Developing and implementing PrEP at your local health center

By Brenda A. Wolfe, MSN, APN, ACRN; Elizabeth Higgins, MSN, WHNP; Michelle Vos, MA; and Amy Whitaker, MD

Pre-exposure prophylaxis (PrEP) is an effective tool in the prevention of HIV acquisition. Advanced practice registered nurses are ideally positioned to introduce and prescribe PrEP, but some may not know how to integrate it into their practice. In this article, the authors describe the logistics of developing and implementing a PrEP program at multiple Planned Parenthood of Illinois (PPIL) health centers. They also discuss the training and support offered to PPIL clinicians during implementation of the program, the evaluation process, and the results. The process from development to implementation and evaluation can be easily adapted to other clinical settings.

Key words: Pre-exposure prophylaxis, PrEP, women, HIV prevention, outpatient health services, reproductive health

re-exposure prophylaxis (PrEP) is the use of antiretroviral medication by HIV-negative individuals to reduce their risk of acquiring HIV. Emtricitabine/tenofovir disoproxil fumarate (ETDF), the only FDA-approved medication for PrEP, is more than 92% effective in preventing HIV acquisition when taken as directed.¹ Information about PrEP should be offered to suitable candidates, as described in the CDC's Clinical Practice Guideline, Preexposure **Prophylaxis for the Prevention** of HIV Infection in the United States^A.² Advanced practice registered nurses (APRNs) working in reproductive health clinics, sexually transmitted infection clinics, obstetrics and gynecology (Ob/Gyn) practices, and other primary healthcare

settings are particularly well positioned to discuss PrEP with their patients and prescribe the medication when indicated. Many clinicians are reluctant to implement

PrEP in their practices—for a variety of reasons. A major concern is the time needed to obtain sexual histories, provide counseling, and complete required paperwork for patients needing financial assistance (mainly for medication provision). Clinical concerns related to prescribing PrEP include drug side effects, a potential lack of adher-



ence to the regimen by patients, and the possibility that patients might engage in riskier sexual behavior³ because, by taking PrEP, they may feel less vulnerable to harm.

Even though ETDF has proved to be highly effective in preventing HIV acquisition, clinicians working in certain types of practices are unlikely to prescribe it. For example, according to a PrEP utilization review, only 3% of PrEP regimens prescribed between 2013 and 2016 were provided in Ob/Gyn offices.⁴ According to this same review, most women accessed PrEP through family medicine and emergency department providers, whereas most men accessed it through family medicine and internal medicine providers.⁴

With the hope of encouraging APRNs to be more proactive in prescribing PrEP and, even more, helping them set up a PrEP program in their own practice venue—the authors share their experience in developing and implementing a PrEP program at 16 affiliates of Planned Parenthood of Illinois (PPIL). They describe the training and support provided to the PPIL clinicians during implementation of the program and discuss the evaluation process and results.

Developing and implementing a PrEP program

Integrating a new service into a private or multispecialty practice requires planning. One of the first steps is to anticipate barriers that may (1) prevent administrators, clinicians, and staff members from fully embracing the program or (2) deter patients from returning for services. The next step is figuring out how to avoid or overcome these barriers as the program is designed and then launched. A host of other decisions about the program must be made and numerous details regarding its implementation must be addressed.

Based on their experience at PPIL, the authors recommend these steps for developing and implementing a PrEP program:

- Ensure that top administrators (e.g., CEO, county commissioners, board of directors) are well versed about PrEP.
- Obtain support from the senior leadership team.
- Determine whether clinicians perceive that PrEP is an appropriate intervention and whether they have concerns about the screening process or the PrEP protocol itself. Provide information and address concerns as needed.
- Train and support clinicians on how to provide PrEP.
- Create a PrEP algorithm for screening and prescribing.
- Train medical assistant staff to screen for and educate about PrEP.
- Inform support staff, schedulers, educators, and administrative staff about PrEP services.
- Include PrEP education in the new-hire orientation program.
- Designate a champion to provide support and on-call assistance. (A clinician can become a PrEP champion via continuing education, experience in prescribing PrEP, or both.)
- Determine whether rapid HIV testing will be performed onsite or outsourced.
- Identify patient visit and laboratory test costs.
- Ascertain whether ETDF will be stocked in-house and/or acquired by patients from offsite pharmacies.
- Identify appropriate diagnostic codes for PrEP services to ensure optimal reimbursement and ability to track visits for program evaluation (at PPIL, the PrEP program developers gave clinicians one specific diagnostic code to

- EP

use when ordering PrEP in order to make the evaluation process easier).

