TiTAN Crete - Tobacco treatment TrAining Network in Crete

B1. Overall Goal & Objectives 2 B2. Technical Approach 2 2.1 Current needs assessment: Why Greece? 3 2.2 Intervention Design and Methods 4 2.3 Program Evaluation 7 2.4 Policy implications 11 2.5 Strengths 11 2.6 Main risks and contingency measures 11 2.7 Dissemination 12 2.8 Future Directions 12 B3. Detailed Workplan and Deliverables Schedule: 12 Workplan 12 Deliverables Schedule 13 Project Timeline 13

Partner 1: Clinic of Social and Family Medicine (CSFM), University of Crete18

F: Letters of Commitment 24

A. Table of Contents

B. Main Section

B1. Overall Goal & Objectives

Our goal is to develop a network of trained primary health care (PHC) providers in Crete, Greece that will integrate treatment of tobacco dependence into daily clinical practice and become champions of tobacco control policy. The above capacity development and creation of this new "node" of the Global Bridges network will be performed through the triangulation of a formal PHC professional training program based on the Global Bridges resources, the local adaptation of an evidence-based approach successfully applied in Canada, and post-training follow-up to enhance sustainability and network development.

<u>Aim 1:</u> To develop a multi-component tobacco treatment training program for PHC providers in Crete, Greece.

Activity 1.1: Develop a faculty of tobacco treatment experts, PHC providers, and stakeholders who will deliver tobacco treatment training to the PHC providers.

Activity 1.2: Create a curriculum/training program on tobacco treatment for PHC based on national and international experience and best practice guidelines.

<u>Aim 2:</u> To adapt and deliver the provider/practice resources to ensure maximal sustainability among PHC providers in Crete, Greece.

Activity 2.1: Conduct a needs assessment with PHC providers in Crete.

Activity 2.2: Produce a set of tools in Greek which are designed to support the 3As model of tobacco treatment.

Activity 2.3: Deliver advanced tobacco treatment training to the existing practice-based research network within PHC in Crete.

Activity 2.4: Perform program evaluation to inform program refinement.

Activity 2.5: Engagement of PHC practice networks for continued expansion of the Global Bridges tobacco treatment network in Greece.

B2. Technical Approach

The mission of the Global Bridges Program is to create and mobilize a global network of healthcare professionals and organizations dedicated to advancing evidence-based tobacco dependence treatment and advocating for effective tobacco control policy. Specifically this project will rest on three main pillars of the Global Bridges Program:

- ✓ Expand the number of healthcare professionals committed to treating tobacco dependence: The project will set up the infrastructure to deliver training as well as set-up practice-level supports to address barriers to delivering evidence-based tobacco treatment, with the overall mission to create champions in both tobacco treatment and advocacy.
- ✓ <u>Promote collaborations across multiple countries and across regions:</u> This project will support a new collaboration between the Faculties of Medicine at Universities of Ottawa (Canada), Crete (Greece) and the Harvard School of Public Health (USA) which has been created for the shared purpose of increasing the number of trained health professionals

2

- committed to treating tobacco dependence in PHC in Crete. These entities bring significant expertise and knowledge in tobacco dependence and capacity development to the project.
- ✓ <u>Building on existing infrastructure:</u> The TiTAN-Crete proposal will be based on an existing Practice-Based Research Network (PBRN), of the Clinic of Social and Family Medicine (CSFM) of the University of Crete. This existing research network is devoted to promoting the provision of PHC in Crete and augmenting the capacity of PHC providers in addressing issues related to health promotion. In line with the above, the CSFM has implemented a post-graduate master's course in General Practice/PHC and developed an extensive practice-based research network of 20 PHC clinics in community catchment areas in Crete-with stellar research achievements. This network will provide an excellent and fertile ground to develop Global Bridges in Greece.

2.1 Current needs assessment: Why Greece?

While Greece "technically" is not a low or middle income country, its current economic crisis has had drastic implications on economic indexes, health care provision and population health. In 2013 the Gross Domestic Product (GDP) for Greece fell —again- by 6.4%, while its national debt according to the World Bank is approximately 300 Billion Euros (half a trillion dollars). The fiscal situation has resulted in large cuts to the nation's social and health care programs and restricted training opportunities and PHC provider services, especially among preventative measures. There has been also been a documented increase in acute and chronic disease prevalence in Greece that is attributed to the current economic situation. The economic crisis hence poses both a challenge to population health, but also an opportunity to enhance the understanding of how tobacco dependence in Greece is responsible for a huge burden of noncommunicable disease morbidity and mortality and health care spending.

Currently, Greece has one of the highest smoking prevalence among members of the European Union, estimated at slightly above 38% of the adult population⁴, a staggering percentage of smokers. In 2011, smoking accounted for almost 200,000 hospital admissions (8.9% of the national total), with attributable hospital treatment costs calculated at over 554 million Euro, which represents 10.7% of the national hospital budget.⁵ These are dramatic numbers for a country with a population smaller than that of New York. Notably though, despite this enormous burden to the healthcare system, our research has indicated that a significant percentage (44%) of tobacco users in Greece are interested in quitting in the immediate future.⁶ Hence, there has never been a more important time for international collaboration and innovation to address the leading preventable cause of death among Greek citizens, tobacco dependence. Now is the time to make tobacco control history in Greece and Global Bridges can help tip the balance.

