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).

Accessibility
Individuals using assistive technology (e.g., screen reader, Braille reader, etc.) who experience difficulty accessing any information should send an email to the Implementation Science Team (NCIdccpsISteam@mail.nih.gov).

424 R&R and PHS-398 Specific
Table Of Contents

SF 424 R&R Face Page

PI: Sorensen, Glorian C

Grant Number: 1 R01 CA200691-01A1

Title: Disseminating an Evidence-Based Tobacco Control intervention for School Teachers in India

FOA: PAR13-055

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

Organization: DANA-FARBER CANCER INST

Department: MO - Center for Comm Based Res

Senior/Key Personnel: Glorian Sorensen

Organization: Dana-Farber Cancer Institute

Role Category: PD/PI

Project Summary/Abstract

There is a profound need for evidence-based interventions that promote tobacco control on a large scale, particularly in low- and middle-income countries. In India in 2010 alone, tobacco use accounted for over 1 million deaths. The *overall goal* of this study is to identify effective strategies for broad-based implementation of evidence-based tobacco control interventions that can be embedded in existing organizational infrastructures and accommodate the realities of low-resource settings. This study builds on an intervention for school teachers, called the Tobacco-Free Teachers/Tobacco-Free Society (TFT-TFS) program, shown to be efficacious in increasing tobacco use cessation and tobacco policy implementation in a cluster randomized controlled trial in the Bihar School Teachers' Study (BSTS). Teachers in India are an important channel for promoting tobacco control, given their roles as community leaders and role models. The next logical step in this research, which is our *objective* here, to develop the knowledge, products and processes needed to take this intervention to scale and disseminate it through readily accessible and sustainable channels. We will test an implementation model for building capacity within education departments to support and deliver this program within schools, using the existing infrastructure for curriculum training in state education departments. Within each state in India, schools are organized within clusters, and cluster coordinators are responsible for directly training principals about curriculum issues. We will build the capacity of cluster coordinators to train and support principals to implement the TFT-TFS program in their schools. Our *central research question* is: Will this evidence-based intervention be successfully adopted, implemented and sustained through existing channels using this implementation process? Accordingly, our *specific aims* are to: (1) determine the extent to which this implementation model meets acceptable rates of program adoption, implementation, reach and maintenance of the TFT-TFS program among schools in the Indian state of Bihar; (2) determine program effectiveness in increasing tobacco use cessation and implementation of tobacco control policies in schools; (3) determine the feasibility of building the capacity of cluster coordinators to train and support principals in program implementation and maintenance in schools, and for the Department of Education to sustain the program; and (4) determine the direct financial costs of program implementation and maintenance. This study uses a non-inferiority design to test the primary hypothesis that program adoption, implementation, and reach will not be inferior to the high standards demonstrated in BSTS; and assesses program effectiveness in improving tobacco use cessation and increasing policy implementation using a cluster randomized design. This research is innovative because it systematically examines the process of scaling up one of the first evidence-based approaches to tobacco use cessation among adults in India. This study is significant because it is expect to improve understanding of implementation processes needed for taking evidence-based interventions to scale.

Project Narrative

The proposed research is *relevant to public health* because it is expected to result in the identification of effective strategies to take evidence-based tobacco control interventions to scale. This research is expected to result in a replicable implementation model that can increase tobacco use cessation among school teachers in India, and potentially more broadly in other low and middle-income countries, and in low-resource settings in the U.S.

Specific Aims

With the increasing global impact of tobacco, there is a profound need for evidence-based interventions that promote cessation and support tobacco control on a large scale. In 2010, tobacco use accounted for over 1 million deaths in India.[8,9] The proportion of deaths attributed to tobacco use is rising rapidly, and these trends are further complicated by the use of multiple forms of tobacco. There is a significant need for broad implementation of effective tobacco control interventions that promote tobacco use cessation and establish a social environment supportive of tobacco control.[10] Little research has studied the processes of bringing effective tobacco control interventions to scale, and there is insufficient evidence to determine the most effective ways to promote tobacco control in low- and middle-income countries (LMICs).

Our ***long-term goal*** is to identify effective strategies for broad-based implementation and maintenance of evidence-based tobacco control interventions that can be embedded in existing organizational infrastructures and can accommodate the realities of low-resource settings. *We build on an intervention for school teachers, called the Tobacco Free Teachers/Tobacco Free Society (TFT/TFS) program, which we have tested and shown to be effective in increasing tobacco use cessation in a cluster randomized controlled trial in the Indian state of Bihar, in the Bihar School Teachers' Study (BSTS).* Teachers are community leaders and role models, and represent a significant and neglected channel for promoting tobacco control both in schools and society at large. To capitalize on the potential of this intervention, we further studied avenues for taking this intervention to scale in a dissemination pilot study funded by the National Cancer Institute's (NCI) Center for Global Health.

The next logical step in this research, which is our ***objective*** here, is to develop the knowledge, products and processes to take this intervention to scale and implement it through readily accessible and sustainable channels. Following findings from our dissemination pilot study, we propose to test an implementation model for building capacity within a State Department of Education (DoE) to support and deliver this program within schools, using the existing DoE infrastructure for curriculum training as an established process. In India, each DoE organizes schools within clusters; cluster coordinators (CCs) are responsible for directly training principals about curriculum issues. We will build the capacity of CCs to train and support principals to implement the *TFT-TFS* program in their schools. Capacity building for both CCs and principals will include training, consultation and technical assistance, and support from leadership and peers. To build sustainability, we will work with the DoE and its education officers to embed the program within existing infrastructures. Our ***central research question*** is: Will this evidence-based intervention be successfully adopted, implemented and maintained through existing channels using this implementation process? This study employs mixed methods, benefiting from a rigorous process tracking system, surveys, and qualitative methods. Accordingly, our ***specific aims*** are:

1. Adoption, Implementation, Reach and Maintenance among Schools: Determine the extent to which this implementation model meets acceptable rates of program adoption, implementation, reach and maintenance of the *TFT-TFS* program among schools in Bihar. *Working hypotheses:* (a) At least 80% of schools asked to participate will **adopt** the program, as measured by completion of the principal training. (b) At least 80% of schools adopting the program will **implement** a minimum standard for program implementation, defined by the number of core implementation components conducted within the school. (c) For **reach**, at least 80% of teachers in schools implementing the program will participate in discussions covering 3 or more of 6 *TFT-TFS* themes. (d) For **maintenance,** at least 80% of schools implementing the program will maintain the minimum standard for program implementation during the maintenance period.
2. Effectiveness: Determine program effectiveness in increasing implementation of tobacco control policies and in promoting tobacco use cessation in schools. We will estimate the difference in the levels of tobacco use cessation among teachers and of tobacco control policy implementation between schools in districts randomly assigned to the intervention compared to those assigned to the control group; and estimate policy implementation and tobacco use cessation in the control schools as indicators of secular trends.
3. Feasibility: Determine the feasibility of building the capacity of cluster coordinators to train and support principals in program implementation and maintenance in schools, and for the DoE to sustain the program.
4. Cost: Determine the direct financial costs of program implementation and maintenance.

The expected outcomes of this study include demonstration of the feasibility of implementation and the effectiveness of the *TFT-TFS* program within the infrastructure of the Bihar DoE, providing a foundation for other state governments to adopt this evidence-based tobacco cessation program for school teachers. As a result of this study we expect to better understand the implementation process and to identify factors that need to be taken into account as evidence-based interventions are taken to scale, findings that we believe will have relevance not only in India and LMIC's, but also within the US.

