Study Protocol

Title: Smoke-free Air Coalitions in Georgia and Armenia: A Community Randomized Trial

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Smoke-free Air Coalitions in Georgia and Armenia: A Community Randomized Trial

Investigators

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A. BACKGROUND AND SIGNIFICANCE

Public health efforts in low- and middle-income countries (LMICs) could be catalyzed by developing and bolstering ways to optimally leverage local talents and resources. One way to accomplish this is to align civil society and governmental public health goals and resources.[1] Civil society advocates, builds coalitions, and provides evidence-based information.[1-6] Local public health protects, assesses, and assures individual, community, and environmental health.[7] Local public health in many LMICs continue to have a disproportionate focus on communicable disease and environmental health, with less attention paid to non-communicable diseases and risk factors such as tobacco use. Developing effective models for aligning civil society and governmental public health at the local level in LMICs has the potential to impact a range of chronic diseases and risk factors, including tobacco. *Local coalitions* have been a dominant strategy in tobacco control in the US, with well-documented success in establishing smoke-free policies specifically.[8-17] Local public health agencies often serve as the lead agency with influential partners from a range of community sectors (e.g., education, health care) collaboratively identifying priorities and actions.[15] Community-based tobacco control efforts have played a key role in shifting social norms and creating community readiness for policy change and enforcement.[15] However, this approach has not been widely leveraged or well-studied in LMICs or those with less democratic traditions than the US. Instead, in many LMICs, smoke-free policy progress has been largely initiated at the national level. Parallel civil society movements at the local level may be needed to build support for policies, shift social norms, and encourage compliance with new policies.

Given their sociopolitical histories and high tobacco use and secondhand smoke exposure (SHSe) rates, Georgia (GE) and Armenia (AM) are two strategic settings for the proposed work. The smoking prevalence is 57.7% and 52.3% in men (6th and 11th highest in the world) and 5.7% and 1.5% in women, respectively.[18] Despite ratifying of the FCTC in 2006 and 2004 in GE and AM, respectively, FCTC-recommended policy implementation has been limited, and tobacco use and related diseases have not declined. The sex disparities in tobacco use suggests a high proportion of nonusers experience SHSe. Drs. Berg and Kegler (co-PIs) and colleagues in GE found that 42% of GE adults report daily SHSe, with 30% reporting past-week SHSe in public places and 54% at home.[19,20] However, we also found high receptivity to public smoke-free policies.[19,20]

B. SPECIFIC AIMS

This proposal will build the capacity of GE and AM researchers to conduct high-quality mixed methods tobacco research and test the Community Coalition Action Theory (CCAT)[21] as a framework for impacting local community-driven policy change to inform such processes for the region more broadly. Researchers from the GE National Center for Disease Control (NCDC) and AM National Institute of Health (NIH) will collaborate with Emory to execute the proposed research, train tobacco control researchers within their organizations and partnering universities (Tbilisi State Medical University [TSMU], American University of Armenia [AUA]), and train practitioners within local communities to build local coalitions for tobacco control policy. Our team is uniquely positioned to conduct this work given our collective expertise in tobacco control, coalition building, and evaluation. We will leverage our prior collaborative research findings regarding high SHSe and high receptivity for smoke-free policies, particularly in worksites and restaurants,[19,20] to develop national and local infrastructure to promote local tobacco control policy implementation, specifically related to smoke-free air.[19,20]

- **Aim 1.** Conduct a matched-pair community randomized controlled trial in 28 municipalities in GE and AM to examine the impact of local coalitions promoting the adoption of smoke-free policies in worksites and restaurants. The primary outcome will be reductions in SHSe (per population-level surveys) over time.
- **Aim 2.** Assess how community context and coalition factors influence adoption and implementation of organizational and municipal smoke-free policies to provide an evidence-base for public health practice.
- **Aim 3.** Disseminate research findings regarding both the effectiveness and the process of establishing and maintaining coalitions, and consequently increasing smoke-free policies and reducing SHSe, to key stakeholders in GE and AM in order to inform future tobacco control research and practice efforts.