Primary health care has an operational advantage in overall health promotion, a key component of which is tobacco prevention and smoking cessation. The World Health Organization (MPOWER)⁷ has called for smoking cessation to be integrated into primary health care globally as patient centered primary care is seen as the most suitable health system "environment" for providing advice on smoking cessation as PHC practitioners have a framework to advocate for smoking cessation within their daily practice.⁷⁻⁹ However, despite the evidence supporting the efficacy of smoking cessation interventions, our team has

documented a practice gap in the rates at which 5As smoking cessation interventions are delivered by primary-care practitioners. ^{10,11} This gap in clinical practice is especially true in developing countries or in countries under fiscal constraints, such as Greece. A study of patients with COPD found only 56.5% of PHC providers in Crete engage in behavioral counselling and only 13% of PHC practitioners engage in pharmacotherapy, indicating the need for improvement in the two domains of tobacco treatment. It is expected rates will be much lower in the general population of tobacco users. Moreover, previous research performed by our team has also indicated a significant lack of evidence-based practice and knowledge in terms of smoking cessation among GPs and health care professionals. ¹⁴

2.2 Intervention Design and Methods

Primary audience for this project: The target audience for the intervention program will be PHC professionals practicing in the catchment area of the PBRN located in Heraklion and surrounding region, Crete, Greece. These 20 practices serve a defined population of 135,761 residents of which 38% of adults are tobacco users. All members of the primary care practice including general practitioners, nurses, midwives, and other allied health professionals will be targeted. This PBRN of the CSFM has successfully collaborated on a number of research projects with members of the investigative team (Lionis, Vardavas) and other groups. 11,14,16-19 The personnel within these practices are expected to be the direct beneficiaries of this program as well as the patients they serve who will benefit from increased cessation support.

Approach: This project will adapt an evidence-based multi-component intervention program originally developed and rolled out in primary care practices in Canada for use in Greece. This intervention will be augmented with resources from the Global Bridges forum, so as to ensure existing tools from these two resources that will be contextualized to the PHC setting of Greece.

Intervention Program: The three A's (Ask, Advise, Act) model will be used as the clinical framework for integrating tobacco treatment into routine primary care practice for this project. We will emphasize a team-based approach which involves nurses, physicians, and community social workers in the delivery of treatment. Strong evidence shows that multi-component interventions that combine practice-based, provider and patient-level intervention strategies are most effective method for increasing provider performance in the delivery of smoking cessation treatment and improving cessation rates among patients. 20-22- As such, the intervention program planned will employ the following evidence-based strategies for increasing the uptake of tobacco treatment in primary care settings: 1) provider training in evidence-based tobacco treatments; 2) real time provider reminders, 3) provider performance feedback, 4) the use of key opinion leaders, 5) practice-outreach support. This project will build on the significant experience of the University of Ottawa Heart Institute (Papadakis, Pipe) in influencing PHC provider behaviors and attitudes related to tobacco control, an approach known as the Ottawa Model for Smoking Cessation. The Canadian primary care treatment network which launched in 2009 now includes more than 70 Primary Care Practices in Ontario serving more than 1.5 million tobacco users and continues to expand. Two evaluations of the

Ottawa Model for smoking cessation in primary care clinics (k=35) documented significant increases in tobacco treatment delivery; an average 16-23% increase in rates of offering support (range 10-40%) and patient quit attempts. ¹⁰

Adaptation to Local Context and Network Capacity Development: Adapting to local context is critical to successful knowledge translation programs.²³⁻²⁴ In this project we will engage local providers in the adaptation of an evidence-based model and will develop and support rollout in daily clinical practice. As such our approach to training will be to ensure early involvement from the local faculty that will support the establishment of a network of local tobacco treatment champions with expertise in evidence-based tobacco treatment and can facilitate the future rollout of the treatment network. Champions have been identified as part as proposal development and will be enhanced throughout the duration of the project. Additionally we will employ tactics to support community mobilization related to tobacco treatment and policy by engaging local and regional municipalities and decision makers.

Theoretical Framework: Ajzen's the Theory of Planned Behavior (TPB) has been used to guide intervention design. We will employ several tactics within the training curricula and multicomponent intervention program to enhance uptake into practice which are grounded in behavioral change theory. Specifically the intervention program will target: i) provider attitudes towards tobacco use and treatment, ii) the establishment of new social and clinical norms related to tobacco treatment in primary care practice settings (normative beliefs), iii) increasing providers perceptions about the ease of delivering tobacco treatment (perceived behavioral control), and iv) providers intentions to deliver 3As treatments to patients. TPB has been used in multiple previous evaluations of smoking cessation interventions. Members of the project team have had extensive experience in the design of theory-based intervention programs and evaluation projects. 10,26-29

Intervention Activities: Below is the description of the methods and approach that will be used:

Aim #1: To develop a multi-factorial tobacco treatment training program for PHC providers in Crete, Greece.

<u>Activity 1.1:</u> Develop a faculty of tobacco treatment experts, PHC providers, and stakeholders who will deliver tobacco treatment training to the PHC providers.