Research Strategy

3.1. Significance: This study responds to an urgent need for evidence-based tobacco control programs in the developing world.[11,12] According to the World Health Organization (WHO), by 2030, more than 8 million people globally are expected to die from tobacco-related causes, 80% of whom will be from LMICs.[13] In India in 2010 alone, an estimated 930,000 people died from smoking,[8] and in 2008, an additional 368,000 deaths were attributed to smokeless tobacco use,[9] illustrating the complex effects of the use of multiple forms of tobacco.[14-16] Reflecting these trends, India has one of the highest oral cancer rates in the world.[17-19] The prevalence of tobacco use among men in India is 48%, and among women, 20%.[16] Growing attention is being paid to these mounting global disparities in tobacco use.[20,21] NCI recently formed its Center for Global Health aimed at reducing the global burden of cancer.[22] Although India was an early signatory to the Framework Convention on Tobacco Control,[23] few resources are available to support tobacco use cessation, the prevalence of quitting remains low, and few social norms support quitting.[16] This study examines the process of bringing an evidence-based tobacco use cessation intervention to scale, using findings from a cluster-randomized trial[5] and responding to the urgent need for tested implementation strategies. There is a delicate balance between ensuring that adequate evidence is available to support dissemination and implementation (D&I) research, and making use of available evidence to provide a response to pressing public health issues, particularly in light of the lag time between efficacy/effectiveness research and implementation of evidence-based interventions in practice.[24] Findings from the proposed study will inform implementation of tobacco control measures in India, in the early stages of planning and initiation, including efforts in schools.

This study will identify strategies to implement and maintain tobacco control efforts through existing organizational infrastructures in low-resource settings. School systems are a pervasive community organization that can be leveraged in support of tobacco control efforts. Teachers play a pivotal role in Indian culture -- as role models and opinion leaders in their communities who are highly respected in society.[25] Through teachers, it is possible to influence tobacco use among students and society-at-large. We will implement this study in the Indian State of Bihar, where the program was first tested and where prevalence of tobacco use is high. Support for tobacco control is growing, however, as evidenced by a recent directive from the Bihar Department of Education (DoE) to strictly implement the Cigarette and Other Tobacco Product Act, which bans smoking in schools.[26] We will work with the DoE to embed this program within existing training structures, and examine the potential for schools to maintain this program beyond the implementation year.

The impact of this research will be significant because it is expected to provide a replicable implementation model that can increase tobacco use cessation among teachers in India. Such knowledge is central to accelerating the pace of moving effective interventions to practice, of particular concern given the documented delays in moving tested interventions to practice.[24,27,28] To ensure relevance to policy makers, we have followed the principles of "*practical trials*"[27,29] with plans to implement the program, and facilitate and evaluate program maintenance; employ multiple evaluation measures relevant to decision makers, including cost; and evaluate effectiveness across multiple outcomes, with a plan to triangulate findings from across multiple sources using both qualitative and quantitative measures.[3]

This study has implications for the US: (1) Findings have implications for research on opinion leaders,[30] exemplified here by teachers who are leaders in their communities; (2) The strategies employed in India can be adapted to address the increasing use of multiple forms of tobacco; (3) The expanded use of rigorous research methods can be applied to D&I research in low-resource settings in the US; and (4) Identifying strategies to support program maintenance will have implications for similar organizations here.

3.2. Innovation: The proposed research is innovative because it systematically examines the process of scaling up one of the first evidence-based approaches to tobacco use cessation among adults in India. Quitting tobacco use is not common practice in India, where the prevalence of former tobacco users has ranged between 3-11%[16,31,32] compared to 21-25% in the US.[33,34] While tobacco control in India has focused on prevention and policy initiatives,[8,30] less attention has been devoted to effective interventions for cessation, with the exception of a few hospital- and community-based approaches.[35-41] *The intervention departs from the usual practice of school-based interventions by focusing on cessation among school teachers,* thereby benefiting teachers themselves; students, through teachers' examples and by placing tobacco control on the school's agenda; and the broader community, by focusing on teachers as opinion leaders and locating this program in an organization central to community norms. *By building capacity among educational leaders and embedding the program within their existing roles, we expect this approach to result in*

high levels of institutionalization within these schools, with the potential for broad-based impact on other school systems in a cost-effective manner. We have purposefully incorporated a plan for building in refinements to the implementation model, which will facilitate maintenance and inform plans for broad-based dissemination.

3.3. Approach

3.3.1. Design overview: *Our overall goal is to develop the knowledge, products and processes needed to broadly disseminate evidence-based tobacco control interventions for school teachers in India through readily accessible and sustainable channels.* We have strong partnerships in place and the full commitment from the Bihar DoE, which will facilitate full participation of all principals and DoE staff in the study.

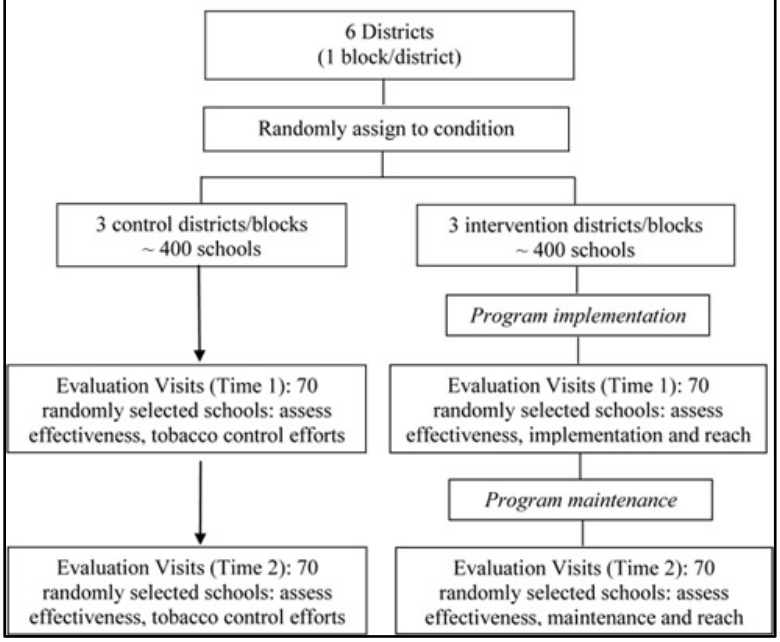
This program is situated within the existing infrastructure of the school system (Fig. 1). All states in India use a similar organizational structure, whereby schools are nested within clusters, which in turn are located within blocks, and blocks, within districts. Training in new curricula, for example, follows a "cascade" transmission, passed through this nested structure. We use this structure, and also build on growing trends in India toward "situated learning," which allow for incorporating adaptations to the local context into training.[42] Following findings from our pilot study, we will build capacity among persons responsible for curriculum training -- Cluster Coordinators (CCs) -- to train and support principals in the implementation of the *TFT- TFS* program. Each CC meets monthly with the 10-12 principals in his/her cluster at the Cluster Resource Center, usually a centrally located school in the cluster. CCs are trained by Block Resource Coordinators; we will build capacity among all CCs within selected blocks at the Block Resource Center.