- **Aim 4.** Capitalize on proposed research and dissemination opportunities to build tobacco control research capacity within the GE NCDC, AM NIH, TSMU, and AUA, as well as practice capacity within local public health centers and their civil society partners.

C. DESIGN

Funder

The project is pending funding by the National Institutes of Health Fogarty International Center.

Participants, setting, recruitment, and procedures

We propose to conduct a matched-pairs community randomized controlled trial (CRCT) to examine the impact of coalitions promoting smoke-free air policies on individual SHSe. In doing so, we will be able to test the CCAT[21] and examine the characteristics and processes of community coalitions that effect change. The Emory team will lead the oversight of the research design and execution of all components of the research. The GE NCDC and AM NIH will oversee the administration of coalition grants to 7 randomly-selected municipalities in each country (total of 14), execute population-level surveys in each of the 14 communities per country (total of 28), and facilitate coalition trainings, in partnership with Emory. TSMU/AUA will execute the evaluation of the coalitions by conducting baseline and follow-up assessments, in collaboration with Emory. Dr. Carla Berg, who has changed job positions since the start of the study and now is at George Washington University, will also be collaborating with Emory in this research study as an external investigator. However, George Washington University will not be recruiting any participants of their own or for their own research. The main study site will continue to be Emory University. Dr. Berg will be serving as the data collection coordinator at GWU, performing tasks such as programming web-based surveys. These activities will lead to the dissemination of significant research findings regarding the impact of coalitions on tobacco control and individual SHSe in LMICs and evidence-based practices for coalition activity. In conducting and disseminating the research, there will be significant research capacity-building within these organizations, as well as practice capacity-building within the local communities.

In brief, throughout the study period, two in-person meetings will be held among the research team each year. In Years 1, 2, and 4, these teams will be held in GE and AM, respectively. One meeting per year will coincide with training/annual meetings of coalition members. In Years 3 and 5, one meeting will coincide with the annual coalition member meeting and one will coincide with an international conference to present baseline and final results, respectively. In addition, after the selection of emerging researchers to hire as research personnel and assignment to co-mentors in the pursuit of research capacity building, the mentees will meet with the mentors semi-annually and deliver annual reports documenting their progress. In terms of research, **Year 1** involves baseline population-level survey data collection in all municipalities, training of coalition leaders (i.e., the local public health center directors) in the municipalities randomly selected for the intervention condition, recruitment of coalition members, and the beginning of the coalition member surveys in intervention municipalities. **Year 2** involves the completion of baseline coalition member survey data collection, additional training of coalition members, completion of the situational assessment, establishment of coalitions and coalition action plans, launching action plans, data entry and analysis, and baseline report development. **Year 3** involves full execution of coalition action plans in intervention communities and additional baseline data analysis. **Year 4** involves final execution of coalition action plans and the beginning of the follow-up data collections (i.e., coalition member assessments in intervention communities, population-level surveys in all communities). **Year 5** involves completion of follow-up data collections, data entry and analysis, final report development, and dissemination efforts via academic publications and presentations at academic conferences, fact sheets for policymakers, white papers, and the regional conference to disseminate the research findings.

Local public health centers will play a key role in the execution of the proposed intervention – coalition action. To provide context for these centers, one of the main priorities of reorienting the health system for GE and AM as independent countries was recognition of the need for prevention. The ***public health system in GE*** was

established in 1994 to improve and strengthen the processes for managing communicable and non-communicable diseases, reorienting the system on preventive services. The Department for Regional Public Health Management within the NCDC, directed by ***Dr. Urushadze (co-I),*** oversees the 68 local public health centers, which are municipal public units. These centers manage programs regarding communicable disease prevention, chronic disease management, and healthy living, as well as measures and activities to meet the health needs of the population living in particular areas. ***Public health services in AM*** evolved from the 1992 Law on Sanitary-Epidemic Safety. In 2002, the country's sanitary and epidemiological services were reorganized as the State Hygiene and Anti-epidemic Inspection under the Ministry of Health. It consists of a headquarters office and seven operations offices in Yerevan as well as 10 regional offices and several additional local public health centers and other facilities within the local municipalities. In the proposed study, directors of these local public health centers will serve as or identify key leaders to engage in the coalition trainings and lead coalition activities.