We will establish the local faculty who will be involved in the championing and deliver training content. The local faculty already identified for this project will be enhanced by the inclusion of one representative from both the Municipality of Heraklion and the region of Crete. The local faculty will work alongside international trainers (Ottawa, HSPH) and experts that will be invited from the Global Bridges network to participate by webinars.

Deliverable 1.1: List of faculty and trainers with identified role in program delivery (D1.1).

<u>Activity 1.2:</u> Create a curriculum/training program on tobacco treatment in PHC based on national and international experience and guidelines of best practice.

The local faculty established in activity 1.1 will support the project team with adaptation of existing training materials. We will adapt the existing Global Bridges training curricula and supplement with training resources developed by University of Ottawa Heart Institute which are specific to PHC practice settings. The adaptation will focus on language, cultural appropriateness, local patient beliefs and attitudes towards tobacco-use and cessation, , local social and clinical norms, provider perceptions about 3As delivery, and practice flow to ensure maximum uptake. The curricula content will consist of 2/3 theory and 1/3 practical (on the job). The curricula will include content on: the burden of tobacco control in Greece, evidencebased tobacco treatment practices in primary care, first-line pharmacothrapies, behavioral counseling techniques for use in busy clinical settings, strategies for intervening with patients ready and not ready to guit smoking, special populations, setting up your practice for success, your role as clinician-advocate in tobacco control. Special emphasis will be placed upon training the PHC providers in overall tobacco control so that they develop the knowledge to act policy advocates at a regional and national level. The program will employ teaching techniques such as role-play and case study approaches known to enhance up-take into practice. The training program will be accredited for continuing medical education credits.

<u>Deliverable 1.2:</u> An accredited modular curriculum/training program on tobacco treatment in PHC (D1.2).

<u>Aim 2:</u> To adapt and deliver the provider/practice resources to ensure maximal sustainability among PHC providers in Crete, Greece:

Activity 2.1: Conduct a needs assessment with PHC providers in Crete.

A needs-assessment will be conducted with PHC providers and stakeholders to better identify barriers and facilitators to tobacco treatment delivery and the types of resources and supports that would be valued by PHC providers. The needs assessment will include a survey of a subsample of 20-30 health care professionals (General Practitioners, nurses and midwives) from the PBRN. An existing survey tool will be adapted by the local faculty for use.

<u>Deliverable 2.1:</u> Report on the needs assessment with key recommendations (D2.1).

<u>Activity 2.2:</u> Produce a set of practice tools in Greek which are designed to support the 3As model of tobacco treatment.

This activity is designed to support tobacco treatment delivery during routine primary care consults and will include patient materials, provider consult forms, and quick reference tools. We will adapt tools that have been developed by the University of Ottawa Heart Institute faculty and successfully implemented over the past several years. These tools will be supplemented by resources from the Global Bridges treatment network. We anticipate this may include an electronic medical record tool, patient self-help resources, etc.

Deliverable 2.2: Practice tools for implementation in PHC settings in Greek (D2.2).

<u>Activity 2.3:</u> Deliver advanced tobacco treatment training program to the existing practice-based research network within PHC in Crete.

In this step we will support the rollout of the tobacco treatment training program and practice support tools to the PBRN. The training program will consist on a longer core session and 4 shorter booster sessions delivered over the 2-month period following the session. We anticipate running 2-4 waves of the training program during this phase. The booster sessions is designed to reinforce the adoption of new practice behaviors and offer practical skill-based training including case-based training focused on patients within a provider's own practice. The format and duration of the training curricula is expected to be further shaped as part of the needs assessment (activity 2.1). Local faculty as well as international global bridges faculty will deliver training curricula. The targeted rollout to the PBRN will serve to pilot the training process, engagement strategies, tools and outcomes. As part of activity 2.3 the project team will also engage in capacity development activities within the Municipality of Heraklion and the Region of Crete that targets health care workers, local government officials, and decision makers. This will occur via a series of participatory "Learning and Action" meetings (1 per week for 1 month) and will include the Local Faculty team and representatives of the Municipality of Heraklion and the Region of Crete to support community-mobilization related to tobacco treatment and policy.

<u>Deliverable 2.3:</u> Report of the execution of tobacco treatment program to PHC practices (D2.3).

Activity 2.4: Perform program evaluation to inform program refinement.

The results of the project evaluation will be used to identify areas of the tobacco treatment program model that should be adapted prior to the next phase of dissemination. See section 2.3 for full description of program evaluation activities.

<u>Deliverable 2.4:</u> Evaluation report and list of recommended program refinements for future network expansion (D2.4).

<u>Activity 2.5:</u> Engagement of PHC practice networks for continued expansion of the Global Bridges tobacco treatment network in Greece.

To test the generalizability and acceptability of the program model developed, the project team intends to conduct outreach activities with an expanded group of PHC in Crete (outside of PBRN) as well as other parts of Greece with a focus on areas in which Medical/Nursing Schools are located who could provide local leadership to network expansion. The project team is committed to establishing the plan for continued expansion of the tobacco treatment network. This will include the specific activities to be undertaken in the continuation of the project.

