Collaborative development of a continuing education program to train healthcare providers on tobacco cessation counseling in the Republic of Macedonia.

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***Abstract**:* Macedonia has one of the highest rates of tobacco use in the world. The country lacks the public health and clinical infrastructure needed to deliver effective tobacco cessation counseling to patients within its health system. In order to address this critical medical, training, and education gap, we propose to develop and implement a comprehensive, culturally appropriate modified Certificate Tobacco Treatment Specialist (CTTS) training program for pulmonary specialists in Macedonia to help their patients quit tobacco. The adaptation of this intervention will be based on formative research, conducted to identify salient economic, socio-cultural and psychological factors associated with tobacco use in Macedonia and barriers and facilitators to successful implementation of existing cessation programs and policies. The CTTS training intervention targets pulmonary specialists who will be trained to disseminate the adapted intervention through their networks of other pulmonologists, primary care physicians, and regional pulmonary care health workers. All providers who are trained in the CTTS program will then implement, on a pilot level, tobacco treatment counseling with their patients. Evaluation will consist of a qualitative process evaluation; a longitudinal quantitative outcomes evaluation; and a brief cross-sectional survey of patients to assess their contact with a trained healthcare provider and impact on their tobacco use. Assessment of the program will focus on the number of trainings conducted and the frequency with which these providers counsel their patients to quit tobacco. Secondary outcomes at the national and policy levels will seek to measure change in attitudes for acceptability of provider-led tobacco cessation programs.

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REVIEWER COMMENTS

The reviewer comments on our letter of intent focused on allocation of the budget, stating "*Please clearly outline in the budget and budget narrative how 80% or more of the funds will go to the European based partner for in-country activities, per the requirement of the RFP*."

To ensure proper distribution of funds according to grant requirements, the budget we designed delivers 80% of the grant award ($160,000) to our partners at the Saints Cyril and Methodius University of Skopje. HFHS will ensure that these funds are paid out according to a pre-established timeline – funds will be dispersed as milestones in program activities are achieved. HFHS' Global Health Initiative (GHI) will be responsible for communicating with partners in Skopje and making payments as they report progress toward achieving grant objectives.

In our budget, funds allocated to the Saints Cyril and Methodius University of Skopje will support the following expenses in Macedonia: program staff (Principal Investigators, Project Lead, Data Collectors), data collection, data management, data analysis, software, training costs, media campaign, and travel costs. Funds allocated to HFHS will support the following expenses in the U.S.: program staff (Investigators and Project Manager), IRB review fee, publication fees, data analysis software, and travel costs.

Travel costs for Macedonian and U.S. staff are shared—the Macedonian team will train at HFHS during month 1, HFHS Project Implementation team visits at months 5, 10, 15, and 20—in order to demonstrate equity in cost-sharing and program design, implementation, and evaluation. As a cross-cultural collaborative, we deeply value face-to-face time in working to accomplish our shared goals, and we believe these exchanges are essential to the success of our partnership.

OVERALL GOAL & OBJECTIVES

Goal— *To develop and implement a comprehensive, culturally appropriate modified Certificate Tobacco Treatment Specialist training program for pulmonary specialists in Macedonia to help their patients quit tobacco.* The goals of the partner organizations, the Saints Cyril and Methodius University of Skopje Faculty of Medicine (hereafter referred to as the University) in Skopje, Macedonia and Henry Ford Health System (HFHS), Global Health Initiative and Center for Health Promotion closely align with the focus of this RFP. The University expresses deep commitment to improving care for patients with complex lung disease and lung cancer in Macedonia, and HFHS is dedicated to improving healthcare for underserved populations, thereby transforming lives and communities through health and wellness. The partner organizations provide a strong administrative and clinical base to achieve the shared goal of building capacity for tobacco-use cessation in the Republic of Macedonia.

Objectives— Macedonian healthcare leaders will partner with HFHS to accomplish the following:

- Explore existing initiatives for pulmonary specialists to advise their high-risk patients (i.e. long-term smokers with poor pulmonary health outcomes) to quit tobacco and leverage relationships to develop a technical approach with a high likelihood of success
- Adapt a Certified Tobacco Treatment Specialists training program to educate pulmonary specialists' peers on the need and techniques for counseling patients to quit tobacco
- Pilot-test the program within the University and associated COPD (Chronic Obstructive Pulmonary Disease) clinics with pulmonary specialists
- Develop plans for broader dissemination to an array of healthcare providers within Macedonia and to other Balkan states where tobacco use is high and support for quitting is minimal
- Use pilot data to secure funding for a randomized control trial to rigorously test the effectiveness of the training program

CURRENT ASSESSMENT OF NEED IN TARGET AREA

Macedonia currently lacks the public health and clinical infrastructure needed to deliver effective tobacco cessation counseling to patients within the country's health system. The current rate of smoking in Macedonia is about 37%,[i] 46.5% for men and 26.7% for women.[ii] Tobacco is very inexpensive[iii] and is part of cultural and socio-economic life for a significant number of Macedonian residents. Tobacco use is significant across all ages and social groups. Various kinds of tobacco use (raw tobacco, cigarettes, etc.) are widely accepted, as the country has been active in raising, cultivating, processing, and consuming tobacco for centuries. Universal health coverage is provided through a system of national health insurance, but tobacco cessation services and medications are not covered, and only a few cessation medications are present in the pharmacies as non-prescription products. It is critically important that we work to reduce smoking rates in Macedonia, as current consumption levels will cause devastating damage to Macedonia's health system, economy, and broader society.

