International Tobacco and Health Research and Capacity Building Program

Program Review 2002-2012

Fogarty International Center

With co-funding partners:

National Cancer Institute
National Institute on Drug Abuse
National Institutes of Health, Office of the Director
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Executive Summary
Globally, tobacco is responsible for 16% of deaths among men and 7% among women and represents one of the most significant threats to global health. To meet this challenge, the Fogarty International Center (FIC), and its partnering Institutions, the National Cancer Institute (NCI), the National Institute on Drug Abuse (NIDA), and Office of Behavioral and Social Sciences Research (OBSSR) at NIH, established the International Tobacco and Heath Research and Capacity Building Program (TOBAC). The program has sought to increase collaborations between investigators in the United States and other high-income countries (HIC) and researchers, institutions, and scientists in low- and middle-income countries (LMICs).

Program Goals
The program solicits collaborative research and capacity building projects that address the burden of tobacco use in low-and middle-income countries (LMICs) by:

- Pursuing observational, intervention and policy research of LMIC relevance and;
- Building capacity in epidemiological and behavioral research, prevention, treatment, communications, implementation, health services and policy research.

<table>
<thead>
<tr>
<th>Year</th>
<th>Applications Received</th>
<th>Grants Awarded</th>
<th>% Funded</th>
</tr>
</thead>
<tbody>
<tr>
<td>2002</td>
<td>64</td>
<td>14</td>
<td>22%</td>
</tr>
<tr>
<td>2007</td>
<td>37</td>
<td>11</td>
<td>30%</td>
</tr>
<tr>
<td>2012</td>
<td>41</td>
<td>9</td>
<td>22%</td>
</tr>
<tr>
<td>TOTAL</td>
<td>142</td>
<td>34</td>
<td>24%</td>
</tr>
</tbody>
</table>

Collaborations
This program encourages grantees to create a global network of researchers by forging new partnerships and collaborations. To this end, grantees from 2002-2012 have been successful establishing working relationships with researchers from more than 30 countries.

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Scientific Publications
Publications allow program grantees to share relevant and important research evidence with the global tobacco community. To date, more than 400 articles have been published with TOBAC support. For a complete list of publications, please see Appendix F.

<table>
<thead>
<tr>
<th>Year*</th>
<th>Journal Articles</th>
<th>Books Published</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>2002</td>
<td>205</td>
<td>5</td>
<td>210</td>
</tr>
<tr>
<td>2007</td>
<td>200</td>
<td>6</td>
<td>169 **</td>
</tr>
<tr>
<td>TOTAL</td>
<td>405</td>
<td>11</td>
<td>416</td>
</tr>
</tbody>
</table>

* year indicates first grant funding year
** we would expect the 2007 cohort to still be publishing

Training Tobacco and Health Researchers
Training the next generation of tobacco scientists is an integral feature of TOBAC. To date, more than 3,500 individuals have received tobacco control research training through long-term mentorship, meeting/workshop support, and/or short courses.

The Framework Convention on Tobacco Control
The Framework Convention on Tobacco Control (FCTC), the first treaty ever negotiated under the auspices of WHO, aims to “protect present and future generations from the devastating health, social, and environmental and economic consequences of tobacco consumption and exposure to tobacco smoke by providing a framework for tobacco control measures.” TOBAC projects have successfully provided empirical evidence on almost all articles of the FCTC.
Generating Evidence and Capacity

TOBAC grantees have contributed to progress on multiple FCTC articles with evidence generation that has informed policy in LMICs.

**Hungary** - In Hungary, a country with some of the highest smoking rates in Europe, local investigators from TOBAC-supported studies demonstrated that taxes are an effective policy intervention for reducing smoking prevalence. Scientific findings were presented to legal and public health officers in the local governments. During the four years following this dissemination of evidence, tobacco sales taxes were increased nine times, an example of how evidence and data can help inform sound national health policy. In addition, following engagement with local researchers trained in the TOBAC program, the State Secretary's cabinet passed national clean air laws that protect non-smokers in public places.

**Syria** - Smoking has long been a popular pastime in the Middle East. Syria is no exception, where more than half of men smoke cigarettes and women are increasingly taking up the habit. Hookahs, or water pipes, are also prevalent partly because of the erroneous perception that they are a "cleaner," "safer" way of consuming tobacco. TOBAC supported a US-Syrian research partnership, which produced the first-ever population surveys on smoking prevalence, as well as additional studies on toxicity, dependence, and on the effectiveness of various cessation approaches and the impact of secondhand smoke. Information generated by the project has been used to inform the country's health policies, including a ban on public smoking.
Program Timeline
Since the TOBAC program’s inception in 2001, the tobacco research field has experienced landmark successes. Key milestones in tobacco control are illustrated below, including those specific to the TOBAC program.

1999: FIC Gathers NIH and WHO experts to brainstorm and form the TOBAC program

2000: TOBAC

2001: FIC Releases the first TOBAC RFA

2002: FIC competitively funds 14 individual TOBAC awards

2003: The FCTC is unanimously adopted by the World Health Assembly

2004: The FCTC is entered into force

2005: The FCTC is entered into force

2006: FIC releases the second TOBAC RFA, citing success in round one

2007: FIC Funds 11 individual TOBAC awards

2008-2011: TOBAC grantees experience success in research, capacity building, and policy

2011: 172 countries are a Party to the FCTC

2011: FIC releases the third TOBAC RFA

2012: FIC competitively funds 9 individual TOBAC awards

2002-2012 TOBAC Grants

<table>
<thead>
<tr>
<th>Year(s) of Award</th>
<th>Grant Title</th>
<th>Principal Investigator</th>
</tr>
</thead>
<tbody>
<tr>
<td>2002</td>
<td>Asian Leadership Training for Tobacco Control Research</td>
<td>Ferry, Linda Hyder</td>
</tr>
<tr>
<td>2002</td>
<td>Cessation Research and Training in India and Indonesia</td>
<td>Lando, Harry Alan</td>
</tr>
<tr>
<td>2002</td>
<td>Egypt Smoking Prevention Research Initiative</td>
<td>Israel, Ebenezer</td>
</tr>
<tr>
<td>2002</td>
<td>Establishment of the Syrian Center for Tobacco Studies</td>
<td>Ward, Kenneth D.</td>
</tr>
<tr>
<td>2002</td>
<td>Mobilizing Youth for Action Against Tobacco in India</td>
<td>Perry, Cheryl Lee</td>
</tr>
<tr>
<td>2002</td>
<td>Monitoring tobacco mortality in 2M adults in 4 countries</td>
<td>Peto, Richard</td>
</tr>
<tr>
<td>2002</td>
<td>South Africa Adolescent Smoking: A Longitudinal Study</td>
<td>Brook, David William</td>
</tr>
<tr>
<td>2002 &amp; 2007</td>
<td>Strengthening monitoring of Indian tobacco mortality</td>
<td>Jha, Prabhat</td>
</tr>
<tr>
<td>2002</td>
<td>Technology Assisted Dominican Republic Tobacco Control</td>
<td>Ossip, Deborah J.</td>
</tr>
<tr>
<td>2002</td>
<td>Tobacco Control in S. Africa: Prevention and Capacity Building</td>
<td>Resnicow, Ken A.</td>
</tr>
<tr>
<td>2002</td>
<td>Tobacco Use Among Argentinean Youth: A Cohort Study</td>
<td>Perez-Stable, Eliseo J</td>
</tr>
<tr>
<td>2002</td>
<td>Psu-Western &amp; Southern African Tobacco Research Project</td>
<td>King, Gary</td>
</tr>
<tr>
<td>2002 &amp; 2007</td>
<td>Epidemiology &amp; Intervention Research for Tobacco Control</td>
<td>Samet, Jonathan M.</td>
</tr>
<tr>
<td>2007</td>
<td>SMS Turkey: Harnessing the power of TXT messaging to promote smoking cessation</td>
<td>Ybarra, Michele</td>
</tr>
<tr>
<td>2007</td>
<td>The Political Economy of Tobacco Control in Southeast Asia</td>
<td>So, Anthony D.</td>
</tr>
<tr>
<td>2007</td>
<td>Increasing Capacity for Tobacco Research in Hungary</td>
<td>Foley, Kristie L.</td>
</tr>
<tr>
<td>Year</td>
<td>Title</td>
<td>Author(s)</td>
</tr>
<tr>
<td>------</td>
<td>----------------------------------------------------------------------</td>
<td>----------------------------------</td>
</tr>
<tr>
<td>2007</td>
<td>Advancing Cessation of Tobacco In Vulnerable Indian Tobacco consuming Youth</td>
<td>Reddy, Srinath K.</td>
</tr>
<tr>
<td>2007</td>
<td>Building Capacity of Tobacco Cessation in India &amp; Indonesia</td>
<td>Nichter, Mark A.</td>
</tr>
<tr>
<td>2007</td>
<td>Network for Tobacco Control among Women in Parana, Brazil</td>
<td>Scarinci, Isabel C.</td>
</tr>
<tr>
<td>2007 &amp; 2012</td>
<td>Responding to the changing tobacco epidemic in the Eastern Mediterranean Region</td>
<td>Maziak, Wasim</td>
</tr>
<tr>
<td>2007</td>
<td>Tobacco Control Research and Training in South America</td>
<td>Perez-Stable, Eliseo J.</td>
</tr>
<tr>
<td>2012</td>
<td>Capacity Building for Tobacco Control in Tunisia, North Africa &amp; Middle East</td>
<td>Lando, Harry Alan</td>
</tr>
<tr>
<td>2012</td>
<td>Tobacco Control Network among Women in Parana, Brazil - II</td>
<td>Scarinci, Isabel C.</td>
</tr>
<tr>
<td>2012</td>
<td>Cinema Smoking and Youth Smoking in Latin America</td>
<td>Sargent, James and Thrasher, James</td>
</tr>
<tr>
<td>2012</td>
<td>Building Capacity for Tobacco Research in Romania</td>
<td>Foley, Kristie L.</td>
</tr>
<tr>
<td>2012</td>
<td>From Production To Retailing: Policy-Oriented Research On Tobacco Economy In Argentina</td>
<td>Champagne, Beatriz Marcet and Schoj, Veronica</td>
</tr>
<tr>
<td>2012</td>
<td>Tobacco Control Policy Analysis &amp; Intervention Evaluation in China and Tanzania</td>
<td>Hu, Teh-Wei</td>
</tr>
<tr>
<td>2012</td>
<td>Preventing tobacco use among adolescents in Uruguay: Project Activate</td>
<td>Stigler, Melissa Harrell</td>
</tr>
<tr>
<td>2012</td>
<td>Building Research and Capacity on the Economic Policy-Tobacco Control Nexus in Africa</td>
<td>Drope, Jeffrey</td>
</tr>
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</table>
1.0 Introduction and Background

1.1 Program Review

The John E. Fogarty International Center (FIC) at the National Institutes of Health (NIH) supports international collaborative research and training programs that advance the NIH mission through international partnerships. Guided by the FIC Framework for program assessment, Fogarty conducts reviews for each of its extramural programs. The purpose of these reviews is to analyze program implementation, identify near-term and long-term outputs, outcomes and impacts.

The *International Tobacco and Health Research and Capacity Building Program* (“TOBAC Program” or “the Program”) was reviewed over the course of several months in early 2013. Established in 2002, the Program’s purpose is to fund “collaborative research and capacity building projects that address the burden of tobacco use in low-and middle-income countries (LMICs) by: (1) pursuing observational, intervention and policy research of LMIC relevance; and (2) building capacity in epidemiological and behavioral research, prevention, treatment, communications, implementation, health services and policy research.” A total of 34 R01 awards were made to investigators at US and international institutions in fiscal years 2002, 2007, and 2012.

This report describes the results of the TOBAC Program review. After a brief background and description of review methodology, review findings and recommendations are then detailed in the following sections: Program Background and Landscape; Program Structure; Program Results; and Policy and Program Outcomes. Appendices include a full list of TOBAC Program awards as well additional documents to support the analyses presented in this report.

This report is part of a larger tobacco-related initiative, conducted through FIC’s Center for Global Health Studies (CGHS), in partnership with OBSSR, NCI, and NIDA. CGHS held a workshop from June 24-25, 2013 that brought together TOBAC grantees and leaders in tobacco research in an effort to promote dialogue and collaboration between leading researchers, research funders, and policymakers in LMICs. Participants discussed common research priorities, opportunities, and synergies. The stated objectives of this larger initiative were to highlight research gaps, opportunities, and emerging new priorities in tobacco-related research and training as they relate to LMICs and enable partnerships between researchers, policy-makers, advocates and research funders. The deliverable is a scientific roadmap in the form of a scientific publication to be published in a peer-reviewed journal and that will help to address gaps in existing research and research capacity and will contribute towards further reducing the global burden of morbidity and mortality caused by tobacco use in LMICs.