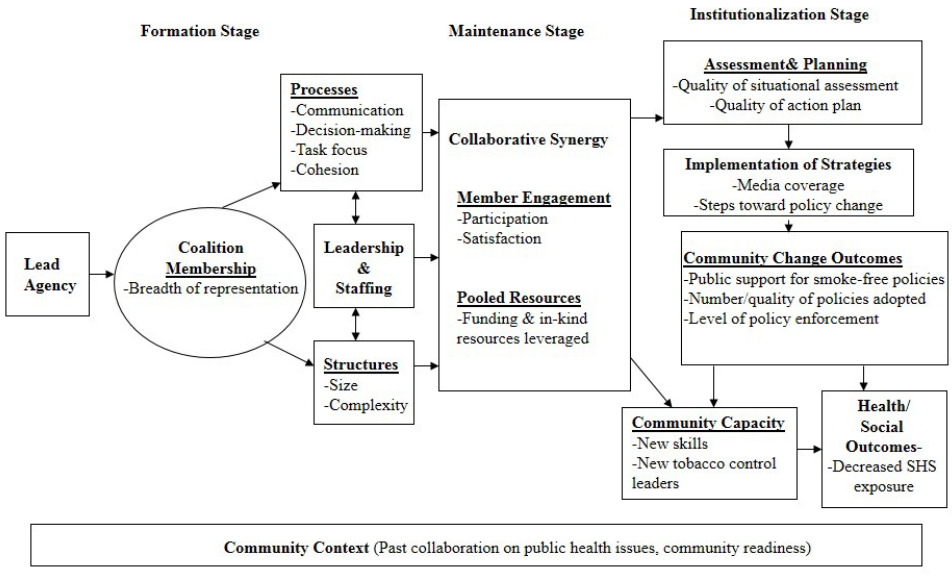
Our study will define a "community" as a distinct municipality, given the division of communities based on the coverage area of the local public health centers. We will include communities with small to medium populations and local public health centers with sufficient capacity to engage in the proposed research. Our partners in GE and AM have identified 14 municipalities within each country fitting these criteria, with populations ranging from ~6,000 to 90,000. An example of GE municipalities and their populations, distances from Tbilisi, and budgets are listed in ***Appendix A***. After confirming interest with local health center directors, we will form matched pairs in each country based on population size, region, and local economy and then randomly select one from each pair as an intervention community and the other as a control. We will use block randomization by country. Randomization will occur after completion of the baseline population-level survey.

Condition Description. In brief, all 28 communities (14/country) will participate in the population-level tobacco survey at baseline and follow-up. Within each country, 7 communities will be randomized to the intervention condition and 7 to the control condition (i.e., 14 communities/condition).

Control Condition. The 14 communities assigned as controls will participate in the population-level survey and be provided with a site-specific summary of findings but will not participate in any aspects of the intervention. Additionally, to examine potential contamination in the control communities, a follow-up interview will be conducted with public health center leaders to assess any local coalition or grassroots actions regarding tobacco control that may have naturally occurred or be influenced by coalition activity in other communities.

Intervention Condition: Coalition Training, Development, and Action. Our intervention will test whether creation of local coalitions for tobacco control is feasible in countries without a grassroots community-building tradition such as former Soviet Union countries, and if established, whether local coalitions can shift social norms regarding SHSe and promote adoption of smoke-free policies in public settings, specifically worksites and restaurants. Our intervention approach will be informed by the CCAT developed by Butterfoss and Kegler.[21] CCAT posits that coalitions form due to a threat, opportunity, or mandate. In the current project, local public health centers will be the lead agency and play the role of convener of the coalition based on an opportunity (e.g., funding and participation in a major research project). In the

Figure 1. Conceptual Model for Creating and Enforcing Smoke-Free Policies at the Community Level in Georgia and Armenia



intervention communities, public health center staff will form a coalition by recruiting partner organizations from civil society and other government sectors (e.g., health care, education), conduct situational assessment, and develop and implement action plans to promote the adoption and enforcement of smoke-free policies in worksites and restaurants, settings selected based on general support for smoke-free policies in these settings[19,20] and the likelihood of impacting population-level SHSe through widespread reach. The GE NCDC and AM NIH will establish subcontracts with the local public health centers in the randomly selected communities to provide funding for local staff to develop local coalitions and to support program activities ($2,500 in Yrs 1 and 4, $5,000 in Yr 2, $7,500 in Yr 3, total=$17,500/municipality).