- Create standing orders for laboratory tests and medications.
- Configure standing laboratory test and medication orders into electronic health records (EHRs).
- Create educational phrases in the EHR for efficient comprehensive documentation.
- Include PrEP services in marketing materials and messages, including those on social media.
- Inform stakeholders and community agencies about available PrEP services.
- Pre-populate and print patient medication assistance forms and co-pay cards for efficient application processing. The Gilead Advancing Access[®]program^B provides information for clinicians and patients to help ensure access to medication.
- Add your clinic and/or clinicians to the PrEP Locator National Directory^C.
- Evaluate the effectiveness of program implementation.
- Address concerns recognized during the evaluation process.

PrEP training and support for clinicians

Written protocols are an important resource for training and supporting clinicians as they implement a new service within their practice setting. Examples of available resources for PrEP protocols and checklists are provided in the *Box*. Planned Parenthood's Medical Standards and Guidelines (MS&Gs) include comprehensive PrEP protocols and algorithms that were used for this purpose at PPIL.

As part of the training at PPIL, the clinicians were asked to review these MS&Gs and attend a 90-minute pre-(continued on page 31)

27

PrEP

(continued from page 27)

sentation on PrEP. The presentation was provided by PPIL's PrEP champion. The presentation included a case study with multiple-choice questions that generated discussion and allowed the clinicians to apply information from the protocols and algorithms. PrEP education included identifying candidates for PrEP, counseling, prescribing, and required follow-up. Information about PrEP-Ception, the utilization of PrEP for HIV sero-discordant couples wanting to conceive, was included in the training.

The clinicians were reminded that most patients are unaware of PrEP; as clinicians, they are responsible for discussing PrEP as part of a comprehensive HIV prevention strategy. Clinicians involved in reproductive healthcare practices are already experienced in taking sexual histories and discussing safer sex practices. Adding PrEP to the conversation simply expands the prevention messages and options for patient protection.

Statistics on HIV prevalence within the communities in which the clinicians practice were provided during the presentation as well. The clinicians were encouraged to share this information with their patients—a strategy aimed at increasing patients' awareness of the level of risk of acquiring HIV based on its prevalence within their community. Too often, patients perceive PrEP candidates as persons who have engaged in promiscuous or dangerous behavior. Clinicians' emphasis on HIV prevalence in the community—as opposed to certain behaviors—as being a factor in acquiring HIV can reduce the stigma.

Upon completion of the PrEP presentation, the clinicians were free to implement PrEP into their practice. Providing routine educa-

Box. PrEP resources

New York State Department of Health AIDS Institute. Clinical Guidelines Program. PREP FOR HIV PREVENTION

- Purpose of this guideline: https://www.hivguidelines.org/prep-forprevention/prep-to-prevent-hiv/#tab_0
- Updates to this guideline: https://www.hivguidelines.org/prep-forprevention/prep-to-prevent-hiv/#tab_1
- PrEP efficacy: https://www.hivguidelines.org/prep-for-prevention/prepto-prevent-hiv/#tab_2
- Candidates for PrEP: https://www.hivguidelines.org/prep-for-prevention/ prep-to-prevent-hiv/#tab_3
- Pre-prescription counseling and assessment: https://www.hivguidelines.org/ prep-for-prevention/prep-to-prevent-hiv/#tab_5
- Prescribing PrEP: https://www.hivguidelines.org/prep-for-prevention/ prep-to-prevent-hiv/#tab_7
- PrEP follow-up: https://www.hivguidelines.org/prep-for-prevention/prepto-prevent-hiv/#tab_8

tion about and screening for PrEP was encouraged. However, the clinicians exercised their own judgment and comfort level in terms of whether they chose to prescribe PrEP themselves or refer patients to another PPIL provider to do so. The PrEP champion was always available to answer questions and provide support. Most questions posed to the champion concerned laboratory tests, co-morbidities, and potential drug interactions, and were typified by the following:

- When monitoring kidney function, which test panel or test (complete metabolic profile, basic metabolic profile, blood urea nitrogen, or creatinine) is the most cost effective?
- How should I proceed if a patient has a slightly low or high creatinine level?
- How often should a hepatitis B antigen be drawn on a patient who wants to restart PrEP?
- Can PrEP be started in a patient with a positive syphilis test result?
- Can use of PrEP be affected by the presence of certain health conditions?
- Can PrEP be prescribed prior to the return of baseline lab test results in a patient with a negative rapid HIV test result?

• Which drugs can potentially interact with PrEP?

Evaluation process and results

Short- and long-term evaluations are important components of a successful change in practice. Barriers can be identified and addressed, lessons can be learned and shared to improve processes, and factors needed to sustain the change can be assessed. Each clinical setting implementing PrEP services can decide how best to implement the evaluation component. However, having an evaluation plan in place from the beginning will help ensure that it occurs.