<u>Deliverable 2.5:</u> Plan for tobacco treatment network expansion in Greece (D2.5).

2.3 Program Evaluation

Evaluation aims and Hypotheses to be tested

An integral part of any intervention program is the framework and metrics behind its evaluation. The aim of the evaluation is to determine whether the Global Bridges Tobacco Treatment Program when delivered among family medicine practitioners increases:

- a) Provider knowledge, attitudes, beliefs, perceived behavioral control, and intentions related to the delivery of tobacco treatment;
- b) Provider behaviors related to the delivery of tobacco treatment interventions

 The secondary objective is to determine the acceptability of the intervention program to family
 medicine practitioners in Greece and identify key areas that would inform planning and
 increase program uptake in future phases of the Global Bridges program in Greece.

Evaluation Setting and Participants: Data collection activities will occur in the PBRN practices which serve patient populations in the region of Heraklion, Crete, Greece - who are the target of the initial phase of this Global Bridges project. A sample of control practices will be recruited from the city of Rethymno and Chania (Crete, Greece) who are not exposed to the intervention program. A two-level recruitment strategy will be employed in which thirty primary care practices will be recruited (15 from intervention community and 10 from control community). Data will be collected from two sources: providers and patients identified from provider practices.

Evaluation design: The evaluation design schema is presented in Appendix A. A two-arm prepost cluster control group design will be used to examine the impact on the program on a) health care providers attitudes, s beliefs, perceived behavioral control, and intentions; and b) rates at which providers deliver evidence-based tobacco treatments to patients who smoke identified in their practice in practices participating in program compared to control practices. Data collection will occur in PHC practices participating in the intervention program and control practices who are not exposed to the intervention program. A survey will be completed with providers from each practice before the intervention program is delivered and repeated four months following the program's introduction. Additionally, from each of the participating practices, a representative cross-sectional sample of eligible smokers will be recruited pre- and post-intervention to assess provider performance in the delivery of smoking cessation intervention.

Provider Sampling: A study-invitation letter and program summary will be sent to all providers working in family medicines in the intervention area (PBRN practices in Heraklion region) and control regions (randomly selected from PHC practices in the West of Crete). A follow-up phone call will occur with all providers by a member of the investigative team one week after the invitation was sent to confirm interest in participation. Brief meetings will be held with practices who express an interest in participating to review the study protocol and consent forms and answer any questions. All providers working at the clinic will sign a study information sheet and consent form and complete a brief survey at baseline and again 4-months following intervention delivery in both the intervention and control community.

Patient Sampling: From each practice, a sample of 28 eligible patients will be recruited before (time 1) and after (time 2) intervention delivery. The pre-intervention assessment will be conducted prior to implementing the intervention program to establish baseline activities of the practice. At both time 1 and 2 a cross-sectional sample of eligible patients will be recruited

from each practice waiting room. During the screening period, a research assistant will be located in the clinic waiting room. The research assistant will screen consecutive patients scheduled for an annual exam or non-urgent appointment for eligibility. Patients will be eligible to participate in the study if they met the following criteria: are a current smoker (>5 cigarette per day on most days of the week); are 18 years of age or older; are scheduled for an annual exam or non-urgent medical appointment; are able to read and/or understand Greek; has the mental capacity to provide informed consent and complete study protocols. Eligible patients who agree to participate in the study will review and sign the study information sheet and consent form with the Research Assistant. Consenting patients will then be given the exit survey to complete. The survey will collect information about whether their physician or another clinician asked about their smoking status (ask); advised them to quit smoking (advise); and provided cessation assistance (assist). The exit survey ill also gather socio-demographic and smoking history, beliefs, and intentions. The post-intervention assessment will involve the collection of data from a second cross-sectional sample of 28 patients in all intervention practices approximately 4-months following the implementation of the intervention within the practice. The methods described in the pre-intervention assessment will be repeated at the post-assessment. Control practices will be sampled once to conserve budget and given relatively short time period between pre-post data collection no temporal changes are expected.

Primary Outcome Measures:

Program Adoption: Participation in TiTAN-Crete Global Bridges training program components; use of Global Bridges Project Toolkit.

Provider Knowledge: Provider knowledge of evidence-based tobacco treatment guidelines will be assessed using a brief 5-10 item knowledge assessment developed by project team.

Theory of Planned Behavior Constructs: Attitudes, Beliefs, Control Beliefs, Subjective Norms, Normative Beliefs, Perceived Behavioral Control, Intentions in next 6-months) related to tobacco treatment delivery will be assessed using pre-post intervention provider survey.

Provider Performance in the Delivery of Cessation Treatments: Performance in the delivery of each of the 3As will be assessed via exit interview with eligible patients. The survey will ask participants to respond either "yes" or "no" or "don't know" regarding whether their PHC provider asked them about their smoking status (ask); advised them to quit smoking (advise); assessed their readiness to quit (assess); provided assistance with quitting (assist); prescribed pharmacotherapy, provided self-help materials, and arranged follow-up support (arrange). Previous research has also found patient exit surveys regarding 3As delivery to be well correlated with criterion measure of an audiotape assessment of the physician-patient interaction (r= .67, p< .001). Several large trials of multi-component interventions in primary care have used patient exit interviews or surveys to assess rates of 5As delivery including extensive experience in three large scale evaluations projects by Dr. Papadakis. 10,31,32

Secondary Outcome Measures: The post-assessment provide survey will explore key themes related to program satisfaction, and sustainability including: quality of global bridges training program, quality of in-practice support, quality of global bridges support materials, feasibility of

maintaining tobacco treatment delivery in 80% of patients, barriers, suggestions for improvement, suggestions for continued engagement of primary care practitioner network.

