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The effect of an HIV preexposure prophylaxis panel management strategy to increase preexposure prophylaxis prescriptions

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Objective: The HIV preexposure prophylaxis optimization intervention (PrEP-OI) study evaluated the efficacy of a panel management intervention using PrEP coordinators and a web-based panel management tool to support healthcare providers in optimizing PrEP prescription and ongoing PrEP care.

Design: The PrEP-OI study was a stepped-wedge randomized clinical trial conducted across 10 San Francisco Department of Public Health primary care sites between November 2018 and September 2019. Each month, clinics one-by-one initiated PrEP-OI in random order until all sites received the intervention by the study team.

Methods: The primary outcome was the number of PrEP prescriptions per month. Secondary outcomes compared pre- and postintervention periods on whether PrEP was discussed and whether PrEP-related counseling (e.g., HIV risk assessment, risk reduction counseling, PrEP initiation/continuation assessment) was conducted. Prescription and clinical data were abstracted from the electronic health records. We calculated incidence rate ratios (IRR) and risk ratios (RR) to estimate the intervention effect on primary and secondary outcomes.

Results: The number of PrEP prescriptions across clinics increased from 1.85/month (standard deviation [SD] = 2.55) preintervention to 2.44/month (SD = 3.44) postintervention (IRR = 1.34; 95% confidence interval [CI] = 1.05–1.73; $P = 0.021$). PrEP-related discussions during clinic visits (RR = 1.13; 95% CI = 1.04–1.22; $P = 0.004$), HIV risk assessment (RR = 1.40; 95% CI = 1.14–1.72; $P = 0.001$), and risk reduction counseling (RR = 1.16; 95% CI = 1.03–1.30; $P = 0.011$) increased from the pre- to the postintervention period. Assessment of PrEP initiation/continuation increased over time during the postintervention period (RR = 1.05; 95% CI = 0.99–1.11; $P = 0.100$).

Conclusions: A panel management intervention using PrEP coordinators and a web-based panel management tool increased PrEP prescribing and improved PrEP-related counseling in safety-net primary care clinics.

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Keywords: HIV preexposure prophylaxis, HIV prevention, panel management, preexposure prophylaxis coordinator, preexposure prophylaxis navigator

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Introduction

Nearly a decade after the U.S. Food and Drug Administration's approval of tenofovir disoproxil fumarate (TDF) and emtricitabine (FTC) for HIV preexposure prophylaxis (PrEP), only 23% of the nearly 1.2 million individuals with a PrEP indication have received a prescription for PrEP [1,2]. Healthcare providers' knowledge of PrEP, willingness to prescribe PrEP, and actual prescription of PrEP have repeatedly been shown to be primary barriers to PrEP uptake in healthcare settings [3–10]. Few effective interventions have been developed to impact the upstream drivers of the PrEP care continuum [11] that influence downstream factors affecting PrEP continuation.

Approaches to population-based care that systematically focus on the health of groups of patients, also known as panel management, using nonclinical staff have been used in the treatment of chronic conditions to improve care and reduce healthcare costs [12]. These strategies allow for the identification of care gaps, training staff as panel managers, developing registries of patients with the identified health condition, and adopting clinical practice guidelines to allow trained staff to take an active role in closing the care gaps [13]. Panel management strategies have resulted in increased efficiency, consistency, and quality of care, and improved health outcomes for HIV, smoking, and hypertension [14–16]. Additionally, panel management programs that have employed computerized clinical support tools to provide relevant care reminders, data registries, and performance feedback have been associated with improved healthcare management [17,18]. Prior observational PrEP studies have shown an association between panel management strategies and patients being referred to providers to receive a PrEP prescription [19]; earlier PrEP starts [20]; and provision of patient education, adherence counseling, and resolution of insurance and pharmacy barriers [21].

In the PrEP optimization intervention (PrEP-OI) study, a nonclinical PrEP coordinator managed a panel of patients on PrEP using a web-based panel management tool, which assisted with HIV risk assessment, automated reminders for follow-up, and a patient's PrEP use timeline. In addition to providing PrEP navigation services (health insurance benefits navigation, referring and linking patients to PrEP providers, or referring patients to other services [e.g. housing]) [19,20], PrEP coordinators can provide the full spectrum of PrEP services, except signing PrEP prescriptions and providing patient clinical consultations (e.g. regarding side effect management or other clinical questions requiring medical expertise) [22]. Therefore, the vast majority of PrEP initiation and continuation activities can be conducted by a PrEP coordinator under the supervision of a healthcare provider. In this manner, PrEP coordinators can influence the entire PrEP care continuum [11] from supporting providers in improving PrEP prescribing practices to counseling patients on PrEP continuation. In this study, we evaluated the impact of PrEP-OI to assist providers from San Francisco Department of Public Health (SFDPH) primary care clinics in PrEP prescription and provision of ongoing PrEP counseling.