Figure 1: DoE Structure

Educational Structure	Implementation Methods by Level
State Department of Education	*DoE support in place for implementation*
⇩	
Districts	*3 districts selected per state*
⇩	
Blocks	*1 block per district, 3 total. All CC's in block trained at Block Resource Center*
⇩	
Clusters	*10-12 clusters per block, 30-36 total. CC's train all principals in their cluster at cluster resource center*
⇩	
Schools	*10-12 per cluster, ~400 total. Principals implement TFT-TFS in their schools*

The primary outcomes -- adoption, implementation, reach and maintenance – were selected to address the central research question of this implementation study, and are assessed using a non-inferiority design. We will assess these outcomes in the Intervention group using data from the process evaluation and Evaluation Visits in a sample of 70 intervention schools at two time points. (Fig. 2.) This rigorous design provides a high bar for comparison of results by using the standards provided by BSTS.[43,44] *(See Appendix A.)* For each outcome, the null hypothesis (what we hope to reject) is that the percentages of schools adopting, implementing and maintaining the program are lower than the targeted percentages, and the alternative hypothesis (what we hope to prove) is that the percentages are equivalent to the targets or greater. Thus, if the program is successful we will be able to say with 95% confidence that these high standards (our targets) have been met. (See detailed Timeline in Appendix B.)

Figure 2. Study Schema



We will use a cluster-randomized design to assess program effectiveness in improving tobacco policy implementation and increasing tobacco use cessation and monitor secular trends in tobacco control. (Fig. 2). We will randomly assign six school districts to condition, and within each district, randomly select one block. Within these blocks in each condition, we will randomly select 70 schools to participate in an Evaluation Visit, during which we will assess our effectiveness outcomes, and compare these outcomes between intervention and control schools at two time points. We will also monitor tobacco control efforts being implemented in control schools. We will additionally examine the feasibility of implementing and maintaining the program, and will also measure cost and effectiveness, of central importance to decision-makers who may adopt this program.

3.3.2. The Study Team: This study is a collaboration between the Dana-Farber Cancer Institute in Boston and the Healis-Sekhsaria Institute for Public Health, based in Mumbai, and builds on multiple collaborations. The team has extensive experience in tobacco control interventions and a strong collaborative network in Bihar, including the School of Preventive Oncology in Patna, which implemented the *TFT/TFS* program in BSTS.

3.3.3. Preliminary studies: This study builds on BSTS and our dissemination pilot study; additional research in Indian schools and worksites; and ongoing tobacco control efforts in India. *(See manuscripts in Appendix C.)*

Bihar School Teachers Study (BSTS; NCI, 2008-2013): We tested the efficacy of the *TFT-TFS* program using a cluster-randomized design. Government schools (N=72) were randomly selected from within 10 districts and randomly assigned within two strata (rural/ urban) to an intervention or a delayed intervention control condition. The study was conducted in two waves across two academic years (2009-10, and 2010-11). We surveyed teachers at baseline (response rate=80%), immediately post-intervention (response rate=72%), and 9 months post-intervention (response rate = 72%). At baseline, 36% of teachers were current tobacco users and 11%, past users.[32] The 7-month *TFT/TFS* intervention was conducted throughout a single academic year.[25,45,46] (See Section 3.3.6.2 for program components.) Process tracking data showed that the intervention was generally delivered as planned, e.g., session delivery was 100% in 33 of the 36 intervention schools and 31 schools implemented all program components.[47] Among respondents to the *immediate post-intervention survey,* the adjusted quit rates among tobacco users were 50% in Intervention and 15% in Control ($p<0.001$). The adjusted 6-month sustained cessation rate was more than double in the Intervention group compared to the Control (19% vs. 7%;$p=0.06$); among participants who had been employed in the school for the entire intervention period, the adjusted 6 month abstinence rates were 20% vs. 5% ($p=0.04$).[5] Although the immediate post-intervention quit rates were higher than might be expected in the US, they are similar to those of other studies in India, which have reported short-term quit rates of 42%-47%.[6,7] The relapse rates indicate the need for ongoing support for quitters; quitting is not common in India, and there are few social supports available for maintenance. To address this concern, the proposed study focuses on maintenance and embedding support within existing organizational structures. In addition, all 36 intervention & one control schools adopted a tobacco-control policy.[48] Higher enforcement of tobacco-control policy was observed in intervention schools at post intervention survey (OR=3.26; CI: 2.35, 4.54) compared to baseline survey.

Dissemination pilot study (NCI, 2014-15): We assessed strategies to implement the *TFT/TFT* program through the DoE, using surveys and focus groups with teachers and principals. Principals reported that they would be most likely to implement the program if the DoE, which has the authority for determining schools' activities, mandated it. Participants reported that the program could be effectively incorporated in activities already underway in the school; and that principals could be trained using approaches to training on curriculum changes and professional development. Over 98% of principals reported that they meet monthly with the CCs, providing opportunities for training and support.[48] We also learned that turnover rates of principals and CCs tend to be low and related mostly to retirement; this stability will contribute to program sustainability.

Mumbai Worksite Tobacco Control Study (NCI, 2010-16; Sorensen PI): We demonstrated the effectiveness of this worksite tobacco control intervention in increasing tobacco quit rates among production workers,[49] and expanded our understanding of the context of quitting in Indian worksites.

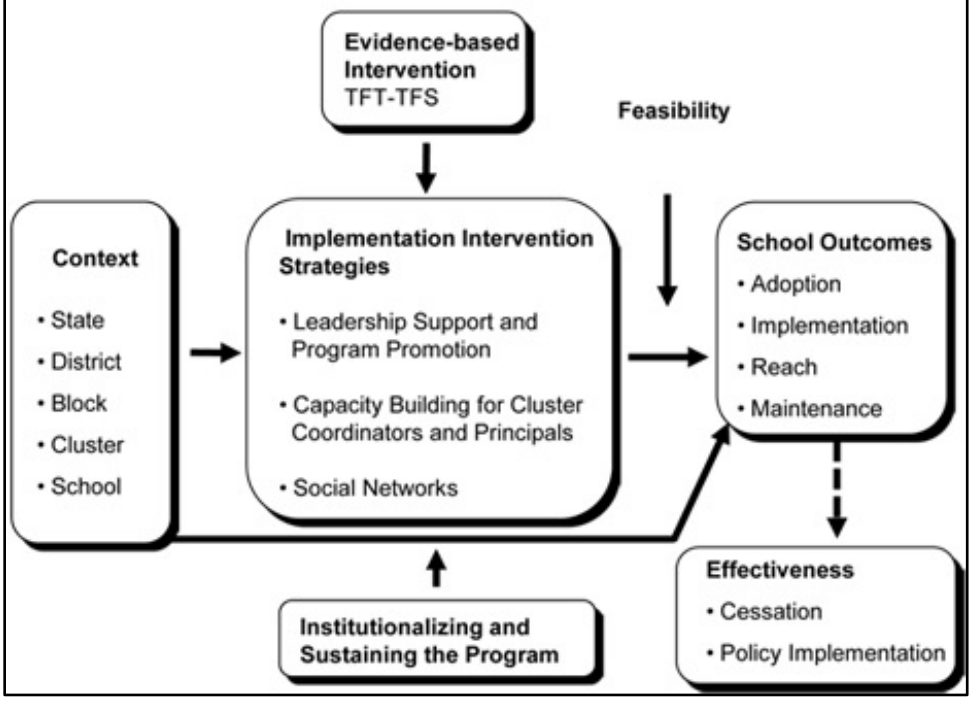
Tobacco use prevention in Mumbai schools: In collaboration with the Salaam Bombay Foundation, we demonstrated the effectiveness of a school-based life-skills tobacco control program in preventing uptake of tobacco use among youth of low socio-economic status in Mumbai, using a quasi-experimental design.[50]

Ongoing tobacco control efforts: Healis and the School of Preventive Oncology also collaborated in

conducting field work for the Tobacco Control Policy India project.[48,51-55] and have strong partnerships in Bihar with the Teachers Association of Bihar, and organizations addressing tobacco control in schools (e.g., Socio Economic and Educational Development Society;[56] Cancer Awareness Society[57]).

