

Advancing Adolescent Tobacco Cessation Intervention Research

An RFA Concept Proposal

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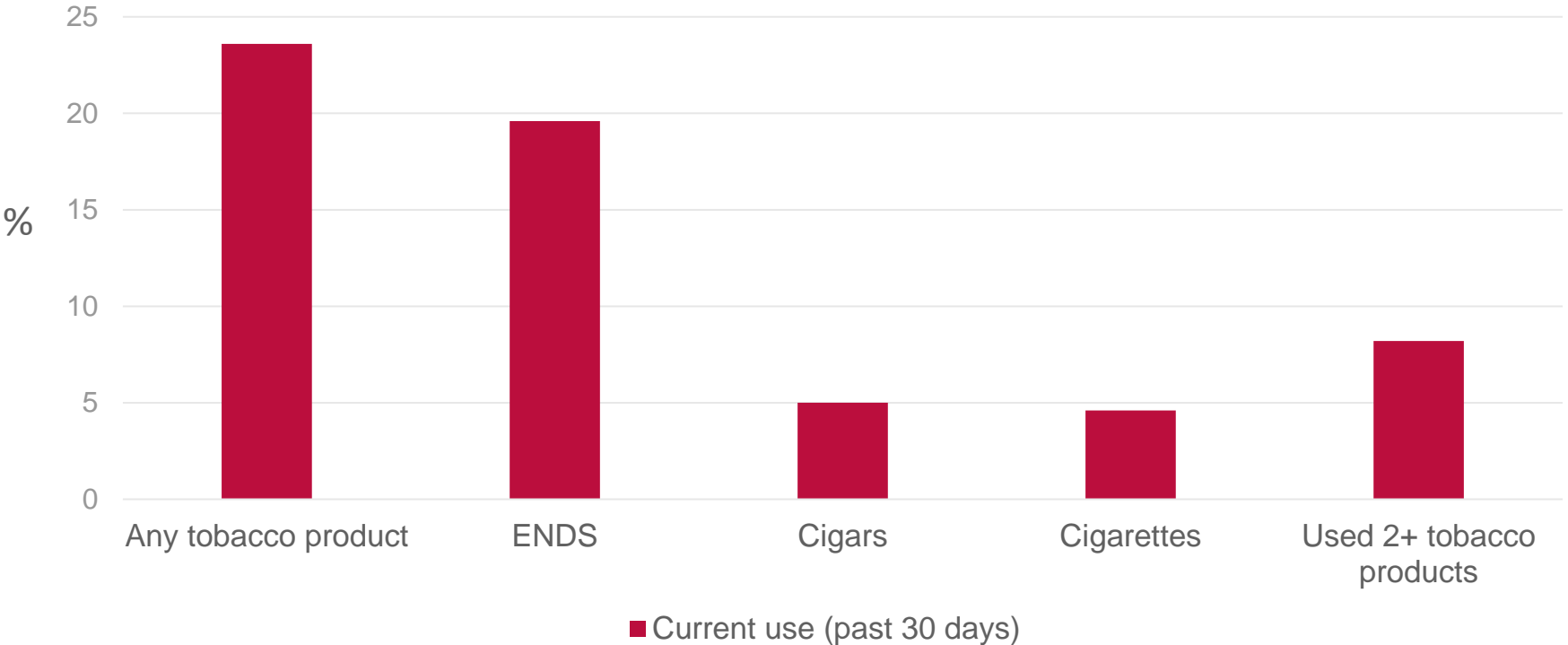
*Program Directors,
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Background: Adolescent Tobacco Use

