Legislation and HIV PrEP/PEP Prescribing for Pharmacists

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Objectives

- Examine aspects of state legislation authorizing pharmacist-prescribed HIV prevention modalities
- Discuss rationales for parameters placed on pharmacist-prescribed HIV prevention regimens
- Evaluate perceptions among certain patients about pharmacist-readiness to prescribe HIV prevention therapies
- Explore challenges and opportunities associated with pharmacist-prescribed HIV prevention implementations
Disclosure(s)

“I have no real or perceived vested interests that relate to this presentation nor do we have any financial relationships with pharmaceutical companies, biomedical device manufacturers, and/or other corporations whose products or services are related to pertinent therapeutic areas.”

Kenric B. Ware, PharmD
United States – HIV (2018)

Local Data: United States

In 2018, there were 1,039,680 people living with HIV in the U.S. In 2018, 37,864 people were newly diagnosed with HIV.


Number of PrEP users, 2019
227,046

Rate of PrEP users per 100,000 population, 2019
81

Percent of PrEP users, by Sex, 2019
- Male: 92.6%
- Female: 7.4%

Percent of PrEP users, by Age, 2019
- Aged 13-24: 14.9%
- Aged 25-34: 39.9%
- Aged 35-44: 23.8%
- Aged 45-54: 15.5%
- Aged 55+: 8.6%

Number of PrEP Users, 2012-2019

HIV State Comparisons (2018)

Georgia

Local Data: Georgia

In 2018, there were 54,600 people living with HIV in Georgia.
In 2018, 2,501 people were newly diagnosed with HIV.

South Carolina

Local Data: South Carolina

In 2018, there were 17,405 people living with HIV in South Carolina.
In 2018, 715 people were newly diagnosed with HIV.

https://aidsvu.org/resources/#/tab-data.  September 6, 2021

Georgia

South Carolina

PreEP (Pre-Exposure Prophylaxis)

Number of PrEP users, 2019
6,434

Rate of PrEP users per 100,000 population, 2019
73

Percent of PrEP users, by Sex, 2019

92.6% Male
8.7% Female

Percent of PrEP users, by Age, 2019

Aged 13-24: 21.7%
Aged 25-34: 37.3%
Aged 35-44: 34.2%
Aged 45-54: 10.9%
Aged 55+: 8.5%

Number of PrEP Users, 2012-2019

PreEP (Pre-Exposure Prophylaxis)

Number of PrEP users, 2019
1,524

Rate of PrEP users per 100,000 population, 2019
35

Percent of PrEP users, by Sex, 2019

92.2% Male
8.9% Female

Percent of PrEP users, by Age, 2019

Aged 13-24: 16.2%
Aged 25-34: 39.4%
Aged 35-44: 25.0%
Aged 45-54: 15.4%
Aged 55+: 7.0%

Number of PrEP Users, 2012-2019

Accessed September 6, 2021

https://aidsvu.org/local-data/united-states/south/georgia/
https://aidsvu.org/local-data/united-states/south/south-carolina/
PrEP vs PEP Review

• Post-exposure prophylaxis (PEP)
  • Three antiretroviral (ARV) medications
  • Use of ARV medications after a high-risk event
    • Occupational (oPEP)
    • Non-occupational (nPEP)

• Pre-exposure prophylaxis (PrEP)
  • Two ARV medications in one pill
    • Two available options on the market currently
      • Different patient considerations for each option
PrEP Parameters

- Fixed – dose product (TDF/FTC) & (TAF/FTC) in single daily dose for those at risk of acquiring HIV

Eligibility for use

- NOT living with HIV
- NOT at risk of HIV acquisition through receptive vaginal sex (TAF-FTC)
- Weight greater than or equal to 35kg
- Creatinine Clearance (CrCl) > 30 mL/min (TAF/FTC)
- CrCl > 60 mL/min (TDF/FTC)
PEP Parameters

- Determine HIV status of source patient
- Begin as soon as possible
  - Preferably within 72 hours
- 3 ARV medications for 4 weeks
- Example of HIV follow-up testing periods
  - 6 weeks, 12 weeks, 4 months, 6 months
Senate Bill No. 159

CHAPTER 532

An act to amend Section 4052 of, and to add Sections 4052.02 and 4052.03 to, the Business and Professions Code, to add Section 1342.74 to the Health and Safety Code, to add Section 10123.1933 to the Insurance Code, and to amend Section 14132.968 of the Welfare and Institutions Code, relating to HIV prevention.

[Approved by Governor October 7, 2019. Filed with Secretary of State October 7, 2019.]

LEGISLATIVE COUNSEL’S DIGEST

SB 159, Wiener. HIV: preexposure and postexposure prophylaxis.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy and makes a violation of these requirements a crime. Existing law generally authorizes a pharmacist to dispense or furnish drugs only pursuant to a valid prescription, except as provided, such as furnishing emergency contraceptives, hormonal contraceptives, and naloxone hydrochloride, pursuant to standardized procedures.