1.2 Methodology

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2 Available online at [http://www.fic.nih.gov/About/Staff/Policy-Planning-Evaluation/Pages/evaluation-framework.aspx](http://www.fic.nih.gov/About/Staff/Policy-Planning-Evaluation/Pages/evaluation-framework.aspx).

3 The CGHS is a new body at the FIC and has been designed to serve as a hub for short-term, project-based scholarship in global health science and policy, short-term training, as well as a forum for international scientific dialogue and collaboration in global health research. A multidisciplinary, multi-sectoral approach is encouraged in all projects, utilizing project-based teams of researchers and individuals who bring diverse expertise from a range of disciplines and sectors. CGHS strives to serve as a catalytic force that brings NIH together with leading low- and middle-income country (LMIC) scientists and policymakers to discuss common research priorities, opportunities and synergies.
The approach to this review of the TOBAC Program was broadly guided by the FIC Framework for Evaluation. All TOBAC Program data were collected and summarized by FIC staff in the Division of International Science Policy, Planning, and Evaluation. An NIH Institute Planning Committee, consisting of representatives from TOBAC Program co-funding Institutes with equities in the Program, including NCI, NIDA, and OBSSR, reviewed and approved the report.

An underlying series of analysis metrics, detailed in Appendix B, were used to gather and review all data, which were collected from several sources. Many data came from NIH databases including the following: NIH RePORT, eSPA, MEDLINE, SPIRES+, IMPAC II and QVR. Specifically, publication data came from an eSPA module that provides a listing of all MEDLINE articles associated with grants. The publication to project link was obtained from SPIRES or SPIRES matches plus publication matches augmented using additional eSPA algorithms (SPIRES+). Further methodology is described in the publications section (Section 4.1.2). Descriptive data on TOBAC applications and awards, including funding, were obtained from the central NIH awards management database (IMPAC II) via the Query/View/Response tool. Co-funding data for non-NIH data were supplemented by FIC Budget Office personal tracking spreadsheets.

Much of the trainee, capacity building, publications, research, collaborations, and policy impact data were extracted from individual annual progress reports and final reports, submitted to NIH between 2002 and 2011, representing the first two of three rounds of the TOBAC Program. However, where possible and appropriate, data reflects information from the most recent round of awards issued in 2012. FIC Global Health Matters publications were used to help determine policy impacts for five individual TOBAC awards.

Grantees were asked to informally volunteer success stories regarding scientific, capacity building and policy impacts of their research via email. When necessary and helpful, semi-structured discussions were conducted with individual awardees (grantee discussion guides can be found in Appendix C) to further elaborate on the elements of evidence, policy, and capacity building successes reported in progress reports. These discussions consisted of open-ended questions covering three main topics: empirical evidence generation, capacity building impacts, and policy impacts. Interviews with other tobacco experts helped shape the overall direction of the report. A focus group conducted with current TOBAC Program awardees helped identify next steps and possible research gaps in LMICs. Partnering NIH Institutes and Centers, including NCI and NIDA, were consulted for history, background, and context of the TOBAC program and the tobacco control research landscape generally.

Information collected on the research landscape of tobacco control research in LMICs was collected through an internet scan for landscape information, including literature reviews in PUBMED using search terms “tobacco control research” and LMIC, and “tobacco control research” and capacity. Landscape information was also obtained from discussions with principal investigators (PIs), NIH Planning Committee members, past peer-review panel members, program funding organizations, and other experts.

There are limitations to this report. First, reported trainee numbers were based on information provided by PIs in progress reports and confirmed via email correspondence. Since there is no official requirement for reporting trainees on NIH R01 grants, the trainee numbers herein almost certainly underestimate the total trainees who have benefited from TOBAC awards. Second, not all publications resulting from the program were linked to the NIH TOBAC grant in PUBMED; some data on publications in non-English journals or publications that are pending was provided by PIs. As a result, the numbers of
publications presented in this report are almost certainly underestimated. Third, informal conversations helped us define the specific policy outcomes described in this report. Since we were not able to speak with all of the TOBAC grantees, and TOBAC projects vary greatly, it cannot be assumed that the experiences relayed in this report are representative of TOBAC grantees overall.

2.0 Program Background and Landscape

Tobacco use is the leading global cause of preventable death, including death from cancer and other serious diseases. Almost six million people die of tobacco use-related illness each year – an average of one person every six seconds – and tobacco use accounts for 10% of adult mortality globally. Tobacco use is increasing in LMICs, which will bear the brunt of the tobacco epidemic in the 21st century. Already, nearly 80% of tobacco-related deaths occur in LMICs. Without a significant shift in worldwide prevalence patterns, smoking will cause eight million deaths annually by 2030. Given these trends, reducing tobacco use must be a central priority in global research and public health efforts.

2.1 The Framework Convention on Tobacco Control

This section describes a key element of the global dialogue in which the International Tobacco and Health Research and Capacity Building Program (TOBAC) was launched, the FCTC. The FCTC, the first treaty ever negotiated under the auspices of the WHO, aims to “protect present and future generations from the devastating health, social, and environmental and economic consequences of tobacco consumption and exposure to tobacco smoke by providing a framework for tobacco control measures.” The FCTC was unanimously adopted by the World Health Assembly in May 2003 and entered into force in February 2005. As of February 2013, 176 countries are parties to the FCTC and are required to put in place evidence-based measures to reduce the demand for and supply of tobacco products. The FCTC now covers about 90% of the world’s population. Notably, the US has signed the treaty but the Senate has yet to ratify it.

The FCTC is widely recognized as a crucial force spurring the adoption of evidence-based tobacco control policies around the world. Research is needed to examine the effect of tobacco control policies adopted in response to the FCTC to understand how best to implement policy and programmatic interventions in LMICs.

Key FCTC provisions include the following: bans on tobacco advertising, promotion, and sponsorship (Article 13); bans on misleading packaging or descriptors indicating that some cigarettes are safer than others (Article 11); mandated warning labels that cover at least 30% of tobacco packaging (Article 11); and encouragement of smoke-free workplace laws (Article 8). The FCTC also encourages price and tax measures to reduce the demand for tobacco products, especially among young populations (Article 6), and requires parties to develop and disseminate evidence-based treatment and cessation resources (Article 14). Very integral to the TOBAC program is the FCTC’s call for research, surveillance, and the exchange of information (Article 20). This article calls on Parties to the treaty to undertake and promote

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national research programs in tobacco control. Article 20 also calls for Parties to establish surveillance efforts to determine the magnitude, patterns, determinants, and consequences of use of tobacco smoke.

Additionally, in 2008, the WHO introduced the MPOWER Framework, a package of six evidence-based tobacco control measures that correspond to parts of the FCTC. These measures include the following: monitoring of tobacco use and prevention policies; protecting people from secondhand tobacco smoke; offering help to quit tobacco use; warning about the dangers of tobacco; enforcing bans on tobacco advertising, promotion, and sponsorship; and raising taxes on tobacco.

2.2 Program Background

In the late 1990s, it became clear to the scientific community working on global tobacco research that tobacco use and related disease was shifting from high-income countries (HIC) to LMICs. Because many LMICs had not yet faced tobacco use as a serious public health challenge, countries lacked the scientific capacity to conduct research that could inform locally relevant policy and programmatic interventions that could curb tobacco use.

In response to these global trends and capacity concerns, FIC convened a series of expert consultative meetings from 1999-2001. These meetings brought together expert researchers from NIH Institutes and Centers (ICs), US Centers for Disease Control and Prevention (CDC), LMICs, and the World Health Organization (WHO) to opine on relevant research priorities and to inform the design of a program that could address both growing research needs and an extraordinary lack of tobacco research capacity in LMICs. FIC encountered overwhelming support for the program, which prompted staff to begin the process of creating a Request for Application (RFA). A long term, in-depth literature review and an examination of then-current research gaps and past efforts rounded out the process of designing the Program.

On June 25, 2001, FIC together with NCI and NIDA initiated the International Tobacco and Health Research and Capacity Building Program (TOBAC) with an RFA using the individual research grant (R01) award mechanism. A copy of the RFA for the most recent round of awards (2012) can be found at http://grants.nih.gov/grants/guide/rfa-files/RFA-TW-11-003.html or in Appendix A. The TOBAC program was designed to address the critical role of research and local research capacity building in reducing the burden of tobacco consumption in LMICs. It aimed to generate a solid evidence base that could inform effective local tobacco control policies and support epidemiologic and behavioral research, as well as prevention, treatment, communications, health services, policy, and, eventually, economic research in LMICs. From the beginning, the program had a focus on sustainability, as it required applications to be accompanied by letters of support from in-country partners or LMIC governments.

The RFA received widespread support from the scientific community and from the Department of Health and Human Services (HHS). Then HHS Secretary Tommy Thompson commented upon the release of the

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RFA: “On my first day on the job, I indicated that this department would be committed to US support and technical assistance on global health, including tobacco control.”

2.3 TOBAC Program Purpose and Scientific Objectives

The specific objectives of the TOBAC program, as identified in the RFA, are two-fold: 1) reducing the burden of tobacco consumption in LMICs by conducting observational, intervention, and policy research of local relevance; and 2) building capacity in epidemiological and behavioral research, prevention, treatment, communications, health services, and policy research. To accomplish these objectives, funded investigators engage in epidemiological, behavioral, intervention, and susceptibility research to enhance knowledge of tobacco-related health problems and risks relevant to LMICs. Policy-related research as well as research conducted on the economics of tobacco use and tobacco control help shed light on the ecosystem of tobacco use and control and a range of factors that determine the feasibility and impact of various policy interventions. Economic-focused research, a category newly added to the 2012 RFA, may also examine the economic burden of tobacco use on health care systems or show the long-term economic effects of tobacco control.

Research capacity building in LMICs is the second tenet and strategic goal of the TOBAC program. Capacity building promotes the advancement of research and enhances the number and knowledge of tobacco investigators in LMICs. The capacity to conduct rigorous tobacco-related research is essential to a country’s ability to implement and evaluate the FCTC. A long-term outcome of capacity building is the improved ability to augment scientific competence and skills nationally and internationally, and the development of a cadre of tobacco researchers with appropriate research training and support who can continue to conduct tobacco related research in LMICs beyond the term of the award.

2.4 Program Model

The TOBAC program model allows investigators in the US and other HICs to gain experience working in low- and middle-income-settings while at the same time strengthening the research base of the US and foreign institutions in LMICs. The program is designed to promote international cooperation between investigators in HICs pursuing research programs on tobacco use and cessation, and scientists and institutions in LMIC where tobacco consumption is a current or anticipated public health urgency by requiring partnerships, collaborations, and capacity building. The administrative architecture of the program reflects this intent with the major portion of the research required to be conducted in the LMIC, and greater than 60 percent of the direct costs requested required to be used in the LMIC for either research and/or capacity strengthening of foreign institutions.

Like many FIC programs, the model emphasizes training and capacity building in addition to scientific research opportunities. However, this award is unique in that it is an R01 grant with an emphasis on capacity building, rather than a more typical FIC D43 or R25 training or education grant that requires a research base or project to be in place for a training award. This is significant in that the Program funds empirical research and capacity building simultaneously. Building capacity is a long-term endeavor; as such, the TOBAC awards fund projects for five-year periods, allowing researchers to build strong regional relationships and develop trust in partnering countries. PIs funded by the program have cited

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the importance of the five-year period in allowing for sustainable capacity building activities in LMICs. Further, the relatively high number of projects that have been funded in multiple cycles highlights the time required to build adequate capacity to conduct research on tobacco, and the utility of long-term project investments in LMICs.

As the RFA states, the TOBAC program model is not intended to provide support for basic biomedical research. Additionally, because of the advent of the CDC’s Global Tobacco Surveillance System (http://www.cdc.gov/tobacco/global/gtss/index.htm), the TOBAC Program is not intended to provide support for surveillance or research focusing primarily on determining the prevalence of tobacco use or secondhand smoke exposure.

