Notice of Funding Opportunity PS-23-005: Expanding Rapid Initiation of Antiretroviral Therapy in Non-traditional Settings: Emergency Department

HIV Research Branch
Division of HIV Prevention
National Center for HIV, Viral Hepatitis, STD, and TB Prevention

Overview

Background

- **Immediate initiation of antiretroviral therapy (ART) is now recommended for anyone newly diagnosed with HIV, regardless of CD4 count.**
- **The rapid ART model, defined as immediate diagnosis, linkage to care, and ART initiation on the same day as a new HIV diagnosis or return to care, should offer an accelerated entry into HIV medical care.**
  - Rapid ART confers a higher rate of engagement in care, reduces the time to viral suppression, and improves morbidity and mortality in people with HIV.
- **The emergency department (ED) offers a unique setting to immediately engage with patients not accessing HIV care services to initiate ART and provide linkage to an HIV provider in the community.**

Purpose

- **To support research investigating how to deploy and optimize rapid ART delivery in emergency departments that are currently routinely screening for HIV infection.**
  - Evaluate acceptability, perceived barriers and facilitators, feasibility, sustainability, and HIV care continuum outcomes.
- **Data will be used to determine whether HIV testing and rapid ART in emergency departments can improve engagement, linkage and retention in care, viral suppression, and decrease HIV infections.**

Award Information

Type of Award	Cooperative Agreement
Fiscal Year Funds	2023
Approximate Annual Funding	$1,500,000
Approximate Number of Awards	3
Budget Period/Length	12 months
Project Period	09/30/2023 to 09/29/2027 (4 years)
Estimated Total Funding	$6,000,000

Subject to the availability of funds

Strategies and Activities

Strategy 1

- **Accurately and effectively diagnose new HIV infections or PWH returning to care in the emergency department.**
  - Provide and encourage an “opt-out” universal HIV testing strategy in the ED to all patients, utilizing point-of-care testing or other rapid diagnostics.
  - Establish collaboration between hospital laboratory and hospital emergency room to prioritize HIV testing and communication of positive tests to ED providers.

Strategy 2

- **Expand rapid ART initiation to patients on the same day as diagnosis or the same day PWH return to care in the ED, and conduct pre- & post-implementation clinical outcome monitoring.**
  - Develop and design an effective implementation study to facilitate rapid ART initiation in EDs.
  - Examine acceptability and barriers to implementation of rapid ART in the ED from both patient and staff perspectives.
  - Establish collaboration between ED site, community/affiliated HIV clinics/providers, and health department, to enhance pre-and post-implementation monitoring.

Strategy 3

- **Provide linkage to care services to patients initiated on ART in the ED.**
  - Implement a patient navigator model in the ED to assist with linkage to HIV care.
  - Establish collaboration and communication channels between ED and community/affiliated HIV clinics/specialist/health departments to ensure linkage to care.

Example Study Variables

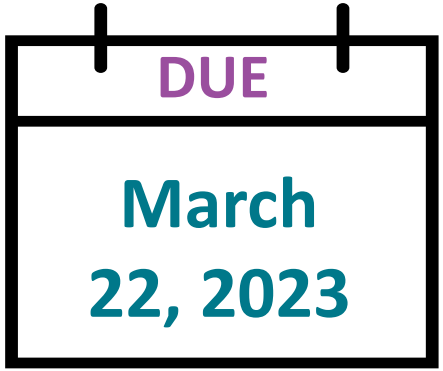
Research Variable Assessed	Study Sample(s)	Data Collection Tool(s)
Health Outcomes Primary: proportion of patients rapidly initiated on ART at diagnosis, linked to HIV medical care, retained in care, achieved viral suppression. Secondary: HIV screening rates and diagnostic yield, time to specific milestones such as time to ART initiation, viral suppression or first clinic appointment, treatment modification incidence.	Patients	Electronic Health Records (in the ED, and in the partnering HIV clinic)
Implementation Process Measures Strategies, adaptation, barriers, structural challenges, facilitators, fidelity	Staff, Leadership	Survey, Interview
Implementation Context and Outcomes Reach, fidelity, appropriateness, acceptability, feasibility, adherence, and sustainability	Staff, Leadership, Patients	Survey, Interview
Cost Labor and non-labor	Staff/Location Setting	Cost Questionnaires

Applicant Eligibility, Evaluation, and Other Info

Important Dates

- **Letter of Intent (LOI): 02/21/2023 (optional; not required)**

- **Applications are due 03/22/2023**
  - Submit via www.grants.gov



Eligibility

- State, county, city or township, or special district governments
- Public and State controlled institutions of higher education
- Independent school districts
- Native American tribal governments and Native American tribal organizations
- Public housing authorities/Indian housing authorities
- Nonprofits having a 501(c)(3) status
- Private institutions of higher education
- For profit organizations other than small businesses
- Small businesses

