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Improving access to pre-exposure prophylaxis for HIV prescribing in a primary care setting

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ABSTRACT

Although emtricitabine–tenofovir was approved for HIV pre-exposure prophylaxis (PrEP) in 2012, use by persons at risk of acquiring HIV has been limited. Because many primary care providers lacked familiarity and comfort prescribing PrEP, at our institution PrEP prescribing was concentrated among the infectious disease specialists, effectively limiting access. This project sought to increase the number of patients receiving new prescriptions for PrEP. The interventions targeted primary care providers (including internal medicine and family medicine), and were designed to increase the number of unique providers offering PrEP to their patients. The overall strategy was to expand the clinical scope of practice for primary care providers through education and provision of detailed care templates in the electronic health record. These initiatives were implemented through a series of informal Plan–Do–Study–Act cycles, then generalised throughout the medical system. To evaluate the success of the project, we queried the electronic medical record for all new prescriptions for PrEP, with provider name and specialty, for all outpatients 18 years of age and older from 2012 through 2020. In 2015, prior to the intervention, only 78 patients received new prescriptions for PrEP at our institution, and only 38% (30 of 78) of these were from primary care clinicians. After the intervention, the number of patients receiving PrEP increased to 190 in 2019, with 85% (162 of 190) prescribed by primary care providers. In addition, the number of primary care providers making a new prescription for PrEP increased from 20 in 2015 to 73 in 2019. We conclude that targeted clinical education, combined with electronic health record templates, was associated with a significant increase in PrEP prescribing.

PROBLEM

In 2011, over 1.2 million people in the USA were living with HIV, with 14% of individuals unaware of their diagnosis.[1] In 2012, emtricitabine–tenofovir as pre-exposure prophylaxis (PrEP) to prevent HIV obtained Food and Drug Administration approval for use in adolescents and adults at high risk of contracting HIV.[2] Despite the 2017 US Preventive Services Task Force Grade A recommendation that PrEP be offered to high-risk populations (including men who had sex with men (MSM) and persons who inject drugs),[3] uptake has been slower than anticipated.[4] A 2017 online survey showed that compared with HIV specialists, fewer primary care providers had heard of PrEP (76% vs 98%) or had prescribed it (17% vs 64%).[5] Moreover, conversations about PrEP are rarely initiated by primary care providers. In a 2019 chart review of 64 Veterans Health Administration patients, 94% of all PrEP prescriptions came from patient-initiated requests.[4]

This work took place in the Department of Primary Care at Virginia Mason Medical Center, a non-profit regional healthcare delivery system with approximately 777 providers (physicians, physician assistants, nurse practitioners), 800 000 outpatient visits and 17 000 hospital visits annually. The Department of Primary Care encompasses providers in both family medicine and internal medicine. Just prior to initiation of this work in 2016, we received feedback from community organisations, and from our own team members that the needs of the local Lesbian/Gay/Bisexual/Transgender/Queer/Intersex/Asexual/Other (LGBTQIA+) community were not being met, specifically around access to PrEP. At our institution, only 78 patients received new prescriptions for PrEP in 2015, and only 38% (30 of 78) of these were from primary care.

In 2016, we formed a multidisciplinary team to improve access to PrEP, with goals of: (1) increasing the number of eligible patients on PrEP and (2) increasing the number of providers who offer PrEP to their patients.

BACKGROUND

The Center for Disease Control and Prevention has estimated over 1.2 million people live with HIV in the USA with persons unaware of their HIV infection contributing to nearly one-third of transmissions.[1] In 2018, there were 37 968 new diagnoses of HIV in the USA and its dependent areas.[6] A disproportionate number of MSM, transgender women and people of colour live with HIV in the USA.[6] Additionally, transgender women carry a

higher burden of HIV compared with cismen (39% vs 26%).[7] Notably, a 2020 San Francisco study showed that compared with cismen, transgender women had less awareness of PrEP (79% vs 98%), fewer conversations with medical providers about PrEP (36% vs 55%) and lower rates of adherence (70% vs 87%).[8]

