

NATIONAL ADVISORY COUNCIL CONCEPT CLEARANCE

Date of Council: February 3-4, 2020
Title of Initiative: Multi-Level HIV Prevention Interventions for Individuals at the Highest Risk of HIV Infection
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Objective: This initiative will support R01 projects that test the effectiveness of multi-level interventions to prevent HIV in high-risk populations experiencing health disparities or subgroups in one or more geographic areas with a high rate of new infections.

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 individuals living with HIV – in geographic hotspots with disproportionate numbers of new HIV infections. New infections disproportionately occur in young men who have sex with men (MSM) from racial/ethnic minority populations, particularly African Americans and Latinos. However, the populations or subgroups at the highest risk of acquiring HIV may vary across geographic hotspots, and the challenges in engaging these high-risk populations may also vary depending on local or state HIV-related resources, laws and policies, and social norms and cultural factors. If these highest risk populations are not successfully engaged in local prevention efforts, the objective of drastically reducing new HIV infections in the next two decades is not likely to succeed.

In addition to engagement of high-risk populations in HIV prevention programs through culturally relevant outreach, such programs, if they are to be effective, must also address the life circumstances and social and structural environments that may make reducing HIV risk challenging. Such factors may include poverty, unemployment, mental health and substance use problems, housing instability, food insecurity, criminal justice involvement, social isolation, intimate partner violence, community violence, stigma and discrimination, lack of access to healthcare, and lack of clinician awareness or willingness to prescribe PrEP. Successful implementation of HIV prevention programs is likely to require adaptation of intervention content, format, or mode of delivery, or additional intervention elements, to be acceptable and feasible to populations that may be experiencing competing priorities and life demands. In addition, interventions are not likely to produce sustained reductions in HIV risk if they are solely focused on individual-level knowledge, attitudes, and behavior. Therefore, multi-level intervention components, including those that involve peers, partners, family members, school systems, community members, community-based organizations, healthcare and other service providers, are necessary.

Description of Initiative: This initiative will support R01 projects that test the effectiveness of multi-level interventions to prevent HIV infection in high-risk health disparity populations or subgroups 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 viral suppression as a prevention strategy. The population focus is expected to include HIV-negative MSM of color and/or transgender women, as these populations have the highest risk for acquiring HIV. Projects may include these populations globally or specific subpopulations that are relevant to the selected hotspots. Examples of subgroups include, but are not limited to, MSM who are African American or Latino; identify as bisexual; have mental health or substance use disorders; belong to house and ballroom communities; or who are under 18, homeless, recent immigrants, involved in the criminal justice system, or engaged in sex work or exchange sex. Justification of the selected target population(s) must be based on (1) local surveillance, clinical, or research data demonstrating a high incidence of new HIV infections and/or low rates of PrEP use, condom use or HIV testing within the hotspot, and (2) evidence that existing local, state, or federal HIV prevention and treatment initiatives are not reaching or not effective for these populations. It is expected that the target populations will be more narrowly defined in urban hotspots, where significant HIV prevention programs and services already exist, than those in underserved urban or rural hotspots, where services are limited for all populations.

Interventions are expected to have the following features:

- Promote PrEP use, condom use, and HIV testing in HIV-negative individuals, with intervention content that can be updated to reflect new prevention options that emerge during the project (e.g., long acting PrEP, HIV vaccine).
- Encompass multiple domains (e.g., biological, behavioral, socio-cultural, environmental, physical environment, health-care system) and multiple levels (e.g., individual, interpersonal, community, societal; see the NIMHD Research Framework: <https://www.nimhd.nih.gov/about/overview/research-framework.html>).
- Use existing evidence-based HIV-prevention interventions or practices (including adaptations), either alone or in combination with new intervention elements. Entirely new interventions are not the focus of this initiative.
- Use the reduction of new HIV infections in the target population as a primary outcome in addition to relevant behavioral outcomes.
- Are led by or conducted in partnership with service providers responsible for delivering HIV prevention services or programs at the local, state, or regional level.
- Emphasize intervention effectiveness, comparative effectiveness, success of intervention implementation strategies, or optimization of multi-component interventions.
- Are tested with participants reflective of the diversity within the target population (e.g., with respect to sexual orientation, gender identity, race/ethnicity, SES, or rural urban status).

- 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 multiple geographic hotspots.
- Use of cluster randomized trials or multi-site quasi-experimental studies.
- Interventions that include clinician- or healthcare setting-level intervention components to enhance cultural competency, reduce health-care related stigma and discrimination, and increase clinician comfort and willingness to prescribe PrEP.
- 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-prevention service providers, including school systems, school-based student or parent associations, community-based organizations, consumer 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