TiTAN Greece & Cyprus – Primary Care <u>Tobacco Treatment</u> <u>TrAining Network</u> in Greece & Cyprus

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Abstract

Goal: Our goal is to expand the Global Bridges Tobacco Treatment Training Network in the WHO Europe region through a focus on primary health care (PHC) providers in Greece and Cyprus.

Target Population: PHC has been acknowledged as a key setting for the delivery of tobacco dependence treatment. The primary target group will be the more than 1950 certified family physicians in Greece and Cyprus, family medicine residents, PHC nurses, allied health professionals and their patients who smoke. The target for the TiTAN-Greece & Cyprus Project is to train 300 PHC providers and residents who are associated with the community-based PHC networks of the medical schools in four geographic regions in Greece (Crete, Athens, Ioannina, Thessaloniki) and Cyprus.

Methods: The TiTAN project will provide leadership and coordination for the dissemination of both a professional training program and practice tools that are tailored to support busy PHC providers with integrating evidence-based tobacco dependence treatment into their practice routines as well as increase the number of tobacco control champions working in Greece and Cyprus.

Assessment: A pre-post evaluation will be used to examine the impact on the program on: i) provider attitudes, knowledge, intentions; and ii) rates of evidence-based tobacco treatments (5As) are delivered to patients who smoke. All PHC providers will be surveyed before and after the intervention program is delivered. We will randomly select a sub-sample of providers and will survey patients from their practice before and after the intervention program in order to validate changes in 5As delivery.

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REVIEWER'S COMMENTS

Reviewer's Comments: Please note that in developing your full proposal, the estimated budget figure you provided in the Letter of Intent can be set aside. For the full proposal stage, please provide a detailed and realistic budget which is clearly linked to your project's objectives, activities and implementation. A properly costed and realistic budget will strengthen your proposal.

Budget Details: A detailed budget and narrative has been provided which includes a careful analysis of cost associated with the execution of the proposed project.

D. MAIN SECTION

1. OVERALL GOAL AND OBJECTIVES:

The overall goal of this project is to expand the Global Bridges Tobacco Treatment Training Network in the WHO Europe region through a focus on primary health care (PHC) providers in Greece and Cyprus. The TiTAN project will provide leadership and coordination for the dissemination of both a professional training program and practice tools that are tailored to support busy PHC providers with integrating evidence-based tobacco dependence treatment into their practice routines as well as expand the number of tobacco control champions working in Greece and Cyprus.

Describe how this goal aligns with the focus of the RFP & goals of applicant organizations:

The focus of this Global Bridges RFP 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 in Europe. Specifically as part of the present project we will:

- i) Expand the number of healthcare professionals committed to treating tobacco dependence: The project will set-up the infrastructure to deliver training and practice-level supports to address barriers to delivering evidence-based tobacco dependence treatment in various regions of Greece and Cyprus. This project will focus on influencing professional practice in primary care practice settings. The World Health Organization (MPOWER) has called for smoking cessation to be integrated into primary health care globally. (1-3) The TiTAN program is designed to move beyond generic smoking cessation training and provide training and protocols which have been tailored for use in busy primary care practice settings including both solo GP practices and group practices which include multi-disciplinary teams.
- **ii)** Build on existing infrastructure & promote collaborations across multiple regions in two Mediterranean countries: This project will support a unique collaboration between the Faculties of Medicine at four Medical Schools in Greece and Cyprus as well as the University of Ottawa Heart Institute (Ottawa, Canada) for the shared purpose of increasing the number of trained health professionals committed to treating tobacco dependence in PHC settings. These entities bring significant experience and knowledge in tobacco dependence as well as links to the PHC community in Greece and Cyprus. Each organization shares a commitment to improve the quality of PHC practice and public health at a national level.
- **iii)** Utilize evidence-based tools & the experience from the Global Bridges TiTAN-CRETE program: This project builds on the established success of the TiTAN-Crete project funded by Global Bridges (2014-2016) which involved the adaptation of the evidence-based "Ottawa Model for Smoking Cessation" originally developed in Canada, for use in PHC settings in Crete, Greece. A training program and tool kit of resources in Greek has been developed, tested, and refined as part of the TiTAN-Crete project. This project will support the further scale-up of these assets to a substantially larger network of PHC providers in the Mediterranean.

Objectives:

The key objectives of your project in terms of learning and expected outcomes.

<u>Objective 1:</u> To disseminate a high-quality tobacco dependence treatment training program to PHC providers and family medicine residents in Greece and Cyprus based on national and international experience and guidelines of best practice.

<u>Objective 2:</u> To disseminate a tool kit of patient/provider resources to support integration of tobacco treatment into PHC settings in Greece and Cyprus.