2.5 Program Niche within NIH

The TOBAC program plays a unique and complementary role in tobacco research and capacity building at NIH. Several NIH ICs fund tobacco-related science, but the TOBAC program is distinct in its inclusion of research capacity building as an integral part of the proposal requirements. The section below will briefly describe the NIH tobacco research landscape to situate the TOBAC program within the NIH portfolio and the broader LMIC tobacco research landscape.

A search in the NIH Foreign Tracking System (FTS) - an NIH system that tracks all NIH-funded extramural research conducted in foreign countries - reveals that 150 grants from 14 NIH ICs have funded international work related to tobacco, nicotine, or cessation and smoking in the past five years. Of these 150 grants, 68 supported research in LMICs. The majority of the 150 international grants come from NCI (37) and NIDA (32), which we will review in more detail below. The National Heart, Lung, and Blood Institute (NHLBI), the National Institute of Environmental Health Sciences, and the National Institute of Aging funded over 10 awards related to tobacco, nicotine, and cessation and smoking from 2008-2012. Figure 1 shows the number of grants funded by Institute, not including the FIC-administered TOBAC awards.

**Figure 1: Number of tobacco-related grants*, by Institute, 2008-2012**

*Grants were extracted from FTS using a keyword search for “tobacco,” “nicotine,” or “cessation”
Along with their financial contributions to fund the TOBAC program, NCI and NIDA each support a substantial tobacco research funding portfolio. Between the two Institutes, over 65 projects related to tobacco have been funded since 2008. Below, we briefly discuss the NCI and NIDA tobacco portfolios in an effort to illustrate the niche of the TOBAC program at NIH.

Led by OBSSR, the Tobacco Policy Modeling Workshop was held on January 16-17, 2013 in Bethesda, MD. Tobacco control experts, modeling and simulation experts, and government officials from NIH, CDC, and the Food and Drug Administration were convened in order to foster the formation of interdisciplinary research teams capable of using mathematical modeling and simulation to address the most pressing policy questions in tobacco control. The meeting also produced recommendations on how to leverage the potential for modeling and simulation to inform tobacco policy decision making. Given the strong policy focus of TOBAC, it will be important to continue the dialogue between individuals who are following up on the recommendations from this workshop meeting and TOBAC program leaders.

International Tobacco Research at NCI

NCI funds a wide range of tobacco research grants and projects that have an international focus. In addition to financially supporting the TOBAC program, NCI supports tobacco control policy research, economic research, research on cessation and interventions, tobacco products and industry research as well as research on lung cancer.

NCI funds innovative tobacco control policy research in the form of the P01 award, Effectiveness of Tobacco Control Policies in High- vs. Low-Income Countries. This program builds upon work begun by the International Tobacco Control (ITC) Project, which is also supported by NCI through two R01 grants. The objective of the ITC Project is to evaluate and understand the impact of the tobacco control policies implemented as part of the FCTC. The ITC Project began in 2002 with annual surveys of smokers in the four major English-speaking countries—the US, the United Kingdom, Canada, and Australia—and has since expanded to more than 20 countries. This project is the only international study that is specifically evaluating the effectiveness of FCTC policies, and as a result, data from the project have quickly become an important source of scientific evidence on the impact of national-level tobacco control policies.

Since 2004, NCI scientists have also been collaborating with the WHO Tobacco Laboratory Network (TobLabNet) and the WHO Study Group on Tobacco Regulation (TobReg) to address research issues related to the establishment of global capacity for tobacco product testing and research, to inform tobacco policies and regulations, and to aid implementation of specific provisions of the FCTC. NCI also funds significant international cessation and intervention research. NCI leads an HHS-wide effort called QuitNowTXT, which includes a library of smoking cessation messages that provide the foundation for an interactive intervention for adult smokers. HHS is pursuing opportunities to forge a global public-private partnership to make the QuitNowTXT program available to other countries. Global partners committed to collaborating with HHS on this initiative include the mHealth Alliance (hosted by the United Nations Foundation), the World Medical Association, the Campaign for Tobacco-Free Kids, the Center for Global Health at the George Washington University, and Johnson & Johnson, Inc.

Finally, NCI also funds a number of grants focused on smoking cessation. Given the large burden of tobacco use in countries like India and China, establishing a far-reaching, evidence-based intervention for cessation is essential to decreasing tobacco-related morbidity and mortality.
NCI and NIDA together fund the majority of tobacco research at NIH. NIDA partners with international collaborators in a variety of regions (e.g., South America, the Middle East, the Eastern Mediterranean, Southern Africa, and India) to support research to: improve surveillance infrastructure; understand factors influencing tobacco use patterns (including water pipe and hookah); optimize tobacco control efforts and prevention; and test interventions for tobacco cessation. In part, this work is carried out through NIDA’s participation in the TOBAC program.

In addition to the support of the TOBAC program, NIDA supports a multi-national and multidiscipline network of tobacco researchers from the US, Canada, and Africa, who are working together to identify political and economic barriers that inhibit tobacco control in Sub-Saharan Africa, a region that is economically vulnerable and now facing the threat of an increasing non-communicable disease (NCD) burden resulting from tobacco use. Additional goals of this research network are to enhance research capacity by supporting the development of tobacco control research scholars and advancing tobacco-related science that can inform long term, effective tobacco control policy.

Other NIDA-funded research awards focus on topics ranging from tobacco addiction susceptibility, to genetic susceptibility of tobacco use and addiction, to cessation and treatment options. NIDA funds basic and genetic research on tobacco use, as well as research on medications and treatment to aid in smoking cessation. NIDA also supports research focused on teen smoking and uptake as well as the prenatal effects of cigarette smoke on a fetus. Research focusing on smoking during pregnancy, the impact of prenatal tobacco exposure, and the effects of early exposure to tobacco in young people and adolescents on development of addiction and other diseases are all current priorities for NIDA.

Finally, NIDA is working with the pharmaceutical industry to develop and evaluate medications to treat tobacco addiction. For example, NIDA researchers are currently completing a multi-center trial evaluating certain substances used for smoking cessation.

Non-NIH sources of support for tobacco research in LMICs

In recent years, the landscape of LMIC tobacco control funding has welcomed partners like the Bloomberg Initiative, the Bill and Melinda Gates Foundation, and others. While these funders do not primarily fund research, they have worked in close coordination with many TOBAC grantees to ensure their efforts are fueled by the data needed to make effective policy arguments. Bloomberg Philanthropies, for example, has funded LMIC authors to ensure journals like *Tobacco Control* are inclusive of LMIC-authored research publications. Bloomberg also supports the training of public health professionals in LMICs in tobacco control practice and funds extensive surveillance activities in LMICs. The investments augment important efforts funded by the American Cancer Society and the World Health Organization. The Framework Convention Alliance and the Campaign for Tobacco-Free Kids are important players in dissemination of evidence and catalyzing linkages between research and policy.

The UN High-Level Summit on Non-communicable diseases in September 2011 offered an opportunity to place tobacco control on the global health and development agenda. The meeting recognized the overlap of the four major NCDs – cancer, cardiovascular disease, respiratory infection, and diabetes - and their major causes, and thus the need for coordination and cooperation between various agencies. The meeting called on the WHO to develop a comprehensive global monitoring framework and prepare recommendations for a set of voluntary global targets for the prevention and control of NCDs, for
consideration by member states in 2012. The Millennium Development Goals, however, currently make no mention to tobacco control.

In LMICs, government funding still pales in comparison to the enormity of the tobacco use epidemic. *The Tobacco Atlas, 4th Edition* calls for substantially increased funding at the country level to reflect the burden that tobacco use poses to health and economies, particularly in areas like LMICs where use rates are increasing.

The TOBAC program plays an important role in the overall tobacco research landscape in that it provides an opportunity for original research via an R01 platform and requires that PIs incorporate research capacity building efforts into their research efforts. The Program not only supplements robust tobacco research portfolios in NIH ICs like NCI and NIDA, its research focus complements the overall international focus on NCDs and tobacco control by major international funders and implementers like the UN, the Bill and Melinda Gates Foundation, and the Bloomberg Initiative.

### 3.0 Program Management and Partnerships

The remainder of this report will provide a comprehensive analysis of the first ten years of the TOBAC program, highlighting its results to date and examining TOBAC’s contributions to the field of tobacco control research, capacity building and partnership development, and policy outcomes.

#### 3.1 Applications

The TOBAC program was launched in FY2002 with re-competing years in FY2007 and FY2012. All applications were subjected to the NIH peer review process, which was overseen by the Center for Scientific Review at NIH.

In its first year (2002), the TOBAC program received 64 applications, of which, 14 (22%) were funded. In FY2007, FIC re-competed the program and a total of 37 applications were received; of these, 11 (30%) were funded. Four of the funded grants were FY2002 grant recipients who reapplied. Additionally, one 2002 project was funded in 2007 under the leadership of a different PI. In FY2012, FIC again re-competed the program, resulting in 41 applications; of these, nine (22%) were funded. Three projects from 2007 were included in these nine successful applications. A total of 28 individual new projects and six re-competed projects were funded from 2002-2012 for a total of 34 awards over the 10 years of the program (n=14 in 2002, n=11 in 2007, and n=9 in 2012). For a complete list of awards by investigator and title, see Appendix D.

#### Table 1: Total Applications received and funded, FY2002-2012

<table>
<thead>
<tr>
<th>Year</th>
<th># of Applications Received</th>
<th># of Grants Awarded</th>
<th>% Funded</th>
</tr>
</thead>
<tbody>
<tr>
<td>2002</td>
<td>64</td>
<td>14</td>
<td>22%</td>
</tr>
<tr>
<td>2007</td>
<td>37</td>
<td>11</td>
<td>30%</td>
</tr>
<tr>
<td>2012</td>
<td>41</td>
<td>9</td>
<td>22%</td>
</tr>
<tr>
<td>TOTAL</td>
<td>142</td>
<td>34</td>
<td>24%</td>
</tr>
</tbody>
</table>

Of the 29 projects, two were awarded directly to an LMIC foreign institution (R01TW007933, direct to India and 1R01TW009288-01, direct to Argentina). The remaining 27 awards were made to HIC institutions, with sub-awards made to foreign collaborators and where, as noted, the major portion of the research was conducted in an LMIC, and greater than 60 percent of the direct costs requested were required to be used in the LMIC for either research and/or capacity strengthening of foreign institutions.

3.2 Funding by IC Program Partners

Over its 10 year duration, the TOBAC program has had a total of eight NIH co-funding partners and one non-NIH funding partner, the CDC (FY2002-2003 only). The NIH co-funding partners during the first round of the TOBAC program (in 2002) included NCI, NIDA, NHLBI, National Center on Minority Health and Health Disparities, Eunice Kennedy Shriver National Institute of Child Health and Human Development, and the National Institute of Nursing Research. During the second round in 2007, NIH co-funding partners included NCI, NIDA and OBSSR. During the third round in 2012, NIH co-funding partners included NCI and NIDA.

In 2002, 14 awards were made; one was administered by NHLBI and the remaining 13 by FIC. During the second round, a total of 11 grants were funded, eight of which were new grants and three of which were made to awardees from the first round of the program who successfully reapplied for funding; NIDA administered 3 grants while FIC administered the remaining 8. In 2012, a total of 9 grants were made; NIDA administered 3 of the awards and the remaining 6 were administered by FIC. A summary of administering institutes can be found in Table 2.

Table 2: Administering Institutes or Centers (2002-2012)

<table>
<thead>
<tr>
<th>Administering IC</th>
<th># of Grants</th>
</tr>
</thead>
<tbody>
<tr>
<td>NIDA</td>
<td>6</td>
</tr>
<tr>
<td>NHLBI</td>
<td>1</td>
</tr>
<tr>
<td>FIC</td>
<td>27</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>34</strong></td>
</tr>
</tbody>
</table>

In terms of total dollars, FIC was the major funder during the first 11 years of the TOBAC program, contributing a total of over $17M. Funding from other ICs during the first round (2002-2006) amounted to $15.3M (70%) of the total $21.9M administered for the program. Funding contributions by other ICs decreased overall during the second round and totaled $6.7M (43%) out of $15.55M of the total administered costs, increasing slightly again in 2012. Figure 2 depicts co-funding levels by year from FIC and other funding partners.
NCI was the largest co-funding partner, contributing over $13.5M over the first 11 years. Of the remaining NIH partners, the next two largest contributions came from NHLBI and NIDA with $2.4M and $5.3M, respectively.