3.3.4. Conceptual model for implementation and maintenance: We have applied the growing literature on D&I science to specify a conceptual model to guide our research[28,58-76] *(Fig. 3.)*. Key components include: *Evidence-based intervention:* This study builds from an evidence-based intervention, the *TFT-TFS* program (Section 3.3.2). We will work with the DoE to communicate the salience of the intervention and its relative advantage at all levels of the DoE.[63] We differentiate between core components, essential to the effectiveness of the intervention, and adaptable elements, allowing for localizing the intervention without undermining its integrity.[28,69,72] (Table 1.)

Figure 3– Conceptual model for implementation and maintenance



Implementation intervention strategies: We will build the capacity of CCs to train and support principals in implementing the *TFT- TFS* program using the existing training infrastructure and supportive social networks.[67,72,77,78] The strategies include processes for getting an intervention into use within an organization:[28,79] (1) leadership support and program promotion, including ensuring a fit with organizational values, articulating the importance of tobacco control for teachers and ensuring the availability of resources (human, financial, physical);[28,58,60] (2) capacity building, including training and technical assistance (TA) for both CCs and principals;[67,72,77,78] and building support among block and district-level officers; and (3) fostering social networks, building from existing relationships among principals within clusters, and among CCs within blocks, to ensure maintenance of the program[11,73] and leverage social capital and build norms in support of implementation.[28,80] We will train CCs following principles of train the trainer,[81-84] and provide TA, both shown to support the transfer of evidence-based practices.[85-87]

Sustaining the program: Planning for sustainability is crucial to long-term institutionalization and continued use of evidence-based interventions.[75,88] We will work with DoE leadership to develop a practical plan to embed *TFT-TFS* into the DoE infrastructure and transition the program to DoE personnel.[89,90]

Context: We will leverage the multi-level educational structure, taking into account the climate and support for implementation. We explored barriers to and facilitators of the intervention implementation as part of the pilot study, and have incorporated these factors into the implementation plans. (See Section 3.3.3.)

Outcomes (adoption, implementation, reach, maintenance and effectiveness): Concordant with the D&I literature, the primary outcomes of this study focus on the implementation process, following guidance from the RE-AIM framework[91-93] and other models.[28,60,63,94] In addition, this study directly examines the effectiveness of the program in improving tobacco control policies and tobacco use cessation among teachers.

3.3.5. Study population, sample, and randomization: We will include rural and urban government schools up to 8th grade in Bihar, and exclude blocks with schools that were part of BSTS. The highest levels within the DoE have already provided permission for schools to participate. (*See letter of support, Section 14*.) In the hierarchical structure of the Indian education system, the DoE's commitment ensures high participation from

CCs, principals and schools, as was shown in BSTS. In Bihar, there are 38 school districts, a total of 534 blocks, and 28,737 schools up to 8th grade. We will randomly select six districts, and randomly assign these districts to intervention and control. Within each district, we will randomly select one block to participate. In intervention schools, within each block, we will train all CCs (10-12 per district, ~400 schools total). No intervention activities will be conducted in the control schools during the Implementation and Maintenance periods. At the end of Maintenance, we will provide intervention materials to the three control districts.

3.3.6. Implementing & maintaining *Tobacco-Free Teacher/Tobacco Free Society* (*TFT-TFS*) Program

3.3.6.1. Justification for the approach:

Application of principles of scaling up: Successful scale-up of an innovation requires high levels of commitment and early involvement of potential users; clear messages on its advantages; local adaptation; and training for skills transfer.[95-97] We have solid commitments from the DoE to implement the program, and have incorporated findings from BSTS and our pilot study into plans to embed the program in existing structures.

Training principals: Our pilot study underscored the pivotal role principals play in their schools, and the opportunities for engaging them during regular trainings. In focus groups, principals reported that assigning principals a lead role would give them autonomy to adapt the program to their schools.

Planning for local adaptations while maximizing fidelity: We have defined core and adaptable program components to support schools in tailoring the program to their local setting, while also ensuring consistency with the original intervention. (Table 1) Based on formative research in BSTS and our pilot study findings,[45,46] we have included components that could be readily sustained. We will provide a step-by-step guide for implementing the core components—those vital to success--and guidance on localizing the program to fit their setting, such as using *TFT-TFS* content in classroom teaching, based on the ADAPT-ITT model.[98]

3.3.6.2. Evidence-based Intervention: TFT-TFS Program: The program is designed to be conducted across an academic year, and repeated as part of maintenance. (See Table 1.) Over two academic years, we will assess program implementation (year 1) and maintenance (year 2). The principal of each school will be trained by the CCs to implement the core program components, taking advantage of monthly meetings at the Cluster Resource Center. The principals will in turn deliver "theme-based" intervention activities in their schools (i.e. six themes – approximately one per month) to: (a) emphasize teachers as role models during the program's 'kick-off'; (b) enhance understanding of the risks associated with tobacco; (c) increase motivation to quit; (d) build skills to quit; (e) address withdrawal; (f) promote skills for cessation maintenance; and (g) build a supportive normative climate for not using tobacco. Principals will be given program materials – which were well-received and implemented with a high degree of fidelity in BSTS[47] - consisting of posters, cessation booklets, discussion guides, a sample tobacco control policy, wall painting instructions and an implementation guide with suggestions for localizing the program to their schools. *(See Appendix D for sample materials.)*.

Table 1: TFT/TFS Program Components: Implementing and Maintaining the Program within Schools

Intervention components	**CORE PROGRAM COMPONENTS**	**ADAPTABLE ELEMENTS TO LOCALIZE PROGRAM (Examples provided)**
Group discussions with teachers about tobacco	Principals will facilitate monthly discussions with teachers, centered on the 6 program themes	Teachers will be encouraged to gather information from local newspapers as a foundation for group discussions; tip sheets will be provided on how to engage youth in dramas, skits and poster drawing contests related to tobacco control
Cessation support for teachers	Principals will facilitate group discussions on steps to quitting and provide quit materials	Additional support may include referrals to WHO cessation centers and receiving SMS messages to help teachers quit using tobacco
Posters and wall paintings for the school	Principals will post 6 themed posters and paint 3 paintings on outside school walls *(see photo-Appendix D)*	Local artists can be engaged to paint policy content on the walls; additional wall paintings or posters from the Ministry of Health and other agencies can be posted
Tobacco policy	Principals will implement tobacco-free policy	Materials on tobacco policy work groups will be provided for schools selecting to incorporate a policy work group.

During the maintenance year, principals will be asked to continue to implement the four program components in their schools (see Table 1). Although we expect low turnover, should new CCs be hired during this period, we will train them to train, support, and provide TA to principals to implement the program; and if new principals are hired, they will be trained by their CC to implement *TFT-TFS* in their school.

