### **Examples of Funded Grants in Implementation Science**

#### Overview

The National Cancer Institute (NCI) frequently receives requests for examples of funded grant applications. Several investigators and their organizations agreed to let Implementation Science (IS) post excerpts of their dissemination and implementation (D&I) grant applications online.

#### **About**

We are grateful to the investigators and their institutions for allowing us to provide this important resource to the community. To maintain confidentiality, we have redacted some information from these documents (e.g., budgets, social security numbers, home addresses, introduction to revised application), where applicable. In addition, we only include a copy of SF 424 R&R Face Page, Project Summary/Abstract (Description), Project Narrative, Specific Aims, and Research Strategy; we do not include other SF 424 (R&R) forms or requisite information found in the full grant application (e.g., performance sites, key personnel, biographical sketches).

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# 424 R&R and PHS-398 Specific

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### SF 424 R&R Face Page

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**Grant Number:** 1 R01 CA203844-01A1

Title: Establishing The Program Sustainability Action Planning Training Model

**FOA:** PAR13-055

FOA Title: DISSEMINATION AND IMPLEMENTATION RESEARCH IN HEALTH (R01)

Organization: WASHINGTON UNIVERSITY

Senior/Key Personnel: Sarah Moreland-Russell

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#### Abstract

The goal of this proposed study is to increase the capacity for sustainability among evidence-based tobacco control (TC) programs. To do this, our study will empirically develop and test the Program Sustainability Action Planning Model and Training Curricula to improve sustainability and institutionalization of these evidence-based programs. This will be accomplished in three aims. First, we will develop our Program Sustainability Action Planning Model and Training Curricula incorporating action planning and experiential learning methods. The Program Sustainability Action Planning Training Curricula will include action planning workshops, development of action plans with measurable objectives to foster institutional changes, and technical assistance. We will deliver this in person training in the form of two day workshops to 12 state TC programs. Aim 2 uses a quasiexperimental effectiveness trial based on the theory of change to assess the Program Sustainability Action Planning Training Curricula in 24 states (12 intervention, 12 comparison). We will collect programmatic and organizational factors that have been established as predictors of sustainability using state level programmatic record abstraction and the Program Sustainability Assessment Tool (PSAT) to assess level of institutionalization at three time points. Data will be used to assess differences in intervention versus comparison states. Finally, our third aim involves widespread dissemination of the Program Sustainability Action Planning Model and Training Curricula. Specifically, we will refine our training and develop electronic and hard copy versions of the curricula and disseminate the materials to State TC programs, programs within OSH and other Divisions at CDC. public health organizations and practitioners, and academic audiences. We will also provide access to refined and tested training materials to the public through our sustaintool.org website. This project is important in establishing the first evidence-based Program Sustainability Action Planning Model and Training designed to help public health programs reach maturity and sustain activities over time. Such long term programmatic sustainment is imperative in order to achieve the full benefit of significant investment in public health research and program development which includes improving long-term health outcomes.

### **Project Narrative**

Evidence-based public health programs can only deliver benefits if they reach maturity and sustain activities over time. In order to achieve the full benefit of significant investment in public health research and program development, we need to understand the factors related to sustainability and develop tools and trainings that support long-term program sustainability. This project aims to develop the Program Sustainability Action Planning Model and Training Curricula and assess the effectiveness of this training in increasing state level tobacco control program capacity for sustainability. Given the established evidence for the state Tobacco Control model, it is vital that these programs continue in all 50 states, both to improve quality of life and reduce the massive healthcare costs incurred by tobacco-related illness.

### **Specific Aims**

The emergence of dissemination and implementation (D&I) science has driven a rapid increase in studies of how new scientific discoveries are translated and developed into evidence-based programs and policies. However, D&I science has paid much less attention to what happens to programs once they have been implemented. Public health programs can only deliver benefits if they reach maturity and sustain activities over time. In order to achieve the full benefit of significant investment in public health research and program development, we need to understand the factors related to sustainability and develop tools and trainings that support strategic long-term program sustainability.

The goal of this proposed study is to increase the capacity for sustainability among evidence-based tobacco control (TC) programs. Although all 50 states have implemented evidence-based TC programs and policies, states vary in their abilities to support and sustain these programs over time. Most states still do not meet the CDC recommended level for funding their TC program allowing for tobacco use to remain the leading cause of preventable disease and death in the US.¹ Also, as part of the 2015 National State-Based Tobacco Control Program Funding Announcement released by the CDC,² all awarded state applicants are "required to develop a sustainability plan" and "provide measures of execution of all activities as outlined in the sustainability plan". There are currently no available resources specifically designed to help states meet this requirement making this project imperative for states to effectively meet this important funding requisite.

This project will deliver training workshops and subsequent dissemination activities in three phases. In Phase 1, we will refine and finalize our evidence-based Program Sustainability Action Planning Model and Training Curricula and deliver to 12 states. The Program Sustainability Action Planning Training will incorporate experiential learning methods<sup>3-6</sup> and includes: action planning workshops, development of action plans with measurable objectives to foster institutional changes, and technical assistance. Phase 2 uses a quasi-experimental effectiveness trial to assess the Program Sustainability Action Planning Training in 24 states (12 intervention, 12 comparison). Evaluation of our training program is centered on the theory of change.<sup>7,8</sup> In Phase 3 we will respond to study results by making any needed revisions and conduct widespread dissemination of our Program Sustainability Action Planning Model and Training Curricula starting with the 12 comparison states.

The proposal builds upon our extensive work in program sustainability in which we have developed the Program Sustainability Framework and Program Sustainability Assessment Tool (PSAT). We have created an action planning curricula which has been developed for a broad audience of public health practitioners and used by 53 programs, yet has not been tied empirically to sustainability outcomes.<sup>9,10</sup> In this proposal, we enhance these existing efforts with a specific focus on refining the training curricula and measuring the effectiveness of the training to increase state TC program capacity for sustainability and institutionalization. Our project aims include:

- 1. Develop the Program Sustainability Action Planning Model and Training Curricula and deliver to 12 state TC programs. To accomplish this aim, we will:
- Refine the current program sustainability action planning training program based on action-oriented training model and incorporating methods of experiential learning.<sup>3-6</sup>
- Recruit TC programs in 24 states, and randomly select 12 programs to receive the Program Sustainability Action Planning Training intervention.
- Conduct a series of two-day in person Program Sustainability Action Planning Training workshops in each intervention state (n=12).
- 2. Demonstrate change in sustainability outcomes in states who received the Program Sustainability Action Planning Training compared to states that did not. To accomplish this aim we will:
- Track validated programmatic and organizational measures associated with sustainability and institutionalization<sup>9-11</sup> across 24 (12 intervention, 12 comparison) state programs using record abstraction at three time points and compare measures in the intervention versus comparison states over time.
- Assess capacity for sustainability across 24 (12 intervention, 12 comparison) state TC programs using PSAT scores at three time points and compare scores in the intervention versus comparison states over time.
- **3.** Actively disseminate The Program Sustainability Action Planning Model and Training Curricula materials. To accomplish this aim, we will
- Refine training and develop electronic and hard copy versions of the curricula and disseminate to: (1) State

TC programs, (2) programs within OSH and other Divisions at CDC, public health organizations and practitioners, and (3) academic audiences.