<u>Objective 3:</u> To provide on-going outreach support and booster education to the network of PHC providers/residents established as part of the TiTAN-Greece & Cyprus project.

Objective 4: Support PHC practitioners in achieving personal cessation

2. CURRENT ASSESSMENT OF NEED IN TARGET AREA:

a. Describe the need for this project in your target area. Only include information that impacts your specific project, linking regional or local needs to those identified on the national basis if appropriate. Describe the need for your project in terms of "what is" versus "what should be".

Greece has the highest smoking prevalence among members of the European Union, estimated at slightly above 38% of the adult population. (4) 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). 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) Primary care practitioners in Greece have access to a large number of tobacco users. Data from the TiTAN-Crete project indicates 38% of all patients screened in PHC settings are tobacco users, which is similar to the national smoking prevalence rates. The vast majority (95%) of PHC providers and family medicine residents in Greece and Cyprus have not received formal tobacco cessation training, offering an important opportunity to intervene and influence professional practice. The European Tobacco Treatment Guidelines as well as other international guidelines recommend smoking status be documented among all patients and all current tobacco users be offered advice to quit and support with quitting including counseling and pharmacotherapy. (7,8) The 5As (Ask, Advise, Assess, Assist, Arrange) model for smoking cessation is recommended for clinical practice settings including primary care. However, despite the evidence supporting the efficacy of smoking cessation interventions, there is a practice gap in the rates at which 5As smoking cessation interventions are delivered by primary-care practitioners. (9,10) This gap in clinical practice is especially true in developing countries(11) or in countries under fiscal constraints, such as Greece. (12,13) There is little data available regarding rates of tobacco treatment delivery in primary care settings in Greece and Cyprus. 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(10) (10). (10)

b. Please include quantitative baseline data summary, initial metrics (e.g., quality measures), or project starting point (please cite data on gap analyses or relevant patient-level data that describes the problem) in your target area. Describe the source and method used to collect the data. Describe how the data was analyzed to determine that a gap existed.

The Global Bridges TiTAN-Crete project upon which this project builds provided some of the first high quality data to characterize knowledge, attitudes, and rates of tobacco treatment in Greece. Primary care providers and a sample of patients from the Heraklion region of Crete were surveyed before and after the implementation of the multi-component tobacco treatment training program. Assessment of provider knowledge of evidence-based tobacco treatment practices was very low when measured prior to intervention. A total of 436 patients were surveyed at baseline as part of the TiTAN-Crete project. Patients were asked to report on tobacco use history and among current tobacco users, and rates at which the 5As were delivered to patients at both the current visit (same day) as well as the past year. Tobacco users smoked an average of 26.0 (SD 13.7) cigarettes per day for an average of 22.3 (SD 11.6) years. The majority (64.1%) of tobacco users reported a readiness to guit smoking in the next 6months, with 24.7% of patients reporting an interest in quitting in the next 30-days. However 63.4% of tobacco users reported not having made a quit attempt in the past year, indicating an important treatment gap. Exit interviews also identified a significant practice gap in the rates at which 5As smoking cessation interventions are delivered by PHC practitioners with 44.8% of patients reporting their PHC provider provided brief advice to guit in the previous 12-month. Furthermore, rates at which assistance with quitting was delivered were very low: 17.8% for assist with quitting; 1.7% for prescribing pharmacotherapy; 5.4% of provide self-help materials; and 2.5% for arranging follow-up. Approximately 30% of GPs involved in the TiTAN Crete project were themselves tobacco users, a rate which has been reported by others in Greece. (14)

3. TARGET AUDIENCE:

Describe the primary audience(s) targeted for this project.

The primary target audiences for this project are the more than 1950 certified family physicians in Greece and Cyprus, family medicine residents, PHC nurses, allied health professionals and their patients who smoke. The target for the TiTAN-Greece & Cyprus Project is to train 300 PHC providers and residents who are associated with the community-based PHC networks of the medical schools across Greece and Cyprus. This network of practitioners in turn has access to a large population of tobacco users, estimated to be approximately 10,000 to 20,000 patients.

a. Describe the level of commitment from the potential participants including your plan for recruitment as necessary.

We have established a strong multi-organization partnership to implement the TiTAN project. Specifically we have established partnerships with divisions of Primary Care in four Medical Schools in geographic regions across Greece as well as the University of Cyprus. A lead / champion has been identified from each faculty who will play an instrumental leadership role in the TiTAN training network's development. Each faculty of medicine has an existing relationship with GPs and primary care professionals in their geographic region and are involved in the delivery of continuing medical education programs for their regions. Our recruitment strategy will utilize local leadership who will co-invite (written and telephone invitations will be used) PHC providers to participate in the TiTAN training program and our partner organizations will co-host the training sessions. National and international experts will be involved in delivering aspects of the training program; in our experience to date this has been an important attraction to increase rates of participation.

b. Demonstrate the scope of your target audience has a potential to impact the goal established in this proposal.