There is a growing anti-smoking push both culturally and in public policy (e.g., bans on smoking in public spaces), yet because of the lack of public health and healthcare infrastructure related to tobacco prevention and cessation, there is little baseline data or information on metrics in our target area. Patient smoking history is not consistently recorded in electronic or paper patient records. As described below, we plan to document and track the number of healthcare providers who are trained to treat tobacco dependence; we believe this number is at or near zero. No data is available on provider self-efficacy or behavioral intention to counsel patients on tobacco cessation, or provider knowledge and perceptions about tobacco use and effectiveness of tobacco cessation programs and counseling. Through the pilot program evaluation, we will document whether an adapted Certified Tobacco Treatment Specialist training program can instill the necessary knowledge, skills and intentions for healthcare providers to counsel their patients on tobacco use and smoking cessation and recommend appropriate treatment modalities. As part of the longitudinal evaluation, we will ask providers to self-report the rate at which they are advising their patients regarding tobacco use. In addition, we will conduct a brief cross-sectional survey with trained health providers' patients to obtain information on whether they discussed tobacco use with their physician and if they have started the process of quitting tobacco. We will also conduct qualitative process evaluation interviews with trained healthcare providers and their patients to obtain more contextual data on the perceptions of the program content, relevancy, and delivery logistics.

TARGET AUDIENCE

The primary audience of this project is pulmonary specialists in Macedonia and their patients. Pulmonary specialists are medical providers (MD, DO) with specialized training in pulmonology, as well as trained healthcare workers (less than MD, DO) in regional dispensary clinics trained in caring for patients with COPD, asthma, and other pulmonary health issues. There are currently no formal training or continuing education programs available for any type of healthcare provider who wishes to counsel their patients on quitting tobacco effectively. Occasionally, short courses on the subject are organized by non-governmental institutions (for example, the Red Cross), but formal education for healthcare providers, including physicians, about treating tobacco dependence is not offered. Existing initiatives are very limited, and their effectiveness is hampered by an influx of income from tobacco growing in Macedonia, in addition to the prevalence of smoking behaviors—even among healthcare providers.

Through the partnership between HFHS, which offers an established, clinically-integrated tobacco cessation service to its patients, and the University, which trains healthcare providers throughout Macedonia, this project will have the reach to recruit enough pulmonary specialists to impact tobacco use among many patients, as well as the content expertise to equip those specialists with the knowledge and skills they need to counsel patients effectively.

Among those benefiting from this project are pulmonary specialists in Macedonia, who will have the opportunity to provide a higher quality of care to their patients and assist them in living

longer, healthier lives; tobacco-using patients in Macedonia, who will have decreased risks associated with respiratory and cardiovascular diseases and increased quality and length of life as a result of quitting tobacco use; and the government of Macedonia, which will benefit from data indicating potential effectiveness of a health system-based smoking cessation program that can realize healthcare cost savings if citizens of their country use tobacco at reduced rates. If this project is fully successful and replicated across all of Macedonia, not only might it help to foster policy change for improved coverage of tobacco cessation services in Macedonia, it may serve as a model for nearby Balkan countries that face similar issues around tobacco use and cessation.

PROJECT DESIGN AND METHODS

The proposed project will lay the necessary groundwork for future conduct of a rigorous randomized control trial of a health-system based smoking cessation program in Macedonia and dissemination of an evidence-based intervention within the country and at a regional level. The project includes three phases:

Phase 1: Formative research to identify salient economic, socio-cultural and psychological factors associated with tobacco use in Macedonia and barriers and facilitators to successful implementation of existing cessation programs and policies. As part of the formative research, we will conduct: 1) secondary data review of key policy and program documents related to tobacco use, associated health outcomes, and smoking cessation programs and campaigns; 2) key policy informant qualitative interviews; and, 3) community-based qualitative interviews with healthcare providers and patients at Saints Cyril and Methodius University Faculty of Medicine and Hospital. In addition, we will establish a Scientific and Policy Advisory Board (SPAB) to support current and future research and program development related to tobacco use in Macedonia.

Phase 2: Adaptation of a Certified Tobacco Treatment Specialist training program and development of evaluation tools. Program adaptation will include: 1) identification of existing programs used in Macedonia and regionally. This information will be culled from the secondary data review conducted as part of the formative research; 2) identification of core elements of these programs based on existing evaluation data [as available]; and, 3) utilization of the formative research and information on core elements of existing programs to modify the Certified Tobacco Treatment Specialist training. In parallel with program adaptation, we will develop/adapt socio-behavioral scales to measure constructs as outlined within the systems model for preventive clinical care (see Figure 1) and identified during the formative research as associated with tobacco use and smoking cessation in Macedonia. These scales will be included in outcomes evaluation tool for the trained specialists.

