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BACKGROUND

Increasing access to HIV pre- and post-exposure prophylaxis (PrEP/PEP) is a high priority to achieve the goals of the Ending the HIV Epidemic Initiative.¹ The Centers for Disease Control and Prevention estimate 1.14 million individuals could benefit from use of HIV pre-exposure prophylaxis.² Yet uptake of PrEP as of 2016 is estimated at 78,360.³ Expanding access to PrEP/PEP through a variety of health care settings is a high public health priority. Broadening the scope of practice to allow pharmacists to be more involved in the delivery of PrEP/PEP may generate greater access, particularly in communities where physicians and other primary care providers are in short supply.

STUDY OVERVIEW

We conducted a qualitative rapid assessment study focused on documenting the acceptability and feasibility of pharmacist-delivered pre-exposure prophylaxis (PrEP) and post-

Currently allowed under California law

In 2013, the California legislature passed SB 493 which designated California-licensed pharmacists as health care providers. The law also authorized pharmacists to furnish self-administered hormonal contraceptives, nicotine replacement products, and prescription medications not requiring a diagnosis that are recommended for international travelers. Pharmacists were also permitted to administer vaccines recommended by the Advisory Committee for Immunization Practices for persons 3 years and older if they meet specified training requirements.

SB493 also established board recognition of a new designation of pharmacists: Advanced Practice Pharmacist (APP). APP are authorized to:

- Perform patient assessments
- Order and interpret drug therapy-related tests
- Refer patients to other health care providers
- Initiate, adjust, and discontinue drug therapy pursuant to an order by the treating prescriber and in accordance with established protocols
- Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers

In 2015, AB 1535 allowed pharmacists, once trained, to furnish naloxone, a medication used to reverse opioid-related overdose.

¹ <https://www.hrsa.gov/ending-hiv-epidemic>

² Smith D et al. *By race/ethnicity, blacks have highest number needing PrEP in the United States, 2015*. 25th Conference on Retroviruses and Opportunistic Infections (CROI 2018), Boston, abstract 86, 2018.

³ Ibid

exposure prophylaxis (PEP) in the State of California. 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 pharmacy (n=2).

FINDINGS

Overall, pharmacist and medical provider informants shared similar opinions about the central benefits as well as the key challenges related to pharmacist-delivered PrEP/PEP services. The chief benefit all informants identified was the potential to create greater access to PrEP/PEP by allowing pharmacists to directly prescribe these preventative medications. Depending on the informant's role, advantages or disadvantages were more heavily emphasized.

Benefits of Pharmacist-Delivered PrEP/PEP

❖ **Accessibility**

Pharmacist Perspectives:

- Patients can walk into a pharmacy and quickly be in contact with a pharmacist.
- Pharmacists currently have a high rate of patient contact – e.g., patients may see their pharmacists as often as 12 times per year. This enhanced access facilitates comfort and familiarity between patient-pharmacist.
- Community pharmacists wish to promote health and well-being for patients in addition to dispensing duties.

Medical Provider Perspectives:

- Pharmacy access to PrEP/PEP is better than no access and may be a good option for people in communities without access to a PrEP/PEP-friendly and knowledgeable provider.

Pharmacist & Medical Provider Perspectives:

- Pharmacies may be open at times when many medical clinics are not.

❖ **Better Utilization of the Healthcare Workforce**

Pharmacist Perspectives:

- Clinical and community pharmacists are highly trained & underutilized. Being able to furnish PrEP/PEP would allow them to fully use their medication expertise.

- Some community pharmacists are already discussing PrEP and PEP with patients because of their role in dispensing. As such, they have familiarity with the drug and the patient population.

Medical Provider Perspectives:

- Increasing access to PEP could be valuable because it is a time-sensitive intervention & pharmacy access may mean broader access
- PrEP access in pharmacies is aligned with efforts toward Ending the Epidemic
- Pharmacists may best serve as a bridge between a patient and a long-term PrEP provider. This may be done by assisting with initiation of PrEP use and then referring to primary care provider for on-going PrEP management.

Pharmacist & Medical Provider Perspectives:

- Involving community pharmacists in delivery of PrEP may help to offset the primary care workforce shortage, as well as HIV care provider workforce shortage.
- Clinic and community pharmacist involvement in furnishing PrEP could free up other clinicians to handle other patient issues

❖ **Standardized Protocol Similar to Other Preventative Medications Already Prescribed by Pharmacists**

Pharmacist Perspectives:

- Allowing pharmacists to prescribe PrEP/PEP is consistent with other types of preventative medications that California law allows pharmacists to furnish. These include: naloxone, oral contraceptives, and vaccines. Prescription privileges for these aspects of preventive 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 would have similar characteristics. The focus of the program would be on dispensing the medication and interpreting/monitoring lab data.