### Significance

- A.1. Sustainability as an important next step in dissemination and implementation (D&I) research. Demonstrating that an intervention is effectively implemented, (the initial process of embedding interventions within settings<sup>12</sup>), is only the first step in impacting the health and wellness of a target population. In order for the population to reap the benefits of an implemented evidence-based intervention, it must be sustained over time. In recognition of this, several recent D&I papers have called explicitly for sustainability research as an essential next step in the field. <sup>10,11,13-21</sup> Program sustainability-the extent that interventions can continue to be delivered over time and institutionalized within settings<sup>12</sup> -is a complex process, often fraught with challenges. <sup>16,21-23</sup> Research consistently indicates that even effectively implemented interventions risk failure when funding ends<sup>10,20,24</sup> or when planning and training stops. <sup>25</sup> In fact, it is estimated that up to 40% of programs fail within two years of losing funding. <sup>26</sup> Implementing a program and then failing to sustain it can have disastrous consequences for the community though loss of trust and waste of valuable community resources. <sup>27</sup> Though there is growing interest in the study of program sustainability, there is little agreement on how to best sustain initiatives over time. <sup>23,28</sup> This is due, in large part, to the historical lack of sustainability assessment tools that are both reliable and widely disseminated disseminated and essential absence of an evidence-based action planning process for sustainability.
- **A.2.** Importance of sustaining evidence-based TC for public health.

As of 2013, 42.1 million- or 1 in 5- adults in the US smoke, which leads to an estimated 480,000 preventable deaths per year due to tobacco use. Approximately 61,000 of those deaths occur from secondhand smoke exposure. According to the Center for Disease Control and Promotion (CDC), if smoking continues at its current rate, more than 5 million of today's youth will die prematurely, and the economic cost of smoking will rise to more than \$300 billion per year.<sup>30</sup>

Tobacco use has long been identified as a major preventable cause of death and disease in the US. There is also little debate that TC expenditure directly impacts tobacco use rates in the US. Between 1985 and 2003, US adult smoking prevalence declined from 29.5% to 18.6%. This sharp decline directly correlated with state TC program funding rates. Farrelly et al. estimates, "If, starting in 1995, all states had funded their TC programs at the minimum or optimal levels recommended by the CDC, there would have been 2.2 million to 7.1 million fewer smokers by 2003." Given the established evidence for the state TC model and the work left to do in this field, it is vital that these programs continue in all 50 states, both to improve quality of life and reduce the massive healthcare costs incurred by smoking-related illness. Failing to sustain evidence-based TC initiatives will likely lead to stagnation in smoking cessation rates and an increase in new smokers.

- **A.3.** The need for evidence-based sustainability training and technical assistance. Empirical evidence has established that program sustainability can be improved through training and technical assistance; 11,31-33 however, to date, no evidence-based program sustainability training curricula exists. Thus, systematic methods are needed to empirically develop, test, and disseminate sustainability training to improve institutionalization of evidence-based programs. While there is a growing body of research on the factors affecting sustainability 11,15,20-23,34 virtually no empirical work has been done to translate the components of program sustainability capacity into practical guides and tools for practitioner utilization. Our work with over 50 public health programs indicates that managers, evaluators, and practitioners need assistance in using sustainability assessment results to inform sustainability planning priorities, along with a clear process for completing a written sustainability plan that is easy to implement.
- **A.4. Importance of utilizing an action-oriented approach.** Literature indicates that the best practice for impacting long-term behavior and institutional change is a hands-on, action-oriented, in-person<sup>35-37</sup> training program. A study that involved action planning training with coalition groups working on substance abuse initiatives in Tennessee found positive changes in sustainability readiness (increased infrastructure capacity) post training,<sup>11</sup> and a meta-review of health behavior change outcomes found that intervention amount, duration, and penetration all impact level of behavior change.<sup>38,39</sup>

Research also highlights the importance of creating an action plan to move sustainability progress forward. Creating a sustainability plan has predicted both program survival and post-launch funding,<sup>40</sup> and obtaining

future funding facilitated the institutionalization process of a new intervention.<sup>41</sup> Additionally, plan specificity and attitude toward intervention predicted plan adherence,<sup>42</sup> and perceived self-efficacy, policy support, and level of institutionalization predicted sustainment of plan initiatives.<sup>25</sup>

#### **B. INNOVATION**

This study makes important contributions to D&I science and is innovative because it:

- 1. Develops the first ever evidence-based Program Sustainability Action Planning Model and Training Curricula. By establishing an evidence-based method for action planning and technical assistance surrounding program sustainability, we are supporting state TC programs and other evidence based public health initiatives to sustain their positive impact in a tumultuous funding climate. In addition, this work will advance the field of study of action planning and technical assistance in general which can contribute to aspects of the D&I field beyond sustainability.
- 2. Links closely with practice at an opportune time. As part of the DP15-1509, National State-Based TC Program Funding Announcement set forth by the CDC, all 2015 awarded applicants (includes all states and territories) are "required to develop a sustainability plan to ensure sustainability and maintaining a state based TC program" and "provide measures of execution of all activities as outlined in the sustainability plan." Our development of the Program Sustainability Action Planning Training and broad dissemination will assist states in fulfilling this requirement and establishing their capacity to continue sustainability planning over time.
- 3. Further advances D&I science related to establishing validated measures for sustainability. The study will also provide further clarity on the challenges, benchmarks, and programmatic factors that contribute to sustainability (versus implementation) of an intervention. We will also use the data collected to explore the predictive validity of the Program Sustainability Assessment Tool, which will enable programs to better plan for and improve the sustainability of effective programs.
- 4. Provides broad dissemination of training materials and results. The curriculum and lessons from the training program will be systematically disseminated (at no cost) to several key audiences (e.g., trainers in federal and state agencies, staff in public health agencies). Since our training program focuses on capacity for sustainability, our methods and approaches will be applicable to numerous other public health issues.

#### C. APPROACH

**C.1. Overview.** The objectives of this project are threefold: 1) refine our current sustainability training using action-oriented planning<sup>35-37</sup> and incorporating methods of experiential learning<sup>3-6</sup> to develop the Program Sustainability Action Planning Model and Training Curricula and deliver workshops to 12 state TC programs; 2) determine change in sustainability outcomes in states who received the training (n=12) compared to states that did not (n=12); and 3) actively disseminate results to facilitate establishment of the Program Sustainability Action Planning Model and Training Curricula.

