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Novel Population-Level Proxy Measures for Suboptimal HIV Pre-Exposure Prophylaxis Initiation and Persistence in the US

Lorraine T. DEAN, ScD[1,2], **Hsien-Yen CHANG, PhD**[2], **William C. GOEDEL, PhD**[3], **Philip A. CHAN, MD**[4], **Jalpa A. DOSHI, PhD**[5,6], **Amy S. NUNN, ScD, MS**[7]

[1]Department of Epidemiology, Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland, USA

[2]Department of Health Policy & Management, Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland, USA

[3]Department of Epidemiology, School of Public Health, Brown University, Providence, Rhode Island, USA

[4]Department of Medicine, Brown University, Providence, Rhode Island; Rhode Island Department of Health, Providence, Rhode Island, USA; Rhode Island Public Health Institute, Providence, Rhode Island, USA

[5]Perelman School of Medicine, University of Pennsylvania, Philadelphia, Pennsylvania, USA

[6]Leonard Davis Institute of Health Economics, University of Pennsylvania, Philadelphia, Pennsylvania, USA

[7]Department of Behavioral and Social Sciences, Brown University School of Public Health, Providence, Rhode Island, USA

Abstract

Objective: In the United States (US), HIV pre-exposure prophylaxis (PrEP) use is suboptimal. Population-level metrics on PrEP use are limited and focus on prescriptions issued rather than how much prescriptions are picked up. We introduce PrEP reversals, defined as when patients fail to pick up PrEP prescriptions at the pharmacy point-of-sale, as a proxy for PrEP initiation and persistence.

Design: We analyzed PrEP pharmacy claims and HIV diagnoses from a Symphony Health Solutions dataset across all US states from October 1, 2015 to September 30, 2019.

Methods: We calculated the percentage of individuals who were newly-prescribed PrEP and who reversed (i.e. patient did not pick up an insurance-approved prescription and pharmacy withdrew the claim), delayed (reversed and then picked up within 90 days), very delayed (reversed and then picked up between 90 and 365 days), or abandoned (not picked up within 365 days), and subsequent HIV diagnosis within 365 days.

Corresponding Author: Lorraine T. Dean, 615 N Wolfe St, Baltimore, MD, 21205 lori.dean@jhu.edu, 410.502.7205, ldean9@jhu.edu.

Data sharing: Data are from a proprietary dataset and are unable to be shared.

Results: Of 59,219 individuals newly-prescribed PrEP, 19% reversed their index prescription. Among those, 21% delayed initiation and 8% had very delayed initiation. Seventy-one percent of patients who reversed their initial prescription abandoned it, 6% of whom were diagnosed with HIV -- three times higher than those who persisted on PrEP.

Conclusions: Nearly 1 in 5 patients newly-prescribed PrEP reversed initial prescriptions, leading to delayed medication access, being lost to PrEP care, and dramatically higher HIV risk. Reversals could be used for real-time nationwide PrEP population-based initiation and persistence tracking, and for identifying patients that might otherwise be lost to care.

Keywords

insurance claim review; pharmacy; HIV Pre-Exposure Prophylaxis; treatment adherence; treatment refusal

Introduction

Pre-exposure prophylaxis (PrEP) for HIV prevention can reduce the risk of HIV infection by greater than 99% when used as directed.[1] Daily oral PrEP use, the most widely-approved PrEP formulation worldwide, has been on the rise in the United States (US) since it was approved by the US Food and Drug Administration (FDA) in 2012. [2, 3] In the US, 220,000 individuals were prescribed PrEP in 2018 alone.[4] Yet, this represents only a small fraction of the 1.2 million people who are estimated to have behavioral indications for PrEP use. [4–6] Among those who initiate PrEP, persistence, or continuous use of PrEP over time, is important to realize PrEP's population-level benefits of reducing HIV incidence.[7, 8] PrEP use remains suboptimal, which we define as initiation and persistence that is imperfect enough to raise HIV acquisition risks for PrEP users. Our recent studies in clinic-based samples find that only 50–60% of patients who intitate PrEP are still on PrEP at six and twelve months; [9, 10] however, nationwide data on PrEP initiation and persistence are limited.

