Social and Behavioral Intervention Research to Address Modifiable Risk Factors for Cancer in Rural Populations

(R01 Clinical Trial Required)

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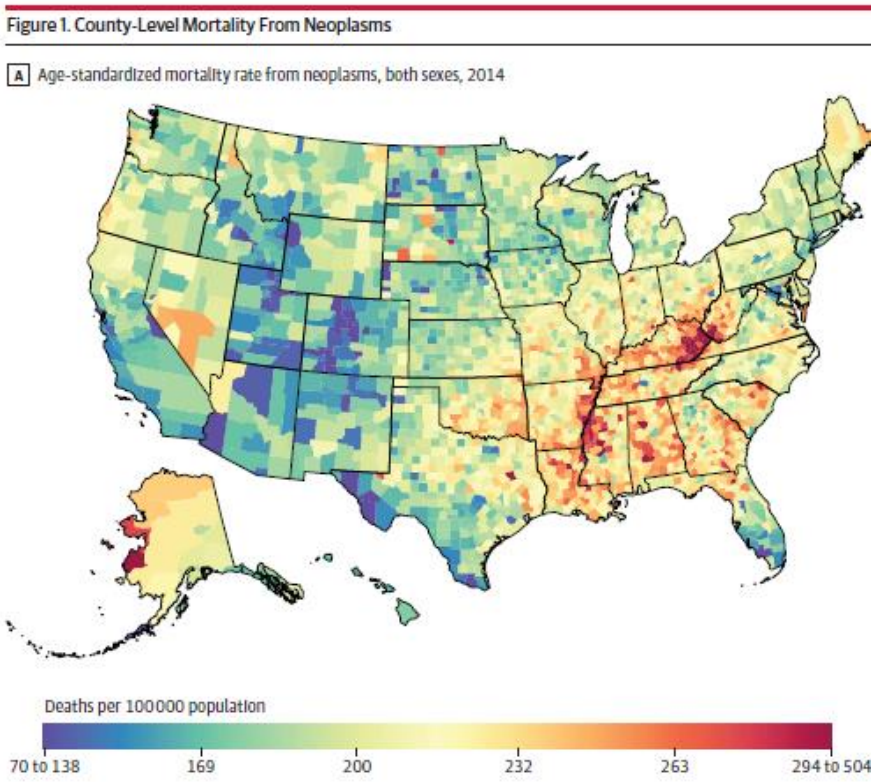
Background: Rural Cancer Burden

- Individuals in rural counties have an 8% higher overall cancer mortality than those in urban areas.
- A rural-urban disparity in mortality has been observed for lung, colorectal, prostate, and cervical cancers.
- There are higher cancer incidence rates in rural areas for many preventable cancers including lung, cervical, colorectal, oropharyngeal, and melanoma.



NCI Leadership in Rural Cancer Control

Year	Activity
2016-2017	Emphasis on rural cancer disparities, *Cancer Currents* blogs
May 2017	NCI Research Conference: "Rural Cancer Control: Challenges & Opportunities," University of Memphis SPH, Memphis, TN
June 2017	*CEBP* commentary: "Making the Case for Investment in Rural Cancer Control: An Analysis of Rural Cancer Incidence, Mortality, and Funding Trends"
October 2017	NCI Workshop: "Understanding Definitions of Rural/Rurality: Implications for Rural Cancer Control," NCI Shady Grove
May 2018	NCI Research Conference: "Accelerating Rural Cancer Control," Natcher Auditorium
FY18 and FY19	P30 rural administrative supplements
April 2018 and September 2019	RFA: "Improving the Reach and Quality of Cancer Care in Rural Populations"