Methods

Study design and intervention

Between November 2018 and September 2019, we implemented the PrEP-OI randomized trial to examine the impact of a PrEP panel management strategy to support providers with PrEP prescription and management (ClinicalTrials.gov Identifier: NCT03532191) [22]. The intervention included centralized PrEP coordination overseen by a PrEP coordinator whose work was supported by a web-based panel management tool called PrEP-Rx, which included a patient's PrEP timeline, patient consultation checklist (e.g. PrEP adverse effects, adherence, protective levels), questions for PrEP coordinators to ask patients at PrEP evaluation and continuation visits (e.g. 'What do you know about PrEP?' or 'How many pills would you estimate you've taken in the last 30 days?'), and scheduled reminders for PrEP coordinators to order quarterly lab tests and/or follow-up with patients regarding PrEP adherence and adverse effects [22,23].

PrEP-OI evaluated the efficacy of the PrEP coordinator plus PrEP-Rx intervention to increase the number of PrEP prescriptions using a stepped-wedge design among SFDPH primary care clinical sites. A stepped-wedge design is a type of one-way crossover design in which all clinical sites began the study with no intervention and one-by-one initiated the intervention every month until all sites were receiving the intervention [24]. The order in which the clinical sites began receiving the intervention was determined at random to maximize internal validity. Outcomes were compared between the preintervention (from November 2018 to intervention implementation) to postintervention (intervention implementation to September 2019) timeframes. The PrEP-OI study protocol, the results from qualitative interviews with providers about the intervention, and the robustness of the intervention during the coronavirus disease 2019 (COVID-19) pandemic have previously been published [22,25,26]. All study procedures were approved by the University of California, San Francisco Institutional Review Board.

A total of 10 SFDPH primary care clinical sites participated in the study, including a three-site clinic under the same management with overlapping providers and drop-in services for adolescents and young adults. All clinics were part of the SFDPH large safety-net system spread over a wide geographic area in San Francisco and

served a demographically diverse patient population. PrEP-OI had four PrEP coordinators who had panels of 50–120 patients each, based on the number of clinics they supported and the needs of the patient population. The PrEP coordinators who were nonclinical support staff members and trained to provide PrEP outreach, HIV risk assessment, PrEP and postexposure prophylaxis (PEP) education and adherence counseling, support for sexually transmitted infection (STI) testing, including self-swabbing instructions, assistance with insurance coverage, lab ordering and monitoring (per standing order protocols), and quarterly follow-ups. PrEP coordinators connected with patients in person or via telephone or text messaging at the PrEP evaluation visit. If a prescription was written, the PrEP coordinators followed up with the patient at one week (to inquire about PrEP pick up, initiation, and side effects), one month, and quarterly thereafter. PrEP coordinators worked with the patients' providers to support timely PrEP refills and address clinical concerns. Detailed description of the PrEP coordinators' training has previously been published [22].

Outcome measurement

Primary outcome

Our primary outcome was the number of PrEP initiation prescriptions per month. We hypothesized that the mean number of prescriptions to initiate PrEP would significantly increase after PrEP-OI versus before this intervention. PrEP prescription and visit data were extracted from the electronic health record (EHR) via manual chart review using a standardized data collection tool. We included PrEP initiation prescriptions for new PrEP starts and PrEP restarts. New starts were defined as the first time a patient received a PrEP prescription in one of the study clinics, including prescriptions for those who were receiving PrEP elsewhere and transferred their care to one of the study clinics. Restarts were defined as receiving a PrEP prescription 60 days or more after the prior prescription end date (i.e. for a prescription with 30 tablets and two refills, the restart date would be any date on or after 150 days from the date the prior prescription was written), or documented PrEP discontinuation based on EHR. A random sample of 10% of collected data was reviewed by another research staff member to ensure data accuracy.