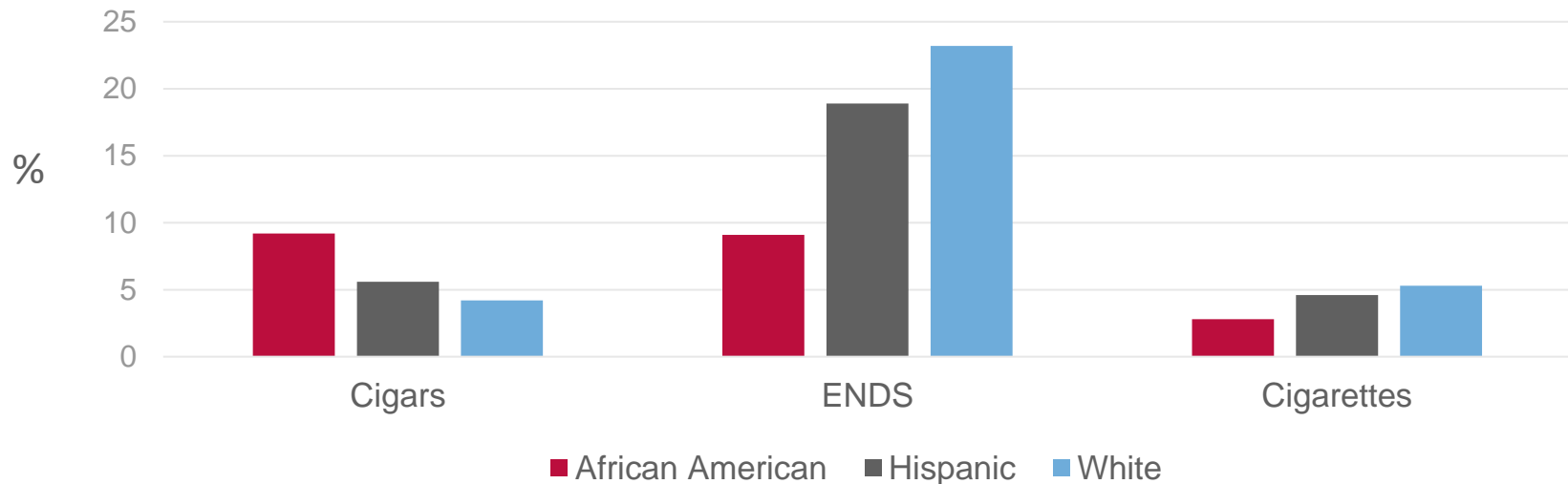
- Most tobacco use begins in adolescence
- Quitting early avoids much of the risk of tobacco-caused morbidity and mortality
- Greater tobacco product diversity
- Complex use patterns: Poly tobacco product use and co-use of tobacco and cannabis



2020 National Youth Tobacco Survey (NYTS) – Current tobacco use (past 30 days) among high school students

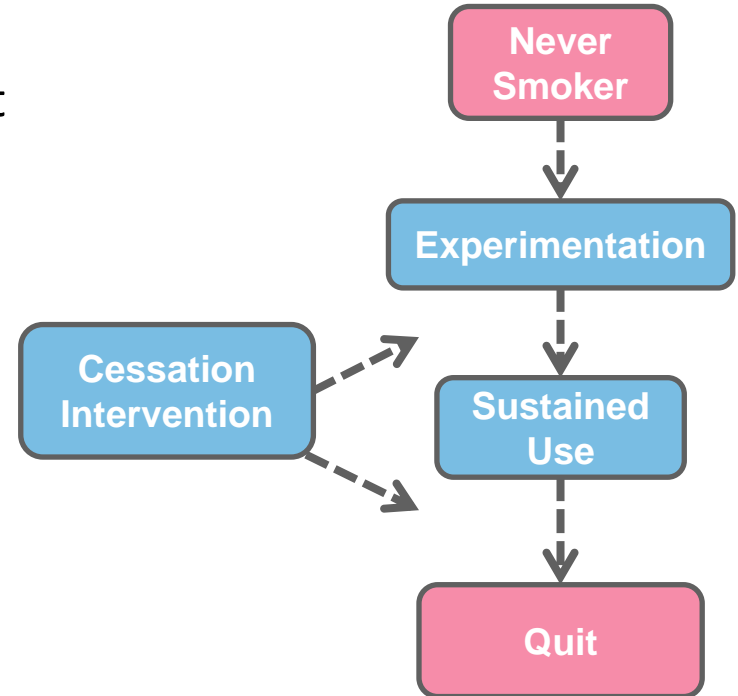


2020 NYTS - Current tobacco product use (past 30 days) by race/ethnicity among high school students



Background: Adolescence and Tobacco Cessation

- Period of greatest risk for initiation, escalation, and entrenchment of tobacco use
- Presents “windows of opportunity” to disrupt escalation and treat established dependence early
- Intense cognitive and psychosocial development:
 - establishing identity and autonomy
 - prefrontal cortex is still developing
 - still developing self-regulation, cognitive control