3.3.6.3. Implementation Intervention Strategies: See Section 3.3.4, conceptual model for the 3 strategies:

Leadership support and ongoing program promotion: Ongoing support from DoE leadership is critical to the successful implementation and sustainability of the *TFT-TFS* program in schools. We will develop a set of brief communication materials that DoE leadership can use to articulate the tobacco problem and the central role schools play in tobacco control; and the benefits of the program to the schools, teachers, and ultimately to students and the community at large.[99] We will also use these materials in meetings with the DoE leadership and with district and block officials, and CCs, who will make them available to principals.

***Capacity building*:** There is growing recognition that capacity building can be enhanced by supporting training with ongoing coaching and TA.[72,78,100,101] We will train CCs to train principals to implement and maintain the program, building on existing training mechanisms. CCs meet monthly with other CCs in their block; we will work through block officers to extend the time of two of these regular meetings during the academic year, to provide training for all CCs in a single block. In turn, CCs will train principals in their cluster during in-depth training sessions (at the beginning and midway through the academic year), and will provide support and TA during their monthly meetings with principals.

Training: For both CCs and principals, the training will focus on three objectives: (1) build knowledge of the *TFT-TFS* program, including knowledge of tobacco use and its harms, the cessation process, and strategies for effective implementation of tobacco policies; (2) build skills to implement and maintain the program, including skills for program planning; effective communications and program promotion; engaging teachers in the intervention; and reflecting on and evaluating the progress and quality of implementation;[28] and (3) build skills for barriers management, including strategies to address barriers to intervention delivery,[63] such as defining and setting aside times for teachers to participate in discussions and addressing barriers to successful implementation of tobacco control policies. Training for CCs will include skills-development to train principals, provide on-going coaching and TA, and facilitate schools' ongoing participation; and will facilitate information exchanges among principals at the Cluster Resource Centers. All training will be participatory and interactive, drawing on the tenets of adult learning principles and situated learning.[42,102-104] Training curricula will include demonstrations, role plays, group discussions, opportunities for behavioral rehearsal and feedback, all important to effective training,[102,103] particularly in LMIC's.[42,105,106] *See Appendix E, sample training material*.

Coaching and TA will support the efforts of program implementers.[86,87] We will build ongoing support for CCs by ensuring the district and block officers know the roles and responsibilities of CCs in training and supporting principals, and that they are equipped to coach and support CCs. Healis staff will call CCs monthly to assist with any challenges, be available for phone support as needed, and will visit block resource centers to help facilitate trainings and provide TA. CCs will use their monthly meetings with principals to provide ongoing support and technical assistance to principals, and will be available by phone between meetings.

Social networks. Using concepts from 'learning networks,' we will create information exchanges for both CCs and principals that encourage shared problem-solving, learning from each others' experiences, and support for program implementation.[11,73,107-109] Exchanges will take place during established meetings of CCs at the block resource centers, and regular meetings of principals at the cluster resource centers. We will provide discussion questions for these information exchanges and ask the CCs to facilitate the discussions with principals in their own clusters. Block resource coordinators will facilitate these exchanges with CCs.[28,110]

3.3.6.4. Institutionalizing and sustaining the program within the DoE infrastructure: Ongoing implementation and maintenance of this program in schools depends on embedding it within the DoE infrastructure– that is, making it part of the way things are done. To achieve this, we will meet regularly with DoE leadership across the five study years to develop and implement a plan to sustain the *TFT-TFS* program. The plan will be based on the needs of the DoE and the experience of CCs and principals in implementing and maintaining the program in schools. In Year 1, we will conduct key informant interviews (KIIs) with DoE leadership to improve our understanding of ways to embed the program into the DoE infrastructure and transition the training and TA roles played by study staff to DoE personnel. During Years 2-4, we will conduct regular consultation meetings with the DoE to review how *TFT-TFS* is being implemented and maintained in the schools. We will use findings from the study to refine the implementation model, and will create a plan to sustain the program,[111] containing (1) Leadership support for the program (i.e. by highlighting how the program links to DoE priorities); (2) Organizational processes and policies, such as writing *TFT-TFS* training and TA roles into DoE job descriptions and performance metrics; (3) Resource allocation, including budgets and identifying cost-effective ways to produce program materials; and (4) Monitoring and evaluation by identifying

how existing DoE tracking systems can be used to evaluate the program over time. No additional DoE personnel will need to be hired; we will work with the DoE to identify relevant strategies to ensure program maintenance and build responsibilities into existing roles in the DoE.

In Year 5, we will support the DoE in sponsoring a state-wide meeting with the 38 District officers, education-related NGOs and the media. Plans for broadly disseminating the program will be announced and district officers will be oriented to the *TFT-TFS* program and how to implement it in their Districts.

3.3.7. Evaluation: The primary evaluation objective is to assess the extent to which the implementation model results in acceptable rates of adoption, implementation, reach and maintenance. We will also measure effectiveness (i.e., policy implementation and tobacco use cessation), feasibility and cost. *(See Table 2.)*

3.3.7.1. Justification of our approach:

This study employs rigorous methods for assessing our primary outcomes (adoption, implementation, reach and maintenance), while also leveraging the advantages and strengths of the randomized design in assessing program effectiveness. A key strength of this study is its use of a Hybrid III design,[1] focusing primarily on implementation outcomes,[27,73,76] with the additional aim of assessing effectiveness of the intervention in improving cessation and policy implementation using a randomized design. The use of the non-inferiority design offers a rigorous approach by using historical controls from BSTS as the standard for comparison, thereby setting a high bar for demonstrating acceptable levels of implementation.

Our primary outcomes are well-aligned with the objectives of D&I research.[43,44] We carefully selected targeted levels of adoption, implementation, reach and maintenance using two criteria: (1) *Feasibility of implementation***:** In BSTS, we observed high levels of program adoption and implementation (see Section 3.3.2), suggesting that high levels are feasible. (2) *Meaningful public health impact:* We have set targeted levels lower than what was achieved in BSTS with a high level of staffing support, but at a level likely to yield meaningful quit rates when implemented at a large scale. Others have documented that even small changes in individual health behaviors can yield significant outcomes when implemented at the population level.[112,113]

We crafted our assessment of implementation and maintenance to minimize the potential for bias from self-report by those implementing the program. Independent evaluators will assess program implementation and maintenance during the Evaluation Visits. We will use these data to validate the process tracking measures. We will measure adoption and reach in all schools based on attendance records, which are less dependent on self-report, and are commonly used in schools to track participation. It is also customary for principals to track programmatic activities in their schools and report these to CCs.

We will measure effectiveness using a randomized design to compare results in Intervention and Control groups. We will assess tobacco policy implementation using an Observation Checklist to assess indicators of policy adoption, along with teachers' reports of implementation.[48] We will assess abstinence from all tobacco use by teachers' self-report at two time points, using surveys conducted during the Evaluation Visits (see Fig. 2).[114] We will use approaches from BSTS to minimize reporting bias of cessation, including use of anonymous surveys, notifying teachers in advance that the results would only be communicated in the aggregate, use of separate intervention and survey staff, and minimal investigator contact with teachers.