Coalition Membership. Per CCAT,[21] a lead agency or convening group, in our project the local public health center, recruits additional coalition members to ensure diverse community representation. We will ask for a minimum of eight members and encourage representation from education, public health, health care, social services, civil society (i.e., non-governmental organizations, community groups, women's organizations, faith-based organizations, professional associations, trade unions, self-help groups, business associations, registered charities, advocacy groups), interested residents affected by cancer and tobacco use, and to the extent possible, media, housing, and business. Coalition leadership and staff will develop operating procedures and structures to facilitate member engagement in the work of the coalition and to ensure that benefits of participation outweigh the costs. We will provide model coalition operating procedures based on our prior work.

Coalition Maturation and Maintenance. According to CCAT,[21] engaged coalition members pool their diverse individual and organizational resources (e.g., connections/access, knowledge of community history, tangible resources such as space/equipment, diverse perspectives, creative talents), which creates the collaborative synergy that results in comprehensive and appropriately tailored action plans and intervention strategies. In the current project, the situational assessment will be combined with coalition member perspectives to develop an appropriate action plan for each community that capitalizes on local strengths and acknowledges local politics and history. Implementation of well-designed intervention strategies, informed by best practices for policy change and enforcement, should result in improved policies, programs, and practices, broadly labeled as community changes by CCAT. These community changes, in turn, lead to health and social outcomes of interest – in this case, reductions in SHSe. Per CCAT, community changes, in combination with collaborative synergy, also lead to increases in community capacity to identify and successfully address other issues of concern to community members. We expect the formation of community coalitions and the planning and implementation process will develop new skills for tobacco control and allow for the emergence of new tobacco control leaders that increase tobacco control capacity at the local level. Changes in policies, practices, programs, and environments; changes in capacity; and changes in health and social outcomes are sustained in the institutionalization stage. Additional CCAT propositions state that coalitions develop in stages and can cycle through these stages as new issues emerge or member composition changes and that community context influences all aspects of coalition behavior. ***Figure 1*** above illustrates how CCAT and its constructs will be operationalized for the current project.

Public health center staff and coalition leaders will attend trainings on skill building in Years 1 and 2 and annual meetings in Years 3-5 in order for the practitioners, coalition members, and research team to collaboratively guide the project. ***Table 1*** below outlines activities by year.

Year 1 Training: Situational Assessment. In Year 1, Drs. Kegler and Berg will provide a protocol and materials to give an overview of the initiative and conduct training to build skills for how to conduct the situational assessment. The delivery of the training will be done by the Georgian NCDC and Armenian NIH staff in the respective countries to ensure translation to Georgian and Armenian as appropriate. Dr. Kegler conducted a similar training on situational assessment for the China Tobacco Free Cities project.[65] See ***Appendix B*** for the presentation and tools (e.g., interview guide) that will be adapted for this training.

Year 2 Training: Coalition Building, Action Planning, and Strategy Selection. In Year 2, Drs. Kegler and Berg will provide protocols and materials to conduct training regarding coalition building, action planning, and selecting intervention strategies. Each public health center will be asked to recruit at least eight coalition members and hold monthly meetings to lead the coalition through an action planning and implementation process. Situational assessment will inform which worksite and restaurant settings to target, as well as additional strategic settings. Action plans will include SMART (specific, measurable, achievable, realistic, and time-based) annual objectives, tasks, timelines, and persons responsible for completing each task. The training will include templates

and examples of action plans (***Appendix B***). We will provide examples of best practices in the US and elsewhere for creating policy change in each type of setting. Dr. Kegler has taught community assessment, program planning, and evaluation to MPH students for 20 years, and was integrally involved in training CDC practitioners in China to conduct similar work.[65] The Emory Prevention Research Center, led by Dr. Kegler, also has such trainings for practitioners, which can be adapted for this project.

