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Publication Date

2020-08-13

DOI

10.1016/j.japh.2020.06.005

Data Availability

The data associated with this publication are available upon request.

Peer reviewed



Contents lists available at ScienceDirect

Journal of the American Pharmacists Association

journal homepage: www.japha.org

RESEARCH NOTES

Attitudes about community pharmacy access to HIV prevention medications in California

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ARTICLE INFO

Article history:

Received 29 January 2020

Accepted 3 June 2020

ABSTRACT

Objective: Increasing access to human immunodeficiency virus (HIV) pre-exposure prophylaxis (PrEP) and postexposure prophylaxis (PEP) is a high priority for the Ending the HIV Epidemic Initiative. Expanding access to PrEP and PEP through a variety of health care settings, including community pharmacies, may increase access in communities most in need. California is the first state to allow community pharmacists to furnish PrEP and PEP directly to consumers. Our objective was to assess attitudes among key stakeholders about a California policy to allow community pharmacists to furnish HIV PrEP and PEP.

Methods: We conducted a qualitative case study with key pharmacy stakeholders. Semi-structured phone interviews were audio-recorded and transcribed verbatim. We generated analytical memos for each interview and working with these analytical memos, we conducted a constant comparison across cases to identify commonalities and differences.

Results: We launched the study in October 2018 and interviewed pharmacists ($n = 7$) working in a variety of settings, including retail-, clinic-, and community-based pharmacies. We also interviewed medical providers ($n = 2$) working in high-volume PrEP clinics and sought input from representatives of large retail chain pharmacies ($n = 2$). Overall, pharmacists and medical provider informants shared similar opinions about the central benefits as well as the key challenges related to pharmacist-delivered PrEP and PEP services. Benefits included: community pharmacists are widely accessible, PrEP and PEP protocols are similar to other preventative medications, policy may lead to efficiencies in the health care workforce, and community pharmacists are authorities on medication adherence. Challenges included: implementation issues may limit pharmacist involvement, and missed opportunities to diagnose and treat other health conditions.

Conclusion: This study characterizes the types of benefits and challenges that can be expected when PrEP and PEP prescribing privileges are extended to community pharmacists. This information may be useful to policymakers and other stakeholders considering legislation to permit direct prescription of PrEP and PEP by pharmacists.

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Background

Despite well-established efficacy of both pre-exposure prophylaxis (PrEP) and postexposure prophylaxis (PEP) to prevent human immunodeficiency virus (HIV),¹ disparities in accessing these biomedical interventions persist.^{2–5} The

Centers for Disease Control and Prevention (CDC) estimates less than 7% uptake among 1.14 million individuals indicated for the use of PrEP.⁶ In California, the State Department of Public Health, Office of acquired immunodeficiency syndrome (AIDS) estimates that there are from 220,000 to 240,000 Californians with an indication for PrEP; however, 2018 estimates of uptake in California reflect the national trend at only 6%–7%.⁷ Improving uptake requires action on multiple fronts including increasing PrEP and PEP awareness and access. Expanding access to PrEP through a variety of health care settings is a high public health priority.⁸ One such setting is the community pharmacy and the expansion of the scope of practice of community pharmacists by allowing them to directly furnish PrEP and PEP, which may generate greater

Disclosure: The authors declare no relevant conflicts of interest or financial relationships.

Funding: California HIV/AIDS Research Program (RP; 15-SF-096) and the National Institute of Nursing Research (R01NR017573).

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access, particularly in communities where primary care providers are in short supply.⁹

Community pharmacists in California and elsewhere contribute significantly to preventative care efforts by administering vaccines, furnishing contraceptives and smoking cessation patches, dispensing naloxone, and playing a key role in syringe access.^{10–15} Patients seeking these services do so in part because community pharmacies are accessible—offering extended business hours, open during weekends, and usually do not require prescheduled appointments.¹⁶ Pharmacists are also a reliable source of medication adherence counseling and medical education, especially for chronic illnesses.^{16,17} In several states, innovative pharmacist-driven PrEP programs are available demonstrating the commitment of some pharmacists to make PrEP easily available.^{18–21} Nearly all of these community pharmacies' PrEP programs are made possible under a formal collaborative practice agreement or a Collaborative Drug Therapy Agreement (CDTA), which requires a medical provider-pharmacist partnership. Arrangements under the CDTA process are not necessarily easily implemented and as such limit the extent to which these types of practices may otherwise flourish.^{22–25}