The average TOBAC award was $307,000 per year between 2002 and 2011. Total costs of the program through FY2012 were approximately $40.7 million, of which FIC contributed approximately 42%.
3.3 Program Snapshot by Region

TOBAC-funded programs have generated evidence in numerous scientific areas. For the purposes of this report, countries were classified according to the World Bank regional categories: Africa, including only Sub-Saharan African countries; East Asia and the Pacific; Europe and Central Asia; Latin America and the Caribbean; Middle East and North Africa; and South Asia. For a full listing of countries included in each World Bank regional category, please see Appendix E.

The TOBAC program has funded research projects in all regions of the world. Over the past 10 years of the program, the majority of awards have supported projects in East Asia and the Pacific, South Asia, and Latin America and the Caribbean. Of the 29 unique TOBAC projects (not including projects that re-competed and were funded in multiple years), 23 (76%) have included work in one of those three regions. Slightly fewer projects were funded in the Middle East and North Africa Region, with research in Syria and Egypt making up the total awards (n=5). Perhaps most notable is the relatively low funding and small number of grants (n=5) in the Sub-Saharan Africa region, with three of the four grants over the 10 year period focusing on work in South Africa.

Figure 4: Total Funding and Number of Grants by Region (2002-2012)
Note: Three awards had collaborators in multiple regions; each region was counted, giving an overall n=40. The funding amounts are split equally across regions.
Figure 5: Total number of awards by region by year (2002-2012)

Note: Three awards had collaborators in multiple regions; each region was counted, giving an overall n=40.

A total of 42 countries are associated with TOBAC project work; a list of these countries is featured in Table 3. Sub-Saharan Africa is the most represented country (although it is the least-funded region), with 6 countries hosting TOBAC activity. The East Asia and Pacific region, the region with the highest number of grants and one of the largest amounts of funding, has TOBAC activity in only four countries, with China and Indonesia hosting the majority of the research and training activity. Finally, South Asian regional activity is completely confined to work in India.

Table 3: TOBAC Activity by Country (2002-2012)

<table>
<thead>
<tr>
<th>Region</th>
<th>Activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Latin America and the Caribbean</td>
<td>8</td>
</tr>
<tr>
<td>Argentina</td>
<td>2</td>
</tr>
<tr>
<td>Brazil</td>
<td>2</td>
</tr>
<tr>
<td>Dominican Rep.</td>
<td>1</td>
</tr>
<tr>
<td>Mexico</td>
<td>2</td>
</tr>
<tr>
<td>Uruguay</td>
<td>1</td>
</tr>
<tr>
<td>Europe</td>
<td>4</td>
</tr>
<tr>
<td>Hungary*</td>
<td>1</td>
</tr>
<tr>
<td>Romania</td>
<td>1</td>
</tr>
<tr>
<td>Russia</td>
<td>1</td>
</tr>
<tr>
<td>Turkey</td>
<td>1</td>
</tr>
<tr>
<td>Middle East and North Africa</td>
<td>6</td>
</tr>
<tr>
<td>Egypt</td>
<td>2</td>
</tr>
<tr>
<td>Syria</td>
<td>2</td>
</tr>
<tr>
<td>Tunisia</td>
<td>1</td>
</tr>
<tr>
<td>Turkey</td>
<td>1</td>
</tr>
<tr>
<td>East Asia the Pacific</td>
<td>9</td>
</tr>
<tr>
<td>China</td>
<td>4</td>
</tr>
<tr>
<td>Indonesia</td>
<td>3</td>
</tr>
<tr>
<td>Region</td>
<td>Awards</td>
</tr>
<tr>
<td>--------------------</td>
<td>--------</td>
</tr>
<tr>
<td>Mongolia</td>
<td>1</td>
</tr>
<tr>
<td>Thailand</td>
<td>1</td>
</tr>
<tr>
<td>South Asia</td>
<td>7</td>
</tr>
<tr>
<td>India</td>
<td>7</td>
</tr>
<tr>
<td>Sub Saharan Africa</td>
<td>8</td>
</tr>
<tr>
<td>Kenya</td>
<td>1</td>
</tr>
<tr>
<td>Malawi</td>
<td>1</td>
</tr>
<tr>
<td>Senegal</td>
<td>1</td>
</tr>
<tr>
<td>South Africa</td>
<td>3</td>
</tr>
<tr>
<td>Tanzania</td>
<td>1</td>
</tr>
<tr>
<td>Zambia</td>
<td>1</td>
</tr>
</tbody>
</table>

### 3.4 Program Snapshot by Research Category

The TOBAC RFA is intended to “solicit collaborative research and capacity building projects that address the burden of tobacco use in LMIC by (1) pursuing observational, intervention and policy research of LMIC relevance and (2) building capacity in epidemiological and behavioral research, prevention, treatment, communications, implementation, health services and policy research.” These goals are reflected in the focus areas of the TOBAC awards, as described below.

Figure 6 shows a breakdown of award by research category. Overall, a majority of the awards from the 2002, 2007, and 2012 grant cycles focus on behavioral research (e.g., risk factor and susceptibility research, attitude and behaviors toward tobacco, initiation, and cessation interventions), and epidemiology. This reflects the categorical suggestions of the RFA, which calls for epidemiological, behavioral, intervention and risk-factor research applications as its first four research areas. TOBAC-funded behavioral research has also addressed important and emerging topics in LMIC tobacco control research such as physician smoking rates, effective cessation interventions, and smoking rates among women.
Epidemiological research represents an important part of the TOBAC portfolio and was particularly well-funded in the first (2002) cycle of grants. The population data that have been produced in countries like India and China have informed the implementation of successful interventions and policies that will be discussed later in this report.

As the TOBAC program matured, a greater number of awards focused on policy and economics research have emerged, while awards focusing on behavioral research have decreased minimally. TOBAC-funded research on the application and efficacy of tobacco control policies in influencing tobacco-related behavior and subsequent adverse health outcomes has increased six-fold from the inaugural round of grants in 2002 to the latest round of awards in 2012. This trend reflects the intention of the RFA, which calls for research on tobacco control policies as a fifth category. This increase also represents the ever-growing importance of the role of research on policy-level interventions. Overall, policy research funded by TOBAC awards is aimed at studying the efficacy and impact on smoking rates of specific FCTC articles.

Like policy-related research, TOBAC-funded research on economic factors influencing tobacco control has increased from 2002 to 2012. The 2012 RFA specifically called for grant applications focused on economic research such as the impact of tax increases on tobacco use and government revenues, the link between tobacco use and poverty, the current and future economic burden of tobacco use on individuals and families, the impact of increasing taxes on tobacco products on illicit trade, and optimal type and structure of tobacco taxes to maximize public health outcomes.12

Tobacco product(s) research makes up a small percentage of the overall TOBAC grants (less than 5% per award year on average), and yet, in many LMICs, the use of diverse forms of smoked and smokeless tobacco is common. Research in this area is still at an early stage and further research into boutique or regionally relevant types of tobacco products may be necessary to understand not only the physiological effects of the products, but also the most effective interventions and policy solutions that can be

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implemented to curb use. It should be noted that the TOBAC program has funded groundbreaking research on water pipe smoking in the Eastern Mediterranean Region.

Finally, very little TOBAC-funded research has focused specifically on the tobacco industry or tobacco industry monitoring or tracking, despite evidence that industry activity in LMICs is increasing as new markets unveil promises of new users and more revenue. TOBAC grants have used tobacco industry documents in research on various FCTC articles, including advertising and media research, but little to no research has been funded that looks specifically at industry practices or monitoring.

A full list of TOBAC-funded awards, including title and abstract, can be found in Appendix D.

4.0 Program Results

Over the past decade, the TOBAC program has resulted in significant scientific advances that have informed the implementation of FCTC objectives, enhanced knowledge of tobacco control in LMICs, increased tobacco research capacity, and improved measurable policy and practice outcomes. A number of TOBAC projects have demonstrated the ability of the program to inform national policy and public health programs in LMICs. In the sections below, we review the contributions of the TOBAC program to tobacco control evidence as they relate to the FCTC articles and in terms of traditional scientific outputs (e.g. publications, citations, posters, etc.). We then discuss and provide data on the increased tobacco control research capacity resulting from TOBAC awards. Finally, we review the policy and public health outcomes informed by TOBAC award contributions in scientific evidence, capacity building, and partnership creation.

In the context of the TOBAC program, scientific evidence and research capacity that inform policy outcomes are inextricably linked. The generation of new evidence and strengthening of relevant research capacity have informed advances in policy. The program results section below - enhanced evidence, enhanced capacity, and the policy and programmatic outcomes reported in Section 5 - inherently have great overlap. To best understand specific TOBAC program contributions, this report will consider each category separately, while acknowledging that each area is linked to the success of the other two. Further, the evidence and capacity outcomes we report below contribute directly to the policy outcomes reported in Section 5. However, it was not possible to determine whether or not the policy changes reported were directly attributable to the TOBAC program alone. As is the case with most policy changes, there is a wide range of factors that influence passage, implementation, and enforcement of policy. So for all impacts reported in this document, it is assumed that TOBAC-related evidence helped to inform policy and programmatic outputs. Where available, direct evidence of such a relationship between TOBAC findings and policy change are provided.

4.1 Enhanced Empirical Evidence

TOBAC projects have contributed to progress in key FCTC areas by generating evidence in epidemiological, behavioral, risk-factor, intervention, cessation, policy, and economic research areas of identified need. The information in the section below is drawn from NIH databases, analysis of progress reports, award-linked publications, information from NIH program officers, and from informal discussions with PIs conducted by FIC evaluation staff.
4.1.1 Tracking TOBAC awards to the FCTC

A September 2012 series of articles from the Society for Research on Nicotine and Tobacco examined the research requirements for effective implementation of the FCTC articles. In addition to citing research gaps and needs and specifically calling for more research in LMIC environments, the authors highlight that the tobacco control research field has changed dramatically from a time when scientists were studying the basic, harmful effects of tobacco use, to a time when research looks more broadly at FCTC efficacy, economic issues of tobacco control, implementation research for LMIC contexts, and work on the tobacco industry’s actions, to name only some areas. The TOBAC projects to date have generated evidence in areas that reflect this overall evolution of tobacco control research.

In fact, TOBAC projects have successfully provided empirical evidence for almost all articles of the FCTC. TOBAC grantees reported that their data is often cited by advocates and governments pushing for either FCTC ratification or implementation and enforcement of laws and regulations that support specific articles. Articles 6 (taxation), 8 (smoke-free spaces), 12 (education and public awareness), 14 (cessation), 20 (research) and 22 (cooperation) are the most addressed articles by TOBAC researchers. All projects address Articles 20 and 22, as required by the RFA. TOBAC researchers heavily focused on some articles, specifically those dealing with smoke-free public spaces and price and tax issues related to tobacco control, that track closely to the categories of policy impacts discussed in a later section. Table 4 below maps the 2002-2012 TOBAC research awards to the FCTC articles they address.