In our experience and based on the literature, 11,31-33 program sustainability can be improved through training and technical assistance. Therefore, systematic methods are needed to empirically develop and test sustainability training to improve institutionalization of evidence-based programs. This will be accomplished in three phases. In Phase 1, (yr. 1, months 1-6) we will refine and finalize our Program Sustainability Action Planning Model and Training Curricula. As part of this refinement, we will incorporate experiential learning methods<sup>3-6</sup> and define learning objectives. The Program Sustainability Action Planning Training will include action planning workshops, development of action plans with measurable objectives to foster institutional changes, and technical assistance. We will also deliver our workshops in Phase 1 (yrs. 1 and 2, months 6-15) to 12 state TC programs. Phase 2 (yrs. 1, 2, and 3) uses a quasi-experimental effectiveness trial to assess the Program Sustainability Action Planning Training in 24 states (12 intervention, 12 comparison). Evaluation of our training program is based on the theory of change that allows for study on how a change (intervention) has influenced the design, implementation, and institutionalization of a program.<sup>7,8,11,28</sup> We will collect data on programmatic and organizational factors that have been established as predictors of sustainability<sup>9,11</sup> using state level programmatic record abstraction and the Program Sustainability Assessment Tool (PSAT)<sup>43</sup> to assess level of institutionalization across intervention and comparison states at three time points. Data will be used to establish the efficacy of the Program Sustainability Action Planning Model and Training Curricula. In Phase 3 (yr. 4, months 36-48), we will adapt our training based on results and disseminate Program Sustainability Action Planning Model and Training materials.

#### C.2. Project team

The proposed study will be directed by a multidisciplinary team of scientists and practitioners with expertise in: program sustainability assessment, tobacco control program and policy evaluation, planning and training, D&I science and methodology, and organizational evaluation methods. This strong, multi-disciplinary team is highly-qualified to conduct the proposed study, building on years of collaborative research among team members. In addition, we will form an advisory committee comprised of expert consultants and key partner organizations with practice based experience to 1) provide input on the training curricula; 2) assist in identifying and recruiting state TC programs; and 3) assist in dissemination of training materials and results (Table 1).

C.2.a. Research Team. Sarah Moreland-Russell, PhD, is an Assistant Professor at the Brown School at Washington University (WU) in St. Louis. Dr. Moreland-Russell has significant expertise in conducting sustainability assessment and training, 31,44,45 designing organizational outcome evaluations, 46,52 and 15+ years working with state and local public health practitioners. **Douglas Luke, PhD,** is Director of the Center for Public Health Systems Science (CPHSS) and led development of the sustainability framework and reliability testing of the PSAT.<sup>43</sup> He has decades of experience in tobacco control program and policy evaluation, and has made significant methodological contributions to the evaluation of chronic disease programs. 53-58 Ross Brownson, PhD is a leader in designing and disseminating training to build capacity for evidence-based practice adoption by public health practitioners.<sup>59-61</sup> Dr. Brownson has a strong background in chronic disease prevention and applied epidemiology<sup>62,63</sup> and brings extensive experience to the project in the design, implementation, and evaluation of interventions and D&I research. 64-68 **Todd Combs. PhD** brings expertise on biostatistical methods and analyses. He currently conducts analyses on a national level evaluation of TC policy progress in state TC programs. 51,69-73 Molly Hastings, MS currently manages the sustainability assessment project for CPHSS and has extensive experience in managing and delivering program sustainability assessment and training, and development and evaluation of organizational outcome evaluations. Laura Brossart has expertise in designing dissemination products. 50,74-78 Table 1 provides an overview of roles and responsibilities for all team members, including consultants and key partnerships.

C.2.b. Consultancies for this project: We will employ three consultants for this project: (1) Monica Eischen, (2) Maryann Scheirer, and (3) James Dearing. **Monica Eischen, BS**, brings 20+ years of experience working with state-level TC programs as the CDC Office on Smoking and Health (CDC-OSH) Program Services Branch Lead. **Maryann Scheirer, PhD**, has 30+ years of experience researching and training programs in program sustainability and is considered a leading expert in the field. 10,15,22,34 **James Dearing, PhD** has 30+ years of experience studying the use of diffusion of innovation concepts to accelerate the spread of evidence-based practices in translational science. 10

C.2.c. Key partnerships for this project – We will maintain our relationship with two key partners and seek their guidance as part of this project: (1) Tobacco Control Network (TCN), and (2) CDC-OSH, Program Services Branch. The TCN is a national public health association comprised of the TC stakeholders from each state, territory, and D.C.

Research team member	Primary responsibility
Sarah Moreland- Russell (PI)	Oversee all aspects of study; Provide expertise and conduct sustainability training and assessment
Douglas Luke Co-In∨estigator	Provide expertise in sustainability, tobacco control program evaluation, and finalizing methodology and dissemination of results
Ross Brownson Co-Investigator	Provide expertise in designing training, tobacco control program evaluation, determining metrics and D&I research
Todd Combs Co-Investigator	Design data collection protocol and complete analysis
Molly Hastings	Provide expertise and conduct sustainability training and assessment
Laura Brossart	Lead development of dissemination materials
Consultants	Primary responsibility
Monica Eischen	Advise programmatic assessment and provide insight into CDC TC program function
Maryann Scheirer	Advise sustainability assessment and planning and provide input on programmatic measures
James Dearing	Provide input on programmatic measures and inform dissemination strategies
Key Partner	Primary responsibility
TC Network	Help recruit states, facilitate across states, help to disseminate final results and training product
CDC-OSH	Provide state updates and help to disseminate results and final training product

This wide representation allows TCN to access wealth of expertise from across the country. The TCN has already formed a sustainability focus group and has assisted our previous efforts in conducting sustainability assessment and training in six state programs (see section C.3.b) (see Letter of Support from TCN). In addition, we will retain our 20+ year partnership with the CDC-OSH, Program Services Branch who is responsible for ensuring that states complete sustainability planning.

#### C.3. Selected projects of relevance to this application

C.3.a. Project 1- Development of Sustainability Framework & Program Sustainability Assessment Tool (PSAT) The Program Sustainability Framework was developed by Dr. Luke et al. using concept mapping, expert input, and extensive literature review. The final framework defines the internal and external factors operationalized into eight domains that affect an organization's capacity for sustainability including: organizational capacity, program evaluation, program adaptation, communications, strategic planning, funding stability, environmental support, and partnerships. The eight domains were translated into an assessment tool- The Program Sustainability Assessment Tool (PSAT)- which programs and organizations can use to evaluate their sustainability capacity. The PSAT (Appendix A) consists of 40 questions, five items in each of the eight domains, with 7-point Likert-scale responses. The PSAT was designed to allow comparisons between programs as well as within-program comparisons over time. The PSAT has an established reliability for public health programs<sup>43</sup> and has been used with more than 1000 programs in the fields of public health, social services, and clinical care in the US and internationally through our online portal, <a href="https://sustaintool.org">https://sustaintool.org</a>.

C.3.b. Project 2- Pilot to test sustainability planning in building capacity in state TC programs. From May 2013-May 2014, Dr. Moreland-Russell and Ms. Hastings collaborated with CDC-OSH and TCN to develop a tailored sustainability planning workshop designed to utilize PSAT results to develop a sustainability plan. This workshop was conducted with six OSH funded state TC programs.<sup>31</sup> In addition, to demonstrate preliminary effectiveness of the workshop in increasing capacity for sustainability across states, pre and post PSAT data were measured. Available post-training data from staff remaining in their role at the time of post-assessment (62%) (collected May-Sept. 2015) indicates improvement across all states for which data are currently available, and provides strong initial evidence of the feasibility and value of the proposed project (Table 2). While this demonstrates preliminary success, further empirical research is needed to establish the evidence for this training.