Predictor Variables: The following core set of predictor variables is examined in this study.

Practice-level variables: Geographic location (postal code, rural/suburban); Size of practice (small, medium, large); allied health professional (yes, no); etc.

Provider-level variables: Socio-demographic (Age, Gender); Training (Years of Practice, Previous Cessation Training); Type (Physician, nurse etc.); TPB variables (Attitudes, Beliefs, Control Beliefs, Subjective Norms, Normative Beliefs, Perceived Behavioral Control, Intentions); etc.

Intervention-level variables: Participation in Global Bridges Training (yes, no); Use of Global Bridges Project Toolkit; Participation in post assessment site visit (yes, no); Type of clinic appointment (annual, acute, follow-up); etc.

Patient-level variables: Socio-demographic variables: (Age, Sex, Ethnicity, Education, Occupation, income, residence); Medical History (Presence of Smoking-related illness, comorbidities, Stress); Smoking History; Indexes of Nicotine Dependence; Past quitting history variables; Beliefs about quitting variables; etc.

Power Calculations and Sample Size: Power calculations were based on rates of provider delivery of tobacco treatment 'advice'. Given the clustered design an inflation factor was used to enlarge the total sample size to account for loss in statistical power. Based on estimates generated from previous research we have estimated that the ICC will be 0.01. We have estimated of 45% in the Control Group, 60% in the Intervention Group. The control group rate was estimated based on previous sampling of primary care practice in Greece. We have assumed the effect in the current project to be 15% based on rates achieved in the University of Ottawa Heart Institute's primary care network following implementation of a similar intervention. The sample size calculation, based on 25 practices (15 intervention practices and 10 control practices), indicates 28 patients per practices. Measurement in the control practices will occur at only one time point. Measurement will occur at two time-points in intervention practices. A total of 630 patients will be sampled in total. All calculations were based on a two-sided test, with 90% power, and an alpha level of 0.05.

Statistical Analysis: Clinic, provider and patient characteristics between groups will be compared using t-tests for continuous variables and Pearson chi-square tests for categorical variables. Multi-level modeling will be used to examine the association between outcomes and all predictor variables entered into the model such that the odds ratio presented for a given variable are adjusted for all other covariates in the model. Individual patients will be grouped by intake clinicians and clinicians grouped by clinic. A three-level model will be constructed for each outcome measure (ask, advise, cessation assistance), with the following levels: patients (level 1), provider (level 2); and clinic (level 3). The effect of the intervention will be estimated using iterative generalized least squares method for binary data. Modeling for each outcome will begin by entering the random effects at clinic and provider level along with fixed effects: an "intercept" term, "dummy" variables for intervention group (intervention vs. control) and time (pre vs. post assessment) and an interaction effect for group x time. Wald tests will be used to obtain p-values and odds ratios with 95% CI will be used to summarize the effect estimates. To

understand the patient- provider and clinic-level factors associated with each outcome, separate multi-level logistic regression analyses will be performed using backward (Wald) stepwise selection to choose significant interaction terms at the 5% level after entering all the main effects in the model.

2.4 Policy implications

One of the key pillars of the Global Bridges network is to create a network of champions for tobacco cessation policies. At a regional and national-level in Greece, this is extremely pertinent for the effective implementation of any relative tobacco control policy. While ideal legislations are formulated (i.e. for smoke free areas, advertising bans, cessation activities), they are rarely and partially implemented, a fact which we have attributed to the lack of "critical mass" of advocates and champions at the regional and national level which could help raise population awareness. ^{15,30,31} This is corroborated by our local research which has indicated that knowledge of the health effects of active and passive smoking is directly associated with population support for the creation of smoke free areas, banning of tobacco advertising and overall tobacco control policies. ^{6,34} Within Greece there has been a notable gap in the involvement of GPs in disease prevention and health promotion activities including tobacco control. ^{11,35,36} Hence we aim to increase the PHC providers knowledge and capacity for behavioral actions not only on smoking cessation, but in tobacco control in general, which would increase the critical mass needed to influence regional tobacco policies.

2.5 Strengths

- Expert team with an extensive background in smoking cessation, primary care and tobacco control policy, and a balance between established and emerging investigators.
- ✓ Research implemented in Crete, Greece will be generalizable to other countries suffering dire economic restraints in which resources are limited and tobacco cessation is not yet integrated in daily clinical practice or PHC training.
- ✓ Building on an established primary care research network (PBRN) that has a track-record of successful collaborations and actively engages in research and translational protocols in clinical practice. This network would be able to directly join the Global Bridges network.
- ✓ Well defined catchment area in Crete Greece, with a specific patient and PHC provider sample size calculations and robust outcomes.
- Collection of data on primary care provider performance in tobacco treatment delivery in Greece which is presently limited.
- ✓ Use of a concurrent control group adjacent to the catchment area but outside of the PCRN; detailed evaluation plan.