This bill would authorize a pharmacist to furnish preexposure prophylaxis and postexposure prophylaxis in specified amounts and would require a
Pre-Exposure Prophylaxis:
Fixed-dose combination of TDF/FTC or equivalent product

Prerequisites:
Training program approved by Board of Pharmacy with input from Medical Board

Allotments:
At least a 30-day supply, and up to a 60-day supply, of PrEP, aligned with certain stipulations

Flexibility offered through inclusion of equivalent product clause

Training content also informed by public health department(s) and other stakeholders

Multiple considerations likely to influence pharmacists’ initiation of 30- versus 60 day-supply

Either allotment strategy will necessitate frequent monitoring/follow-up efforts
30 versus 60-day prescriptions

What are reasons that a pharmacist may prescribe a 30 or 60-day PrEP supply?
CA PrEP Prescribing Stipulations

‡Patient **NOT** living with HIV

**Absent any signs/symptoms of acute HIV**

- No reports of contraindicated medications
- Pharmacist counseling of ongoing PrEP use
- ≤ 60 day supply to a single patient no more than once every 2 years

‡HIV testing conducted within 7 days by FDA-approved testing devices. If negative test results are not available, pharmacists shall order an HIV test. If patient is found to be living with HIV, pharmacist or testing entity assumes responsibility for furnishing a list of primary care providers in the vicinity.
Why might the legislation forbid a single patient from receiving a 60-day supply of PrEP from a pharmacist more than once every 2 years?
Post-Exposure Prophylaxis

(A) 2 NRTIs plus 1 INSTI
or
(B) 2 NRTIs plus 1 PI
or
(C) Suitable alternative regimen

Other classes of ARVs, e.g., NNRTIs, not included in guidance

NNRTIs are no longer highly recommended in HIV treatment guidelines

Possibly higher occurrences of drug-drug interaction potential and adverse effects/safety concerns with some NNRTIs

NRTI: Nucleoside Reverse Transcriptase Inhibitor; NNRTI: Non-nucleoside Reverse Transcriptase Inhibitor; PI: Protease Inhibitor; INSTI: Integrase Strand Transfer Inhibitor
Factors impacting choice of dolutegravir or raltegravir

Use of darunavir and ritonavir *but not* darunavir and cobicistat

Availability of different regimens prone to vary by locations
CA PEP Prescribing Stipulations

- Pharmacist evaluates patient and surmises exposure was within last 72 hours
- Pharmacist provides HIV testing or concludes patient is willing to be tested
- Pharmacist provides counseling on key points related to PEP
- Pharmacist coordinates with patient’s PCP or works to facilitate access to a PCP

PCP: Primary care provider
How do some patients view pharmacists prescribing PrEP?

- Study conducted at a specialty pharmacy providing antiretroviral therapy in Arizona
- Over 95% of study population identified as male
- Majority of participant ages ranged from 20 – 29 years old
- Race/ethnicity representation consisted of approximately 70% White/non-Hispanic, 25% Hispanic, and 5% Asian American
How do some patients view pharmacists prescribing PrEP?

Over 90% of participants stated they would be willing to consult a pharmacist for HIV PrEP information or testing.

Almost 20% of participants expressed discomfort having a pharmacist prescribe their first HIV PrEP prescription.

Roughly 20% of participants expressed that increasing accessibility to HIV PrEP would result in decreased use of barrier protections.

N = 49
Patient perspectives on pharmacists prescribing PrEP – Analysis

Burden of HIV in Arizona may not completely coincide with states in the Southeastern U.S.

Lack of representation from individuals not identifying as male

Absence of African-American study participants hampers the generalizability of these results

Reasons for roughly 20% of participants’ discomfort with pharmacists prescribing PrEP:
- Rather consult with their physicians
- Reservations about adequate pharmacist preparations
Challenges to pharmacists prescribing PrEP & PEP

- Maintenance of adequate ARV supply
- Access to laboratory results (Examples)
  - Markers of kidney dysfunction
  - Markers of liver dysfunction
- Equitable comfort level among pharmacists with HIV care
- Capacity to test for other STIs
  - Syphilis, Gonorrhea, Chlamydia

ARV: Antiretroviral
STI: Sexually Transmitted Infection
Opportunities for pharmacists prescribing PrEP & PEP

- Revisit pharmacy curricula
- Laboratory Testing / Diagnostic Tools
- Counseling Strategies
- Partnerships with CBOs
- Develop/Sustain Synergy

CBOs: Community-Based Organizations
Opportunities for pharmacists prescribing PrEP & PEP

- Coordination of patient care rooms/areas
- Role(s) of pharmacy technicians
- Enhanced training
- Appointments
- Vaccinations
- Workflow
Dispensing with older perceptions