C.3.c. Project 3 - Evaluation of all CDC Chronic Disease Programs (n=56) capacity for sustainability. From September to December of 2013 Dr. Moreland-Russell and CPHSS staff delivered PSAT assessment, training and technical assistance (TA) to 56 US states and territories to support sustainment of the CDC's Coordinated Chronic Disease Programs initiative. All training and TA was provided by webinar and telephone (travel expenses made visiting each state prohibitive). A comprehensive report was produced and provided to CDC Coordinated Chronic Disease programs highlighting challenges and opportunities related to sustainability

Table 2. State TC Program PSAT Score pre and post training

State	2013	2015
Arizona	4.5	5.0
Indiana	3.6	4.5
Virginia	3.5	3.9
Rhode Island	4.5	4.7
Nevada	3.0	3.7

across all programs. CDC staff reported that the assessment, training and TA provided was significantly beneficial for state program planning and recently requested an additional webinar/workshop training series to over 400 grantee programs.

<u>C.3.d. Project 4. Delivery of sustainability action planning to build community level capacity for sustainability.</u> Dr. Moreland-Russell and Ms. Hastings have extensive experience facilitating sustainability trainings in a number of community-based settings using a variety of delivery methods:

Building capacity for sustainability among Healthy Eating Active Living (HEAL) sites in Missouri. From November 2014 – June 2015, Dr. Moreland-Russell and Ms. Hastings conducted a PSAT assessment in 36 HEAL sites and then facilitated action planning with all sites. As part of this training, each site was provided with the training and tailored materials. With guidance, all sites then developed sustainability action plans. Positive feedback in the form of training evaluations indicated that attendees found the workshop to be useful for their work (87%) and were highly satisfied with the workshop content and format (87%). When qualitatively asked about the most useful part of the training, respondents' answers included understanding program sustainability, clarity of the planning process, and the usefulness of the materials provided (sample plans, tailored planning worksheet, plan template).(See Letter of Support from HEAL).

Building capacity among Brownsville Partnership Grantees in Brooklyn, New York. From March to June 2015, Dr. Moreland-Russell and Ms. Hastings conducted sustainability assessment and action planning with three grantees funded through the Brownsville Partnership in Brooklyn. The PSAT assessments and trainings focused on sustaining three health initiatives including integrating healthy foods into bodegas, a youth farmer's market, and a neighborhood walking initiative, and again received positive feedback. 100% of grantees who viewed the Introduction to Sustainability webinar and attended the sustainability planning workshop reported the information provided was informative, useful for their work and resulted in intention to complete a sustainability plan in the next year.

Sustainability assessment and capacity building for Canadian Partnership against Cancer (CPAC) grantees. From February 2014 to January 2015, Dr. Moreland-Russell and Ms. Hastings partnered with CPAC to assess the sustainability capacity of five cancer prevention coalitions across Canada as a part of the "Healthy Canada by Design" initiative. Multiple partners from each coalition completed the PSAT and then coalition-specific action planning for sustainability was conducted via webinar for each coalition. Coalitions then developed and submitted their action plans for TA. The Program Sustainability Framework, PSAT assessment, and planning process have been presented at two national CPAC conferences and shared with Canadian Aboriginal leaders.

Sustainability assessment and capacity building for OASIS Institute Healthy Habits program. In 2013, Dr. Moreland-Russell and CPHSS staff partnered with Healthy Habits, a nationwide network of programs

housed in the OASIS Institute, a non-profit organization, active in 43 cities and serving more than 59,000 individuals each year. The Healthy Habits program participated in PSAT assessment and an action planning workshop to create a sustainability plan which is still in use today. A 2015 re-assessment of the program using the PSAT indicated improvement in sustainability capacity across all domains (Table 3).

Domain	2013	2015
Environmental Support	4.1	5.6
Organizational Capacity	5.4	5.8
Communications	5.4	5.8
Strategic Planning	3.8	4.6
Overall Score	4.7	5.1

<u>C.3.e. Project 5 - Vast experience working with state TC programs</u>. In addition to the work outlined above, our group has extensive experience in engaging state-level public health programs in large scale research and evaluation projects, further demonstrating our capacity to successfully carry out this study. Such projects include two CDC-funded projects: (1) evaluation of how eight state TC programs implemented the *1999 Best Practices for Comprehensive TC;* (2) evaluation of the D&I of evidence based guidelines across 10 state TC programs; and a current NIH-funded research project, which involves collection of point of sale policy information from TC program practitioners in 48 states and 96 localities, documenting TC program policy innovations and assessing changes in the overall policy environment. 51,52

<u>C.3.f.</u> <u>Project 6 - Development of dissemination products used for state TC programmatic use.</u> One of our main objectives is to use our research results to design tools and guides that can be used by state and local level public health practitioners to inform policy development and improve programmatic interventions. Specifically, In collaboration with CDC, we have developed a series of User Guides addressing several topics (Youth Engagement, Coalitions, Point of Sale Strategies, Tobacco Pricing, Policy Advocacy, and Health Equity) designed to provide state and local TC partners with practical guidance on implementing evidence-based strategies. <sup>50-52,74-78</sup> In addition, we have developed 15 case studies and 3 nationwide reports that have been utilized by states. In an evaluation of our dissemination efforts, state TC programs reported frequent use of these tools with 44% of states reporting using our User Guides and 27% of states using the 2014 Point-of-Sale Report to the Nation.

#### C.4. Conceptual model and study design.

Our conceptual model is driven by the theory of change<sup>7,8,11,28</sup> and stems from our comprehensive definition of sustainability as the existence of structures and processes within an adaptive system that allow a program to effectively implement and maintain evidence-based policies and activities that improve health over time.<sup>16</sup> This definition is deliberately broad, and moves beyond the characteristics of the program itself to include organizational and other system characteristics. This sustainability definition contains several key elements including: (1) Sustainability is an ongoing (cyclical) change process that requires action-oriented planning<sup>35-37,42,81</sup> to strengthen system capacity. Systems include the program, the auspice organization, the community, and the funder. (2) Programs rely on structures and processes that contribute toward adequate system capacity as a necessary condition for program sustainability.<sup>82</sup> A sustainable program must be integrated into normal organizational operations.<sup>83</sup> The characteristics of these programmatic and organizational structures, processes, and community and funder supports<sup>9</sup> build programmatic capacity for sustainability and institutionalization overtime. (3) What is to be sustained is an evidence-based innovation (TC program for the purpose of this project) which is part of a prevention system. Because the innovation is evidence-based, sustainability is essential in attaining positive health impacts.<sup>84</sup>

Figure 1. Sustainability Theory of Change Conceptual Model



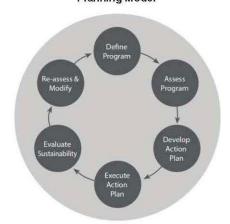
The underlying theory of change of our conceptual model is presented in Figure 1. This prescriptive model outlines a set of causal factors which will help in evaluating the effectiveness of the Program Sustainability Action Planning Model and Training Curricula in increasing capacity for sustainability. This model is an adaptation from Johnson's conceptual model of sustainability planning for coalitions working on substance abuse initiatives. 11,28 We propose that sustainability planning played out through a 6 step action planning training process (described in the next section) can directly affect sustainability readiness and capacity for sustainability as defined by enhancement of programmatic and organizational attributes and community stakeholder and funder support. Increased readiness and capacity for sustainability will mediate the effect of the sustainability action planning training on sustainability success in the form of institutionalization. For the purposes of this project, institutionalization is defined as the continuous integration of the program into normal operations of the organizational system. The health effects result after the evidence-based program is sustained over time.