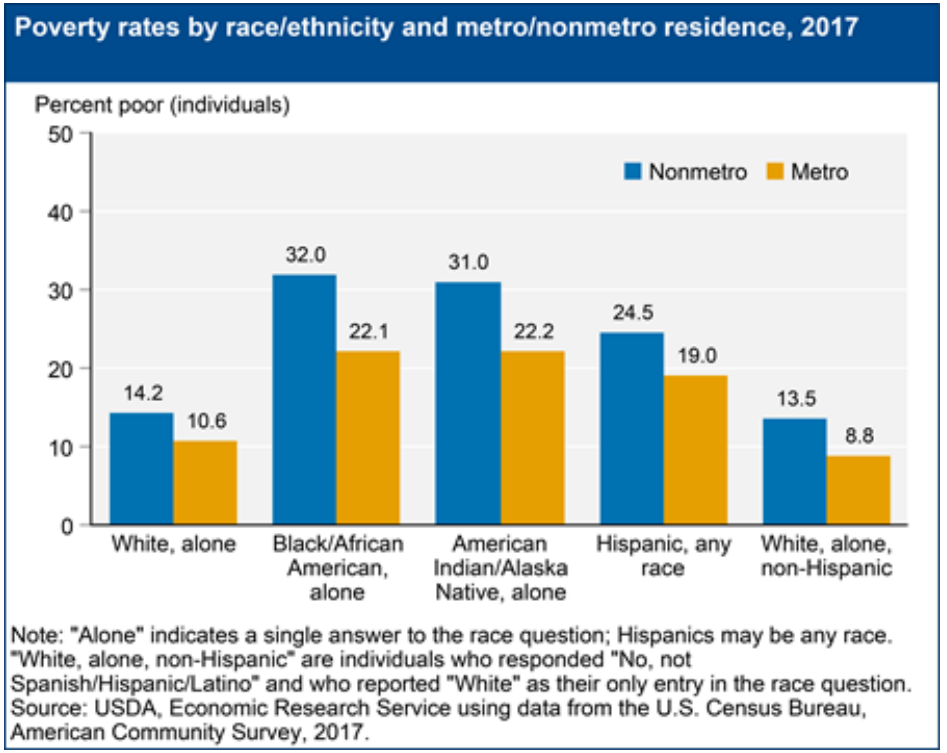
DCCPS Rural Funding Initiatives Across the Cancer Control Continuum

Cancer Control Continuum	Funding Initiative		
	Rural Supplements (FY18 & FY19)	Rural RFA (FY19 & FY21)	Proposed PAR (FY21)
[Capacity Building]	✓		
Prevention			✓
Detection			
Diagnosis		✓	
Treatment		✓	
Survivorship		✓	

Challenges & Strengths

Rural Challenges

- Higher poverty rates than urban areas
- Lower educational attainment
- Higher proportion of elderly
- Few resources for public health infrastructure
- Higher proportion of uninsured
- Geographic and social isolation
- Insufficient transportation
- Insufficient broadband access
- Higher medical mistrust
- Cancer-related fatalism
- Hospital closures
- Lack of access to health services; HPSAs



Rural Strengths

Individual, organizational, community, and cultural assets may be leveraged to inform intervention development

- Strong relationships and social networks
- Social support
- Resilience
- Values such as self-sufficiency, independence, and autonomy
- Strong local- and community-based organizations
- Connectivity across sectors/community cohesion

Rural-Urban Disparities in Behavioral Risk Factors for Cancer

- **Tobacco**
  - Higher rates of cigarette smoking and smokeless tobacco use
  - Rural youth are more likely to use tobacco products and use them more frequently than urban peers
- **Diet, Physical Activity & Weight**
  - Higher rates of obesity, lower rates of physical activity, and poorer diets in rural adults and youth
- **Alcohol**
  - Higher rates of alcohol abstinence in rural areas, but those who *do* drink have a higher prevalence of current alcohol disorder and of individuals exceeding daily alcohol limits
- **UV Exposure and Sun Protective Behavior**
  - Less likely to wear sunscreen, and higher indoor tanning use among rural teens
- **HPV Vaccination**
  - Rural HPV vaccination rates are 10% lower than in urban areas
  - Rural populations are less likely to know that HPV causes cervical cancer
  - Strong provider recommendations for HPV vaccination are less common in rural than urban areas
- **Germline Genetic Testing for Cancer Susceptibility**
  - Lower levels of awareness and utilization of cancer genetic risk assessment
  - Less access to genetic counselors

PAR Objective

To solicit applications to develop, adapt, and test individual-, community- or multi-level interventions to address modifiable risk factors for cancer in rural populations (defined as USDA RUCC or RUCA non-metropolitan areas or FAR rural areas).

