

WHAT ABOUT POST-EXPOSURE PROPHYLAXIS (PEP)?

PEP Implementation in the South

A Capacity Building Providers Network (CPN) Collaboration between:

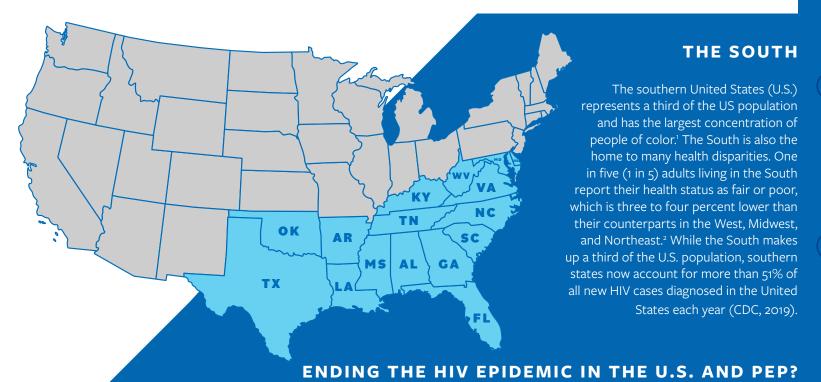






INTRODUCTION

This brief provides an overview of HIV Post-exposure Prophylaxis (PEP) in the southern United States ("the South"). The goal is to provide an overview of prevention with PEP to drive collective action between: Jurisdictional and local public health departments, community-based organizations (CBOs), and community health clinics, to increase and improve prevention with PEP. The Socio-Ecological and Collective-Impact models were utilized as frameworks to guide recommendations to increase awareness, acceptance, and access to PEP in the South.



On February 5, 2019, the U.S. government announced plans to end the HIV epidemic by 2030. This plan, Ending the HIV Epidemic in the U.S., focuses on four areas or "pillars" of HIV prevention: Diagnose, Treat, Prevent, and Respond. Each pillar outlines different activities and interventions. In the high-level description of the Prevent pillar, PrEP and syringe service programs (SSPs) are referenced, but PEP is not included. Increasing PEP use is an important and necessary strategy in ending the HIV epidemic (John, S., et.al). Without PEP being mentioned at the top level of the EHE plan, PEP may be neglected as a prevention tool. With roughly half of the 57 phase one EHE jurisdictions in the South, PEP is important to reaching EHE goals and objectives.

¹https://www.cdc.gov/hiv/pdf/policies/cdc-hiv-in-the-south-issue-brief.pdf

² Health and Health Coverage in the South: A Data Update, https://www.kff.org/racial-equity-and-health-policy/issue-brief/health-and-health-coverage-in-the-south-a-data-update/

³Key Strategies in the Plan, <u>https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/key-strategies</u>

⁴ Post-Exposure Prophylaxis (PEP) Awareness and Non-Occupational PEP (nPEP) Prescribing History Among U.S. Healthcare Providers. https://link.springer.com/article/10.1007%2Fs10461-020-02866-6

OVERVIEW OF PEP IMPLEMENTATION IN THE SOUTH

In 2005, PEP was recommended as a clinically effective way to prevent HIV after exposure.⁵ In a national study on PEP awareness and prescribing in the U.S, of the 480 healthcare providers participating, 12.5% were unaware of PEP, 43.5% were aware but hadn't prescribed nPEP, and 44.0% had prescribed nPEP for potential sexual exposures to HIV. Two hundred (200) of these providers were from the South and more of these providers were "PEP unaware" than those in other regions of the U.S.⁶ Fewer providers in the U.S. South had prescribed nPEP compared to providers in other regions. More training on clinical implementation and prescribing PEP is needed. As well as increasing PEP programmatic implementation strategies in public health settings (health departments, CBOs, and clinics).

In the 2019 National HIV Prevention Inventory (NHPI), developed by NASTAD, of the 55 participating health-departments, 22 health departments reported having nPEP programs (five were located in the South). The majority (64%, 14) provide nPEP outreach and education through CBOs and STD clinics, an increase from 12 HDs in 2014 (21%) and 10 HDs (17%) in 2009. While nPEP programs supported by health departments are increasing, implementation barriers must be overcome to increase nPEP programs and access.