C.5.a. Development of Program Sustainability Action Planning Training. We will incorporate previous training experience and utilize empirical recommendations<sup>6,35-37,42,81,85</sup> to refine our current training into a cyclical 6 step action-oriented training program (Figure 2) based on Kolb's experiential learning theory. Experiential learning (the process of creating knowledge through the transformation of experience) is comprised of four elements: concrete experience, reflective observation, abstract conceptualization, and active experimentation.<sup>6</sup> In our model, concrete experiences (defining and implementing the TC program) are the foundation for reflective

observation (assess program). These reflections are refined into abstract concepts from which new directions arise (development and execution of action plan). These conclusions can be actively tested (assess program) and serve as guides to creating new experiences (modify plan). The theory and our model emphasize active engagement in the learning process in all aspects of the cycle.<sup>6,85</sup> Each step of the process is designed and delivered in a manner that ensures the program will have the capacity to repeat the activities independently in subsequent years.

Step 1. Program definition. The essential first step in building capacity for program sustainability is to clearly define the program (or the <u>set of activities</u>) and ensure the definition is recognized and understood across all stakeholders. Sustainability is complex and requires a flexible process that should be engaged in by multiple stakeholders. Clarity around program parameters is particularly important when external partners or stakeholder are involved in order to successfully outline a plan for building programmatic capacity for sustainability. <sup>86,87</sup>

Figure 2. Program Sustainability Action Planning Model



Step 2. Assessment. The assessment stage involves examining program and system capacities. The PSAT is one tool that will be used to assist states in examining the factors that contribute toward sustainability and identify which areas need attention during the planning process.

Step 3. Development of Action Plan. Action Planning is the self-creation of a plan based on environmental cues with the expectation that creating a written plan will bridge the gap between intention and execution.<sup>81</sup> Action plans are most successful when participants are interested in learning and actively engaged in the planning process.<sup>35-37,42,85</sup> Using experiential learning methods of reflective observation and abstract conceptualization (Kolb), stakeholders review PSAT results as a group, define and agree on the activities they are trying to sustain, discuss PSAT domains that are most important and most modifiable for the program, write a broad goal clarifying what they would like to sustain, choose a domain (or two) to focus on in their plan, write a specific, measurable objective for that domain, and then outline all the steps needed to accomplish the objective. They then define who will be responsible for each step, what success will look like, resources needed, and a timeline. Specific and concrete plans have a greater likelihood of being implemented.<sup>36,37</sup>

Step 4. Execution of plan. This step involves execution of the action plan. The primary and secondary individuals responsible for "holding" the plan and driving execution of the plan are identified, a plan completion timeline is established, and a meeting schedule is agreed upon by all stakeholders. Two "holders" are identified in order to mitigate the risk that the departure of the primary holder will interrupt progress. At each meeting the plan is reviewed and updated. The team also engages in troubleshooting to address barriers to completion.

Step 5. Evaluation of plan. This step involves process and outcome evaluation methods. For the evaluation of the action plan execution process, we will work with the state programs to develop and track a set of process and outcome metrics for each objective outlined in the plan.

Step 6. Re-assessment and Modification of plan. The state TC program action plans are intended to be flexible, not static and should be continuously revised in response to changes in the environment, organization, or funding. State programs will be instructed to re-assess sustainability capacity using the PSAT and other assessment indicators at least yearly, and revise their sustainability plan objectives accordingly using the action planning process and materials provided during their initial workshop and follow-up TA. States will be also be instructed to recruit all staff who completed PSAT the previous year, plus any new key staff, making sure that the same programs (and any new key partners) are included each year.

#### C.5.b. State recruitment and selection

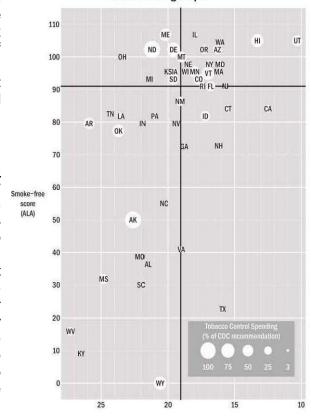
Recruitment. A total of 24 state TC programs will be recruited to participate in this study. We believe this number is feasible for three main reasons: (1) this training will be in high demand because of the CDC's requirement for all state TC programs to complete a sustainability plan; (2) our strong relationships and past success in evaluating state level TC programs; (3) our project consultant's 20+ years working directly with state level tobacco programs (Eischen).

State selection. We will select 12 states to receive the training and 12 as comparison states. To ensure that both the intervention and comparison groups are equally diverse in terms of tobacco control, states will be stratified using the following three criteria: (1) tobacco control policy progress, (2) smoking rates, and (3) funding for TC program. Tobacco control policy progress is operationalized as the American Lung Association's (ALA) 2015 Smoke-free Score for each state.88-90 The ALA "grades" each state annually according to the comprehensiveness of its smoke-free policies (higher scores indicate more comprehensive smoke-free policies). 2013 adult smoking rates are used for smoking rates<sup>90</sup> and funding is measured as the actual amount spent on tobacco control as a percentage of the CDC-recommended amount of spending for FY2015.88,91 Together, these three indicators characterize states' needs (smoking rates), inputs (funding), and environments (policy). States will also be chosen based on willingness to participate and receipt of prior sustainability training. Figure 3 is divided into quadrants by the median smoking rate and median Smoke-free Score. The size of the circles within each quadrant represents the varying levels of funding. The quadrants delineate the primary selection guidelines. Six states from each quadrant representing varying levels of funding will be randomly assigned to either the intervention or comparison group. This process will guard against selecting a disproportionate number of well- or poorly-funded programs for each group. Furthermore, it will ensure both the intervention and comparison groups are evenly varied in terms of needs and policy

Figure 3 is divided into quadrants by the median smoking rate and median Smoke-free Score. The size of the circles within each quadrant represents the varying levels of funding. The quadrants delineate the primary selection guidelines. Six states from each quadrant representing varying levels of funding will be randomly assigned to either the intervention or comparison group. This process will guard against selecting a disproportionate number of well- or poorly-funded programs for each group. Furthermore, it will ensure both the intervention and comparison groups are evenly varied in terms of needs and policy environments.

