

NATIONAL ADVISORY COUNCIL CONCEPT CLEARANCE

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Title of Initiative: Promoting Viral Suppression among Individuals from Populations Experiencing Health Disparities Engaged in HIV Care

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Objective: This initiative will support R01 intervention projects to promote antiretroviral therapy (ART) initiation, ART adherence, and suppressed viral load for people living with HIV (PLWH) from populations experiencing health disparities engaged in HIV care.

Background: *The objective of the Ending the HIV Epidemic: A Plan for America* is to reduce new HIV infections in the United States by 75% in five years and by 90% by 2030 (<https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview>). This will be accomplished by implementing proven strategies to prevent new HIV infections – including use of pre-exposure prophylaxis (PrEP) by high-risk HIV-negative individuals and achieving an undetectable viral load through antiretroviral therapy (ART) among people living with HIV (PLWH) – in geographic hotspots with disproportionate numbers of new HIV infections. According to the CDC, PLWH engaged in HIV care but not virally suppressed account for 20% of new HIV transmissions.

To meet the *Plan for America* objectives, the target level for viral suppression among PLWH is 95%. According to the CDC, about two-thirds (63%) of PLWHs currently demonstrate 12-month viral suppression, with significant disparities evident. Among PLWH in HIV care, racial/ethnic minorities, less educated and lower SES individuals, and adolescents and young adults are less likely to be prescribed ART, achieve viral suppression on ART, and maintain sustained viral suppression than their more advantaged or older counterparts. Lack of suppression, coupled with unprotected sexual contact or injection drug use, contributes to an elevated risk of HIV transmission within these groups. Better strategies are needed to promote ART initiation and adherence in PLWH from populations experiencing health disparities engaged in HIV care, and to reduce HIV risk behaviors during periods of non-suppression. Although a variety of interventions exist to improve adherence to ART and other medications, many of those focus on health education and text message reminders, and do not address social determinants associated with poorer ART adherence and viral suppression. Such factors include poverty, unemployment, mental health and substance use problems, housing instability, food insecurity, criminal justice involvement, lack of social support, intimate partner violence, community violence, stigma and discrimination, and lack of access to culturally competent HIV care or pharmacy services. As a result, many adherence interventions are less effective with PLWH from populations experiencing health disparities or show initial effects that dissipate over time. In addition, many existing ART adherence interventions do not address HIV risk behaviors during periods of non-suppression. Therefore, multi-domain, multi-level interventions that address social determinants of health are needed to help PLWH from populations experiencing health disparities initiate and sustain ART adherence and reduce HIV-risk behaviors.

Description of Initiative: This initiative will support R01 intervention projects to promote ART initiation, ART adherence, and suppressed viral load for PLWH engaged in HIV care in one or more geographic hotspots (see <https://files.hiv.gov/s3fs-public/Ending-the-HIV-Epidemic-Counties-and-Territories.pdf> for a list of hotspots). The companion HIV initiative for FY2021 will address HIV prevention in high-risk,

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HIV-negative individuals. The population focus for this initiative is expected to be primarily men who have sex with men (MSM) and transgender women of color, as these populations have elevated rates of new HIV infection as well as risk of HIV transmission. Other populations with low levels of viral suppression may also be included as appropriate. The justification of the geographic hotspots should be based on surveillance, clinical, or research data indicating that rates of viral suppression within the hotspot(s) as a whole, or for the specific target population within the hotspot, are lower than the national average.

Interventions are expected to have the following features:

- Based in one or more HIV care settings, rather than interventions that are delivered independently from ongoing HIV care.
- Are delivered by personnel from the HIV care setting or collaborating service providers rather than research personnel.
- Are focused on one or more NIH-designated populations experiencing health disparities (Blacks/African Americans, Hispanics/Latinos, American Indians/Alaska Natives, Asians, Native Hawaiians/Other Pacific Islanders, socioeconomically disadvantaged populations, underserved rural populations, and sexual and gender minorities), including but not limited to, MSM and transgender women.
- Simultaneously promote ART initiation/adherence and reduce high risk sexual and drug use behaviors during periods of non-suppression to prevent HIV transmission to sexual partners.
- Address relevant multi-domain, multi-level determinants of poor ART adherence, viral non-suppression, and high-risk HIV behaviors (see the NIMHD Research Framework: <https://www.nimhd.nih.gov/about/overview/research-framework.html>).
- Use direct assessment of viral load (not only self-report) as the primary outcome in addition to relevant behavioral outcomes (e.g., ART adherence, condom use, PrEP use by sexual partners).
- Emphasize intervention effectiveness, comparative effectiveness, implementation strategies, or optimization of multi-component interventions.
- Are supported by relevant preliminary data. However, it is not expected that all intervention elements or implementation strategies will have been pilot tested.
- Have potential for sustainability and scalability after the funded project is over.

Areas of special interest include but are not limited to the following:

- Testing of interventions in HIV care settings in multiple geographic hotspots.
- Use of cluster randomized trials or multi-site, quasi-experimental studies.
- Interventions that directly engage partners in ART adherence and HIV risk behavior reduction intervention components.
- Interventions that include clinician- or clinic-level intervention components to enhance cultural competency and reduce health-care related stigma and discrimination.
- Engagement of members of the target high-risk populations experiencing health disparities or subgroups as investigators, advisors, or peer interventionists.

- Collaboration with diverse local stakeholders in addition to HIV care providers, including other types of healthcare providers, school systems, school-based student or parent associations, community-based organizations, consumer organizations, patient advocacy organizations, and faith-based organizations.
- Projects that examine cost of intervention implementation and delivery.

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