In addition to engaging partners, steps for policy change include documenting local problems (e.g., observations, key informant interviews), formulating policies (e.g., developing/sharing model policies for different sectors), building awareness (e.g., creating promotional materials, holding awareness and earned media events, developing press releases to media, using social media), and persuading decision-makers (e.g., meeting with decision-makers, encouraging/supporting surveys to assess support for policy change, finding/sharing personal stories, making health/cost savings arguments).[95,96] We will remain sensitive to the four step policy-making process:[95] 1) *formulation* refers to identifying potential solutions or approaches (e.g., drafting policies/action plans); 2) *enactment* includes identifying a champion or sponsor and formally approving the policy or action; 3) *implementation* involves developing a plan for implementation, communicating the policy or action, training relevant staff or volunteers, and actually conducting the required activities and tasks; and 4) *maintenance* refers to ensuring sustained implementation and enforcement of the changes.

Table 1. Coalition Activities by Year

Year	Coalitions Activities
1	1. Attend situational assessment training 2. Begin situational assessment: -summarize population data -review tobacco-related data (new, existing) -conduct ≥10 key informant interviews
2	1. Complete situational assessment 2. Form a multi-sectoral community coalition 3. Develop, begin to implement action plan to promote policies in worksites, restaurants
3	1. Continue to implement action plan
4	1. Continue to implement action plan 2. Plan for sustainability

Annual Coalition Meetings. In Years 3 to 5, the coalition members will attend annual meetings with the research team in order for local coalition leaders and members to problem-solve challenges and share success stories. Training topics will be determined based on needs identified by grantees (e.g., use of media in tobacco control, other topics relevant to the policy change process). In Year 5, the coalitions will be offered the opportunity to present their research findings within the larger regional meeting open to a broader constituency.

Technical Assistance (TA) Process. TA will be provided by the GE NCDC, AM NIH, and Emory research teams and will consist of monthly check-in e-mails or calls to ensure accountability and assist with challenges that arise. Standardized procedures for documenting coalition meetings and activities will be implemented.

Data Collections: One data collections will address Aim 1, and two data collections will address Aim 2.
Assessment 1: Population-level Survey (addressing Aim 1). The GE NCDC and AM NIH will conduct cross-sectional population-level surveys in Year 1 (baseline) and in Years 4/5 (follow-up) in the intervention and control communities. A multi-stage, clustered sample design will be used to select 50 participants within each municipality. Eligible participants will be adults aged 18-65. The most recent census data for each country and the respective municipalities will be used to establish the sampling frame. The "random walk" method will be used for selecting the households within each municipality. For households with more than two eligible adults, the "Kish method" used in the WHO's STEPS surveys will be applied.[104] In the KISH method, all eligible participants from the household are first ranked according to age in decreasing orders (males followed by females). Then, participants are selected using the KISH table identifying the last digit of household and number of eligible participants.[104] Using this approach, our prior research resulted in an 89.9% response rate.[20]
Assessments 2 & 3: Coalition Assessment (addressing Aim 2): Mixed methods will be used to measure constructs in our conceptual model related to Aim 2. Coalition assessments conducted by TSMU/AUA will include: 1) coalition member surveys; and 2) semi-structured interviews with coalitions leaders and staff. More detail on specific roles are outlined in the sections below.

We plan to enroll a total of 4,000 participants for all of our assessments over the various data collection periods.

D. MEASURES

Assessment 1: Population-level Survey. Data will be collected in person by NCDC/NIH staff using hard copy and/or technology-assisted procedures. The survey will assess the following primary and secondary outcomes and covariates.