PPIL implemented evaluations at 4, 12, and 18 months using EHR data, one-on-one meetings between the clinicians and the PrEP champion, and clinician surveys. Along the way, these evaluations provided valuable insights. Early on, some clinicians needed and were provided with more information about the PrEP protocol, as well as guidance on initiating the conversation about PrEP with patients who might not consider themselves vulnerable to HIV. One year after implementing PrEP services, the clinicians reported that they had received appropriate training but that they gained complete confidence in themselves and the process only after seeing a patient for whom they prescribed PrEP. They reported that the more times they prescribed PrEP, the easier it became to do so. During the first year, 18 (75%) of the 24 PPIL clinicians reported prescribing PrEP and all 24 expressed interest in prescribing PrEP.

The PrEP champion used information from one-on-one meetings with the clinicians, as well as the 4-month and 1-year evaluations, to provide a second presentation on PrEP that was focused on common guestions about abnormal lab test results and drug interactions, strategies for increasing PrEP use specifically for women at risk for HIV acquisition, PrEP use during pregnancy and breastfeeding, use of PrEP for patients with co-morbidities, and use of an iPhone app, NefroCalc^D, for easy calculation of estimated creatinine clearance. A chart audit conducted at 18 months post-implementation (4 months after the second presentation) identified a significant increase in the number of new patients receiving PrEP, demonstrating the importance of ongoing education and discussion with staff when implementing a new program.

Summary

At PPIL, PrEP services were implemented immediately following an initial educational presentation. A system-wide approach to implementation was utilized rather than executing the service one health center at a time. Clinicians did not find screening and prescribing PrEP during routine visits problematic. Ongoing education, support, evaluation, and dialogue resulted in clinicians prescribing PrEP for an increased number of patients. Staff continue to look at strategies to remove barriers to medication adherence crucial to PrEP efficacy and to better facilitate PrEP follow-up visits.

Clinical implications

According to the CDC, a total of 1,232,000 persons in the U.S. would benefit from PrEP.¹ Among this group are 492,000 men who have sex with men, 115,000 adults who inject drugs, and 624,000 heterosexually active adults, of whom 468.000 are women.¹ Information about PrEP should be included routinely when APRNs caring for women are discussing reproductive and sexual health. Women should be informed if they reside in areas with high HIV prevalence and should be helped in identifying their own individual risk factors. APRNs caring for women should consider implementing PrEP services as an HIV prevention strategy. The steps described by the authors for developing, implementing, and evaluating PrEP services at PPIL provide guidance that can be adapted to a variety of clinical settings.

Brenda A. Wolfe is Director of Clinical Initiatives and Education, Elizabeth Higgins is Associate Medical Director, Michelle Vos is Business Intelligence Manager, and Amy Whitaker is Medical Director, all at Planned Parenthood of Illinois in Chicago. Brenda A. Wolfe reports that she serves on the Gilead HIV Speaker Bureau. The other authors state that they do not have a financial interest in or other relationship with any commercial product named in this article.

Acknowledgments

Implementation of PrEP would not have succeeded without the hard

work and dedication of the clinicians; support from reproductive health assistants who were invaluable in screening and counseling patients; and support from the leadership team, health center managers, and staff at Planned Parenthood of Illinois. A special acknowledgment goes to the technical team for their assistance in capturing the metrics that allowed for evaluation, quality improvement, and sharing of the data.

References

- Smith DK, Handel MV, Wolitski RJ, et al. Vital signs: estimated percentages and numbers of adults with indications for preexposure prophylaxis to prevent HIV acquisition — United States, 2015. *MMWR Morb Mortal Wkly Rep.* 2015;64(46):1291-1295.
- CDC. Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2017 Update: A Clinical Practice Guideline. cdc/ gov/hiv/pdf/risk/prep/cdc-hivprep-guidelines-2017.pdf
- 3. Monthly Prescribing Reference. Why are Clinicians Reluctant to Prescribe PrEP to High-Risk Patients? April 6, 2015. empr.com/ news/why-are-clinicians-reluctantto-prescribe-prep-to-high-risk-patients/article/407448/
- 4. Truvada for PrEP Utilization by Gender and Provider Specialty. November 2016. Email communication with Staci Bush.

Web resources

- A. cdc.gov/hiv/pdf/risk/prep/cdc-hivprep-guidelines-2017.pdf
- B. gileadadvancingaccess.com/hcp
- C. preplocator.org/about-us/
- D. download.cnet.com/NefroCalc/ 3000-2129_4-75598175.html