Phase 3: Pilot implementation and evaluation of the smoking cessation intervention program. Prior to program implementation, we will utilize a train-the-trainer model to maximize program sustainability. The smoking cessation intervention program will be piloted and evaluated at Saints

Cyril and Methodius University of Skopje Faculty of Medicine and associated COPD specialist clinics. The outcome evaluation instrument will be implemented at baseline and post-intervention (6 months post training) to document changes in healthcare providers' knowledge, perceptions, and attitudes and experiences related to tobacco use, and smoking cessation policies and programs. A brief cross-sectional survey with trained providers' patients will provide additional data on communication about smoking between patients and providers and potential impact on patient tobacco use. All quantitative survey data will be collected on an m-health application (GuideVue) (see the Evaluation Design section). A qualitative process evaluation will be conducted with trained health providers and patients to assess program to acceptability and accessibility of the intervention, and content relevance.

Data from the formative phase and the process and outcome evaluations will be used to further modify the Certified Tobacco Treatment Specialist training program content, delivery mechanisms, and materials prior to conduct of a randomized control trial (RCT) to establish rigorous scientific evidence of program effectiveness within the Macedonian health system.

Methodological Approach. The U.S. National Institutes of Health[iv] recommends the use of mixed methods for research that will benefit from real-life contextual understandings, multi-level perspectives, and cultural influences. The proposed program will utilize a mixed methods approach including: 1) utilization of quantitative data to assess magnitude and frequency and qualitative data to assess socio-cultural context; 2) inclusion of multiple perspectives (e.g., policy makers, healthcare providers, patients); 3) use of a structured triangulation[v] method; and, 4) an interdisciplinary approach to engage a range of expertise to address the biosocial complexities of tobacco use and cessation interventions.

*Theoretical Framework***.** In order to maximize our ability to identify core concepts and procedures in the adaptation and implementation of the Certified Tobacco Treatment Specialist training program and to identify effective future interventions strategies, we are basing our research on a modified 'systems model of preventive clinical care'.[vi] A unique feature of this model is the inclusion of factors related to the broader policy landscape, the health system, the health care provider and the patient within a single framework. The categories are defined and details regarding application of this framework for the current study are outlined in below in Table 1.

Figure 1

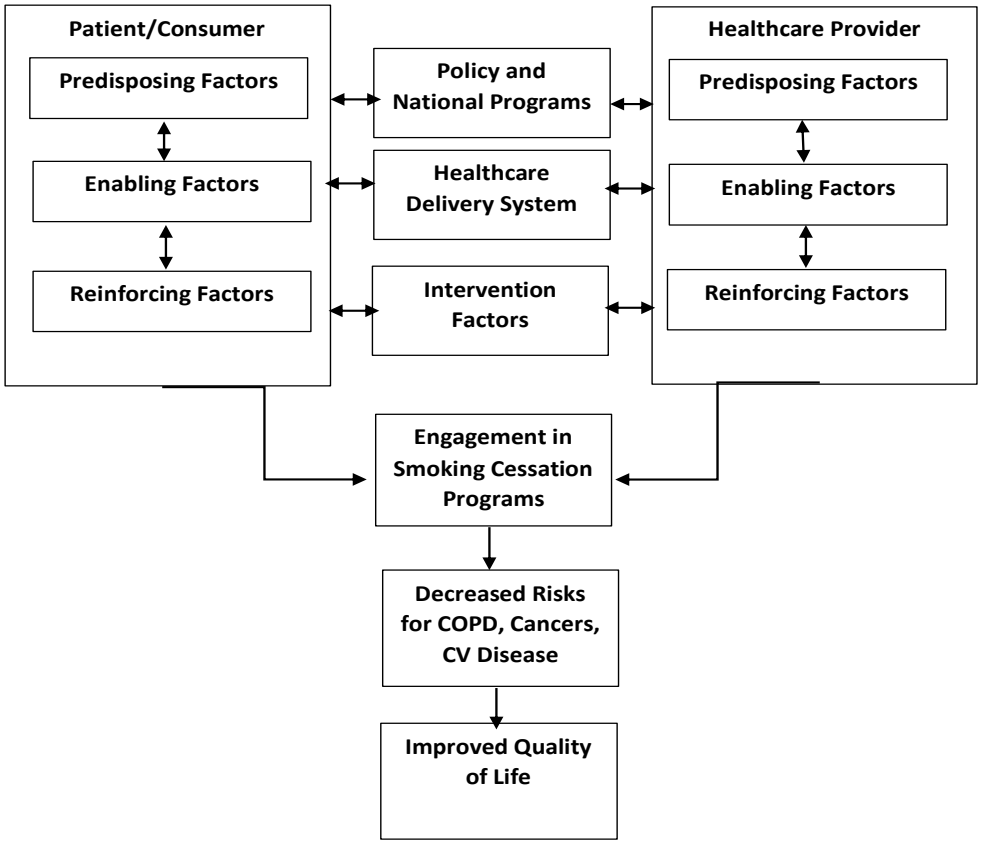

Table 1. Systems model of preventive clinical care and associated constructs for smoking cessation

