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Harm Reduction at the Pharmacy

By Chelsea Boyd



Leveraging pharmacists' expertise as healthcare providers is one way to improve health outcomes for people who may struggle to access other healthcare providers and traditional harm reduction service providers.

Introduction

In many areas, pharmacies are among the most accessible locations to receive healthcare. In fact, according to estimates from the Centers for Disease Control and Prevention (CDC), 90 percent of the U.S. urban population lives within 2 miles of a pharmacy, and 70 percent of the rural population lives within 15 miles of a pharmacy.¹ Pharmacists are also highly trained medical professionals, and the United States Surgeon General and the CDC have recognized that pharmacists are clinicians who can expand the preventive care workforce and improve population health.²

Pharmacies have begun offering a number of preventive services including administering vaccinations, conducting medication therapy management and providing point-of-care tests (POC) for diabetes, cardiovascular diseases and infectious diseases.³ This expanded role also enables pharmacists to provide harm reduction and other services. Harm reduction encompasses a pragmatic set of strategies to reduce negative outcomes from risky behaviors.⁴ Drug use and sexual health are two areas where harm reduction strategies are particularly effective and where pharmacies could have a significant impact if provisions were expanded for harm reduction services.

Pharmacies could provide services such as selling nonprescription syringes (NPS); dispensing naloxone; offering POC tests for human immunodeficiency virus (HIV) and hepatitis C virus (HCV); prescribing pre-exposure prophylaxis (PrEP) or post-exposure prophylaxis (PEP); and dispensing medication for opioid use disorder (MOUD). Although many of the changes required to implement these services must be made at the pharmacy level, there are some policy changes that should be implemented to encourage pharmacies to offer more harm reduction services. This policy short summarizes harm reduction as a public health strategy, explains the importance of harm reduction, describes harm reduction initiatives that pharmacies can provide and suggests policies that can improve harm reduction access at pharmacies to positively impact drug- and sexual-health-related outcomes.

About Harm Reduction

Harm reduction encompasses a set of strategies aimed at mitigating negative outcomes for those who engage in risky behaviors.⁵ The concept of harm reduction is applicable to a number of risky behaviors but is most frequently associated with decreasing the negative consequences of drug use and improving sexual health.

Traditionally, harm reduction services have been provided by community organizations and health departments.⁶ For example, syringe service programs (SSPs) are harm reduction programs that provide sterile syringes and injecting equipment to people who use drugs

United States Population and Pharmacy Access

Rural - - - - - Population
70 percent live within 15 miles of a pharmacy



Urban - - - - Population
90 percent live within 2 miles of a pharmacy





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(PWUD). These programs also often offer wraparound services such as naloxone; HIV and HCV testing; equipment for smoking drugs; referrals to treatment services; wound care; food and housing assistance; syringe disposal; and safer sex supplies. Despite strong evidence that SSPs are cost-effective ways to decrease infectious disease transmission that do not increase crime, drug use or syringe litter, they remain controversial. Stigma against PWUD and local opposition often prevent new SSPs from opening.

Although the number of SSPs in the United States nearly doubled from 2015 to 2017, as of September 2021, there were only 392 known SSPs in operation. This presents significant barriers for people trying to access harm reduction services. One study of 29,382 people with HCV between 15 and 29 years of age found that 80 percent of people lived more than 10 miles from an SSP, and the median distance to an SSP was 37 miles. The same study found that to reach 95 percent of the people currently living more than 10 miles from an SSP, about 2,200 additional programs need to be established. These estimates show how expanding access to harm reduction services through pharmacies could be beneficial, as about 90 percent of Americans live within 5 miles of a pharmacy.

Why Harm Reduction Services Are Needed

The United States faces a number of public health challenges that could be at least partially alleviated by expanded harm reduction services. From April 2020 to April 2021, the CDC estimates that 100,306 fatal drug overdoses occurred in the United States, most of them attributable to opioids. PWUD, especially those who inject drugs, are also at a higher risk of contracting HIV, HCV and hepatitis B viruses. Harm reduction services offer a pragmatic strategy for reducing these risks.

When it comes to harm reduction, drug use and sexual health are intertwined. Injection drug use is also associated with higher odds of contracting syphilis, chlamydia or gonorrhea. Furthermore, having sex with a person who injects drugs or being a person who exchanges money or drugs for sex are both risk factors in acquiring sexually transmitted infections and are associated with injection drug behaviors.