C.5.c. Delivery of Program Sustainability Action Planning Training (intervention protocol). The Program Sustainability Action Planning Training will be designed to assist states in completing each of the 6 steps in the action planning process and consists of three components (1) pre-workshop preparation, (2) an in person two day workshop, and (3) ongoing technical assistance and support. Each component will be defined by active learning and participation by multiple stakeholders. A sustainability workgroup will be defined for each state consisting of 5-12 members who are actively involved in TC initiatives in the state. In our experience we have found that the desired organizational outcome (institutionalization) is best achieved if an integrated workgroup comprised of internal state health department staff (i.e., the program coordinator and TC program director); external

Figure 3. Selection criteria for intervention and control groups



stakeholders (i.e., TC coalition members or national TC advocacy groups); and policy makers (especially if there is a TC champion in the state) complete the PSAT and actively participate throughout the 6 step action planning process. To ensure training fidelity, delivery of all training components will be overseen by Dr. Moreland-Russell and Ms. Hastings. They have conducted over 20 trainings together and have established rigorous training protocols to guide their processes and procedures and ensure consistency in training delivery.

Preparing for the workshop. Approximately two months before scheduled workshop, we will work with the state tobacco control program manager to identify the list of TC stakeholders who will be involved in workgroup based on our standardized workgroup selection criteria.<sup>31</sup> Once a list is determined, we will work with the program manager to plan a time to conduct an introduction to sustainability webinar. This webinar educates listeners on the Program Sustainability Framework (8 domains), defines the parameters one should use when completing PSAT items (i.e., define the "program"), explains how to complete the PSAT online, and provides a time for state-specific Q & A. This pre-workshop webinar is important for two reasons: (1) it familiarizes all workgroup members with the components of sustainability as outlined in our framework, and (2) introduces the PSAT and steps for completing the PSAT online. The webinar instructs users to answer N/A to PSAT items they are unable to accurately assess. The pre-workshop webinar generally lasts 45 minutes. The PSAT will be administered online to all workgroup members and results will be aggregated into a report that will be disseminated to the participants prior to the start of the in person workshop.

Workshop Day 1. The workshops will take place in each state at the state health department (unless a more convenient site is determined). Trainers will follow an instructor manual and will provide several materials for completing the main goals for each day. The main goals for Day 1 will include defining the program and reviewing assessment results. Activities for Day 1 will include clarifying the program's mission and vision and specifying the population it currently serves; reviewing the current activities and services that the program is implementing; and clarifying any program and organizational capacities that will be necessary to sustain the activities. PSAT scores will be used to identify sustainability areas that need attention. These goals align with Steps 1-2 of the Program Sustainability Action Planning Model as outlined in section C.5.a.

Workshop Day 2. The main goal for Day 2 is to develop an action plan. Activities for Day 2 include outlining action plan components including: (1) specific, measureable, attainable, realistic, and time-sensitive (SMART)

objectives; (2) specific action steps (activities) for achieving objectives; (3) a timeline for completion of each objective; (4) persons responsible for completing each objective; (5) a clear definition of outcomes and measures for successful completion of each objective and overall plan. Handouts will be provided to the workgroup including an action plan template and spreadsheets that allow for easy tracking and analysis of action plan outcomes. These goals align with Step 3 of the Program Sustainability Action Planning Model as outlined in section C.5.a.

Technical Assistance and Support. Following the in person two day workshop, the state TC program will be responsible for executing the action plan and tracking progress in achieving plan objectives (Steps 4-6 in action planning model). Technical assistance is an essential step in the proposed action planning process and will be focused on building each state program's capacity for quality implementation of the action plan. Plan Technical assistance built on best practice indicators will include state-specific quarterly plan review and feedback, assistance in troubleshooting problems with step completion, sharing insights on plan successes from other similar states, and facilitating connections between similarly-focused states. The research team will remain "on call" for states who need assistance beyond the planned quarterly calls. States will also have access to our website <a href="https://sustaintool.org">https://sustaintool.org</a>, which contains a wealth of information on general action plan execution and domain-specific resources to support plan completion and execution. The website is updated quarterly with new resources and materials. States will be encouraged to retake the PSAT at 12 months and repeat the action planning cycle to revise their action plan based on PSAT results and environmental changes, using the indicators and process provided in the original training cycle.

<u>C.5.d. Data collection and Measures for Aim 1.</u> Several process measures will be collected to assess the effectiveness of the training and support delivered. All measures will be collected via survey at the completion of each training component or tracked by review of programmatic records (i.e., action plan, meeting minutes). Quantitative data collected for this aim will be analyzed using descriptive statistics. Qualitative analysis of programmatic records will be conducted following procedures outlined in C.6.a. Appendix B provides an example instrument for collecting this information.

Dosage delivered is the number of units of an intervention delivered or provided.101 For this study, this measure will be defined by the number of hours of training and technical assistance provided to each state.

Dosage received is the extent to which participants engage with or use the materials provided.101 This will be measured by whether or not the action plan is completed and implemented, whether the workgroup utilizes the resources and materials provided, and the extent to which the action plan is implemented.

Participant reactions will be measured by the extent to which the participants felt that the objectives of the training and technical assistance were achieved, satisfaction with the training and technical assistance and perceived usefulness of the training and support provided.

<u>C.5.e.</u> Comparison state protocol. Comparison state programs will participate in the PSAT assessment and record abstraction at three time points as outlined in C.6.a. Comparison states will receive a detailed sustainability assessment report outlining the state's PSAT scores. Comparison states will not receive any other component of the training until year four of this project when they will be offered the finalized materials. Some comparison states might independently implement sustainability plans over the course of the grant. We will track implementation and account for it in analyses.

# C.6. (Aim 2): Demonstrate change in sustainability outcomes in states who received the Program Sustainability Action Planning training compared to states who did not.

The <u>overall goal</u> for the Program Sustainability Action Planning Training and subsequent dissemination activities is to <u>increase sustainability of evidence-based state TC programs through the institutionalization of the program</u>. To determine the extent of reaching this goal, we will design a quasi-experimental effectiveness trial to document differences in organizational and programmatic measures and program sustainability assessment scores between intervention and comparison states. We will rely on two sources of data for this study: 1) state-level program records for measures of predictors of sustainability and institutionalization,<sup>9,11</sup> 2) PSAT scores. While we anticipate that our study will impact behavioral risk factors for tobacco-related diseases (*e.g.*, rates of smoking and initiation), the dependent variable for our study involves measures of program institutionalization and sustainability.

C.6.a. Data collection methods

Program Sustainability Assessment Tool (PSAT)

The PSAT has established reliability and face validity for effectively measuring program capacity for sustainability. The PSAT contains 40 questions (5 items per 8 domains) and is measured on a 1-7 scale where 1 indicates "To little or no extent" and 7 indicates "To a very great extent". Users also have the option to choose N/A (Not able to answer), and are encouraged to do so if they are not familiar with that aspect of the program. The PSAT is directly linked to the eight domains outlined in the sustainability framework (see section C.2.a). Since this framework will be used to guide the action planning for each state, the scores from the PSAT will be important in assessing programmatic challenges and strengths related to sustainability. The sample for our survey is the workgroup defined by the program manager in each of the 24 participating states. We anticipate that 5-12 people in each state will complete the survey. PSAT scores are aggregated across participants for each state so that each state will have an overall PSAT score. Power calculations indicate that surveying workgroups in 24 states (12 intervention, 12 comparison) at three time points- intervention states at baseline and 12 and 24 months post training and comparison states at baseline and 12 and 24 months after baseline collection- will sufficiently capture group differences (Figure 4).