PEP IMPLEMENTATION BARRIERS

As Leshin et al (2019) highlights, "The effectiveness of post-exposure prophylaxis (PEP), a major strategy in the battle against HIV, depends on awareness of this modality and its proper timing among high-risk groups." There are many patient and clinic barriers to the use of nPEP. Patients have reported difficulty managing medication adherence, the cost of the medications, and provider awareness and knowledge. However, there is limited research with priority populations demonstrating factors influencing their use of PEP. When considering the clinical barriers, provider awareness and knowledge are enablers of nPEP availability to those at highest risk for acquiring HIV.

THE BASICS: What is PEP?

PEP is the use of antiretroviral drugs after a possible exposure to stop HIV seroconversion. PEP must be started as soon as possible to be effective—within 72 hours of a possible exposure. PEP is often categorized by workplace or occupational exposures, oPEP, (i.ea needle stick in a clinical setting) and by non-occupational, nPEP, (i.e sexual, needle sharing, sexual assault, etc.). While PEP includes both oPEP and nPEP, this document primarily focuses on nPEP in the South, and will be referred to as PEP throughout this document.

⁵ Antiretroviral postexposure prophylaxis after sexual, injection-drug use, or other nonoccupational exposure to HIV in the United States: recommendations from the U.S. Department of Health and Human Services, https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5402a1.htm

⁶ Post-Exposure Prophylaxis (PEP) Awareness and Non-Occupational PEP (nPEP) Prescribing History Among U.S. Healthcare Providers. https://link.springer.com/article/10.1007/82F510461-020-02866-6

⁷Leshin D, Olshtain-Pops K, Moses A, Elinav H. Limited awareness of the effective timing of HIV post-exposure prophylaxis among people with high-risk exposure to HIV. Eur J Clin Microbiol Infect Dis. 2019 Apr;38(4):779-784. doi: 10.1007/s10096-019-03476-4. Epub 2019 Jan 24. PMID: 30680571.

In the NHPI assessment, health departments shared that the most significant challenges to implementation of nPEP programs are 1) lack of funding (61%, 33), 2) provider unwillingness to provide nPEP (41%, 22), and 3) lack of community awareness of nPEP (39%, 21). Gaining an understanding of nPEP implementation barriers can assist when working to develop strategies to overcome these challenges.

While a considerable number of resources and efforts have been provided to increase the accessibility and acceptability of PrEP, the utilization of PEP in the prevention of HIV incidence has lagged⁸. Although the CDC has <u>published guidelines for PEP</u>, jurisdictions across the United States and six Dependent Areas (DAs) have implemented these guidelines with varying degrees of effectiveness.

Another implementation barrier is paying for PEP. Paying for PEP can be a challenge for multiple reasons, particularly if a provider is unaware of the available options for paying for PEP. Medicaid and most private insurance plans cover PEP. For those who are uninsured or underinsured, payment assistance programs and cost sharing programs are available. Due to the need for PEP treatment within 72 hours of an exposure, accessing these payment assistance programs can be challenging for the client. Other challenges to consider are the costs of the provider visit and accompanying labs that may be a part of the healthcare center's protocol. Increasing PEP access among public health and safety net providers can assist in navigating these challenges.

Paying for PEP

PEP is covered by Medicaid and most insurance plans, with payment and cost sharing assistance programs available. The following resources are available to assist navigating different financial assistance programs available for PEP.

Pharmaceutical Company Patient Assistance
Programs and Cost-Sharing Assistance
Programs for Pre-exposure Prophylaxis (Prep)
and Post-exposure Prophylaxis (Pep). Each
pharmaceutical company has different
policies for applying and delivery of
medications for Pep. This resource developed
by NASTAD provides detailed instructions for
each company's program.

Billing codes for PEP. The Illinois Department of Public Health in conjunction with the Illinois Public Health Association developed a helpful billing manual for HIV testing and related services (including PEP and PrEP). The resource also provides information on general coding principles. While this resource was not developed in the South, it can greatly assist southern jurisdictions with billing code questions.

For survivors of sexual assault, some State Attorney General Offices assist with coverage for PEP. Each state has different programs available. The United States Justice Department local resources page includes information for each state to learn more about their available programs.