Category and Definition	Target Group	Constructs
Policy and National Programs National level policies regarding tobacco sales (e.g., excise taxes), use of tobacco in public spaces, advertising restrictions, anti-smoking campaigns	Policy makers and health administrators	Perceived efficacy of current laws and policies Prioritization of smoking cessation within current health policies Knowledge of medical, social, and economic sequelae associated with tobacco use
	Healthcare providers	Knowledge of current laws and policies Self-efficacy for advocating for laws/policies Perceived effectiveness of laws/policies
	Patients	
Healthcare Delivery System National level healthcare system (public & private), associated professional organizations, NGOs	Healthcare providers	Perceived support of the health system for engaging in preventive medicine (smoking cessation program)
	Patients	Barriers to healthcare services Barriers to smoking cessation programs
Intervention Factors Characteristics of the specific intervention and variables which	Healthcare Providers	Barriers to engagement with the smoking cessation program (time, costs) Perceived efficacy of the smoking cessation program
	Patients	

Table 1. Systems model of preventive clinical care and associated constructs for smoking cessation

Category and Definition	Target Group	Constructs
may decrease or increase accessibility of the program		Level of engagement with the smoking cessation program
Pre-disposing Factors Relate to motivation to perform or promote a particular health behavior (smoking cessation)	Healthcare providers	Educational experience Experience with smoking cessation programs Personal smoking experience
	Patients	Experience with smoking cessation programs Perceptions of social roles (e.g., gender) and use of tobacco Perception of difficulty of quitting
Enabling Factors Relate to skills and resources needed to perform or promote a particular health behavior	Healthcare providers	Knowledge of treatment options Knowledge of smoking cessation programs Self-efficacy for supporting patients engagement in smoking cessation actions
	Patients	Knowledge of treatment options Knowledge of health outcomes Knowledge of smoking cessation programs Self-efficacy for engaging in smoking cessation program
Reinforcing Factors Relate to factors that support or reward engagement or promotion of a particular health behavior	Healthcare providers	Professional support for promotion of smoking cessation programs Perception of positive health outcomes for patients
	Patients	Social support for quitting use of tobacco Outcome expectations of quitting Perceived positive impact of health and life quality Perceived broader social norms for tobacco use Subjective norms for smoking among peers and support network

Formative Research. The proposed formative research will include assessment of tobacco and smoking cessation policies and programs, and socio-cultural and psychological barriers and facilitators for successful implementation of a smoking cessation program within the Macedonian health system. The formative research will also be used to identify populations which may be a higher risk for tobacco use[vii] [viii] and potential avenues for targeted intervention messaging for those populations.

Policy Research Objectives. The engagement of policy makers is an essential component of program development and implementation. This engagement must include eliciting input from policy makers in relation to current country-level health priorities [ix] and their participation in decisions regarding how specific health programs fit within the larger political and health system infrastructures and policy objectives. In the current proposal, we will conduct face-to-face

interviews with policy makers (phase 1) and through the establishment of a Scientific and Policy Advisory Board (SPAB) (explained later in this section). The objectives of the policy component are to identify:

1. Lessons from experiences with on-going smoking cessation and tobacco policies and programs in Macedonia and determine how these lessons and contributing political-economic factors could apply to an intervention within the health system infrastructure;
2. Links between policies and program development and delivery, and how to capitalize on facilitators and address barriers as they might relate to a health system based intervention;
3. Available resources related to smoking cessation and tobacco use, how those resources are utilized by policy makers, and needs for additional resources to enhance decision-making regarding tobacco policies in Macedonia;
4. Perceived constituent support for specific laws and policies related to tobacco use and smoking cessation campaigns;
5. Effective communication channels for reporting progress of the proposed program to policy makers including regularly scheduled meetings of the SPAB.

Review and Cataloguing of Key Policy and Program Documents. Secondary sources of information will be collected and summarized during the formative phase and up-dated throughout the proposed project. These documents will include governmental and non-governmental public health reports, relevant data on related health issues (e.g., respiratory diseases), documents related to tobacco program and policy developments and implementation, and scientific papers and reports on smoking cessation program evaluations. Documents will be identified through standard research search mechanisms, as recommended during key policy informant interviews and by SPAB members), and through our local colleagues at Saints Cyril and Methodius University. Non-English documents will be reviewed by trained translators and summaries and key points translated into English. A database will be developed to catalogue the policy and program documents by topic and sources.

Key Policy Informant Interviews. During the formative phase, a series of face-to-face interviews will be conducted with identified National policy makers and program administrators, opinion leaders, and other key stakeholders in the areas of tobacco use and smoking cessation. The Macedonian research investigators will identify potential respondents and contact them with information about the project and proposed program. Respondents will include representatives from the Ministry of Health, other Ministries associated with tobacco and smoking policies and regulations, National Health Insurance administrators, International and National NGOs, National professional associations (e.g., Medical Societies), and university and hospital administrators. Additional stakeholders will be identified during the interview process. We estimate approximately 10 to 15 interviews. The face-to-face interviews will be conducted individually or in small groups. The interviews will be semi-structured using an interview guide developed by the research team. These methods have been found to be appropriate for interviewing high-level informants and for creating an informal atmosphere conducive to expression of ideas. [x] This method also allows for probing and clarification of responses, as well as the identification of new

issues to explore. Each interview will be ~45-60 minutes. Interviews will be digitally audio-recorded with permission from the respondent(s) and extensive notes will also be taken during the interview process. The notes will allow immediate access to the data to identify emerging issues and adapt the interview guide as needed. Audio-recorded data will be transcribed and translated into English (as necessary). Information on data management and analysis will be explained later in this section.