- Proposals should focus on primary prevention, targeting one or more of the modifiable risk factors that contribute to cancer disparities in rural populations
- Proposals should assess and address myriad social determinants of health, cultural factors, policies, and health care and technology access barriers that may contribute to rural cancer disparities.
- FOA also encourages implementation science research, to incorporate efficacious cancer control interventions into broader, sustainable health programs that are designed to reach rural populations and allow local customization and adaption.
- Applicants are strongly encouraged to collaborate with organizations and programs with experience or infrastructure (e.g., telemedicine, behavioral health services) designed to address other health or social problems in rural populations that could afford substantial opportunities to cancer prevention and control investigators.
    - Examples include, but are not limited to, Federally Qualified Health Centers, community health centers, rural health centers, and community organizations.

Example Applications May Target:

- Behavioral risk factors for cancer in rural populations (primary outcomes)
  - Tobacco use
  - Diet, Physical Activity, and Weight
  - Alcohol consumption
  - UV exposure and sun-protective behavior
  - HPV vaccination
- Social determinants and structural/system characteristics that contribute to rural disparities in behavioral risk factors for cancer (secondary outcome measures or mediators of effect)
  - Economic and spatial barriers to healthy food access and/or physical activity in low density rural environments
  - Technology, communication, and health information inequalities that may contribute to cancer disparities in rural populations

Study Designs

- The PAR is labeled “Clinical Trial Required” in order to solicit intervention applications that meet the NIH definition of a clinical trial:
  1. Human subjects
  2. Prospectively assigned to one or more interventions
  3. Health-related biomedical or behavioral outcome
- These are not drug or device trials.
- Applications may propose either pragmatic or explanatory trials to test effects in real-world/usual conditions or under ideal/controlled conditions.
  - Experimental or quasi-experimental study designs
- Applications may propose individual, clinic, and/or community-level units of analysis
  - Individual or cluster randomization

PAR Justification

- *Referral:* Special referral is not requested (no SEP).
  - Applications will be triaged to a CSR standing study section such as Community Influences on Health Behavior (CIHB).
  - CSR will be asked to cluster the applications and recruit reviewers with relevant rural health research expertise to review clustered applications.
- *Review:* Special review criteria are requested.

  1) Applicants must clearly define and describe the rural population(s) in which the intervention research will be conducted. Rural populations must be geographically defined using the USDA Economic Research Service's Rural-Urban Continuum Codes (RUCC) or Rural-Urban Commuting Area (RUCA) codes for non-metropolitan areas, or Frontier and Remote Area (FAR) codes.

  2) Applicants must collaborate with local organizations or programs with the relevant experience and infrastructure to participate meaningfully in intervention development and delivery in rural areas.
- *Receipt:* Two receipt dates per year are requested to accommodate 8-10 applications per round so that applications can be clustered for review in a CSR standing study section.
- NIMHD has indicated interest in signing on.

Relevance to NCI Mission and HHS Priorities

- NCI Cancer Disparities Activities Committee (CDAC) support for PAR
- FY21 Bypass Budget includes rural populations when outlining populations that suffer disproportionately from some cancers; has goals related to developing public health interventions to reduce the risk of cancer and supporting research to reduce cancer disparities
- National Advisory Committee on Rural Health and Human Services' 2019 Policy Brief and Recommendations to the HHS Secretary
  - Recommended an expansion of NCI's rural cancer control program to fund partnerships with rural and tribal providers to implement cancer control research
  - 2019 HHS Rural Health Task Force Four-Point Strategy to Transform Rural Health
    - I/Cs have been asked to respond with FY20 Rural Action Proposals that can be accomplished within existing budget resources

Feedback from BSA Subcommittee

- **Content**
  - Remove genetic testing/genetic counseling from scope
    - Possibly consider separate PAR for genetic testing/genetic counseling in rural populations
    - Focus the language of the PAR only on the 5 primary prevention behaviors that are measurable intervention outcomes: tobacco use; diet, physical activity and weight; alcohol; UV exposure and sun protective behavior; HPV vaccination
  - Specify eligible RUCC, RUCA, and FAR codes
    - RUCC 4-9; RUCA 4-10; FAR Level 4
- **Mechanism**
  - Consider changing FOA type from a PAR to an RFA
  - Consider changing mechanism and maximum direct costs in order to formalize and incentivize collaboration with local organizations and programs