



THE ONTARIO TOBACCO
RESEARCH UNIT UNITÉ
DE RECHERCHE
SUR LE TABAC
DE L'ONTARIO

Generating knowledge for public health

Evaluation of the Risk-Based Enforcement Pilot:

A Risk Categorization Model for Youth Access to Tobacco

Final Report

Bo Zhang
Jolene Dubray
Robert Schwartz

February 2014

Suggested Citation: Zhang B, Dubray J, Schwartz R. *Evaluation of the Risk-Based Enforcement Pilot: A Risk-Categorization Model for Youth Access to Tobacco Final Report*. Toronto: Ontario Tobacco Research Unit, February 2014.

Acknowledgements

We would like to thank the enforcement staff at the three participating public health units for assisting in the development of the risk assessment questionnaire, sharing their tobacco enforcement expertise and experiences, and giving their dedication to the year-long intervention.

We would also like to thank Marilyn Pope who provided editorial comments and Sonja Johnston who provided production assistance.

Table of Contents

Acknowledgements.....	iii
List of Tables	v
Acronyms and Abbreviations	vi
Executive Summary.....	1
Summary of Findings	2
Background	3
Tobacco Vendor Risk Categorization	4
Intervention Design	5
Tobacco Inspection System	8
Evaluation Objectives.....	9
Methods.....	10
Data.....	10
PHUs A and C	10
PHU B	10
Other PHUs	10
Compliance Data Analysis.....	11
Findings	13
Number of Tobacco Vendors and Inspections	13
Number of Tobacco Vendors and Inspections: PHU A.....	13
Number of Tobacco Vendors and Inspections: PHU B.....	16
Number of Tobacco Vendors and Inspections: PHU C.....	19
Number of Tobacco Vendors and Inspections: Three Pilot PHUs vs. Other 33 PHUs.....	21
Compliance by Intervention.....	25
Compliance in PHU A	25
Compliance in PHU B	26
Compliance in PHU C	27
Compliance: Three Pilot PHUs vs. Other 33 PHUs	28
Logistic Regression Analysis of Compliance	30
Discussion.....	34
Appendix.....	38
Youth Access Enforcement Prior to the Pilot Project	38
Overview of the Risk Categorization Model for Youth Access to Tobacco Pilot Project	38
Risk Assessment Questionnaire	39
References	42

List of Tables

Table 1: Risk Category Cut-off Values, by Public Health Unit Site	5
Table 2: Intervention Schedule, by Risk Category and Public Health Unit Site	6
Table 3: Number of Inspections and Tobacco Vendors by Intervention in PHU A	14
Table 4: Number of Inspections and Tobacco Vendors by Intervention in PHU B	17
Table 5: Number of Inspections and Tobacco Vendors by Intervention in PHU C	20
Table 6: Number of Inspections and Tobacco Vendors by Intervention: Three Pilot PHUs vs Other 33 PHUs	23
Table 7: Compliance with Youth Access Restriction in PHU A, by Intervention and Risk	26
Table 8: Compliance with Youth Access Restriction in PHU B, by Intervention and Risk	27
Table 9: Compliance with Youth Access Restriction in PHU C, by Intervention and Risk	28
Table 10: Compliance with Youth Access Restriction: Three Pilot PHUs vs Other 33 PHUs	30
Table 11: Logistic Regression Analysis of Compliance, Comparison Between 3 Pilot PHUs and Other 33 PHUs	32
Table A-12: Public Health Unit Enforcement Practices Prior to the Pilot Project	38
Table A-13: Risk Assessment Questionnaire and Response Values	40
Table A-14: Risk Assessment Questionnaire and Question Weighting, by Public Health Unit Site	41

Acronyms and Abbreviations

CI	Confidence Interval
OR	Odds Ratio
OTRU	Ontario Tobacco Research Unit
PHU	Public Health Unit
<i>SFOA</i>	<i>Smoke-Free Ontario Act</i>
TEO	Tobacco Enforcement Officer
TIS	Tobacco Inspection System

Executive Summary

Since 1994, it has been illegal to sell or supply a tobacco product to a person under the age of 19 in Ontario (youth access restriction). Enforcement of the youth access restriction has been ongoing since that time. In 2009, the Ontario Ministry of Health Promotion and Sport initiated an exploration of new approaches to enforcing the *Smoke-Free Ontario Act* that would focus on risk of non-compliance. As a result of that exploration, a risk categorization model for youth access enforcement was piloted in three public health units over a 12-month period in 2011-2012.

Tobacco vendors were categorized according to their individual risk for selling tobacco products to underage youth. Tobacco vendors in each of the participating public health units were categorized into four risk categories (no-risk, low-risk, moderate-risk, and high-risk) based on scores derived from a series of seven core questions and up to two elective questions on a risk assessment questionnaire. Measures on the questionnaire included: complaint and enforcement history, geographic indicators, type of ownership and operation type. Once scored, each tobacco vendor received intervention visits (i.e., compliance check, enforcement check, etc.) according to the intervention schedule established for each risk category. In general, vendors in the no-risk group received no intervention visits, vendors in the low-risk group received 0-1 intervention visit, vendors in the moderate-risk group received 2 intervention visits, and vendors in the high-risk group received 4-5 intervention visits.

Following the completion of the 12-month intervention, all three public health units returned to the standard youth access enforcement practice that consists of two annual compliance checks or enforcement checks to every tobacco vendor in their region.

The purpose of this evaluation is to explore how well the risk categorization model is working for youth access to tobacco enforcement. This report focuses on the findings of compliance trends over a four year period (24 months pre-intervention, 12 months during the intervention, and 12 months post-intervention) by comparing compliance in the pre- to post-intervention period. Analysis in this report was restricted to vendors that received inspections both in the pre- and post-intervention periods.

Summary of Findings

Pilot findings provide strong support for risk-based enforcement. These findings suggest that 1) increasing the number of visits to moderate- and high-risk vendors can increase compliance; 2) no- and low-risk vendors should continue to receive one visit per year to maintain compliance.