Establishment of the Scientific and Policy Advisory Board (SPAB). After completion of the policy formative phase, we will identify National level policy makers and health administrators, and University leaders to participate in the SPAB. Additional members will include local representative from multilateral and regional health organizations (e.g., WHO). The purpose of the SPAB is to: 1) comment on program adaptation and provide feedback on emerging issues related to program implementation; 2) participate with the research team on interpretation of research findings; 3) identify dissemination mechanisms and venues; and, 4) collaborate with the research team on identifying next-steps and resources to enable development and implementation of a RCT and future program implementation at the National and Regional levels. The SPAB will meet by Skype/conference call on a quarterly basis. When possible, meetings will also be arranged when U.S. team members are in Skopje. The SPAB will also be key participants in the post-program dissemination workshop (see the Workplan and Deliverables section).

Community-based Formative Research. For the proposed project, we are defining the community as the Saints Cyril and Methodius University of Skopje Faculty of Medicine Hospital and associated COPD clinics. To date, there is very limited data on the barriers and facilitators for implementation of a health-system based smoking cessation program in Macedonia or the region. In order to adapt the program effectively, it is necessary to have knowledge regarding socio-cultural and psychological factors which affect tobacco use and smoking cessation efforts from the perspectives of multiple stakeholders. The objectives of the community-based formative research are to identify:

1. Healthcare providers' (pulmonary physicians and specialists) and patients' perceptions of barriers to healthcare within the Macedonian health system;
2. Healthcare providers' knowledge regarding tobacco use within patient populations and perceived barriers to decreasing tobacco use in diverse socio-cultural population groups (e.g., ethnic, gender, age);
3. Healthcare providers' perception of their role and self-efficacy in promoting smoking cessation;
4. Healthcare providers' perceptions of professional support in delivery of preventive medicine including promotion of smoking cessation;
5. Patients' knowledge regarding the risks of tobacco use for themselves and their communities;
6. Patients' perceptions of social roles and settings within their communities which promote or discourage use of tobacco;

7. Patients' and healthcare providers' knowledge and perceptions of treatment options and smoking cessation programs, policies, and campaigns and their effectiveness;
8. Patients' and healthcare providers' personal experiences with smoking cessation and the challenges for success.

It is important to note, that while the primary objective of the intervention program is to train healthcare providers to communicate with patients about tobacco use and facilitate patient participation in smoking cessation interventions, a secondary objective is to also decrease rates of tobacco use among healthcare professionals in Macedonia. In a study at Saints Cyril and Methodius University, 25% of medical students reported tobacco use. [xi]

The community-based research will be conducted at the Saints Cyril and Methodius University of Skopje Faculty of Medicine and community COPD clinics. The community formative research will include face-to-face individual qualitative interviews with healthcare providers (including pulmonary physicians and other pulmonary healthcare specialists), and a diverse selection of patient representatives from the health system catchment area population. A purposeful recruitment and sampling strategy will be employed with significant input from the Macedonian research investigators and team. While qualitative sampling is less stringent than methods used for quantitative research, certain measures will be utilized to ensure that participants are representative of significant dimension of the targeted populations (healthcare providers and patients). [xii] Sampling dimensions for healthcare providers will include: 1) position; 2) years of practice; 3) demographics, e.g., age, gender. Sampling dimensions for patients will include: 1) tobacco use status (past or current); 2) health status (e.g., presence/absence of cardiovascular, respiratory chronic conditions); 3) socio-economic and demographic characteristics. Other dimensions may be identified during the formative research and will be added to the list.

An estimated 8 to 10 interviews will be conducted each with healthcare providers and patients (total 16 to 20 interviews). As is standard practice in qualitative research, 'data saturation' will be used to finalize our sample size. Data saturation refers to the point at which no new information or themes are emerging with the data – this approach allows for sufficient data to fully assess observed patterns. As with the key policy informants, we will develop interview guides which are specific for healthcare providers and patients, but which have parallel topics to allow for comparability across groups. Data collection will follow procedures outlined for the key policy informant interviews.

Qualitative Data Management and Analysis. All transcribed and translated qualitative data (key policy informants, healthcare providers, patients) will be entered into a qualitative data management software program. Within the management software program, each transcript will be linked to demographic (e.g., gender, ethnicity) and other salient information about the respondent (e.g., years' experience as provider, tobacco use status). The research team will develop a coding dictionary. Code words will be based on project objectives, key components of the Certified Tobacco Specialist Training, and constructs within the systems model for preventive

clinical care (see Table 1). All data will be coded by trained research assistants in Macedonia with 20% double coding to ensure consistency across coders. Double coded transcripts will be reviewed by Dr. Linda Kaljee and Project Manager at HFHS and inconsistencies will be discussed via conference call/Skype with coders and resolved through clarification of code definitions and application.