Background: Evidence-base for Adolescent Cessation Interventions

- **Two thirds of adolescent tobacco users report wanting to quit**
- **Nearly two thirds report trying to quit**
- Few empirically-validated tobacco cessation interventions
- Systematic reviews in 2017 (Cochrane) and 2020 (USPSTF)
- Major conclusions:
 - Little support for the tested behavioral interventions
 - No support for medication interventions
 - No studies for non-cigarette tobacco products
 - Few studies in populations with greater tobacco use burden
 - Promise for mobile technology delivery modes (e.g., text messaging)



Widespread Recognition of the Research and Practice Gap



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- NCI: extramural expert report for TCRB prioritized youth tobacco cessation research (2016)
- FDA: public workshop on youth tobacco cessation (2019)
- CDC: Interagency Committee on Smoking or Health meeting on youth tobacco cessation (2020)
- USPSTF: found insufficient evidence to assess the balance of benefits and harms of primary-care feasible interventions for tobacco cessation for adolescents (2020)
- AAP: called for adolescent cessation research on interventions delivered by pediatric health care providers

Portfolio Analysis

- Adolescent tobacco cessation intervention research is a significant funding gap
- No active grants funded by NCI with a focus on adolescent cessation interventions
- 3 active grants funded by NIDA
- No current or recent FOAs focused on adolescent tobacco cessation

Purpose and Scope of the RFA

- To stimulate research on the development and evaluation of tobacco cessation interventions for adolescents, with a focus on ages 14-20 years
- Interventions to treat established tobacco dependence or disrupt escalation of tobacco use
- Interventions for the broad range of tobacco products and use patterns
- Improve the effectiveness of existing tobacco cessation interventions, including accessibility, utilization, and reach
- Build in and/or plan for dissemination and implementation
- Consider the needs of and includes populations that experience a greater burden of tobacco use

Example Research Questions

- What comprises an effective digital therapeutic intervention for adolescent tobacco cessation and how can we maximize efficacy of these approaches?
- How can we effectively intervene with youth across developmental trajectories of tobacco use?
- How can we maximize the reach, uptake and engagement with adolescent-focused tobacco cessation interventions, particularly in populations of youth that experience tobacco-related health disparities?
- How can we effectively treat tobacco use among youth, in the context of dual or polyuse of tobacco products?

Budget Request

- We propose funding 10 awards using R01 and R34 mechanisms
- 2 receipt dates (FY23 and FY24)
 - 2 R34 awards and 2 R01 awards in FY23
 - 2 R34 awards and 4 R01 awards in FY24
- Year 1 set aside for awards in FY23: \$3 million
- Year 1 set aside for new awards in FY24: \$5 million
- Total cost across both project periods: \$33.5 million over six years

Justification for RFA

- Focus on adolescents aged 14-20 to address a major time of escalation and transition to regular use and address the greatest evidence gap
- R01: for research projects that are hypothesis-driven with strong preliminary data
- R34: for clinical trial planning activities, including feasibility and pilot studies to inform intervention viability and/or trial design
- Dedicated review group with experience in tobacco cessation and adolescent development, understand potential research challenges
- Convene grantees to share measures and methods, challenges and solutions
- **The overall goal of this RFA is to generate effective tobacco cessation interventions for adolescents for the range of tobacco products and complex use patterns**

Clarifications in Response to BSA Subcommittee Feedback (Drs. Hatsukami, Basen-Engquist and Robison)

- **Priority Populations:** Highlight and expand discussion of the need for research with adolescents from population subgroups who experience disproportionate burden of tobacco use
- **Pharmacologic Treatments:** Pharmacologic treatment approaches are not the focus of this FOA, but **will** allow applications where pharmacologic treatments are adjuncts to behavioral treatment approaches, particularly for non-cigarette tobacco products
- **Recruitment, Retention and Engagement:** The R34 mechanism is intended to be used to address these foci and these activities can also be built into an R01
- **Dissemination and Implementation:** Emphasize the need to consider the potential for future adoption, implementation, and sustainability of interventions at all stages of intervention planning and development
- **Budget Flexibility:** Consider budget flexibility due to the high cost of intervention research and different needs from year to year of an intervention

Thank you!



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