2.6 Main risks and contingency measures

Risk 1: Lack of time among GPs within PBRN for program participation.

Risk mitigation and contingency plans: We have engage local key opinion leaders in program team; we will conduct repeated follow up; utilize local mass media to draw attention to the project; integrate the proposal in CSFM research activities; further engage PHC authorities of Crete and regional government; and partner with additional community practices.

11

Risk 2: Participation dropout, reduced interest over time.

Risk mitigation and contingency plans: Active engagement with the participants of the PCRN, follow-up contacts to maintain engagement, relative flexibility and understanding of their time constraints, potential recruitment of a larger pool of participants if necessary.

2.7 Dissemination

The dissemination activities of the TiTAN-Crete project are two directional, focused on both national implementation and international outreach through the Global Bridges network. Dr. Lionis and Dr. Vardavas have a large network of collaborators in both the national health care system in Greece including clinician network and policy makers as well as local networks within the projects target region. Dr. Lionis is also very involved in national and European primary care guideline development. Specifically, the dissemination activities will focus on the practicebased clinical and policy implications, which would allow for a scale up of the TiTAN-Crete project. The research team will provide relevant information to public health groups, media and legislative bodies in Greece. We will also make our work available through a dedicated section of the CSFM website and through frequent content uploading via the www.globalbridges.org resources domain and forum so that the created and adapted tools may be used by other researchers and clinicians within Global Bridges network. We will also seek publication of our findings in international peer-reviewed journals and present our findings at national and international meetings, including the 2015 WCTOH and the 2015 ERS conferences. Dr. Vardavas, as the recipient of the 2014-2017 ECTOH young professionals award, and an ERS tobacco control committee member will be participating in these conferences with his expenses already covered.

2.8 Future Directions

Our project's future direction is to provide the methodology, tools and resources that would support the long-term development of a training protocol for PHCP in Greece in the area of smoking cessation, and facilitate direct linkages to the Global Bridges network. Moreover, this project may be extended to other PHC internists and undergraduate medical/nursing students from Greece so that they may be channeled into the Global Bridges network and receive the training needed to cultivate a critical mass of clinicians who are champions of tobacco control policy, this will be specifically addressed in Activity 2.5. Since Greece is under dire financial constraint, the model/approach developed within this proposal may be used as a "road map" of how PHC services with limited resources may enter and participate actively as nodes within the Global Bridges network. This is extremely relevant to Global Bridges role in developing a sustainable network in countries, where financial and organizational constraints may hinder the implementation of tobacco cessation actions.

B3. Detailed Workplan and Deliverables Schedule:

Workplan

The TiTAN-Crete project has a specific flow of activities that will be adhered to so as to ensure efficient implementation. This workplan has been outlined above (section 2.2) and below in tabular format. In short, during months 1-2, we will assemble the multidisciplinary team of

faculty and experts available regionally, internationally and through the Global Bridges Network (Deliverable 1.1), concurrently during months 1-4 we will develop the curriculum and training program (Deliverable 1.2), so that it is ready for implementation and shared on the global bridges site. Subsequently as part of Aim 2, we will perform a needs assessment among PHC providers in Crete during months 3-6 (Deliverable 2.1) and adapt the tools needed to implement tobacco cessation in PHC settings in Crete (Deliverable 2.2). The program will be set up, implemented and pre-and-post tested between months 7-14 (Deliverable 2.3), with project evaluation and refinement during months 13-18 (Deliverable 2.4). Finally we will create a plan to expand the tobacco treatment network into other areas in Greece during the final 2 months so as to create a new "node" of the Global Bridges Network in Greece (Deliverable 2.5). In parallel, the project team will ensure execution of quality control and dissemination activities.

Deliverables Schedule

Deliverable 1.1: List of faculty and trainers with identified role in program delivery (Month 2).

Deliverable 1.2: A curriculum/training program on tobacco treatment in PHC (Month 6).

Deliverable 2.1: Report on the needs assessment with key recommendations (Month 6).

Deliverable 2.2: Practice tools for implementation in PHC settings in Greek (Month 6).

Deliverable 2.3: Report of the execution of tobacco treatment program (Month 14).

Deliverable 2.4: Report with recommendations for future network expansion (Month 18).

Deliverable 2.5: Plan for tobacco treatment network expansion in Greece (Month 20).

Project Timeline This project will be completed over a 2-year timeframe.

							Voor 2			
	Year 1						Year 2			
Month	1-2	3-4	5-6	7-8	9-10	11-12	13-14	15-16	17-18	19-20
Project Management										
Finalize IRB issues										
Bi weekly team meetings										
Monitoring, quality control										
Dissemination activities										
Reports						Rep 1				Rep 2
Aim 1										
Activity 1.1: Faculty	D1.1									
Activity 1.2: Curriculum			D.1.2							
Aim 2										
Activity 2.1: Needs assessment			D.2.1							
Activity 2.2: Practice tools			D.2.2							
Activity 2.3: Intervention							D2.3			
Activity 2.4: Evaluation									D2.4	
Activity 2.5: Sustainability										D.2.5

<u>Table Footnote:</u> Shaded areas indicate timeframe; Rep: reports; D1/1-2/5: represent deliverable dates.