Efforts at identifying patients at higher risk of transmitting HIV depend on consistent and thoughtful discussions of sexual history between patients and clinicians. Existing literature suggests that most primary care clinicians do not consistently discuss sexual health or engage in taking sexual histories.[9] Such efforts may be compounded by limited time in a clinic visit, provide unease at discussing sexual history, patient unease at disclosing sexual behaviours and/or partners with their clinicians, and lack of training in taking a sexual history among clinicians. Clinic note templates combined with clinician education about these templates have previously been shown to be effective in increasing adherence to disease management strategies, including for diabetes[10] and smoking cessation.[11] Once risk status is ascertained, clinicians must discuss and recommend PrEP to patients. Currently, in the USA, many discussions about PrEP are introduced by patients, not by clinicians.[9]

MEASUREMENT

To measure the effectiveness of our intervention, we identified two primary metrics. The first was the number of providers who prescribed PrEP in any given year in primary care. This is an indication of our success as an institution in educating and supporting primary care providers in the use of this medication. Second was the number of unique patients who received a new prescription for PrEP in any given year, a marker for access to appropriate care.

Data collection and analysis

To determine each of these metrics, we performed queries of the electronic health record (EHR) for all prescriptions for PrEP (emtricitabine–tenofovir), with patient and prescriber information for all outpatients 18 years of age and older from 2012 through 2020. Since medications used for PrEP are also used as part of combinations of medications to treat HIV, we excluded individuals who had a positive HIV test at any time prior or during the study period, since seroconversion during PrEP therapy is rare. We also excluded patients who had a medication order by an emergency medicine provider, since these prescriptions are more likely to be for post-exposure prophylaxis. To separate patients receiving prescriptions of emtricitabine–tenofovir for HIV treatment rather than for prevention, we also excluded patients who had orders for emtricitabine/rilpivirine/tenofovir, efavirenz/emtricitabine/tenofovir, bictegravir/emtricitabine/tenofovir, or efavirenz/lamivudine/tenofovir.

Provider specialty and degree were also downloaded from the electronic medical record. Provider characteristics were summarised according to their specialty, with least common specialties (for example, hospitalist, neurology, gynaecology) grouped together in an 'Other' category. The time period 2012–2016 was the baseline pre-intervention period, with 2017 and 2018 serving as the intervention period, and 2019–2020 the follow-up (post-intervention) period. Statistical analysis was performed using StataMP V.16.0 (Stata Corp, College Station, Texas, USA). The t-test was used to compare means, and the X^2 to compare proportions before and after the intervention.

Baseline measurement

In the pre-intervention years 2012 through 2016, an average of 50.2 patients/year received new prescriptions for PrEP at our institution (table 1). Just 47% (117 of 251) of these patients were from primary care (ie, family medicine and internal medicine) clinicians. During the same years, PrEP prescriptions were written by an average of 24 unique providers/year, of whom an average of 15 were in primary care (figure 1). This represents only a small percentage of the approximately 163 total providers in primary care prior to the intervention.

DESIGN

This work began in late 2016 when a multidisciplinary group of providers and staff members formed an interest group to elevate care for the LGBTQIA+ population. This group was formally organised as 'Proudly VM' in 2017, with the hospital medical director as executive sponsor. Through a series of meetings in late 2016 and early 2017, the group heard from stakeholders at our institution as both patients and employees, who identified that access to PrEP was an incompletely met need in the LGBTQIA+ community. At this time, PrEP was most commonly initiated through a referral to an infectious disease specialist, which the group felt to be an unnecessary barrier. Thus, the group advocated that patients access PrEP through their individual primary care providers.

The overall design to improve access to PrEP was to expand the clinical scope of practice for providers in primary care through education and provision of detailed care templates in the EHR. These initiatives were implemented through a series of informal Plan–Do–Study–Act (PDSA) cycles, then generalised throughout the medical system.