- Overall, the risk categorization model worked on average in the 3 pilot PHUs.
- The overall compliance rate improved from 84% in the pre-intervention period to 91% in the post-intervention period in the 3 pilot PHUs.
- The overall compliance rate increased from 86.8% in the pre-intervention period to 87.2% in the post-intervention period in the other 33 PHUs during the same time.
- In PHU C, there was a significant and substantial increase in compliance in the moderate- and high-risk vendors from the pre- to the post-intervention period in adjusted analyses, while the compliance was maintained in the no- and low-risk groups. During the intervention period, vendors in the no-, low-, moderate-, and high-risk groups received 0, 0, 2 and 4 intervention visits respectively, same as planned.
- In PHU A, there was a significant increase in compliance in the moderate- and high-risk vendors in unadjusted analyses, but the increase was not significant after adjusting for test shoppers' age and gender. The compliance rate in the low-risk vendors decreased significantly from 94% in the pre-intervention period to 79% in the post-intervention period in the adjusted analysis. Vendors in the no-, low-, and moderate-risk groups received the same intervention visits as planned (0, 0 and 2 respectively) during the intervention period, but vendors in the high-risk group received 2 fewer intervention visits than the planned 4 intervention visits.
- In PHU B, there was no significant increase in compliance in vendors in any risk group from the pre- to the post-intervention period in unadjusted analyses. However, compliance in low-risk vendors decreased significantly from 100% in the pre-intervention period to 89% in the post-intervention period in the adjusted analysis. Vendors in the no-, low-, and moderate-risk groups received more intervention visits (1.2, 1.7 and 2.7 respectively) compared to planned visits (0, 1 and 2 respectively) during the intervention period, while vendors in the high-risk group received 4.9 intervention visits same as planned (5 visits).
- The 3 pilot PHUs were not a representative sample of all PHUs in Ontario and adherence to protocol was imperfect. Sample sizes in PHUs A and B were small, making detection of significant changes challenging.
- Continued study is needed to support broad implementation of risk-based enforcement.

Background

Through the passage of the *Tobacco Control Act* in 1994, it became illegal to sell or supply a tobacco product to a person under the age of 19 in Ontario (youth access restriction). Enforcement of the youth access restriction has been ongoing since that time. The youth access enforcement procedure – i.e., sending an underage youth into a tobacco vendor to attempt to purchase a tobacco product (also known as a “test shop”) – has essentially remained the same since 1994, with a couple of minor changes; all public health unit test shoppers now complete the sale if a clerk is willing to sell a tobacco product, and some public health units now allow their test shoppers to carry and show ID if requested by the clerk. The frequency in which each tobacco vendor has received a test shop increased in 2006 at the time of the *Smoke-Free Ontario Act* implementation. All public health units (PHUs) were required to conduct at least two test shops per year for each vendor. In 2009, the Ontario Ministry of Health Promotion and Sport asked the Ontario Tobacco Research Unit (OTRU) to research new approaches to enforcing the various sections of the *Smoke-Free Ontario Act*. Specifically, the research was to discover enforcement approaches that identified risk for non-compliance and considered risk for non-compliance in the management of enforcement activities.

In 2009-2010, OTRU undertook a rigorous review of the literature and relevant documents; interviews with Tobacco Enforcement Officers; a risk-assessment web-survey of public health unit enforcement managers, supervisors and staff; an analysis of risk-factors for non-compliance with the *Smoke-Free Ontario Act* using data from the Ontario Ministry of Health and Long-Term Care’s *Tobacco Inspection System* (TIS) database; and, case studies to gather information about innovative enforcement approaches. For the pilot project *Risk Categorization Model for Youth Access to Tobacco*, public health units were recruited to participate from June through September 2010. Of the eight public health units that showed an interest in participating, three were selected based on consultations between OTRU and the Ontario Ministry of Health Promotion and Sport (2 smaller public health units with outlying or remote areas and 1 urban public health unit). All of the selected public health units were included in the development of the pilot project. As such, various aspects of the pilot project were customized to best capture risk of non-compliance at the local level and to minimize the impact on local enforcement resources.

Tobacco Vendor Risk Categorization

Risk scores for each tobacco vendor were calculated by summing the weighted values obtained from each response to the risk assessment survey. The range of possible risk scores for tobacco vendors was 0 to 100. Higher risk scores denoted greater risk of selling tobacco products to underage youth. (Details about how the scores were calculated and what consisted of the questions can be found in the Appendix of this report and in our interim report).¹

Initially, three risk categories were considered for the pilot project: low-risk, moderate-risk, and high-risk. A fourth risk category (no-risk) was added to reduce the resources allotted to tobacco vendors considered least likely to be non-compliant with the youth access restriction. Each risk category was defined by a range of risk scores, which was modeled from the Risk Categorization Model for Food Retail/Food Service Establishments.² The distribution of overall risk scores for each public health unit was also taken into account; therefore the range of risk scores that defined each risk category in the pilot varied by public health unit (Table 1). Please note that the number of vendors in each level of risk category in Table 1 reflects the vendor population for each PHU in 2010. These numbers might not match with those shown in later sections due to vendors closing for business in the post-intervention period and lack of inspection data in the Tobacco Inspection System database in the pre-intervention period (PHU C only). The risk categorization for each vendor was kept throughout the pre- and post-intervention, based on the risk category defined in the pre-intervention period for comparison purposes, although vendors might change their risk category from the pre- to the post-intervention according to the criteria set in the pre-intervention.

Public health units were given the opportunity to override and change a tobacco vendor's risk category if they felt that the assigned risk categorization was inaccurate due to the receipt of a complaint, the issuance of a charge, or other anecdotal evidence of non-compliance. Only a handful of tobacco vendors were re-categorized during the intervention, either based on previous knowledge and experience with the tobacco vendor, or as a result of the outcome of the first intervention visit. In most cases the risk category was upgraded to moderate-risk or high-risk; only a few were downgraded to low-risk. The majority of enforcement staff kept the risk categories that were assigned at the beginning of the intervention.¹

Table 1: Risk Category Cut-off Values, by Public Health Unit Site

Risk Category	PHU A		PHU B		PHU C	
	Risk-score cut-off	No. tobacco vendors	Risk-score cut-off	No. tobacco vendors	Risk-score cut-off	No. tobacco vendors
No-risk	0	9 (4.6%)	0	6 (3.1%)	0	22 (3.0%)
Low-risk	1.0 – 25.0	88 (45.1%)	1.0 – 25.0	70 (36.7%)	1.0 – 30.0	392 (53.0%)
Moderate-risk	25.1 – 55.0	75 (38.5%)	25.1 – 55.0	97 (50.8%)	30.1 – 60.0	164 (22.2%)
High-risk	55.1 – 100	23 (11.8%)	55.1 – 100	18 (9.4%)	60.1 – 100	162 (21.9%)
Total		195 (100%)		191 (100%)		740 (100%)