⁸ Fagan J, Frye V, Calixte R, Jain S, Molla L, Lawal A, Mosley MP, Greene E, Mayer KH, Zingman BS. "It's Like Plan B but for HIV!" Design and Evaluation of a Media Campaign to Drive Demand for PEP. AIDS Behav. 2020 Dec;24(12):3337-3345. doi: 10.1007/s10461-020-02906-1. https://pubmed.ncbi.nlm.nih.gov/32390059/



STAKEHOLDERS ROLE IN ADVANCING PEP IMPLEMENTATION

Engaging with key stakeholders can greatly assist with increasing PEP implementation in the South. The following key stakeholders can impact the provision and access of PEP, and overall PEP implementation through collective action.

KEY STAKEHOLDERS: THE PRIMARY CARE CLINICIAN AND HIV PROVIDERS

The role of the primary care physician (PCP) should not be underestimated for optimal implementation. In practice, the PCP may serve as a conduit to overcoming psychosocial barriers - particularly stigma, perception of low risk - and/or complex medical conditions. Henny et al (2019)9 examined factors associated with improved HIV screening and prescribing of nPEP and PrEP among a representative sample of PCPs in the Southeast. Fewer than half of PCPs in the study reported a "good" understanding of nPEP. Similarly to PrEP, the more HIV-related training a PCP attended, the more familiar they were to PEP.

Rodriguez et al (2013)¹⁰ surveyed 142 HIV providers¹¹ in Miami-Dade County (Florida) and the District of Columbia to assess knowledge, attitudes, beliefs, and practices related to the delivery of nPEP. The study found that an additional barrier to utilizing nPEP may be the absence of protocols to guide HIV providers in their respective institutions. While the majority of respondents were aware of CDC's guidelines, the majority also indicated that there were no written nPEP protocols. Providers at clinics without a written nPEP protocol were less likely to prescribe nPEP than those that did have a written protocol. Considering HIV providers are "most expected to receive referrals for nPEP", written nPEP protocols may be lacking more among the larger clinician community.

Other enabling factors for nPEP prescription were:



✓ Client advocacy

Patients that requested nPEP received the prescription.



✓ Provider perception and experience

Belief that nPEP would lead to antiretroviral resistance. Providers who prescribed nPEP before were more likely to prescribe it again.



Practice size

Providers in larger practices were more likely to prescribe than those at smaller practices

PCPs and HIV providers are important stakeholders for increasing access and uptake of PEP. Increased HIV-related training, particularly for PCPs in regions (MSAs, counties, etc.) with high HIV incidence, should include PEP content so that providers can more readily assess, screen, and prescribe to individuals that would benefit from the intervention. The development and implementation of nPEP protocols will take the collective action of PCPs, HIV providers, and their respective administrative staff, to address the barriers affecting nPEP provision in their practice.

⁹ Henny KD, Duke CC, Geter A, Gaul Z, Frazier C, Peterson J, Buchacz K, Sutton MY. HIV-Related Training and Correlates of Knowledge, HIV Screening and Prescribing of nPEP and PrEP Among Primary Care Providers in Southeast United States, 2017. AIDS Behav. 2019

Nov;23(11):2926-2935. doi: 10.1007/s10461-019-02545-1. PMID: 31172333; PMCID: PMC6803031.

¹º Rodríguez AE, Castel AD, Parish CL, et al. HIV medical providers' perceptions of the use of antiretroviral therapy as nonoccupational postexposure prophylaxis in 2 major metropolitan areas. Journal of Acquired Immune Deficiency Syndromes (1999). 2013 Nov;64 Suppl 1:S68-79. DOI: 10.1097/qai.obo13e3182a901a2.

[&]quot; In the study, HIV providers are defined as those that treated at least one person living with HIV, in the last year, and provide care to people without HIV as Infectious Disease specialists, STD clinic providers and/or primary care providers.



CBOs are on the front line for health access particularly for community members with challenges. As trusted sources of information, health education and services, CBOs help minimize barriers to access for communities burdened by inequitable social and structural determinants of health, including but not limited to socioeconomic status (SES), immigration policy, insurance, geographic location, and societal stigma (Ross and Williams, 2002; CDC 2007).1213 Community based health educators, including HIV testers, working within non-clinical settings are particularly effective in reaching individuals unaware of their status, and act as advocates to accessing HIV prevention services. Better training and systems for providing linkages to PEP are needed for this workforce, including training on screening for PEP eligibility by testers at the community level and navigation to PEP with established prescriber partnerships.