STRATEGY

The first phase of the project was to understand and standardise the ideal PrEP visit, with the aim of developing clinical decision-making tools to improve clinician comfort in prescribing PrEP. Use of PrEP is conditioned on both being a suitable candidate and having follow-up care. Accordingly, an internal medicine provider and an infectious disease specialist partnered to identify key components of a PrEP initial visit. These include taking a sexual history (ie, number, sex and gender of partners, body

Table 1 Number of providers who wrote new PrEP prescriptions, by provider specialty by year, N=216 unique providers

	2012	2013	2014	2015	2016	2017	2018	2019	2020
Primary care									
Internal medicine	10	3	11	19	29	46	48	60	51
Family medicine	1	0	0	1	1	2	5	13	13
Specialty care									
Infectious	2	6	5	6	4	7	5	6	3
Haematology-oncology	1	0	1	1	2	1	0	1	0
Surgery	0	2	1	0	2	3	2	6	3
Other	1	0	1	4	4	5	3	5	9
Degree									
Doctor or medicine or osteopathy	14	8	19	27	37	49	52	71	57
Physician assistant-certified or nurse practitioner	1	3	0	4	5	15	11	20	22
Total	15	11	19	31	42	64	63	91	79

PrEP, pre-exposure prophylaxis.

parts used for intercourse, condom use, STI (sexually transmitted infection) history), social history, assessing risk of HIV transmission and appropriateness of PrEP (ie, risk of transmission should be high, but patient should be accountable enough to adhere to treatment), screening for STIs, assessing risk of complications (increased STIs, pregnancy, renal dysfunction) and counselling.

The initial two physicians then formed a larger multispecialty (ie, internal medicine, infectious diseases, haematology-oncology) PrEP and Sexual History Task Force of physicians and allied health staff to develop a template for the EHR at all outpatient primary care sites in the institution. The template comprised the care elements required for the PrEP visit (figure 2), including key questions that the clinical primary care providers could input during PrEP prescription decision-making

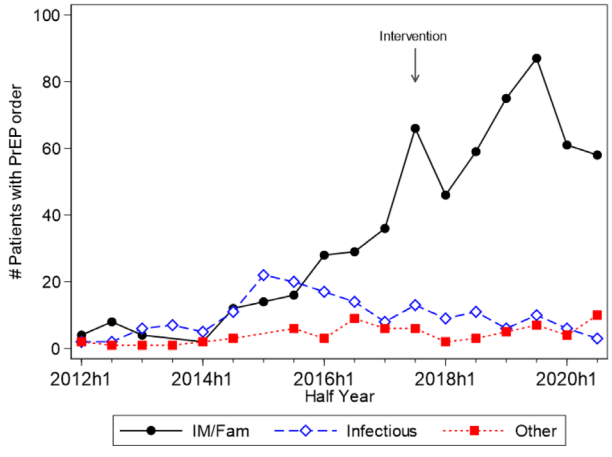

Figure 1 Number of patients with new orders for PrEP over time. Fam, family medicine; IM, internal medicine; PrEP, pre-exposure prophylaxis.

(ie, sexual history and condom use, information on risks and benefits, as well as the drug dosage and administration, indications for specialty referral, required initial and follow-up labs and recommended vaccines). The initial template went through multiple revisions after input from several infectious disease and HIV care specialists, and after review by the local evidence-based medicine champion. The template also went through an initial informal PDSA trial by providers on the Proudly VM affinity group. On 16 July 2017, the template was formally approved by the Department of Primary Care Best Practices Task Force, an institutional oversight group compromising primary care and specialty providers, experts in information technology, clinic leadership and management. The template was then distributed to all primary care providers for use.

Development of the PrEP template helped the task force identify several areas in need of improvement. Early on, the team realised prescribing providers would need to be comfortable taking sexual histories and swabbing for STIs, in line with the US Center for Disease Control recommendations on PrEP prescribing. An initial consideration for improving access to PrEP was to train pharmacists to aid in PrEP prescribing. At our institution, pharmacists are integrated directly into primary care practice, and provide monitoring and medication dosage adjustment for a number of chronic medical conditions, including diabetes and hypertension. However, appropriate monitoring of patients on PrEP includes rectal, oral and vaginal swabbing for STIs, which we realised were outside of the scope of practice of pharmacists. Accordingly, inclusion of pharmacists in PrEP prescribing could not be implemented, and PrEP care was limited to physician, advanced registered nurse practitioner and physician assistant providers. Since initial development, the