Intervention Design

The aim of the intervention was to test the effectiveness of a risk-based model in the enforcement of the youth access restriction on tobacco vendors over a 12-month period. To this end, an intervention schedule was developed according to risk, where high-risk tobacco vendors received the most intervention visits and no-risk and low-risk tobacco vendors received fewer intervention visits. Intervention schedules differed by public health unit to ensure that the number of intervention visits was manageable given the locally available enforcement resources (Table 2). PHU B followed a 0-1-2-5 intervention schedule: where no-risk tobacco vendors received no intervention visits; low-risk tobacco vendors received one intervention visit; moderate-risk tobacco vendors received two intervention visits; and, high-risk tobacco vendors received five intervention visits over the course of the year. PHUs A and C focused their intervention visits on the moderate-risk and high-risk tobacco vendors by selecting a 0-0-2-4 intervention schedule where no-risk and low-risk tobacco vendors received no intervention visits; moderate-risk tobacco vendors received two intervention visits; and, high-risk tobacco vendors received four intervention visits over the course of the year.

Table 2: Intervention Schedule, by Risk Category and Public Health Unit Site

		No risk	Low risk	Moderate risk	High risk	Total
PHU A	Tobacco Vendors	9	88	75	23	195
	Intervention schedule (# of intervention visits)	0	0	2	4	
	Total intervention frequency	0	0	150	92	242
PHUB	Tobacco Vendors	6	70	97	18	191
	Intervention schedule (# of intervention visits)	0	1	2	5	
	Total intervention frequency	0	70	194	90	354
PHU C	Tobacco Vendors	22	392	164	162	740
	Intervention schedule (# of intervention visits)	0	0	2	4	
	Total intervention frequency	0	0	328	648	976

Scheduling of the intervention visits was left to the discretion of each public health unit with the condition that the intervention visits should be at least one month apart so that the visits were dispersed throughout the intervention period. Any tobacco vendor who opened for business during the 12-month intervention period was excluded from the intervention since neither baseline data, nor risk categorization would be available. However, any existing tobacco vendor who changed ownership during the intervention period continued to be visited as per the assigned intervention schedule since the enforcement history remains with the physical address in TIS.

Participating public health units continued to follow the Ontario Ministry of Health Promotion and Sport's *Protocol for Determination of Tobacco Vendor Compliance*³ during the intervention. For example, if a complaint was received for a no-risk tobacco vendor that was not assigned any intervention visits, the public health unit conducted an inspection and documented it in TIS as per usual protocol (in analysis, this was counted as an inspection). Furthermore, in the case where a tobacco vendor receiving an intervention visit required a follow-up visit due to the issuance of a warning, charge, or the receipt of a complaint, the follow-up visit counted toward the intervention frequency assigned to that tobacco vendor.

The type of inspection included as an intervention visit varied by public health unit to align with local enforcement resources. Intervention visits consisted of compliance checks or enforcement

checksⁱ in PHUs B and C. PHU A included other types of inspections in the intervention. High-risk tobacco vendors in PHU A received one enforcement check, two ‘*Who is 25?*’ compliance checks,ⁱⁱ and one policy and procedure visit where in-store youth access policy training and procedures were assessed by the Tobacco Enforcement Officer. Moderate-risk tobacco vendors in PHU A received one enforcement check and one ‘*Who is 25?*’ compliance check.

All intervention visits were conducted by public health unit Tobacco Enforcement Officers who are responsible for enforcing the *Smoke-Free Ontario Act*, including: youth access compliance checks or enforcement checks, display and promotion inspections, workplace and enclosed public places inspections, restaurant and bar inspections, education visits, school inspections, and responses to complaints (see Table A-12 in the Appendix). During the intervention period, some tobacco vendors in the participating public health units received additional *Smoke-Free Ontario Act* inspections that were not included as intervention visits. PHUs B and C continued to conduct annual tobacco vendor education and display and promotion compliance checks to all tobacco vendors including the no-risk and low-risk tobacco vendors. Conversely, PHU A did not conduct any tobacco display and promotion compliance checks for any of the vendors. PHU A did provide some education to high-risk tobacco vendors only, as part of the policy and procedure visit during the intervention period. The no-risk and low-risk tobacco vendors in PHU A did not receive any *Smoke-Free Ontario Act* inspections during the course of the intervention. This was a departure from their previous youth access enforcement practices. Typically, PHU A Tobacco Enforcement Officers conduct 1–2 education visits throughout the year in addition to the two annually required compliance checks or enforcement checks.

PHU B was the first public health unit to start the intervention, beginning April 1, 2011 and ending March 31, 2012. PHUs A and C both began the intervention July 1, 2011 and finished June 30, 2012.

ⁱ Both compliance and enforcement checks are conducted by sending an underage youth (test shopper) into a tobacco vendor to attempt to purchase a tobacco product (also known as a ‘test shop’). The enforcement action planned as the result of a successful tobacco purchase attempt determines the type of inspection. When a tobacco product is sold to a test shopper during a compliance check, a warning is issued. When a tobacco product is sold to a test shopper during an enforcement check, a charge is laid.

ⁱⁱ During a ‘*Who is 25?*’ compliance check, a 19-24 year-old test shopper is sent into a tobacco vendor to verify whether clerks are asking for identification from anyone who appears under the age of 25, as they are required to do under the *Smoke-Free Ontario Act*. Feedback is provided immediately to the clerk. Warning letters are issued after two consecutive failed checks. No charges are laid during these compliance checks.

In the pre-intervention period, the actual number of inspections for vendors in the no-risk, low-risk, moderate-risk, and high-risk groups were 2.8, 2.5, 2.4 and 2.6 in PHU A, 3.0, 2.6, 2.8 and 2.8 in PHUB, and 1.1, 1.1, 1.3 and 1.4 in PHU C, respectively.

(Please note that the two terms “inspections” and “intervention visits” were used interchangeably in this report.)