THE TAKEAWAY: The CBO is a key access point for HIV prevention, particularly for priority populations. Nonclinical providers, including community health promoters and outreach workers, testers and educators working in regions (MSAs, counties, etc.) with high HIV incidence, need concentrated training and support to assess, screen and navigate individuals that would benefit from PEP. This is even more crucial for the context of the South, where large rural areas, limited

public transportation options, and other structural factors impact the time needed to efficiently link an individual to PEP.



KEY STAKEHOLDERThe Pharmacist

Increasing access points for PEP can greatly assist in reducing barriers to this intervention strategy. As PEP must be acquired within 72 hours of exposure, time is of the essence. Physician access can be limited, especially on nights and weekends, and getting an appointment can often take time. Increasing pharmacist prescribed PEP is an opportunity that would allow for faster access and assist in reducing barriers. States around the country are starting to pass legislation to expand prescribing access to pharmacists. New York, California, and Colorado are among these states that have passed this legislation. While none of these states are in the South, they serve as positive examples for southern jurisdictions to look to when modifying their legislation and policies. To highlight these legislative changes further, the North Carolina AIDS Action Network (NCAAN) developed a "Pharmacy Distributed PrEP and PEP" brief, describing the different legislation passed and proposed to address the expansion of pharmacist prescription of PrEP/PEP. This brief can greatly assist other southern states when looking to adopt similar policies.

Ban Prior Authorization for PEP

Prior authorization is the approval from a health plan required before receiving a service or filling a prescription for the service or prescription to be covered by a healthcare plan. Through this process, clinicians must justify the medication as medically necessary and may be asked to document that the patient meets specified clinical criteria. Prior authorization requirements have been shown to reduce both necessary and unnecessary medication use.14 The delays that prior authorizations create are an additional barrier to PEP access, especially with time being a significant factor for effective intervention. Both California and Colorado's PrEP/PEP pharmacy initiation laws prevent health insurance providers from requiring individuals to receive a prior authorization for both PrEP and PEP.

¹² Ross, M., & Williams, M. (2002). Effective Targeted and Community HIV/STD Prevention Programs. The Journal of Sex Research, 39(1), 58-62. Retrieved March 24, 2021, from http://www.jstor.org/stable/3813425

¹³ Centers for Disease Control and Prevention (CDC). Rapid HIV testing in outreach and other community settings--United States, 2004-2006. MMWR Morb Mortal Wkly Rep. 2007 Nov 30;56(47):1233-7. PMID: 18046300.

¹⁴ Regional Disparities in Qualified Health Plans' Prior Authorization Requirements for HIV Pre-exposure Prophylaxis in the United States. https://jamanetworkopen/fullarticle/2766669

PRACTICE RECOMMENDATIONS:

To address the barriers and opportunities named above, the following are recommendations health departments, physicians, and CBOs can utilize increase PEP implementation across the South.

HEALTH DEPARTMENTS

- ☐ Establish protocols and procedures guiding nPEP implementation and utilization.
 - □ Disseminate guidance to local health departments and community-based organizations.
- ☐ Establish jurisdictional and local level HD nPEP hotlines and/or directory of access points.
- ☐ Provide ongoing training to increase knowledge and awareness among clinical and non-clinical providers and community members.
- ☐ Conduct Public Health Detailing with providers at Emergency Rooms, urgent care centers, family planning/OBGYN centers, and primary care centers to increase willingness to prescribe nPEP and availability.
- ☐ Request and participate in cultural humility, and implicit bias workshops.
- □ Develop practices that are culturally responsive to the community members served.
- ☐ Provide and ensure sustainable funding for nPEP linkage and navigation within "targeted testing" HIV prevention programs.
- ☐ Establish ongoing, dedicated PEP marketing to community members, clinicians and nonclinical community providers that is culturally responsive to your focus populations for HIV prevention.
- □ Expand PrEP Drug Assistance Program (PrEP-DAP) by adding a PEP Drug Assistance Programs (PEP-DAP) (funding permitting).

PHYSICIANS AND ADVANCED PRACTICE CLINICIANS

- ☐ Review the AIDS Educational and Training Center's (AETC) nPEP provider toolkit.
- ☐ Request and participate in cultural humility, and implicit bias workshops.

