

Legislation and HIV PrEP/PEP Prescribing for Pharmacists



Kenric B. Ware, PharmD, MBA, AAHIVP
kbware@southuniversity.edu
803.935.9695

**South University School of
Pharmacy**

**Associate Professor of Pharmacy
Practice**



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

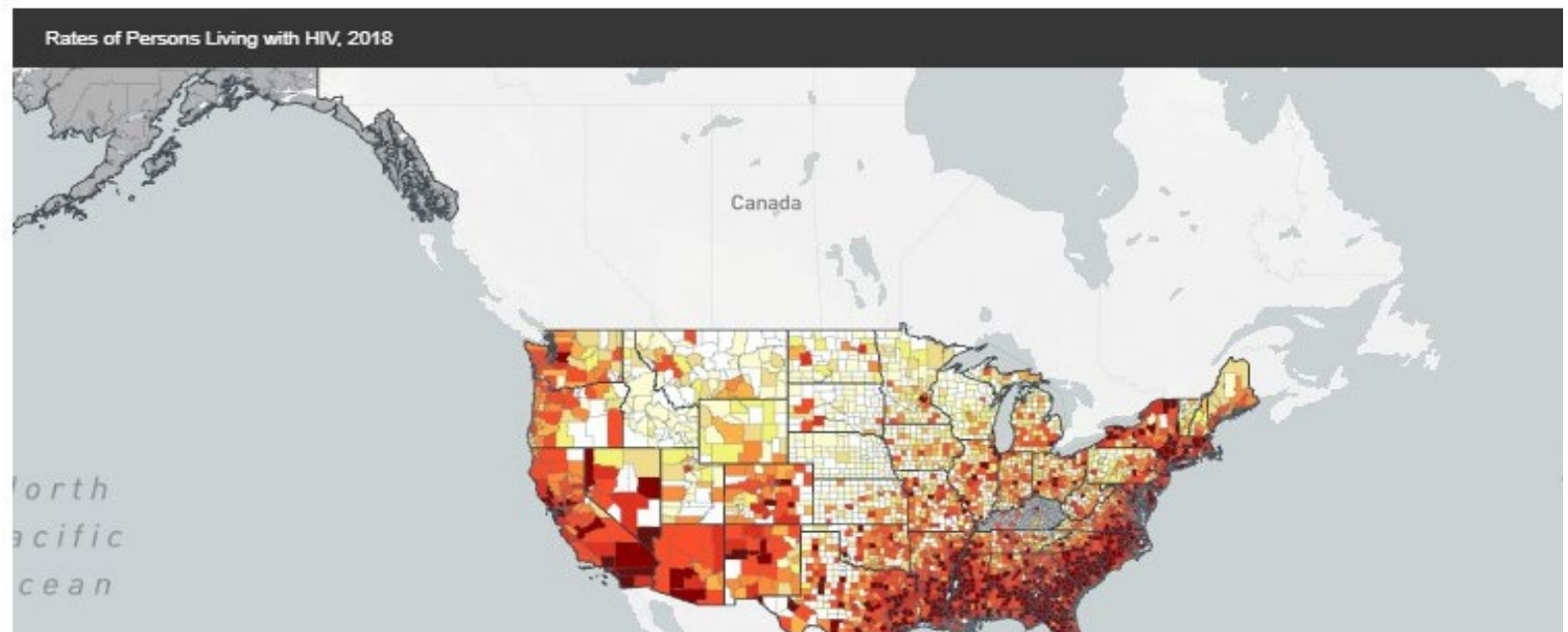
United States – HIV (2018)

HOME > LOCAL DATA > UNITED STATES

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.



United States – HIV PrEP (2019)

PrEP (Pre-Exposure Prophylaxis)

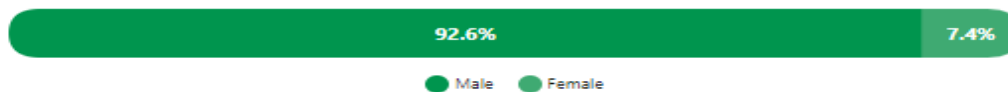
Number of PrEP users, 2019

227,046

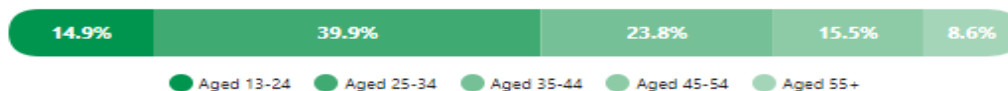
Rate of PrEP users per 100,000 population, 2019