TABLE 4: TOBAC Projects by FCTC Article they address (awards are listed in all relevant categories)

<table>
<thead>
<tr>
<th>FCTC Article</th>
<th>TOBAC awards addressing this article</th>
</tr>
</thead>
</table>
• Foley, K. - Increasing Capacity For Tobacco Research In Hungary (2007)  
• Foley, K. - Increasing Capacity for Tobacco Research in Romania (2012)  
• Schoj & Champagne - From Production To Retailing: Policy-Oriented Research On Tobacco Economy In Argentina (2012)  
• So, A - The Political Economy of Tobacco Control in Southeast Asia (2007) |
| Article 8: Protection from Exposure to Tobacco Smoke | • Foley, K. - Increasing Capacity For Tobacco Research In Hungary (2007)  
• Foley, K. - Increasing Capacity for Tobacco Research in Romania (2012)  
• Lando, H. - Cessation Research and Training in India and Indonesia (2002)  
• Loffredo, C. - Egypt Smoking Prevention Research Initiative (2002)  
• Perez-Stable - Tobacco Control Research and Training in South America (2002 and 2007)  
• Samet - Epidemiology & Intervention Research for Tobacco Control in China (2002 and 2007)  
• Scarinci, I - Network for Tobacco Control among Women in Parana, Brazil (2007) |

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| Article 10: Regulation of Tobacco Product Disclosures | • No TOBAC projects have directly focused on this Article. |
| Article 11: Packaging and Labeling of Tobacco Products | • No TOBAC projects have directly focused on this Article. |
• Lando, H. - Cessation Research and Training in India and Indonesia (2002)  
• Loffredo, C. - Egypt Smoking Prevention Research Initiative (2002)  
• Ossip-Klein, D. - Technology Assisted Dominican Republic Tobacco Control  
• Perry, C - Mobilizing Youth for Action Against Tobacco in India (2002)  
• Reddy, S. - Advancing Cessation of Tobacco In Vulnerable Indian Tobacco consuming Youth (2007)  
• Scarinci, I - Network for Tobacco Control among Women in Parana, Brazil (2007)  
• Stigler, MH - Preventing tobacco use among adolescents in Uruguay: Project Activate (2012) |
• Perez-Stable - Tobacco Control Research and Training in South America (2002 and 2007)  
• Sargent & Thrasher - Cinema Smoking and Youth Smoking in Latin America (2012) |
| Article 14: Demand Reduction Measures Concerning Tobacco Dependence and Cessation | • Foley, K. - Increasing Capacity For Tobacco Research In Hungary (2007)  
• Foley, K. - Increasing Capacity for Tobacco Research in Romania (2012)  
• Lando, H. - Cessation Research and Training in India and Indonesia (2002)  
• Lando, H. - Capacity Building for Tobacco Control in Tunisia, North Africa & Middle East (2012)  
• Loffredo, C. - Egypt Smoking Prevention Research Initiative (2002)  
• Nitcher, M – Building Capacity of Tobacco Cessation in India & Indonesia (2007)  
• Ossip-Klein, D. - Technology Assisted Dominican Republic Tobacco Control  
• Perez-Stable - Tobacco Control Research and Training in South America (2002 and 2007)  
• Reddy, S. - Advancing Cessation of Tobacco In Vulnerable Indian Tobacco consuming Youth (2007)  
• Ybarra, M. - SMS Turkey: Harnessing the power of TXT messaging to promote smoking cessation (2007) |
• So, A - The Political Economy of Tobacco Control in Southeast Asia (2007) |
<table>
<thead>
<tr>
<th>Article 16: Sales to and by Minors</th>
<th>• Foley, K. - Increasing Capacity For Tobacco Research In Hungary (2007)</th>
</tr>
</thead>
</table>
• Scarinci, I - Network for Tobacco Control among Women in Parana, Brazil (2007)  
• Schoj & Champagne - From Production To Retailing: Policy-Oriented Research On Tobacco Economy In Argentina (2012) |
| Article 20: Research, Surveillance, and the Exchange of Information | • All TOBAC Projects. |
| Article 22: Cooperation in the Scientific, Technical, and Legal Fields, and Provision of Related Expertise | • All TOBAC Projects; addressing this article is a requirement of the RFA (capacity building). |

All 29 individual TOBAC projects specifically address Article 20 of the FCTC which calls for research, surveillance, monitoring, and exchange of information, and outlines the minimum amount of evidence needed in every country. TOBAC projects have addressed the research needs of the FCTC by providing empirical evidence that supports the articles or demonstrates to governments why implementation of FCTC articles will benefit the health or economy of their country. In 2004, Wipfli et al outlined five necessary research areas that fulfill the FCTC’s fundamental research and surveillance obligations:

1. basic health statistics, including cause specific mortality data;
2. estimates of the burden of disease caused by smoking;
3. data on tobacco prevalence and use;
4. standardized measures and methods to monitor tobacco control policy and program progress; and
5. industry tracking, including cost of cigarettes, advertising and promotion, brand stretching, and sponsorship.

A number of TOBAC awards directly address these five basic evidence needs. In the paragraphs below, we examine examples of the contribution of select TOBAC Projects to the specific needs of Article 20 outlined above. The examples below provide a snapshot of the type of work the TOBAC program has produced related to the FCTC and do not represent a comprehensive analysis at the many ways and areas in which TOBAC projects have produced evidence related to Article 20.

1. **Research addressing basic health statistics, including cause specific mortality data**

A major obstacle to tobacco control in LMICs is the lack of reliable, local evidence evaluating the extent to which tobacco contributes to death from particular diseases and about any large changes in these epidemiological trends. The TOBAC program funds research that addresses this challenge. For example,
a 2002 TOBAC grantee received support for six prospective cohort studies in four countries, China, India, Russia and Egypt, which together included two million adults. For each participant, the study collected tobacco and alcohol habits using locally validated questions, blood pressure, height and weight, peak expiratory airflow, personal identifiers (with consent for long-term follow-up), previous history of selected tobacco-related diseases, and a few questions relevant to the population. Follow-up included monitoring the underlying cause of all deaths in the cohorts over the following years.17

Establishing basic health statistics and estimates of the burden of disease is essential to successfully enacting tobacco control measures in LMICs. Without an understanding of the mortality rates, use rates, and general prevalence, the case cannot be made to policymakers that tobacco use is a problem deserving of national attention. To address these data needs, a 2002 TOBAC award that was competitively re-funded in 2007, took on this challenge by measuring the mortality consequences of tobacco smoking and chewing among 1.3 million households in India (about 7.6 million people) that were already enrolled in the Indian Sample Registration System – a large demographic sampling survey. This study, the Million Death Study, was one of the largest prospective studies of adult health in the world and established critical data about tobacco use in India, including that: 1) 37% of males aged 25-69 smoke, with up to 9-fold variation by state; 2) illiterate men had a 4-fold higher risk of smoking bidis, and a 2.5 fold lower risk of smoking cigarettes than did those with grade 10 or higher education; 3) smoking bidis or cigarettes already causes about one in three adult male deaths (a proportion equal to that seen in the US about two decades ago); and 4) smoking causes nearly half of tuberculosis deaths in India.18

2 & 3. Research addressing estimates of the burden of disease caused by smoking and data on tobacco prevalence and use

TOBAC-funded research has built a body of evidence in the area of prevalence and use of tobacco products in regions including the Middle East and North Africa, South Asia, East Asia, Latin America, Sub-Saharan Africa, and Europe. In Syria, and subsequently in Egypt, country governments and public health professionals had virtually no data on tobacco use in the form of water pipe smoking despite its popularity as a national pastime. A TOBAC grantee exposed the dangers and documented the prevalence of water pipe use. This important research was the first data-based evidence of the spread of water pipe use in the Eastern Mediterranean Region. The data obtained on use patterns in both countries has been subsequently used to guide the development of culturally-relevant smoking cessation programs. This work has gone on to inform significant policy progress, which we will discuss later in this report.19

A PI funded in 2002 conducted research in Southern and Western Africa focused on prevalence and risk factors; psychopathology and tobacco use among youth; community influence and protective factors in tobacco use among high school students; qualitative studies of the tobacco use among adolescent girls; and a study of the ethnographic and traditional cultural uses of tobacco. This research, which addressed

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the paucity of evidence in this region of the world in 2002, helped fill a significant knowledge gap as well as capacity building needs.\textsuperscript{20}

4. \textit{Research addressing standardized measures and methods to monitor effectiveness of tobacco control policy and program progress}

Standardized measures and methods to monitor tobacco control policy and program progress are necessary to understand the impact of implementing the FCTC articles and to compare various strategies. Physician smoking rates may be one such metric in analyzing the efficacy of tobacco control policy and program implementation. An intervention evaluating physician smoking rates and cessation programs in Argentina revealed that more than half (59\%) of physicians interviewed had not received formal training about counseling patients on behavioral techniques to quit smoking, 41\% had not received information about prescribing or recommending nicotine replacement therapy, and 43\% had not received information about the medical treatments available to help patients stop smoking. This study shed light on an important aspect of tobacco control that could have implications for the development and assessment of tobacco control strategies.\textsuperscript{21}

TOBAC-funded research in China focuses on healthcare worker smoking rates as well as the economic burden of tobacco use. The initial TOBAC funding this grantee received in 2002 allowed the PI to develop a research agenda and to disseminate scientific evidence once it was developed. The PI commented that without the evidence generated by the TOBAC grant, the advocates and implementers working in China would not have had the data needed to quickly inform policy makers of evidence regarding the effectiveness of tobacco control policies.\textsuperscript{22}

5. \textit{Research addressing industry tracking, including cost of cigarettes, advertising and promotion, brand stretching, and sponsorship}

Although no TOBAC projects have focused directly on industry tracking, a number of projects have examined promotion via film, especially concerning cigarette promotion to youth. A 2012 research project aims to demonstrate a causal link between movies and smoking with key scientists in Argentina and Mexico, with the overarching aim of enhancing research on movie and marketing risk factors for youth smoking. These researchers will also assess the prevalence of adolescent ownership of tobacco branded merchandise (e.g., t-shirts and collectable packs) to determine if receptivity to these products acts in synergy with movie exposures. The specific research aims of the study are to: 1) develop the capacity for researchers to track tobacco use and brand placement in the domestic film market (which accounts for about 10\% of movies viewed in each country); and 2) to develop the capacity for researchers to conduct longitudinal school-based surveys of adolescents to determine the importance of media and marketing risk factors in promoting smoking.\textsuperscript{23}

Research that examines the political economy of tobacco use is increasingly relevant in LMICs. Research from HICs demonstrates that tobacco use exacts a heavy economic toll in health care costs


\textsuperscript{23} Thrasher, James and Sargent, James. R01TW009274. \textit{Cinema Smoking and Youth in Latin America}. Funded 2012.
and lost productivity on individual users, families, communities, and countries. Research in LMICs indicates that the economic burden is similar and is exacerbated in socio-economically disadvantaged communities. Research that examines the interplay between political variables and economic processes that influence tobacco use and control in LMICs is an essential step in crafting and implementing effective tobacco control policies and understanding how these policies influence tobacco-related behaviors. One TOBAC grantee examined the political economy of tobacco control in Cambodia, Malaysia, Thailand, Vietnam, Laos, Indonesia, and the Philippines, conducting studies that situated the impact of tobacco in the larger context of sustainable development, and enabling a strong, local evidence base to encourage effective translation of research into policy. Other TOBAC awards in Asia and Latin America have evaluated the value of crop substitution for tobacco farmers to generate evidence that tobacco control policies need not be harmful to economies of tobacco-producing countries.

4.1.2 Publications, Citations, and Presentations of TOBAC Grantees

In this section, we will discuss the specific quantitative scientific contributions of TOBAC awards by examining numbers of publications, citations, and grant renewal metrics. The first 10 years of the program have produced many contributions to scientific knowledge by way of published literature. Data on TOBAC-linked publications, citations, and presentations were obtained from NIH databases (specifically, an eSPA module that provides a listing of all MEDLINE articles associated with grants), annual progress reports, and was supplemented by email data submissions and informal discussions with grantees. Because complete publication information was not available for all projects, this analysis likely underestimates the actual research outputs in many cases.

TOBAC grantees have published in many peer-reviewed journals, with articles linked to their awarded grants in PUBMED, as required by the NIH Grants Policy Statement. They have also published in local, LMIC journals, often in a non-English language, and often in journals not available through the PUBMED database. Grantees also have a number of publications in progress that are not yet available in traditional scientific literature databases. Unless indicated otherwise, the analysis below reflects the number of publications linked to the NIH-funded award in PUBMED. However, all reported publications - PUBMED linked, non-PUBMED linked, and in progress - were counted in the overall number to ensure the full scale of the scientific contributions of TOBAC awardees is represented.

Grantees published 416 scientific publications overall including PUBMED linked articles, non-PUBMED linked articles, and articles in progress. Of these, grantees published 309 peer-reviewed and non-peer reviewed articles in journals available in PUBMED. Among them are prestigious journals of scientific interest, public health journals, and journals specific to tobacco control, including: The Lancet, Nicotine

For each publication that results from NIH grant-supported research, grantees must include an acknowledgment of NIH grant support and a disclaimer stating the following: “This publication was made possible by Grant Number ______ from ________.” or “The project described was supported by Grant Number ______ from ________” and “Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the [name of awarding office or NIH]."

A manual count from progress reports revealed that grantees attended more than 200 conference and poster presentations. Additionally, 33 new sets of curricula were created, which relates not only to scientific output measures but also to training and capacity building, discussed later in this report.

Grantees published research on a broad range of scientific issues, from tobacco products, to treatment interventions, to the effect of taxes on tobacco uptake. Figure 7 below indicates that the majority of publications associated with TOBAC grants in PUBMED have focused on the risk factors, attitude and behaviors, products, treatments, and health risks associated with tobacco use. TOBAC grantees have published relatively little on taxes and other economic issues, capacity building efforts, socio-economic factors that interplay with tobacco control, and media influence.