Secondary outcomes

Secondary outcomes compared clinic visits before and after PrEP-OI to assess whether PrEP was discussed in the clinic visits (i.e. PrEP-related visits) and if various PrEP counseling topics were addressed 90 days postprescription. Data were extracted from the EHR by two study staff members. We included all in-person primary care, nursing, pharmacy, urgent care, prenatal, infectious diseases, and behavioral health visits, as well as all telephone encounters where PrEP was discussed. Visits were categorized as PrEP-related or not PrEP-related based on whether a PrEP discussion was documented in the EHR. Additionally, we collected data on whether postprescription visits (within 90 days of prescription) included discussions related to four counseling topics: assessment for PrEP initiation/continuation – 'did someone assess whether the patient had initiated or was continuing PrEP?'; assessment of HIV risk – 'did someone take a sexual history, ask about injection drug use or acute HIV symptoms?'; risk reduction counseling – 'did someone discuss ways to reduce HIV risk beyond using PrEP (e.g. recommending condom use, use of safe injection kits or asking/talking to partners about HIV status)?'; and PrEP adherence assessment/counseling – 'did someone ask about missed doses, doses taken, or discuss the importance of PrEP adherence?' Visits within 90 days of prescription was chosen to emphasize the importance of follow-up around PrEP initiation, and to allow for time between PrEP prescription and the follow-up visit at three months, as required by CDC guidelines [27]).

Statistical analysis

Because our intervention was designed to influence prescribing practices at the clinic, a clinic-level construct, we operationalized the primary outcome of PrEP prescriptions at the clinic-level and used a negative binomial model to estimate the incidence rate ratio (IRR) for the effect of the intervention on the number of PrEP prescriptions in the post versus the preintervention period [28]. Data were summarized by clinic and month to compare the number of PrEP prescriptions across clinics in months preintervention versus postintervention. Because the intervention was provided at the clinic level, generalized estimating equations (GEE) with an exchangeable correction matrix were used to account for clustered observations by clinic. An indicator for time (rescaled in months) and an interaction term for intervention by time were included in the model to account for potential time effects and were removed from the model through backwards elimination if their *P*-values were not significant ($P > 0.05$).

Secondarily, our study also sought to investigate whether the intervention affected discussions between providers and individual patients on a per-patient basis. We therefore operationalized all secondary outcomes at the level of the individual. For the secondary outcome evaluating number of PrEP-related visits, we used a log Poisson model to estimate the risk ratio (RR) for the effect of the intervention on whether PrEP was discussed during the visit (yes/no) [29]. Data were organized by visit to compare visits in the time period preintervention versus postintervention based on the date of PrEP prescription. GEE with an exchangeable correlation matrix was used to account for clustering by clinic. We used the same backward elimination modeling approach as above. As an exploratory analysis, we also examined models that included and excluded visits with PrEP coordinators to determine if the presence of PrEP

coordinators, which was a primary component of the intervention, contributed to the effect on PrEP-related visits.

For additional secondary outcomes, we examined whether any of the four PrEP counseling topics (i.e. PrEP initiation/continuation, risk reduction, HIV risk, and adherence) were noted in documentation of visits within 90 days of a PrEP prescription; we included all prescriptions in which any of the 90 days fell within the study period. For the adherence outcome, we excluded prescriptions for which the patient reported not initiating PrEP. Prescriptions with no subsequent visit within 90 days of the prescription date were coded as not having discussed these topics in the 90-day period. We used a log-Poisson model to estimate the risk ratio for the effect of the intervention on each PrEP counseling topic. We evaluated each topic individually and as a composite variable (i.e. where any of the four topics were discussed within 90 days of a PrEP prescription). We compared prescriptions initiated in the time period preintervention versus postintervention. GEE was used to account for clustering by clinic. We used the same backward elimination modeling approach as above. In cases where the interaction was significant, we fit slopes for time (in months) separately within the pre and the post time periods to examine how changes in the outcome over time varied by receipt of the intervention. For outcomes with significant interaction effects involving preintervention and postintervention with time, we report the simple slopes for time within preintervention and postintervention followed by the interaction effect. We used SAS version 9.4 (SAS Institute Inc., Cary, North Carolina, USA) for data analysis.

Results

A total of 10 clinical sites were included in the trial during the study period from November 1, 2018 to September 30, 2019. Clinic size ranged from 2225 to 11 781 patients with a median clinic size of 3922 patients (inter-quartile range= 3286, 5126). During the study time period, a total of 319 PrEP prescriptions were provided of which 259 prescriptions met study inclusion criteria for new starts and restarts (115 prescriptions preintervention period and 144 prescriptions postintervention). Of the 1930 visits during the study period, 66% ($N=1275$) were PrEP-related and 34% ($N=655$) were not PrEP-related. Nearly half of the clinic visits were with a primary care provider (47%; $N=904$), 18% ($N=342$) were with a PrEP coordinator, and 35% ($N=678$) were with another type of provider (e.g. nonprimary care physician, nurse practitioner, physician assistant; pharmacist; nurse).