This project involves two Greek speaking Mediterranean countries and will serve to create a large network of PHC practitioners trained in evidence-based tobacco treatment. While the TiTAN Crete Project focused on the adaptation of the Ottawa Model for Smoking Cessation in Greece and pilot testing of the training program and tool kit, the current project will focus on the scale-up of the training program nationally. An organized network involving local PHC champions will assist with engaging the GP community in five regions in Greece and Cyprus. The target is to train a minimum of 300 PHC practitioners. This target offers a critical mass of trained practitioners. We will train local GP champions who will serve as key opinion leaders locally. The end goal is to have an organized tobacco treatment network tailored to the realities of PHC in Greece and Cyprus that takes advantage of both national and international expertise and local champions.

c. Describe who will directly benefit from the project outcomes. Include in this description whom, beyond the primary target, would potentially benefit from the project in terms of this being a model for others to replicate or expand.

Primary care providers will receive new knowledge, skills, and practice tools and resources. Patients served by primary care providers will benefit from increased rates of tobacco treatment delivery from trained primary care health care professionals. These increased rates of intervention are expected to increase the number of patients who make a quit attempt, use evidence-based treatment, and achieve cessation. This project may offer a model for other European countries in terms of the creation of an organized primary care tobacco treatment network. The training program, tool kit and dissemination model used in the present project has the potential to be used by other groups working in primary care practice settings and likewise these assets could be adapted for use in other settings within Greece and Cyprus (e.g. Hospital).

4. PROJECT DESIGN AND METHODS:

a. Include a description of the overall strategy, methodology and analysis linking them to the goal of the project.

Overall, this project will support the expansion in Greece and Cyprus of an evidence-based multi-component intervention program ("the Ottawa Model for Smoking Cessation") originally developed for use in PHC practices in Canada, which has been successfully adapted and pilot tested in the GP network in Heraklion Greece as part of the TiTAN-Crete project. Adapting to local context and use of local champions is critical to successful knowledge translation programs. In this project we will engage regional PHC champions and national and international tobacco control experts to ensure a successful, active network of clinicians is established. The project team will coordinate multiple training activities in national sub-regions that will be delivered in partnership with existing practice networks and will include measurement of changes achieved. A large proportion of PHC providers use tobacco personally and this has been shown to decrease rates of tobacco treatment delivery. As secondary target of this project will be to offer cessation support to PHC providers who are interested in quitting.

Clinical Tobacco Treatment Model: The 5As 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 that 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. (7,15,16) 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; and, 5) practice-outreach support.

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 5As treatments to patients (See Figure 1- Conceptual Framework). TPB will also be used as the evaluation framework for assessing impacts of the intervention program on various interim outcomes as well as 5As delivery. 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. (9,17-20)

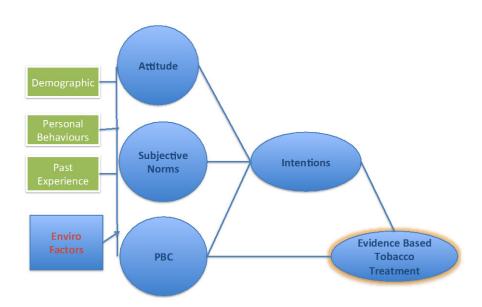


Figure 1: Conceptual Model of Intervention Effects

TITAN Crete Intervention Program: The TiTAN Crete program has adapted the existing curricula and resources originally developed at the University of Ottawa Heart Institute and which are specific to primary practice settings [20]. To facilitate maximum uptake the intervention program was adapted to reflect: language; cultural appropriateness; local patient beliefs and attitudes regarding tobacco-use and cessation; local social and clinical norms; provider perceptions surrounding 5As delivery; and, practice characteristics. The TiTAN multi-component training includes a 1-day foundational tobacco treatment training program for general practitioners, the dissemination of provider and patient resources, as well as e-learning activities including follow-up continuing medical education webinars.

Provider Training: The training program consists of a one-day core session addressing tobacco use with patients in the context of a busy primary care practice setting. The training program content will be standardized for all regional sites to ensure fidelity with the learning objectives. The training includes information regarding: the neurobiology of nicotine addiction; health effects of tobacco use; the role of primary care providers in motivating cessation; evidence-based tobacco treatment practices; techniques for delivering brief cessation advice; conducting a quit plan and follow-up visit; use of first-line cessation pharmacotherapy; motivational interviewing techniques; and, special populations. The curriculum design was designed to be 2/3 theory and 1/3 practical. The program employs teaching techniques including role-play and case-study approaches known to enhance practice change. The training program is based on evidence-based practices as outlined in the European Tobacco Treatment Guidelines.

