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

FOA Concept Proposal

Mark Parascandola, PhD, MPH
Program Director, Tobacco Control Research Branch, DCCPS
Acting Chief, Research and Training Branch, Center for Global Health

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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

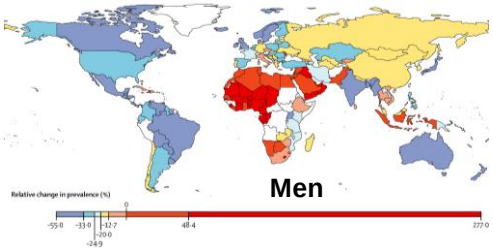
Background: Tobacco Use Among PLWH

Introduction of ART has led to

- ↑ *Increase in life expectancy*
- ↓ *Decrease in AIDS mortality*
- ↑ *Increase in non-communicable diseases*

- 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)

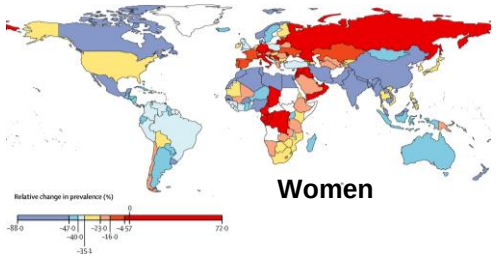


Global trends and projections for tobacco use, 1990–2025: an analysis of smoking indicators from the WHO Comprehensive Information Systems for Tobacco Control

Ver Bilano, Stuart Gilmour, Trevor Moffiet, Edouard Tursan d'Espaignet, Gretchen A Stevens, Alison Commar, Frank Tuyl, Irene Hudson, Kenji Shibuya

Lancet 2015; 385: 966–76

- 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	Diagnosis of HIV/TB provides teachable moments for tobacco use cessation	Integration of services can provide the region with many benefits
• 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)	• 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 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

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