

Roles for Pharmacists in the “Ending the HIV Epidemic: A Plan for America” Initiative

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Abstract

In 2019, President Trump announced a new initiative, Ending the HIV Epidemic: A Plan for America (EHE). EHE will use 3 key strategies—diagnose, treat, and prevent—to reduce new HIV infections at least 90% by 2030, as well as new laboratory methods and epidemiological techniques to respond quickly to potential outbreaks. Partnerships are an important component in the initiative’s success. Pharmacists and pharmacies can play important roles in EHE, including dispensing antiretroviral therapy and providing HIV screening, adherence counseling, medication therapy management, preexposure prophylaxis, and nonprescription syringe sales. The objective of this report is to discuss potential roles that pharmacists and pharmacies can play under the key strategies of EHE.

Keywords

HIV, public health, prevention, health care, health policy, Ending the HIV Epidemic, pharmacists

In 2018, about 1.2 million people were living with HIV infection in the United States, and an estimated 36 400 new HIV infections had occurred.¹ Because of substantial advances in HIV prevention, care, and treatment, people with HIV (PWH) who are aware of their status and achieve viral suppression can live healthy lives and have virtually no risk of sexually transmitting the virus to their partners.²⁻⁴ Furthermore, people at risk for HIV infection from sexual contact and from shared use of drug injection equipment can reduce their risk by using prevention strategies, such as HIV preexposure prophylaxis (PrEP), a daily medicine that reduces the risk of contracting HIV infection,⁵⁻⁹ and syringe services programs (SSPs).¹⁰ Identifying PWH and people at high risk for HIV infection is an important step in improving health outcomes and reducing transmissions. More than 80% of HIV transmissions may come from people who either are not aware of their HIV status or are aware of their HIV status but not in care.¹¹ Data also suggest that disproportionately affected communities are not benefiting from prevention tools such as PrEP.¹²

In 2019, President Trump announced a new initiative, Ending the HIV Epidemic: A Plan for America (EHE).¹³ EHE will use 3 key strategies—diagnose, treat, and prevent—to reduce new HIV infections by at least 75% by 2025 and by 90% by 2030. EHE will also use new laboratory

methods and epidemiological techniques to respond quickly to potential outbreaks.¹³ The US Department of Health and Human Services is leading this effort in partnership with health departments, health care and prevention services providers, advocates, community and faith-based organizations, and academic and research institutions.¹³ During the first phase, which is already underway, resources will be infused in 57 jurisdictions—48 counties; Washington, DC; and San Juan, Puerto Rico—which together accounted for >50% of new HIV diagnoses in 2016 and 2017—and in 7 states with a substantial burden in rural areas (ie, >75 cases and ≥10% of HIV diagnoses in rural areas).¹³ The effective use of partnerships is a critical component in the success of the initiative. Pharmacists and pharmacies can play a key role in this effort.

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Pharmacists are accessible health care providers who practice in settings that are conducive to delivering HIV treatment and prevention services.¹⁴ Pharmacies provide a non-stigmatizing and acceptable venue to receive health services^{14,15} and have more flexible business hours than health clinics.^{16,17} More than 90% of people in the United States who reside in urban areas live within 2 miles of a pharmacy; about 70% who reside in rural areas live within 15 miles of a pharmacy.^{16,17} The proximity of pharmacies makes pharmacists and pharmacies optimal partners in EHE efforts.

However, roles for pharmacists in the EHE initiative will be determined by the regulatory boundaries in which pharmacy is practiced (ie, the pharmacist's scope of practice). The scope of practice is established by state legislatures and regulated by boards and agencies.¹⁴ For example, pharmacists have the authority to administer influenza, pneumococcal, and zoster vaccines in all 50 states.¹⁵ Furthermore, some states allow pharmacists to dispense medications, including naloxone, contraceptives, and nicotine-replacement therapy.¹⁵ Successes from these pharmacist-led interventions

provide support for expanding the role of pharmacists to other prevention and treatment areas such as HIV. This report discusses potential roles that pharmacists can play under the key strategies of the EHE initiative (Table).

Pharmacists' Roles in the EHE Initiative

Diagnose

HIV testing serves as an entry point to care for PWH and prevention services for people at risk for infection. The Centers for Disease Control and Prevention recommends that all people aged 13-64 years be tested for HIV at least once in their lifetime; people with known HIV risk factors should be tested more frequently.¹⁸ However, it is estimated that of the 1.1 million people in the United States with HIV, approximately 1 in 7 is not aware of their infection.¹ Pharmacists and pharmacies can serve as partners in increasing the number of people aware of their HIV status and

Table. Potential roles for pharmacists^a in Ending the HIV Epidemic: A Plan for America^b