Figure 7: Publications Associated With a TOBAC Award, by Topic (2002-2011)

NOTE: Publications were classified in all relevant content areas. N = 356 classifications out of 309 publications. Classification by category was done as follows: exposure includes second-hand smoke and occupational or ambient air pollutants; types of tobacco includes categories like water pipes, hookah, and smokeless tobacco; media includes advertising, mass media, promotion, and packaging; policies includes trade, regulatory, legal, and government research; and economics includes family expenditures on tobacco, and taxes.

Figure 8 illustrates the specific population focus of the first two rounds of TOBAC grants. The majority of publications do not have a specific population focus, but of those that do, a focus on adolescents (age 13-17) and adults (age 26+) make up the top two populations with 60 and 56 publications, respectively. Thirty-three publications focused on young adults and university populations, aged 18-25. Publications focused specifically on men, women, children age 0-12, health professionals, households, and racial and ethnic groups make up the remainder, with fewer than 20 publications per group.

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27 Manual count of non-peer reviewed papers from grantees’ progress and final reports.
In addition to spanning a wide-range of scientific research topics, TOBAC-linked publications cover a broad geographic span of LMICs. Figure 9 demonstrates the regional focus of publications linked to a TOBAC grant; publications in PUBMED were categorized by the regional focus of the article. The largest number of publications was in the East Asia and Pacific region, which boasts almost 60 publications. Between the 2002 and 2007 funding rounds, this region received nine awards, and through the TOBAC program, from 2002 to 2012, received a total investment of almost $10 million. The Middle East and North African region, which has four TOBAC awards from the 2002 and 2007 rounds and only 16% of the total overall funding (4th in funding rank among all regions for 2002 and 2007 combined), had almost as many publications as the East Asia and Pacific region. The majority of the remaining publications come from the South Asian region, followed by publications with a global focus and the Latin America region. The total publication numbers generally reflect the total regional investment from TOBAC awards. Considering that the Sub-Saharan Africa and the European region have the smallest percentage of funding in 2002 and 2007, it is not surprising that fewer than 30 total publications are tied to grants in those regions.

A notable trend in the analysis of publications is the limited amount of publications focused on the Sub-Saharan African region compared to other regions of the world. Many experts agree that Africa is currently a focus of the tobacco industry due to previously low use rates, relatively little regulation, and a large population of women and youth who are susceptible to advertising and other promotion that glamorized or assigns status to smoking cigarettes and other forms of tobacco use. Future iterations of TOBAC may call for more focus on regions at high risk, with limited resources, and a limited history of TOBAC-related accomplishments.
4.1.3 Competitive Renewal of 2002 and 2007 Projects

In addition to a sizable contribution of scientific publications, TOBAC grantees showed scientific relevance in their ability to successfully compete for grant renewal. In the second round of funding (2007), 21% TOBAC awards made in 2002 were competitively renewed; 18% awards made in 2007 were competitively renewed in 2012. Two projects have received competitive renewal in both 2007 and 2012, bringing the projects to their eleventh year of continuous study. Additionally, one 2002 grantee’s project was funded via a different PI in the 2007 round, and the original PI successfully competed for funding again in 2012 with a different focus area. This continuity of funding demonstrates not only rigorous science and methodology, but also the value of further extending research and capacity building activities beyond the five-year award period. Because of the long-term nature of the research and capacity building in-country, the five competitively renewed awards had valuable impacts on both tobacco control science and policy and applied interventions at national and local levels.

4.2 Enhanced Research Capacity

Given the growing rates of tobacco use and related-disease burden in LMICs, building local and national capacity to address research and evidence needs is an essential step in combating the epidemic. The 2012 WHO FCTC Global Progress Report states that “important measures to accelerate implementation of Article 20 include the following: strengthening national capacity among the Parties for and collection of tobacco-related data (including prevalence, exposure to tobacco smoke, mortality and the economic impact of tobacco use) by those indicators that Parties are required to report in the reporting
instrument of the WHO FCTC; and building or strengthening research capacity, including by training and supporting those engaged in tobacco-control activities.\textsuperscript{28}

Training the next generation of researchers on the science of tobacco control is an integral part of the TOBAC program. In fact, the RFA asserts that “capacity building promotes the advancement of research and enhances the number and the knowledge of tobacco investigators in LMIC. A long-term outcome of capacity building is the improved ability to augment scientific competence and skills nationally and internationally, and the development of a cadre of tobacco researchers with appropriate research training and support who can continue to conduct tobacco control research in LMIC beyond the term of the award. Capacity building activities also provide opportunities for investigators from HIC to gain knowledge of and experience in tobacco control issues in LMIC.”\textsuperscript{29}

In addition to encouraging training of individual researchers, the TOBAC RFA encourages research capacity building activities that promote institutional capacity strengthening in multidisciplinary tobacco control research. The Program also supports the development of “in-country” tobacco control infrastructure at the institution, academic, and non-governmental organization (NGO) levels. This infrastructure includes institutionalized research capacity as well as the capacity to translate research evidence into tobacco control policies, on country- and project-specific bases.

To determine the capacity building outcomes for TOBAC grantees, we examined the number and nature of trainees reported from 2002-2011 awards. We also examined annual progress reports and conducted qualitative interviews with select grantees to learn more about institutional capacity and partnership and collaboration efforts that resulted from the program.

4.2.1 Trainees

Table 5: Trainee Information for TOBAC Program (2002-2011)

<table>
<thead>
<tr>
<th>Start Year</th>
<th>Number of Grants</th>
<th>Masters</th>
<th>PhD</th>
<th>Post Doc</th>
<th>Other long term trainees (&gt; 3 months)</th>
<th>Short term trainees (&lt; 3 months)</th>
<th>Individuals at workshops or meetings</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>2002</td>
<td>12**</td>
<td>19</td>
<td>26</td>
<td>19</td>
<td>904</td>
<td>504</td>
<td>181</td>
<td>1653</td>
</tr>
<tr>
<td>2007</td>
<td>11</td>
<td>38</td>
<td>27</td>
<td>15</td>
<td>143</td>
<td>61</td>
<td>1582</td>
<td>1866</td>
</tr>
<tr>
<td>TOTAL</td>
<td>23</td>
<td>57</td>
<td>53</td>
<td>34</td>
<td>1047</td>
<td>565</td>
<td>1763</td>
<td>3519</td>
</tr>
</tbody>
</table>

**Peto and Resincow are missing from the 2002 count. Accordingly, these counts likely underestimate the true number of trainees who have been involved with TOBAC grants.

Table 5 shows that 3,519 trainees benefitted from the TOBAC program by participating in TOBAC-funded training activities, an average of just over 153 individuals per grant. This result reflects the underlying capacity building principle that is built into all TOBAC awards.

Figure 10 illustrates the total percentage breakdown of the type of trainees TOBAC grants have produced. Notably, the smallest groups include perhaps the most advanced trainees – Masters, PhD, and Post Doc candidates. However, over 1,000 long-term trainees (trained from 6-12 months) were trained in tobacco control research and policy fields. Half of the trainees were workshop and meeting participants, suggesting that gatherings that bring together networks of researchers and other stakeholders are an important and integral part of capacity building in LMICs. A number of PIs reported workshops and regional meetings as primary venues for training and capacity building.
Figure 11: Regional Trainee Information for TOBAC Program (2002-2011)
Note: Trainees are categorized by regional focus of the TOBAC grant, not by their country of origin. One grants trained trainees in both Indonesia and India, hence the 0.5 trainee number in both South Asia and East Asia regions.

Figure 11 depicts a regional breakdown of trainees and reveals that the South Asia region boasts over five-times more TOBAC trainees than other regions. This is due almost entirely to two awards that trained field staff to conduct epidemiological research (Jha, 2002 n=904) and in other workshops and meetings (Reddy, 2007 n=544). This analysis reveals a very low number of trainees in the Sub-Saharan African region, where there is a great need for research capacity building given the predicted rise in tobacco usage rates over the next 10 years. Because only three TOBAC grants were awarded to the African region in 2002 (and none in 2007), the low number of trainees is proportional to the funding awarded to the region. There are similarly low rates in the Europe and Central Asia and Middle East and North African (MENA) regions, explained by the presence of only one award in the European region in 2007, aimed at building capacity in Hungary, and four total awards in the MENA region in 2002 and 2007, two focused on Syria and two on Egypt.

4.2.2 Partnerships and Collaborations

One critical aspect of long-term capacity building is new and strengthened partnerships and collaborations among researchers and other stakeholders at local and international levels. Robust collaboration and communication among partners is integral to the dissemination and implementation of best practices in research and capacity-strengthening that can be adapted by tobacco control researchers in other countries and regions. The TOBAC program is intended to generate useful scientific information and promote collaboration between investigators and institutions in the US or other HICs and LMICs with shared interests in reducing the consequences of tobacco consumption. TOBAC grantees employ many models of partnership and collaboration building, from technical and research
exchange, to more formal collaborations among researchers, to strengthening relationships with NGOs as a means to ensuring that evidence is used in program implementation.

We examined annual progress reports, publications related to TOBAC grants, and conducted informal discussions with select grantees to determine the ability of TOBAC grantees to foster communication and collaboration among partners.

There is evidence that the TOBAC program has helped create a global network of researchers who can collaborate in research and building capacity in LMICs. In the 2002 cycle, 66 new partnerships and collaborations were reported by PIs, (some of which were networks among other TOBAC researchers) most of which were new partnerships between HIC scientists and LMIC institutions and researchers. In the 2007 cycle, an additional 74 partnerships and collaborations were reported. The need and urgency for new collaborations and relationships in tobacco control research in LMICs was underscored by one expert who expressed that “the field [of tobacco control researchers] and program implementers needs to better understand the impact of partnerships and collaborations. This type of work takes a lot of time and the unique 5-year nature of the FIC grants allows for that time. Even though new funders are coming to the table, we need to ensure they understand that getting local researchers involved and building capacity is the only way to ensure sustainable funding.”

Robust partnerships and collaborations are an essential ingredient for the next generation of locally relevant research evidence with the potential to inform policy. We will further discuss specific examples of TOBAC grantees successful partnerships and collaborations as they relate to policy outcomes in Section 5.

4.2.3 Notable TOBAC Capacity Building Models

The models that TOBAC projects use to build capacity are as unique as the data they generate from their projects. As this R01 structure allows for a high amount of interpretation of the capacity building requirements, different projects approach the goal in many different ways. The section below highlights some models of TOBAC capacity building that have proved particularly effective in creating research capacity.

A TOBAC grantee working on capacity building in China, Mexico, and Brazil wrote: “no single existing definition or model fully encapsulates capacity development because models used have varied from simple individual training approaches to multi-level and multi-factorial approaches aimed at systemic change.” Their particular model, similar but not identical to other TOBAC models, focused on individual skill and tool development, building networks and leadership opportunities for trainees, and collecting and orientating local, empirical data. Their model ties capacity building closely to the need to build international partnerships, citing it as an essential element of sustainable research capacity building in LMICs.

30 Manual count from 2006 overall TOBAC progress report, Fogarty International Center, 2006. Numbers in progress reports were reported by PIs with no uniform definition of “networks” provided by NIH/FIC. For this reason, the type of networks reported vary.

TOBAC grantees report training students, researchers, and other trainees in areas ranging from tobacco control research based on the scientific foci of the project, to research specifically related to the FCTC, to strategies than encourage and enable translation of evidence into policy and program. As referenced earlier in this report, one grantee built and trained large epidemiological teams to conduct morbidity and mortality studies in relation to tobacco use for over 2 million adults in India. Other training programs have focused on building research capacity in regions of great need, such as Sub-Saharan Africa and the Middle East, to increase the expertise of researchers across the spectrum of tobacco control. These efforts have resulted in groups of trained, in-country staff that are capable of technical support, research design, and knowledge dissemination.

The TOBAC PIs interviewed for this report repeatedly emphasized the value of understanding and sharing the various capacity building models used by TOBAC researchers. Below, we feature select models as examples of the varied, successful ways PIs design capacity building efforts in country.

**Latin America**

Brazil has the highest tobacco consumption rates in Latin America and the second highest tobacco production rates in the world. It also has one of the highest prevalence rates of smoking among women and girls. In order to establish community and institutional capacity to promote gender-relevant tobacco control efforts, one TOBAC grantee engaged in a community-based participatory research and training module that increased research capacity, and built the basis for a network for fostering communication and collaboration among well respected national partners, which was key to using evidence to inform policy (as we’ll discuss further in the next section).

