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

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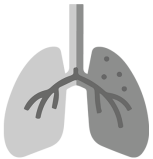
NIH NATIONAL CANCER INSTITUTE

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)



The risks of serious **SMOKING-RELATED** health **CONSEQUENCES** are much **HIGHER** for those living with **HIV**

https://www.cdc.gov/tobacco/campaign/tips/stories/brian.html

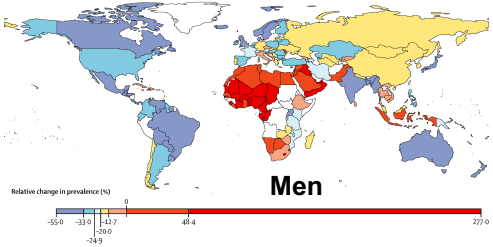
Background: Tobacco Use Among PLWH

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)

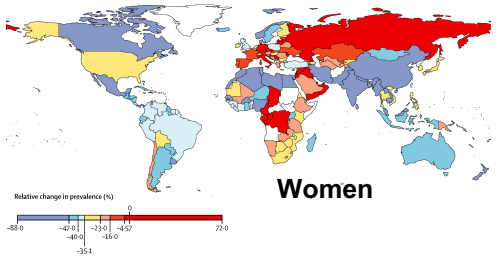


Global trends and projections for tobacco use, 1990–2025: an analysis of smoking indicators from the WHO Comprehensive Information Systems for Tobacco Control

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: 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
- Anticipate funding 4+ U01 awards
- Build on previous NCI/NIDA PARs (PAR-18-22/23, R01/R21) “Tobacco Use and HIV in Low and Middle Income Countries”

Tobacco Use and HIV in Low and Middle-Income Countries (U01 Clinical Trial Optional)

- Notice: RFA-CA-20-037
- Application Deadline: **September 24, 2020**
  - https://grants.nih.gov/grants/guide/rfa-files/RFA-CA-20-037.html
- Additional Information:
  - https://www.cancer.gov/about-nci/organization/cgh/research-training
- Use appropriated NIH AIDS research funds
- Anticipate funding 4+ U01 awards
- Build on previous NCI/NIDA PARs (PAR-18-22/23, R01/R21) “Tobacco Use and HIV in Low and Middle Income Countries”

Tobacco Use and HIV in Low and Middle-Income Countries (U01 Clinical Trial Optional) RFA-CA-20-037

- This FOA aims to bring together transdisciplinary teams of investigators to adapt interventions developed and tested in other challenging settings or low-resource populations and to test their robustness among persons living with HIV (PLWH) in LMICs.
- Responsive applications must propose research that will be conducted with PLWH in one or more LMICs
- Research may also address the behavioral and sociocultural factors and conditions that are associated with tobacco use among PLWH and may also address tobacco-related health disparities among PLWH.

Applicant Institutions

- Non-domestic (non-U.S.) Entities (Foreign Institutions) **are** eligible to apply.
- Non-domestic (non-U.S.) components of U.S. Organizations **are** eligible to apply.

Required Registrations

- Registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more.
- Dun and Bradstreet Universal Numbering System (DUNS)
- System for Award Management (SAM)
- eRA Commons
- Grants.gov

Specific Research Objectives -- Primary

- What types of tobacco cessation interventions are most effective in PLWH in LMICs to achieve improved tobacco abstinence as well as HIV-related treatment outcomes?
- How can evidence-based smoking cessation interventions be adapted to improve smoking cessation outcomes among PLWH in LMICs?
- How can the robustness and translatability of interventions from challenging or low-resource settings (e.g. persons with substance abuse or mental health comorbidities) be evaluated in the context of PLWH in LMICs?
- What innovative but previously tested strategies can be scaled-up for PLWH in LMICs, including use of community health services, mobile technology, and behavioral counseling?

