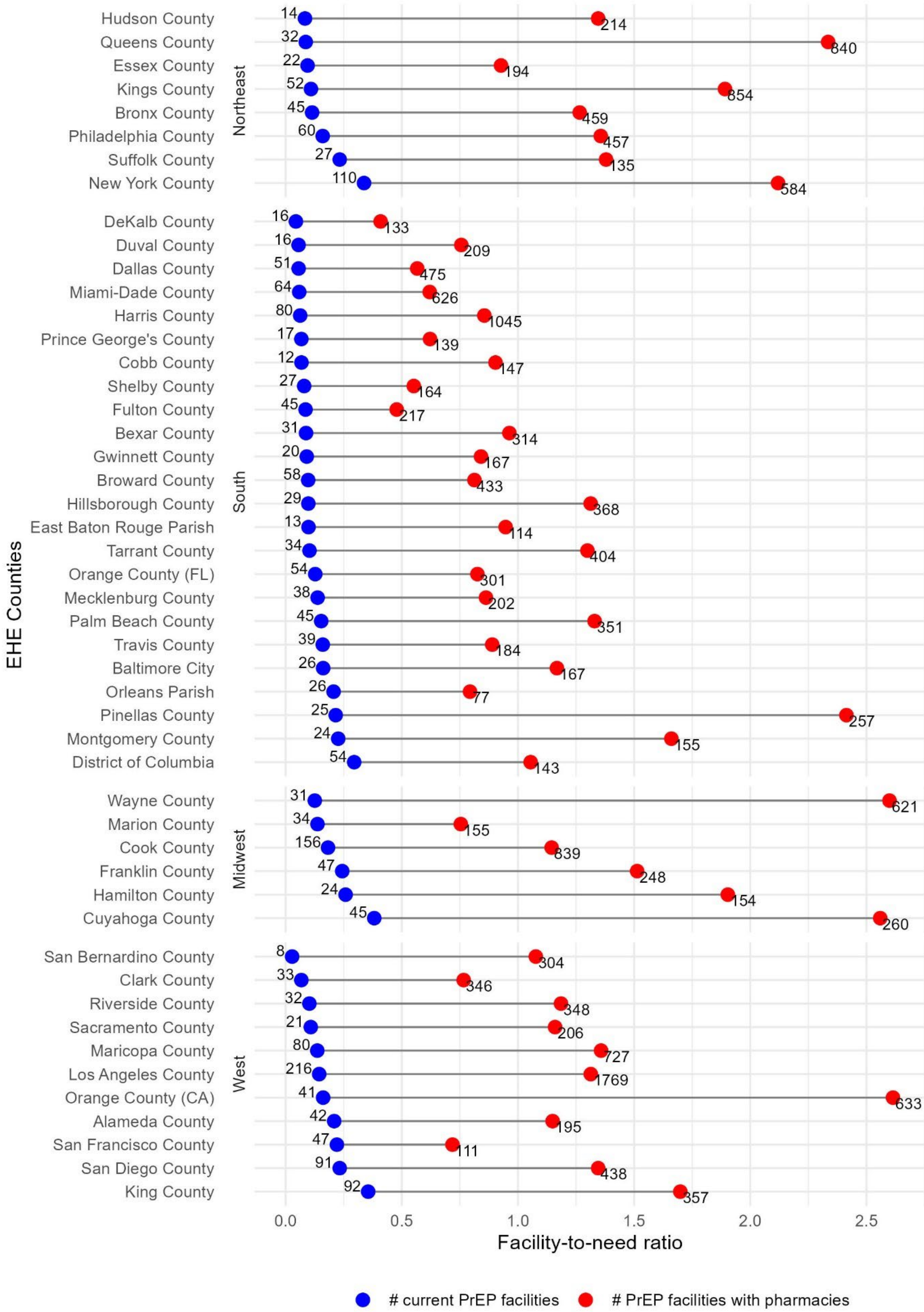


Figure 4: Facility-to-need ratios for EHE Phase I counties

Discussion

Our study builds upon the growing literature on PrEP access and evaluated geospatial accessibility to PrEP services using multiple access measures. In line with prior studies, we conclude that PrEP deserts persist in the US, and access to PrEP facilities remains inequitable, with the greatest proportion of PrEP deserts in rural or Southern areas with the 30-minute desert definition.[34,38,144] While we observed a decline in the prevalence of 30-minute PrEP deserts from a 2020 estimate of 17.3%,[122] more than one in eight census tracts were still classified as PrEP deserts under both primary access measures. To our knowledge, this is the first study to examine the potential geographic areas and populations that could benefit from a federal policy permitting community pharmacists to provide PrEP services across all US states.

We found that community pharmacies could drastically reduce the prevalence of PrEP deserts and potentially expand access to an additional 34.7 to 41.0 million people, but challenges would persist. Approximately 1.47 million people (< 1% of all tracts) would continue to reside in PrEP deserts using the 30-minute definition, with 9.95 million people (4.5% of tracts) under the low income and low access definition. Additionally, based on our calculations of PrEP facility-to-need ratios in the EHE phase I jurisdictions, we concluded that offering PrEP at community pharmacies could increase these jurisdictions' access to PrEP facilities by 3.5 to 38.6-fold, further supporting Harrington et al.'s seminal study focused in the Southeastern US.[139] Because the EHE phase I jurisdictions account for 50% of new US HIV diagnoses, this analysis also allowed us to gain insight into the potential impact of community pharmacies on PrEP access relative to each area's need and HIV burden.

The persistent geographic, racial, and socioeconomic disparities that shape access to essential healthcare services in the US like primary, hospital, pharmacy, and specialty care are also observed in HIV prevention.[130,131,145–150] Previous research has also linked healthcare access deserts and extended travel to healthcare with increased economic costs and poorer health outcomes.[41–43,151] The persistent PrEP deserts concentrated in the Midwest and South US identified in our study align with prior research that have demonstrated lower PrEP awareness, perceived HIV risk, and PrEP utilization in rural, Southern communities and areas where racial and socioeconomic HIV disparities are pronounced. [20,21,112,122,152–159] Additionally, past studies have suggested that unequal access to PrEP providers may contribute to disparities in PrEP utilization,[32–37] further emphasizing the importance of increased provider access.

Our analysis supports past PrEP and pharmacy access studies and demonstrates how these deserts disproportionately impact areas with lower socioeconomic status, as indicated by higher poverty, uninsurance, income inequality, and social vulnerability.[34,122,148] Our findings emphasize the profound wealth inequality observed in access, which reflect the access inequities reported across the broader healthcare landscape.[130,131,145–150,160] Furthermore, under the low income and low access measure, we found that PrEP desert tracts had notably higher percentages of black and Hispanic residents compared to PrEP oases. Because this distribution shifts when we consider the addition of pharmacies, pharmacy-based PrEP has the potential to alleviate some racial disparities in PrEP access. However, under the 30-minute definition, we note that the observed disparities would persist even with the addition of pharmacies, as tracts that were identified as dual deserts had the same or worse socioeconomic characteristics compared to PrEP desert, pharmacy oasis tracts.

Addressing barriers to PrEP access not only requires geospatial access to facilities, but also culturally sensitive healthcare providers such as community pharmacists who can provide nonmedical support including non-English language, short wait times, and extended operating hours that better align with community needs.[35,120,125,161] Past research has not only reported the willingness of pharmacists and pharmacy technicians to engage in PrEP-related activities like screening, evaluation, and initiation,[162–167] but patients have also shown receptiveness to being screened or prescribed PrEP in a community pharmacy setting.[139,168–170] Several of these studies emphasized the potential for pharmacy-based PrEP delivery to attract diverse patient populations, including younger individuals and black MSM, who account for the largest proportions of new HIV diagnoses. We also note that an individual's HIV risk and PrEP eligibility can change over time, and the convenience of seeing a PrEP provider without an appointment or long waits could notably increase use.[161,162]

However, we need to acknowledge the challenges of implementing pharmacy-based PrEP in real-world settings, which could severely limit its uptake and impact, as observed in California. Early assessments of California's PrEP legislation revealed that only 3% and 11% of surveyed pharmacies or pharmacy staff furnished PrEP under the policy in the 2 and 3 years, respectively, after policy enactment.[171,172] Implementing and scaling pharmacy-based PrEP requires additional training, resources, and workflow integration, potentially burdening pharmacies that already face resource constraints and staff burnout,[172–174] and lack of reimbursement for pharmacist services has also been noted as a barrier.[172,173,175] Pharmacists and pharmacy staff have not only expressed concerns around adequate training for evaluating and initiating patients on PrEP, but also for assisting with PrEP navigation (prescription coverage), fostering stigma-free environments, ensuring privacy, and processes of referral to other providers.[161,162]

To address these challenges, future work should focus on viable strategies to scale pharmacy-based PrEP nationwide, which will require optimizing community pharmacy workflows, ensuring adequate support staff and resources, and assessing cost-effectiveness and financial sustainability. Furthermore, federal recognition of pharmacists as healthcare providers and establishing reimbursement mechanisms could incentivize more pharmacies to offer PrEP services. Future research is also needed to determine the most appropriate measure of PrEP access, as our sensitivity analyses revealed a wide range of results and conclusions that may be drawn from different access definitions and thresholds. Lastly, because patients may face a myriad of other barriers to PrEP, we acknowledge simply increasing access does not automatically equate to increased PrEP utilization, and additional strategies may be needed to address these barriers and promote uptake.

Our study has several limitations warranting consideration. First, racial minorities and low-income communities disproportionately depend on alternative modes of transportation that we did not consider such as public transit, walking, and biking.[176] This could further exacerbate disparities observed in PrEP access and utilization. Our study was also constrained by the limitations of our two primary datasets. Since the NPINS PrEP directory does not include all facilities that can provide PrEP or the number of providers at each facility, we potentially overestimate the number of PrEP deserts. On the other hand, hundreds to thousands of pharmacies in the 2022 NCPDP data have closed, with additional impending closures, which likely overestimates the potential impact of community pharmacies. However, because we estimated that the 34.7 to 41.0 million individuals currently residing in PrEP deserts could gain access through 17,000 to 35,000 pharmacies, we concluded that community pharmacies would likely still make a substantial impact despite the closure of a proportion of these locations.

Conclusions

Our geospatial study strengthens existing research by employing multiple measures to evaluate nationwide access to PrEP facilities and community pharmacies. We found that if a federal policy was to empower community pharmacists to initiate PrEP for patients nationwide, the majority of PrEP desert tracts and their >34 million residents could gain access to PrEP facilities. Our findings emphasize the geographic, racial, and socioeconomic disparities in PrEP access and demonstrate the potential of community pharmacies to bridge access gaps, ultimately promoting PrEP uptake and supporting efforts to end the US HIV epidemic.

CHAPTER 4. The potential clinical and economic impact of community pharmacy-based HIV pre-exposure prophylaxis for men who have sex with men in Atlanta, Georgia

Abstract

Objectives: The ongoing US HIV epidemic highlights the need for innovative strategies to promote pre-exposure prophylaxis (PrEP) use and reduce HIV incidence. Community pharmacy-based PrEP provides opportunity to expand access to this highly effective preventative therapy. This study evaluated the potential health and economic impacts of community pharmacy-based PrEP for men who have sex with men (MSM) in the Atlanta metropolitan area, which has one of the highest burdens of HIV in the US.

Methods: We adapted a dynamic transmission compartmental model to a hypothetical policy change permitting community pharmacists to initiate PrEP for eligible MSM. We compared the addition of community pharmacy-based PrEP to the status quo (traditional clinic-based) and conducted scenario analyses with varying assumptions related to PrEP adherence, persistence, and telehealth delivery. Using a healthcare sector perspective we projected the costs (2023 US dollars) and outcomes of(HIV cases averted, quality-adjusted life-years [QALY]) over a 50-year time horizon.

Results: We projected 34,670 new HIV cases and 89.5 million QALYs, at a cost of $423.8 billion, in the Atlanta metropolitan area under our status quo scenario. The addition of community pharmacy-based PrEP has the potential to reduce HIV incidence by 13.5%, increase QALYs by 0.2%, and decrease costs by 0.02% over the 50-year time horizon. Our scenario analyses consistently found pharmacy-based PrEP to be either cost-savings or cost-effective compared to the status quo.

CONCLUSION: A policy permitting community pharmacies to provide PrEP services could lead to substantial clinical benefits and cost savings in Atlanta. However, additional research is needed to address challenges in scale-up and ensure financial sustainability to realize the full potential of pharmacy-based PrEP interventions. Our study offers valuable insights for policymakers to improve access to HIV PrEP and work towards ending the HIV epidemic in the US.

Background

While the US has made great strides in combating the HIV epidemic, there were still over Despite effective treatment and prevention methods, HIV continues to be a public health crisis in the US and globally, with over 37,500 new HIV diagnoses in 2022.[1] In response to the continued epidemic, the US launched Ending the HIV Epidemic (EHE) initiative in 2019, with the goal of reducing new HIV infections in the US by 90% by 2030 and averting an estimated 250,000 HIV cases.[4] US efforts are supported by substantial federal funding. For example, President Biden's Fiscal Year 2025 budget request allocated $7.75 billion for HIV, $1.0 billion for domestic HIV prevention, and $593 million for scaling up and implementing EHE initiatives.[79,177]

The HIV epidemic in the US presents unique challenges, including racial and geographical disparities in HIV prevention and treatment. The Centers for Disease Control and Prevention (CDC) estimated that men who have sex with men (MSM) accounted for 57.9% of people living with HIV (PLWH) and 67.3% of new diagnoses and that more than half of new diagnoses occur in the South in 2022.[1] These disparities highlight the need to understand and address the microepidemics within each local area, as each have unique demographics, epidemiology, transmission dynamics, and health system infrastructure.[178] It is also important to tailor localized interventions to address the specific needs of each microepidemic. Each area's healthcare infrastructure, resources, political climate, and provider scopes of practice should all be considered. In this study, we focus on the Atlanta metropolitan area, which has a disproportionately high burden of HIV (Appendix C1). With 25.4 new diagnoses for every 100,000 people in 2021, Atlanta ranked third in HIV incidence across all US metropolitan area,[179] reiterating the pressing need for multifaceted approaches to effectively combat the HIV epidemic.

Pre-exposure prophylaxis (PrEP) has emerged as a critical tool in the fight against HIV, with three effective therapies approved in the US since 2014, including two daily oral medications (generic and branded tenofovir disoproxil fumarate/emtricitabine [TDF/FTC] and branded tenofovir alafenamide/emtricitabine [TAF/FTC]) and a bimonthly injection (branded cabotegravir long-acting [CAB-LA]). [11,61,180] [6–8] PrEP is not only highly effective at reducing the risk of HIV acquisition,[6–9,117,118] but numerous studies have also demonstrated its cost-effectiveness. [12–14,181–183] However, uptake of PrEP remains low, with only 31.3% of the 1.21 million PrEP-eligible Americans on therapy in 2022.[1,61] PrEP coverage in Georgia remains suboptimal, with only 35.2% of eligible individuals on therapy in 2022.[1]

PrEP-eligible individuals face many barriers such as high costs, uninsurance, lack of PrEP awareness or perceived HIV risk, fear of stigma, and cultural and social norms.[9,24–26,28,31,120,121] Inadequate access to healthcare providers comfortable with having these conversations and prescribing PrEP further exacerbates disparities, especially in rural and Southern areas.[32–37] Siegler et al. estimated that 13% of MSM live more than 30 minutes away from a PrEP facility,[184] and analysis conducted in Chapter 3 identified 16.7% of Atlanta metro's census tracts, with approximately 965,000 residents, were low income and low access PrEP deserts, in which there are no PrEP facilities within: one mile for tracts with low vehicle access (>100 households without vehicles), two miles for tracts in urban areas, 10 miles for tracts in suburban areas, and 20 miles for tracts in rural areas.

Community (i.e, chain, independent, grocery) pharmacies present an opportunity to expand access to PrEP in communities with limited or no access, given their convenient proximity to many US residents, established infrastructure, availability outside of standard business hours, and embedment in communities. Numerous pharmacy-based PrEP programs have been established in the US since 2015 through mechanisms such as collaborative drug therapy agreements, institutional or state protocols, and state policies.[9,49,51,54–57,127] Since 2019, over 17 states have passed legislation authorizing pharmacists and pharmacies to provide PrEP care.[58,59] An early analysis suggests a notable increase in annual PrEP fills among states with these policies in place compared to those without,[60] but the full effects of pharmacy-based PrEP remains to be seen due to the recent policy enactments and the scale of individual programs. To address these gaps, we utilized a mathematical dynamic transmission model to assess the potential long-term clinical and economic impact of pharmacy-based PrEP interventions in the Atlanta metropolitan area.