Patient and Provider Tools: Provider and patient tools were translated and adapted for use in primary care settings in Greece. A tool kit of resources will be distributed to providers which includes: patient tobacco use survey; provider consult form; provider medication reference sheet; patient quit plan booklet; and, waiting room posters. The provider consult form uses a checklist style set-up and provides real-time reminders for conducting an initial smoking cessation visit and follow-up appointments. The TiTAN Crete tools are available online at www.titan.uoc.gr We will also ensure dissemination of the Greek Version of the 2016 European Tobacco Treatment Guideline to GPs involved in the training network which will be released later in 2016.

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

Objective 1: To disseminate a high quality tobacco treatment training program to PHC providers in Greece and Cyprus based on national and international experience and guidelines of best practice.

<u>Activity 1.1:</u> Develop a faculty of experts in Greece and Cyprus who will deliver tobacco treatment training to a large network of PHC providers. This local faculty will be enhanced by the inclusion of national international trainers.

The project will begin by the development of a strong faculty who are familiar with the training program and teaching methods that will be employed. Our team includes international (S. Papadakis, A. Pipe) and national (C. Gratziou, P. Katsaounou, C. Vardavas, I. Tsiglianni) tobacco treatment experts in tobacco control who will co-deliver the foundational training and webinars. These team members will be enhanced by local faculty who will be involved in the championing and co-delivering training content. The training curricula developed for the TiTAN Crete content will be reviewed by the faculty and as needed modified as appropriate for the

present project. A 1-day training and orientation session to the TiTAN Crete training program will be delivered to all faculty members to ensure a common understanding of learning goals, and training content.

Activity 1.2: Generate list of PHC in each geographic sub-region

We will work with the four Medical Schools collaborating on the TiTAN project to identify all PHC providers working with the medical schools and/or their geographic area.

Activity 1.3: Conduct needs assessment of PHC providers training and provider needs.

A standardize needs assessment developed as part of the Ottawa Model for Smoking Cessation has been translated to Greek and will be used to identify to identify local needs of PHC providers from each sub-region. Both local champions and 1-2 PHC working in each sub-region will participate in the needs assessment. As required the training curricula and TiTAN resources will be tailored to meet these needs.

<u>Activity 1.4:</u> Deliver a 1-day foundational training program in five regions across Greece & Cyprus on tobacco treatment in PHC based on international experience and best practice guidelines.

We will deliver 1 to 2 1-day foundational training sessions in each of the five geographic regions (Crete, Athens, Ioannina region, Thessaloniki and region, Nicosia and region) targeted as part of the present project. Training sessions will be delivered by two faculty members at least one of whom is a physician. Where possible local faculty will co-deliver the training curricula with our national/international tobacco treatment colleagues. The training program will be accredited for continuing medical educations credits.

<u>Objective 2:</u> To disseminate a tool kit of patient/provider resources to support integration of tobacco treatment into PHC settings in Greece and Cyprus.

<u>Activity 2.1:</u> Disseminate the 'TiTAN Tool Kit' to PHC clinicians and their patients which include: patient tobacco use assessment form, provider consult form for initial and follow-up visits, cost of medications reference sheet, patient quit plan self-help booklet, a new reduce-to-quit patient resource, and video case studies.

The "toolkit" of resources will be distributed in hard-copy and disseminated to PHC providers involved with the TiTAN project. They will also be available online. In addition to the tools developed as part of the TiTAN Crete project we will develop a "reduce to quit" patient resource which is tailored for patients interested in using this approach to cessation.

Objective 3: To provide on-going outreach support and booster e-learning opportunities to the network of PHC providers/residents established as part of the TiTAN-Greece & Cyprus Project.

<u>Activity 3.1:</u> Establish an active list-serv that provides proactive outreach, ongoing training, and two-way interaction between PHC providers and tobacco experts in the TiTAN network. In collaboration with our partners will establish a list serv of PHC practitioners that can be used to communicate with PHC practitioners in Greece and Cyprus. The TiTAN Crete website will be re-launched and be used as a hub for accessing materials, and other training resources in Greek.

<u>Activity 3.2:</u> Establish a quarterly webinar series and e-learning platform in collaboration with the EPACTT-PLUS project to provide booster training in special topics in tobacco control to the TiTAN PHC network.