The survey will be conducted online using established methods for Web-based surveys. 102 To enhance the survey response, we will employ the well-established method developed by Dillman. 103 First, all members of the sample will receive a personalized, advanced notice email. This helps to identify the purpose of the survey and establish its legitimacy. Second, approximately one week after the advance email is sent, all members of the workgroup receive the survey link. In all cases, the replies to the surveys will be anonymous. Third, approximately one week after completion of the PSAT, a follow-up email will be sent to all members of the sample. It will thank those who have already responded and request a response from those who have not yet responded. Finally, once data collection is closed, the workgroup members will receive a detailed sustainability report that includes their responses and an aggregated score for the program. For intervention states, this report will serve in the assessment and planning phases. All correspondence will come from WU and the TCN (an important professional association for our sample). The CDC has also agreed to allow us to participate on the OSH Program Service Branch calls to make CDC program officers aware of their state's participation and for promotion of our study. We have had previous success with online administration of surveys including the PSAT. Response rate for PSAT administration across the six TC states (see section C.3.b) was 86% (123 out of 143). In another study, in which we administered an email survey among all 50 state TC managers in three waves, with an overall response rate of 97%. 51,78 In addition, as outlined in the projects highlighted in section C.3., we have years of experience and building partnerships with state TC programs and CDC-OSH.

#### Program record abstraction

A review and abstraction of state level TC program public records will be performed for all 24 states at three time points- baseline and at the annual CDC progress reporting time (June) in years 2 and 3. This will help in evaluating the impact of the training intervention on the capacity for sustainability and institutionalization of the TC program within the organization.

Step 1: Identifying relevant records and measures. Relevant state-level TC program records will be identified within the 24 selected states from various sources. First, all state tobacco programs are required by CDC (DP15-1509 funding requirements<sup>2</sup>) to submit an annual progress report. We will begin by using our consultants and empirical literature to identify relevant state-level programmatic measures documented in these annual progress reports. We have also reviewed the DP15-1509 funding requirements for relevance and have outlined the connection between state reporting requirements and established predictors of sustainability and outcomes in Appendix C. This will increase our likelihood of retrieving all relevant information and provide empirical evidence with which to substantiate the responses in the PSAT and identify and address any potential bias therein. In addition, for those metrics not included in the report, we will review state health agency websites and publically available state level government documentation. Dr. Brownson has extensive experience in collecting this type of information and has incorporated similar strategies in three other studies.

Step 2: Data abstraction. TC program records will be reviewed and data will be abstracted by two trained evaluators using standardized methods and data collection tools created by the research team. The development and use of a standardized instrument for the review and abstraction will improve inter-rater reliability and will provide quantitative data for monitoring trends and intervention effects.

Step 3: Establishing reliability and validity. Data collected via record review and abstraction are subject to bias that may result from rater subjectivity. In order to determine the agreement between the two evaluators, a baseline reliability evaluation will be conducted early in the process to calculate inter-rater reliability. In order to determine validity of self-reported data from the PSAT, agreement between self-reported and record-based information will be assessed. Both inter-rater reliability and validity of self-reported data will be checked at baseline and two other time points.

#### C.6.b. Measures

<u>Dependent variables.</u> Institutionalization is our main outcome measure and will be defined by: (1) *PSAT scores*; (2) *program establishment in organizational procedures*; (3) *program establishment in organizational budget*; (4) *percentage of organizational budget allotted to program*; and (5) *percentage of CDC-recommended TC program funding level spent annually*. The last four measures are conventional measures of institutionalization<sup>9,10</sup> and are being used to safeguard against any possible bias due to the inter-relatedness of the PSAT scores and the training. These variables will be captured from data obtained through record abstraction outlined in section C.6.a.

*PSAT scores*: Each of the eight domains in the PSAT contains five questions measured on a 7-point Likert scale. The overall PSAT score reflects the average of the eight domain scores for each state's program.

Program anchored in law, regulation, or other organizational rules: This variable is defined as whether a state's TC program is established or continued through state statute or regulation, and/or if the program is stated in organizational doctrine as a permanent component of the auspice organization (i.e., the state health department, the division of chronic disease prevention). This variable is a direct measure of formal institutionalization of TC programs and will be measured as a simple binary quantity, zero for "not present in law, regulation, or rule" and one for "present in law, regulation, or rule."

Program included as part of regular budget: This variable is defined as whether a state's TC program is a regular (annual, quarterly, or otherwise) item of the budget of its auspice organization (i.e., state health department). Like the first measure above, this variable directly indicates formal institutionalization and will take one of two possible values, zero for "not included in budget" and one for "included in budget."

Percentage of organizational budget allotted to TC program: This variable is defined as the percentage of the state health department budget garnered by its TC program. The measure will be continuous and theoretically range from 0% (no funding) to 100% (entire health department budget). This quantity measures institutionalization of a program both individually and relative to other state health programs.

Percentage of CDC-recommended TC funding level actually spent. This variable is defined as the amount of program funding as a percentage of the amount recommended by the CDC. This quantity measures institutionalization of a program relative to an objective level of funding computed uniformly from state characteristics by the CDC.<sup>91</sup> The measure ranges from 0% (no funding) to over 100% (above the CDC-recommended level).

Independent and control variables. Numerous independent variables will be analyzed for our study. The following section highlights the key metrics as they relate to the program, organization, community, and funder. The data for these metrics will be collected using record abstraction as described in section C.6.a. We are confident in our ability to collect these measures via abstraction of existing records because states are required to report on each of these measures in their annual TC program progress reports. We will determine final measures based on empirical literature and advisement of advisory group.

A variety of *programmatic attributes* include amount of funding, diversity of funding sources, number of staff working on program, staff quality and commitment, program leader's abilities and commitment, and overall program scope and mission (*e.g.*, services offered, priority populations). Previous research has shown that these programmatic factors predict project continuation and institutionalization.<sup>9</sup>

Organizational attributes associated with program institutionalization and sustainability include the size of the organization, perception of importance of the program within the organization, organizational leader involvement and support of the program, and involvement of staff in the program.<sup>9</sup>

Several *community level factors* have also been shown to predict program institutionalization and sustainability. Specifically, the numbers of community/stakeholders involved with and supporting the program are factors associated with program institutionalization.<sup>9</sup>

Funder support including involvement and percent of program budget covered have also shown to be predictive of program sustainability.<sup>2,9,11,105</sup> In addition, programs beginning with relatively high capacity for sustainability will have less room for improvement than those with less initial capacity, and programs that

experience changes in leadership during the study period may see reoriented strategies and goals. To address these issues, baseline PSAT scores and a binary variable indicating leadership change will be incorporated into the analysis.

#### C.6.c. Data processing and quality control

Carefully designed data processing procedures are necessary to ensure that data are accurate, consistent, and complete. The project team has developed a highly effective system to ensure that the final data set is as error-free as possible. These successful procedures will be adapted for this study, resulting in high-quality, efficient data control processes. The following section includes a brief discussion of key data processing steps.