Methods

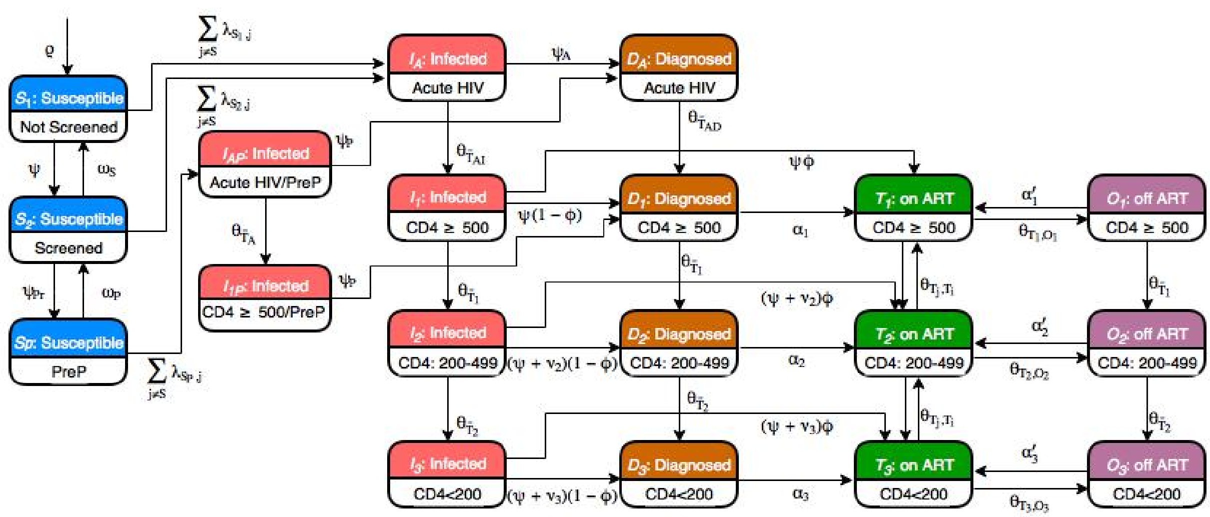
Overview

We adapted the Localized HIV Economic Model ("LEMHIV"), a mathematical model, to project the potential impact of pharmacy-based PrEP interventions over a 50-year time horizon (2023 to 2072) in order to estimate the long-term and downstream outcomes and costs. Our analysis focused on twenty counties in Georgia's Atlanta metropolitan area (Appendix C1) and evaluated several hypothetical pharmacy-based PrEP scenarios under varying assumptions.

HIV Transmission Model

The LEMHIV is a compartmental model that captures the HIV microepidemics of six cities or metropolitan areas that account for 25% of US PLWH: Seattle, Washington; New York City, New York; Los Angeles, California; Atlanta metropolitan, Georgia; Baltimore metropolitan, Maryland; and Miami-Dade, Florida.[182] The model simulates the disease progression of individuals aged 15 to 64 across 19 compartments representing the stages of: susceptible, acute HIV infection, undiagnosed infection, diagnosed infection, and diagnosed on and off antiretroviral therapy (Figure 6). Susceptible individuals may or may not undergo HIV screening, and the model includes three PrEP-related health states for MSM who are susceptible, experiencing acute HIV infection, or have undiagnosed HIV infection with a CD4 count above 500. HIV natural history and progression are simulated from acute HIV infection to chronic HIV by CD4 level. Population demographics are captured across 45 strata of: biological sex (female, male), race/ethnicity (black, Hispanic, non-Hispanic white and others), HIV risk behavior (MSM, people who inject drugs [PWID], MSM who inject drugs [MWID], heterosexual [HET]), and risk behavior intensity (low, high). Further, the model captures assortative and proportional mixing by race/ethnicity and sexual risk behavior intensity and includes interventions of PrEP, syringe service programs, and opioid agonist treatment. We initialized the model in 2015 and used the 2014 5-year American Community Survey (ACS) to inform the starting demographic distribution of the area. The model is publicly available, and additional details of the model conceptualization, parameterization, calibration, and prior cost-effectiveness analyses are well published.[19,185–191]

Figure 6: Localized HIV Economic Model Schematic[185,186]



Krebs et al. 2019; Zang et al. 2020

Simulated Scenarios

First, we established a status quo to reflect the current state of the HIV epidemic and prevention efforts, where PrEP services are provided in traditional settings, such as by physicians or at clinics. Subsequently, we simulated various pharmacy-based PrEP scenarios to gauge their potential impact. Model inputs for these scenarios were extrapolated from established pharmacy-based programs for PrEP and other services, including hormonal contraception, medication therapy management, and chronic disease management.[192–198] Patient out-of-pocket costs related to PrEP were not considered, given the US Preventative Services Task Force's Grade A recommendation for PrEP, which requires no cost-sharing from commercial and Medicaid plans.[62]In our primary comparison, we assumed that pharmacy-based PrEP would increase PrEP use linearly by 50% over a 24-month scale-up period, with sustained usage throughout the 50-year time horizon. Our assumption for uptake on an early assessment of state policies related to pharmacy-based PrEP, which found that PrEP prescriptions increased by 24% one year after and 110% two years after passage of these state legislation.[60] The more conservative estimate was chosen to account for potential lags in implementation and patient awareness, but we explored a range of uptake in probabilistic sensitivity analyses.

We assessed three additional pharmacy-based PrEP scenarios varying assumptions around the intervention. In our second comparison, we simulated enhanced PrEP adherence and persistence based on findings from studies evaluating pharmacist and pharmacy-based medication services.[48,51,199,200] However, some states' pharmacy-based PrEP policies have limits on the day supply of PrEP that pharmacists may initiate,[59] which may lead to disruption in care and one contributor of PrEP discontinuation. Therefore, for our third scenario, we also simulated a higher discontinuation rate to assess the potential impacts of those restrictions. Finally, recognizing the increasing prevalence of telehealth, we also included a scenario considering the potential impact of telemedicine-based pharmacy PrEP services. We assumed PrEP uptake would increase by 25% over 24 months with this intervention. Lastly, probabilistic sensitivity analyses with 2,000 parameter sets were conducted to characterize model uncertainty.

Cost-Effectiveness Analysis

We employed a healthcare sector perspective and evaluated the impact of adding pharmacy-based PrEP to existing efforts by estimating quality-adjusted life-years (QALYs), new HIV cases, and costs. For PrEP-related costs, we drew upon published literature, the Federal Supply Schedule, and Physician and Clinical Laboratory Fee Schedules from the Centers for Medicare and Medicaid Services (Table 8). [201,202] Our analysis incorporated the use of both generic and branded oral (TDF/FTC and TAF/FTC) and injectable (CAB-LA) PrEP formulations, with cost and efficacy parameters weighted based on the estimated distribution of each therapy's use.

Costs associated with pharmacy-based PrEP services derived from analogous community pharmacy-based services, as noted above. Considering the recommendations of the US Preventative Services Task Force (USPSTF), which advocate for HIV, sexually transmitted infection (STIs), and other laboratory tests prior to initiating PrEP, we incorporated the costs of rapid point-of-care or self-testing for HIV and STIs at initiation and every three months, as well as standard laboratory costs for all other indicated tests at initiation (e.g., creatinine clearance, hepatitis B). All remaining costs associated with each of the 19 health states and model inputs are detailed in previous LEMHIV publications.[185,186]

We inflated costs to 2023 US dollars and discounted costs and outcomes at 3% per year.[203,204] We calculated incremental cost-effectiveness ratios (ICERs) as cost per QALY gained and applied a willingness-to-pay threshold of $150,000 per QALY.[205] All model simulations and analyses were conducted in R (version 4.2.1). We report our analysis according to the

Consolidated Health Economic Evaluation Reporting Standards (CHEERS) 2022 guidelines (Appendix B).[206]

Table 8: Key PrEP inputs

Parameter	**Value (Range)**	**Source**
PrEP therapy		
Drug cost[1]		
Generic TDF/FTC, monthly (USD)	67.15 (30.00 – 325.01)	201
Brand TDF/FTC, monthly (USD)	1,107.18 (885.74 – 1,328.61)	201
Brand TAF/FTC, monthly (USD)	1,537.00 (1,306.00 – 1,703.00)	201
CAB-LA, bimonthly (USD)	3,869.01 (3,095.21 – 4,642.81)	181,183,207
Distribution of PrEP therapy		
Generic TDF/FTC users	55% (40 – 75%)	208–210
Brand TDF/FTC users	10% (5 – 30%)	208–211
TAF/FTC users	30% (8 – 40%)	208–211
CAB-LA users	5% (1 – 15%)	Assumed
Oral PrEP efficacy at optimal adherence (≥ 4 doses/week)	96% (90 – 99%)	185,192
CAB-LA efficacy	99% (90 – 99%)	117,212
Status quo		
HIV testing cost[1] (USD)	24.81 (17.10 – 28.90)	202
Other testing cost[1] (USD)	112.91 (17.27 – 135.49)	185,202
Adherence for oral PrEP	63% (50 – 81.9%)	185,213
Median duration on PrEP, days	238 (99 – 507)	211
Pharmacy-based PrEP		
Increase in uptake	50% (25% - 120%)	60
Point-of-care HIV/STI testing cost[1] (USD)	41.64 (35.49 – 47.89)	202,214,215
PrEP screening and consultation cost[1] (USD)	40.78 (25.42 – 86.09)	216–221
Additional pharmacy-based PrEP scenarios (with 50% uptake)		
Increased adherence	83.7% (70 – 95%)	51,211
Increased persistence: Mean duration on PrEP, days	302	51
Decreased persistence: Mean duration on PrEP, days	241	51
Telehealth PrEP		
Increase in uptake	25% (10% - 40%)	Assumed
In-home HIV test kit cost[1] (USD)	24.81 (21.09 – 28.53)	215
PrEP screening and consultation costs[1] (USD)	30 (15 – 100)	222
Discontinuation, probability	0.046	53,223

[1]Costs are reported in 2023 US dollars (USD)

CAB-LA, long-acting cabotegravir; HIV, human immunodeficiency virus; PrEP, pre-exposure prophylaxis; STI, sexually transmitted infection; TDF/FTC, tenofovir disoproxil fumarate/ emtricitabine; TAF/FTC, tenofovir alafenamide/ emtricitabine

Results

The results of our analyses are shown in Table 2. Under the status quo, the Atlanta metropolitan area was projected to experience 34,670 new HIV cases and 89.46 million QALYs over the 50-year period, with total healthcare costs amounting to $423.8 billion. In our primary comparison, implementing pharmacy-based PrEP was estimated to result in 29,979 new HIV cases, and 89.47 million QALYs. This translates to averting 4,690 (13.53%) HIV cases and gaining 15,384 (0.02%) QALYs. Total costs were projected to be $423.7 billion, indicating that pharmacy-based PrEP was cost-saving compared to the status quo. Our probabilistic sensitivity analysis revealed that the intervention was QALY saving in 85.7% of parameter sets, cost-effective in 4.0%, and dominant in 81.0% compared to the status quo (Figure 7).

In scenario analyses, enhancing adherence and persistence on PrEP led to additional QALYs gained and further reduced costs, resulting in cost-savings. Conversely, simulating decreased persistence yielded less favorable outcomes, with lower QALYs and increased costs; nonetheless, the intervention was considered cost-effective with an ICER of $37,337. Lastly, when we simulated telehealth-delivered pharmacy-based PrEP with lower uptake, QALYs increased modestly with a slight increase in costs, resulting in an ICER of $1,253, indicating cost-effectiveness.

Figure 7: Probabilistic sensitivity analysis for the primary comparison (pharmacy-based PrEP vs status quo)

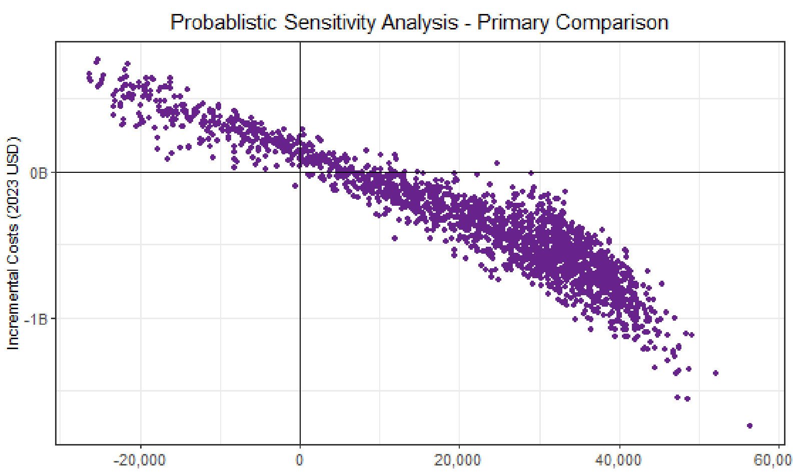


Table 9: Health and economic outcomes

Scenario	New HIV Cases, N (95% CI)	QALYs, N (95% CI)	Costs,[1] $ (95% CI)	Incremental			ICER, $/QALY
				New HIV cases, N (% Change)	QALYs, N (% Change)	Costs $ (% Change)	
Status quo	34,670 (24,110 – 8,395)	89.46 M (89.31 – 9.51 M)	423.8 B (420.3 – 430.3 B)	-	-	-	-
Pharmacy-based PrEP[2]	30,059 (22,872 – 2,284)	89.47 M (89.35 – 9.53 M)	423.7 B (417.6 - 434.1 B)	-4,611 (-13.3%)	15,384 (0.02%)	-59.69 M (-0.02%)	Dominant (-3,879)
Pharmacy-based PrEP[2] with increased adherence (83.7%) and reduced discontinuation (2.5%)	29,979 (17,001 – 7,965)	89.48 M (89.36 – 9.56 M)	423.1 B (418.7 – 429.2 B)	-4,694 (-13.5%)	20,601 (0.02%)	-461.3 M (-0.11%)	Dominant (-14,984)
Pharmacy-based PrEP[2] with increased discontinuation (15%)	31,001 (20,044 – 8,839)	89.47 M (89.35 – 9.53 M)	423.7 B (419.93 – 429.24 B)	-3,669 (-10.6%)	8,092 (0.01%)	302.1 M (0.07%)	37,337
Pharmacy-based tele-PrEP[3]	32,847 (20,090 – 8,927)	89.47 M (89.35 – 9.53 M)	423.8 B (419.89 – 429.21 B)	-1,823 (-5.3%)	6,155 (0.01%)	7.71 M (-0.01%)	1,253

B, billion; ICER, incremental cost-effectiveness ratio; M, million; QALY, quality-adjusted life-years; tele-PrEP, telehealth-based PrEP; USD, US dollars

[1]Costs are reported in 2023 USD

[2]With 50% increase in PrEP uptake over 24 months

[3]With 25% increase in PrEP uptake over 24 months

Discussion

Because of the substantial health and economic implications of the HIV epidemic, it is essential to explore and implement effective and cost-effective approaches to increase HIV prevention efforts and PrEP use. Our model-based analyses contribute to the evidence supporting non-traditional PrEP delivery methods in the US by evaluating the potential long-term clinical and economic impacts of community pharmacy-based PrEP. In the primary pharmacy-based PrEP scenario, we estimated that 14.5% of HIV cases would be averted and 0.02% QALYs would be gained compared to the status quo. These promising findings suggest that expanding access to PrEP through community pharmacies could not only offer substantial clinical benefits but also yield cost savings over time. Furthermore, across all our comparisons, we found that community pharmacy-based PrEP would be cost-saving or cost-effective regardless of our assumptions around adherence, persistence, and delivery method. Overall, this study provides insights into the potential health and economic benefits of community pharmacy-based PrEP services. It informs decision makers and stakeholders of a nontraditional method of PrEP delivery, ultimately contributing to the broader efforts to end the HIV epidemic in Atlanta and the US.

Our findings are consistent with existing research that have demonstrated the effectiveness and cost-effectiveness of PrEP therapy and pharmacy-based services separately. Prior studies have highlighted the cost-effectiveness of PrEP among high-risk MSM, with ICERs estimated to range from $4,745 to $50,000 per QALY gained.[12–14] Evidence from several cost-effectiveness studies and systematic reviews of pharmacist-provided interventions such as medication review, deprescribing, diabetes management, smoking cessation, hypertension, medication therapy management, and weight loss has consistently demonstrated their effectiveness and cost-effectiveness, or even cost-saving potential.[218,224–228] For example, a recent modeling study from Dixon et al. concluded that pharmacist-prescribing for managing hypertension could potentially save $1.137 trillion and 30.2 million life-years.[220] Additionally, prior research has also established the cost-effectiveness or cost-savings aspects of pharmacy-based HIV care,[47,215,229] but our study is the first to evaluate the cost-effectiveness of community pharmacy-based PrEP.

