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Project Summaries

[Evaluating How Tobacco Control Policies are Shaping the Nicotine Delivery Market](#)

Project 1 Summary

Project 1 assesses trajectories of the use of VNP and their interactions with tobacco products, and, in collaboration with Project 3 (which assesses non-smoking youth) aims to evaluate how VNP and smoked tobacco product regulatory policies differentially influence tobacco and nicotine use behaviors in three countries – the United States (US), England (EN), and Canada (CA), selected because they have similar smoking rates and share similar histories of cigarette product regulations but have divergent policies regulating VNP.

Project 1 has three specific aims:

1. To describe how the patterns of VNP and cigarette use differ among smokers and recent ex-smokers both over time and between important sub-groups (e.g., age groups, gender, income, those planning to quit smoking, nicotine dependence level), in particular whether the interactions between VNP and cigarette use vary across the three countries.
2. To examine how differences in tobacco control and VNP policies between and within the US, EN, and CA are related to differences in the patterns of VNP and cigarette use. In particular, when policies on VNP and/or cigarettes change in a country, this study will evaluate how these policy changes impact the use of VNP and cigarettes in comparison to countries where no policy change has occurred.
3. To contribute new information on the methods for monitoring health behaviors such as VNP use by comparing characteristics of the online samples recruited in this study with samples collected by conventional survey methods (e.g., PATH Household survey and other national surveys in EN and CA); and to explore the extent to which the behavior of the self-identified early adopters of VNP (i.e., regular users who have used VNP for some years) can provide useful indications of the behavior of the broader sample of adult smokers and hence, the mainstream population.

Project 2 Summary

There is a large gap in understanding the functions of vaporized nicotine products (VNP); i.e. what they do and what exposures they achieve with each episode of use, and the extent to which this might vary and thus average out over time. This project is designed to answer a broad set of questions about the evolution of the nicotine delivery marketplace in countries with differing policy frameworks towards VNP.

Project 2 aims to answer three major questions:

1. How does the policy environment in a country affect the mix of product types and brands (both VNP such as e-cigarette and conventional cigarette) used most commonly?
2. Does regulation of VNP as a medicine versus recreational use affect VNP contents, labeling accuracy, nicotine emission and delivery, and unit variability?
3. Do product characteristics and/or brand preferences shift as VNP use changes with time? Surveillance of product characteristics during the project period will allow the investigative team to elucidate the potential roles of consumer preference, regulation, and larger market dynamics (e.g., mergers and acquisitions) in changes to product performance and brand share.

Project 3 Summary

Project 3 seeks to increase the understanding of the factors that predict VNP uptake among youth and to examine policy measures that may prevent uptake among non-smokers. Participants will be recruited through

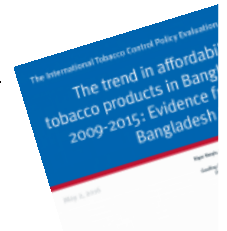
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Neilsen's consumer panel, using the same methodology across the three countries. Quotas will be used to recruit equal proportions of "never" smokers and "experimental" smokers in each country. After completing baseline survey measures, participants will be randomized to one of the following: 1) a discrete choice experiment; 2) an auction experiment; or, 3) a "no experiment" control condition. The discrete choice experiment and auction experiments will be used to assess the overall level of VNP demand for each participant, as well as to test how promotion and product attributes affect VNP demand. Due to the number of attributes that will be tested, the project will be conducted in two sequential studies, with separate cohorts used in each study. Study 1 (n=4,500 in each country) will examine the influence of five product attributes: product type, nicotine level, flavor, brand, and price. A separate cohort will be recruited using the same methods for Study 2 (n=4,500 in each country), which will examine the influence of three promotional attributes— advertisements, modified risk claims on packaging, and health warnings—in the context of price and product type. Analyses will consist of the following: 1) tests between countries to examine differences in VNP uptake between baseline and follow-up; 2) analysis of the discrete choice and auction experiments at baseline to estimate the effect of product and promotional attributes on consumer demand; 3) tests to examine which of the baseline measures is best able to predict individual-level VNP uptake at 12-month follow-up: measures of susceptibility assessed in the "no experiment" control group, or aggregate measures of demand from the discrete choice and auction studies. Overall, Project 3 would be the first to directly compare differences in VNP uptake among youth across countries. The project also has the potential to advance the methodological framework for predicting youth uptake and estimating the efficacy of policy measures prior to their implementation.

Project 3 has aims:

1. To examine international variations in VNP uptake among youth in the US, Canada, and England;
2. To estimate the influence of policy measures on consumer demand for VNPs among youth, using methods from the fields of marketing (discrete choice experiments) and economics (auction experiments); and,
3. To develop the methodological framework for policy evaluation and pre-market testing of nicotine products.

Project 4 Summary

The goal of Project 4 is to use the Experimental Tobacco Marketplace to empirically assess the effects of regulatory changes on tobacco consumption among smokers. The specific aims will address how factors such as dose, price, environmental constraints (smoke-free work environments), and flavors affect consumption and substitutability of cigarettes and vaporized nicotine products. In these within-subject studies, the research team will examine choices in the Experimental Tobacco Marketplace with some purchases actualized. This novel method will increase the external validity of modern regulatory science. Moreover, the obtained results will help direct policymakers' decisions about the availability and pricing of alternative, potentially less harmful, tobacco products.

Project 5 Summary

Patterns of tobacco use may change dramatically as a result of the new vaporized nicotine products (VNPs), such as e-cigarettes. The use of VNPs has surged, likely driven by the perception that they are less harmful than regular cigarettes and are useful smoking cessation aids. At the population level, however, their use may delay cessation of cigarettes by employing VNPs as "bridge" products to avoid smoking restrictions, and may attract never smokers that may later become smokers. The uptake and use of these products will be influenced by the regulatory context in which they are brought to market. In dynamic situations such as these, modeling provides a "virtual laboratory" to synthesize existing evidence and compare the impact of multiple policies and regulations on health outcomes.

Project 5 has four specific aims:

1. To develop a conceptual framework for predicting the impact that tobacco control policies have on VNP and smoked tobacco use rates. Inputs and parameters will be developed in conjunction with the Project Leaders in this Program Project, based on the relevant literature and the advice of outside expert panels
2. To develop an economic model of tobacco industry behavior and product regulation. Product use will depend on appeal, addiction, and acute toxicity, as determined by industry pricing, product content, and marketing. The model will distinguish the role of traditional cigarette and specialized VNP firms in the evolution of the VNP market and consider how cigarette and VNP industry dynamics are influenced by various regulatory options.
3. To develop models that would examine trends in VNP and cigarette use, the effects of policies on use, and health consequences. Models of cigarette and VNP use will be developed for the Canada, England, and the US that will be used to examine the potential role of policies aimed at cigarettes and VNP use in each nation and compared to the other nations. Results will be disseminated to inform the FDA and other regulatory agencies and provide documentation and results in user friendly formats.

4. To build comparable models for middle and low income countries, with adequate local data. We will compare the role of supply vs. demand-reducing policies affecting the VNP and cigarette use and associate health effects.

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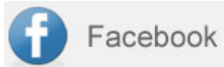
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