Tobacco Inspection System

The Tobacco Inspection System (TIS) is a database used by 36 public health units in Ontario to report on inspection activities for compliance with various aspects of the *Smoke-Free Ontario Act*. TIS allows for the data capture and management of inspection activity such as: routine inspections, re-inspections resulting from corrective action, high volume of charges laid, and issuing automatic prohibitions.⁴ All three participating public health units continued to enter the outcomes of each intervention visit into TIS. A risk module in TIS was launched during the course of the intervention. This module contained the risk assessment questionnaire and tobacco vendor risk scoring for each of the three participating public health units. Also, a risk report was added to the system to allow enforcement staff to view tobacco vendors by their assigned risk category and the date of the last inspection.

Evaluation Objectives

The objective of the evaluation study was to explore how well the risk categorization model is working for youth access to tobacco enforcement. Specifically, to:

1. Assess whether increasing the frequency of intervention visits for high-risk tobacco vendors changes compliance rates over time.
2. Assess whether decreasing the frequency of intervention visits for low-risk and no-risk tobacco vendors changes levels of compliance over time.
3. Explore whether the risk categorization model correctly identifies tobacco vendors that were thought to be high-risk for non-compliance.

In the current report, we are focusing on the first two specific objectives. The third objective was examined in our interim report.¹

Methods

Data

Inspection data for all tobacco vendors in all 36 public health units in Ontario were extracted from TIS by the Tobacco Control Unit, Health Promotion Division, Ontario Ministry of Health and Long-Term Care. Extracted information included PHU name, tobacco vendor ID, date and time of inspection, vendor type (e.g., gas station, independent convenience store, etc.), inspection type (compliance check or enforcement check, etc.), test shoppers' age and gender, complaint received, age of shopper requested, government photo ID requested, proof of age examined, sale of tobacco completed, vendor compliant, education provided, education materials provided, warnings issued, charges laid, and inspectors' comments (e.g., no infractions found during *SFOA* inspection).

Data on risk categorization for the three PHUs were then merged with the inspection data from TIS, based on the tobacco vendor ID. Three intervention periods were assigned for the three PHUs.

PHUs A and C

- Pre-intervention: July 1, 2009 – June 30, 2011
- Intervention: July 1, 2011 – June 30, 2012
- Post-intervention: July 1, 2012- June 30, 2013

PHU B

- Pre-intervention: April 1, 2009 – March 31, 2011
- Intervention: April 1, 2011 – March 31, 2012
- Post-intervention: April 1, 2012- March 31, 2013

Other PHUs

For comparison purposes, the corresponding three periods for the remaining 33 PHUs were as follows, inspections continued as stipulated – i.e. two visits to each vendor each year.

- Pre-intervention: July 1, 2009 – June 30, 2011
- Intervention: July 1, 2011 – June 30, 2012
- Post-intervention: July 1, 2012- June 30, 2013

Compliance Data Analysis

Inspection data from all 36 public health units in the province were analyzed to assess changes in youth access compliance in the pre- and post-intervention periods: pre-intervention (24 months before the start of the intervention), and post-intervention (one year following the completion of the intervention), while the intervention was implemented in 12 months. Compliance with the youth access restriction was measured using tobacco sales to test shoppers less than 19 years of age. Compliance among the three participating public health units was compared to compliance from the remaining 33 public health units to ensure that changes in compliance were not due to a secular trend (i.e., increasing or decreasing over time). Inspections were excluded from data analysis if they were classified as “no inspection” (no information available on sale to underage youth, warnings or charges, etc.), “store closed”, or “no longer selling tobacco”.

Number of vendors and inspections and compliance rate were summarized by risk (no-, low-, moderate-, and high-risk) and intervention (pre-, during, and post-intervention periods) in the three pilot PHUs and by intervention in the remaining 33 PHUs.

The compliance rate with the youth access restriction was calculated as follows.

$$\frac{\text{No. vendors not selling tobacco to a test shopper under 19 years of age in a given year}}{\text{Total no. vendors receiving test shopping by youth under 19 years of age in a given year}}$$

A tobacco vendor may receive more than one inspection during any given year. A vendor was classified as a non-compliant vendor if the vendor sold tobacco products in any given year to a test shopper less than 19 years of age. A vendor might have two inspections with non-compliance in a year, but the vendor was counted only once as a non-compliant vendor in the given year.

Because some vendors had compliance information in the pre-intervention period but not in the post-intervention period (e.g., missed inspections or closed in the post-intervention) and others had compliance information in the post-intervention period but not in the pre-intervention period (e.g., missed inspections in the pre-intervention period or new vendors in the post-intervention period), analysis for compliance was restricted to vendors with compliance

information in both the pre- (one or two years before the intervention) and post-intervention periods. For the three pilot PHUs, vendors without risk categorization information were excluded.

General linear models were used to compare the difference in number of inspections by different conditions. If there was a significant difference for the overall comparison, T-test for two group comparison was conducted to find which two groups had the difference. For the comparison of number of inspections between two intervention periods in the same vendors, paired T-test was used. Chi-square test was used to determine the difference in compliance in different risk groups in the same intervention period. The McNemar's test⁵ was used to determine the difference in compliance rates in the same vendors for the pre- to the post-intervention comparison. Logistic regression using the generalized estimating equations (GEE)⁶ was used to assess the impact of risk categorization on compliance by comparing the compliance between the pilot PHUs and the remaining 33 PHUs and from the pre- to the post-intervention period, adjusted for potential confounding variables (including store types, test shoppers' age and gender, previous charges and warnings), while taking into account repeated measures within each tobacco vendor.

Findings

In this section, the number of tobacco vendors and inspections in all 36 PHUs are reported first, followed by the compliance rates, and then findings from logistic regression are reported.

Number of Tobacco Vendors and Inspections

The number of tobacco vendors and inspections is an important piece of information for work planning in each PHU for youth access enforcement.

Number of Tobacco Vendors and Inspections: PHU A

In PHU A, only a small number of tobacco vendors were categorized in the no-risk group (1.3%). The majority of vendors were categorized in the low (40%) and moderate-risk (46%) groups. The remaining 13% of tobacco vendors were in the high-risk group (Table 3).