Strategy	Potential role
Diagnose all people with HIV as soon as possible	<ul style="list-style-type: none"> • Pharmacies serve as HIV testing venues through partnerships with health departments and community-based organizations (CBOs). • Pharmacists perform HIV testing through collaborations with local or state health departments, CBOs, and/or clinics.
Treat people with ART rapidly and effectively to reach sustained viral suppression	<ul style="list-style-type: none"> • Pharmacists improve adherence to treatment among people with HIV through medication adherence counseling, reminder tools, adherence packaging for medications, synchronized prescription refills, linkage to medication, and cost-savings programs. • Pharmacists proactively identify people with HIV in need of adherence support through routine review of prescription refill histories. • Pharmacists conduct medication therapy management to improve adherence and viral suppression among people with HIV.
Prevent new HIV transmissions by using proven interventions, including preexposure prophylaxis (PrEP) and syringe services programs	<ul style="list-style-type: none"> • Pharmacists provide PrEP services for people at high risk of HIV through collaborative practice agreements with medical providers.^a • Pharmacists support access to sterile syringes and injection equipment through nonprescription syringe sales and education on safe disposal of injection equipment.^a • Pharmacists assist with linkage to substance use disorder treatment, testing and linkage to care, and treatment for HIV and hepatitis C.
Respond quickly to potential HIV outbreaks to get needed prevention and treatment services to people who need them	<ul style="list-style-type: none"> • Pharmacists provide rapid access to antiretroviral therapy for people diagnosed with HIV. • Pharmacists provide PrEP and nonoccupational postexposure prophylaxis services for people at risk of acquiring HIV.^a • Pharmacies serve as testing sites in areas where transmission clusters are detected. • Pharmacists and pharmacies serve as sources for sterile injection equipment in collaboration with health departments.^a

^aPharmacists' scope of practice is determined by state legislatures and regulated by boards and agencies. Services are provided within the boundaries and standards set by these agencies.

^b"Ending the HIV Epidemic: A Plan for America" is a US Department of Health and Human Services initiative to reduce new HIV infections by at least 75% by 2025 and by 90% by 2030.¹³

linked to care by using pharmacists as HIV testers and counselors and/or pharmacies as HIV testing venues.^{16,19-22}

Because of their accessibility and non-stigmatizing environment, pharmacies may serve as important testing venues for people who have never been tested for HIV and/or for those who live in areas where testing through other organizations (eg, community-based settings) is not available.²²⁻²⁴

There are 3 basic models for HIV testing in pharmacies: the stand-alone pharmacy model²⁵; a collaborative model, in which testing is conducted by pharmacists through partnerships with local or state health departments, community-based organizations (CBOs), or clinics²²; and the pharmacy venue-based testing model.²⁶

In the stand-alone model, pharmacies develop and operate their own HIV testing programs. This model requires pharmacies to conduct point-of-care testing, provide training to staff members, create a plan for linking patients to care and prevention services, integrate testing activities into existing pharmacy duties, and provide financial support for the program.²⁵ For pharmacies that provide HIV testing, referral procedures should be in place to link patients to local HIV providers or to the health department for HIV prevention, care, and treatment. Pharmacies must have valid Clinical Laboratory Improvements Amendment Certificates of Waiver and adhere to Clinical Laboratory Improvements Amendment regulations to serve as HIV testing sites.¹⁴

In the collaborative model, pharmacists perform HIV testing in pharmacies through collaborations with local or state health departments, CBOs, or clinics.²² This model allows for shared responsibilities and costs among the collaborators. Health departments and CBOs provide linkages to care and prevention services. In the third model, pharmacies serve as the venue for HIV testing; health departments, CBO staff members, or other outside entities provide all testing, linkages to care, and prevention services.²⁴

Each model offers options for pharmacists to play a key role in HIV testing. Opportunities exist in the EHE initiative for pharmacists and pharmacies to play a role in increasing access to HIV testing services and achieving EHE benchmarks.

Treat

An essential element to successful HIV treatment is adherence to antiretroviral therapy (ART). Adherence to ART leads to viral suppression, which in turn leads to decreased morbidity and mortality for PWH and decreased transmission risk to sex partners.^{2,27,28} Assisting PWH with adherence to therapy is a key role for pharmacists under the EHE initiative.

Pharmacists can assist patients with adherence to therapy by providing counseling (eg, one-on-one adherence counseling, disease and education counseling), reminder tools (eg, prescription refill reminders, medication planners), adherence packaging (eg, blister packs), and help for patients with

managing medication side effects.²⁹⁻³⁴ Pharmacists can also assist PWH with adherence to ART by facilitating access to medications through synchronization of prescription refills, linkage to medication cost-savings programs, and assistance with resolving patients' health insurance-related problems.³³

Pharmacists can proactively identify PWH who are in need of adherence support through routine review of prescription refill histories to identify people who are not filling their ART prescriptions.^{35,36} Once noncompliant patients are identified, pharmacists can tailor adherence interventions to each person with a consequential gap in their refill history. Pharmacists can also use these data to inform primary providers of the need to implement adherence interventions with their patients.