81

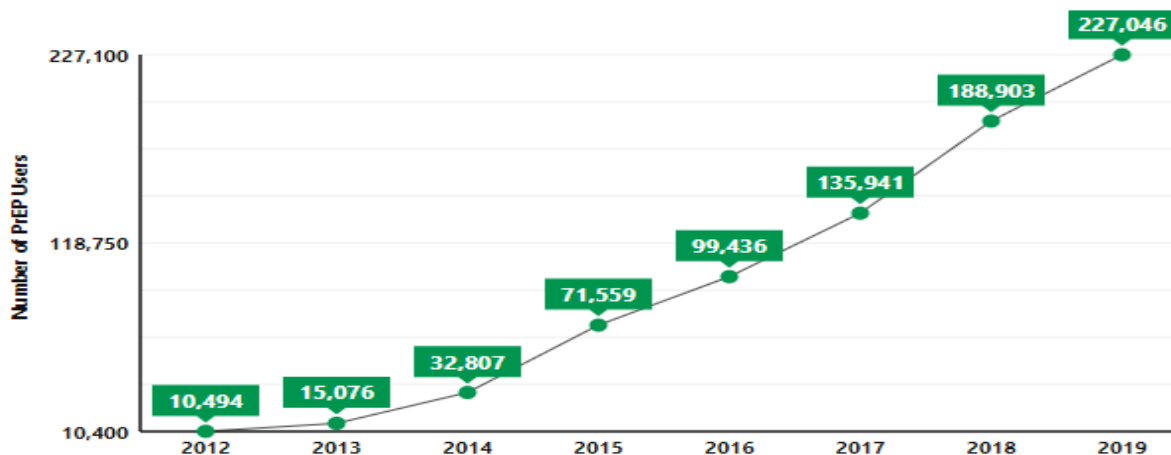
Percent of PrEP users, by Sex, 2019



Percent of PrEP users, by Age, 2019



Number of PrEP Users, 2012-2019

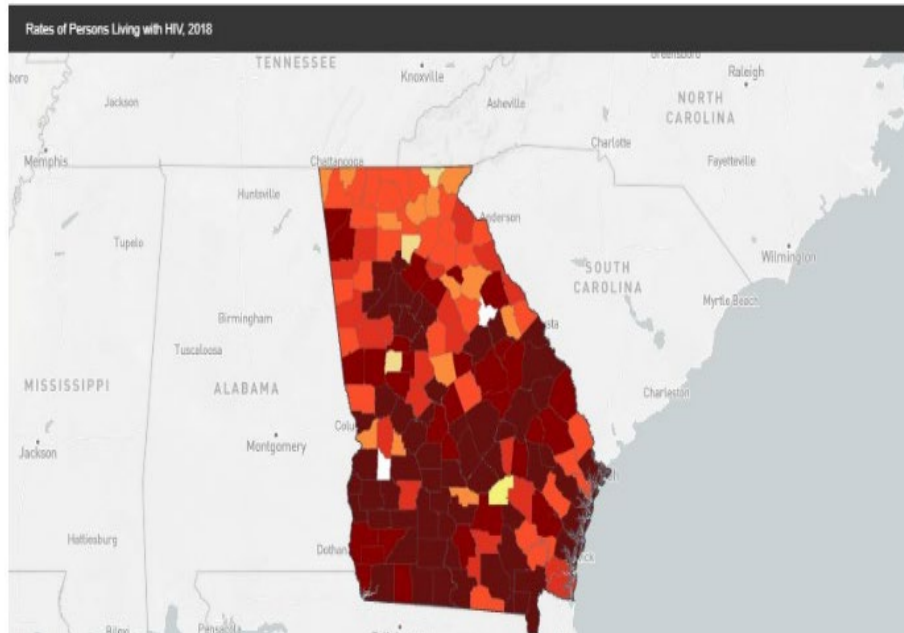


HIV State Comparisons (2018)