Innovations that involve pharmacists in generating greater access to preventative medications such as PrEP and PEP require policy-level changes. However, few state legislatures have been willing to innovate in this arena. In California, HIV advocates effectively promoted legislation that expanded the role of pharmacists to prescribe PrEP and PEP directly. The intent of the legislation was to allow pharmacists that are working in community pharmacies to furnish PrEP and PEP directly. Senate Bill 159 (SB 159) was introduced to the California Legislature in 2019. Although the original language in the bill sought to allow pharmacists a broad scope of prescribing privileges, the California Medical Association stressed the importance of physician involvement. The legislators arrived at a consensus on language, stating that pharmacists must follow CDC guidelines when initiating PrEP and that they may furnish up to a 60-day supply of PrEP once every 2 years and a 28-day supply of PEP. There are no stated restrictions on the number of times pharmacists may furnish a 28-day course of PEP. The bill further specified that new formulations of either PrEP or PEP were allowable as long as the California Medical Board determined that another drug or drug combination met the same clinical eligibility recommendations provided in CDC guidelines. Because of the 60-day supply restriction, pharmacists will be expected to refer patients to a primary care provider for ongoing PrEP access. However, resources to ensure adequate linkage to ongoing PrEP services are beyond the scope of this bill.

Objective

Our objective was to assess key stakeholder attitudes about this legislation to allow community pharmacists to furnish HIV PrEP and PEP.

Methods

While this legislation was under consideration, we conducted a qualitative, rapid assessment study to document the acceptability and feasibility of pharmacist-delivered PrEP and

PEP in the State of California. We launched our case study approach²⁶ in October 2018 and recruited pharmacists ($n = 7$) working in a variety of settings (i.e., clinic and community pharmacies) and performing a variety of roles (e.g., consulting, education, and dispensing). We also included physicians working in high-volume PrEP clinics ($n = 2$) and sought input from pharmacists serving in senior management positions within a large retail chain pharmacy ($n = 2$). The first author conducted the interviews, which were primarily conducted over the phone, audio-recorded, and professionally transcribed. On the basis of our interview topics on benefits, feasibility, and challenges related to furnishing PrEP and PEP, the first author generated analytical memos for each interview. Working with these analytical memos, the team conducted a constant comparison across cases to identify commonalities and differences. Our analytical strategy combines elements of Miles and Huberman's pragmatic approach to thematic analysis²⁷ with elements of grounded theory (i.e., use of analytical memos and constant comparison).²⁸ As a form of member checking, we distributed a draft of the findings to several key informants for input on our interpretations.²⁹ The University of California San Francisco Committee on Human Research reviewed and approved all research activities associated with this study (approval no. 18-26017).

Results

Interviewees outlined numerous benefits of pharmacist involvement in PrEP and PEP access as well as noted areas in which more work would be required. Medical providers held a slightly different perspective and were not entirely supportive of expanding the pharmacists' scope of practice to include PrEP. However, pharmacist-furnished PEP was widely accepted among all interviewees. Exploring the overlap as well as understanding areas of disagreement may help us to develop systems that might accommodate all perspectives.

Community pharmacists are widely accessible: "...access is one of the primary attractive features of allowing pharmacists to prescribe HIV prevention medications." All interviewees emphasized and often led with statements indicating that pharmacists and pharmacies are easily accessible to patients. In contrast to clinics, pharmacy hours extend well beyond typical business hours, and pharmacists are often approachable, available to answer questions, dispense medications and vaccines, and provide clinical advice. This low barrier to entry contrasted with the highly structured system of a medical clinic in which patients are often separated from the entire medical team, and their movements are highly orchestrated. Pharmacists may also have high rates of patient contact, particularly in instances when a patient comes in monthly to pick up their medications—this enhanced contact was described as fostering comfort and familiarity between patients and pharmacists.