We focused our analysis on the Atlanta metropolitan area because of its high HIV prevalence and incidence, low PrEP utilization, and diversity in urbanicity and demographics across the region.[1,179] Because the policy landscape of pharmacy practice varies across states, each with distinct regulations and statutes governing pharmacist scope of practice, it is important to use localized models that can capture microepidemics and local policies. In Georgia, pharmacists currently lack recognition as healthcare providers, and mechanisms for pharmacy-based services such as PrEP are limited. However, exploratory efforts, like PrEP screening in community pharmacies, are underway in Atlanta.[230] Aim 2 identified that community pharmacies could expand access to PrEP for nearly 780,000 residents of the 965,000 living in PrEP deserts, and a recent examination of Georgian healthcare access revealed that community pharmacies could increase access to primary care services by more than 50% in 95% of the state's counties.[231] Thus, our study serves as a foundational step in highlighting the potential clinical and economic advantages of pharmacy-based PrEP in the Atlanta region. It not only supports the recognition of pharmacists as healthcare providers, but also emphasizes their crucial role in public health initiatives such as ending the HIV epidemic.

Our scenario analyses revealed that pharmacy-based PrEP could be cost-saving if it effectively promotes PrEP adherence and persistence. Conversely, our scenario with decreased persistence (i.e., increased discontinuation) revealed that pharmacy-based PrEP may not be cost-saving, but it would remain cost-effective. Therefore, policies that lend themselves to decreased persistence, such as limits on days' supply or treatment duration by pharmacists could lead to diminished health benefits and higher costs. However, we note that decreased persistence could also be due to changes in perceived HIV risk. Additionally, the COVID-19 pandemic highlighted the advantages of telehealth and PrEP delivery via telehealth ("tele-PrEP.).[232] Tele-PrEP can substantially expand access to PrEP, especially for rural communities that may lack access to both PrEP facilities and community pharmacies. Tele-PrEP programs in Iowa and Washington have successfully delivered PrEP through telehealth,[53,233,234] and a pharmacist-led tele-PrEP program at the Veterans Affairs demonstrated comparable health outcomes compared to clinic-based PrEP.[223] Our analysis revealed the cost-effective potential of pharmacy-based tele-PrEP for overcoming geographical barriers inherent to in-person PrEP services.

Pharmacists, pharmacy staff, and patients have reported interest in providing or receiving PrEP services at community pharmacies.[139,168–170] However, many barriers hinder scale up of pharmacy-based PrEP initiatives. First, solely enacting policies authorizing pharmacists to initiate PrEP does not guarantee effective implementation. Although California passed legislation permitting community pharmacists to dispense PrEP without a prescription, implementation has been limited.[171,172] Our findings demonstrate the wide scale health and economic benefits of pharmacy-based PrEP from healthcare sector and public health perspectives, but our study scope was limited and we did not consider the costs that would be incurred by pharmacies such as pharmacist and pharmacy staff time, training, equipment, and other startup costs.

Notable barriers to scale-up of pharmacy-based PrEP included constrained resources of time, staffing, and space, which are often compounded by reimbursement challenges.[172,173,175] Surveys and interviews with pharmacists and patients have highlighted concerns such as inadequate space, resources, PrEP training, and privacy.[31,162,169,170,235] Previous research focusing on the integration of novel pharmacy tasks or services has emphasized the substantial time and financial investments needed for real-world implementation.[216,236] Those operation and implementation costs may not be offset by third-party reimbursements and raise concerns about feasibility and sustainability. However, we first evaluate the cost-effectiveness of pharmacy-based PrEP from a wider lens to establish the initial evidence necessary to advocate for policy and reimbursement updates among policymakers and payers. For example, several states have enacted legislation permitting pharmacists to bill as healthcare providers, while others have policies requiring certain payers to cover pharmacist services such as PrEP care.[59,237,238]

The Kelley-Ross Pharmacy Group's One-Step PrEP® program has successfully provided PrEP care since 2015.[51] It demonstrates the feasibility and long-term sustainability of community pharmacy-based PrEP, given the appropriate workflow and billing mechanisms. Future work should focus on devising efficient scale-up strategies and ensuring financial sustainability, as well as developing reimbursement mechanisms to incentivize the implementation and expansion of pharmacy-based PrEP services. Generating revenue through these services could help promote adoption within pharmacies and ensure viable, long-term impact in combating the HIV epidemic. Furthermore, our scenario analyses highlight the importance of adherence and persistence for successful PrEP programs, and additional research is needed to understand how programs can strengthen and promote these to reach the full potential of pharmacy-based PrEP programs. Additionally, it is essential to consider the patient perspective when designing pharmacy-based programs to scale-up. A recent study employing a discrete choice experiment and latent class analysis revealed heterogeneity among MSM's preferences for various aspects of pharmacy-based PrEP, stressing the importance of tailoring programs to meet diverse patient needs.[239]

Our study has several notable strengths. This analysis is particularly timely considering recent legislative changes at the state level. Our findings are relevant and applicable to current health policies already being enacted or currently being considered. Second, our use of a complex calibrated and validated dynamic transmission model parameterized specifically to the Atlanta metropolitan area allows us to capture the intricacies of the region's microepidemic. This allows us to more accurately assess the potential impact of interventions, accounting for local factors such as population demographics, transmission dynamics, and healthcare infrastructure. Of particular importance is the ability to account for herd immunity in the model, which enables us to comprehensively evaluate the downstream effects of pharmacy-based PrEP on both costs and outcomes. By considering the broader implications beyond individual patients on PrEP, such as the prevention of secondary HIV transmission, we provide a more holistic understanding of the potential benefits of these pharmacy-based PrEP interventions.

We also note several limitations in this study. First, our analysis focused exclusively on MSM and MWID and excluded other high-risk populations such as heterosexual men, women, and PWID. Therefore, our estimates do not capture the full potential of pharmacy-based PrEP, and future work should expand upon this analysis by incorporating additional these risk groups. We also did not include costs related to pharmacy personnel time, capacity, and opportunity costs, Further, we were constrained the compartmental model's ability to capture individual-level characteristics, histories, and heterogeneity within factors such as age groups, risk groups, and patient preferences. Lastly, because our study focused on the Atlanta metropolitan area's population and HIV microepidemic, our findings are not generalizable to other geographic regions, as each area has its own unique demographic, microepidemic, and policy profile.

The HIV epidemic continues to be a major public health crisis in the US, and the associated high clinical and economic costs emphasize the need for further expansion of PrEP uptake in populations at high risk of HIV acquisition. Based on our cost-utility analysis, we conclude that pharmacy-based PrEP would be clinically beneficial and cost-saving in the Atlanta metropolitan area. The ability for community pharmacists and pharmacies to screen and initiate PrEP would drastically expand the public's access to PrEP facilities, ultimately helping to prevent the spread of HIV to known high-risk individuals and contributing to the EHE's efforts to reduce HIV incidence. Our study also contributes valuable evidence for policymakers. By demonstrating the potential benefits of expanding pharmacists' roles in HIV prevention, we build the case for broader scopes of practice at both state and national levels. Our findings emphasize the crucial role of community pharmacists and pharmacies in public health initiatives such as ending the HIV epidemic.

CHAPTER 5. Summary

PrEP is a safe, effective method to prevent HIV acquisition, but uptake is consistently low after more than a decade of PrEP availability. The ongoing US HIV epidemic and its racial, geographic, and socioeconomic disparities emphasize the need to approach PrEP care through different lenses and consider innovative delivery methods. This dissertation contributes to the literature surrounding PrEP utilization and nontraditional PrEP delivery, and it serves as a foundation for future studies.

The HIV epidemic has demonstrated the complex interplay of SDOH and biological, psychological, and interpersonal factors, but published investigations of factors connected to PrEP use have been limited to individual-level analyses or assessing a constrained set of population-level characteristics. In Chapter 2, I conducted an exploratory, ecological analysis using population-level data related to HIV, geography, and a comprehensive collection of social determinants of health to identify factors that are predictive of PrEP utilization. Using the best performing model, XGBoost, I was able to determine the most important features for PrEP prediction such as access to healthcare providers and facilities, health behaviors, and racial distributions. Additionally, the SHAP values provide insight into the magnitude, direction, and potentially nonlinear impact of each feature on the predicted PrEP utilization rate. Policymakers could consider focusing resources and efforts on understanding and targeting the features with the highest SHAP values for their county, as these had the greatest impact on the predicted PrEP use rate.

Chapters 3 and 4 build upon the currently limited evidence base for community pharmacy-based PrEP in the US. I found that 36.1 million to 50.95 million people in the US live in PrEP deserts, depending on the measure used. However, if a federal policy empowered community pharmacists to initiate PrEP, 34.66 to 40.99 million people would gain access to over 17,000 to

35,000 PrEP access points where there are currently none. However, 1.47 to 9.95 million individuals would still be without access. By demonstrating the capacity for community pharmacies to bridge these PrEP access gaps, I make the argument for expanding pharmacists' abilities and recognition as healthcare providers. I further strengthen this argument by demonstrating the cost-savings or cost-effectiveness of community pharmacy-based PrEP in the Atlanta metropolitan area, which has one of the highest HIV burdens in the country. However, it should be noted that pharmacy closures could substantially limit the reach and impact of community pharmacy-based PrEP in Atlanta and nationwide.

Overall, this compilation of work provides insights into PrEP utilization and the potential impact of community pharmacies, there are still many questions that are left unanswered. Chapter 2 provides a basis for future studies to further investigate these important predictors, their relationships, and potential causal impact on PrEP use. These will allow researchers and public health officials to identify potential targets of future PrEP interventions.

Additionally, there are many future steps for community pharmacy-based PrEP. First, policy evaluation of the effects of relevant pharmacy-based state legislation is needed. Because the first pharmacy-based legislation was recently passed in 2019, this dissertation was not able to assess the effectiveness of these policies due to data limitations and implementation delays. A rigorous evaluation of the effects of these policies would provide further evidence of the widespread effects of these policies. Next, future work is needed on the implementation side of pharmacy-based PrEP, such as workflow optimization, support staff, and reimbursement mechanisms, as noted within the discussions of Chapters 3 and 4. PrEP-focused training programs, such as the American Pharmacists Association's new Pharmacy-Based HIV Prevention Services Certificate Training Program, are essential for preparing pharmacists to provide PrEP care. Additionally, training on cultural competency, anti-stigma, and non-discrimination will be critical for successful scale-up and impact.

In order to increase PrEP uptake and meet EHE goals to end the HIV epidemic, it is crucial to better understand drivers of PrEP use and develop innovative delivery mechanisms. This dissertation lays the groundwork for future research on PrEP utilization and provides an evidence base for policies to expand pharmacy-based PrEP nationwide.

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Appendix

Appendix A: Supplementary material for Chapter 2

Appendix A1: Data sources

We extracted census tract demographic estimates related to gender, race, and age from the 2020 US Census[85] and several socioeconomic measures from the five-year 2022 American Community Survey (ACS) such as median household income, poverty, public assistance, Gini index, education level, internet access, and insurance coverage.[86] Each county's metropolitan status was based on the 2023 Rural-Urban Continuum code of 1, 2, or 3, as defined by the US Department of Agriculture (USDA).[108] We followed the US Census Bureau's classification for census region and division.[240]

For the SDOH included in our final dataset, we used two sources that previously compiled measures of SDOH from other databases. First, we used the University of Wisconsin Population Health Institute's County Health Rankings and Roadmaps, which is a database that contains county-level SDOH estimates such as premature death, food environment index, flu vaccination, air pollution, housing problems, child care burden, and traffic volume.[87] The second aggregated data source we used was the Agency for Healthcare Research and Quality's (AHRQ) Social Determinants of Health Database. This source provided estimates for features including uncontrolled toxic sites, healthcare provider and facility density, drug-related deaths, emergency department visits, and violent crimes.[109]

We pulled additional measures of healthcare access from the Health Resources and Services Administration (HRSA), which publicizes medically underserved area designations, health professional shortage areas designations, and Ryan White recipients.[99,100] We calculated PrEP facility density (number of facilities per 100,000 of the population) as a proxy for PrEP access, using data derived from the CDC's National Prevention Information Network and population estimates from the 2020 US Census.[97] We obtained county social vulnerability indices from the CDC/ Agency for Toxic Substances and Disease Registry (ATSDR),[105] 2022 unemployment rates from the Bureau for Labor Statistics[96], and area deprivation index from the *sociome* R package, available from researchers at the Cleveland Clinic.[104] The University of Michigan Institute for Social Research publishes census-tract historic redlining mapped to 2020 Census boundaries, and this measure was included in our dataset by taking the median historic redlining score for each county.[107] Features capturing adult literacy and numeracy were based on a survey of adult skills and sourced from the Program for the International Assessment of Adult Competencies (PIAAC).[103]

We utilized state-level estimates for data not available at the county-level. KFF (formerly Kaiser Family Foundation) provided information on state HIV-related features such as HIV mortality, Medicaid coverage of HIV testing and PrEP, Medicaid expansion status, HIV deaths, number of HIV syringe exchange programs, state sex and HIV education policies, and minor's authority to consent to STI services.[88–94] Indicators for states' PrEP drug assistance programs (PrEP DAP) were drawn from NASTAD.[95] We included the CDC's categories for state HIV and STD criminalization laws related to potential HIV exposure: "criminalize or control behaviors through HIV-specific statutes and regulations," "criminalize or control behaviors through STD/communicable/infectious diseases specific statutes", "sentence enhancement statues", and none.[101,102] We drew upon the Human Rights Campaign Foundation's equality index for state LGBTQ+ advocacy categories: "working towards innovative equality", "solidifying equality", "building equality", and "high priority to achieve basic equality".[106]

Appendix A2: Correlation between PrEP rate and features

Feature	Pearson's Correlation Coefficient	p-value		Feature	Pearson's Correlation Coefficient	p-value
Number of Ryan White recipients	0.483	< 0.001		Motor vehicle deaths per 100k population	-0.155	< 0.001
Traffic volume	0.473	< 0.001		Teen births per 1k females	-0.148	< 0.001
HIV prevalence rate	0.422	< 0.001		Gender pay gap (% per $)	0.145	< 0.001
Total census population	0.330	< 0.001		% of census tracts that are 30-minute PrEP desert	-0.138	< 0.001
% Race – Asian	0.315	< 0.001		Federally Qualified Health Centers Rate	0.138	< 0.001
Mental health providers per 100k pop	0.289	< 0.001		Rural health clinic rate	-0.136	< 0.001
% Households without vehicles	0.287	< 0.001		% Ethnicity - Hispanic	0.132	< 0.001
% Education – Bachelor's degree	0.279	< 0.001		Healthy food environment index	0.130	< 0.001
% Education – High school	-0.266	< 0.001		Premature death	-0.126	< 0.001
% Adults - Obese	-0.264	< 0.001		HIV treatment facility rate	0.119	< 0.001
Indian health service facility rate	0.250	< 0.001		Primary or secondary syphilis rate	0.119	< 0.001
Historic redlining	0.244	< 0.001		Census region – West	0.115	< 0.001
Median household income	0.244	< 0.001		Membership associations per 10k pop	-0.112	< 0.001
% Access to exercise	0.242	< 0.001		Medically underserved area	-0.111	< 0.001
% Race – White	-0.233	< 0.001		Gini index	0.111	< 0.001
% Females in state who have ever tested for HIV	0.232	< 0.001		PrEP provider rate	0.110	< 0.001
% Adults - Smokers	-0.230	< 0.001		% Veterans	-0.109	< 0.001
% Household – owner occupied	-0.228	< 0.001		PrEP DAP – copay coverage	0.106	< 0.001
% Males in state who have ever tested for HIV	0.226	< 0.001		% Adults poor or fair health	-0.102	< 0.001
% Households with severe problems	0.224	< 0.001		Mental health facility rate	0.102	< 0.001
SVI – Race percentile	0.219	< 0.001		Early, nonsecondary syphilis rate	0.202	< 0.001