CHIEF COMPLAINT: STD Prevention

ASSESSMENT:
[_] Z11.4 Encounter for screening for human immunodeficiency virus
[_] Z72.51 High risk heterosexual behavior
[_] Z72.52 High risk homosexual behavior
[_] Z72.53 High risk bisexual behavior

[_] The patient meets criteria for prophylaxis:
- [_] Sex with HIV positive partner. *(Particularly if partner has a detectable viral load.)*
- [_] Man who has sex with men who have condomless sex, multiple sex partners, anonymous sex partners.
- [_] Woman who has condomless sex with men who have a history of IVDU or having sex with men.
- [_] Injection drug users who report sharing needles/equipment in the last 6 months.
- [_] The patient strongly desires to be on prophylaxis. *(Includes women with multiple partners, anyone who has sex with commercial sex workers or sex with a partner who frequents commercial sex workers, etc.)*

PLAN:
[_] We discussed the risks and benefits of HIV prophylaxis with emtricitabine 200 mg / tenofovir 300 mg daily.
Potential benefits: Reduction of risk of acquiring HIV.
Potential risks include: Reduced renal function or very rarely lactic acidosis, osteoporosis, acquisition of other STDs. While PreP reduces risk of acquiring HIV, it is still possible to acquire HIV while on PreP, and it is possible to acquire a drug resistant strain of HIV.
The patient was counseled on using condoms, symptoms of acute HIV, duration of therapy, cost, follow up every 3 months, and adherence. *(not a "morning after" pill).*

[_] Referral to Infectious Diseases due to [_] pregnancy, [_] CKD, [_] transaminitis [_] complication from PreP [_] other: _

[_] Studies today to include:
- [_] HIV Screen *(initial visit and every 3 months)*
- [_] Syphilis Screen *(initial visit and every 3 months)*
- [_] Chlamydia and gonorrhea *(initial visit and every 3 months)*
  - [_] Urine [_] Urethral [_] Rectal [_] Throat [_] Vaginal
- [_] Beta HCG *(initial visit and every 3 months)*
- [_] Serum creatinine *(initial visit and every 6 months)*
- [_] Urinalysis (only if at risk for renal disease) *(initial visit and every 6 months)*
- [_] HCV *(initial visit and every 12 months)*
- [_] Anti-HBs, HBsAg *(initial visit only)*

[_] If HBsAg negative, initiate HBV immunization series.
[_] Initiate HAV series if no history of vaccination. Consider TWINRIX if patient needs both HAV and HBV.

[_] If HIV returns negative, a script for 3 months for emtricitabine 200 mg / tenofovir 300 mg daily will be sent to the patient's pharmacy as soon as the test result returns. Patient will be informed of the test result and of the prescription.
Follow up in 3 months with labs prior.

[_] Greater than 50% of _ minutes was spent in face to face counseling regarding issues noted above.

HPI:
_

Sexual History

The patient has sex with [_] men, [_] women, [_] transgender or non binary partner
The patient has [_] oral sex, [_] vaginal sex, [_] receptive anal sex, [_] insertive anal sex
Condom use: [_] Yes, [_] No, [_] Sometimes; please indicate what % of the time condoms are used_
History of STD: [_] No, [_] Yes: _

Social History
Ever used IV drugs: [_] No, [_] Yes.
If yes: Last use: _ Frequency: _ Substances used: _

EXAMINATION:
[_] General: Patient is well appearing and in no acute distress

Vital Sign, Problems, Allergies, Medications
***Vital signs, *Prob_allerg_meds**

CDC Resources for Providers:

Resources including handouts (English, Spanish):
https://www.cdc.gov/hiv/risk/prep/index.html

Guidelines:
https://www.cdc.gov/hiv/pdf/PrEPguidelines2014.pdf

Figure 2 Electronic health record template for pre-exposure prophylaxis primary care visit. CKD, chronic kidney disease; HAV, hepatitis A vaccine; HBsAg, hepatitis B serum antigen; HBs, hepatitis B serum; HBV, hepatitis B vaccine; HCG, human chorionic gonadotropin; HPI, history of present illness; PrEP, pre-exposure prophylaxis; TWINRX, combined hepatitis A and B vaccine.