To monitor progress toward and achieve public health goals for reducing HIV transmission by increasing PrEP use,[11] practitioners and researchers need proxies for population surveillance or a barometer for "how we are doing" for nationwide PrEP initiation and persistence. The ability to quickly and easily identify patients who fail to initiate PrEP is also key in identifying and implementing timely interventions to reduce HIV incidence. Yet limited evidence exists on how PrEP initiation failures (i.e. after a patient is prescribed PrEP but does not start taking it) could be identifed on a population level and in a timely manner to have a broad and meaningful impact. Studies of PrEP adherence, persistence, and retention fail to capture those who never actually start on PrEP.[12] Furthermore, among patients who initiate PrEP, little is understood about how best to measure PrEP persistence over time. Current monitoring and surveillance have focused on individual-level measures that might not be suitable for population-level tracking. In response to the limited accuracy of self-report, measurement of PrEP drug concentrations in hair follicles, urine, and dried blood spots have been recommended,[13] but these measures often incur costs of laboratory processing, personnel, and specialty equipment. These tools require patient presentation for services, making them impractical for measuring PrEP initiation and persistence on a

population level and in real-world settings. Even real-world longitudinal cohort data are limited and the frequency with which existing surveillance data are reported are insufficient to capture the dynamic nature of PrEP uptake and ongoing PrEP use.[14]

Innovative measures are needed to better understand and identify opportunities for intervention on how to enhance PrEP initiation and persistence. In the US, the Centers for Disease Control (CDC) estimates that 85–90% of PrEP prescriptions are filled at commercial pharmacies (i.e., not demonstration projects or military health plans), making pharmacies a potential venue for tracking and monitoring PrEP use in real-world settings. In this study, we introduce several measures that can be calculated from pharmacy point-of-sale claims data to generate population-level proxy estimates of suboptimal PrEP initiation: a PrEP prescription *reversal*, or insurer approved PrEP prescriptions that are not initially picked up at the pharmacy point-of sale; a PrEP prescription *delay*, or the percentage of PrEP prescriptions that are initially reversed but picked up after a certain length of time; and PrEP prescription *abandonment*, or a prescription that is not picked up within 365 days. Among those who initiate PrEP (not reversed), we also report the number of prescriptions that were picked up later that year as a proxy for persistence. Examining how many times PrEP prescriptions are filled over time aligns most closely as a proxy for population-level PrEP persistence, which we define as whether or not the patient is taking the prescribed medicine continuously over time. (This is differentiated from adherence, representing how much of a drug regimen a patient is taking as prescribed, and retention, as the extent to which patients continue to engage in PrEP clinical care.) This study had two objectives: (1) Introduce and estimate population-level measures of PrEP initiation and persistence using pharmacy point-of-sale claims data; and (2) Report the percentage of persons with a new HIV diagnosis by these novel metrics of PrEP initiation and persistence.

Methods

Study Design and Sample

We analyzed data from the Symphony Health Solutions Integrated Data Verse by Source Healthcare Analytics, LLC (SHA). This dataset has been used in previous studies in several disease areas, including HIV PrEP.[14–17] The SHA dataset is a large, proprietary database containing claims for the vast majority (over 274 million) of patients in the US, including all insurance types and across every US state, culling data from patients at over 65,000 pharmacies, 1,500 hospitals, 800 outpatient facilities, and 80,000 physician practices. The dataset has 80–85% of all PrEP prescription claims in the US.[18] SHA obtains individual-level patient data from the National Council for Prescription Drug Programs. Prescription claims are linked to each patient to provide a longitudinal database of a patient's history with the prescription across data sources (e.g, pharmacy, hospital), and the complete lifecycle of a prescription from initial adjudication (decision by insurance to approve and pay for the prescription) through final paid or patient reversed status. Data included all pharmacy types (retail, hospital, and mail-order) from insured and uninsured patients documented in claims paid by commercial insurance plans, Medicaid, Medicare Part D, PrEP assistance programs and co-pay cards, and point-of-sale cash paid by patients out-of-pocket. This unique combination of data across payor types and capturing the full

prescription life cycle with longitudinal data on the patient is typically not available in traditional insurance-based claims data set. All data were de-identified in compliance with the Health Insurance Portability and Accountability Act. The John Hopkins University Institutional Review Board deemed the study exempt from informed consent procedures because no identifiable data were collected directly from patients.