We will work in partnership with the EPACTT-PLUS project (Global Bridges) to deliver a series of booster education sessions via webinar. The webinars will be used to reinforce the adoption of new practice behaviors and offer practical skills-based training focused on patients in the GP's own practice including advanced tobacco treatment topics (eg. cessation in pregnancy, mental health populations, advanced use of pharmacotherapy).

Objective 4: Support PHC in achieving personal cessation

<u>Activity 4.1:</u> We will offer support with quitting via the tobacco treatment network and existing specialized smoking cessation clinic (Dr. Katsaounou) to PHC providers who smoke and are interested in quitting.

b. Describe the way the project planned addresses the established need and produces the desired results.

The project planned will address the training gap documented among PHC providers in Greece and Cyprus. We expect the multi-component training program will influence provider knowledge, attitudes, behavioural control in regards to cessation and will in-turn increase rates of tobacco treatment delivery delivered to patients within their practice.

- c. Indicate how you will determine if the target audience was fully engaged in the project. As part of the present project we will track metrics including the proportion of clinicians invited who agree to participate in the program. We will include pre and post assessment measurement (see section 5 evaluation design) to assess changes in PHC providers knowledge, attitudes, and social norms related to tobacco treatment and we will assess the impact on tobacco treatment delivery in their practice. Providers will rate their satisfaction with the intervention program and we will track participation in follow-up webinars. Providers will participate in a qualitative evaluation of the project in which we will be able to receive feedback on strengths and weaknesses of the intervention program.
- d. Include a description of the measures you have taken to assure that this project idea is original and does not duplicate other projects or materials already developed.

There is a large number of existing tobacco treatment training programs available internationally. The present project will utilize assets from the original TiTAN Crete project, which as described have been adapted and pilot tested. We will enhance this toolkit based on feedback received from PHC providers involved in this pilot project and the needs assessment (Activity 1.2) planned in the present project. The innovation of the present project is reflected in the significant scale-up of a formalized training network in association with medical schools in Greece and Cyprus. The network will move beyond one-time training and will include the dissemination of provider and patient tools to assist with the integration of tobacco treatment into clinical routines.

e. If appropriate, show how this project builds upon existing work, pilot projects, or ongoing projects developed either by your institution or other institutions related to this project.

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 and the experience

and assets created as part of the TiTAN Crete Project (2014-2016). 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.(9) The TiTAN Crete project resulted in significant improvements in rates of provider tobacco treatment knowledge, attitudes as well as 5As delivery. Significant increases in knowledge were documented in 6/13 of the knowledge domains between the pre and post assessment. Post-assessment data collection is currently partially completed (75%) and will conclude at the end of April 2016. Table 1 presents preliminary results of the pre and post assessment conducted as part of the TiTAN Crete project.

Table 1: Rates of 5As delivery before and after the TiTAN Crete Intervention Program

5As	Pre	Post	Delta	p-value
	n=436	n=332		
Ask	58.0%	75.0%	17.0%	.000
Advise	52.5%	76.2%	23.7%	.000
Assess	33.7%	60.1%	26.4%	.000
Assist	16.1%	62.3%	46.2%	.000
Assist - Quit Date	7.1%	10.8%	3.7%	.183
Assist – Discuss Medication	7.6%	32.5%	24.9%	.000
Assist – Prescribe Medication	1.6%	2.7%	1.1%	.297
Assist – Self-help Materials	3.9%	16.9%	13.0%	.000
Arrange	4.1%	13.6%	9.5%	.000

This project will involve the dissemination of a "toolkit" of resources for PHC providers and patient self-help materials. As previously noted this "toolkit" was translated and adapted from the Ottawa Model for Smoking Cessation for use in the national activities planned second of the TiTAN project. While not a primary objective of the Crete project, cessation was achieved in 75% (3/4) of GPs who reported personal tobacco use. Given this unanticipated success and the link between GPs personal tobacco use and patient treatment rates, supporting PHC providers with quitting will be a secondary target of the present project. (14)

f. If your project includes the development of tools note if they will be available publically at no cost.

The "toolkit" will be accessible via the project website to the public at no cost. We have budgeted for printing of materials for distribution in hard copy to clinicians who will be involved in the present project.

5. EVALUATION DESIGN

a. In terms of the metrics used to assess the need for this project, describe how you will determine if the practice gap was addressed for the target group.

A robust evaluation will be conducted alongside project knowledge translation activities. Significant increases in knowledge, attitudes and tobacco treatment rates have been demonstrated in the TiTAN Crete (2014-2016). Evaluation activities will assist with examining

the generalizability (external validity) of these findings in different regional settings and primary care models (solo versus team-based).