The benefits of harm reduction programs extend beyond decreasing the spread of infectious diseases.¹⁸ Utilizing harm reduction programs is associated with a decrease in injection drug use.¹⁹ Also, compared to people who do not use harm reduction programs, new harm reduction program users are five times more likely to enter substance use treatment and three times as likely to stop using drugs entirely.²⁰ Naloxone distribution alone is associated with decreasing drug use among PWUD by up to 53 percent and increasing treatment utilization by 25 percent.²¹ For these reasons, access to harm reduction services are necessary.

Pharmacies Can Provide Harm Reduction Services

Disparities in access to harm reduction services exist across a spectrum of demographic factors, and geography is a significant barrier for many people.²² Be it lack of public transportation, distance, mobility limitations or other factors, there are limits to how accessible traditional harm reduction programs and SSPs can be, whether they are located in an urban, suburban or rural location. Pharmacies are a viable solution for eliminating geographic and other barriers to these services.

NPS Sales

While SSPs are one location where PWUD can access sterile syringes, pharmacies offer another opportunity for syringe distribution. According to one study, only three to 18 syringes are distributed for every 100 injection events.²³ Furthermore, of the 220 rural counties that the CDC has designated as vulnerable to HIV and HCV outbreaks due to injection drug use, only 7 percent have SSPs.²⁴ Expanding access to sterile syringes through NPS sales is one way to increase syringe supplies for PWUD.

State law governs the legality of NPS sales. Most state laws allow NPS sales at the discretion of pharmacists or make NPS sales voluntary.²⁵ Some states require pharmacists to log the names and addresses of people who buy NPS, which can deter PWUD from accessing sterile syringes from a pharmacy.²⁶ Research indicates that regardless of the

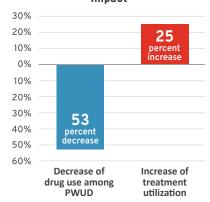
Estimated Number of Fatal Drug Overdoses

(From April 2020-April 2021)



Harm reduction services offer a pragmatic strategy for reducing the risks associated with drug use.

Naloxone Distribution Impact



This data suggests that access to harm reduction services are necessary.





legality of NPS sales, pharmacies and pharmacists often have their own policies that prohibit or restrict NPS sales.²⁷ In fact, the estimated percentage of pharmacies that refuse to sell NPS in Colorado, Missouri, Kentucky and Connecticut—states that do not prohibit the practice—is between 25 and 47 percent.²⁸

Surveys show that fewer than 30 percent of pharmacists say they are willing to sell NPS to someone who they suspect uses illicit drugs, and some evidence suggests that pharmacies in regions with the highest opioid overdose rates are less likely to sell NPS.²⁹ This runs counter to the recommendations of the American Pharmacists Association recognizing that "pharmacists are well-positioned to provide sterile syringes to people who inject drugs."³⁰ Overall, research indicates that decreasing barriers to NPS sales reduces syringe sharing, although the degree to which barriers are reduced is variable due to lack of clarity in state laws and inconsistent pharmacy uptake.³¹

Naloxone Distribution

Pharmacies also have a role to play in naloxone distribution. Legislation passed in all 50 states and the District of Columbia allowing pharmacists to dispense naloxone without a prescription, although how this is accomplished varies by state. ³² A survey of pharmacists in North Carolina found that 44 percent reported dispensing naloxone less than once per month. ³³ Similarly, a survey of California pharmacists found that only 24 percent correctly indicated that they could dispense naloxone without a prescription. ³⁴ Nevertheless, evidence shows that expanding access to naloxone in pharmacies increases naloxone prescriptions and decreases opioid overdose deaths. ³⁵ Although naloxone access laws have been expanded across the country, pharmacists need additional education about the drug and their ability to provide it without a prescription. ³⁶ It should also be noted that the American Medical Association and American Pharmacists Association have released statements that recommend making naloxone available over the counter to further increase access. ³⁷ This would require naloxone manufacturers to submit applications to the Food and Drug Administration (FDA), something policymakers have urged. ³⁸

HIV and HCV Testing

The need for expanding access to HIV and HCV testing is also significant. In 2018, 10 percent of new HIV cases were attributed to people who inject drugs.³⁹ According to the CDC, people who inject drugs should be tested for HIV at least annually; however, only 55 percent of this population report being tested in the last 12 months.⁴⁰ As for HCV, it is estimated that more than 40 percent of people who inject drugs are HCV positive.⁴¹ Among the whole population, one in seven people living with HIV and 50 percent of people living with HCV are unaware of their diagnosis.⁴² Expanding access to testing could help identify cases of HIV and HCV more quickly, allowing for more rapid engagement in treatment, resulting in better health outcomes.