In addition to adherence counseling, pharmacists can conduct medication therapy management (MTM).³⁷ Compared with traditional patient counseling, which is typically a one-directional conversation with a patient, MTM is a 2-way, patient-centered discussion.³⁷ MTM includes a medication therapy review, in which the pharmacist interviews the patient to gather the patient's history and concerns about his or her conditions and medication use.³⁷ The pharmacist can create a plan to address any medication-related problems identified during MTM. This plan may include referring the patient to his or her physician, collaborating with physicians to resolve problems, or working directly with the patient.³⁷ MTM programs have been used to improve health outcomes and overall costs for chronic diseases such as hypertension, diabetes, and asthma; to improve ART adherence; and to decrease the use of contraindicated regimens in HIV care.³⁸⁻⁴¹

To conduct MTM most effectively for ART adherence, pharmacists can collaborate with primary medical care providers to share patient clinical information (eg, HIV viral load and drug resistance test results, CD4 counts, failed drug regimens) with the patient's consent and as allowed by laws that protect the sharing of private medical and personal information. Because HIV viral suppression depends on additional factors other than adherence (eg, drug resistance, individual treatment history, concomitant medications), sharing clinical information allows pharmacists to effectively evaluate the patient's therapy and recommend appropriate treatment interventions.^{42,43} Studies show that when pharmacists and primary medical care providers share patient information and collaboratively address therapy-related problems, HIV outcomes, including viral suppression and retention in care, improve.^{42,43}

Prevent

The literature on pharmacists' roles in providing PrEP services is robust.^{14,44-50} Pharmacist-led PrEP clinics are currently operational in Washington State,⁴⁵ Missouri,⁵¹ Colorado,⁴⁷ New York,⁵² and Iowa⁵³; settings include community pharmacies, ambulatory care clinics, and telemedicine.^{14,45,47,51-53} These programs are supported by

collaborative practice agreements between pharmacists and medical providers.^{14,44,54,55} Collaborative practice agreements allow qualified pharmacists to assume professional responsibility for conducting clinical services, such as patient assessments; ordering laboratory tests; and administering drugs, in the context of a defined protocol.^{54,55} PrEP services are delivered under collaborative drug therapy management agreements (ie, coordinated drug therapy management under formal partnerships between pharmacists and prescribers).⁴⁴⁻⁵³

Pharmacists' roles in providing PrEP services include identifying patients at risk for HIV infection, initiating PrEP if appropriate and supported by regulations in their state, assisting patients with addressing barriers to adherence, ordering laboratory results, and providing follow-up care.^{14,44,54,55} Results from existing PrEP services programs suggest that pharmacist-led PrEP clinics provide effective methods for expanding the use of PrEP to patients at risk for infection.^{14,44-53}

Providing access to sterile syringes and injection equipment through SSPs is an effective method for reducing HIV transmission among people who inject drugs (PWID).⁵⁶⁻⁶² SSPs are community-based prevention and intervention programs that offer a range of services, including facilitating access to and disposal of sterile syringes and injection equipment for PWID.⁵⁶⁻⁵⁸ SSPs, which are typically located in urban areas, can also provide linkage to substance use disorder treatment; comprehensive, integrated prevention and harm-reduction services; and testing and linkage to care and treatment for infectious diseases (eg, HIV, hepatitis C).⁵⁶⁻⁵⁸ Research shows that SSPs are safe, effective, and cost saving for reducing the transmission of HIV.⁵⁹⁻⁶²

Pharmacists have an important role in providing access to sterile syringes and injection equipment for PWID through nonprescription syringe sales in pharmacies.⁶³⁻⁶⁵ Most PWID in the United States use SSPs and pharmacies as their primary sources for sterile syringes.⁶⁴ Most pharmacies, however, do not offer comprehensive services (eg, harm reduction or safe disposal of injection equipment).⁶³ In the EHE initiative, pharmacists can complement the role of SSPs in HIV prevention efforts by providing access to sterile syringes for PWID in areas where SSPs are unavailable, particularly in rural areas.⁶³ The current roles of pharmacists could be expanded through partnerships with SSPs and training for pharmacists to deliver harm-reduction services, discuss safe syringe disposal, perform HIV and hepatitis C testing, provide counseling and education, and link patients to appropriate health care. Pharmacists and pharmacy associations should consider collaborating with state or local health departments to implement a jurisdiction-wide policy that provides pharmacists with training and a program for safe distribution and disposal of syringes.