PrEP and PEP can be implemented using standardized protocols similar to other preventative medications California community pharmacists are allowed to furnish. Allowing community pharmacists to prescribe PrEP and PEP is consistent with other facets of preventative medications that California law permits pharmacists to furnish, including naloxone, oral contraceptives, smoking cessation products, and vaccines.

Prescription privileges for these aspects of preventative care have been extended to pharmacists because the medications and vaccines do not require a diagnosis, are administered according to formalized guidelines that specify dose and timing, and can be delivered as discrete services (e.g., administering a vaccine usually does not require that one also treat a medical condition at the same time). PrEP and PEP would be similarly focused on dispensing the medication and for PrEP, ordering and interpreting the initial panel of laboratory testing.

Increasing community pharmacist scope of practice may relieve pressures from the primary care workforce: "...allowing pharmacies to provide immunizations really does help with the gap of immunizing people." Clinical and community pharmacists are highly trained and, many argue, underused. Enabling community pharmacists to be able to furnish PrEP and PEP would allow them to use their medication expertise fully, and it would have the added benefit of addressing the persistent shortage of primary care providers. Furthermore, some community pharmacists are already discussing PrEP and PEP with patients because of their role in dispensing these medications. As such, they have familiarity with the medications and the patient population.

Community pharmacists are considered the authority on medication adherence and adherence counseling: "Pharmacists have unique data on which to base [adherence] conversations. They've got a refill record right in front of them." Pharmacists are well-positioned to provide crucial advice about adverse effects and counsel on the importance of medication adherence to individuals seeking a 28-day course of PEP. For PrEP, community pharmacists have unique access to data on the frequency with which a patient refills a PrEP prescription. These data may open the door to conversations about medication adherence in a way that is unique to pharmacists. Furthermore, community pharmacists offer adherence tools such as refill reminder services that may facilitate PrEP adherence and persistence in PrEP care.

Implementation issues may limit pharmacist involvement: "We can't do our work for free." Although several interviewees perceived community pharmacy settings as not conducive for private consultations, others noted that they routinely engaged in sensitive conversations with patients and argued that discussing PrEP or PEP would be no different than discussing contraceptive options or offering advice on naloxone. Assuming a pharmacist was willing to counsel patients about PrEP and PEP and furnish one or the other to a patient, the lack of systems to order labs was then raised as a potential challenge. Whether insurers would cover the cost of labs ordered by a pharmacist was also raised as a concern. In addition, pharmacists advocated for reimbursement for the provision of consultation services.

Pharmacy environments are not inherently conducive to furnishing PEP and PrEP: "It's going to raise a lot of questions for implementation." Pharmacists, pharmacy representatives, and providers raised questions related to determining procedures for securing and ordering HIV test results as well as stressed the importance of developing systems for care coordination and communication between community pharmacists and primary care providers. Providers raised concerns about how community pharmacists may handle drug toxicity or medical complications that could be directly attributed to

PrEP or PEP use. They further raised the possibility that conducting a sexual risk assessment may cause discomfort for community pharmacists and noted that pharmacists are busy and may not have time to take on additional tasks such as furnishing PrEP and PEP.

Access to PEP, in particular, is very limited: "Offering PEP in community pharmacies is a plus." PEP was described as a "time-sensitive intervention," and, as such, providers and pharmacists pointed out the advantages of creating greater access to PEP through community pharmacies. One provider noted that PEP is typically accessed through emergency departments and urgent care rather than primary care providers, meaning that the channel of access is already 1 that strays from ordinary care-seeking behavior; therefore, pharmacist involvement was not considered an extraordinary step. Overall, PEP was widely perceived as a straightforward medication for community pharmacists to furnish.

