Tobacco Cessation, HIV and Comorbidities in Low- and Middle-Income Countries (LMICS)

FOA Concept Proposal

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Background: Tobacco Use Among People Living with HIV/AIDS (PLWH)

- Smoking prevalence is higher among PLWH compared to the HIV negative population (2 to 3 times greater than the general population)
- PLWH who smoke tobacco are more likely than nonsmokers with HIV to:
  - Suffer greater morbidity and mortality
  - Develop certain cancers (lung, head and neck, cervical and anal)
  - Develop pneumonia, COPD, and heart disease
  - Progress from HIV to AIDS
  - Have a poorer response to antiretroviral therapy (ART)

https://www.cdc.gov/tobacco/campaign/tips/stories/brian.html
Background: Tobacco Use Among PLWH

Introduction of ART has led to

- Globally: 37M PLWH; 23M on ART
  - Global burden of HIV is in LMICs
  - 75% on ART in sub-Saharan Africa
- Tobacco use declining in HICs, but burden shifting to LMICs
  - 84% of world’s 1.3B smokers live in LMICs

### Estimated relative percentage changes in prevalence of tobacco smoking (between 2010 and 2025)

- Decreases in the prevalence of tobacco use are projected for many countries, except for multiple African countries, the eastern Mediterranean, Southeast Asia (for men only), northern Asia (for women only) and Europe (for women only)
Challenges for Tobacco-Use Interventions

Smoking cessation interventions for PLWH present additional challenges

- Lower cessation rates
- Complications with other substance abuse, mental illness, socio-economic status

Bulk of the evidence base for tobacco cessation comes from HICs

- LMICs may have limited resources and access to pharmacologic treatments, fewer trained professionals, and diverse cultural and social contexts
- However, there are promising intervention strategies tested in challenging and low-resource settings which could be adapted for PLWH in LMICs

There’s a need to creatively adapt and integrate tailored tobacco control interventions into existing activities in LMIC context
Opportunities for Tobacco-Use Interventions

- HIV treatment context provides an opportunity to intervene in a coordinated way:

  **Utilize existing infrastructure for community interventions**
  - In LMICs this infrastructure may provide a unique opportunity for implementing low-cost tobacco interventions (e.g. cessation services, community participation, and public health outreach to affected families)

  **Diagnosis of HIV/TB provides teachable moments for tobacco use cessation**
  - Patients are more likely to be concerned about improving ART regimens and lung health with HIV/TB diagnosis, and may be more willing to accept a provider’s advice to quit smoking

  **Integration of services can provide the region with many benefits**
  - Integration is likely to bring economic benefits, including reduced health care costs and waste, reductions in family poverty, and improved results of HIV/AIDS programs in already overburdened countries
New RFA Request: Tobacco Use and HIV in Low- and Middle-Income Countries

Goal: To bring together transdisciplinary teams of investigators to adapt interventions developed and tested in challenging or low-resource populations and to test their robustness among PLWH in LMICs

- Use appropriated NIH AIDS research funds
- Will seek co-funding/participation from NIDA, NIMHD, FIC
- Anticipate funding 4+ R01/U01 awards this round
- Estimated total cost: $12.5 million; Year 1 (2021) set-aside: $2.5 million
- Build on previous NCI/NIDA PARs (PAR-18-22/23, R01/R21) “Tobacco Use and HIV in Low and Middle Income Countries”
Discussion with BSA Review Subcommittee

Changes to Mechanism
- Drop R21 option
- Utilize U01 mechanism for additional NCI involvement and coordination across funded projects

Integrate two companion RFAs: Domestic and Global (LMIC)
- Domestic: Improving Smoking Cessation Interventions among People Living with HIV (RFA-CA-18-027/28)
- LMIC: Tobacco Use and HIV in Low- and Middle-Income Countries (PAR now proposed as RFA)
- All investigators participate together in annual PI meetings
- Working groups to share research methods, common measures, and early results
Example Research Aims

- What types of tobacco cessation interventions are most effective in PLWH in low-resource settings in LMICs to achieve improved tobacco abstinence as well as disease treatment outcomes?

- Test the robustness and translatability of interventions from challenging or low-resource settings (e.g. substance abuse or mental health comorbidities) to challenging setting of PLWH in LMICs

- Adapt innovative but tested strategies with potential for scale-up for PLWH in LMICs, including use of community health services, mobile technology, and behavioral counseling.

- Identify and address barriers to integrating tobacco control interventions into existing healthcare systems and the HIV prevention and treatment context in LMICs

- Understand the social and behavioral context of tobacco use in PLWH in LMICs influence tobacco use behavior and cessation outcomes
Current NCI Grant Portfolio

12+ active tobacco control research grants in LMICs

10 active grants with a focus on tobacco cessation in PLWH

- Testing a range of innovative approaches which could be applied in LMIC settings, including use of peer navigators, community health services, mobile technology, and behavioral counseling.

- Two LMIC focused projects:
  - Optimizing smoking cessation interventions for PLWH in Nairobi, Kenya PI: Seth Himelhoch, University of Maryland (R01CA225419) Goal: Comparing behavioral and pharmacologic interventions in PLWH who smoke recruited through methadone maintenance clinic in Nairobi
  - Feasibility and acceptability of a text messaging intervention to increase smoking cessation in Vietnam (R21CA225852) Goal: Compare effectiveness and cost-effectiveness of three multi-component tobacco cessation interventions embedded in outpatient HIV clinics in Viet Nam
Additional Review Criteria

- Reviewers will be asked to consider the following:
  - Prior evidence for the proposed intervention in a challenging population and/or low-resource setting (in the US or LMIC)
  - Relevance of the expected findings for the LMIC setting
  - Potential for the intervention to be scaled up in the LMIC setting
  - Strength of the research environment in both US and LMIC institutions, as well as evidence of prior successful collaboration

- Studies should be designed for dissemination (e.g., feasibility/acceptability of the intervention for PLWH and providers) and suitable for the intended context