Primary Outcome. Measures of individual-level of ***changes in SHS exposure*** will be adapted from the Global Adult Tobacco Survey (GATS)[105] and CDC's National Adult Tobacco Survey (NATS).[106] The GATS assesses SHSe by first asking about locations they came into contact with in the past 30 days (e.g., workplace, government buildings/offices). Follow-up questions for those who had been in contact with each location then assess SHSe in each location (e.g., "Did anyone smoke inside of any government buildings or government offices that you visited in the past 30 days?") The GATS assesses SHSe in the home by asking, "How often does *anyone* smoke inside your home? Would you say daily, weekly, monthly, less than monthly, or never?" While we will administer these measures in order to facilitate cross-country comparisons, we will also create a SHSe index by assessing *frequency* of SHSe in the past week, adapting items from CDC's NATS, which assess number of days in the past 7 days one was exposed to SHS in the home, in vehicles, at work, in indoor public places, and in outdoor public places.[106] As the impact of coalition activities on SHSe may be modest, a continuous measure assessing a larger outcome range provides greater sensitivity for detecting changes.

Secondary Outcomes. ***Changes in attitudes regarding SHSe*** will be assessed by adapting the GATS item, "Based on what you know or believe, does breathing other people's smoke cause serious illness in non-smokers?"[105] to assess the *degree* to which they believe smoke causes illnesses. ***Changes in attitudes regarding smoke-free environments*** will be assessed by asking, "For each of the following places, indicate how you feel about a policy prohibiting smoking in that kind of place (e.g., workplaces, indoor areas on school grounds, outdoor events, restaurants, bars; responses are strongly oppose to strongly favor).[105] An index score will be created from these responses.[20] ***Changes in home policies*** will be assessed by asking, "Which of the following best describes the rules about smoking inside of your home: Smoking is allowed inside of your home, smoking is generally not allowed inside of your home but there are exceptions, smoking is never allowed inside of your home, or there are no rules about smoking in your home?"[105] Because individual workplaces may be affected by coalition activity, we will assess ***changes in workplace policies*** by asking, **"**Which of the following best describes the indoor smoking policy where you work: Smoking is allowed anywhere, smoking is allowed only in some indoor areas, smoking is not allowed in any indoor areas, or there is no policy?"[105] We will also measure ***changes in enforcement of smoke-free policies in various settings*** by asking, "In the past 7 days, how many times have you seen someone using tobacco in a location where it is prohibited?"

Covariates. *Sociodemographic characteristics* (e.g., age, sex, household income, marital status) will be assessed. (Sex as a biological variable: Roughly equal numbers of males and females will be recruited to the study, particularly important given the sex differences in tobacco use rates, SHSe, and receptivity to policy change.[20]) *Tobacco use and cessation-related factors* will be assessed using standardized GATS measures.[105]

Assessment 2: Coalition Member Survey. The coalition member survey will be conducted in Years 1/2 and Years 4/5 by our research partners (AUA, NCDC). Each local coordinator will provide research staff from AUA and NCDC with coalition member contact information (email, phone, addresses). The research staff will send each coalition member a link to an online survey programmed by the GWU team. Programming of the survey does not require access to personal identifiers such as e-mail addresses. Two back-up methods will be used to increase response rate for those coalition members who may not have reliable access to the internet: 1) A pdf of the survey will be emailed or mailed to the coalition member to complete and return to research staff and 2) research staff will schedule a phone call with the coalition members to complete the survey. We will send up to ten reminders to coalition members to complete the survey. See ***Appendix C*** for a sample coalition member survey.

Coalition Membership. ***Representation*** will be assessed by the number of community sectors represented on the coalition (of 15 sectors). This number will be summed to form a coalition-level measure.[27]

Coalition Processes. ***Communication*** is defined as the frequency and productivity of communication among members and staff, per a 5-point semantic differential scale.[11] Four-point Likert scales will assess ***decision-making*** (the extent to which members have influence on decisions such as setting goals and objectives for the

initiative);[11,27] ***task focus*** (e.g., this is a down to earth, practical coalition);[11,27,97] and ***cohesion*** (e.g., group spirit among members).[27,97]

Leadership and Staffing. ***Leadership*** will be measured by an 8-item scale assessing skills of the coalition leaders in guiding the coalition (e.g., asks you to assist with specific tasks).[27] ***Staffing*** skill in supporting the coalition (e.g., usually available for assistance) will be assessed using an 8-item scale.[27]

Coalition Structure. ***Coalition size*** will be operationalized as the number of active coalition members. Coordinators will provide rosters of members who had attended at least one meeting in the past six months.[27] Coalition ***complexity*** is the number of committees per coalition (1=no committees to 3=≥3 committees).[27]