In the pre-intervention period, there was no difference in the number of inspections among vendors with different risk categories; all received 2.47 inspections on average, while the majority (57%) of vendors received 3 or more inspections per year and approximately one third (28%) received 2 inspections per year. During the intervention period, vendors in the moderate and high-risk groups received close to 2 inspections on average, while the majority of vendors in the no-risk and low-risk groups did not receive any inspections, except for a few vendors (one inspection per vendor for three vendors in the low-risk group). During the intervention period, the majority of vendors in the moderate and high-risk groups received 2 inspections (85%-90%). In the post-intervention period, there was no difference in the number of inspections among vendors with different risk categories; all received, on average, 3.67 inspections per vendor per year, while the majority (79%) of vendors received 4 or more inspections per year (Table 3).

Compared to the pre-intervention period, vendors in all risk groups received significantly fewer inspections during the intervention period. In the post-intervention period, all vendors received significantly more inspections compared to the pre-intervention period and during the intervention period, except for vendors in the no-risk group due to small sample size (not significant for the comparison between pre- and post-intervention periods) (Table 3).

Generally, vendors in the no-risk, low-risk and moderate-risk groups received inspections as planned (0, 0, and 2 inspections during the intervention period in the three risk groups,

respectively). However, vendors in the high-risk group only received 2 inspections on average rather than 4 inspections as planned. PHU A conducted 205 fewer inspections during the intervention compared to the pre-intervention period {i.e., 153 vendors*[(1.13 (mean # intervention visits during the intervention period) – 2.47 (mean # inspections in the pre-intervention period))]}, and 389 fewer inspections compared to the post-intervention period {i.e., 153 vendors *[(1.13 (mean # intervention visits during the intervention period) – 3.67 (mean # inspections in the post-intervention period))]}.

Table 3: Number of Inspections and Tobacco Vendors by Intervention in PHU A^a

Intervention	No-risk	Low-risk	Moderate-Risk	High-risk	Total
Pre-intervention					
Two years before intervention					
Time period	July 2009 – June 2010				
Inspections – no.	5	156	178	54	393
Vendors – no.	2	60	69	20	151
Mean no. inspections ^b	2.50	2.60	2.58	2.70	2.60
Frequency of inspections – no. (%) ^c					
1	-----	6 (10.0%)	8 (11.6%)	-----	14 (9.3%)
2	1 (50.0%)	18 (30.0%)	17 (24.6%)	9 (45.0%)	45 (29.8%)
3	1 (50.0%)	31 (51.7%)	40 (58.0%)	9 (45.0%)	81 (53.6%)
4	-----	4 (6.7%)	4 (5.8%)	1 (5.0%)	9 (6.0%)
5	-----	1 (1.7%)	-----	1 (5.0%)	2 (1.3%)
One year before intervention					
Time period	July 2010 – June 2011				
Inspections – no.	6	137	154	49	346
Vendors – no.	2	57	69	20	148
Mean no. inspections ^b	3.00	2.40	2.23	2.45	2.34
Frequency of inspections – no. (%) ^c					
1	-----	12 (21.1%)	14 (20.3%)	3 (15.0%)	29 (19.6%)
2	-----	10 (17.5%)	25 (36.2%)	5 (25.0%)	40 (27.0%)
3	2 (100.0%)	35 (61.4%)	30 (43.5%)	12 (60.0%)	79 (53.4%)
Pre-intervention (two years)					
Time period	July 2009 – June 2011				
Inspections in 2 years – no.	11	293	332	103	739
Vendors – no. (%) ^d	2 (1.3%)	61 (39.9%)	70 (45.8%)	20 (13.1%)	153 (100%)
Mean no. inspections ^b	2.75	2.50	2.41	2.58	2.47 (NS) ^e
Median no. inspections ^b	3.00	3.00	3.00	3.00	3.00
Min-max no. inspections ^b	2-3	1-5	1-4	1-5	1-5
Frequency of inspections – no. (%) ^{c,f}					
1	-----	18 (15.4%)	22 (15.9%)	3 (7.5%)	43 (14.4%)

Evaluation of the Risk-Based Enforcement Pilot: Final Report

2	1 (25.0%)	28 (23.9%)	42 (37.3%)	14 (35.0%)	85 (28.4%)
3	3 (75.0%)	66 (56.1%)	70 (50.7%)	21 (52.5%)	160 (53.5%)
4	-----	4 (3.4%)	4 (2.9%)	1 (2.5%)	9 (3.0%)
5	-----	1 (0.9%)	-----	1 (2.5%)	2 (0.7%)
During intervention					
Time period	July 2011 – June 2012				
Inspections – no.	0	3	131	39	173
Vendors – no.	2	61	70	20	153
Mean no. inspections ^b	0.00 ^{*g}	0.05 ^{**g}	1.87 ^{**g,h}	1.95 ^{*g,h}	1.13 ^{**e,g}
Median no. inspections ^b	0.00	0.00	2.00	2.00	2.00
Min-max no. inspections ^b	0-0	0-1	0-2	1-3	0-3
Frequency of inspections – no.(%) ^c					
0	2 (100%)	58 (95.1%)	2 (2.9%)	-----	62 (40.5%)
1	-----	3 (4.9%)	5 (7.1%)	2 (10.0%)	10 (6.5%)
2	-----	-----	63 (90.0%)	17 (85.0%)	80 (52.3%)
3	-----	-----	-----	1 (5.0%)	1 (0.7%)
Post-intervention					
Time period	July 2012 – June 2013				
Inspections – no.	7	221	257	77	562
Vendors – no.	2	61	70	20	153
Mean no. inspections ^b	3.50	3.62 ^{**i}	3.67 ^{**i}	3.85 ^{**i}	3.67 (NS) ^{e **i}
Median no. inspections ^b	3.50	4.00	4.00	4.00	4.00
Min-max no. inspections ^b	3-4	1-5	1-5	2-4	1-5
Frequency of inspections – no.(%) ^c					
1	-----	1 (1.6%)	3 (4.3%)	-----	4 (2.6%)
2	-----	8 (13.1%)	3 (4.3%)	1 (5.0%)	12 (7.8%)
3	1 (50.0%)	6 (9.8%)	9 (12.9%)	1 (5.0%)	17 (11.1%)
4	1 (50.0%)	44 (72.1%)	54 (77.1%)	18 (90.0%)	117 (76.5%)
5	-----	2 (3.3%)	1 (1.4%)	-----	3 (2.0%)

* p<0.01; ** p< 0.001; NS: not significant.