Feature	Pearson's Correlation Coefficient	p-value		Feature	Pearson's Correlation Coefficient	p-value
Primary care providers per 100k pop	0.205	< 0.001		School segregation index	0.187	< 0.001
Clinical nurse specialist per 100k pop	0.168	< 0.001		Metropolitan area	0.183	< 0.001
Dentists per 100k pop	0.163	< 0.001		% Internet – No access	-0.173	< 0.001
% Below poverty	-0.098	< 0.001		% Education – Less than high school	-0.068	0.001
Gonorrhea rate	0.094	< 0.001		% Insurance – private	0.068	0.001
Suicide deaths per 100k pop	-0.093	< 0.001		% Adults insufficient sleep	-0.063	0.003
Numeracy percentile	0.092	< 0.001		Deaths due to injury per 100k pop	-0.062	0.004
SVI – transportation percentile	0.091	< 0.001		% Adults with diabetes	-0.060	0.005
Nurse practitioner rate	0.090	< 0.001		State building towards equality	-0.057	0.007
SVI – housing percentile	-0.090	< 0.001		Air pollution	0.055	0.010
Has syringe exchange program	0.089	< 0.001		Toxic site treatment	0.054	0.010
Chlamydia rate	0.088	< 0.001		Firearm fatalities per 100k pop	-0.052	0.014
HIV, HCV and HTCA facility	0.087	< 0.001		% Household – live alone	0.051	0.017
% Adults - Excessive drinkers	0.086	< 0.001		Hospital emergency department rate	-0.050	0.018
Physician assistant rate	0.084	< 0.001		% Female Medicare w/ mammography	-0.049	0.020
Median female age	-0.083	< 0.001		State HIV/STI education: Parental notice required	0.046	0.030
Advance nurse rate	0.090	< 0.001		Median male age	-0.045	0.035
HCV treatment facility	0.078	< 0.001		Psychiatric hospital rate	-0.044	0.036
Working towards equality	0.077	< 0.001		Inpatient alcohol rehab rate	-0.043	0.040
Average school funding gap ($)	0.075	< 0.001		% Limited English speaker	0.039	0.063
Preventable hospital stays per 100k Medicare	-0.075	< 0.001		State mandates sex education	0.039	0.064
Census region – Northeast	0.073	< 0.001		State is solidifying equality	0.039	0.068
HIV law - Sentence Enhancement	0.102	< 0.001		% Medicare FFS with flu vaccination	0.039	0.068
Literacy	0.100	< 0.001		SVI – overall percentile	0.037	0.079

Feature	Pearson's Correlation Coefficient	p-value		Feature	Pearson's Correlation Coefficient	p-value
Drug morality rate	0.072	< 0.001		% Females	0.037	0.080
% Race – Black	0.072	< 0.001		Certified mental health center rate	-0.036	0.085
State high priority equality	-0.070	0.001		% PLWH receiving HIV care	-0.036	0.086
% Census tracts that are low income and low access PrEP deserts	-0.069	0.001		Drinking water violation	0.035	0.097
% Race – American Indian/Alaskan Native	0.069	0.001		SVI – socioeconomic status percentile	0.034	0.106
% Children single parent household	0.033	0.118		Medicaid expansion state	-0.016	0.448
State HIV law - None/General Criminal Statutes	0.033	0.121		% Median income for childcare costs	-0.016	0.463
% Race – Pacific Islander	0.033	0.122		% Driving deaths with alcohol	0.015	0.477
State HIV law - Criminalize or Control Actions Through STD/Communicable/Infectious Diseases Specific Statutes	-0.031	0.141		% Insurance – None	0.009	0.655
State HIV education – mandated	-0.030	0.152		% Live births with low birthweight	-0.008	0.698
Number of syringe exchange programs	0.028	0.179		Health provider shortage area	-0.008	0.698
State HIV/STI education - Parental consent required	0.028	0.189		% Unemployment rate	-0.007	0.733
Hospital rehabilitation rate	0.027	0.195		% Households – with children	0.007	0.758
State HIV/STI education – opt out	0.027	0.205		Hospital ambulance rate	-0.006	0.769
PrEP DAP – copay	0.026	0.219		Census region – South	0.002	0.926
% PLWH virally suppressed	-0.024	0.267				
Childcare centers per 1k under 5	0.018	0.390				

Appendix A3: Characteristics of training and test sets

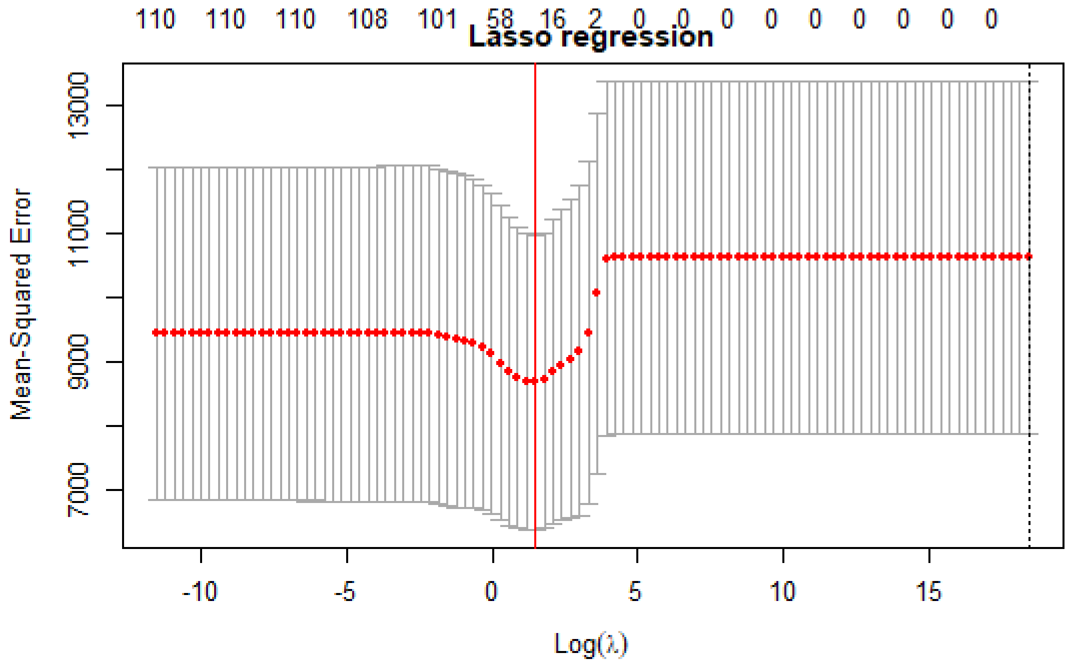
	Training set (N=1,670)	**Test set (N=557)**	**Overall (N=2,227)**
PrEP rate[1], Median (Min - Max)	67.0 (0 – 1,850)	66.0 (0 - 568)	67.0 (0 – 1,850)
HIV prevalence rate[1], Median (Min - Max)	140 (0 – 2,380)	135 (1.00 - 1800)	139 (0 – 2,380)
Population, Median (Min - Max)	41,400 (216 – 9,940,000)	48,300 (1,530 – 3,290,000)	43,000 (216 – 9,940,000)
Census Region, N (%)			
Midwest	461 (27.6%)	172 (30.9%)	633 (28.4%)
Northeast	146 (8.7%)	56 (10.1%)	202 (9.1%)
South	836 (50.1%)	263 (47.2%)	1,099 (49.3%)
West	227 (13.6%)	66 (11.8%)	293 (13.2%)
Metropolitan area, N (%)	803 (48.1%)	305 (54.8%)	1108 (49.8%)
% Female, Median (Min - Max)	50.6 (34.5 - 57.7)	50.5 (8.8 - 55.2)	50.6 (34.5 - 57.7)
Age (years) - Female, Median (Min - Max)	42.0 (24.4 - 60.5)	42.1 (20.4 - 68.9)	42.0 (20.4 - 68.9)
Age (years) - Male, Median (Min - Max)	39.5 (24.1 - 59.1)	39.4 (22.5 - 67.7)	39.5 (22.5 - 67.7)
% Race - White, Median (Min - Max)	80.2 (3.26 – 97.2)	80.4 (16.8 – 97.4)	80.3 (3.26 – 97.4)
% Race - Black, Median (Min - Max)	3.69 (0 – 87.5)	3.87 (0 – 80.8)	3.73 (0 – 87.5)
% Race - Asian, Median (Min - Max)	0.731 (0 – 43.0)	0.79 (0.091 – 32.4)	0.75 (0 – 43.0)
% Race - American Indian and Alaskan Native, Median (Min - Max)	0.436 (0 – 93.8)	0.437 (0.0632 - 23.4)	0.436 (0 - 93.8)
% Race - Pacific Islander, Median (Min - Max)	0.0383 (0 - 14.0)	0.038 (0 – 12.1)	0.0381 (0 - 14.0)
% Ethnicity - Hispanic, Median (Min - Max)	5.16 (0.50 – 97.7)	5.34 (0.632 - 95.2)	5.20 (0.501 – 97.7)
% Households living below poverty, Median (Min - Max)	13.5 (1.7 - 55.8)	13.0 (3.92 - 33.8)	13.4 (1.7 - 55.8)
Household income (USD), Median (Min - Max)	62,000 (28,800 – 170,000)	64,000 (31,700 – 145,000)	62,400 (28,800 – 170,000)
Unemployment rate[1], Median (Min - Max)	3.50 (0.900 - 13.0)	3.50 (1.80 - 14.7)	3.50 (0.900 - 14.7)
Gini coefficient[2], Median (Min - Max)	0.447 (0.348 - 0.598)	0.445 (0.371 - 0.604)	0.447 (0.348 - 0.604)
% Household - Single occupant, Median (Min - Max)	14.8 (1.21 - 28.9)	14.7 (3.60 - 29.2)	14.8 (1.21 - 29.2)

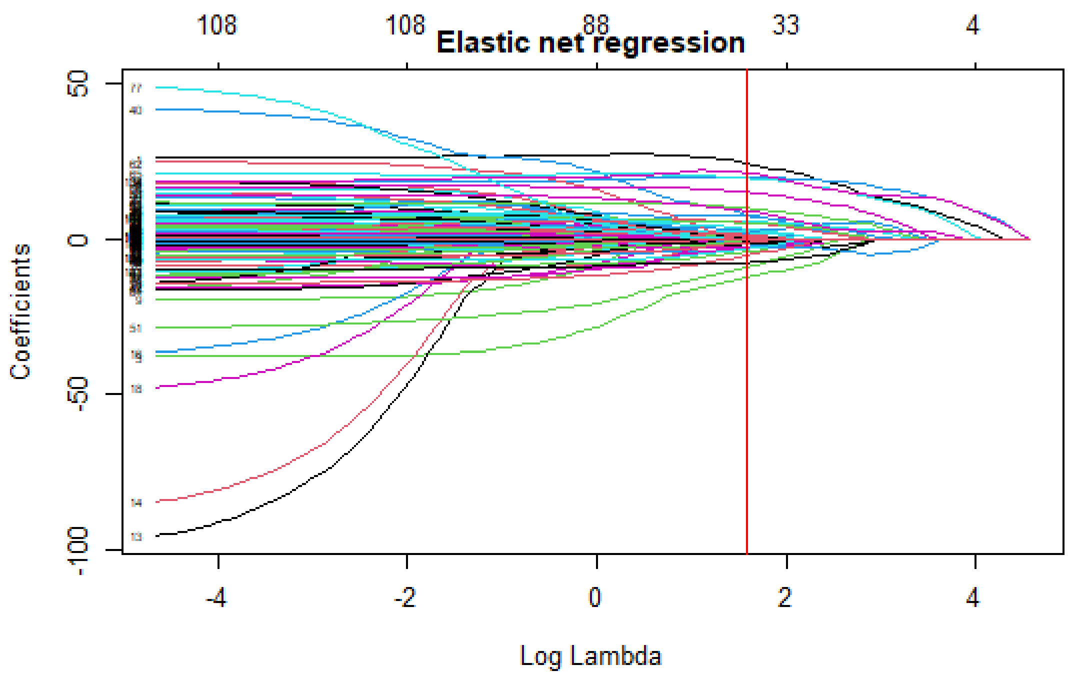
% Without internet, Median (Min - Max)	12.4 (0 - 49.8)	12.0 (1.79 - 38.2)	12.3 (0 - 49.8)
Overall social vulnerability index percentile[3], Median (Min - Max)	55.0 (0.0300 - 99.8)	48.6 (0.250 - 99.9)	53.6 (0.0300 - 99.9)
% Education - Less than high school, Median (Min, Max)	10.6 (1.79 - 39.6)	10.1 (2.44 - 42.4)	10.5 (1.79 - 42.4)
PrEP provider rate[1], Median (Min - Max)	0 (0 - 38.0)	0 (0 - 14.8)	0 (0 - 38.0)
Primary or secondary syphilis rate[1], Median (Min - Max)	6.50 (0 - 267)	6.60 (0 - 112)	6.50 (0 - 267)
Chlamydia rate[1], Median (Min - Max)	340 (0 - 2790)	326 (5.40 - 1460)	334 (0 - 2790)
Early, non-secondary syphilis rate [1], Median (Min - Max)	4.40 (0 - 221)	4.70 (0 - 117)	4.40 (0 - 221)
Gonorrhea rate[1], Median (Min - Max)	113 (0 - 2300)	114 (0 - 791)	114 (0 - 2300)
State with Medicaid expansion, N (%)	1,138 (68.1%)	373 (67.0%)	1,511 (67.8%)
State with PrEP DAP copay coverage, N (%)	439 (26.3%)	154 (27.6%)	593 (26.6%)
State with PrEP DAP medication coverage, N (%)	396 (23.7%)	138 (24.8%)	534 (24.0%)

PrEP, pre-exposure prophylaxis; PrEP DAP, PrEP drug assistance program; USD, US dollars
[1]Rates are reported as per 100,000 of the county population.
[2]The Gini index is a measure of income inequality ranging from 0 to 1, with higher values representing greater inequality.
[3]The overall social vulnerability index percentile gives the

Appendix A4: Lambda cross-validation for lasso and elastic net regressions

These are the results of the 10-fold cross-validation for lambda, plotted as the log(lambda). The optimal lambda is indicated by the red lines.





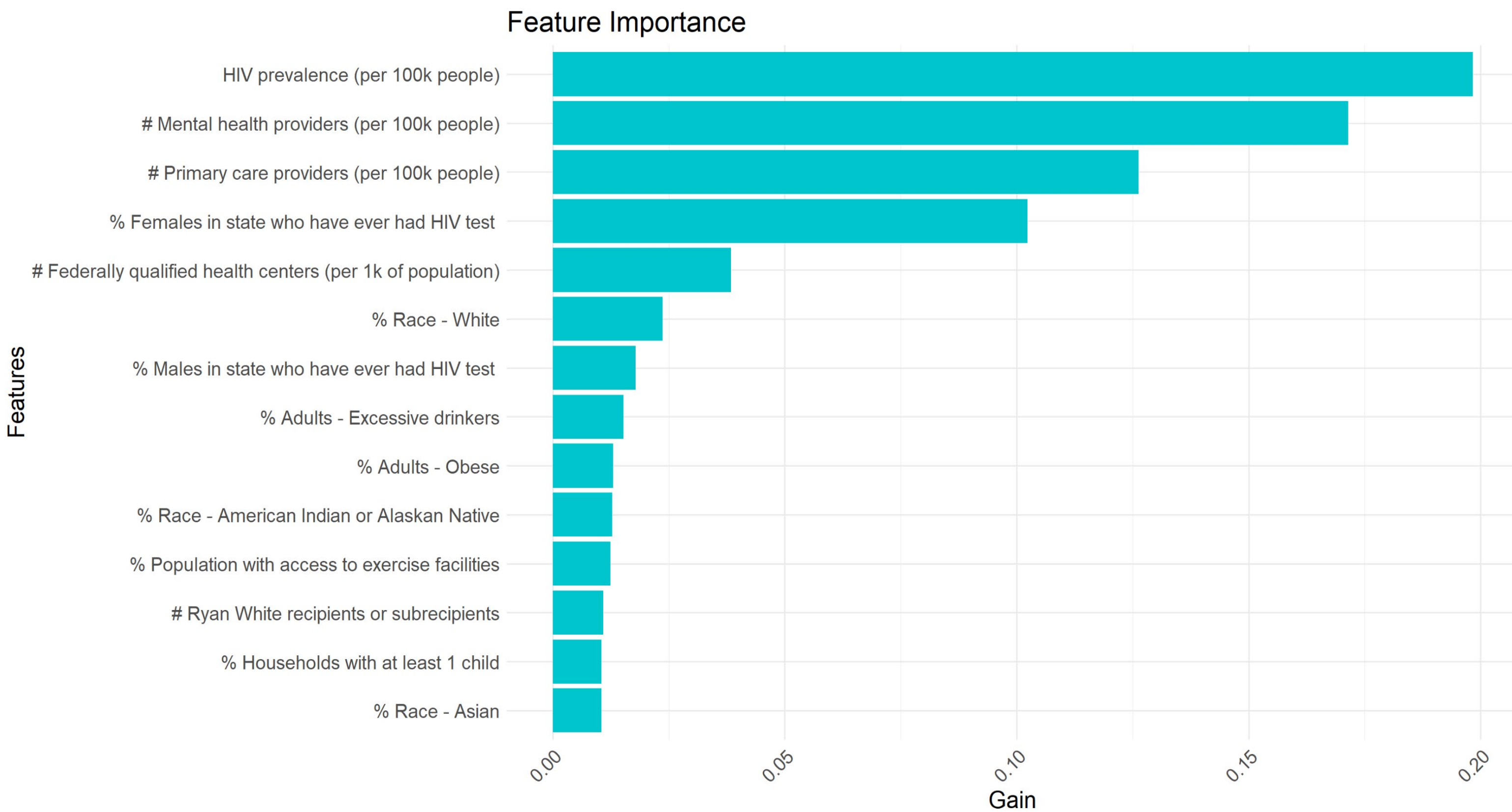
Appendix A5: Cross-validated XGBoost tuning parameters