Georgia

Local Data: Georgia

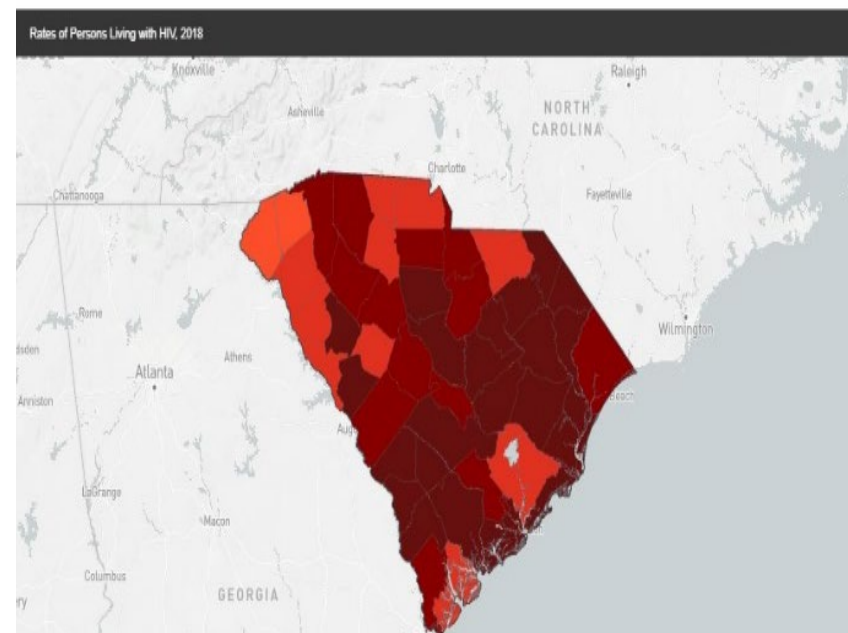
In 2018, there were 54,600 people living with HIV in Georgia.
In 2018, 2,501 people were newly diagnosed with HIV.



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.



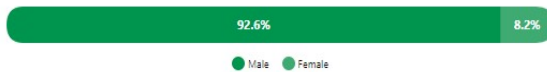
HIV PrEP State Comparisons (2019)

Georgia

PrEP (Pre-Exposure Prophylaxis)

Number of PrEP users, 2019
6,434

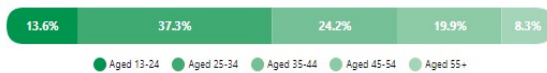
Percent of PrEP users, by Sex, 2019



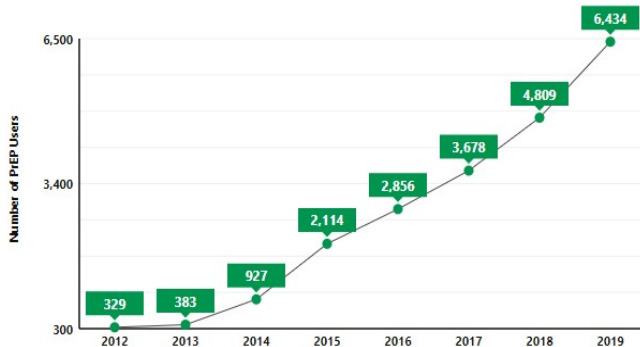
Rate of PrEP users per 100,000 population, 2019

73

Percent of PrEP users, by Age, 2019



Number of PrEP Users, 2012-2019

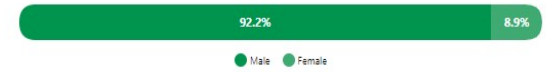


South Carolina

PrEP (Pre-Exposure Prophylaxis)

Number of PrEP users, 2019
1,524

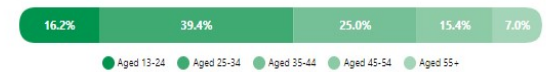
Percent of PrEP users, by Sex, 2019



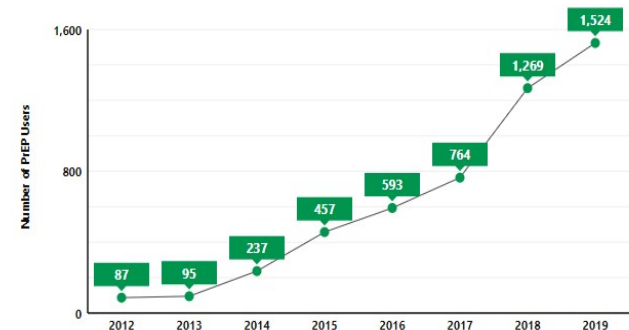
Rate of PrEP users per 100,000 population, 2019

35

Percent of PrEP users, by Age, 2019



Number of PrEP Users, 2012-2019





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)

3

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

2



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

Excerpts from California (CA) Pharmacist HIV PrEP / PEP Bill

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. 14



Maximum Prescribing Quantity

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?