Evaluation aims:

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, beliefs, perceived behavioral control, and intentions related to the delivery of tobacco treatment;
- b) Provider behaviors related to the delivery of tobacco treatment interventions; and
- c) Provider satisfaction with training program, resources, and network outreach activity and areas for improvement.

Evaluation Design: The evaluation design schema is presented in Appendix A. A pre-post evaluation design will be used. All PHC providers will be surveyed before, immediately following the training session and 4-months after the intervention program is delivered. Additionally, a random sample of providers will be identified from which a cross-sectional sample of eligible smokers from their practice will be surveyed pre- and post-intervention to assess provider performance in the delivery of 5As tobacco treatment intervention. Qualitative interviews will be completed with a sub-sample of providers at the end of year 1.

Provider Sampling: An invitation letter and program summary will be sent to PHC providers identified in Activity 2.1. A follow-up phone call will be placed to all providers by a member of the investigative team, one week after the invitation was sent to confirm interest in participation. Providers will sign an information sheet and consent form and complete a brief survey at baseline (Time 1), immediately following the foundational training (Time 2) and again 4-months following intervention delivery (Time 3) to assess outcomes of interest. Semi-structured interviews will be conducted with 10 PHC providers at the end of year 1 in order to inform year 2 activities.

Patient Sampling: In order to gather information about rates of 5As delivery, a sub-sample of 20 providers will be randomly selected. Provider eligibility will include: 1) participation in training program; 2) a GP employed in a primary care practice; and, 3) a minimum of 25 patients per day seen in the practice in order to ensure efficient use of data collection resources. From this sub-sample of providers, 16 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. 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; and, have 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 will 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 16 patients 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.

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 15-item knowledge assessment to examine key concepts addressed as part of training. The knowledge assessment has been tested as part of the TiTAN Crte project.

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. The survey instrument was developed based on previous research that examined behavioral factors most closely associated with tobacco treatment delivery and uses a 5-point Likert scale (strongly agree to strongly disagree). (21)

Provider Performance in the Delivery of Cessation Treatments: Performance in the delivery of each of the 5As 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 5As delivery to be well correlated with criterion measure of an audiotape assessment of the physician-patient interaction (r= .67, p< .001). (22) 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. (9,23,24)

Secondary Outcome Measures: The post-assessment survey and qualitative interviews 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, 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.

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 (5As), 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 time (pre vs. post assessment). 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.

Sample Size Calculation: 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. We have estimated that the ICC will be 0.01. (9) All calculations were based on a two-sided test, with 90% power, and an alpha level of 0.05. We have estimated rates of advice to be 53% at baseline and the effect in the current project to be 20% based on rates achieved in the TiTAN Crete project. The sample size calculation, based on 20 randomly selected practices, indicates 16 patients per provider are required. A total of 640 patients will be sampled at the pre-post assessment.

b. Quantify the amount of change expected from this project in terms of your target audience

As per the theoretical model we expect to see a 50-70% increase in provider tobacco treatment knowledge. We also expect to see a 20% increase in rates at which advice to quit and offer of assistance with quitting is delivered. The expected changes in rates of treatment delivery are based on those observed in Canada (Ottawa Model) and the TiTAN Crete project (See Table 1).

c. Describe how you plan for the project outcomes to be broadly disseminated.

The established investigative team has a large network of collaborators in both the national health care system in Greece and Cyprus and clinician networks in each of the projects subregions to support dissemination activities. Furthermore assets created have the potential to be used beyond the scope of the TiTAN-Greece & Cyprus project within PHC practice settings in Europe and support the establishment of a strong PHC arm of the Global Bridges Network in the Mediterranean. We will present findings at national and international meetings, including the Joint Meeting of the North American and European Society for Research on Nicotine and Tobacco (8-11 March 2017, Florence, Italy), the European Conference on Tobacco or Health (23-25 March 2017, Oporto, Portugal), and the 17th World Conference on Tobacco or Health

(March 2018, Cape Town, South Africa). Our team also will aim to publish our findings in international peer-reviewed journals in order to disseminate.

In addition the TiTAN website (http://www.titan.uoc.gr), created as part of the 2014-2016 TiTAN Crete project will be used as a central hub for communication with the practice network and can be accessed by professionals in Greece as well as other nations. Members of our project team (Dr. Constantine Vardavas and Dr. Sophia Papadakis) also work closely with the European Network on Smoking Prevention and Cessation (ENSP) and will ensure the integration of assets created as part of the present are disseminated to the broader tobacco treatment community in Europe. We have already shared as part of a second Global Bridges funded project, EPACTT (EuroPean Accreditation Curriculum on Tobacco Treatment), the "Ottawa Model for Smoking Cessation" / TiTAN tool kit, which has been adapted for use in five languages for use in Eastern European PHC settings.