Providers see benefits of involving community pharmacists but explain fears related to "what if" scenarios. Medical provider interviewees perceived pharmacists as lacking the proper training to diagnose, assess, or manage medical conditions. They argued that PrEP users might come in with other medical questions or issues that could be addressed in a primary care setting, but not in a pharmacy (e.g., spots on one's genitals, nausea unrelated to PrEP and PEP). A patient who is seeing a pharmacist for PrEP and PEP and is not otherwise engaged in medical care may be missing opportunities to address other health maintenance issues for example, vaccinations that may be important such as Hepatitis A and B and meningitis (note that pharmacists are allowed to provide the aforementioned vaccines if they fulfill training and record-keeping requirements, which may not be widely understood by medical providers). However, it is common for patients on PrEP to be treated presumptively for sexually transmitted infections, which does not currently occur in community pharmacies offering PrEP. Finally, medical provider interviewees expressed concern that persons receiving PrEP and PEP in a pharmacy setting may give them a false sense that they are receiving medical care.

Discussion

California is the first state to allow community pharmacists to furnish PrEP and PEP to consumers directly. This new law presents an opportunity to study this innovation in PrEP delivery. Ostensibly, the law creates greater and more convenient access to a 60-day supply of PrEP in 2 years or a 28-day supply of PEP. It may also offer relief to the existing PrEP and PEP delivery systems, albeit temporarily. Community pharmacists who opt to participate in PrEP and PEP delivery will be on the front line to observe the effectiveness of the law as designed. It is possible that more pharmacists will pursue setting up a CDTA so that they may furnish PrEP on an ongoing basis rather than playing the role of PrEP initiator. With California setting this precedence or "road map" for the rest of the country to expand the scope of practice among community pharmacists, other states may pursue similar policies.³⁰ It is also possible that this new policy will inspire or generate alternative pharmacist-delivered PrEP and PEP models.

The premise of SB 159 is that a PrEP seeking individual may approach a pharmacist to secure a 30- to 60 day supply of

medications. Community pharmacists are expected to refer these consumers to primary care for ongoing PrEP services. Thus, under the best-case scenario, patients will have relatively easy access to PrEP initially and will be referred to local PrEP-knowledgeable medical providers. The 60-day supply may seem arbitrary because there is no precedent for pharmacists to furnish a preventative medication temporarily. However, the legislature agreed that in some cases, it might take longer than 30 days for an individual to be linked to a primary care provider for ongoing PrEP care, and, thus, the language shifted from a 30-day to 60-day supply. Whether 60 days is enough time for a pharmacist-initiated PrEP consumer to link to primary care services is unknown. This may be an opportunity to integrate community pharmacist-initiated PrEP with PrEP telehealth services. All of these assumptions and questions provide us with a unique opportunity to study whether the increased access does generate increased PrEP use and appropriate, persistent PrEP use. In other words, we have the opportunity and obligation to study the effectiveness of this policy change.

Conclusion

There are several questions that surface under this new law. First, it is unclear whether there is an incentive for pharmacists to be involved in furnishing PrEP and PEP if they may do so only temporarily. For example, it may be difficult to build a workflow that will accommodate pharmacy settings. It may be difficult to build in support to address payer issues as well as referrals to PrEP-competent primary care providers, particularly in rural areas facing a shortage of primary care providers in general. In particular, reconciling whether greater involvement of community pharmacists as PrEP providers will be a disservice to patients who would otherwise receive greater benefits from seeing a traditional primary care provider or whether this version of task-shifting turns out to be a relief on the primary care system is yet to be determined. The perspective that PrEP services should be done under the supervision of a primary care provider is built on the logic that medical providers can detect and intervene on a number of health issues that a pharmacist is not trained to do. If PrEP is maintained under the auspices of primary care, advocates argue that PrEP patients may then reap the full benefits of primary care. However, we must also consider the consequences of restricting access to PrEP to clinical settings, even telehealth settings, in areas with a primary care workforce shortage and the potential for deepening HIV disparities. Identifying situations that might warrant allowing pharmacists to serve as the PrEP provider on an ongoing basis will be important. In California, we have a parallel mechanism: community pharmacists have contraceptive prescribing authority. If we consider PrEP and PEP as comparable to contraceptives, then perhaps we may get to the point of supporting continuous, uninterrupted access to PrEP via community pharmacists.

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