We carefully considered and opted against collecting biochemical data to verify quitting for several reasons: (1) Cessation is not our primary outcome, as is appropriate for D&I research.[3] (2) Biochemical validation is most sensitive to determining smoking status; in India, however, smoking prevalence is relatively low, and use of smokeless tobacco is most common. Biochemical validation for smokeless tobacco use among adults has only been conducted in hospital or clinic settings in India,[4] and there are no reports to date of such studies in field conditions in India. (3) There are no laboratory facilities in Bihar for assessment of saliva or urine samples. There are also significant obstacles to using rapid screening tools that adhere to rigorous, standardized methods in community settings in rural India. (4) Our pilot experiences in collecting biochemical samples in BSTS suggested high error rates and low sensitivity and specificity (that is, the test was equally inaccurate in predicting never users, self-reported quitters, and users).

Our study uses mixed-methods, increasingly in use in D&I research,[92,115,116] **particularly appropriate for evaluating implementation and maintenance,**[93] **and which we have successfully used among teachers in India.**[45,46,117] Mixed methods integrate the strengths of quantitative approaches in assessing the magnitude and frequency of constructs, with qualitative research to explore their meaning.[118-123] Here, as part of our feasibility assessment, we use qualitative data to explore feasibility, including barriers and facilitators to program implementation and maintenance.[120-124]

3.3.7.2. Overview of Data Sources and Data Collection Methods (See also by aim in Section 3.3.7.3.)
Evaluation Visits: The Evaluation Visits will include 2 randomly selected schools per district (~70 schools per condition at each time point; see Fig. 2). In the Control group, at each time point schools will be randomly selected from all schools in the district. In the Intervention group, at Time 1, schools will be randomly selected from schools that have adopted the program; at Time 2, we will select an independent random sample of 70 schools from those determined to have implemented the program based on process tracking data, in order to assess maintenance among program implementers. We have timed the Evaluation Visit to provide a proximal measure of implementation and maintenance, in order to capture visible indicators of program implementation, e.g., wall paintings and posters, and to collect self-reports of implementation close to the time of program delivery. Data collection methods include:

- *Observation Checklist:* We will use the BSTS Observation Checklist to assess indicators of tobacco policy implementation (e.g.,display of No Tobacco Use signs inside the school premises, observation of spitting marks, wrappers and empty packets of bidi, cigarette and smokeless tobacco products) in five locations inside the school: classrooms, corridors, toilets, dustbins and playground. We will also record the presence of the 3 wall paintings and the display of posters in intervention schools at both time points. *(See Appendix F.)*

Table 2. Measures Summary

Outcome	Measure	Data source
Program adoption	• Principals' participation in training with CCs	• Attendance logs (Process tracking)
Program implementation	• Implementation of 4 program components	• Teacher/principal surveys • Observation checklist (Evaluation Visit) • Process tracking
Program reach	• Teacher participation in the program	• Attendance logs (Process tracking) • Teacher surveys (Evaluation Visit)
Program maintenance	• Implementation of 4 program components	• Teacher/Principal survey • Observation checklist (Evaluation Visit) • Process tracking
Tobacco use cessation	• Teacher self-report	• Teacher surveys (Evaluation Visit)
Tobacco policy implementation	• Indicators of policy implementation	• Teacher surveys • Observation checklist (Evaluation Visit)
Feasibility	• Principal participation in training with CCs • CC interactions with principals • Barriers & facilitators to: o Implement/maintain program o Train and support principals o Support CCs o DoE sustain program	• Attendance logs (Process tracking) • Monthly checklist • Principal surveys (Evaluation Visit) • Focus groups with CCs • KIIs - Block/District officers • Process tracking + KII's with DoE leadership
Cost	• Estimated time to participate for staff, CC, principal, teachers	• Process tracking

- *Teachers' Survey*: All teachers in Evaluation Visit schools will be invited to participate in this self-administered survey. Data collection procedures will follow those from BSTS (response rates=72-80%). Surveys will assess tobacco use status by type of tobacco; cessation; perceptions of school tobacco control policies, including display and enforcement of policies; awareness of tobacco control efforts; and in Intervention schools, awareness of and participation in the *TFT-TFS* program.
- *Principals' Survey:* Principals in all Evaluation Visit schools will be asked to complete a survey assessing tobacco policy implementation, any tobacco control efforts, and their tobacco use status. In intervention schools, we will assess program components implemented, ease of program implementation, factors influencing program implementation and maintenance, and competencies developed. We anticipate a high response rate based on BSTS experiences and the commitment from the DoE to support participation.

Process tracking in schools, cluster, and the DoE: The process tracking system will also serve as a monitoring tool to support program implementation and maintenance. At the school level, borrowing from the BSTS process tracking system *(Appendix G),* principals will be asked by their CC to complete a monthly checklist to capture completed intervention activities, including teacher attendance. Study staff will make monthly phone calls to CCs to ensure collection of these data. At the cluster level, we will use attendance records to measure principals' completion of *TFT-TFS* training. This system will also capture costs associated with implementation.

We will validate the process tracking measures of implementation against measures collected in the Evaluation Visit. At the district and DoE level, we will maintain qualitative tracking logs to document meetings with district and DoE officials, e.g., barriers, solutions and development of a sustainability plan.

Focus groups with Cluster Coordinators will include one per block in the intervention condition, at post-Implementation and post-Maintenance, using an open-ended moderator guide, to assess perceptions of the training, materials and approaches, and barriers to and facilitators of implementing the training.

Key informant interviews (KIIs): With *district and block coordinators* in the selected districts and blocks at two time points (post-Implementation and post-Maintenance) we will explore factors influencing support for the program and their perceptions of barriers and facilitators to the program. These KII's will be conducted in intervention and control districts in order to monitor potential extraneous differences between districts. With *DoE Leadership,* in Year 1, KIIs will assess needs related to embedding the TFT-TFS program in the organizational infrastructure; and in Year 5, we will assess progress on their sustainability plan.

3.3.7.3. Data Sources, Measures and Analysis by Specific Aim

Aim 1—Adoption, Implementation, Reach and Maintenance:

Program Adoption: *Working hypothesis:* At least 80% of schools asked to participate will **adopt** the program.

Data source: Process tracking data: Principal attendance at the training, based on attendance logs.

Measure: Adoption will be a dichotomous measure (adopted/ did not adopt). Schools will be coded as adopting the program if the principal completes the initial training session; others will be coded as non-adopters.

Program Implementation: *Working hypothesis:* At least 80% of schools adopting the program will **implement** a minimum standard for program implementation.

Data sources: (1) Evaluation Visit, including the Observation Checklist assessing the presence of posters and wall paintings of the policy; and surveys of principals and teachers to assess implementation of the program components delivered. (2) Process tracking data, including principals' monthly checklist documenting intervention components completed and teacher participation in them, to be collected by CCs during standing monthly meetings with principals. Data collected in the Evaluation Visits will be used to validate the process tracking data, resulting in a validated measure of program implementation based on the process tracking data.

Measure: Implementation will be a dichotomous measure (successfully vs. inadequately implemented). A school will be coded as having successfully implemented the program if these core program components were completed: (1) discussions with teachers addressed at least 3 of the 6 themes; (2) cessation materials were distributed to all teachers; (3) at least 4 of the 6 wall posters were hung; and (4) the tobacco policy was posted as a wall painting. If a school did not complete these core program components, it will be coded as inadequate implementation. As secondary outcomes, we will assess the extent to which each of the individual core components were implemented, and examine the percent of schools implementing all core components. Finally, the data from the Evaluation Visit will be compared to comparable data from the process tracking forms to assess the validity of the process tracking data as an accurate measure of implementation.

