

NIMHD National Advisory Council Concept Clearance Form

Date of Council: May 24 – 25, 2021

Title of Initiative: Innovative Multi-Level Approaches and Strategies to Prevent, Test and Treat HIV in Primary Care Settings in Health Disparity Populations in Geographic Hot Spots

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Objective: This initiative will support R01 projects that examine innovative approaches and strategies to prevent, test and treat HIV among health disparity populations or subgroups within primary care settings located in geographic areas with a high rate of new infections.

Background: In 2019, the U.S. Department of Health and Human Services launched the *Ending the HIV Epidemic: A Plan for America (EHE)* initiative to end the U.S. human immunodeficiency virus (HIV) epidemic by 2030 (<https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview>). A critical component of the EHE initiative involves early diagnosis of HIV infection, along with prevention of new transmissions, treatment of infections, and response to HIV outbreaks. HIV testing is the first step in identifying persons with infection who need to be engaged in treatment and care, as well as persons with a negative test result who are at high risk for infection and can benefit from preexposure prophylaxis (PrEP) and other prevention services.

To end the HIV epidemic, testing of patients during primary care visits should be leveraged to increase the percentage of diagnosed infections and reduce transmission. Of the approximately 38,000 new infections that occurred in the US in 2018, 69% occurred in gay and bisexual men. Black and Hispanic men who have sex with men (MSM) accounted for the largest share of new diagnoses. Moreover, of those new diagnoses among gay and bisexual men, racial and ethnic disparities continue to exist: 37% were among Blacks and 30% were among Hispanics, while 27% were among Whites, with a much lower percentage for other racial groups.

Physicians' offices and other primary care settings are important venues for HIV testing in the U.S. However, while several hundred million visits were made annually to physician offices, community health centers, and emergency departments (EDs) by persons aged 13–64 years during 2009–2017, HIV testing occurred at <1% of visits to physician offices, <3% of visits to CHCs, and <1% of visits to EDs.

Patients seen in primary care settings could benefit from having established care with rapid transition into treatment for those who test HIV positive, or prevention services for those at risk who test negative. For those at high risk who test negative, providers in primary care settings are well positioned to offer PrEP and other preventive services. The CDC estimates that 1.2 million adults in the U.S. might benefit from preexposure prophylaxis preventive treatment, but only a minority—some 205,000—are using it, therefore there is a significant unmet need to increase access for those at risk for the virus. Given the large numbers of individuals who have indications for PrEP, there are not enough practicing specialists to meet the need; and specialty settings are less likely to be available in rural areas or other underserved settings. Moreover, PrEP is a preventive intervention for otherwise healthy individuals, and primary care clinicians can provide it at the point of first contact.

Clinician knowledge gaps constitute an important barrier to persons at risk for HIV being prescribed PrEP. Educating primary care providers and removing barriers to screening while increasing the extent to which testing occurs during primary care visits will advance prevention, care and treatment strategies. Clinicians may be cautious about prescribing PrEP because of concerns regarding its effectiveness in practice or because of anticipated unintended consequences associated with its use. In addition, clinicians in primary care settings may be reluctant to prescribe PrEP due to bias and discrimination: there may be a perception that men of color, transgender women, youths and other groups at risk for HIV will not adhere to it.

Among primary care providers, many continue to conduct risk-based instead of routine opt-out HIV testing. With an opt-out testing model—where the default is to test unless the patient refuses—an HIV test could easily be added when a patient has annual full panel blood work performed. Studies from both urban and rural primary care settings found patient acceptance rates of routine testing between 47% and 62%. These results demonstrate the potential for primary care settings to play a much larger role in early diagnosis and linkage to care.

Overall, primary care settings are an underutilized venue to provide HIV testing, preventive care, and treatment to populations who may not seek services in HIV or other specialty settings due their lack of acceptability or accessibility. More research is therefore needed to understand how to best deliver HIV-related services in primary care settings to high risk populations that experience health disparities.

Description of Initiative: This initiative will support R01 projects that test innovative approaches and strategies to prevent, test and treat HIV among health disparity populations or subgroups within primary care settings located in geographic areas with a high rate of new infections. Priority populations for this research includes MSM and transwomen of color. Primary care settings may include: general internist, family medicine and OB/GYN practices; OB/GYN clinics; pediatric and adolescent medicine practices; school-based health centers; college/university health centers; medical clinics within drugstores; federally qualified health centers; and similar venues where primary care is delivered. Studies of healthcare settings that already provide HIV testing and treatment as part of routine care—such as HIV clinics or sexual and gender minority (SGM)-focused clinics—are not a priority for this initiative. Neither are observational studies that only identify predictors of testing, without evaluating their intervention effects.

Areas of specific interest to NIMHD may include, but are not limited to, the following:

- Increasing engagement in primary care of high-risk populations without a usual source of healthcare.
- Enhancing physician awareness and willingness to prescribe PrEP or ART.
- Enhancing cultural competence of clinicians and reducing implicit bias towards SGM and/or racial/ethnic minority populations.
- Promoting patient engagement and treatment adherence through linkages with community-based programs and services.

- Promoting patient engagement and treatment retention through peer, family and community support.
- Studies of strategies to expand the provision of HIV prevention and care services within primary care settings across multiple domains (clinicians and staff, service delivery structure, financing, etc).
- Studies that examine the effectiveness of new or existing programs or services.
- Implementation research studies that examine the uptake and sustainability of evidence-based interventions or practices.
- Increasing HIV testing in primary care settings using innovative testing models.

This initiative is aligned with the following High Priority topics for using NIH AIDS-designated funds:

- Reducing Incidence of HIV/AIDS.
- Research to Reduce Health Disparities in the incidence of new HIV infections or in treatment outcomes of those living with HIV/AIDS.