For the primary outcome, the mean number of PrEP prescriptions across clinics increased from 1.85 per month during the preintervention period (standard deviation [SD] = 2.55) compared to 2.44 (SD = 3.4) prescriptions per month postintervention (Table 1). There was no statistically significant interaction for group-by-time and no significant time main effect; therefore, these indicators were removed from the model. Following backward elimination, we found that there was a 34% increase in the number of PrEP prescriptions during the postintervention compared to preintervention time period (IRR = 1.34; 95% confidence interval [CI] = 1.05, 1.73; $P=0.021$).

For the secondary outcomes, PrEP-related visits significantly increased from 64% of all visits in the

Table 1. Primary and secondary outcomes of the PrEP-OI study.

Primary oOutcome	Preintervention Mean PrEP prescriptions per month (SD)[a]	Postintervention Mean PrEP prescriptions per month (SD)[a]	Ratio measure Incidence rate ratio (95% CI)	*P*-value
PrEP prescriptions (starts/restarts), $N=121$ clinic months from 10 clinical sites	1.85 (2.55)	2.44 (3.37)	1.34 (1.05, 1.73)	0.021
Secondary outcomes	Estimated proportion (%)	Estimated proportion (%)	Risk ratio (95% CI)	
PrEP-related visits, $N=1924$ visits	63.9	71.8	1.13 (1.04, 1.22)	0.004
Discussed during visit within 90 days of PrEP prescription, $N=386$ prescriptions				
- PrEP initiation/continuation	62.7	70.8		
- Test of interaction[b]	—	—	1.08 (1.01, 1.16)	0.035
- Preintervention period[a]	—	—	0.97 (0.94, 1.00)	0.051
- Postintervention period[a]	—	—	1.05 (0.99, 1.11)	0.100
- Risk reduction	31.9	37.0	1.16 (1.03, 1.30)	0.011
- HIV risk	47.4	66.3	1.40 (1.14, 1.72)	0.001
- PrEP adherence	41.6	48.7	1.17 (0.87,1.58)	0.306
Any of the four topics discussed	68.4	70.3		
- Test of interaction[b]	—	—	1.10 (1.01, 1.19)	0.024
- Preintervention period[a]	—	—	0.97 (0.94, 1.00)	0.076
- Postintervention period[a]	—	—	1.07 (1.00, 1.13)	0.035

CI, confidence interval; PrEP-OI, preexposure prophylaxis optimization intervention; SD, standard deviation.
[a]Due to significant interaction, we fit slopes for time within pre and postintervention periods.
[b]Difference between slopes.

preintervention period to 72% of visits in the postintervention period (Table 1). The likelihood of PrEP being discussed in a visit was 13% higher postintervention compared to preintervention (RR = 1.13; 95% CI = 1.04, 1.22; $P = 0.004$). After removing the PrEP coordinator visits, there was no significant difference in PrEP-related visits in the post versus preintervention periods (RR = 0.95; 95% CI = 0.87, 1.04; $P = 0.257$), suggesting that the effect of the intervention was likely driven by the PrEP coordinators.

Among prescriptions where any of the 90 days after PrEP prescription fell within the study period ($N = 386$), prescriptions in the postintervention period were more likely to have subsequent visits in which documentation specified discussion of HIV risk (RR = 1.40; 95% CI = 1.14, 1.72; $P = 0.001$) and risk reduction (RR = 1.16; 95% CI = 1.03, 1.30; $P = 0.011$) compared to preintervention. The likelihood of adherence counseling did not differ in the post versus preintervention period (RR = 1.17; 95% CI = 0.87, 1.58; $P = 0.306$). For the outcome of PrEP initiation/continuation counseling, there was a significant interaction between time and the intervention ($P = 0.035$). Preintervention, there was a marginally significant decrease over time in the likelihood of assessing PrEP initiation/continuation within 90 days of PrEP prescription (RR = 0.97; 95% CI = 0.94, 1.00; $P = 0.051$). However, postintervention, the likelihood of discussing PrEP initiation/continuation within 90 days of PrEP prescription increased over time (RR = 1.05; 95% CI = 0.99, 1.11; $P = 0.100$), although not statistically significant. Similarly, for the secondary outcome of discussing any of the four topics (i.e., PrEP initiation/continuation, risk reduction, HIV risk, and adherence) within 90 days of PrEP prescription, there was an interaction between time and the intervention ($P = 0.024$). In the preintervention period, there was a nonstatistically significant decrease over time in discussing any of the four topics (RR = 0.97; 95% CI = 0.94, 1.00; $P = 0.076$). Postintervention, the likelihood of discussing any of the four topics increased over time (RR = 1.07; 95% CI = 1.00, 1.13; $P = 0.035$).