^a Vendors received inspections in both the pre- and post-intervention periods.

^b Mean, median, minimum and maximum numbers of inspections calculated per vendor per year.

^c Percentages calculated based on vendors in the same risk group and same intervention period.

^d Percentages calculated across all risk groups.

^e Comparison across all four risk groups in the same intervention period.

^f Frequency of inspections for the pre-intervention (two years together) based on one year and two years before the intervention, individually (i.e., per vendor per year).

^g Comparing to the pre- and post-intervention periods in the same risk group.

^h Comparing to the no-risk and low-risk groups in the same intervention period.

ⁱ Comparing to the pre-intervention period in the same risk group.

Number of Tobacco Vendors and Inspections: PHU B

In PHU B, only a small number of tobacco vendors were categorized in the no-risk group (4%). Approximately one third of vendors were categorized in the low-risk group (32%). The majority of vendors were categorized in the moderate-risk group (55%). Vendors in the high-risk group consisted of 9% of all vendors (Table 4).

In the pre-intervention period, vendors in the moderate-risk (2.84 inspections per vendor per year) and high-risk (2.77 inspections per vendor per year) groups received significantly more inspections compared to those in the low-risk group (2.56 inspections per vendor per year), and there was no difference in the number of inspections among other risk groups. The majority (67%) of vendors received 3 or more inspections per year and approximately one third (28%) received 2 inspections per year in the pre-intervention period. During the intervention period, vendors in the high-risk group received significantly more inspections than those in any other risk group; vendors in the moderate-risk group received significantly more inspections than those in the no-risk and low-risk groups; there was no difference in the number of inspections between the no-risk and low-risk groups. During the intervention period, the majority (67%) of vendors in the moderate-risk group received 3 or more inspections and one third (29%) received 2 inspections; all vendors in the high-risk group received 4 or more inspections. In the post-intervention period, there was no difference in the number of inspections among different risk groups, while the majority (80%) of vendors received 2 or more inspections (Table 4).

Compared to the pre-intervention period, vendors in the no-risk and low-risk groups received significantly fewer inspections during the intervention period. Vendors in the moderate-risk group received a similar number of inspections in the pre-intervention and during the intervention periods. Vendors in the high-risk group received significantly more inspections during the intervention period compared to the pre-intervention period. In the post-intervention period, vendors in all risk groups received significantly fewer inspections compared to the pre-intervention period; vendors in the no-risk and low-risk groups received significantly more inspections compared to the intervention period; vendors in the moderate-risk and high-risk groups received significantly fewer inspections compared to the intervention period (Table 4).

Generally, vendors in the no-risk, low-risk and moderate-risk groups received somewhat more inspections than the planned number of inspections (0, 1, and 2 inspections during the intervention period for these risk groups, respectively). Vendors in the high-risk group received somewhat fewer inspections (4.85 inspections) than the planned 5 inspections. PHU B conducted 39 fewer inspections [i.e., $148 \times (2.50 - 2.76)$] during the intervention period compared to the pre-intervention period, but 70 more inspections [i.e., $148 \times (2.50 - 2.03)$] compared to the post-intervention period.

Table 4: Number of Inspections and Tobacco Vendors by Intervention in PHU B^a

Intervention	No-risk	Low-risk	Moderate Risk	High-risk	Total
Pre-intervention					
Two years before intervention					
Time period	April 2009 – March 2010				
Inspections – no.	17	106	234	41	398
Vendors – no.	6	41	79	13	139
Mean no. inspections ^b	2.83	2.59	2.96	3.15	2.86
Frequency of inspections – no. (%) ^c					
1	-----	3 (7.3%)	6 (7.6%)	1 (7.7%)	10 (7.2%)
2	1 (16.7%)	11 (26.8%)	6 (7.6%)	1 (7.7%)	19 (13.7%)
3	5 (83.3%)	27 (65.9%)	54 (68.4%)	7 (53.9%)	93 (66.9%)
4	-----	-----	11 (13.9%)	3 (23.1%)	14 (10.1%)
5	-----	-----	2 (2.5%)	1 (7.7%)	3 (2.2%)
One year before intervention					
Time period	April 2010 – March 2011				
Inspections – no.	19	119	221	31	390
Vendors – no.	6	47	81	13	147
Mean no. inspections ^b	3.17	2.53	2.73	2.38	2.65
Frequency of inspections – no. (%) ^c					
1	-----	5 (10.6%)	-----	-----	5 (3.4%)
2	1 (16.7%)	18 (38.3%)	32 (39.5%)	9 (69.2%)	60 (40.8%)
3	4 (66.7%)	18 (38.3%)	39 (48.2%)	3 (23.1%)	64 (43.5%)
4	-----	6 (12.8%)	10 (12.4%)	1 (7.7%)	17 (11.6%)
5	1 (16.7%)	-----	-----	-----	1 (0.7%)
Pre-intervention (two years)					
Time period	April 2009 – March 2011				
Inspections in 2 years – no.	36	225	455	72	788
Vendors – no. (%) ^d	6 (4.1%)	47 (31.8%)	82 (55.4%)	13 (8.8%)	148
Mean no. inspections ^b	3.00	2.56	2.84**e	2.77*e	2.76**f
Median no. inspections ^b	3.00	3.00	3.00	3.00	3
Min-max no. inspections ^b	2-5	1-4	1-9	1-5	1-5
Frequency of inspections – no. (%) ^(c,g)					
1	-----	8 (9.1%)	6 (3.8%)	1 (3.9%)	15 (5.2%)
2	2 (16.7%)	29 (33.0%)	38 (23.8%)	10 (38.5%)	79 (27.6%)
3	9 (75.0%)	45 (51.1%)	93 (58.1%)	10 (38.5%)	157 (54.9%)
4	-----	6 (6.8%)	21 (13.1%)	4 (15.4%)	31 (10.8%)
5	1 (8.3%)	-----	2 (1.3%)	1 (3.9%)	4 (1.4%)
During intervention					
Time period	April 2011 – March 2012				
Inspections – no.	7	78	222	63	370
Vendors – no.	6	47	82	13	148
Mean no. inspections ^b	1.17***h	1.66***h	2.71***i,j	4.85***h,k	2.50***f,h