- □ Develop practices that are culturally responsive to the community members served.
- ☐ Conduct comprehensive, gender affirming and non-stigmatizing sexual histories with all clients.
- ☐ Connect to additional resources and provider detailing.

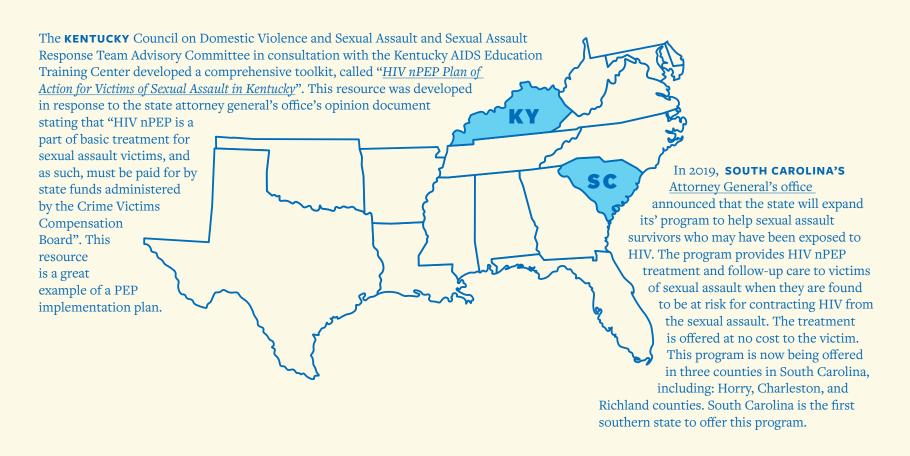
COMMUNITY-BASED ORGANIZATIONS

Non-clinical providers and HIV testers are trusted sources of care to community members most affected by HIV.

Recommendations:

- □ Nonclinical providers: Become familiar and comfortable with screening and linking individuals that are within the 72 hour exposure window period. Incorporate open ended questions, such as "What brings you in today?"
- ☐ Educate all staff on PEP, such as front desk personnel, to ensure clients receive accurate information when calling for more information and resources.
- ☐ Request and participate in cultural humility, and implicit bias workshops.
- □ Develop practices that are culturally responsive to the community members served.
- □ Conduct comprehensive, gender affirming and non-stigmatizing sexual histories with all clients.
- $\hfill \square$ Engage the larger community to increase awareness and reduce stigma.
- □ Advocate on behalf of your community to local legislators, policy makers, and larger medical institution representatives to increase the accessibility and availability of PEP.

Southern Spotlight



CONCLUSIONS

Barriers in the South may be similar to those in other regions, but are exacerbated by: extensive social and structural determinants of adverse health outcomes such as, stigma and low awareness/knowledge of PEP as a prevention method, particularly among adolescents, cisgender women who have sex with men, etc. The availability, or lack thereof, of culturally responsive clinical and nonclinical providers may worsen the historical reality of medical mistrust, creating further inaccessibility to PEP. Furthermore, providers themselves may need to reassess their own attitudes and beliefs about PEP, risk compensation, and possible effects such as antiretroviral resistance if the individual does indeed seroconvert.

As phase one EHE jurisdictions work to implement their EHE plans, ensure PEP is included in the conversation and as a Prevent strategy. Avoid prioritizing one needed strategy against another and focus on the fact that different strategies have different "places" in prevention and complement, rather than compete with one another.

Finally, there is a need for more evaluation and research on PEP implementation in the South. Little is known about evidence-based practice, policy, and tailored models for priority populations in the southern states, and particularly how legislation, Medicaid expansion regulations, and large rural geographical contexts, impact efficient and effective PEP uptake.

TECHNICAL ASSISTANCE IS AVAILABLE

To assist with the recommendations described throughout this brief, technical assistance is available. CDC funded health departments and community-based organizations in the South are eligible to receive technical assistance and capacity building support! The South includes: AL, AR, Baltimore, DC, DE, FL, GA, Houston, KY, LA, MD, MS, NC, OK, SC, TN, TX, VA, and WV. Capacity building in the South is provided by, My Brother's Keeper, Inc., the Latino Commission on AIDS, and NASTAD.

ADDITIONAL REFERENCES

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