Both HIV and HCV tests are available as POC tests.⁴³ There are several steps that pharmacies must accomplish before being allowed to conduct POC tests. Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), pharmacies can apply through the Centers for Medicare and Medicaid Services for a CLIA waiver to perform POC tests.⁴⁴ State-specific regulations must also be met and staff must be appropriately trained to conduct the test.⁴⁵ COVID-19 led to an increase in the number of CLIA-waivered pharmacies.⁴⁶ Between 2015 and 2020, pharmacies represented the largest growth in CLIA-waivered facilities, with about 28 percent of pharmacies possessing a waiver by 2020.⁴⁷

Currently, HIV testing in community pharmacy settings is more common than HCV testing. Studies in pharmacies demonstrate the feasibility of offering HIV and HCV testing and suggest that providing this service would expand access to testing and improve chronic disease management. Importantly, pharmacists report willingness to conduct these POC tests, with one survey finding that 81 percent reported that they would be likely or very likely to provide POC testing for HIV if there were structures in place for referral in the event of a positive test result and if they were provided with a script as a template for post-testing counseling. Another consideration for POC testing in pharmacies is patient acceptability. One study found that less than 10 percent of patients surveyed were aware that a finger-stick POC test for HCV is available; however, about 72 percent were willing to receive HCV testing at a community pharmacy once they were made aware of the



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test.51 Expanding access to HIV and HCV testing increases diagnostic opportunities, which potentially expedites patients' connection to treatment.

PrEP and PEP Initiation

Regular testing for HIV is vital to prevention efforts; however, there are also medications that can help people protect themselves. PrEP is a pill or shot taken to prevent HIV infection.⁵² PEP differs from PrEP in that it is used to prevent HIV after a known exposure.⁵³ PEP should only be used in emergency situations, and a patient must begin treatment within 72 hours of exposure.⁵⁴ Both are highly effective at preventing HIV infection.⁵⁵

California Senate Bill No. 159, passed in 2019, makes California the first state to allow pharmacists to prescribe PrEP and PEP.⁵⁶ The law specifies that pharmacists must complete a training program approved by the California State Board of Pharmacy to obtain certification before prescribing these medications.⁵⁷ Notably, the bill still requires physician involvement, as pharmacists are restricted to providing each patient a 60-day prescription for PrEP every two years and a 28-day supply of PEP with no restrictions on frequency.⁵⁸ The bill also requires pharmacists to comply with CDC guidelines for prescribing these medications and requires referral to a primary care physician to furnish refills of PrEP.⁵⁹ Additionally, the bill mandates reimbursement of pharmacists at 85 percent of the rate of physicians for providing PrEP and PEP services. 60

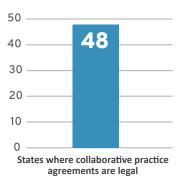
California's move to allow pharmacists to provide PrEP and PEP initiation is a policy-level solution to expanding access to these preventive services. However, collaborative practice agreements are another method that allow pharmacists to prescribe. 61 Collaborative practice agreements involve a partnership between a physician and a pharmacy and have been shown to improve HIV health outcomes and medication adherence. 62 Under this model, pharmacists initiate PrEP in one visit, taking a history, making a risk assessment and completing laboratory testing and education before dispensing the medication. 63 At one such program in Seattle, Washington, 75 percent of participants remained engaged in the program after three years.⁶⁴ Collaborative practice agreements are legal in 48 states and supported by the U.S. Surgeon General and the Centers for Medicare and Medicaid Services.⁶⁵ In fact, Washington, Missouri, Colorado and Iowa have pharmacist-led PrEP programs under these agreements already. 66 Unfortunately, collaborative practice agreements are not necessarily easy to establish, can present reimbursement challenges and require a significant time commitment from pharmacists, which can all be barriers to program establishment.67

MOUD Distribution

Utilizing pharmacists to dispense MOUD is another way to incorporate harm reduction services into the pharmacy setting. Although these programs are not currently permissible in the United States, they are not without precedent internationally. Canada, Australia and the United Kingdom permit some form of pharmacy-based distribution of methadone, which is one form of MOUD.⁶⁸ Under these programs, a physician or addiction specialist prescribes methadone, then sends the patient to a pharmacy to receive the daily, observed dose of medication.⁶⁹ This differs from the United States model, in which methadone must be provided by an opioid treatment program certified by the Substance Abuse and Mental Health Services Administration. 70 Interestingly, pharmacies in the United States were allowed to dispense methadone until opioid treatment programs were mandated in 1972.71 Expanded access to methadone is necessary because there are many areas of the country where patients have limited access to opioid treatment programs.⁷²