Median no. inspections ^b	1.00	2.00	3.00	5.00	2.00
Min-max no. inspections ^b	1-2	1-3	0-4	4-6	0-6
Frequency of inspections – no.(%) ^c					
0	-----	-----	1 (1.2%)	-----	1 (0.7%)
1	5 (83.3%)	20 (42.6%)	2 (2.4%)	-----	27 (18.2%)
2	1 (16.7%)	23 (48.9%)	24 (29.3%)	-----	48 (32.4%)
3	-----	4 (8.5%)	48 (58.5%)	-----	52 (35.1%)
4	-----	-----	7 (8.5%)	6 (46.2%)	13 (8.8%)
5	-----	-----	-----	3 (23.1%)	3 (2.0%)
6	-----	-----	-----	4 (30.8%)	4 (2.7%)
Post-intervention					
Time period	April 2012 – March 2013				
Inspections – no.	13	93	169	25	300
Vendors – no.	6	47	82	13	148
Mean no. inspections ^b	2.17^h	1.98^{***i}	2.06^{***i}	1.92^{***i}	2.03 (NS)^{f ***i}
Median no. inspections ^b	2.00	2.00	2.00	2.00	2.00
Min-max no. inspections ^b	2-3	1-4	1-4	1-4	1-4
Frequency of inspections – no.(%) ^c					
1	-----	12 (25.5%)	13 (15.9%)	5 (38.5%)	30 (20.3%)
2	5 (83.3%)	26 (55.3%)	54 (65.9%)	5 (38.5%)	90 (60.8%)
3	1 (16.7%)	7 (14.9%)	12 (14.6%)	2 (15.4%)	22 (14.9%)
4	-----	2 (4.3%)	3 (3.7%)	1 (7.7%)	6 (4.1%)

* p<0.05; ** p<0.01; *** p< 0.001; NS: not significant.

^a Vendors received inspections in both pre- and post-intervention periods.

^b Mean, median, minimum and maximum numbers of inspections calculated per vendor per year.

^c Percentages calculated based on vendors in the same risk group and same intervention period.

^d Percentages calculated across risk groups.

^e Comparing to the low-risk group in the same intervention period.

^f Comparison across all four risk groups in the same intervention period.

^g Frequency of inspections for the pre-intervention (two years together) based on one year and two years before the intervention, individually (i.e., per vendor per year).

^h Comparing to both the pre- and post-intervention periods in the same risk group.

ⁱ Comparing to the no-risk and low-risk groups in the same intervention period.

^j Comparing to the post-intervention period in the same risk group.

^k Comparing to the no-risk, low-risk and moderate-risk groups in the same intervention period.

^l Comparing to the pre-intervention period in the same risk group.

Number of Tobacco Vendors and Inspections: PHU C

In PHU C, only a small number of tobacco vendors were categorized in the no-risk group (4%). The majority of vendors were categorized in the low-risk group (51%). Vendors in the moderate-risk and high-risk groups consisted of 20% and 25% of all vendors, respectively (Table 5).

In the pre-intervention period, vendors in the moderate and high-risk groups received significantly more inspections compared to vendors in the no-risk and low-risk groups and vendors in the high-risk group received significantly more inspections than vendors in the no-risk group, while there was no difference in the number of inspections among other risk groups. In the pre-intervention period, the majority (77%) of vendors received only one inspection per year. During the intervention period, vendors in the high-risk group received significantly more inspections compared to vendors in other risk groups; vendors in the moderate-risk group received significantly more inspections compared to no-risk and low-risk groups; there was no difference in the number of inspections between vendors in the no-risk and low-risk groups. During the intervention period, the majority (93%) of vendors in the no-risk or low-risk groups did not receive any inspections; the majority (99%) of vendors in the moderate-risk group received 2 or 3 inspections; and the majority (90%) of vendors in the high-risk group received 4 or more inspections. In the post-intervention period, there was no difference in the number of inspections among all risk groups; all received, on average, 2.03 inspections per vendor per year (Table 5).

Compared to the pre-intervention period, vendors in the no-risk and low-risk groups received significantly fewer inspections during the intervention period, while vendors in the moderate and high-risk groups received significantly more inspections during the intervention period. In the post-intervention period, vendors in all risk groups received significantly more inspections compared to the pre-intervention period. There was no difference in the number of inspections between the periods during the intervention and in the post-intervention in the moderate-risk group. In the high-risk group, however, vendors received significantly fewer inspections in the post-intervention period compared to the intervention period (Table 5).

The planned inspections during the intervention period were 0, 0, 2, and 4 for vendors in the no-risk, low-risk, moderate-risk, and high-risk groups, respectively. Vendors in these groups received comparable inspections as planned. PHU C conducted 81 more inspections [i.e., $351 \times (1.46 - 1.23)$] during the intervention period compared to the pre-intervention period, but 200 fewer inspections [i.e., $351 \times (1.46 - 2.03)$] compared to the post-intervention period.