Reach: *Working hypothesis:* At least 80% of teachers in schools implementing the program will participate in teacher discussion sessions addressing at least 3 of the 6 themes.

Data sources: Process tracking data, including the number of the school's teachers participating in each teacher discussion, and the themes discussed, as reported by the principals. Attendance records will be collected by CCs during monthly meetings with principals, and collected by study staff during monthly process tracking calls with CC's. These data will be compared with self-reports from the teachers' survey, conducted during the Evaluation Visits, assessed using BSTS questions on program awareness and participation.

Measures: Reach will be measured as the mean proportion of teachers who attended the program activities. A second measure of reach will be obtained from self-report on the teacher's survey.

Maintenance: *Working hypothesis:* At least 80% of schools implementing the program will maintain the minimum standard for program implementation during the maintenance period. Data sources and measures will follow those used for implementation, to be collected for the maintenance period.

Data sources: (1) Evaluation Visits, as described for the Implementation measure. (2) Process tracking data, to be collected as described for the Implementation measure from all schools.

Measure: *Maintenance* will be a dichotomous measure (successfully vs. inadequately maintained), using the same measure defined for Implementation, collected during the Maintenance period.

Data analysis for the Primary Aim: Program Adoption, Implementation, Reach and Maintenance: The school is the unit of intervention and analysis; all measures will be assessed at the school level. Schools will be nested within cluster, which will be taken into consideration in the analysis. We will compute estimates of adoption, implementation, reach, and maintenance, with appropriate 95% confidence intervals. The null hypothesis for each is that the rate is lower than the outcome-specific target. We will reject that hypothesis if the lower limit of the confidence interval is above the equivalence bound described in Section 3.3.7.4.

Our primary measure of implementation and maintenance is a composite measure based on implementation of four components: teacher discussions, cessation materials, posters and wall paintings, and the tobacco policy. Each of the components will also be analyzed individually to estimate the level of implementation of each. The percent of schools that achieve successful implementation in each component as well as the percent that implement all program components will be computed along with the 95% confidence interval. These analyses will follow the same approach in assessing maintenance.

Using data from the 70 schools that participate in the Evaluation Visit, we will assess the validity of the process tracking data by examining the agreement between measures assessed by the process tracking and during the independent Evaluation Visit. For continuous measures (e.g. percent of teachers attending at least 50% of sessions), we will use the intra-class correlation. For categorical measures (e.g. implementation), we will use the kappa or generalized kappa statistic. All these measures range from 0 (or less than 0), indicating no more agreement than what is expected by chance to +1 indicating perfect agreement. We will consider agreement of +0.6 or greater to be indication of satisfactory agreement between the measures.[48]

Aim 2: Effectiveness: Determine program effectiveness in increasing implementation of tobacco control policies and tobacco use cessation. We will compare these data between the intervention and control schools, and in control schools, estimate the level of tobacco policy implementation and tobacco use cessation and monitor other tobacco control efforts. This information will be useful for understanding secular trends in India during a period of rapid change related to tobacco education and behavior change.

Data sources: Data to assess both measures of effectiveness will be collected during the Evaluation Visit, including intervention and control schools at Times 1 and 2. To assess *cessation,* we will conduct a self-administered survey of all teachers present during the visit, using data collection procedures used in BSTS (response rates=72-80%). The assessment of *policy implementation* will also follow BSTS measures, including data from the Observation Checklist and Teachers' Survey. Data on other tobacco control efforts will be assessed in the Principal Surveys during the Evaluation Visits.

Measures: *Cessation:* Based on the Teachers Surveys, we will compute 7- and 30-day quit prevalence among teachers who reported using any tobacco in the last 9 months (the length of the academic year), and compare measures between intervention and control schools at Times 1 and 2. *Policy implementation* will be based on the Observation Checklist, including the number of physical locations in the school and grounds with evidence of tobacco use (range 0 – 10, lower score indicates less evidence of tobacco use); and on the Teachers' Survey, as a composite of five questions regarding presence of a tobacco policy and it's enforcement at the school (range 0-5, higher score indicates stricter policy).[48]

Data analysis: Analyses will use the school as the unit of intervention and analysis and control for the grouping of schools within clusters, and will be conducted at 2 time points. For *cessation*, we will calculate the school-specific quit prevalence and average over the schools in each treatment condition. The difference in quit prevalence between intervention and control schools and 95% confidence interval will be estimated using statistical methods for mixed effect modeling, with the cluster included as a random effect. For *policy implementation* we will compute the difference and 95% confidence interval in the mean scores on the policy measures of intervention and control schools, controlling for the grouping of schools within clusters. We will compute the means or proportions and the change over time in the intervention and control schools separately. In the intervention schools this will provide an estimate of the maintenance of the program. In the control schools, these data and data on other tobacco control efforts will provide an estimate of the secular trends over time in the absence of our intervention.

Aim 3: Feasibility: Determine feasibility of building the capacity of cluster coordinators to train and support

principals in program implementation and maintenance in schools, and for the DoE to sustain the program. *Data sources:* (1) Process tracking to document the number and proportion of principals in each cluster who participate in each of the two training sessions offered by CCs, as documented by attendance logs of principals attending the training. CCs will also complete a checklist each month to document interactions they have had with principals, including trainings, information exchanges, coaching and TA. Study staff will collect the checklists and attendance records during regular visits to the Block Resource Centers and during phone calls with the CCs. We will also document the tobacco use status of CCs as a potential barrier to implementation. (2) Process tracking logs, capturing qualitative data on study staff meetings with DoE officials. (3) Evaluation Visit Principal Surveys, including barriers and facilitators to program implementation. (4) Focus groups with CCs, to identify barriers and facilitators to implementing the training. A total of 3 focus groups, one per block, will be conducted. (5) KII's with district and block coordinators, to assess perceptions of barriers and facilitators to CCs' participation in the program, and factors influencing program implementation and maintenance. (6) KII's with DoE leadership in Year 5, to assess barriers and facilitators to institutionalizing the program within existing structures. An independent evaluator from the Healis team will conduct these KII's. *Measures:* *Feasibility* will be measured as (1) the proportion of principals in the cluster who attended the trainings, using attendance logs, (2) barriers and facilitators to principals' implementation in the schools, based on the Principal Surveys; (3) barriers and facilitators to CCs' implementation of the training and support for the program among district, block and cluster officers, using qualitative data; and (4) DoE support for sustaining the program, based on KII's with DoE leadership.

Data analysis: For analysis of principal participation, the cluster will be the unit of analysis. Using the percentage of principals who attend the training within each cluster, we will compute the mean over all clusters as well as the 95% confidence interval. For analysis of the Principal Survey data, the principal will be the unit of analysis and we will compute the mean and standard deviation of principal responses controlling for the nesting of principals within clusters. For the qualitative data, we will conduct content analysis, a method used in anthropology to analyze qualitative data collected in the form of texts.[125] Analysis will entail intensive reading and group discussion of the full transcripts, followed by coding and thematic formulation processes based on the construction of structured, hierarchical database indexing.[126]

Aim 4: Costs: Determine the direct financial costs of program implementation and maintenance.

Data sources: Staff time, resource use and unit costs will be tracked based on the process tracking system. Costs will be assessed for the implementation period and maintenance period.