❖ **Adherence Monitoring**

Pharmacist Perspectives:

- Pharmacists have access to data on the frequency with which a patient refills a PrEP prescription. This may open the door to conversations about adherence in a way that is unique to pharmacists.
- Pharmacies' tools can facilitate PrEP adherence. These include automatic refills, automated refill reminders, and reminder calls/text messages to pick up medications.

Challenges of Pharmacist-Delivered PrEP/PEP

❖ Implementation Issues

Pharmacist Perspectives:

- Laboratory ordering and receiving systems are not typically in place.
 - Faxing lab results is possible, but not ideal.
 - Insurance may not cover the cost of labs ordered by a pharmacist.
- Reimbursement for consultation services is needed.
 - Alternate Perspective: A small number of informants noted that pharmacists are currently advising patients in a consultative fashion and are not reimbursed. They still perform the work because of their commitment to patient care. These informants also noted that reimbursement could happen in the future.
 - Note: Not all pharmacists expressed concern about the lack of reimbursement of pharmacist labor to conduct PrEP/PEP-related assessment and consultative services.
- Need for a philosophical shift to recognize pharmacist labor as more than dispensing; public may not see pharmacists as healthcare providers.
- Efforts to train and scale-up pharmacist-delivered PrEP/PEP needs to be weighed against competing options for new initiatives within pharmacies e.g., creating mini-medical clinics, offering Hep C treatment.
- National pharmacies deal with 50 different state laws making standardization and scalability difficult.

Medical Provider Perspectives:

- Some tasks associated with furnishing PrEP are outside of the scope of pharmacist training, e.g., STI testing.
- Communication between retail-based pharmacist and patient's primary care provider would be necessary; primary care provider would need to know about patient's use of PrEP/PEP as well as any immunizations administered.

Pharmacist & Medical Provider Perspectives:

- Absence of pharmacy space that is private and conducive to patient confidentiality.
 - Alternative Perspective: A small number of informants noted that pharmacists are currently having private, confidential conversations with patients over the counter without a private room, suggesting a traditional exam room may not be required.
- Pharmacist training on PEP and PrEP is needed.
 - Awareness of PEP and PrEP Warmlines should be a part of training

❖ Missed Opportunities to Diagnose and Treat Other Health Conditions

Medical Provider Perspectives:

- Pharmacists are not trained to diagnose and are not in a position to assess or manage medical conditions. PrEP users may come in with other medical questions or issues that could be addressed in a primary care setting, but not by a pharmacist, e.g., spots on one's genitals, nausea unrelated to PrEP/PEP.
- A patient who is seeing a pharmacist for PrEP and is not otherwise engaged in medical care may be missing opportunities to address other health maintenance issues
- It is common for patients on PrEP to be treated presumptively for STDs. This would not occur in retail-based pharmacies offering PrEP, as a medical provider would need to prescribe treatment for the STD.
- Receiving PrEP in pharmacy setting may give patients a false sense that they are receiving *medical care*.

CONCLUSIONS

Study participants generally supported expanding the role of retail-based pharmacists to allow prescribing of PrEP/PEP. Informants identified a number of advantages of prescription privileges as well as some challenges. Pharmacist-informants perceived themselves to be well positioned to assist in creating low barrier access to PrEP and PEP services. Medical providers expressed support as well as concerns. Given our research design, we cannot definitively conclude whether the potential benefits ultimately outweigh the potential challenges. Instead our data help to characterize the kinds of benefits and challenges that can be expected if PrEP and PEP prescribing privileges are extended to pharmacists. This information may be useful to policymakers and other stakeholders considering legislation to permit direct prescription of PrEP/PEP by pharmacists.



Comparison Case Example -- Immunizations

SB 493 effectively expanded pharmacist scope of practice by allowing them to administer immunizations. The outcomes of this legislation include: 1) increasing immunization uptake, e.g., flu vaccines 2) immunizations by pharmacists are reimbursable 3) immunization registry requirement created as a workaround to the absence of interoperable electronic medical records. Large chain pharmacies designed internal trainings to prepare pharmacists deliver immunizations. Pharmacist delivered immunization helps to meet public health goals of cost-effective, widespread immunization uptake.

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