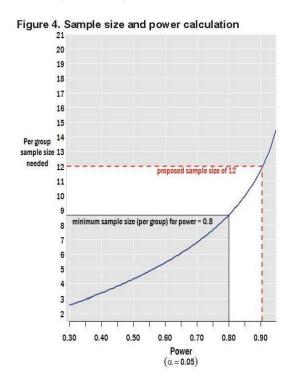
Data entry. All questionnaires are entered on-line minimizing data entry errors. Responses will be automatically checked for the appropriate value, range and data type (categorical, character, numerical).

Data coding. Data from record abstraction that requires qualitative coding will be processed as outlined above. Any unusual situations will be referred to the Project Coordinator who will be responsible for handling all coding decisions, and all codes will be carefully documented in a study-specific list to ensure consistency.

Electronic data cleaning. Electronic data cleaning is efficient and systematic in detecting errors. Our data manager, in consultation with the research team, will create a set of editing specifications to check for inconsistencies across variables. The data set will be checked against these. A computer printout will then be produced indicating where any errors exist in the data. If necessary, respondents will be contacted to verify or clarify responses. Data preparation staff will then correct those errors and run the data set against the specifications a second time to ensure that all corrections have been made. The user will perform all necessary operations (from cleaning data through generating variable definition code in the Statistical Analysis System (SAS)<sup>106</sup> (programming language) by selecting options from on-screen menus. All errors detected will be corrected in accordance with the procedures specified in the study protocol. The end products of this process will be a codebook for each instrument and thoroughly cleaned data files ready for analysis.

#### C.6.d. Statistical power

To estimate the sample size needed for the study, an a priori power analysis was performed using data from a natural experiment. The data consists of Pre and Post PSAT averages from previous work with five tobacco control programs that received action planning and training (see section C.3.b.), and five programs that did not receive action planning or training for which pre- and post-PSAT scores are available. To determine effect size, t-tests of differences-in-means were conducted for the two groups using the changes in PSAT scores between the Pre and Post PSAT data. The standardized differences and t-statistics yielded an effect size of 1.25, which is a large effect size according to Cohen's criteria. 107 Using R statistical environment with packages from Del Re<sup>108</sup> and Champely, <sup>109</sup> the effect size with power = 0.8 and  $\alpha$  = 0.05 project the necessary sample size to be approximately 9 (programs) per group. Since these calculations are based on a natural experiment, which we note occurred over a period of time that also saw changes to the recommended action planning,<sup>2</sup> we are careful not to overstate the anticipated power and therefore conservatively propose a sample size one-third larger than calculated, 12 per group as shown in Figure 4. This sample is also sufficient to measure the main goal of the study, to discern whether the training, and accompanying PSAT significantly increase institutionalization of state TC programs. 108-110



<u>C.6.e.</u> <u>Data analyses.</u> Descriptive statistics will be calculated (e.g., frequencies and measures of central tendency and dispersion), for both the intervention and comparison group at each of the three data collection time points to assess baseline averages and changes. Multiple comparisons across groups and times will be drawn for independent and dependent variables. All continuous measures will be examined for non-normality and all relationships will be examined for linearity where applicable. Strategies for addressing issues encountered will be applied as necessary such as different functional forms, category scaling, and robust error

calculations. In addition, the dose reception and delivery, and participant measures from Aim 1 (C.5.d). will be used to calculate rates of adoption and implementation of training recommendations (intervention states) and other potential actions taken (comparison states, C.5.e).

To incorporate the influence of idiosyncratic characteristics of the state programs, longitudinal regression analysis will be used to model the outcome for each of the dependent variables. This analysis is modeled in Equation 1.

$$\beta_0 + \beta_1 PSAT_{i,t=0} + \beta_2 G_i + \beta_3 D_{i,t} + \beta_4 (G_{i,t} * D_{i,t}) + B_{5-k} X_{i,t} = Y_{i,t}$$
 Equation 1

where i = state, t = time 1 or 2,  $PSAT_{i t=0}$  = baseline PSAT score,  $G_i$  = group (intervention or comparison),  $D_{it}$  = dose variable,  $(G_{it} * D_{it})$  = an interaction between the group and dose terms,  $X_{it}$  = a vector of programmatic, organizational, community and funder variables, and  $Y_{it}$  = the outcome variable. This analysis will ultimately be used to test Hypothesis 1, that the impact of the training is nonzero and positive.

$$H_o: \hat{\beta}_{intervention} = 0$$
  $H_a: \hat{\beta}_{intervention} > 0$  Hypothesis 1

The multivariate approach allows us to account for the numerous influences found in programmatic, organizational, community, and funder attributes. Data collection at different time points also allows for measuring changes in these variables, and the influence these changes have on institutionalization outcomes. In addition, the level of adoption and implementation of action plans both from the training (intervention states) and from other initiatives (comparison states) will vary across programs and time. Varying levels of action plan implementation across states must be acknowledged. Multivariate longitudinal analyses also allow us to control for differing degrees of dosage reception and delivery (described in C.5.d.). We have successfully used similar dose variables.<sup>111,112</sup>

C.7. (Aim 3): Actively disseminate The Program Sustainability Action Planning Model and Training Curricula materials and study results to support future adoption. The results of this study will be actively disseminated and used in three different ways. First, the team will use study results to make any needed revisions to the Program Sustainability Action Planning Model and Training Curricula. Working closely with CDC-OSH staff and other stakeholders (e.g., funders, practitioners), electronic versions of final materials and supporting instructional videos will be developed and made available to all state TC programs in order to support them in independently completing sustainability assessment and action planning work, annually. We will develop a standardized reporting form (in line with current reporting requirements as deemed by CDC2) to support ongoing data collection and fidelity to the training model. State TC programs that wish to access materials will be required to complete the reporting form. It is reasonable to assume that the online materials will be utilized by most tobacco control programs, as DP15-1509 requires annual sustainability plan reports. Second, we will collaborate with CDC to train program officers for interorganizational dissemination. Final materials will be made available to other public health programs through our website, https://sustaintool.org, which already provides a wealth of sustainability resources and is frequented by diverse audiences. Finally, we will disseminate findings about the impact of the Program Sustainability Action Planning Model and Training Curricula on programmatic and organizational sustainability outcomes in high-visibility cancer, public health, and dissemination and implementation science journals and conferences.

#### C.8. Project Timeline and Management.

While our study is ambitious, our experience and partnerships ensure we will be able accomplish all activities on time (Table 4).

Table 4. Project Timeline		Υ	1			Y	2			Υ:	3			Y4		
Task	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4
AIM 1								-						300		
Develop Program Sustainability Action Planning Model and Training														T		
Recruit 24 State TC programs																
Conduct 2-day Program Sustainability Action Planning with 12 TC programs																
Provide technical assistance to 12 intervention state TC programs		П											$\Box$			
Routinely gather feedback on the training and technical assistance through record abstraction and evaluation instrument																
AIM 2	-30 3			10 - 15		·								10.00		
<ul> <li>Conduct PSAT and record abstraction in 24 states to track sustainability outcomes using validated programmatic measures</li> </ul>																
Compare state-level sustainability outcomes in intervention vs. comparison														Т		
AIM 3		- T								(1)				l See	550	
Develop versions of Model and Training for broad dissemination																
Disseminate training and results to state TC programs, CDC, practitioners, and academic audiences								j								

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