Indicators of Member Engagement. ***Participation*** will be assessed by asking which of 7 roles they had played on the coalition (e.g., helped to assess needs and/or assets of the community).[27] We will ask about 10 roles in the implementation phase. The number of roles will be averaged for each respondent. ***Satisfaction*** will be assessed by asking how satisfied members were with 7 aspects of the planning phase (e.g., programs and/or activities selected) and 11 aspects in the implementation phase, using a 4-point Likert scale.[27]

Assessment 3: Key Informant Interviews will be conducted by phone or in person with health center staff serving as coordinators, health center directors, and at least one active coalition member not employed by the health center. These interviews will take 30-45 mins, and be audio-recorded, transcribed, and analyzed. We will adapt interview guides from our prior coalition evaluations and assess progress toward policy change, barriers and facilitators to policy change with a focus on community context, new or strengthened partnerships, resources mobilized, and opportunities for new tobacco control leaders to emerge.[29,98-101]

E. RISK OF PARTICIPATION

Study participants may experience risks related to loss of privacy or breach of confidentiality related to responses to surveys or interviews. We have put in placed several safeguards to minimize this possibility.

F. BENEFITS TO SUBJECTS OR FUTURE BENEFITS

There are no specific benefits anticipated to individual participants. However, the study has the potential to benefit population health in general since the findings can inform health services for immigrant populations.

G. INCENTIVE

No incentives will be offered for participation.

H. DATA ANALYSIS

For Aim 1: Population-level Survey

Power Calculation. We powered the CRCT on the ***primary outcome of SHSe*** per the population-level survey. We determined power using closed equations to calculate the minimum number of clusters for a CRCT for a specific effect size and intra-class correlation (ICC) and used Moerbeek and Teerenstra's formulas for CRCTs with fixed cluster sizes.[107] We assumed a conservatively high ICC of 10% (especially for a matched-pair design), 50 participants per cluster, and small to medium effect size (d=.35).[108] Calculations indicated that 28 communities provided adequate power. If the ICC is lower, we are powered to detect smaller effects (.27 or .24 if the ICC's are 5% or 3%, respectively).[109] Our sample size is larger than one in a comparable study.[110]

Analyses. First, we will assess key variables for normality of distributions. For both baseline and follow-up samples, we will use PROC GLIMMIX to compare sociodemographics in intervention and control conditions as well as the two countries. We will use multilevel modeling to assess intervention impact. Multilevel modeling allows to model both individual- and community-level variances, predictors, and cross-level interactions simultaneously.[111-113] This allows for unbiased estimates of effects. For the primary outcome of SHSe, we will assess intervention impact using a two-level model adjusting for individual- and cluster-level covariates while

accounting for unmeasured differences between clusters. Models will be built sequentially, adding first individual- and then community-level covariates including country and baseline means, and finally intervention assignment.[114] Random effects for the intercept and intervention impact will be modeled in all models. This allows for differences in the outcome across communities, both due to the intervention and due to other unmeasured factors. For secondary outcomes, multilevel models with the appropriate link function (i.e., linear for continuous outcomes, Poisson for count outcomes, binary for dichotomous outcomes) will be built similarly to those for the main outcome. Additional analyses will model cross-level interaction effects (i.e., community-level moderators of the intervention effect). Dr. Berg, from George Washington University, will lead many of the analyses.

For Aim 2: Coalition Assessment

Both qualitative and quantitative analysis will be used. Qualitative analysis will involve a multiple case study of six coalitions (a high, medium, and low performer in each country with performance defined by number of policies passed). After reviewing a subset of the interview transcripts (translated to English), the evaluation teams from the two countries, plus the George Washington University research team, will meet to discuss their general findings and to develop a codebook, using the conceptual model as sensitizing constructs. Once the team is coding consistently (examining transcripts from across countries), one team member in each country will code independently. Any discrepancies in the coding will be discussed and resolved. We will use standard content analysis methods to identify themes, as well as site-ordered matrices based on level of implementation to identify patterns of factors influencing implementation. Community name and participant roles will be identifiable during the analysis phase. While individual study participant names will not be included, it may be possible to identify respondents and/or partners based on information available in the qualitative transcripts. Dr. Kegler has led several multiple case studies.[29,98,115]