PrEP template has gone through multiple improvement cycles, particularly with upgrades to the EHR enabling direct integration of templates of this sort directly into the patient record.

The second phase of the project was provider education and outreach, with the aim of increasing the number of clinicians prescribing PrEP. The PrEP and Sexual History Task Force developed an educational curriculum for primary care clinicians, deemed the 'PrEP Road Show'. This presentation was first trialled to the Department of Primary Care leadership committee in November 2017, and following revisions, presented alongside the PrEP EHR template at eight clinic sites between January and July of 2018. The road show was an approximately 30-minute presentation, including a formal didactic component, open discussion of best practices and review of any challenges regarding delivery of PrEP care. The road show was generally presented during regular clinic provider meetings, ensuring the presentations would be well attended. Members of the task force made themselves available for follow-up conversations with any of the providers requesting additional clinical guidance.

As the road show progressed, we received feedback from multiple clinicians that they had insufficient skills and comfort at taking sexual histories to implement PrEP prescribing. Based on this input, we expanded the road show to include conversations at the end with more experienced clinicians at each site about their approach to sexual history taking, and any lessons learnt. In addition, the team created a set of videos for training on sexual history taking, which were shared through the internal internet site.

The PrEP Road Show was supplemented by Grand Rounds presentations to the entire medical staff on 'Taking a Sexual History' (February 2018) and 'Prescribing PrEP' (April 2018). In addition, a required educational module for all providers on 'Intro to your LGBTQ patients' was completed by over 850 providers and staff by October 2017. This provided general guidance on the needs and cultural concerns when caring for patients from the LGBTQIA+ community.

To sustain the work, the Proudly VM team continued with high-visibility community outreach, including educational booths at and sponsorship of local LGBT pride events. These efforts were publicised at our institution to remind providers and staff that PrEP and other care for LGBTQIA+ patients were available and important. In addition, the institution committed to offering Grand Rounds presentations on aspects of care for LGBTQIA+ patients at least annually. In 2020, care for LGBTQIA+ patients including both PrEP and transgender care was codified as an organisational goal.

RESULTS

We identified 848 unique patients from the electronic medical record who received a new order for PrEP between 1 January 2012 and 31 December 2020. The mean age was 37 years (SD=12, range 18–87) and 89% (756 of 848) were male. Seventy-one per cent (602 of 848) had at least one laboratory result at our institution, and 55% (469 of 848) had at least one high-risk diagnosis code in the billing database during the study period. Figure 1shows the absolute number of patients receiving new PrEP prescriptions. Most of the patients (71%) received a PrEP prescription from a primary care provider (605 of 848), followed by an infectious disease specialist (172 of 848, 20%). The number of new patients who received a PrEP prescription per year increased from 19 patients in both 2012 and 2013, to 190 patients in 2019. The proportion of patients prescribed PrEP by an internal medicine or family medicine provider increased from 2012 to 2019, and the absolute number of patients for all providers also increased through year 2019. However, the number of patients with new PrEP prescriptions decreased in 2020, likely due to the COVID-19 pandemic and advice to socially distance.

Table 1 shows the number of providers writing new PrEP prescriptions, by provider specialty. Two hundred sixteen unique providers wrote new PrEP prescriptions during the study period. The most common provider specialties were internal medicine (133 of 216, 62%) and family practice (26 of 216, 12%). Most (162 of 216, 75%) were either MD or DO providers. The absolute number of unique providers increased from 15 providers in 2012 to 91 providers in 2019, but decreased in 2020 to 79 providers (table 1). A decrease in the proportion of infectious disease providers writing new PrEP prescriptions can be seen throughout the study period. There was an increase in the number of primary care providers after the intervention, but not enough to explain the large increase in primary care providers prescribing PrEP. Pre-intervention, approximately 9.2% (15 of 163) of primary care providers prescribed PrEP to new patients, increasing to 33.4% post-intervention (69 of 205) ($p<0.001$).

The number of patients with new PrEP prescriptions increased gradually prior to the intervention, but figure 1 demonstrates an abrupt increase in the number of patients newly prescribed with PrEP by primary care providers in 2016, consequent to the time of intervention.