Respond

The detection of an HIV cluster or outbreak indicates gaps in prevention services that must be addressed to improve access to services such as HIV testing, ART, and PrEP. Pharmacists' roles in screening, treatment, and prevention of HIV are transferable to responding to HIV clusters and outbreaks. In the EHE initiative, laboratory and epidemiological techniques such as infectious disease cluster detection and response will be used to identify where HIV infections are spreading.¹³ These techniques will allow health officials to respond quickly to potential outbreaks and implement strategies to stop transmission.¹³

Infectious disease cluster detection and response are core activities of health departments.^{66,67} A molecular HIV cluster is a group of people with diagnosed HIV infection who have genetically similar HIV strains.⁶⁶ These strains may be identified through analysis of HIV molecular sequence data that are generated through drug resistance testing.⁶⁶ A health department response to cluster detection typically involves increased case investigation, partner services (ie, testing and referring contacts of cases), and increased testing in the at-risk community for HIV and other infections that are transmitted sexually or through shared injection equipment.⁶⁷ Pharmacists' roles to support an HIV outbreak response will vary depending on the size of the outbreak; geography; and availability of HIV testing, prevention, and care services. For example, in a well-resourced urban area, the local health department disease investigators and the available care resources may be sufficient to provide most support.⁶⁷ The pharmacist's role in this setting is to provide rapid access to ART for people diagnosed with HIV, PrEP for people at risk of acquiring HIV, and nonoccupational postexposure prophylaxis for people with recent exposure to HIV. Because this response might include providing medications for people who are underinsured or uninsured, planning for cluster responses involving pharmacists should include a negotiated model for providing reimbursement.

In rural areas, the cluster response detection may extend across many counties, cities, and towns.^{68,69} Pharmacies may be well positioned in this scenario to serve as convenient HIV testing sites for contacts of people in the investigation. Pharmacies may also serve as a testing location and source for rapid ART, PrEP, and nonoccupational postexposure prophylaxis for people in the community who may not be known to be in the transmission clusters. Pharmacists can provide all test results to the health department in real time under established agreements.

Response to HIV cluster investigations involving injection drug use requires access to sterile injection equipment; referral to SSPs is preferred for PWID in areas where established SSPs exist.⁷⁰⁻⁷² However, HIV clusters can occur in regions where SSPs are not present, whether not allowed by law or simply not yet established. In the absence of SSPs, pharmacists and pharmacies can be sources for sterile

injection equipment (syringes and needles) and sharps containers for disposal. In this scenario, pharmacists could collaborate with the health department to create a pharmacy distribution model or voucher program for over-the-counter dispensing and waste management of syringes.⁷⁰ Through collaborations with health departments, pharmacists and pharmacies will be perceived as key players in responding to potential HIV outbreaks caused by injection drug use.^{70,71}

Conclusions

Pharmacists can assist with national efforts to end the HIV epidemic by delivering a range of HIV prevention, care, and treatment services. These services include dispensing ART and providing HIV screening, adherence counseling, MTM, PrEP, and nonprescription syringe sales. Because of extended hours of operation, accessible locations in communities disproportionately affected by HIV, and non-stigmatizing atmospheres, pharmacies can also play a pivotal role in the EHE initiative by increasing access to services for PWH and people at risk for infection.

Expanded roles for pharmacists and pharmacies in the EHE initiative, however, will require substantial financial and human capital resources, training of pharmacists and pharmacy personnel, and supportive state legislation. Pharmacists and all pharmacy personnel should receive training, including cultural sensitivity training, in methods for delivering HIV prevention and treatment services.¹⁴ Furthermore, pharmacists must recognize and be knowledgeable about methods to address the myriad social and structural factors that can impede progress toward ending the HIV epidemic in the United States, including lack of health insurance and access to quality health care,⁷³ HIV-related stigma,⁷⁴ and homelessness.⁷⁵ These factors can lead to negative prevention and care outcomes for people at risk for HIV infection and PWH. Finally, supportive state laws that expand the scope of pharmacy practice to include HIV prevention, treatment, and care efforts facilitate roles for pharmacists in EHE efforts. For example, California recently passed legislation⁷⁶ that authorizes pharmacists to furnish PrEP and nonoccupational postexposure prophylaxis if certain conditions are met (eg, patient meets the clinical eligibility criteria as outlined in federal guidelines).

The EHE initiative provides a unique opportunity to reduce new HIV infections in the United States by at least 90% by 2030. EHE goals cannot be achieved without strong partnerships between federal agencies and key partners in targeted geographic areas, including pharmacists and pharmacies. Pharmacists are in a unique position to play an important role in ending the HIV epidemic. To facilitate this role, pharmacists can collaborate with public health agencies, CBOs, and other health care professionals to provide services and identify and address gaps in care. EHE resources for pharmacists are available online.⁷⁷

Authors' Note

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

Declaration of Conflicting Interests

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