After all transcripts are coded, a search grid will be developed and implemented. The search grid will include related code sets, as well as transcript identifiers (e.g., respondent group [policy makers, healthcare providers, patients], demographics [gender, age]) to be used for comparative purposes. Code sets will be run and key findings listed with supporting text from the transcripts. These summaries will be reviewed for emergent issues and additional code sets will be developed and implemented. The initial search grid will focus on: 1) experiences with smoking cessation intervention programs; 2) political and economic facilitators and barriers to implementation and effective outcomes from smoking cessation programs; 3) socio-cultural facilitators and barriers to implementation and effective outcomes from smoking cessation programs; 4) perceptions of the roles and responsibilities of policy makers, administrators, healthcare provider, and community members for decreasing tobacco use; and, 5) prioritizing smoking cessation with other health programming in Macedonia. Data will be analyzed for patterns and consistencies, and well as contradictions within and across groups of respondents.

PROGRAM ADAPTATION

Adaptation of Certified Tobacco Treatment Specialist Intervention. To best equip healthcare providers in Macedonia with the tools they need to address tobacco use with their patients and counsel them to quit effectively, we plan to adapt elements of programs used in the U.S. for training of Certified Tobacco Treatment Specialists (CTTS). These training programs are intended for healthcare professionals for whom a significant portion of their work time is devoted exclusively to counseling patients to quit tobacco, and typically represent a commitment of multiple days of training to solidify counseling techniques and knowledge. Because healthcare provider time to devote to tobacco cessation counseling is limited, we anticipate that a condensed version of this training lasting 1-2 days will be more appropriate to their capacity. However, the condensed training would still include all of the key elements encompassed in typical CTTS training. This material would be adapted for cultural appropriateness and revised with information about tobacco use that is specific and relevant to the Macedonian patient population.

As with CTTS training in the U.S., we anticipate our project's training would begin by reviewing the cultural backdrop and context of tobacco use in Macedonia. This will be accomplished through the formative research and additional literature reviews and be inclusive of a comprehensive review of tobacco's health effects; history and current trends of tobacco use in Macedonia; nicotine addiction and other determinants of tobacco dependence; and best practices for health systems and healthcare professionals. Significant time will be devoted to appropriate counseling approaches for assisting patients in quitting, particularly Motivational

Interviewing and other cognitive and behavioral modalities. Medications and other quit aids and strategies would also be reviewed. The ultimate goal would be to develop healthcare providers' skills in treatment planning for tobacco cessation, helping them to support patients in creating a quit plan and setting a quit date, and encouraging follow-up to prevent relapse.

Training Process. Eight pulmonary specialists from the University's Faculty of Medicine will be trained in the adapted CTTS intervention. These pulmonary specialists are medical providers who, as trained trainers, will facilitate training workshops with other pulmonologists, and a cadre of non-physician pulmonary care medical workers. We anticipate each facilitator will train 8 to 10 healthcare providers at the University and through the COPD community clinics (also see sample size estimate in Outcome Evaluation). Macedonia has an infrastructure with approximately 14 regional clinics designed to support the treatment of patients with COPD, asthma, and other pulmonary-related health problems. These pulmonary health workers may play an important role in the dissemination of the intervention and the education and counseling of patients and medical providers in their regional clinics.

EVALUATION DESIGN

The proposed program will include: 1) a qualitative process evaluation; 2) a longitudinal quantitative outcomes evaluation; and, 3) a brief cross-sectional survey of patients to assess their contact with a trained healthcare provider and impact on their tobacco use. All quantitative data will be collected using an m-health application (GuideVue).

Development of evaluation tools. The content of the evaluation tools will be based on the constructs within the systems model for clinical prevention research (see Figure 1 and Table 1). Formative qualitative research data will be used to modify existing scales, e.g., subjective norms, self-efficacy, to address socio-cultural contexts specific to Macedonia. Once scales are adapted and translated, we will conduct qualitative *cognitive interviews* with the target populations (healthcare providers and patients) to assess: 1) mutual understanding of the scale items; 2) appropriateness and usability of the response options; 3) readability; and, 4) translation issues. We estimate approximately 4 to 6 interview per target group. Extensive notes will be taken during the cognitive interviews and changes incorporated into the scales after review of the notes. After these changes have been completed, we will conduct a quantitative pilot with 20 respondents per target group to assess scale internal consistencies (Cronbach's alpha). Modification will be made to the scale to optimize internal consistency to $\alpha \geq .65$.

Once all changes are completed and translated into Macedonian, the final evaluation tool will be back-translated to English to maximize accuracy of the translation and ensure original intent is maintained. Any issues with translation of terms will be reviewed with local investigators and a decision reached on the best wording choice.

Data Collection. Outcome evaluation surveys will be self-administered. Data will be collected at baseline (pre-intervention) and post-intervention (6 months after training). The outcome evaluation data will be collected electronically using Android tablets equipped with GuideVue. GuideVue is a customizable training and data collection applications and employs a simple point-and-click interface for easy self-administration of surveys. Data can be initially sorted without internet access and later synced to the database when internet is available. GuideVue will also provide data collectors with on-going access to standardized data collection procedures to maximize consistency across individuals and data collection points (baseline/post-intervention). Trained data collectors will be available to answer questions and address any technical issues. Data will be downloaded on a daily basis through a secure web-site.