- The following types of Higher Education Institutions are always encouraged to apply for CDC support as Public or Private Institutions of Higher Education:
  - Hispanic-serving Institutions
  - Historically Black Colleges and Universities (HBCUs)
  - Tribally Controlled Colleges and Universities (TCCUs)
  - Alaska Native and Native Hawaiian Serving Institutions
  - Nonprofits (Other than Institutions of Higher Education)
- Governments/Other:
  - Eligible Agencies of the Federal Government
  - U.S. Territory or Possession
  - Faith-based or Community-based Organizations
  - Regional Organizations

Evaluation Criteria

- **Significance**
  - Does the work have potential to result in a rapid ART delivery model that increases ART initiation and use among newly diagnosed PWH?
  - Will the work help to understand determinants of a successful intervention?
  - Will the work provide information for further integration of rapid ART treatment services in the United States?
  - Does the application utilize local epidemiologic and other relevant program or clinical data to demonstrate the need for improved implementation strategies to facilitate better outcomes for populations that may benefit from this research?
  - Are the proposed set of project activities methodologically strong, and yet realistic to accomplish, such that they will contribute significantly to HIV treatment implementation research in the United States?
  - If successful, do the research results have the potential to be scalable and reach a large portion of populations of newly diagnosed PWH?

Evaluation Criteria

- **Investigators**
  - Have the investigators conducted health-related implementation research studies in clinical settings such as emergency departments?
  - Have the investigators conducted HIV treatment research in clinical settings such as emergency departments?
  - Does the investigator team have experience working in EDs that currently provide opt-out testing for HIV?
  - Have the investigators published more than one scientific article that reports implementation research study findings in peer-reviewed journals?
  - Does the investigatory team have an affiliation or a partnership with outpatient HIV clinics that may serve as study sites for rapid initiation of ART, linkage to care, and follow up?
  - Does the application demonstrate that project staff and collaborators are knowledgeable and experienced in implementation science and how it applies to HIV treatment?

Evaluation Criteria

- **Innovation**
  - Does the application clearly describe the proposed research questions and any innovation that the results may lead to?
  - Do the proposed partnerships provide opportunities for innovation?

Evaluation Criteria

Approach

To what extent:

- Does the application demonstrate partnership with one or more emergency departments with outpatient HIV clinic for rapid initiation of ART, linkage to care, and follow up?
- Are the proposed choice of ED and clinic sites justified?
- Does the clinical population volume and retention demonstrate the need for and ability to implement the rapid ART implementation study?
- Is the approach presented in the research plan consistent with the implementation research logic model?
- Does the application describe strategies and capacities for insurance benefits navigation, patient navigation, and other cost issues to support the patient's initiation of ART?
- Does the application describe strategies to conduct formative work and use evaluative and iterative strategies to assess for study readiness?
- Does the application describe an approach to recruit, train, and provide interactive assistance to staff and providers and educate collaborators?
- Does the application describe strategies to support clinicians?
- Does the application describe change infrastructure strategies, to integrate opt-out HIV testing and rapid ART interventions into ED workflow processes?
- Does the application describe a plan to collect and manage the relevant study data elements?

Evaluation Criteria

- **Environment**
  - Is the institutional support, and other resources available, adequate for the project activities proposed?
  - Does the project use critical partnerships or collaborations to maximize the potential for success in study implementation and translation into practice?
  - Does the project support key stakeholder involvement throughout the research process?
  - Does the application describe plans to conduct the study in geographic areas experiencing issues with new diagnoses of HIV, initiation of ART, linkage to care and/or sustained viral suppression?
  - Does the application describe emergency departments currently conducting HIV opt-out testing or have plans to initiate opt-out testing?
  - Does the application describe appropriate affiliations with clinical centers that have infrastructure/staff for insurance and cost navigation to prescribe and provide rapid initiation of ART?
  - Does the application include letters of collaboration and support from proposed partners that reflect their role and capacity to participate in the research project?

Website & Contact Information

- **Website**
  - https://www.cdc.gov/hiv/funding/announcements/ps23-005/index.html
- **Agency Contacts**
  - Program Official/Scientific Research Contact
    - Jocelyn Patterson Mosely, MPH, MA - Email: jpatterson@cdc.gov
  - Peer Review Contact
    - Gregory Anderson, MPH, MS - Email: GAnderson@cdc.gov
  - Financial/Grants Management Contact
    - Sharon Cassell – Email: SCassell@cdc.gov

Thank you!

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