6. DETAILED WORKPLAN & DELIVERABLES SCHEDULE: Workplan

The workplan objectives and main activities to be under as part of the taken TiTAN-Greece & Cyprus project have been outlined above (Section 4) and below in tabular format. In short, during months 1-2, the assembled faculty and GP leads will complete an orientation to the tobacco training program (Deliverable 1.1). Concurrently during months 1-4 we will assemble to contact list of GPs, recruit and schedule the regional training sessions (Deliverable 1.2). We will perform a needs assessment among PHC providers in each sub-region during months 3-6 (Deliverable 1.3) and as required adapt the tools needed to implement tobacco cessation in these PHC settings. The foundational training program will be delivered in the five targeted regions between months 5-16 (Deliverable 1.4). In months 5-16 the TiTAN "toolkit" will be enhanced and disseminated to GPs to support integration of tobacco treatment in clinical routines (Deliverable 2.1 and 2.2). We will update and re-launch the TiTAN website (Deliverable 3.1) as well as launch the tobacco treatment webinar series (Deliverable 3.2). Project evaluation activities will be implemented alongside Implementation activities including the pre-assessment (month 3-8) and post-assessment data collection activities (months 13-18). In parallel, support will be provided to all PHC interested in quitting smoking (Deliverable 4.1). The project team will meet bi-monthly and all partners will meet quarterly to ensure high quality execution of the project objectives and dissemination activities.

Deliverables Schedule

Deliverable 1.1: PHC Champions' training session held (Month 2).

Deliverable 1.3: Foundational training sessions scheduled for all regions (Month 2).

Deliverable 1.2: Contact list for all PHCs in target regions in Greece and Cyprus (Month 3).

Deliverable 1.3: Report on the needs assessment with key recommendations (Month 6).

Deliverable 1.4: Report of the execution of foundational tobacco treatment training sessions in all regions (Month 16).

Deliverable 2.1: TiTAN "Toolkit" disseminated to PHC settings (Months 5-16).

Deliverable 3.2: TiTAN website re-launched (Month 4/5).

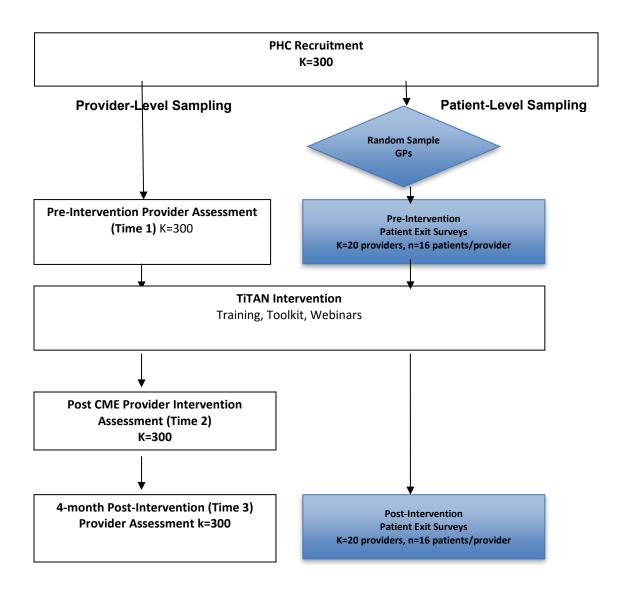
Deliverable 4.1: Support provided to all PHC providers interested in quitting (Month 12).

Deliverable 4.2: Final report on program impacts (Month 20-22).

<u>Project Timeline</u> This project will be completed over a 2-year timeframe.

Year	Year 1						Year 2					
Activities / Month	1-2	3-4	5-6	7-8	9-10	11-12	13-14	15-16	17-18	19-20	21-22	23-24
	S-O	N-D	J-F	M-A	M-J	J-A	S-O	N-D	J-F	M-A	M-J	J-A
Project Management												
Project start-up activities												
Kick-off meetings (all partners)												
Bi-monthly PM meetings												
Quarterly partner meetings												
Finalize IRB Submissions												
Finalize training calendar (regional)												
Monitoring, quality control												
Global Bridges Reporting (Global Bridges)			R1			R2		R3		R4		
Objective 1:												
Activity 1.1: Faculty Training & Development												
Activity 1.2: Generate GP Contact List												
Activity 1.3: Needs Assessment												
Activity 1.4: Deliver Regional Training												
Objective 2:												
Activity 2.1: Enhance Tool kit												
Activity 2.2: Disseminate Tool kit												
Objective 3:												
Activity 3.1: E-blasts & website re-launch												
Activity 3.2: Deliver webinar series												
Objective 4:												
Activity 4.1: GP Cessation Support												
Evaluation Activities												
Provider Baseline Assessment (T1)												
Patient Baseline Assessment (T1)												
Provider Post-CME Assessment (T2)												
Provider Follow-up Assessment (T3)												
Patient Follow-up Assessment (T3)												
Dissemination Activities												
TiTAN website re-launch & Updates												
Press Release #1 (national & local)												
Conference Presentation (SRNT, ECTH, WCTH, WONCA, ERS)	1			SRNT/ ECTH			ERS			WCTH		
Manuscript Preparation												
Press Release #2 (national and local)												