Measurable Outcomes. The **primary outcome** is healthcare provider engagement in the promotion of smoking cessation after participating in the Certified Tobacco Treatment Specialists training program (Hypothesis 1). The **secondary outcomes** are identification of factors which increase likelihood of engagement in the promotion of smoking cessation, as described in the theoretical framework (Hypotheses 2-6).

Table 2 Hypotheses and associated variables	
H1. At post intervention compared to baseline, trained healthcare providers will be more likely to report discussing tobacco use with their patients.	Frequency of discussing tobacco use with patients (continuous)
H2. At post intervention compared to baseline, trained healthcare providers will be more likely to report a positive experience with smoking cessation training (pre disposing factor)	Reported attitudes regarding smoking cessation training (categorical)
H3. At post intervention compared to baseline, trained healthcare providers will be more likely to report a knowledge of treatment options for smoking cessation (enabling factor)	Knowledge scale for treatment options (continuous)
H4. At post intervention compared to baseline, trained healthcare providers will report feeling more self-efficacious discussing smoking cessation with patients (enabling factor)	Self-efficacy scale for communication with patients about smoking cessation (continuous) Provider – patient communication scale (continuous)
H5. At post intervention compared to baseline, trained healthcare providers will report greater professional support for engaging with patients about smoking cessation (reinforcing factor)	Professional support scale (continuous) Social norms for healthcare providers' roles in decreasing tobacco use
H6. At post intervention compared to baseline, trained healthcare providers will report patients are healthier and lead a better quality of life as a result of the providers' communication about smoking cessation	Perceived patient health status (categorical) Perceived patient quality of life (categorical)

Sample Size Calculation. The sample size is based on the primary outcome (hypothesis 1). For conduct of a t-test (continuous variable) with an effect size of .4, power .9 and α=.05, a minimum sample size of 55 is needed. Eight facilitators and 64 to 80 physicians and other pulmonary care specialists will be trained for a minimum total of 72 participants.

Quantitative Data Management and Analysis. Prior to data analysis, variables will be created for scales. We will compute descriptive statistics and data will be screened for missing cases, outliers, and normality of distributions. We will identify demographic subgroups of interest by systematically categorizing individuals (e.g., gender, professional education). Bivariate analysis including Pearson's chi-square (categorical variables), and independent t-tests and ANOVA (continuous variables) will provide data regarding associations and relationships between salient groups and outcome measures[xiii]. Multinomial logistic and linear regression analysis will be used to control for confounding factors and further refine relationships between independent variables and healthcare providers' levels of engagement with the smoking cessation program.

Process Evaluation. We will conduct a qualitative process evaluation with participating healthcare providers after the initial training and again at 6 months post-training. The purpose of the first set of interviews will be to obtain information regarding the providers' experiences with the Certificate Tobacco Treatment Specialist program including: 1) perceived relevancy of the materials and content; 2) delivery of the information; and, 3) time commitment and workload. The second set of interviews will focus on experiences of the healthcare providers implementing the training within their practice and their perceptions of patient acceptance of the information/treatments offered. In addition, we will conduct qualitative interviews with patients at 6 months post-training. These interviews will focus on patients' experiences with information and treatments provided by their physician, perceived impact on their ability to decrease/stop tobacco use, impact of change in tobacco use on their health and quality of life, challenges faced in relation to smoking cessation, and familial/peer support for their decision to stop tobacco use. These process evaluation will be combined with other data sources to make additional changes to the Certificate Tobacco Treatment Specialist program and training materials, identify issues facing patients who are attempting to stop tobacco use, and adapt scales for future evaluation of impact of the program on patients. We anticipate conducting 6 to 8 interviews each with healthcare providers and patients (total 12 to 16 interviews). Data management and analysis will follow procedures described in the Formative Phase.

Brief Cross-sectional Survey of Patients. In order to increase knowledge of impact of the training, a cross-sectional survey will be conducted with patients. This brief survey will include items on: 1) patient demographics; 2) patient medical conditions; 3) communication with the trained healthcare provider about tobacco use (e.g., during the last six months, did your healthcare provider ask you if you smoke or use tobacco?); and, 4) stage of change scale for tobacco use.
The survey will be conducted 6 months post-training in the pulmonary clinics staffed by the trained healthcare providers. Respondents will be screened for current or recent use of tobacco (have you used tobacco in the past 6 months) and only those with a history of tobacco use will be included in the survey. We will randomly select participants (e.g., every 5th patient coming for an appointment on the days of data collection). Based on confidence interval of .05 and confidence level of 95%, we will need to interview 377 patients.

Trained data collectors will enter data in the GuideVue and similar management procedures will be used as described for the outcome evaluation survey. Descriptive and bivariate analysis will be conducted to describe relationships between demographic and medical conditions and stage of change for tobacco use, and between communication and stage of change for tobacco use.

DETAILED WORKPLAN AND DELIVERABLES SCHEDULE

Our project will proceed in four phases: Program Development (Phase 1), Program Implementation (Phase 2), Program Evaluation and Dissemination (Phase 3).