The research training and capacity building model for the Brazil-based TOBAC program was organized into three modules open to faculty, students, and other health professionals in partnering institutions. The three modules addressed: 1) tobacco control generally; 2) clinical aspects of tobacco use; and 3) research and research methodology (a longer, more in depth module). Only some trainees from the first two modules were selected to participate in the final, more detailed model which included biostatistics, bioethics, research design, and lessons on applying for and obtaining research funds. Trainees were mentored during this process and were asked to craft a research proposal that focused on tobacco use among women in Brazil. The proposals were then evaluated for funding by a panel of experts and members of the network the PI had built. Four proposals were chosen for funding, furthering the ability of the program to generate evidence. The model was repeated in a second year with a larger number of trainees. The research team is currently developing a similar structure for undergraduate students in order to engage individuals about the importance of tobacco control early in their careers. The State Health Department of Brazil has videotaped one part of this module to train Health Department employees working in tobacco control. The TOBAC grantee reports that Brazil is an ideal place for this type of capacity building given the passage and implementation of national tobacco control laws. The national laws set the stage for research, capacity building, implementation, and evaluation at the local level. This model, as well as others that focus on research training capacity at local levels, are replicable in other states in Brazil. This type of training is also unique in that it uses a teachable moment (the social

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movement toward women’s emancipation in Brazil) to empower women to empower others in the areas of cessation or avoiding smoking initiation.

While the above model focuses on individual scientist training to build capacity, other models look to build the institutional and organizational capacity of partnering universities and organizations in order to both train individual researchers in tobacco control science and to provide leadership and expertise in dealing with tobacco control research evidence at national levels. In Mexico, a grantee working with the National Institute for Public Health helped initiate a capacity building program in tobacco control research at an institutional level. Now, the Mexican National Institute for Public Health has a well-established and locally sustained research program that plays a leadership role nationally and provides regional training and coordination among national tobacco control researchers. Additionally in countries like China, Syria, and Hungary, capacity building and infrastructure activities of TOBAC grantees have increased institutional research capacity across diverse organizations and institutions engaged in tobacco control research.

**Middle East and North Africa**

In Syria, research exploring the dangers and documenting the prevalence of water-pipe smoking lead to the establishment of the Syrian Center for Tobacco Studies (SCTS), which became the leading tobacco control research institution in Syria. SCTS has provided advanced tobacco control research training to more than a hundred Syrian scientists from across the region. The training has focused on not only intervention, cessation, and water-pipe related research but has also expanded to include training on research to evaluate policy implementation. Throughout the funding of the grant, SCTS has extended its research capacity building reach beyond Syria to address the tobacco epidemic in surrounding countries. Scientists working with SCTS have formed research collaborations in Jordan through another NIH-FIC grant. In 2011, SCTS was named the top institution in Syria in terms of productivity of high-quality biomedical research - outpacing much larger institutions with greater resources. Trainees from SCTS have published 16 research papers as first authors, obtained more than 20 prestigious fellowships (e.g., H.H. Humphrey Fellowship, Fulbright), and landed several academic positions within and outside the Eastern Mediterranean Region (e.g., National Science Board in Syria, scientist at St. Jude Children’s Research Hospital, faculty at University of Memphis).

As a testament to the increasing reputation of the SCTS, it became an internship/practicum site for US graduate students: two MPH students from the University of Southern California and George Washington University had two-month internships at SCTS and published their first research papers with SCTS data. In addition, several institutions outside Syria have sought advice from SCTS on building a center for research excellence in a developing county setting. SCTS is an outstanding example of the kind of flexible capacity building strategies that the TOBAC program encourages. This particular award has successfully re-competed in both the 2007 and 2012 award rounds, allowing more than a decade for

capacity building effort in Syria and the broader region. Finally, in Syria, one TOBAC-trained individual was selected for the Syrian Higher Commission for Scientific Research.

Europe

The PI working in Hungary in 2007 and Romania in 2012 emphasized that foreign scientists identified educational exchange trips to the US as pivotal moments in their understanding of tobacco control research and capacity building needs. The project brought small groups of Hungarian scientists to the US for conferences, shadow opportunities, and training. The same PI also highlighted the importance of clear and regular communication with partners and trainees in country. Within this communication structure, she emphasizes holding partners and trainees accountable to project goals to ensure progress and overall growth of individuals. The extended presence of the PI in an LMIC is not always possible, but the PI cited as an essential element in her success in building research capacity and enabling tobacco control research evidence to influence policy; this specific PI was in country for six months on a Fulbright prior to her TOBAC grant initiation in 2007.

This PI listed a number of essential steps that helped her achieve real policy impacts: 1) clear communication with structure and frequency imposed by a regularly managed schedule; 2) monitoring and accountability of in-country partners; 3) creating a diverse local team with links to policy and scientific leadership who can speak for the need for increased capacity; 4) ensuring buy-in and recognition by the Ministry of Health, Ministry or Science, or Ministry of Finance early in the project, if possible; and 5) framing efforts in terms of the desired policy outcomes, or in other words, paying constant attention to translation. The PI’s model for capacity building is featured in Figure 12.

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One TOBAC PI working in China successfully built research capacity using a two-pronged method that revolves around the R01 design of the TOBAC program. The PI built a cadre of researchers (7 PhD and 12 Masters-level) in both the US at the University of California at Berkeley, and in China at Fudan University, who are now heavily published and some of whom are now faculty at the universities or have gone on to roles like technical advisors to the Chinese government and with Chinese NGOs. This PI used the traditional R01 model to build research skills and create empirical evidence in the form of PhD theses. Additionally, the PI focused on disseminating tobacco control research evidence and building capacity at a national Chinese NGO by creating and giving media trainings, tobacco control economics workshops, and other presentations and trainings based on the evidence generated by his work. This PI has also forged important partnerships with the Bloomberg Initiative, the Bill and Melinda Gates Foundation, and the Chinese Center for Disease Control and Prevention (China CDC).

Another example of capacity building in research and policy emerged from a TOBAC grantee who organized a network and subsequent workshops in Southeast Asia regarding the challenges of identifying smuggled and counterfeit cigarettes. This effort convened policy makers together with

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researchers from various countries in the region to discuss these issues. The grantee stated the importance of the partnerships and collaborative efforts in an annual progress report: “The project built upon a unique regional collaboration that bridges concerns of policymakers and researchers in Southeast Asia in advancing locally relevant research on tobacco control. The collaboration of officials from Ministries of Finance, Customs, Justice, and Health over seven countries in the ASEAN Region is an important part of understanding illicit trade in tobacco products within the region. Gaining access to data for researchers is often facilitated by a personal relationship with ministry officials. Importantly, the workshop may have been one of the first gatherings in which officials from each country sat together and discussed the difficulty of identifying smuggled and counterfeit cigarettes while looking at samples from each country, sharing data about the country-level techniques for marking cigarettes, and discussing plans for future work in this area. This significantly enriched discussions of research work plans for FIC’s regional investigators.”

In some cases, individuals trained via TOBAC grants have gone on to hold high-level and influential positions in LMICs. In Cambodia, for example, one grantee built the research capacity of Cambodian Ministry personnel by assembling technical, in-country research teams to design and implement national surveys of tobacco use in order to achieve objectives of FCTC and implement the monitoring phase of the WHO MPOWER initiative. Also in Cambodia, research capacity building efforts culminated in the advancement of one Cambodian trainee to the role of the National Professional Officer for Tobacco Control, a WHO position in Cambodia. Similarly, a Laotian TOBAC trainee went on to work as the Coordinator of Southeast Asia Initiative on Tobacco Tax in the Laotian Ministry of Finance. In such cases, high-level national officials have a working knowledge of evidence-based tobacco control research and robust communication and collaborations between researchers and influential policymakers is enhanced.

### 4.3 Policy and Program Outcomes

Although there is an ever-growing body of tobacco control evidence, much has been written about how advances in research do not always lead to adaptation of evidence-based practices in real-world settings. Implementation science seeks to examine research translation to optimize adoption of scientific advances in the real world and at scale and ensures that the evidence generated has the greatest population impact in a relatively small amount of time. TOBAC grantees recognize the importance of translating evidence to policy. In addition to contributing research to a growing scientific field and overall capacity in LMICs, data generated by TOBAC-funded researchers has collectively been a critical evidence base that continues to inform international and national tobacco control policy.

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Indeed, TOBAC grants have contributed to increased awareness and evidence relevant to policy issues related to tobacco control in LMICs. As the program continues to mature and research capacity grows in countries where grants are awarded, more examples of evidence-based policy outcomes should follow. For the purposes of this report, we classify program outcomes in two categories: 1) changes in health policy and 2) changes in public health practice. To determine the contribution of TOBAC grantees’ research and capacity building efforts to changes in country-level and local policies and programs, we examined progress reports and publications related to TOBAC grants and conducted informal discussions with select grantees.

Before describing what is known about policy outcomes, it must be acknowledged that available evidence regarding impacts was limited. In some cases, the available evidence was not sufficient to establish the degree to which the research and capacity resulting from TOBAC awards contributed to policy or programmatic outcomes. For all outcomes described, TOBAC-related research and data are reported by PIs to have contributed to the passage or implementation of a policy or program. Finally, there is no reason to believe that the experiences of the PIs who participated in discussions are representative of the larger pool of TOBAC awardees.

4.3.1 Research Evidence and Capacity Informing Policy

Review of progress reports and publications reveals evidence of policy outcomes specific to the implementation FCTC articles. TOBAC grantees have contributed to progress on multiple FCTC articles with not only research, but also effective dissemination of their research results as a means to inform policy and policymakers, including: Article 6, which commits parties to use tax and price policies to reduce tobacco use; Article 8, which mandates parties to protect citizens from exposure to tobacco smoke in workplaces, public transport, and in public places, often with indoor-air or clean-air legislation; and to a lesser extent, other FCTC articles such as 17, 15, and 14. Current projects are generating data to inform policy related to the articles listed above as well as Article 15, which focuses on illicit trade in tobacco products. To track policy outcomes for the purposes of this report, we examined progress related to: 1) economics and price policies (FCTC article 6) and 2) policies that address exposure to second-hand smoke and smoking bans in public places (FCTC article 8), the two areas where the evidence available suggested the most policy outcomes. However, this focus and the examples described below are not a comprehensive analysis of policy advancement informed by TOBAC grantees projects and should be viewed as case studies of the impact that research and capacity building can have under the TOBAC program.

Before discussing policy outcomes specific to taxation and smoke-free spaces, it is important to note an overarching policy outcome: the important role of TOBAC-supported research in FCTC ratification. Because the TOBAC program was conceived and established before the treaty was adopted (2003) and entered into force (2005), TOBAC grantees in the initial round of awards had a unique chance to use their data to inform a country of the tobacco landscape before they signed and ratified the treaty. PIs working in China and Syria both reported that evidence from their research played a large role in justifying the country ratification of the FCTC and subsequent implementation of its articles, which we will discuss in detail below.

Article 6: Policy Outcomes Related To Tobacco Taxes and Economics

Tobacco taxes and tobacco control economics are relatively new to the tobacco control research agenda and growing areas of influence that are capturing the attention of Ministers of Health and others in
LMICs. Article 6 of the FCTC encourages parties to increase the cigarette tax as a means to increase the retail price, which will eventually lead to decreased cigarette consumption. The WHO has heralded the excise tax on tobacco products as the single most effective tobacco control measure.\textsuperscript{43} TOBAC grantees have reported significant policy outcomes in this area, as described by select successes below.