Discussion

In this randomized trial of a PrEP panel management strategy, we found that PrEP prescriptions and PrEP-related visits increased in clinics once the PrEP-OI intervention was implemented. The increase in PrEP related visits was largely related to the influence of the PrEP coordinators, as suggested by the lack of effect when removing the coordinators from the model. In visits within 90 days of PrEP prescription, we found that PrEP-OI increased counseling about risk reduction and HIV risk, but not counseling about PrEP adherence. Discussions assessing PrEP initiation/continuation appeared to decrease over time during the preintervention period but changed course to increase over time once the intervention was delivered. Similarly, discussions of any of the four counseling topics had a slight decrease over time preintervention, which changed to increase over time once the intervention was delivered.

Other observational studies have shown that PrEP panel management strategies can lead to patient referrals for PrEP initiation, earlier PrEP starts, resolution of PrEP medication coverage challenges, and patient adherence counseling [19–21]. We add to this knowledge-base by providing evidence from a randomized trial of a PrEP panel management strategy using PrEP coordinators with a web-based PrEP panel management support tool. We found that PrEP-OI increased PrEP prescriptions and PrEP-related visits. Provision of the PrEP-OI intervention positively influenced clinical discussions regarding PrEP in general and specifically, counseling on HIV risk reduction beyond PrEP and assessment of HIV risk (by taking a sexual history and asking about drug use and acute HIV symptoms). These data are important given the low frequency of sexual history taking among primary care providers [30]. These findings highlight the significant benefit of using PrEP panel management strategies to increase PrEP prescription and counseling.

Of note, we did not find an increase in counseling on PrEP adherence. We believe that this may be due to several reasons, such as adherence counseling being provided prior to the initial PrEP prescription. It is possible that PrEP adherence was not discussed if a patient had previously been on PrEP or not appropriately documented. Given these issues, PrEP-OI could be further modified to ensure that adherence counseling is being conducted and documented by the PrEP coordinators.

There are several limitations to this study. First, we included a small number of clinical sites ($N = 10$) with a year of follow-up. The small number of clinics and short timeframe limited the precision of our estimates and our ability to understand how practices at the clinics might have changed over time as PrEP-OI became more established. Second, the study used a stepped-wedge design; therefore, results may be affected by temporal changes in medical practice. However, we tested interactions between the intervention and time and evaluated time effects in the models. Third, there may have been intra- or inter-clinic variabilities in the extent of documentation within the EHR, particularly when the EHR changed during the study period. Lastly, all clinics were primary care safety net clinics in San Francisco which may limit the generalizability of the results to other locations or clinic types. Future iterations of the intervention can improve counseling and monitoring of PrEP adherence and test the cost-effectiveness of the intervention. While we may not be able to separate the

impact of the PrEP coordinator from PrEP-Rx, we believe that PrEP-Rx is a support tool and would likely not be used to its full potential without the presence of individual(s) designated as PrEP coordinator(s).

In summary, the deployment of a PrEP panel management strategy using PrEP coordinators with a web-based PrEP panel management support tool to assist providers from SFDPH primary care clinics increased PrEP prescriptions and provision of ongoing PrEP counseling related to assessment of HIV risk and HIV risk reduction. PrEP coordinators may be efficient and effective team members to simultaneously address numerous clinical barriers to PrEP implementation [9], including a lack of providers' PrEP knowledge and concerns about PrEP costs, adherence, follow-up and laboratory monitoring, and provider discomfort discussing sexual activities. Additionally, they can assist with access and adherence to newer PrEP regimens, such as long-acting injectables. We noted many of these themes and the benefit of PrEP coordinators in qualitative interviews with providers in clinics where we implemented PrEP-OI [25]. Therefore, we believe the results of this study can provide valuable insight into methods to improve the PrEP continuum of care.

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Conflicts of interest

Potential conflicts of interest: A.L. has received funding for investigator sponsored research from Gilead Sciences and ViiV Healthcare. All other authors declare no competing interests.

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