Hyperparameter	**Optimal value**
Maximum depth	2
Eta	0.267
Subsample	0.895
Colum sample by tree	0.606
Minimum child weights	15
Maximum delta step	6

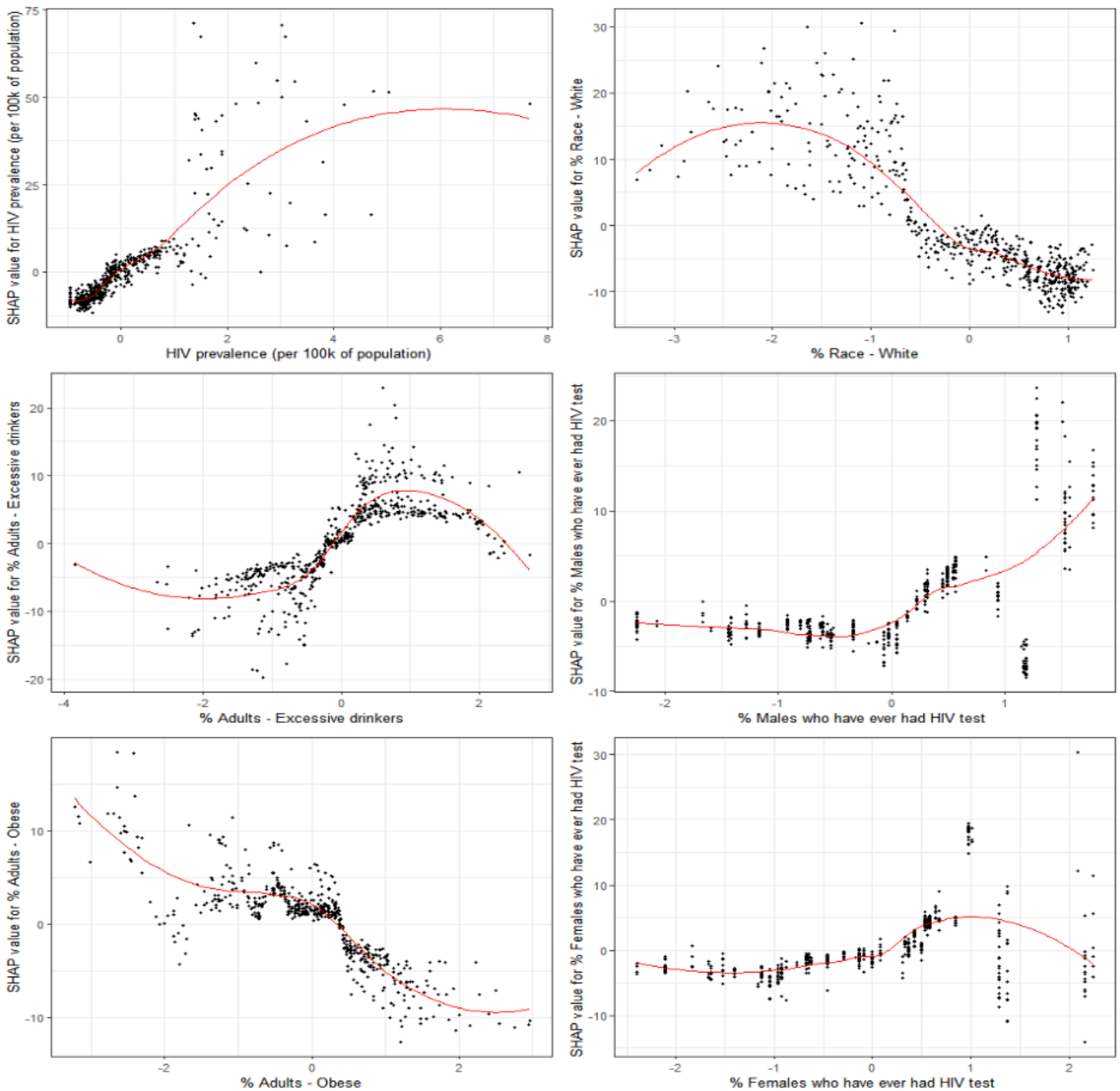
Appendix A6: Training and test set RMSE

	Training RMSE	**Test RMSE**
Simple linear regression	79.14	65.94
Recursive feature elimination – linear regression	81.48	71.35
Stepwise selection regression	83.63	66.13
Forward selection	80.39	71.94
Backward selection	83.70	66.13
Lasso	78.17	78.50
Elastic net	78.73	78.66
Random forest	75.68	66.21
RFE – random forest	67.72	70.99
Decision trees	82.83	74.54
XGBoost	67.67	64.42

Appendix A7: Feature importance plot based on XGBoost



Appendix A8: SHAP dependence plots for the top six important features



Appendix B: Supplementary material for Chapter 3

Appendix B1: Ending the HIV Epidemic Phase I jurisdictions

Counties			States	
Arizona	**Massachusetts**		Alabama	Missouri
Maricopa County	Suffolk County		Arkansas	Oklahoma
California	**Michigan**		Kentucky	South Carolina
Alameda County	Wayne County		Mississippi	
Los Angeles County	**Nevada**			
Orange County	Clark County			
Riverside County	**New Jersey**			
Sacramento County	Essex County			
San Bernadino County	Hudson County			
San Diego County	**New York**			
San Francisco County	Bronx County			
Florida	Kings County			
Broward County	New York County			
Duval County	Queens County			
Hillsborough County	**North Carolina**			
Miami-Dade County	Mecklenburg County			
Orange County	**Ohio**			
Palm Beach County	Cuyahoga County			
Pinellas County	Franklin County			
Georgia	Hamilton County			
Cobb County	**Pennsylvania**			
DeKalb County	Philadelphia County			
Fulton County	**Tennessee**			
Gwinnett County	Shelby County			
Illinois	**Texas**			
Cook County	Bexar County			
Indiana	Dallas County			
Marion County	Harris County			
Louisiana	Tarrant County			
East Baton Rouge Parish	Travis County			
Orleans Parish	**Washington**			
Maryland	King County			
Baltimore City	**Washington, D.C.**			
Montgomery County				
Prince George's County				

Appendix B2: Measures of access

	Definition	Threshold
Census tract-level measures		
Drive time	The drive time from the census tract centroid is greater than the threshold	15 minutes
		30 minutes*
		45 minutes
		60 minutes
Combination of distance and low income	Low income: ≥20% poverty rate, median family income ≤ 80% the state median income, or if in a metropolitan area, median family income ≤ 80% the area's median family income Low access: the closest facility is greater than the distance threshold for at least 33% of census tract population	0.5 miles for areas with low vehicle access (>100 households don't own a vehicle), 1 mile for urban, 5 miles for suburban, and 10 miles for rural
		1 mile for areas with low vehicle access, 2 miles for urban, 10 miles for suburban, and 20 miles for rural*
Distance alone	Distance from the census tract centroid is greater than the thresholds for the area	1 miles for tracts with low vehicle access (>100 households don't own a vehicle), 2 miles for urban tracts, 10 miles for suburban tracts, and 20 miles for rural tracts
		0.5 miles for tracts with low vehicle access, 1 miles for urban tracts, 5 miles for suburban tracts, and 10 miles for rural tracts
		2 miles for urban tracts, 5 miles for suburban tracts, and 15 miles for rural tracts
Presence in tract	There is a facility within the geographical bounds of the census tract	
No convenient access		10% live further than 2 miles for urban, 10% live further than 5 miles for suburban, and 30% live further than 15 miles for rural
EHE jurisdictions measures		
Facility-to-need ratio	The number of services facilities divided by the number of new HIV diagnoses	

* Designates definitions used in the primary analysis

Rationale for the primary measures of access

We considered several factors when we defined our primary access measures, including urgency of the service, patient willingness to travel, and frequency of use relative to other resources and health services.[130,132,241] For our thresholds for accessibility, we considered the urgency and cadence of visits associated with PrEP services to be similar to primary care and opted for a 30-minute drive time threshold. This aligns with previous studies on PrEP deserts and other healthcare services like breast imaging, hospital care, and perinatal care.[34,38,112,122,149,242–244] Furthermore, because past research has not assessed patients' willingness to travel for PrEP care, we used insights from a health care consumer survey in Washington state, which indicated that patients were willing to spend 28.4 minutes and 20.4 miles traveling for routine care.[245] For our combination measure using income and distance, we doubled the distances commonly used for food and pharmacy deserts because of our understanding that PrEP services, while important, are generally less critical than access to food and pharmacies. Additionally, the frequency of visits for patients on PrEP is typically lower than grocery stores and pharmacies, with recommended monitoring occurring every 3 months.[62]

We also note that SDOH associated with desert status varied across our measures, which is consistent with a recent study by Luan et al. that utilized 25 different measures to evaluate spatial accessibility to PrEP in New York City.[246] The investigators identified inconsistent associations between SDOH and PrEP access across their measures. The primary exception was the consistent linkage of income inequality to lower PrEP access, which aligns with our findings.

Appendix B3: Comparison of classification results using the two primary access definitions

		Low Income and Low Access Definition			
		Dual desert	**PrEP desert, Pharmacy oasis**	**PrEP oasis, Pharmacy desert**	**Dual oasis**
30-Minute Drive Time Definition	**Dual desert**	190 (0.23%)*	42 (0.05%)	20 (0.02%)	380 (0.46%)
	PrEP desert, Pharmacy oasis	1,239 (1.5%)	1,869 (2.3%)	169 (0.2%)	7,115 (8.6%)
	PrEP oasis, Pharmacy desert	7 (0.008%)	0 (0%)	5 (0.006%)	9 (0.011%)
	Dual oasis	1,569 (1.9%)	9,127 (11.0%)	558 (0.67%)	60,430 (73.0%)

* N (% of total tracts)

Appendix B4: Characteristics of pharmacies in PrEP deserts

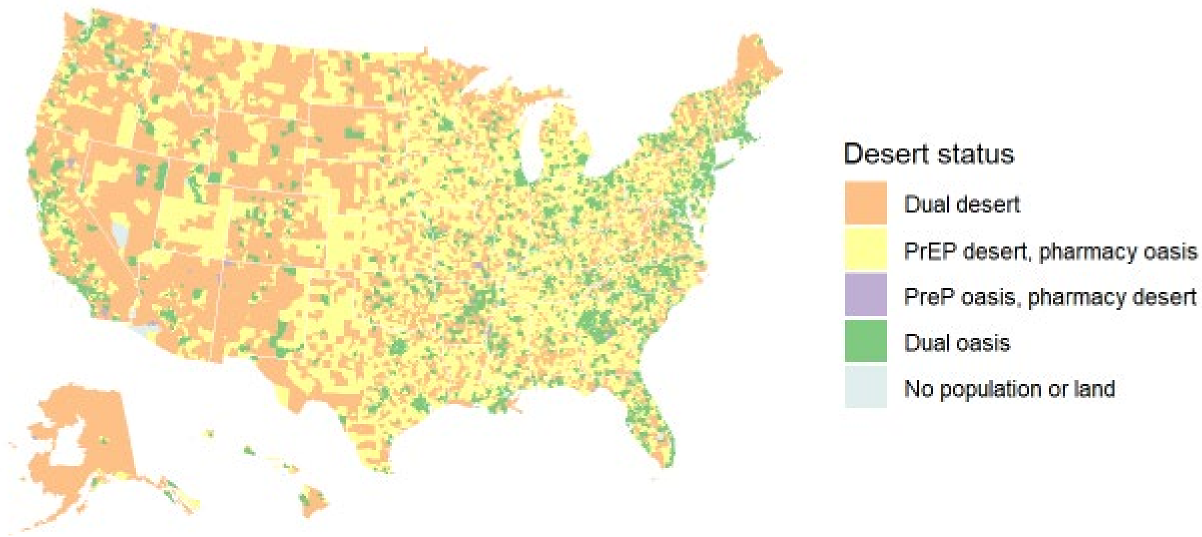
	Pharmacies in 30-minute PrEP deserts (N= 17,620)	**Pharmacies in low income and low access PrEP deserts (N = 35,137)**
Pharmacy type, N (%)		
Chain	9,858 (55.9%)	21,775 (60.9%)
Franchise	263 (1.5%)	463 (1.3%)
Independent	7,499 (42.6%)	12,899 (36.1%)
Missing	0 (0%)	590 (1.7%)
Open 24 hours, N (%)	243 (1.4%)	967 (2.7%)
Non-English language support, N (%)	1,911 (10.8%)	6,403 (17.9%)

Appendix B5: Desert status - summary

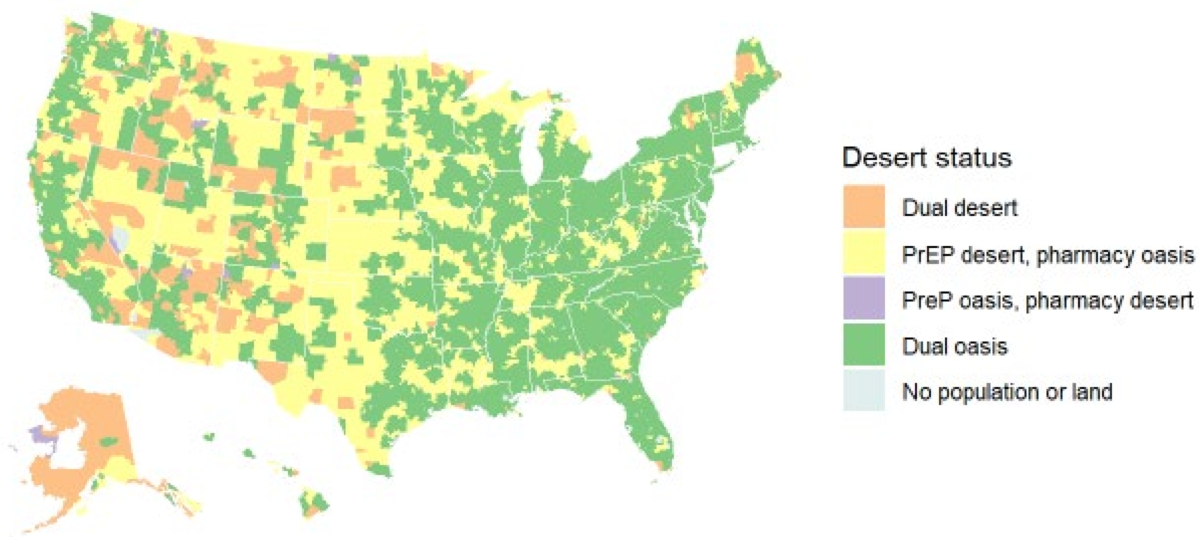
	Time			Low income and low access*	Distance*		Convenient access	Located within tract
	15 minutes	45 minutes	60 minutes	0.5 / 1 / 5 / 10	0.5 / 1 / 5 / 10	1 / 2 / 10 / 20		
Dual desert	4,056 (4.9%)	297 (0.4%)	158 (0.2%)	8,708 (10.5%)	24,893 (30.1%)	9,452 (11.4%)	8,594 (10.4%)	45,823 (55.4%)
PrEP desert, Pharmacy oasis	18,417 (22.3%)	5,226 (6.3%)	2,683 (3.2%)	9,155 (11.1%)	31,643 (38.2%)	36,114 (43.7%)	22,469 (27.2%)	31,666 (38.3%)
PrEP oasis, Pharmacy desert	66 (0.1%)	15 (0.0%)	9 (0.0%)	268 (0.3%)	642 (0.8%)	3,807 (4.6%)	3,246 (3.9%)	1,139 (1.4%)
Dual oasis	60,190 (72.8%)	77,191 (93.3%)	79,879 (96.6%)	64,598 (78.1%)	25,551 (30.9%)	33,356 (40.3%)	48,420 (58.5%)	4,101 (5.0%)

* Presented as miles from population-weighted census tract centroid in low vehicle access tracts / rural tracts / suburban tracts / urban tracts