Excerpts from CA Pharmacist HIV PrEP / PEP Bill

Post-Exposure Prophylaxis

(A) 2 NRTIs plus 1 INSTI

or

(B) 2 NRTIs plus 1 PI

or

(C) Suitable alternative regimen

(A)

TDF/FTC + Raltegravir or
TDF/FTC + Dolutegravir

(B)

TDF/FTC + Darunavir
and ritonavir

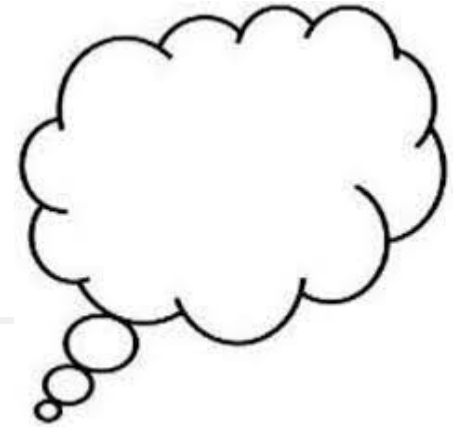
Other classes of ARVs,
e.g., NNRTIs, not included
in guidance

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



Therapeutic Thoughts



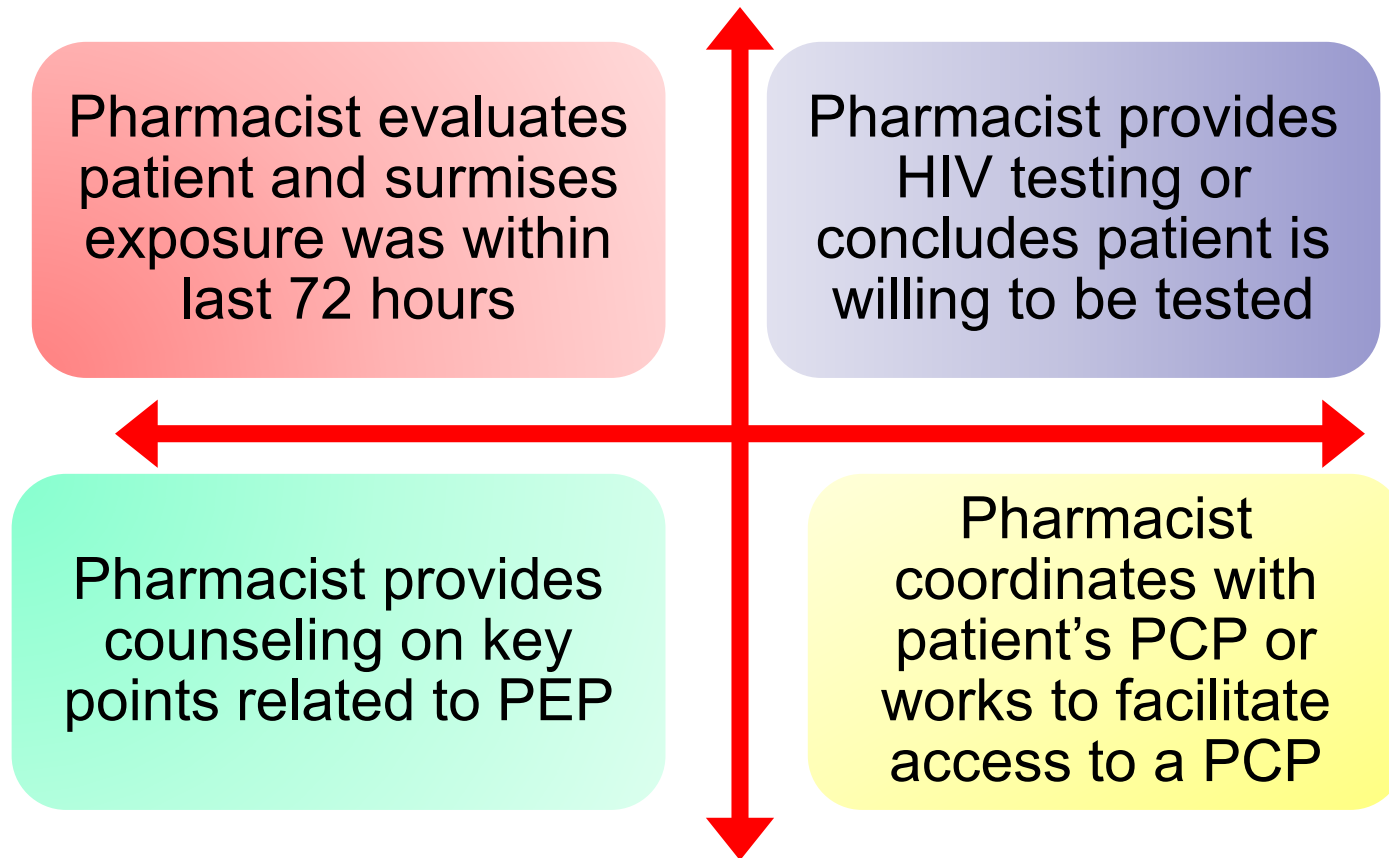
Factors impacting choice of dolutegravir or raltegravir



