

Abstract: Tobacco Cessation Interventions with Ohio Appalachian Smokers

PI: Mary Ellen Wewers

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This **Competitive Revision Application** is in response to PAR-12-010 and will be integrated with a Parent Application entitled "Tobacco cessation interventions with Ohio Appalachian smokers" (R01 CA129771). The Parent Application is a five year project which was awarded January 1, 2010 through December 31, 2014. The specific aims are to: 1) evaluate the efficacy of a lay-led (LL) intervention in promoting long term abstinence from tobacco; and 2) examine the association between 12 month abstinence and selected individual, interpersonal, organizational, neighborhood and community, and societal factors among adult Appalachian tobacco users exposed to a tobacco cessation intervention. A third aim is exploratory and includes the characterization of activity patterns using space-time measures among adult Appalachian tobacco users exposed to a tobacco cessation intervention. Using a group-randomized trial design, 6 counties were randomized to the LL intervention and 6 to control. A total of 708 smokers will be recruited in the 12 counties. The control condition includes proactive telephone counseling via the Ohio Quit Line. LL group participants receive face-to-face counseling, supervised by a county health department nurse, and delivered by a trained lay educator. A county Extension agent assists with recruitment and retention efforts in this project.

Social-contextual factors are assessed at a baseline interview administered to all participants. Activities are conducted in 3 waves, with 2 intervention and 2 control counties in each wave. Space-time activity geographical patterns of pro- and anti-tobacco exposures, or features, will be described among selected participants in the last four counties during weeks 1, 6 and 12 of treatment. At end of treatment and 6 and 12 months later, LL and control group participants will be reassessed for tobacco use via self-report with cotinine-validation. The primary analysis will employ a mixed-model analysis of covariance (ANCOVA) with a logit link to examine 12 month point prevalence and prolonged abstinence. Secondary outcomes will be examined using the same mixed-model ANCOVA with link functions selected based on the distribution of each variable.

In addition to research staff on the campus of The Ohio State University (OSU), the project is coordinated **locally** through county agencies that include the local health department and county Extension Service. The intervention is delivered by **lay educators**. Figure 1 depicts the 12 counties assigned to participate in the study. The project includes three separate waves of participant recruitment, enrollment, protocol implementation, and follow-up data collection. We are currently in Wave 2. During Wave 1, we enrolled 236 participants and, to date, 118 of 236 additional participants (50%) have been enrolled in Wave 2. We have successfully adhered to our proposed timeline. Wave 3 starts October 2012 with participant enrollment (n=236) commencing March 1, 2013.

Integration of Parent Application into the Competitive Revision

During the three separate waves of the project, we hire and train a county nurse, OSU Extension agent, and project interviewer, for a total of 12 field staff (3 staff x four counties). As such, we have an existing county infrastructure and are viewed as credible by our county stakeholders. This Competitive Revision will take advantage of the existing staff capacity and existing county locations (e.g. OSU Extension county offices and county public health departments) to accomplish its aims. Since 1998, we have been able to sustain an active Ohio Appalachian field staff that has been trained to conduct well-controlled tobacco-related research. All field staff has completed extensive training in the areas of human subjects, study recruitment and retention, protocol implementation and data collection techniques.

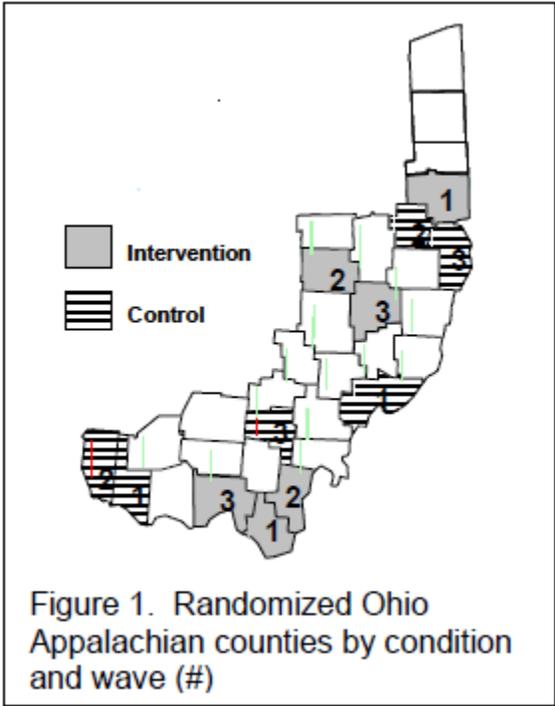


Figure 1. Randomized Ohio Appalachian counties by condition and wave (#)