Another MOUD is buprenorphine. Unlike methadone, patients are not required to take buprenorphine under direct observation by an opioid treatment program, which allows them to access treatment through a pharmacy with a valid prescription. Nevertheless, there is accumulating evidence that pharmacies may limit access to buprenorphine due to unclear Drug Enforcement Administration (DEA) regulations.⁷³ Because controlled substance wholesalers are required to monitor orders from pharmacies and report suspicious activity to the DEA under The SUPPORT for Patients and Communities Act (SUPPORT Act) of 2018, pharmacists sometimes limit the amount of buprenorphine they order or the number of prescriptions they dispense. 74 One study found barriers to obtaining a buprenorphine prescription at 30 percent of pharmacies in counties with a high

Collaborative Practice Agreement: the Other Harm Reduction Method



Collaborative practice agreements

have been shown to improve HIV health outcomes and medication adherence. Unfortunately, they are not easy to establish.





opioid overdose burden and additionally found that one in five pharmacies were unable or unwilling to fill an entire buprenorphine prescription.⁷⁵ Exploring the possibility of allowing pharmacies to dispense methadone and clarifying that there is no DEA mandated "cap" on buprenorphine dispensing could improve access to MOUD.

Policy Considerations

Although many of the changes required to expand the availability of harm reduction services at pharmacies are not policy-level changes, there are some policy considerations that could encourage pharmacies to expand their harm reduction services.

First, clarifying (and when necessary, relaxing) NPS sale laws and removing requirements to record personal information for people who inject drugs would decrease barriers to obtaining NPS from pharmacies. Second, states should explore passing legislation that expands pharmacists' ability to initiate PrEP and PEP. For states in which collaborative practice agreements are not permitted, these may become the first step toward providing PrEP and PEP access at pharmacies. In states that allow collaborative practice agreements, exploring legislation similar to California Senate Bill No. 159 could further expand access to necessary medications. Third, federal policymakers should consider removing buprenorphine from the list of controlled substances that must be monitored by wholesalers. In the meantime, the DEA should clarify that there is no "cap" on buprenorphine dispensing to encourage pharmacies to stock and fill these prescriptions.

Fourth, federal policymakers should consider allowing pharmacies to dispense methadone rather than limiting dispensing to opioid treatment programs. In fact, legislation was introduced in the U.S. House of Representatives (H.R. 6279) and Senate (S.3629) in December 2021 and February 2022, respectively, that would allow pharmacies to dispense methadone and expand take-home flexibilities for patients. Fifth, federal policymakers can continue to encourage naloxone manufacturers to seek FDA approval to make naloxone available over the counter. Although naloxone is available behind the counter without a prescription, making it over the counter will further expand access and decrease barriers to accessing this lifesaving medication.

Finally, state policymakers should convene pharmacist representative organizations and healthcare credentialing groups to appropriately prepare for expanding the scope of practice for pharmacists and to understand the implications of expansion for health providers. Washington, Texas and Tennessee have passed legislation recognizing pharmacists as healthcare providers and allowing pharmacists to bill for clinical services. This could clear the way for pharmacists to provide more POC testing, PrEP and PEP because it would make providing these services more financially sustainable. The score is a service of the servi

Conclusion

Pharmacies are one of the most accessible healthcare establishments.⁸² As the United States confronts the opioid epidemic, more than 1.5 million annual cases of chlamydia and high rates of undiagnosed HIV and HCV, pharmacies can play an important role in harm reduction for PWUD and for the community as a whole.⁸³ Policymakers can remove barriers to pharmacies offering harm reduction services by passing legislation that reimburses pharmacists as healthcare providers and allows expanded scope of practice. Additionally, policymakers can clarify existing policies to ensure that they are not unnecessarily deterring pharmacists from providing NPS or buprenorphine.

Despite the barriers to offering harm reduction services, examples of pharmacies that provide them are available and are demonstrably successful. Leveraging pharmacists' expertise as healthcare providers is one way to improve health outcomes for people who may struggle to access other healthcare providers and traditional harm reduction service providers.



State policymakers should convene pharmacist representative organizations and healthcare credentialing groups to appropriately prepare for expanding the scope of practice for pharmacists and to understand the implications of expansion for health providers.

About the Author

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