Phase 1 will take place during the third and fourth quarters of 2016, and encompasses the hiring of project staff, identification of physician champions, formative research and program adaptation required to create the training program for providers. Deliverables from this phase include a policy and community assessment, a messaging strategy for recruitment of physician participants in Macedonia, and the training program itself.

Phase 2 will take place during the first quarter of 2017, and is centered on the research and adaptation of the Certified Tobacco Cessation Specialist intervention. Data review of formative research along with cooperative identification of appropriate intervention program elements takes place in this phase. The full adaptation of the intervention will require an iterative approach with providers and health educators to find the most culturally appropriate fit, so some data collection and cognitive interviewing will take place. The scales for the outcome evaluative will also be developed in this phase. A distribution of funds will take place to the Macedonia team upon the final adaptation of the intervention.

Phase 3 will take place during the remaining quarters of 2017 and all of 2018. This phase includes the training of facilitators for the training program, identification and recruitment of providers to be trained, delivery of provider training and implementation of the communication strategy, and a period of time for providers to put their new cessation counseling knowledge and skills into practice. This phase also includes implementation of the longitudinal trained healthcare provider outcome evaluation, the patient brief cross-sectional survey, and the qualitative process evaluation. Deliverables from this phase include completion of train-the-trainer sessions, delivery of provider training, and data sets for the outcome evaluation, the patient survey, and the process evaluation. Distribution of funds will occur upon completion of these deliverables.
Toward the end of the third quarter, we will review and refine the CTTS training materials based on the outcomes and process evaluation results. Deliverables from this phase include analyses of the evaluation data sets and a revised and refined protocol for the provider training program. Distribution of funds will occur upon completion of these deliverables.

Dissemination Plan. Final elements of Phase 3 include sharing training materials with hospital administration and the Macedonian Ministry of Health, drafting and submitting manuscripts to relevant journals, developing a plan to expand the training to other Balkan countries and

convening a national/regional training to deliver the program to a larger group of European providers. Deliverables from this phase include the submission of at least one manuscript to a journal for publication, convening the national/regional training, and developing and disseminating a presentation describing the program and its results. The final distribution of program funding will be distributed to Macedonian partners upon completion of these deliverables. The complete work plan listing project milestones and deliverables appears in Table 3, and includes specific legends to indicate when evaluation activities will take place and when program funds will be dispersed.

Table 3.

WORK PLAN

Tasks (Deliverables in *Bold Italics*)	Task Lead	Month Due Date	Q3 2016	Q4 2016	Q1 2017	Q2 2017	Q3 2017	Q4 2017	Q1 2018	Q2 2018	Q3 2018	Q4 2018
Phase 1: Formative Research												
Identify Macedonian Physician Champions	MPI	Sept 16										
Identify & Conduct ***Community Needs Assessment***	ALL	Sept 16	★	$$								
Conduct Formative Research (CBPR) into Use & Culture of Tobacco	HFPI	Nov 16		★								
Phase 2: Adaptation of Certified Tobacco Treatment Specialist Intervention												
Conduct Data Review & Identify Core Program Elements for Intervention	HFPI/GHI	Jan 17										
Adapt ***Certified Tobacco Specialist Training Intervention***	ALL	Jan 17				$$						
Build Socio-behavioral Scales for Pilot Evaluation	HFPI	Feb 17										
Phase 3: Pilot Implementation												
Conduct ***Training of Trainers*** (Macedonian Physician Champions) at HFHS Detroit	HFPI	May 17				★						
Identify 100 Pulmonary & Family Med Providers for Pilot Intervention	MPI	May 17										
Conduct ***Provider Training***	PROG/HFPI	Jun 17				★	$$					
Providers Conduct Motivational Interviewing (***Data Collection/Analysis***)	PROG	Sep 17					★	★	★	★		
Providers Conduct Quit-Planning Counseling Sessions (***Data Collection/Analysis***)	PROG	Oct 17					★			★		
Conduct Qualitative Interviews with Providers (***Data Analysis***)	MPI	Jan 18							★	★		
Conduct Qualitative Interviews with Patients (***Data Analysis***)	MPI	Mar 18							★	$$ ★		
Make Changes to Intervention Curriculum	HFPI/GHI	May 18								★	★	
Refine ***Provider Training Materials***	HFPI	Sep 18										
Share Training Materials with Hospital/University Admin	PROG	Sep 18										
Share Training Materials with Ministry of Health	PROG	Sep 18										
Identify Expansion Partners	MPI	Aug 18										
Create & Implement ***Expanded Provider Training***	ALL	Sep 18									$$	
Convene a ***National/Regional Training for European Providers***	PROG	Oct 18									★	
Draft Executive Summary	GHI	Nov 18										
Draft and Submit ***Journal Manuscript(s) for Publication***	HFPI	Dec 18										
Create & Disseminate ***Presentation***	MPI/HFPI	Dec 18										

Legend

Responsible Parties

Macedonia Principal Investigators (MPI)

HFHS Principal Investigators (HFPI)

Macedonia Program Staff (Prog)

HFHS Program Coordinator (GHI)

Whole Team (ALL)

Key Timeline Elements

★ Evaluation Component/Feedback Loop

$$ Payment Disbursement to Macedonian Partners

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