Appendix A: Pre-Post Evaluation Design with Nested Patient-level Sampling



E. References

- (1) World Health Organization. WHO Report on the Global Tobacco Epidemic; The MPOWER Package. 2008.
- (2) Vardavas CI, Symvoulakis EK, Lionis C. Dealing with tobacco use and dependence within primary health care: time for action. Tob Induc Dis 2013 Feb 26;11(1):6-9625-11-6.
- (3) Stead L, Bergson G, Lancaster T. Physician advice for smoking cessation. Cochrane Database Syst Rev 2008 Apr 16;(2)(2):CD000165.
- (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 Oct;23(5):772-776.
- (5) Tsalapati K, Vardavas CI, Athanasakis K, Thireos E, Vozikis A, Pavi E, et al. Going up in ashes? Smoking-attributable morbidity, hospital admissions and expenditure in Greece. Eur J Public Health 2014 Mar 27.
- (6) Schoretsaniti S, Filippidis FT, Vardavas CI, Dimitrakaki C, Behrakis P, Connolly GN, et al. 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 Jan;39(1):140-145.
- (7) Fiore MC, Jaén CR, Baker TB, et al. *Treating Tobacco Use and Dependence: 2008 Update.* Clinical Practice Guideline. 2008.
- (8) European Network on Smoking Prevention. European Smoking Cessation Guidelines. 2012.
- (9) 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 Jun;56(6):390-397.
- (10) 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 Dec;16(6):385-386.
- (11) 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 Nov 29;11:94-2296-11-94.
- (12) Vardavas CI, Patelarou E, Chatzi L, Roumeliotaki T, Sarri K, Murphy S, et al. Factors associated with active smoking, quitting, and secondhand smoke exposure among pregnant women in Greece. J Epidemiol 2010;20(5):355-362.

- (13) 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(5):269-273.
- (14) Duaso MJ, McDermott MS, Mujika A, Purssell E, While A. Do doctors' smoking habits influence their smoking cessation practices? A systematic review and meta-analysis. Addiction 2014 Jul 8.
- (15) 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 Jun 17;51(3-4):199-213.
- (16) 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 Mar;99(3):299-312.
- (17) 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 Aug 27;8:181-6963-8-181.
- (18) 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 Feb 14;11:11-230X-11-11.
- (19) Tsiantou V, Shea S, Martinez L, Agius D, Basak O, Faresjo T, et al. Eliciting general practitioners' salient beliefs towards prescribing: a qualitative study based on the Theory of Planned Behaviour in Greece. J Clin Pharm Ther 2013 Apr;38(2):109-114.
- (20) Lionis C, Petelos E, Shea S, Bagiartaki G, Tsiligianni IG, Kamekis A, et al. 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 Feb 17;15(1):34-2296-15-34.
- (21) Papadakis S, Pipe AL, Reid RD, Tulloch H, Mullen KA, Assi R, et al. Effectiveness of performance coaching for enhancing rates of smoking cessation treatment delivery by primary care providers: Study protocol for a cluster randomized controlled trial. Contemp Clin Trials 2015 Sep 5;45(Pt B):184-190.
- (22) 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 Mar;18(2):183-188.
- (23) 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 Apr 21;96(8):594-603.

- (24) 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 Apr;22(4):478-484.
- (25) Papadakis S, Gharib M, Hambleton J, Reid RD, Assi R, Pipe AL. Delivering evidence-based smoking cessation treatment in primary care practice: experience of Ontario family health teams. Can Fam Physician 2014 Jul;60(7):e362-71.
- (26) Reid RD, Mullen KA, Slovinec D'Angelo ME, Aitken DA, Papadakis S, Haley PM, et al. Smoking cessation for hospitalized smokers: an evaluation of the "Ottawa Model". Nicotine Tob Res 2010 Jan;12(1):11-18.
- (27) 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 June 2013;56(6):390-397.
- (28) Papadakis S, Cole A, Reid R, Coja M, Aitken D, Mullen K, et al. Increasing rates of tobacco treatment delivery in primary care practice: Evaluation of the "Ottawa Model for Smoking Cessation". . Annals of family practice (in press).