Examples of direct policy outcomes have emerged from the work of a grantee who examined the economic costs of smoking, the impact of a tobacco tax, and the cost effectiveness of tobacco control interventions in China - the world's largest producer of cigarettes and highest smoking rates overall. TOBAC-funded research, in coordination with the China CDC and the State Administration of Taxation in China found that 2009 tobacco taxation adjustments in China had generated an additional RMB 50 billion in tax revenue. The research findings were brought to the attention of senior Chinese government officials at a high-level seminar and the media coverage that followed propelled the issue to the national agenda. This data directly informed Chinese health officials, who subsequently endorsed national policy changes regarding tobacco sales. The grantee, funded by re-competition in 2012, will continue to examine the impact of the tobacco tax adjustment and organize workshops to disseminate evidence in China for officials from the Ministry of Finance and State Administration of Taxation, among many other scientific and capacity building aims.\textsuperscript{44}

In Hungary, a country with some of the highest smoking rates in Europe, local investigators focused on opportunities to relay scientific findings via educational presentations to legal and public health officers of local governments. Soon after this evidence was presented to policy makers, tobacco sales tax increased nine-times over from 2007-2011 - providing an example of how evidence and data can help inform sound national health policy. Around the same time, the State Secretary's cabinet passed national clean air laws for protection of non-smokers in public places. The PI responsible for the research that contributed to such broad policy impacts also characterized the 5-year time period of the TOBAC grants as “short,” stating that implementation science is a slow process and their specific project benefitted from broader macro forces that allowed policy changes to move quickly. Generally, she surmised, it would take a more significant investment of time.\textsuperscript{45}

In India, the Centre for Global Health Research (CGHR), which was partially funded through a 2007 award, has been a pioneer in initiating and strengthening a domain of discourse and translating evidence to policy for tobacco control at the national and state levels. CGHR also provides scientific data to national governments regarding effective tobacco control policies. Their research evidence shows that economic and epidemiologic consequences of tobacco consumption are considerable. The availability of this data has accelerated the tobacco control efforts within the Indian government. In the latest (2013-2014) budget announcements, the finance minister of India announced a hike in excise duty of cigarettes by about 18 percent.\textsuperscript{46}

Illicit trade can undermine the effects of Article 6 as it was intended. For this reason, contributions to evidence and policy concerning illicit trade are often seen in support of, or considered jointly with, efforts related to Article 6. The 2007 TOBAC project “The Political Economy of Tobacco Control in

Southeast Asia” focused on measuring the magnitude of illicitly traded tobacco in the Southeast Asian region and understanding the magnitude of illicitly traded tobacco in the region. The study focused on the need for independent estimates, local capacity for generating these data, and a robust methodology repeatable at reasonable cost.47 A 2012 grantee is looking at similar issues in the Sub-Saharan Africa region over the next 5 years.48

**Article 8: Policy Outcomes Related to Protection from Exposure to Secondhand Smoke**

There is no safe level of exposure to tobacco smoke – whether as the smoker or as a person exposed to secondhand smoke (SHS). As such, Article 8 aims to protect people by eliminating smoking in all indoor workplaces and public places as well as semi-outdoor spaces like patios or outdoor dining areas. Evidence from our review demonstrates that TOBAC grantees have created evidence that contributed to policy outcomes related to the implementation of Article 8, as described by the select outcomes described below.

The involvement of the Chinese Government in the China National Tobacco Corporation, the largest cigarette manufacturer in the world and a virtual monopoly in China, makes tobacco control policy implementation an important challenge in China. On May 1, 2011, the Chinese Government enacted a smoking ban on enclosed places such as hotels, restaurants, theaters, and waiting rooms at railway stations and airports. The regulation also bars cigarette vending machines in public places. This policy shift was informed by evidence generated by a TOBAC grantee, who collaborated with the Chinese Academy of Medicine to design an intervention program to reduce environmental tobacco smoke exposure at home. His work provided a tobacco control model for use at the provincial level in China and informed program and policy development at the national level. The same PI works in Mexico, which recently passed a national law requiring smoke-free indoor public places and workplaces; the National Institute for Public Health provided key technical support as the law was developed.49

Local researchers in Hungary, who were trained under the TOBAC program, presented evidence to the Hungary State Secretary's cabinet, which subsequently passed national clean air laws that protect non-smokers in public places such as workplaces and restaurants. Another law that was passed recently prohibits smoking within five meters of bars, which is believed to have had an impact on smoking at outdoor cafes. One of the aims of the work in Hungary, and now by the same PI in Romania, is training scientists, public health officials, NGO representatives, and other research users, so that they can take the lead in national tobacco control planning and ultimately reduce the tobacco use rates in their country.

The work in Hungary helped Hungarian scientists not only become research experts in tobacco control science, it also helped them understand the appropriate data needed to inform lawmakers about the harmful impacts of tobacco and SHS.50 When asked about the critical elements that facilitated her success, the PI commented that her ability to live in-country was instrumental to enabling robust

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relationships with Hungarian government officials. She encouraged future research funding to create opportunities for scientists to live in-country so that they can really understand the culture of the science and policy they hope to inform. She also commented that it took 18 months to break the unique country barriers to research progress, which emphasizes the need for long-term research and capacity opportunities to successfully and sustainably inform policy.51

Smoking has long been a popular pastime throughout the Middle East. In Syria, more than half the men smoke cigarettes and women are taking up the habit at increasing rates. Hookahs, or water-pipes, are also prevalent partly because of the erroneous perception they are a “cleaner,” “safer” way of consuming tobacco. One grantee led a research partnership to conduct the first ever, national survey to determine smoking prevalence, as well as additional studies on the toxicity, dependence, the effectiveness of various cessation approaches, and the impact of secondhand smoke. Information generated by the project has been used to inform the country’s health policies, including a ban on public smoking. It is now illegal to smoke in Syrian restaurants and cafes, campuses and offices, taxis or buses, and anywhere else in public. The ban includes limitations on water-pipes, which are especially popular among teens, young adults and women. When asked about the impact of the research, the investigator said, "The inclusion of water-pipe smoking restrictions in the ban is clear evidence of our direct involvement in public policy."52 Additionally, the emergence of the Syrian Center for Tobacco Studies, a center established in the first round of the TOBAC program, boosted the ability to inform regional and international tobacco control policy, as demonstrated by the recent election of a staff member as the regional representative on the Board of Directors of the Framework Convention Alliance.53

Other Notable Policy Outcomes

In addition to policy outcomes related to Articles 6 and 8, TOBAC grantees have experienced outcomes in other areas of FCTC policy. The success stories below are a representative sampling of other policy areas where work funded by the TOBAC program has contributed to significant policy outcomes.

One grantee generated evidence based on research related to tobacco in movies in India. This evidence informed new laws on the depiction of tobacco use in movies. These laws require movies to show health disclaimers at the beginning and the middle of the movie, scroll warning during the period of display of tobacco products, provide editorial justification for such display, blur scenes depicting tobacco use or product close-ups, and require a parental guidance rating for children under 12 years of age. Subsequently, these laws were amended in September, 2012; they are now required to have health spots and audio-visual disclaimers at the beginning and the middle of the movie, provide editorial justification for such display, and have prominent static warning messages during each period of display. India is currently the only country with such stringent tobacco control laws that restrict tobacco use exposure in Indian and foreign films released in India.54

Also in India, research from TOBAC-funded project revealed that the use of smokeless tobacco products (SLT) is widely acceptable in India and associated with family and cultural tradition, socialization, and

medicinal use. SLT is also regarded as “gateway product” for tobacco products among adolescents. These factors are further compounded by low taxation. The results of surveillance work by the TOBAC grantee were shared with the Indian Ministry of Health and Family Welfare, helping to inform future policies. While there is no effective national ban on smokeless products in India, regulation on the sale of any edible product having tobacco and nicotine as its ingredient is completely prohibited.

### 4.3.2 Changes in Public Health Practice

In addition to informing outcomes related to federal and local legislation, TOBAC grantees have reported numerous improvements in public health practice as a result of their work— from the very local to those at a broader level. Many of these advances are related to FCTC Article 14, which concerns measures that reduce tobacco dependence and cessation. Eleven total TOBAC grantees have focused on this article in some way.

A TOBAC grantee working on smoking rates in hospitals in China, for example, centered on pregnant women as vectors for tobacco cessation education. Researchers working on this project first focused on the prevalence of smoking among Chinese physicians—around 45%—and widely distributed that data. The grantee worked with hospitals to educate administrators about the value of smoke-free policies, while also training the doctors and nurses to talk to new mothers about the danger of second-hand smoke to unborn babies. Because of China’s one-child policy, mothers were very receptive to this message. Expecting mothers were also educated about ways to communicate with their spouses about the health dangers of secondhand smoke directly related to the harm it could cause to their infant. As a result of this intervention, about 20% of spouses started smoking only outside the home and 7% of spouses quit using tobacco altogether. The intervention has been expanded to many other hospitals in the region.\(^{55}\)

Almost all TOBAC projects have informed a change in public health practice at varying levels. The examples of this type of impact are too numerous to describe in a report of this nature. In lieu of description, we refer readers to the project abstracts in Appendix D for descriptions of interventions and research that have lead to changes in public health practice in LMICs.

5.0 Conclusion

Overall, the TOBAC program has experienced success in generating evidence to inform implementation of the FCTC as well as national and international tobacco control policy, in building tobacco control research capacity in LMICs, and in supporting scientific advances that are moving the field forward. Grantees have built partnerships, networks, and collaborations that will expand beyond the five-year timeline of the TOBAC grants.

Some notable opportunities exist that could be possible foci for future iterations of the TOBAC program. First, the scientific outcome metrics used to quantify outcomes in this report (e.g., publications, trainees) all show very little progress in Sub-Saharan Africa. This is a direct result of a small number of TOBAC projects being funded in that region with relatively few funds compared to other regions like East and South Asia. As the tobacco industry turns its focus to growing African markets, tobacco control research and capacity needs in the region will increase. Given this, there is an opportunity to bolster efforts against the epidemic by expanding research and capacity-building activities in this region.

The 2012 TOBAC RFA featured a new focus on the economic aspects of tobacco control. Economic issues, including illegal trade and governance, have been identified as new complexities that tobacco control research need to address. A continued focus on research informs these aspects will only improve tobacco control outcomes in LMICs in the future.

Further, tobacco is a risk factor for all major NCDs (i.e., cardiovascular disease, cancer, diabetes, chronic respiratory infection). Given this, scientists who work in different disease areas have a common interest in researching cessation, preventing initiation, health risks, and effects of tobacco use, as well as regulatory effects on use. Therefore, there is an opportunity for cross-pollination and collaboration between researchers working on these diseases and those looking specifically at tobacco control issues in LMICs. The TOBAC program should encourage this type of partnership and collaboration.

Changing social norms and sophisticated marketing efforts from the tobacco industry in many LMICs have increased the susceptibility of women to tobacco use. Factors such as culture, tradition, and limited economic means have long constrained tobacco use among women in many LMICs, where the prevalence of women’s smoking remains less than 5% overall. However, the prevalence of smoking among women appears to be increasing in some countries, fueled in part by tobacco companies’ marketing efforts. Research is needed to assist countries in decreasing or at least maintaining the relatively low smoking prevalence that exists among women in many LMICs. Only a handful of TOBAC grantees have focused their research efforts specifically on women and girls. Of the 333 TOBAC-related publications analyzed, less than 20 of them focused primarily on women and girls. There is a demonstrated need for more knowledge in this area.

In many LMICs, the use of diverse forms of smoked and smokeless tobacco is common. In contrast to the well-studied adverse health effects of manufactured cigarettes, the adverse health effects of non-cigarette tobacco products are not well studied. In addition, there have been few studies of the health effects of industry-produced tobacco alternatives, such as electronic cigarettes, which deliver nicotine to

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the respiratory system without producing smoke. One TOBAC grantee has produced trailblazing evidence about water-pipe use and prevalence in Syria and the Middle East, but generally research in this area is still at an early stage. Global tobacco control efforts, including those of TOBAC grantees, should look to expand our knowledge about the trends and use of these products, their health effects, and effective cessation interventions.

The findings of this review clearly indicate that the TOBAC Program has contributed significantly to tobacco control evidence and capacity building efforts, and informed policy advancements in the LMICs where projects have focused. Continued research and capacity building efforts in LMICs will ultimately help bolster the broader field of tobacco control and result in improved health for populations in these countries.
Acronyms

CDC   US Centers for Disease Control and Prevention
CGHR  Centre for Global Health Research
CGHS  Fogarty International Center’s Center for Global Health Studies
China CDC Chinese Center for Disease Control and Prevention
FCTC  Framework Convention on Tobacco Control
FIC   Fogarty International Center
HHS   US Department of Health and Human Services
HIC   High-Income Countries
ICs   National Institutes of Health Institutes and Centers
ITC   International Tobacco Control Project
LMICs Low- and Middle-Income Countries
MENA Middle East and North African
NCD   Non-Communicable Disease
NCI   National Cancer Institute
NGO   Non-Governmental Organization
NHLBI National Heart, Lung, and Blood Institute
NIDA  National Institute on Drug Abuse
NIH   National Institutes of Health
OBSSR Office of Behavioral and Social Sciences
PIs   Principal Investigators
RFA   Request for Application
SCTS  Syrian Center for Tobacco Studies
SLT   Smokeless Tobacco Products
TOBAC International Tobacco and Heath Research and Capacity Building Program
TobLabNet WHO Tobacco Laboratory Network
TobReg WHO Study Group on Tobacco Regulation
WHO   World Health Organization

Appendices (currently another document)