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

Availability of different regimens prone to vary by locations

CA PEP Prescribing Stipulations



PCP: Primary care provider

How do some patients view pharmacists prescribing PrEP?

Journal of the American Pharmacists Association 61 (2021) e75–e79



Contents lists available at [ScienceDirect](#)

Journal of the American Pharmacists Association

journal homepage: www.japha.org



RESEARCH NOTES

Patient perspectives of pharmacists prescribing HIV pre-exposure prophylaxis: A survey of patients receiving antiretroviral therapy

N = 49

- 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?

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journal homepage: www.japha.org



RESEARCH NOTES

Patient perspectives of pharmacists prescribing HIV pre-exposure prophylaxis: A survey of patients receiving antiretroviral therapy

N = 49

- 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



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

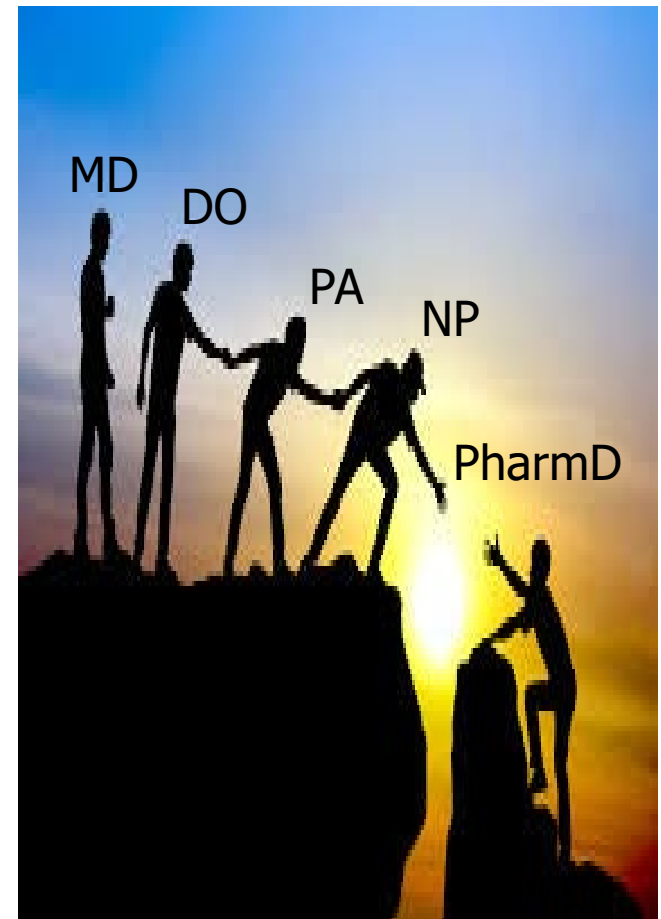
Reasons for roughly 20% of participants' discomfort with pharmacists prescribing PrEP:

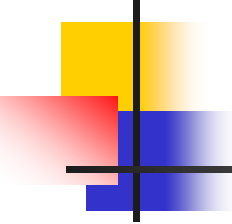
- Rather consult with their physicians
- Reservations about adequate pharmacist preparations

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

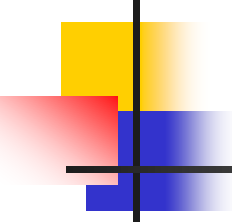
Laboratory Testing /
Diagnostic Tools

Counseling
Strategies

Partnerships
with CBOs

Develop/Sustain

Synergy



Opportunities for pharmacists prescribing PrEP & PEP

Coordination
of patient care
rooms/areas

Appointments

Vaccinations

Role(s) of
pharmacy
technicians

Enhanced training

Workflow

Dispensing with older perceptions