For this study, we used an extract of the 2015–2019 SHA dataset that included pharmacy and medical claims for patients with claims for tenofovir disoproxil fumarate/emtricitabine (TDF/FTC). Claims for tenofovir tenofivir alafenamide/emtricitabine (TAF/FTC) were not included because its formulation had not yet been FDA-approved for PrEP during our observation window. Rejected claims were not assessed because rejections often represent the failure for an eligible prescription to meet an insurance plan's formulary coverage. Rejections may also reflect limits due to prior authorization policies or administrative errors, rather than patient refusal to fill an insurer-approved PrEP prescription.

Patients were the unit of analysis. The sampling frame included individuals with an insurer-approved PrEP prescription from September 30, 2016 to June 2, 2018, followed through September 30, 2019. The first PrEP prescription during this period was deemed as each patient's index prescription. Next, our sample was limited to patients who had at least one pharmacy claim during the 365 days prior and 365 days post index date, as a marker for database inclusion during the study periods of interest (in keeping with prior analysis).[19] Finally, since this analysis was focused on individuals with a new insurer-approved prescription for PrEP, we excluded patients with a history of HIV diagnosis or PrEP pharmacy claims in the 365 day period period before the index prescription.

Patients with an eligible claim for PrEP were identified through a multi-step process based on several previously published algorithms.[20–22] To differentiate use of TDF/FTC for HIV PrEP versus for treatment of HIV, post-exposure prophlylaxis (PEP), or Hepatitis B Virus (HBV), we only included persons who: had a claim of TDF/FTC with a supply of >28 to 91 days; had no ICD9/10 diagnosis codes for HIV or HBV, aand no claims for HIV medication during the 365 days before or 30 days after the index prescription (based on the CDC definition[20]). For persons with multiple PrEP claims with conflicting status on the same date, we assigned one final claim status, prioritizing approved claim status over reversed claim status.

Measures

We characterized suboptimal PrEP initiation by three metrics based on the outcome of the index prescription. First, we classified all patients (yes or no) according to whether they had a *reversed* (insurer-approved and adjudicated prescription that was not obtained by the patient) index claim. Once an insurer approves and determines their financial responsibility for the payment to the provider (adjudication), which generally happens the same day or within a few days of the prescription being prescribed, a patient has the option to pick up the prescription. If the patient does not pick up the prescription (typically within 10–14 days of insurance approval depending on the pharmacy's policy and the patient's health insurance plan), the pharmacy withdraws it or "reverses the claim". In our sample, for those who picked up PrEP after an initial reversal, we calculated the number of days from index

until pick-up. Next, we classified patients with a reversed claim that was later picked up within 90 days as having *delayed PrEP initiation*. The 90-day time window was informed by a previous analysis of prescription reversals for oral anti-cancer medications.[15] Patients with a reversed index claim who picked up PrEP between 90 and 365 days were considered having *very delayed initiation*. Patients were classified as having *abandoned* PrEP if there was no evidence of pick-up within 365 days of the index reversal. Among those who abandoned, we assessed whether or not the patient was *abandoned to HIV treatment*, as no evidence of prescription pick-up within 365 days due to documented HIV diagnosis. HIV diagnosis was assessed by data reported in the claims of an ICD9/10 code indicating HIV infection or prescription for HIV treatment. Among patients picking up their index PrEP (i.e. did not have initial reversal), we assessed a proxy for PrEP persistence as the number of PrEP prescriptions that were picked up (not reversed) over the 365 day post-index follow-up period.