References

- 1. World Bank. Greece 2012. http://www.worldbank.org/en/country/greece.
- 2. Kentikelenis A, Karanikolos M, Papanicolas I, Basu S, McKee M, Stuckler D. Health effects of financial crisis: Omens of a Greek tragedy. *Lancet*. 2011;378:1457-1458.
- 3. Kentikelenis A, Papanicolas I. Economic crisis, austerity and the Greek public health system. *Eur J Public Health*. 2012;22:4-5.
- 4. Filippidis FT, Vardavas CI, Loukopoulou A, Behrakis P, Connolly GN, Tountas Y. Prevalence and determinants of tobacco use among adults in Greece: 4 year trends. *Eur J Public Health*. 2013;23:772-776.
- 5. Tsalapati K, Vardavas CI, Athanasakis K, Thireos E, Vozikis A, Pavi E, Behrakis P, Kyriopoulos I. Going up in ashes? smoking-attributable morbidity, hospital admissions and expenditure in Greece. *Eur J Public Health*. 2014.
- 6. Schoretsaniti S, Filippidis FT, Vardavas CI, Dimitrakaki C, Behrakis P, Connolly GN, Tountas Y. 5-year trends in the intention to quit smoking amidst the economic crisis and after recently implemented tobacco control measures in Greece. *Addict Behav.* 2014;39:140-145.
- 7. World Health Organization. WHO report on the global tobacco epidemic; the MPOWER package. Geneva:2008. Available

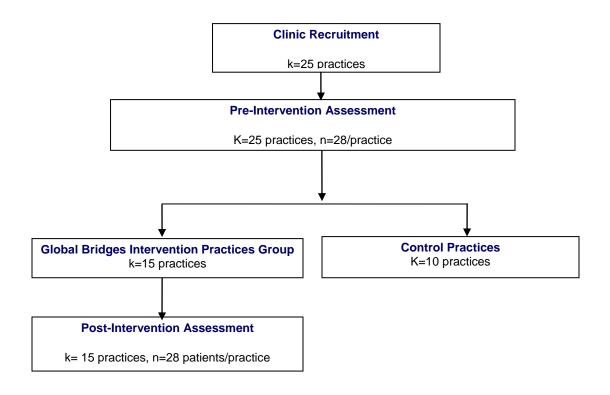
from: www.who.int/tobacco/mpower/mpower report full 2008.pdf.

- 8. Vardavas CI, Symvoulakis EK, Lionis C. Dealing with tobacco use and dependence within primary health care: Time for action. *Tob Induc Dis*. 2013;11:6-9625-11-6.
- 9. Stead L, Bergson G, Lancaster T. Physician advice for smoking cessation. *Cochrane Database Syst Rev.* 2008;(2):CD000165.
- 10. Papadakis S, McDonald PW, Pipe AL, Letherdale ST, Reid RD, Brown KS. Effectiveness of telephone-based follow-up support delivered in combination with a multi-component smoking cessation intervention in family practice: A cluster-randomized trial. *Prev Med*. 2013;56:390-397
- 11. Kotsoni C, Antonakis N, Markaki A, Lionis C. Do patients with chronic obstructive pulmonary disease receive smoking cessation advice and interventions in rural crete? report from a medical audit study. *Aust J Rural Health*. 2008;16:385-386.
- 12. Omole OB, Ngobale KN, Ayo-Yusuf OA. Missed opportunities for tobacco use screening and brief cessation advice in south african primary health care: A cross-sectional study. *BMC Fam Pract*. 2010;11:94-2296-11-94.
- 13. Papadopoulos G, Vardavas CI, Limperi M, Linardis A, Georgoudis G and Behrakis P. Smoking cessation can improve quality of life among COPD patients: validation of the clinical COPD questionnaire into Greek. *BMC Pulmonary Medicine*. 2011; 11:13
- 14. Lionis C, Petelos E. The impact of the financial crisis on the quality of care in primary care: An issue that requires prompt attention. *Qual Prim Care*. 2013;21:269-273.
- 15. Patelarou E, Vardavas CI, Ntzilepi P, Warren C, Barbouni A, kremastinou J, Connolly G, Behrakis P. Nursing education and beliefs towards tobacco cessation and control: a cross-sectional national survey (GHPSS) among nursing students in Greece. *Tobacco Induced Diseases* 2011; 9:4.