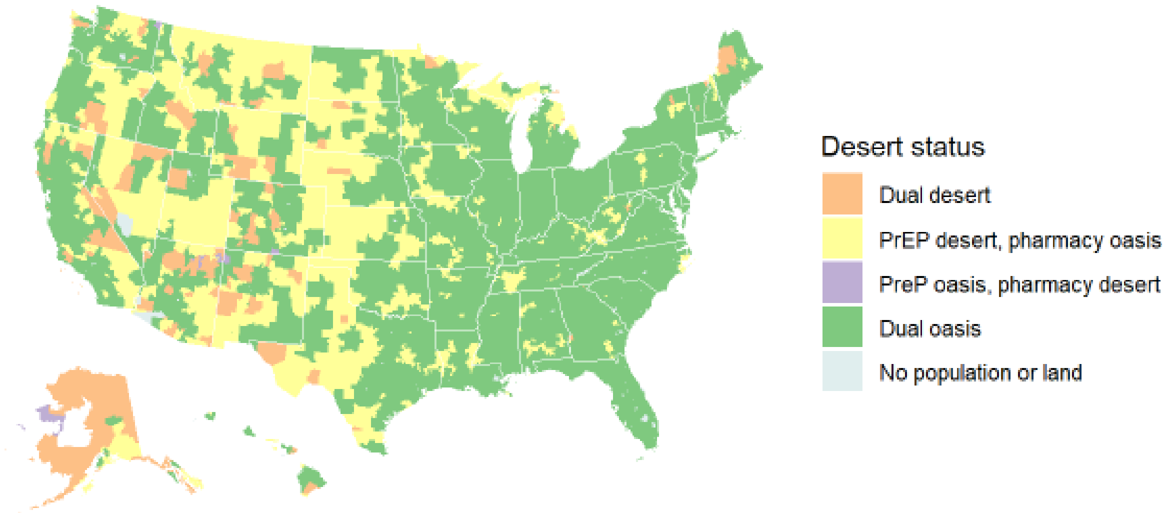
Appendix B6: Census tract-level deserts defined by 15-minute drive



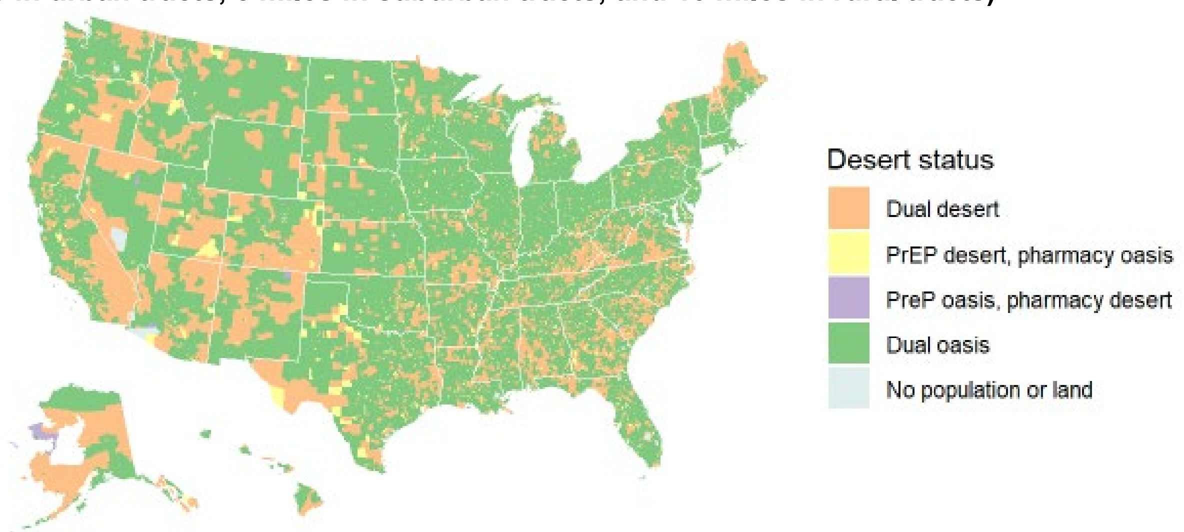
Appendix B7: Census tract-level deserts defined by 45-minute drive



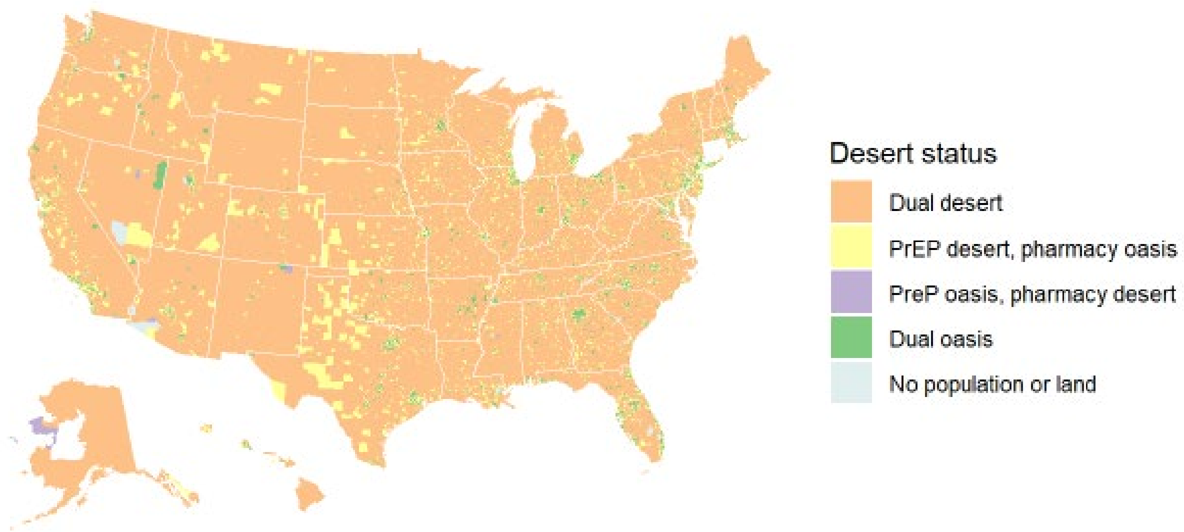
Appendix B8: Census tract-level deserts defined by 60-minute drive



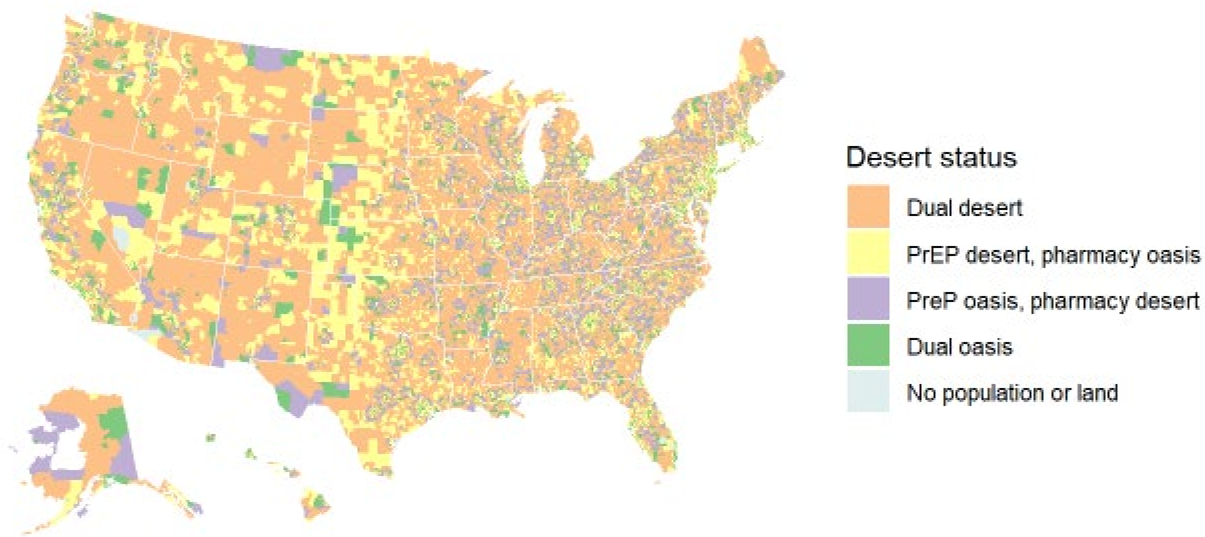
Appendix B9: Census tract-level deserts defined by low income and low access at original food and pharmacy desert distances (0.5 miles in low vehicle access tracts, 1 mile in urban tracts, 5 miles in suburban tracts, and 10 miles in rural tracts)



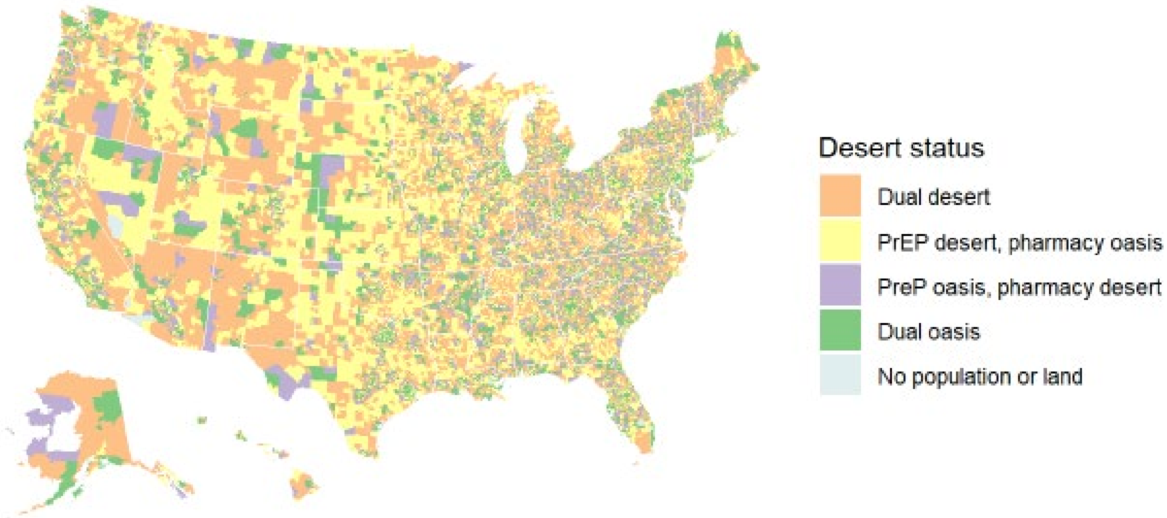
Appendix B10: Census tract-level deserts defined by distance only with thresholds: 0.5 miles in low vehicle access tracts, 1 mile in urban tracts, 5 miles in suburban tracts, and 10 miles in rural tracts



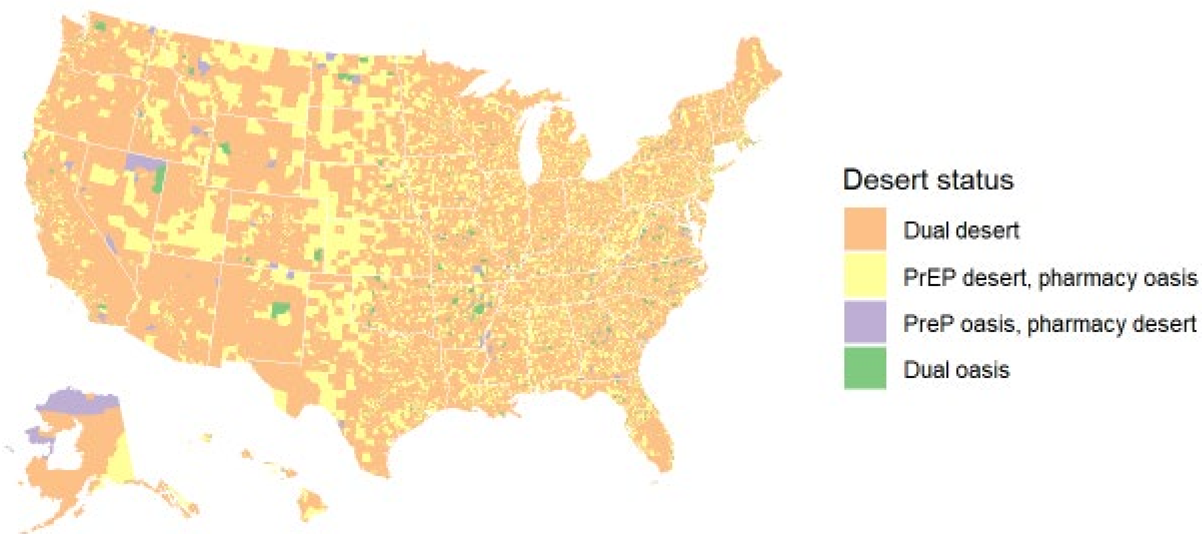
Appendix B11: Census tract-level deserts defined by distance only with thresholds: 1 miles in low vehicle access tracts, 2 mile in urban tracts, 10 miles in suburban tracts, and 20 miles in rural tracts



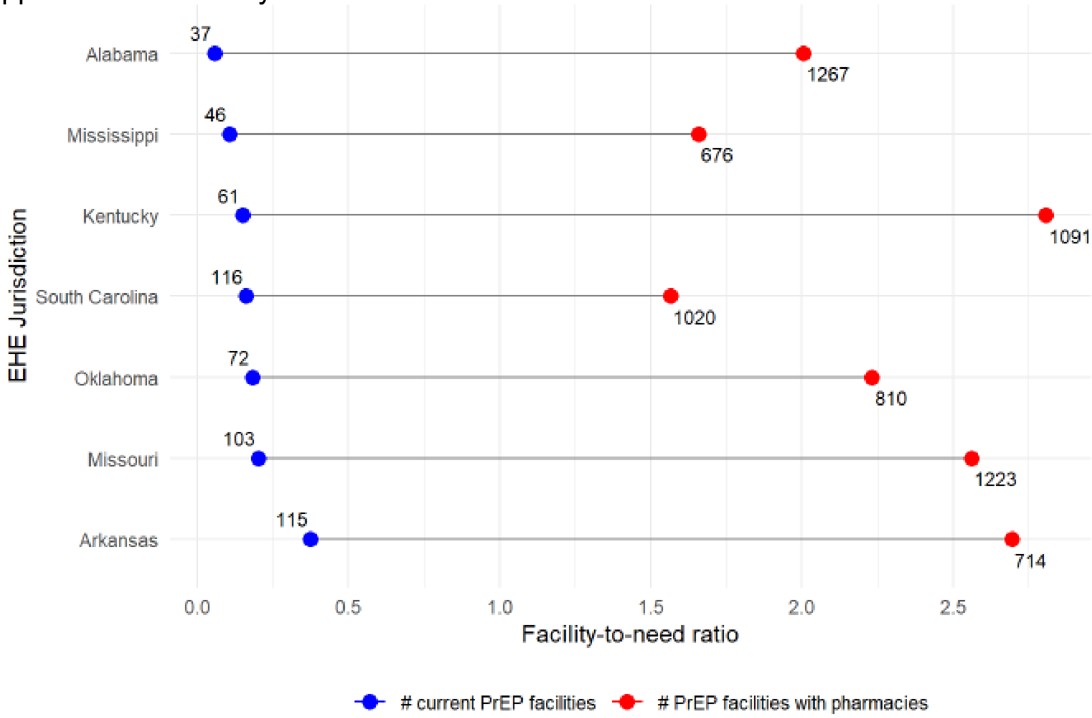
Appendix B12: Census tract-level deserts following CMS's definition of convenient access



Appendix B13: Census tract-level deserts defined by presence of PrEP facilities or pharmacies within the census tract