Analysis

Demographic characteristics were examined for the study sample. Age categories were based on those used by the CDC for HIV surveillance reporting. Sex, race/ethnicity, income, and education were available at the individual level on a subset of patients, as obtained through a partnership between SHA and KBM Marketing group.

We estimated the percentage of patients with a new insurer-approved PrEP prescription who had (1) reversed, (2) delayed initiation, (3) very delayed initiation, or (4) abandoned PrEP, as previously defined. Among patients who picked up their PrEP prescription (i.e. did not have initial reversal), we calculated the percentage of patients who picked up 6 or fewer, 7–11, and 12 or greater PrEP prescriptions over the 365 day post-index follow-up period. For each metric of initiation and persistence, we calculated the percent of associated new HIV diagnoses, with the numerator as the number of persons diagnosed with HIV during the 365 day post-index follow-up period and the denominators as the number of patients reversing, delaying or abandoning. Since this was a descriptive study introducing novel measures of suboptimal PrEP initiation and persistence, all reported results are unadjusted. No multivariate analyses were conducted. All analyses were conducted using SAS version 9.4 (SAS Institute, Cary, NC).

Role of the Funding Source

The funding source had no involvement in the study design, collection, analysis, interpretation of the data, or dissemination of the results.

Results

Our final sample included 59,219 individuals with a new insurer-approved PrEP prescription. Nearly 93% of these prescriptions were for a 30-day supply of PrEP. Table 1 describes the demographic characteristics of the sample. The plurality of individuals with a new insurer-approved PrEP prescription were 25–44 years old, were predomoninatly male, non-Hispanic White, with annual income under $75,000 and roughly equally distributed across educational attainment groups.

Figure 1 shows the percentage of PrEP initiation and persistence among patients newly prescribed PrEP. Among the sample of 59,219 patients, 19% (n=11,388) had a reversal of their index PrEP prescription. Patients who later picked up PrEP did so an average of 197 (SD=81) days later. Nearly one-fifth (n=2,344; 21%) of those initially reversing had delayed initiation, and an additional 8% (n=962) had very delayed initiation. Approximately 71% (n=8,082) of patients who reversed their initial prescription abandoned it.

We assessed suboptimal PrEP persistence among the 47,831 (81%) patients in our study sample who picked up an index PrEP prescription. Over 365 days, 58% percent of patients picked up a total of 6 or fewer prescriptions, one-quarter picked up 7 to 11 prescriptions, with the remaining (17%) picking up 12 or more prescriptions.

Figure 1 also shows that the percentage of patients diagnosed with HIV within 365-days of the index prescription was the highest among the patients who abandoned their PrEP prescription (6%), which was nearly three times higher than those who picked up their initial prescripton (2%). Among those who initiated PrEP prescription, the percentage of persons with HIV diagnoses dropped substantially with increasing levels of persistence (3.5% of those picking up six or fewer prescriptions, 0.7% of those who picked up 7 to 11 prescriptions, and <0.1% of those who picked up at least 12 prescriptions).

Discussion

This study was among the first to use PrEP prescription reversals to estimate suboptimal PrEP initiation across the United States.[23–25] We find that nearly 1 in 5 individuals who had been newly prescribed a PrEP prescription by a physician did not pick up their insurance-approved PrEP from the pharmacy. Over a quarter of these patients ultimately filled the PrEP prescription after a delay, but the vast majority abandoned their prescription. Reversed initial prescriptions resulted in delays in receipt of PrEP of an average of 197 days, being lost to care, and dramatically higher HIV incidence than those who picked up their initial precriptions. However, even among those who initiated PrEP prescriptions we found poor persistence with over half the patients picking an equivalence of a half-year's supply of PrEp and less than one-fifth filling the equivalence of a year's worth supply (suggesting continuous use). Although PrEP initiation and persistence estimated in our study is higher than have been reported in demonstration studies and limited-sample studiess,[9, 10, 25–27] it is still suboptimal given that HIV incidence was so high in the reversal group. HIV incidence was multiple folds higher among those with poorest persistence (abandoners) than those who picked up PrEP prescriptions continuously throughout the year: 1.5 times higher than those picking up six or fewer prescriptions, 8 times higher than those picking up 7 to 11 prescriptions and over 100 times higher than those who picked up at least 12 prescriptions over the year.