Measures*:* Cost to be monitored include: (1) Healis staff time related to intervention delivery (i.e., training CCs and providing ongoing support); (2) CCs time, including participation in the training with Healis staff and to train principals in the *TFT-TFS* program; (3) cost of printed materials and other training-related supplies; and (4) school costs, including principals' time and teacher time spent in training and intervention-related activities.

Costs related to staff time will be calculated by multiplying salaries (e.g., hourly) and time (e.g., number of hours) spent on intervention preparation, delivery and training. Study staff will obtain staff wages from the DoE. Time spent by CCs and principals will be tracked through the process tracking system, including the duration of sessions and number of participants at meetings and intervention activities. Healis staff will maintain a weekly log to ensure that time devoted to the intervention is distinguished from time spent with research and evaluation. In estimating the cost of printed materials, only production costs will be included; the time and resources spent in preparing the content of the materials will be excluded since these costs would not be incurred in a non-research setting. As our primary focus is to estimate and project the financial expenditures related directly to program implementation and maintenance, indirect costs due to lost wages of participants will not be included in the base- case analysis but may be estimated in secondary analyses to determine the full societal cost of the intervention. *Data analysis and outcomes:* We will calculate the total costs of the implementation and maintenance years by summing the costs of the individual components. We will determine significant associations of total and component costs with co-factors, such as rural/urban location, school size, student-to-teacher ratio, or district. These cost outcomes and analyses not only will be descriptive, but importantly, they will be used for projecting the financial expenditures of implementation and maintenance, and ultimately, scale-up across other states over time, to facilitate budgetary planning and resource allocation at the level of the DoE. Cost outcomes can be combined with the effectiveness outcome (Aim 2) to provide a measure of efficiency (e.g., cost per case of tobacco use cessation among teachers) that can be ultimately compared against other cessation efforts.

3.3.7.4. Sample size considerations: The primary aim is to determine the extent to which this implementation model meets acceptable rates of program adoption, implementation, reach and maintenance of the *TFT-TFS* program. As described above (Fig. 1) we will recruit three districts and select one block in each district in which to implement the program. Each block is comprised of 10 to 12 clusters and each cluster is comprised of 10 to 12 schools for a total sample of approximately 400 schools nested in approximately 33 clusters in 3 blocks. Adoption and reach will be assessed in all schools recruited. Implementation will be assessed in a random sub-sample of schools that adopt the program. (Section 3.3.7.3). All analyses will control for the nesting of the schools within the 33 clusters. We anticipate that the effect of the further nesting of clusters within blocks will negligible.

Aim 1 uses a non-inferiority design. That is, for each outcome (i.e., adoption, reach, implementation and maintenance), the null hypothesis is that the percentage for the intervention schools is lower than the target and the alternative hypothesis is that the percentage in the intervention schools is equivalent to the target or greater. The null hypothesis will be rejected if the 95% confidence interval on the outcome variable is within the non-inferiority bounds.[43,44] For each outcome we assume that π is the target proportion of schools who achieve that outcome and P is the proportion of schools that actually achieve the outcome. Delta (δ) or the equivalence margin is the largest difference between π and P that would allow us to consider the schools having achieved the target. The equivalence bound is π-δ. The lower limit of the 95% confidence interval must be greater than this value in order for us to conclude that the outcome was consistent with the target.

For our power estimation we assume 12 schools in each of 33 clusters for a total sample of 396 schools. Expected sample size for each outcome measure is based on the target to be achieved. If 80% of the 12 schools recruited in each cluster adopt the program and 80% of those implement it, then 8 schools will be evaluated for reach in each cluster (264 schools total). Among schools that adopt the program, 2 schools will be randomly selected from each cluster for a total of ~66 schools that will receive the Evaluation Visit, which we will use to evaluate implementation. To estimate the power for these outcomes, we include the variance inflation factor, which includes a measure of the within-cluster correlation (intra-cluster correlation [ICC]).

Table 3 shows the equivalence bounds for each primary outcome at 80% power and three levels of intra- cluster correlation (ICC). Based on our prior experience with worksite based studies we expect that the ICC will be approximately 0.01. We have computed equivalence bounds for ICC=0 and ICC=0.05 for comparison. If the ICC = 0.01, then we will have 80% power to detect our targets for adoption, and reach with equivalence bounds of 0.74 and 0.72, respectively. Thus for adoption we have at least 80% power of obtaining a confidence interval with a lower limit of 74% if the rate for that measure is 80% or higher.[127] For implementation and maintenance, the corresponding equivalence bound is lower, 0.63, due to the smaller sample size.

Table 3. Equivalence bounds for determining that the schools met the target for each outcome at 5% significance level & 80% power[128]

Outcome	Target (π)	Expected sample size	Equivalence bound (π-δ)		
			ICC = 0	ICC = 0.01	ICC = 0.05
Adoption	80%	396	0.75	0.74	0.71
Implementation & Maintenance	80%	66	0.65	0.63	0.55
Reach	80%	264	0.73	0.72	0.68

We have chosen a priori equivalence bounds of .70 for adoption and reach and 0.60 for implementation and maintenance. These bounds will provide greater than 80% power to detect our intervention as equal to or better than the targets for all four outcomes. If the process tracking measure of implementation proves to be valid we will evaluate implementation in the entire sample of schools using that measure and an equivalence bound of 0.70, and follow similar approaches for maintenance.

3.3.8. Potential problems and alternative solutions: Although our experiences in BSTS and our pilot study solidly support plans for this study, we also acknowledge that potential problems could arise; we have carefully considered key possibilities and prepared alternative solutions. **First**, based on our experiences, we expect a high proportion of schools to participate in the program given the strong DoE support; there is nonetheless a small possibility that we could observe lower-than-expected levels of program adoption. In that event, we would turn to additional avenues to engage principals and schools; we have strong networks of community partners and direct relationships with schools at the state, district and block levels. Our collective experiences in implementing the *TFT/TFS* and other school-based programs would provide a firm foundation for expanding

our program promotion efforts. **Second,** our working hypothesis is that CCs will be able to provide the necessary training and support for principals to implement and maintain the program. Our experiences in implementing the *TFT/TFS* program in BSTS and findings from our pilot study clearly support the feasibility of this approach. We nonetheless recognize that there is an unlikely chance that CCs could encounter challenges in providing adequate support to principals. Should this happen, we would work with partners inside the school system and with NGO's to increase support for principals, exploring options through other key stakeholders. For example, we would work with the DoE to identify others to participate in capacity building efforts; explore collaborations with the Bihar Teachers Association and community partners to expand phone and in-person contacts with principals; and identify other supportive approaches based on formative research.

3.3.9. Expected outcomes and future directions: *The outcome of this research is expected to be a replicable and sustainable implementation model that will foster tobacco use cessation among school teachers in India*. At the conclusion of this project, we expect to have a tested scalable model for implementing and maintaining a tobacco control intervention for teachers in India that can be readily adapted to diverse settings and will perform effectively in low-resource settings. We expect to have solidified our already-strong relationships with the Bihar DoE, with the likely outcome that they will institutionalize the program within schools throughout the state. These results will contribute to bringing evidence-based tobacco control interventions into practice in LMICs and in low-resourced settings in the US, where there is a profound need for such approaches. In addition, these findings will generate new knowledge to inform efforts to take evidence-based interventions to scale by contributing to the growing D&I literature, including in the US.

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