Power Calculation. We will use coalition member survey data to assess the extent to which CCAT propositions are supported by our data. Many CCAT constructs are conceptualized at the coalition level, which implies a sample size of 14 for these analyses. At the organizational-level, 14 communities will give us sufficient power to detect large effects, specifically $d \geq 0.80$ in paired t-tests and $rho \geq 0.55$ in correlations ($\alpha = .10$).

Analyses. We will conduct all analyses for Aim 2 at the community-level (i.e., coalition-level average scores will be created for all models). This analysis strategy is preferable over individual analyses that account for clustering because we aim to understand the coalition impact, compared to individual impact, on policy.[30,33] We will report univariate properties first and then assess relationship strengths using t-tests and correlations. Due to the small sample size (N=14), we will set alpha at .10 as others have done in coalition research.[30,33,116] We will use chi-square tests, t-tests, and Spearman correlations to assess bivariate relationships. Based on these analyses, we will conduct multivariable regression analyses to identify which contextual (e.g., country) and coalition factors from our conceptual model predict intermediate outcomes, such as member participation and satisfaction, action plan quality, and number of smoke-free policies passed, with a small set of predictors.

I. TRAINING

Emory research staff training for the study will review basic principles and focus on procedures specific to the protocol. Similar trainings will occur at the GE NCDC, the AM NIH, and AUA for all study staff. Training will cover: (1) sampling strategy and recruitment, (2) eligibility confirmation for potential participants, (3) survey and interview data collection, (4) adverse event handling and reporting, (5) data safety and monitoring, (6) protocol adherence. We will establish security procedures (outlined below in Confidentiality). All study staff members will obtain CITI training certificates.

J. PLANS FOR DATA MANAGEMENT AND MONITORING

Given the nature of the research, requiring minimal invasive assessments and no interventions, we have determined that there is no need for a data safety and monitoring board.

K. CONFIDENTIALITY

With regard to minimizing risk of loss of confidentiality or privacy, confidentiality will be protected at all times and potential risks minimized systematically.

Study participants will be assigned a permanent unique study ID number upon enrollment, which will be the only identifier associated with any of the survey data and addresses. A key linking personal identifying information (name, other household members who are taking the survey, and address) with study ID number will be kept in a separate encrypted data file stored secured research shared drives (i.e. not on personal computers that are vulnerable to theft) in the study's data coordinating centers in either the GE NCDC or the AM NIH and then transferred to the study's data coordinating center at Emory University Rollins School of Public Health. Files will be accessed only on an as needed basis for the conduct of the study. Physical security of the data center's servers and files is maintained with double-locked keyed doors during all hours. Only authorized persons are allowed access. Identifying information will be kept in a secured folder in encrypted version for the duration of the study data management purposes. Once all phases of the study have been conducted, the identifiers will no longer be needed and will be deleted from the data sets.

L. INFORMED CONSENT

Regional and local public health and community-based organization leaders will complete a capacity assessment. This capacity assessment survey will be used to ensure comparability across intervention and comparison communities. This will be completed prior to conducting consent for other aspects of the study. Statements of consent for each of the data collections are included in this application.

We are asking for waiver of documentation of consent for the coalition member survey. The primary mode of data collection for this survey will be via an online platform such as SurveyMonkey or SurveyGizmo. However, to ensure a high response rate, the two backup methods of data collection for those with unreliable internet access are mailing a PDF of the survey and conducting the survey via a phone call, both of which would make obtaining documentation of consent burdensome for the participants. Since the survey does not entail more than minimal risk, we believe a waiver of documentation of consent is appropriate.

M. PLANS TO INFORM PARTICIPANTS OF NEW FINDINGS

We will disseminate the research findings through presentations, publications, and other printed materials. Given the nature of the study, no immediate health consequences are anticipated. However, any concerns will be discussed in a timely matter, and problems or unanticipated implications will be addressed immediately.

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