Our results also suggest that the first 90 days after an initial precription pick-up failure may be critically important, as patients who do not pick up within 90 days are highly unlikely to pick up their prescription and risk subsequent HIV infection. Patients who were less likely to fill a PrEP prescription may already face increased risk of HIV due to intersecting vulnerabilities around access, economic challenges, or structural challenges that converge

at the pharmacy point-of-sale experience, such as insurance copayments and deductibles or stigma associated with accessing PrEP in commercial settings.[9, 10, 28, 29] Yet, over a quarter did pick up an initially reversed prescription within 90 days, and some even later on in the year, suggesting that there are still windows of opportunity for engaging patients in care after an initial reversal. More research is needed to understand why PrEP reversals at the pharmacy point-of-sale occur and provide further insights for understanding populations facing the most challenges in accessing PrEP.

Altotgether, our results support that PrEP reversals may be a useful population-level proxy for suboptimal PrEP initiation and persistence. Much in the same way that existing resources like PrEPVu (http://map.aidsvu.org/map?prep=1) use claims data to report on the number of PrEP prescriptions issued, adding information on the number of prescriptions reversed may give a population-level view of the likelihood that PrEP is reaching patients who need it. When extracted in aggregate from monthly claims data, reversal data can be available as soon as a few months later as a way for ongoing population-level tracking of PrEP. The primary challenge may instead be public access to expensive privately-held databases; however, these costs could be borne by the federal government for surveillance. While it is unlikely that individual pharmacies would be willing to release data on PrEP reversals, reversals can be used within pharmacies (especially specialty pharmacies and large retail pharmacy chains) to alert staff,[24, 30] to follow up with patients who have reversed in order to re-engage them in care, to assess their ongoing need for PrEP, or to identify barriers to their use of PrEP.

Limitations

While our analysis suggests that pharmacy claims data are a useful tool for generating population-level proxy estimates for suboptimal initiation and persistence, results must be considered in light of their limitations. First, because the same drug formulations used for PrEP may also be used for post-exposure prophylaxis, or HIV and HBV treatment, what is classified as a prescription claim for PrEP may be different based on which algorithm is applied to claims data. Our analysis adapted the CDC algorithm for identifying PrEP prescriptions,[20] but another algorithm may have yielded different estimates. Second, our analysis was unable to determine if gaps in PrEP were due to patients leaving the data capture (e.g., patient moved to a pharmacy or facility that is not captured in the dataset), which may have been misclassified as a reversal or abandonment, and may have overestimated reversal or abandonment. We attempted to minimize this misclassification in our sample selection criteria by requiring evidence of pharmacy activity before and after issuance of a PrEP claim; however, this requirement may have excluded those prescribed PrEP who were otherwise healthy and unlikely to use any other form of medical care. The concomitant higher HIV incidence with lower prescription pick-ups is further validation of the strength of using reversed and picked up claims as proxy measures for initiation and persistence, as it suggests that patients who are classified as having reversed PrEP are likely not getting PrEP from any other sources. Third, claims data may underestimate HIV cases, but it is unlikely to be differential by reversal status. Finally, like any other population-level metric, PrEP reversals cannot tell us whether or not a patient is actually

taking their medication after it is picked up from the pharmacy, though it may be a crude proxy if they continuously pick up their medication.

Conclusion

This study has presented useful proxies for population-level indicators for PrEP initiation and persistence using pharmacy claims data. We find high levels of suboptimal initiation and persistence with PrEP. The high correlation of these measures with the occurrence of HIV over follow-up suggests the validity of these measures for population-level surveillance. The pharmacy point-of-care may be an important opportunity to identify patients who are at risk of falling out of care and to provide services to enhance PrEP initiation and persistence.