Appendix B14: Facility-to-need ratios for EHE Phase I states



Appendix B15: Results of additional regressions

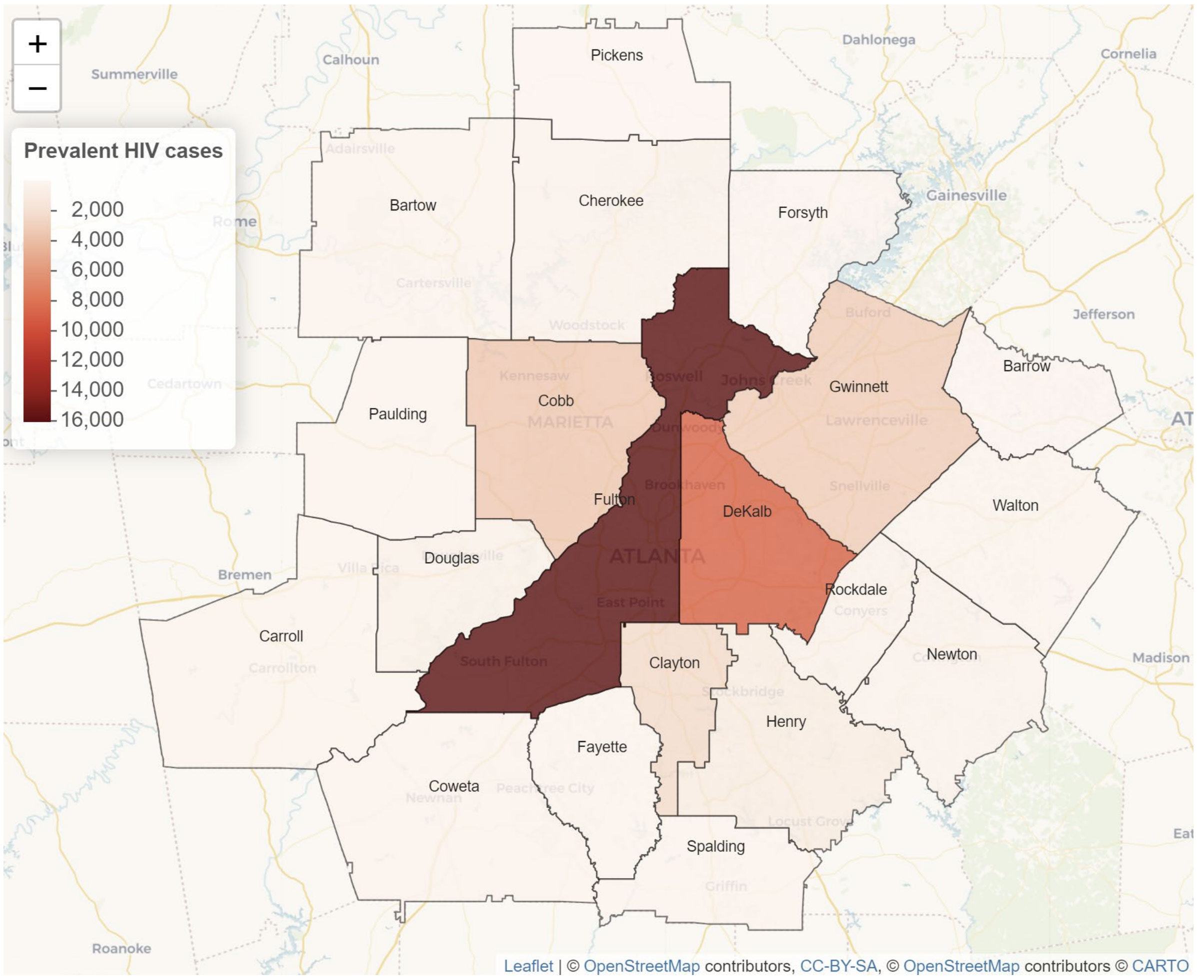
Additional analyses using logistic regression were conducted to identify SDOH associated with PrEP deserts. The outcome variable was binary PrEP desert (yes/no).

	30-minute deserts		Low income and low access	
Predictors	**Odds Ratios (95% CI)**	**p**	**Odds Ratios (95% CI)**	**p**
(Intercept)	0.03 (0.03 – 0.03)	**<0.001**	0.04 (0.04 – 0.04)	**<0.001**
Census tract population	0.7 (0.68 – 0.72)	**<0.001**	1.16 (1.13 – 1.19)	**<0.001**
% Female	0.84 (0.82 – 0.86)	**<0.001**	1.03 (1.01 – 1.05)	**0.004**
Median male age	1 (0.96 – 1.04)	0.887	0.98 (0.95 – 1.02)	0.325
Median female age	0.91 (0.87 – 0.95)	**<0.001**	1 (0.97 – 1.04)	0.836
% Race – White	0 (0.00 – 5.2E26)	0.635	4.5E+32 (0.17 – 1.16E32)	0.055
% Race – Black	0 (0.00 – 3.4E19)	0.621	6.5E+24 (0.27 – 1.5E24)	0.055
% Race - Other	0 (0.00 – 3.99E26)	0.626	7.3E+24 (0.32 – 1.7E24)	0.055
% Ethnicity - Hispanic	1.08 (1.02 – 1.14)	**0.01**	0.84 (0.81 – 0.88)	**<0.001**
Gini index	1.04 (1.01 – 1.07)	**0.019**	0.88 (0.86 – 0.90)	**<0.001**
Median household income	0.36 (0.33 – 0.39)	**<0.001**	0.03 (0.02 – 0.03)	**<0.001**
Area deprivation index	1.2 (1.14 – 1.26)	**<0.001**	0.54 (0.51 – 0.58)	**<0.001**
% Education - Less than high school	0.88 (0.83 – 0.92)	**<0.001**	1.12 (1.08 – 1.16)	**<0.001**
% Insurance - None	1.46 (1.32 – 1.62)	**<0.001**	1.52 (1.45 – 1.60)	**<0.001**
% Insurance - Private	0.86 (0.81 – 0.90)	**<0.001**	1.38 (1.28 – 1.48)	**<0.001**
% Insurance - Public	1.68 (1.59 – 1.79)	**<0.001**	1.43 (1.35 – 1.52)	**<0.001**
% Unemployed	1.92 (1.77 – 2.08)	**<0.001**	0.89 (0.87 – 0.91)	**<0.001**
Urbanicity - Rural	1.55 (1.45 – 1.65)	**<0.001**	0.79 (0.76 – 0.81)	**<0.001**
Urbanicity - Suburban	1.15 (1.12 – 1.18)	**<0.001**	0.86 (0.84 – 0.88)	**<0.001**
Census region - Northeast	4.08 (3.88 – 4.29)	**<0.001**	0.95 (0.92 – 0.98)	**0.001**
Census region - South	1.62 (1.54 – 1.70)	**<0.001**	0.92 (0.89 – 0.95)	**<0.001**
Census region - West	0.66 (0.63 – 0.68)	**<0.001**	1.13 (1.09 – 1.16)	**<0.001**
Medically underserved area	0.92 (0.89 – 0.95)	**<0.001**	0.98 (0.96 – 1.00)	0.077
Health provider shortage area	1.12 (1.08 – 1.17)	**<0.001**	1.05 (1.03 – 1.08)	**<0.001**

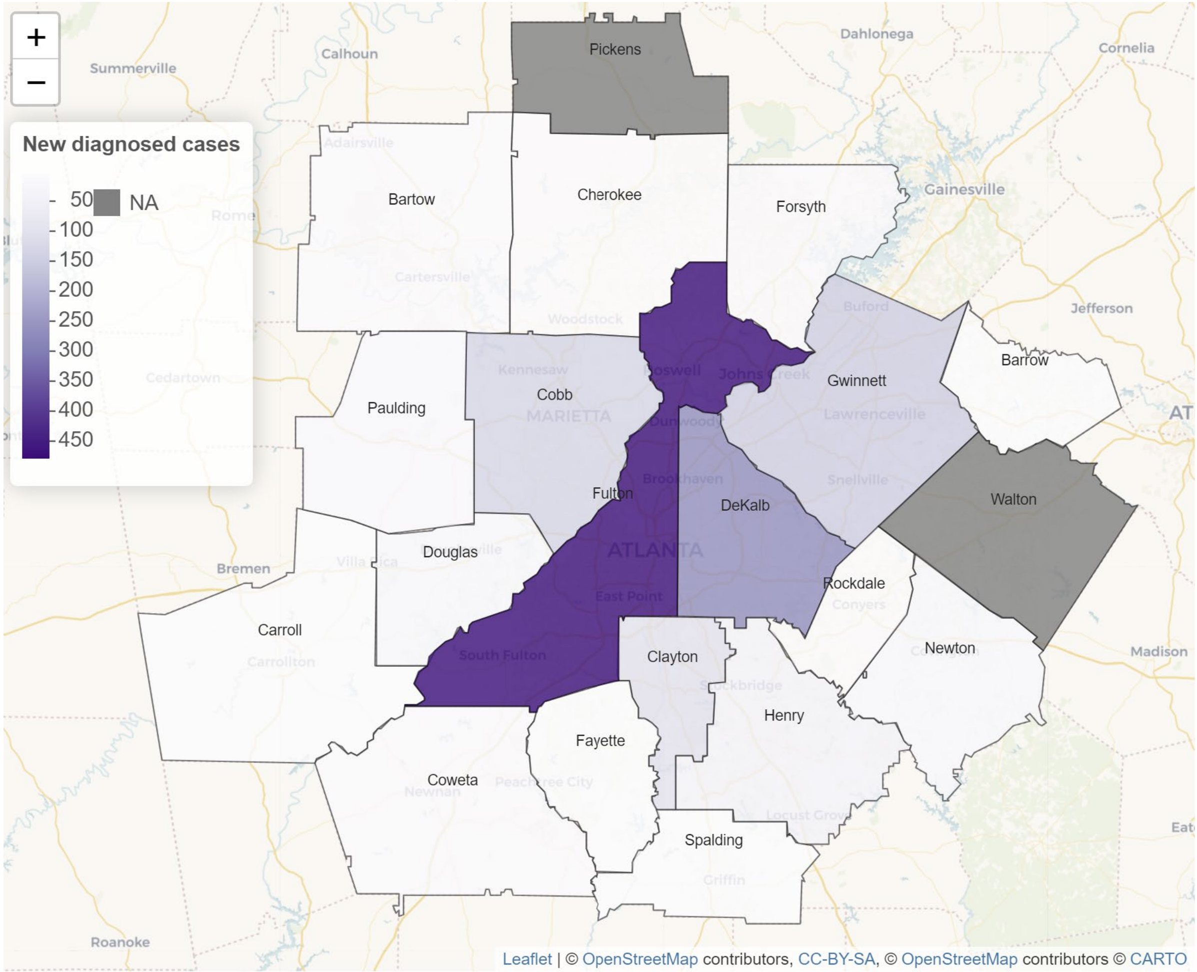
Appendix C: Supplementary material for Chapter 3

Appendix C1: 20 Atlanta metropolitan counties in LEMHIV by HIV cases, new HIV diagnoses, PrEP deserts, and pharmacy deserts

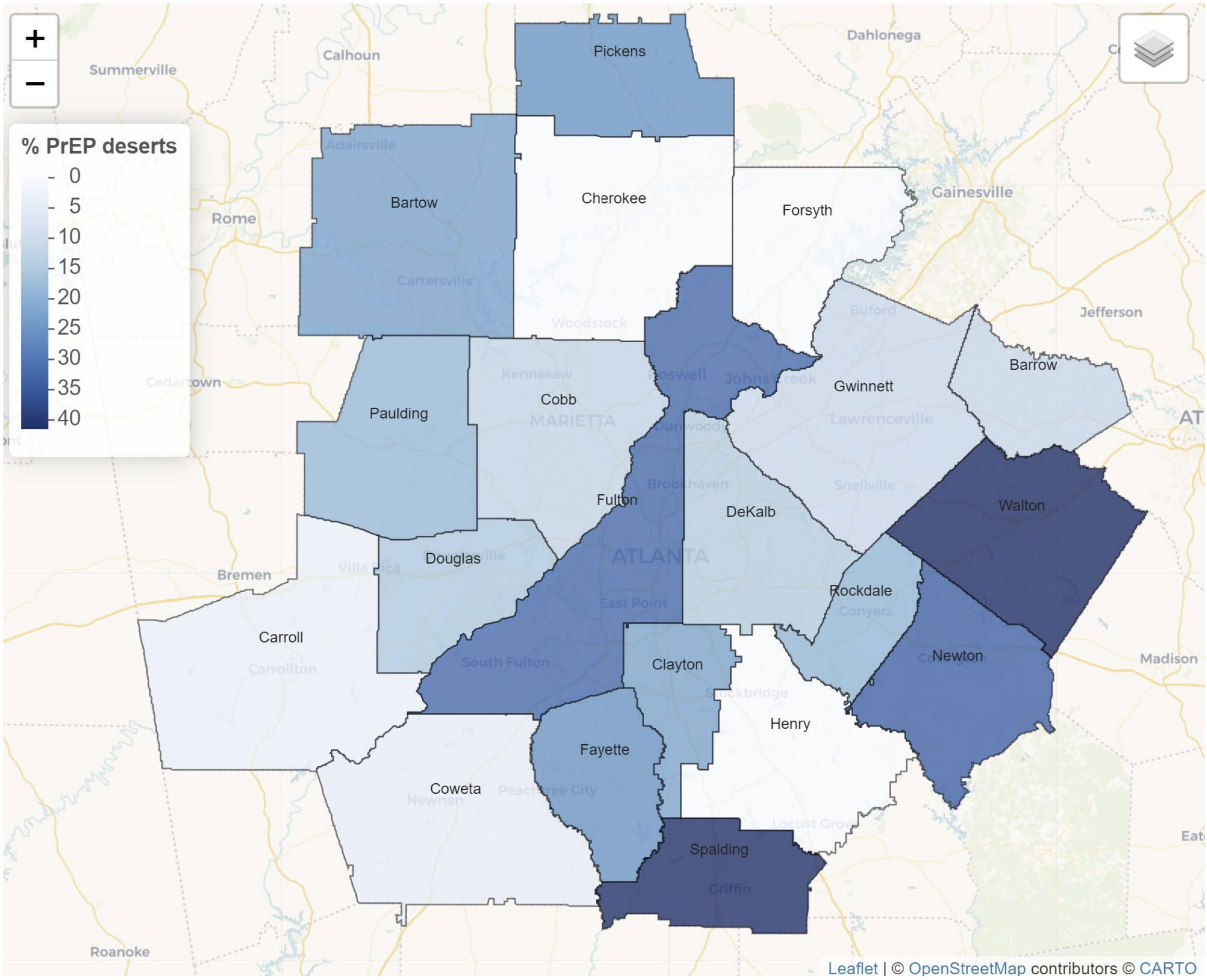
Atlanta counties by prevalent HIV cases



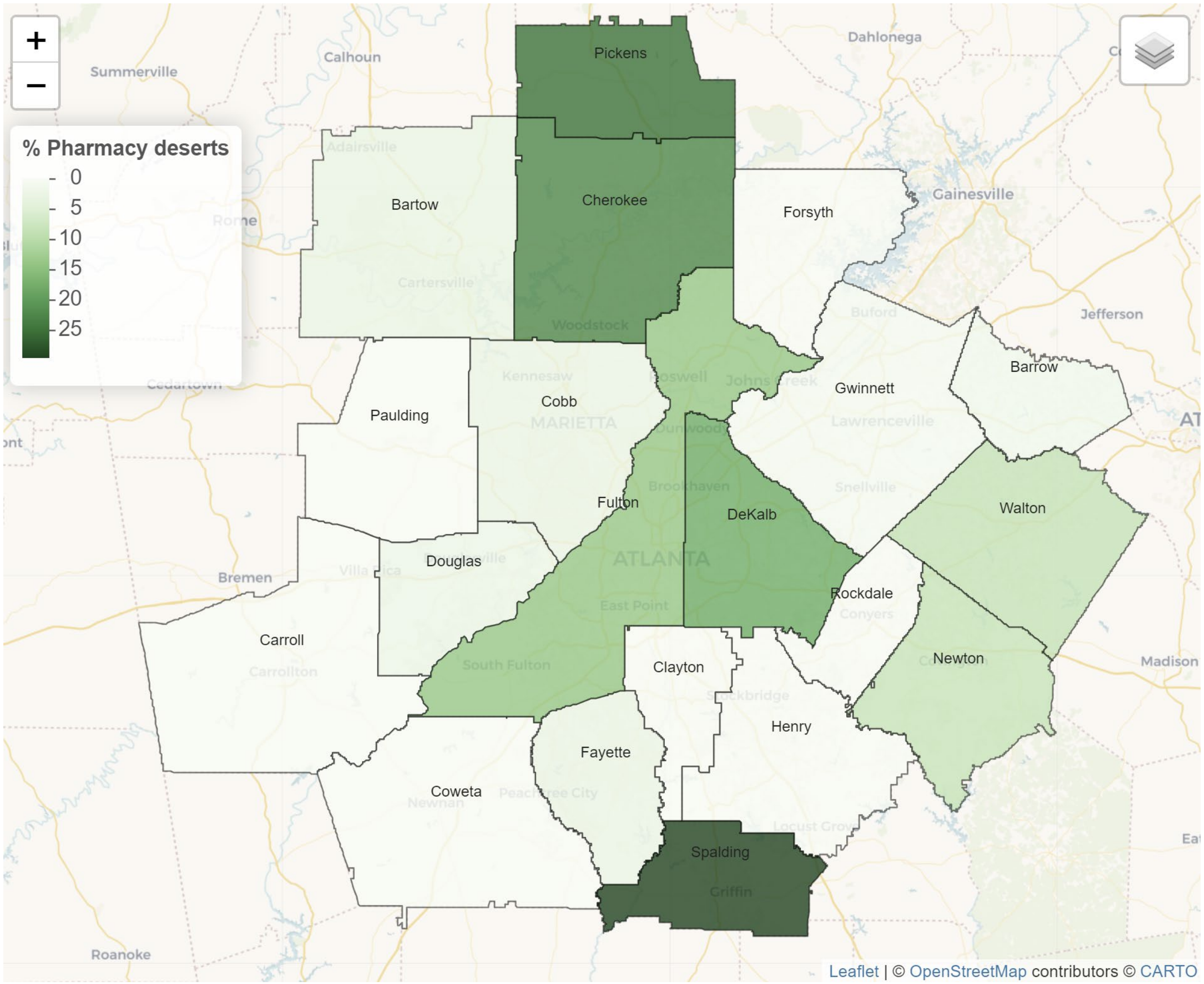
Atlanta counties by new HIV diagnoses



Atlanta counties by percentage of census tracts that are PrEP deserts



Atlanta counties by percentage of census tracts that are pharmacy deserts



Appendix C2: Ordinary differential equations

Example ODEs for MSM and Heterosexual HIV risk groups, with parameters to be changed highlighted in red:

1. $\frac{dX_{S_1}}{dt} = \rho \sum_{\forall i} X_i + \omega_S X_{S_2} - \eta_t X_{S_1} - (\sum_{j \neq S} \lambda_{S_{1,j(t)}}) X_{S_1} - \mu_S X_{S_1} - \rho_m \sum_{i \neq S} X_i$

2. $\frac{dX_{S_2}}{dt} = \psi X_{S_1} + \omega_p X_{S_p} - \omega_S X_{S_2} - \eta_t X_{S_2} - (\sum_{j \neq S} \lambda_{S_{2,j(t)}}) X_{S_2} - \mu_S X_{S_2}$

3. $\frac{dX_{S_P}}{dt} = \eta_t (X_{S_2} + X_{S_2}) - \omega_P X_{S_P} - (\sum_{j \neq S} \lambda_{S_{p,j(t)}}) X_{S_P} - \mu_S X_{S_P}$

4. $\frac{dX_{I_A}}{dt} = (\sum_{j \neq S,} \lambda_{S_{1,j(t)}}) X_{S_1} + (\sum_{j \neq S} \lambda_{S_{2,j(t)}}) X_{S_2} - \psi X_{I_A} - \theta_{\overline{T}_A} X_{I_A} - \mu_{\overline{T}_A} X_{I_A} + \rho_m X_{I_A}$

5. $\frac{dX_{I_1}}{dt} = \theta_{\overline{T}_{AI}} X_{I_A} - \psi X_{I_1} - \theta_{\overline{T}_1} X_{I_1} - \mu_{\overline{T}_1} X_{I_1} + \rho_m X_{I_1}$

6. $\frac{dX_{I_2}}{dt} = \theta_{\overline{T}_1} X_{I_1} - (\psi + \upsilon_2) X_{I_2} - \theta_{\overline{T}_2} X_{I_2} - \mu_{\overline{T}_2} X_{I_2} + \rho_m X_{I_2}$

7. $\frac{dX_{I_3}}{dt} = \theta_{\overline{T}_2} X_{I_2} - (\psi + \upsilon_3) X_{I_3} - \mu_{\overline{T}_3} X_{I_3} + \rho_m X_{I_3}$

8. $\frac{dX_{1_{AP}}}{dt} = (\sum_{j \neq S} \lambda_{S_{P,j(t)}}) X_{S_p} - \psi_P X_{I_{AP}} - \theta_{T_A} X_{I_{1P}} - \mu_{T_A} X_{I_{AP}} + \rho_m X_{I_{AP}}$

9. $\frac{dX_{I_{1P}}}{dt} = \theta_{\overline{T}_A} X_{I_{AP}} - \psi_P X_{I_{1P}} - \mu_{\overline{T}_1} X_{I_{1P}} + \rho_m X_{I_P}$

10. $\frac{dX_{D_A}}{dt} = \psi X_{I_A} + \psi_P X_{I_{AP}} - \theta_{\overline{T}_A} X_{D_A} - \mu_{\overline{T}_A} X_{D_A} + \rho_m X_{D_A}$

11. $\frac{dX_{D_1}}{dt} = \theta_{\overline{T}_{AD}} X_{D_A} + \psi(1 - \varphi_1) X_{I_1} + \psi_P X_{I_{1P}} - \theta_{\overline{T}_1} X_{D_1} - \alpha_1 X_{D_1} - \mu_{\overline{T}_1} X_{D_1} + \rho_m X_{D_1}$

12. $\frac{dX_{D_2}}{dt} = \theta_{\overline{T}_1} X_{D_1} + (\psi + \upsilon_2)(1 - \varphi_2) X_{I_2} - \theta_{\overline{T}_2} X_{D_2} - \alpha_2 X_{D_2} - \mu_{\overline{T}_2} X_{D_2} + \rho_m X_{D_2}$

13. $\frac{dX_{D_3}}{dt} = \theta_{\overline{T}_2} X_{D_2} + (\psi + \upsilon_3)(1 - \varphi_3) X_{I_3} - \alpha_3 X_{D_3} - \mu_{\overline{T}_3} X_{D_3} + \rho_m X_{D_3}$

14. $\frac{dX_{T_1}}{dt} = \sum_{j \neq 1} \theta_{T_j, T_1(t)} X_{T_j} + \alpha_1 X_{D_1} + \alpha'_1 X_{O_1} + \psi \varphi_1 X_{I_1} - \sum_{j \neq 1} \theta_{T_1, T_j(t)} X_{T_1} - \theta_{T_1, O_1(t)} X_{T_1} - \mu_{T_1} X_{T_1} + \rho_m X_{T_1}$

15. $\frac{dX_{T_2}}{dt} = \sum_{j \neq 2} \theta_{T_j, T_2(t)} X_{T_j} + \alpha_2 X_{D_2} + \alpha'_2 X_{O_2} + (\psi + \upsilon_2) \varphi_2 X_{I_2} - \sum_{j \neq 2} \theta_{T_2, T_j(t)} X_{T_2} - \theta_{T_2, O_2(t)} X_{T_2} - \mu_{T_2} X_{T_2} + \rho_m X_{T_2}$

16. $\frac{dX_{T_3}}{dt} = \sum_{j \neq 3} \theta_{T_j, T_3(t)} X_{T_j} + \alpha_3 X_{D_3} + \alpha'_3 X_{O_3} + (\psi + \upsilon_3) \varphi_3 X_{I_3} - \sum_{j \neq 3} \theta_{T_3, T_j(t)} X_{T_3} - \theta_{T_3, O_3(t)} X_{T_3} - \mu_{T_3} X_{T_3} + \rho_m X_{T_3}$

17. $\frac{dX_{O_1}}{dt} = \theta_{T_1, O_1(t)} X_{T_1} - \alpha'_1 X_{O_1} - \theta_{\overline{T}_1} X_{O_1} - \mu_{\overline{T}_1} X_{O_1} + \rho_m X_{O_1}$

18. $\frac{dX_{O_2}}{dt} = \theta_{T_2, O_2(t)} X_{T_2} + \theta_{\overline{T}_1} X_{O_1} - \alpha'_2 X_{O_2} - \theta_{\overline{T}_2} X_{O_2} - \mu_{\overline{T}_2} X_{O_2} + \rho_m X_{O_2}$

19. $\frac{dX_{O_3}}{dt} = \theta_{T_3, O_3(t)} X_{T_3} + \theta_{\overline{T}_2} X_{O_2} - \alpha'_3 X_{O_3} - \mu_{\overline{T}_3} X_{O_3} + \rho_m X_{O_3}$

Appendix C3: CHEERS 2022 Checklist

Topic	No.	Item	Location where item is reported
Title			
	1	Identify the study as an economic evaluation and specify the interventions being compared.	Title
Abstract			
	2	Provide a structured summary that highlights context, key methods, results, and alternative analyses.	Abstract
Introduction			
Background and objectives	3	Give the context for the study, the study question, and its practical relevance for decision making in policy or practice.	Background
Methods			
Health economic analysis plan	4	Indicate whether a health economic analysis plan was developed and where available.	Methods
Study population	5	Describe characteristics of the study population (such as age range, demographics, socioeconomic, or clinical characteristics).	Methods - HIV Transmission Model
Setting and location	6	Provide relevant contextual information that may influence findings.	Background; Methods - Overview & HIV Transmission Model
Comparators	7	Describe the interventions or strategies being compared and why chosen.	Methods - Simulated Scenarios
Perspective	8	State the perspective(s) adopted by the study and why chosen.	Methods - Cost-Effectiveness Analysis
Time horizon	9	State the time horizon for the study and why appropriate.	Methods - Cost-Effectiveness Analysis
Discount rate	10	Report the discount rate(s) and reason chosen.	Methods - Cost-Effectiveness Analysis
Selection of outcomes	11	Describe what outcomes were used as the measure(s) of benefit(s) and harm(s).	Methods - Cost-Effectiveness Analysis
Measurement of outcomes	12	Describe how outcomes used to capture benefit(s) and harm(s) were measured.	Methods - Cost-Effectiveness Analysis
Valuation of outcomes	13	Describe the population and methods used to measure and value outcomes.	Methods - Cost-Effectiveness Analysis

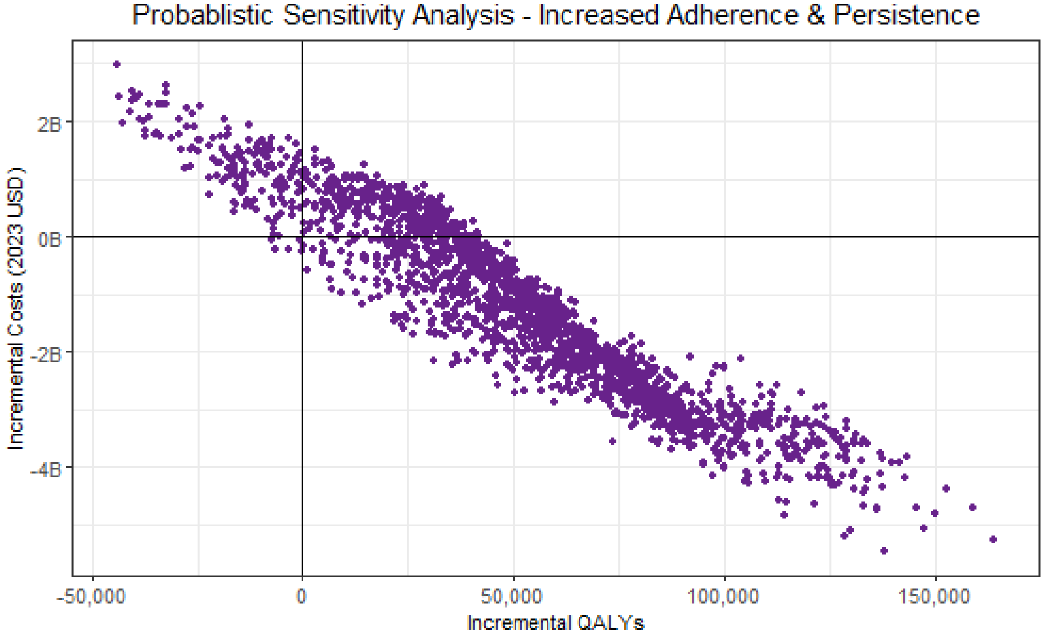
Topic	No.	Item	Location where item is reported
Measurement and valuation of resources and costs	14	Describe how costs were valued.	Methods - Cost-Effectiveness Analysis
Currency, price date, and conversion	15	Report the dates of the estimated resource quantities and unit costs, plus the currency and year of conversion.	Methods - Cost-Effectiveness Analysis
Rationale and description of model	16	If modelling is used, describe in detail and why used. Report if the model is publicly available and where it can be accessed.	Methods - HIV Transmission Model
Analytics and assumptions	17	Describe any methods for analysing or statistically transforming data, any extrapolation methods, and approaches for validating any model used.	Methods
Characterising heterogeneity	18	Describe any methods used for estimating how the results of the study vary for subgroups.	Methods
Characterising distributional effects	19	Describe how impacts are distributed across different individuals or adjustments made to reflect priority populations.	Not reported
Characterising uncertainty	20	Describe methods to characterise any sources of uncertainty in the analysis.	Methods
Approach to engagement with patients and others affected by the study	21	Describe any approaches to engage patients or service recipients, the general public, communities, or stakeholders (such as clinicians or payers) in the design of the study.	Not reported
Results			
Study parameters	22	Report all analytic inputs (such as values, ranges, references) including uncertainty or distributional assumptions.	Methods; Table 1
Summary of main results	23	Report the mean values for the main categories of costs and outcomes of interest and summarise them in the most appropriate overall measure.	Results; Table 2
Effect of uncertainty	24	Describe how uncertainty about analytic judgments, inputs, or projections affect findings. Report the effect of choice of discount rate and time horizon, if applicable.	Results, Table 2, Figure 2
Effect of engagement with patients and others affected by the study	25	Report on any difference patient/service recipient, general public, community, or stakeholder involvement made to the approach or findings of the study	Not applicable
Discussion			

Topic	No.	Item	Location where item is reported
Study findings, limitations, generalisability, and current knowledge	26	Report key findings, limitations, ethical or equity considerations not captured, and how these could affect patients, policy, or practice.	Discussion
Other relevant information			
Source of funding	27	Describe how the study was funded and any role of the funder in the identification, design, conduct, and reporting of the analysis	Funding Statement
Conflicts of interest	28	Report authors conflicts of interest according to journal or International Committee of Medical Journal Editors requirements.	Conflict of Interest

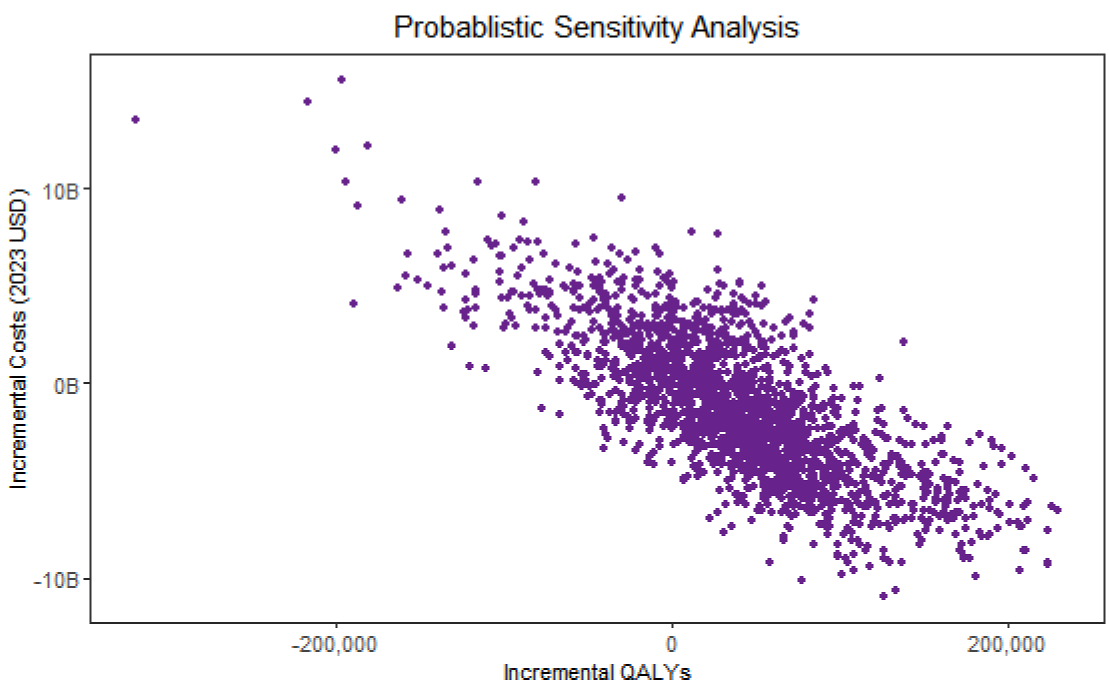
From: Husereau D, Drummond M, Augustovski F, et al. Consolidated Health Economic Evaluation Reporting Standards 2022 (CHEERS 2022) Explanation and Elaboration: A Report of the ISPOR CHEERS II Good Practices Task Force. Value Health 2022;25. doi:10.1016/j.jval.2021.10.008

Appendix C4: Probabilistic sensitivity analysis results for the three additional scenarios

C4.a: PSA results for pharmacy-based PrEP with higher adherence and persistence



C4.b: PSA results for pharmacy-based PrEP with lower persistence



C4.c: PSA results for pharmacy-based PrEP with Tele-PrEP