LESSONS AND LIMITATIONS

In this project, we demonstrate success in expanding provider comfort with use of PrEP, and in the number of patients accessing this treatment through a quality improvement intervention. We are now able to better address the needs of our community and provide appropriate medication to help prevent the spread of HIV.

Our success was facilitated by the institutional lean culture, that emphasises teamwork, innovation and standardisation, all of which were cornerstones of this work. In addition, the participation of clinical champions who were already established in the departments of primary care and various specialty departments, combined with the relatively small size of our institution, likely contributed. This work also benefited from the support of the

pre-existent institutional Best Practices Task Force, with a track record of implementing evidence-based practices, and on the structure of sectional meetings at each of the primary care clinical sites. Without these resources, success would have been substantially more difficult.

We acknowledge the limitations of this work. Our results are from a single institution and may not be generalisable. In addition, we can only report trends at our institution, and do not know if the change can be attributed to overall increases in rates of use of PrEP in the community, even in the absence of the quality improvement work. It is notable that there was an increase in the number of patients receiving initial PrEP prescriptions prior to the intervention, though the rate of increase did accelerate with the intervention. Though we had success in greatly increasing the number of providers prescribing PrEP as a preventive therapy, many primary care providers are still not prescribing PrEP to new patients. This may reflect the composition of their panels but raises concern about unmet patient needs. We also note that the majority of our patients were male. The most common risk factor for HIV in our population was MSM, and this is reflected in our sample. However, the intervention was designed to improve access to PrEP to all high-risk individuals, regardless of gender.

One limitation of this study is that we do not have access to medical records outside of our institution. Chart review revealed that some patients without laboratory testing at our institution were getting their diagnostic testing outside of our hospital and clinics. Accordingly, we did not try to assess compliance with PrEP-associated testing, though this may have been affected by the project. Liu and colleagues have previously demonstrated an increase in appropriateness of PrEP-associated laboratory testing after implementation of a multidisciplinary PrEP task force.[12] In addition, we attempted to exclude patients who had HIV and were taking emtricitabine–tenofovir as part of their HIV treatment regimen. However, this can be hard to determine through a retrospective record review. In general, HIV-positive patients could be identified through the diagnostic codes in the EHR, and were not included in this analysis. However, a small number of patients with HIV may have been included in our analysis if they were receiving emtricitabine–tenofovir as part of a therapeutic regimen, were not identified through a diagnostic code in the EHR and did not have a positive HIV test.

During the period of review, the average age of patients receiving emtricitabine–tenofovir at our institution was 37 years. In 2016, the rate of new HIV diagnoses in MSM aged 13–29 years was quadruple than that of men over 50 years.[13] While we saw an increase in prescriptions, we learnt more work needs to be done to reach younger patients at risk. Likewise, the project's scope did not specifically address people of colour or transgender, which provides further opportunity for outreach.

Finally, we identified a small decrease in the number of both providers and patients in 2020. This is likely related to the COVID-19 pandemic, with fewer patients engaging in high-risk sexual behaviour and fewer seeking medical care, as has been reported previously.[14] PrEP use has also declined. We continue to support primary care providers in prescribing PrEP for the anticipation of increasing patients engaging in high-risk sexual behaviour as COVID-19 eases. Current efforts include reminder education sessions and continued updating of the care templates in the EHR.

CONCLUSIONS

We conclude that our quality improvement intervention to improve patient access to PrEP was successful, with increasing numbers of primary care providers prescribing PrEP and increasing numbers of patients receiving this treatment. Our ability to care for this often underserved portion of our community has been enhanced. During the project, we realised that clinicians were willing to learn, and implementation of an easy-to-use clinical decision-making template and dedicated education helped them to do so. This led to a fivefold increase in PrEP prescriptions, and a doubling of unique providers over a 5-year period. Our template remains in wide use, and we continue to provide clinical education devoted to HIV prevention on an annual basis.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not required.

Ethics approval This investigation was performed as part of a quality improvement project and a waiver was granted from the Benaroya Research Institute Institutional Review Board. All patient-identifiable data were kept confidentially in a quality improvement database, and shared only anonymised and in aggregate.

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