- 16. Boutou AK, Tsiata EA, Pataka A, Kontou PK, Pitsiou GG, Argyropoulou P. Smoking cessation in clinical practice: Predictors of six-month continuous abstinence in a sample of greek smokers. *Prim Care Respir J.* 2008;17:32-38.Brotons C. Control of cardiovascular risk factors in primary healthcare: Do we control the factors or the risk? *Med Clin (Barc)*. 2005;124:415-416.
- 17. Rovina N, Nikoloutsou I, Dima E, Michailidou M, Roussos C, Gratziou C. Smoking cessation treatment in a real-life setting: The greek experience. *Ther Adv Respir Dis.* 2007;1:93-104.
- 18. Vardavas CI, Agaku I, Patelarou E, Anagnostopoulos N, Nakou C, Dramba V, Giourgouli G, Argyropoulou P, Antoniadis A, Gourgoulianis K, Ourda D, Lazuras L, Bertic M, Lionis C, Connolly G, Behrakis P, Hellenic Air Monitoring Study Investigators. Ashtrays and signage as determinants of a smoke-free legislation's success. *PLoS One*. 2013;8:e72945.
- 19. Lionis C, Tatsioni A. Conducting research in rural primary care medicine: Do we need more experimental research or guidance? *Rural Remote Health*. 2012;12:2267.
- 20. Anderson P, Jane-Llopis E. How can we increase the involvement of primary health care in the treatment of tobacco dependence? A meta-analysis. *Addiction*. 2004;99:299-312.
- 21. Fiore MC, Jaén CR, Baker TB, et al. *Treating tobacco use and dependence: 2008 update.* Clinical practice guideline. 2008.
- 22. Papadakis S, McDonald P, Mullen KA, Reid R, Skulsky K, Pipe A. Strategies to increase the delivery of smoking cessation treatments in primary care settings: A systematic review and meta-analysis. *Prev Med.* 2010;51:199-213.
- 23. Harrison MB, Legare F, Graham ID, Fervers B. Adapting clinical practice guidelines to local context and assessing barriers to their use. *CMAJ*. 2010;182:E78-84.
- 24. Cabana MD, Rand CS, Powe NR, Wu AW, Wilson MH, Abboud PA, Rubin HR. Why don't physicians follow clinical practice guidelines? A framework for improvement. *JAMA*. 1999;282:1458-1465.
- 25. Ajzen I. Theory of planned behaviour. *Organizational Behavior and Human Decision Processes*. 1991;50:179-211.
- 26. Oikonomidou E, Anastasiou F, Pilpilidis I, Kouroumalis E, Lionis C, Greek General Practice Dyspepsia Group. Upper gastrointestinal endoscopy for dyspepsia: Exploratory study of factors influencing patient compliance in Greece. *BMC Gastroenterol*. 2011;11:11-230X-11-11.
- 27. Samoutis GA, Soteriades ES, Stoffers HE, Zachariadou T, Philalithis A, Lionis C. Designing a multifaceted quality improvement intervention in primary care in a country where general practice is seeking recognition: The case of Cyprus. *BMC Health Serv Res*. 2008;8:181-6963-8-181.
- 28. Tsiantou V, Shea S, Martinez L, Agius D, Basak O, Faresjo T, Moschandreas J, Samoutis G, Symvoulakis EK, Lionis C. Eliciting general practitioners' salient beliefs towards prescribing: A qualitative study based on the theory of planned behaviour in Greece. *J Clin Pharm Ther*. 2013;38:109-114.
- 29. Lionis C, Petelos E, Shea S, Bagiartaki G, Tsiligianni IG, Kamekis A, Tsiantou V, Papadakaki M, Tatsioni A, Moschandreas J, Saridaki A, Bertsias A, Faresjo T, Faresjo A, Martinez L, Agius D, Uncu Y, Samoutis G, Vlcek J, Abasaeed A, Merkouris B. Irrational prescribing of over-the-counter (OTC) medicines in general practice: Testing the feasibility of an educational intervention among physicians in five European countries. *BMC Fam Pract*. 2014;15:34-2296-15-34.

- 30. Pbert L, Adams A, Quirk M, Hebert JR, Ockene JK, Luippold RS. The patient exit interview as an assessment of physician-delivered smoking intervention: A validation study. *Health Psychol*. 1999;18:183-188.
- 31. Unrod M, Smith M, Spring B, DePue J, Redd W, Winkel G. Randomized controlled trial of a computer-based, tailored intervention to increase smoking cessation counseling by primary care physicians. *J Gen Intern Med*. 2007;22:478-484.
- 32. Katz DA, Muehlenbruch DR, Brown RL, Fiore MC, Baker TB, AHRQ Smoking Cessation Guideline Study Group. Effectiveness of implementing the agency for healthcare research and quality smoking cessation clinical practice guideline: A randomized, controlled trial. *J Natl Cancer Inst*. 2004;96:594-603.
- 33. Vardavas CI, Dimitrakaki C, Schoretsaniti S, Patelarou E, Filippidis FT, Connolly GN, Tountas Y. The role of the non-smoker in enforcing smoke-free laws. *J Public Health Policy*. 2011;32:46-59.
- 34. Schoretsaniti S, Filippidis FT, Vardavas CI, Tzavara C, Dimitrakaki C, Behrakis P, Connolly GN, Tountas Y. Prevalence and determinants of SHS exposure in public and private areas after the 2010 smoke-free legislation in Greece. *Int J Environ Health Res*. 2013.
- 35. Brotons C. Commentary: External validity of studies on primary care prevention of hypercholesterolemia. *Aten Primaria*. 2003;32:514-516.
- 36. Lionis C, Symvoulakis EK, Vardavas CI. Implementing family practice research in countries with limited resources: A stepwise model experienced in Crete, Greece. Fam Pract. 2010;27:48-

Appendix A: Pre-Post Cluster Randomized Control Group Design



17