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Conflicts of interest and source of funding:

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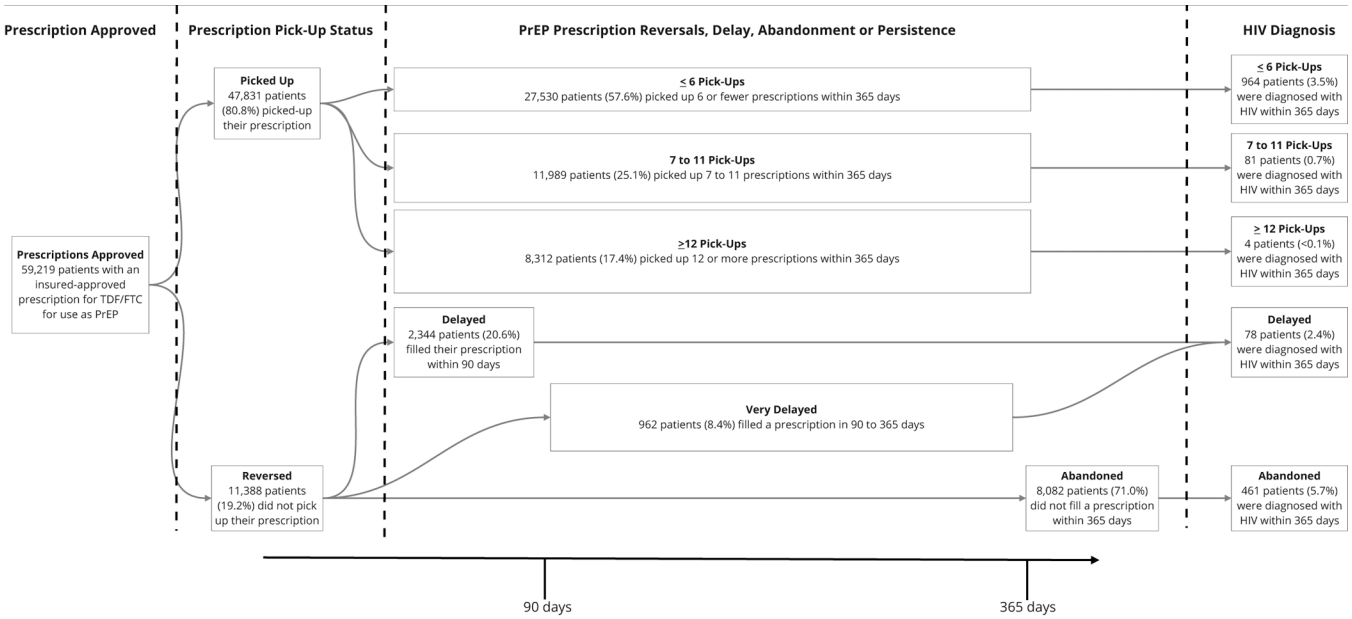

Figure 1.

PrEP Prescription Reversals, Delay, Abandonment and Persistence for Individuals with New Insurer-Approved PrEP Prescriptions

Figure shows the percentages for which patients followed for up to one year picked up or failed to pick up PrEP prescriptions from the pharmacy initially, at 90 days, and at 365 days.

Table 1.

Demographic Characteristics of Study Sample of Individuals with a New Insurer-Approved PrEP prescription

	All Patients
N	59,219
Age Group	
<18	0.35%
18–24	9.19%
25–34	39.62%
35–44	24.20%
45–54	15.21%
55+	11.44%
Male	88.55%
Race/Ethnicity	
Non-Hispanic Black	10.49%
Non-Hispanic White	43.81%
Hispanic	11.02%
Other	3.05%
Unknown	31.63%
Household Income	
<$30k	15.99%
$30k-49999	15.49%
$50k-74999	12.27%
$75k-99999	8.72%
$100k+	14.55%
Unknown	32.97%
Education	
High School or Less	27.28%
Some college	16.55%
Associates or more	25.62%
Unknown	30.55%