Specific Research Objectives -- Secondary

- What are the barriers to integrating tobacco control interventions into the existing HIV prevention and treatment context in LMICs?
- What is the cost-effectiveness of integrating smoking cessation within HIV treatment?
- How does the social and behavioral context of tobacco use in PLWH in LMICs, including the use and abuse of other substances, influence tobacco use behavior and cessation outcomes?
- How does the use or co-use of other tobacco products (e.g., electronic nicotine delivery systems [ENDs], hookah smoking, smokeless tobacco) impact cessation behavior as well as HIV progression and treatment outcomes?
- How does smoking impact adherence to treatment among patients with HIV, including those with TB or other comorbidities?

Non-Responsive Projects

- The following types of studies would not be responsive to this RFA, and applications proposing such non-responsive projects will not be reviewed:
  - Studies focused on biological mechanisms or disease processes;
  - Studies that do not test an intervention that is intended to reduce cigarette smoking among PLWH;
  - Studies that lack a control or comparison group;
  - Studies that employ non-evidence-based tobacco cessation interventions;
  - Studies that do not consider the LMIC context of the intervention being evaluated.

Additional Review Criteria

- What is the potential for the proposed intervention, if successful, to be scaled up in the LMIC setting?
- What is the potential that this project will lead to the successful implementation of effective cessation services for PLWH in LMICs?
- Are the proposed interventions sufficiently well supported by the existing evidence and preliminary data?
- Is prior evidence for the proposed intervention provided from other challenging or low resource environments?
- Is the research design appropriate to estimate the effect of the intervention on cigarette smoking cessation outcomes?
- Are the proposed plans for dissemination suitable for the intended context?
- Is the strength of the research environment in both the U.S. and foreign institution adequate for the proposed project?
- Is evidence provided of prior successful collaboration among the team?

Other Notes

- Responsive applications should address High Priority topics of research identified in the NIH HIV/AIDS Research Priorities and Guidelines for Determining AIDS Funding (see NOT-OD-20-018) https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-018.html
- Highest overarching priorities for HIV/AIDS research effective FY 2021 to FY 2025 are:
  - 1) reduce the incidence of HIV/AIDS
  - 2) develop the next generation of HIV therapies with improved safety and ease of use
  - 3) discover a cure for HIV/AIDS
  - 4) reduce HIV-associated comorbidities and coinfections.

U01 Mechanism

The role of the NIH is to work in a partnership with the award recipients to support and stimulate their research; it is not to assume direction, prime responsibility, or a dominant role in the activities.

PI

- Defining objectives and approaches
- Overseeing study conduct
- Cooperating with NCI
- Administratively managing the grant.

NCI

- Monitoring progress
- Participate in Program Steering Committee.
- Facilitating collaborations between awardees
- Reviewing major changes
- Providing technical assistance

U01 Mechanism

Areas of Joint Responsibility

- The Program Steering Committee will serve as the non-voting organizational body for the NCI and awardees and consists of:
- Two representatives of each award (the contact PD/PI and designated backup senior investigator)
- Two NCI Project Scientists.
- The Program Steering Committee will be organized and conducted by the NCI staff on a regular basis with required awardee attendance.

Coordination of Research Networks

Annual Grantee Meetings: Awardees will be expected to participate in an annual investigators' meeting that may be hosted at NCI or at another location or, if required, may be held virtually.

Standardization and Coordination: Funded investigators will, to the extent possible, be expected to collaborate on and report key common variables in a standardized manner.

Companion RFA: Domestic: Improving Smoking Cessation Interventions among People Living with HIV (RFA-CA-18-027/28)

Timeline

- **Open Date (Earliest Submission Date)** August 24, 2020
- **Letter of Intent Due Date(s)**
  - 30 days prior to the application due date
- **AIDS Application Due Date(s)** September 24, 2020
- **Scientific Merit Review** January/February 2021
- **Advisory Council Review** May 2021
- **Earliest Start Date** July 2021

Contacts

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