Table 5: Number of Inspections and Tobacco Vendors by Intervention in PHU C^a

Intervention	No-risk	Low-risk	Moderate Risk	High-risk	Total
Pre-intervention					
Two years before intervention					
Time period	July 2009 – June 2010				
Inspections – no.	0	0	2	16	18
Vendors – no.	0	0	2	14	16
Mean no. inspections ^b	0	0	1.00	1.14	1.13
Frequency of inspections – no. (%) ^c					
1	-----	-----	2 (100%)	12 (85.7%)	14 (87.5%)
2	-----	-----	-----	2 (14.3%)	2 (12.5%)
One year before intervention					
Time period	July 2010 – June 2011				
Inspections – no.	16	202	87	121	426
Vendors – no.	15	178	69	82	344
Mean no. inspections ^b	1.07	1.13	1.26	1.48	1.24
Frequency of inspections – no. (%) ^c					
1	14 (93.3%)	156 (87.6%)	52 (75.4%)	50 (61.0%)	272 (79.1%)
2	1 (6.7%)	20 (11.2%)	16 (23.2%)	26 (31.7%)	63 (18.3%)
3	-----	2 (1.1%)	1 (1.5%)	5 (6.1%)	8 (2.3%)
4	-----	-----	-----	1 (1.2%)	1 (0.3%)
Pre-intervention (two years)					
Time period	July 2009 – June 2011				
Inspections in 2 years – no.	16	202	89	137	444
Vendors – no. (%) ^d	15 (4.3%)	178 (50.7%)	71 (20.2%)	87 (24.8%)	351 (100%)
Mean no. inspections ^b	1.07	1.13	1.25^{*e}	1.43^{**e *f}	1.23^{**g}
Median no. inspections ^b	1.00	1.00	1.00	1.00	1.00
Min-max no. inspections ^b	1-2	1-3	1-3	1-4	1-4
Frequency of inspections – no. (%) ^(c,h)					
1	14 (93.3%)	156 (87.6%)	54 (76.1%)	62 (64.6%)	271 (77.2%)
2	1 (6.7%)	20 (11.2%)	16 (22.5%)	28 (29.2%)	68 (19.4%)
3	-----	2 (1.1%)	1 (1.4%)	5 (5.2%)	11 (3.1%)
4	-----	-----	-----	1 (1.0%)	1 (0.3%)
During intervention					
Time period	July 2011 – June 2012				
Inspections – no.	1	12	145	355	513
Vendors – no.	15	178	71	87	351
Mean no. inspections ^b	0.07^{**i}	0.07^{**i}	2.04^{**e,f,j}	4.08^{**i,k}	1.46^{**g}
Median no. inspections ^b	0.00	0	2.00	4.00	0
Min-max no. inspections ^b	0-1	0-1	1-3	0-5	0-5
Frequency of inspections – no. (%) ^c					
0	14 (93.3%)	166 (93.3%)	1 (1.4%)	1 (1.1%)	181 (51.6%)
1	1 (6.7%)	12 (6.7%)	66 (93.0%)	-----	14 (4.0%)

2	-----	-----	4 (5.6%)	-----	66 (18.8%)
3	-----	-----	-----	8 (9.2%)	12 (3.4%)
4	-----	-----	-----	59 (67.8%)	59 (16.8%)
5	-----	-----	-----	19 (21.8%)	19 (5.4%)
Post-intervention					
Time period	July 2012 – June 2013				
Inspections – no.	29	362	148	175	714
Vendors – no.	15	178	71	87	351
Mean no. inspections ^b	1.93**j	2.03**j	2.08**j	2.01**j	2.03(NS)g **j
Median no. inspections ^b	2.00	2.00	2.00	2.00	2.00
Min-max no. inspections ^b	1-2	1-3	1-3	1-5	1-5
Frequency of inspections – no.(%) ^c					
1	1 (6.7%)	18 (10.1%)	4 (5.6%)	15 (17.2%)	38 (10.8%)
2	14 (93.3%)	136 (76.4%)	57 (80.3%)	61 (70.1%)	268 (76.4%)
3	-----	24 (13.5%)	10 (14.1%)	7 (8.1%)	41 (11.7%)
4	-----	-----	-----	3 (3.5%)	3 (0.9%)
5	-----	-----	-----	1 (1.2%)	1 (0.3%)

* p<0.05; ** p< 0.001; NS, not significant.

^a Vendors received inspections in both pre- and post-intervention periods.

^b Mean, median, minimum and maximum numbers of inspections calculated per vendor per year.

^c Percentages calculated based on vendors in the same risk group.

^d Percentages calculated across risk groups.

^e Comparing to the low-risk group in the same intervention period.

^f Comparing to the no-risk group in the same intervention period.

^g Comparison across all four risk groups in the same intervention period.

^h Frequency of inspections for the pre-intervention (two years together) based on one year and two years before the intervention, individually (i.e., per vendor per year).

ⁱ Comparing to both the pre- and post-intervention periods in the same risk group.

^j Comparing to the pre-intervention period in the same risk group.

^k Comparing to the no-risk, low-risk and moderate-risk groups in the same intervention period.

Number of Tobacco Vendors and Inspections: Three Pilot PHUs vs. Other 33 PHUs

Because the three pilot PHUs were not randomly selected from all PHUs, the remaining 33 PHUs may be more similar to the combined three pilot PHUs rather than any one of the three. Thus, analysis was conducted for the three pilot PHUs combined.

In the three pilot PHUs, only a small number of vendors were in the no-risk group (3.5%); the majority were in the low-risk (44%) and moderate-risk (34%) groups; and 18% were in the high-risk group.

In the pre-intervention period, the number of inspections per vendor per year was significantly higher in the moderate-risk group compared to that in the no-risk, low-risk, and high-risk groups; there was no difference in the number of inspections among other risk groups. The number of inspections in the moderate-risk group in the three PHUs was significantly higher than that in the remaining 33 PHUs, while there was no difference in the number of inspections in other risk groups compared to the remaining 33 PHUs.

During the intervention period, vendors in the moderate and high-risk groups of the three PHUs and in the 33 remaining PHUs received significantly more inspections than vendors in the no-risk and low-risk groups of the three PHUs; vendors in the high-risk group of the three PHUs also received significantly more inspections than vendors in the moderate-risk group of the three PHUs and vendors in the other 33 PHUs.

In the post-intervention period, vendors in the moderate-risk group of the three PHUs received significantly more inspections than vendors in other groups, while there was no difference in the number of inspections among other groups.

Compared to the pre-intervention period, vendors in the no-risk and low-risk groups received significantly fewer inspections during the intervention period; vendors in the moderate-risk groups and in the other 33 PHUs received comparable inspections during the intervention period; but vendors in the high-risk group received significantly more inspections during the intervention period. In the post-intervention period, vendors in the low-risk, moderate-risk groups of the three PHUs and vendors in the other 33 PHUs received significantly more inspections compared to the pre-intervention and during the intervention periods; vendors in the high-risk group received significantly more inspections in the post-intervention period compared to the pre-intervention period, but fewer inspections compared to the intervention period; vendors in the no-risk group received comparable inspections compared to the pre-intervention period but significantly more inspections compared to the intervention period.

Compared to the other 33 PHUs, the three pilot PHUs conducted 215 fewer inspections during the intervention period [i.e., $652 * (1.62-1.95)$].

Table 6: Number of Inspections and Tobacco Vendors by Intervention: Three Pilot PHUs vs Other 33 PHUs

Intervention	No-risk ^a	Low-risk ^a	Moderate-risk ^a	High-risk ^a	3 Pilot PHUs	Other 33 PHUs
Pre-intervention (two years together)						
Inspections – no.	63	720	876	312	1971	24492
Vendors – no. (%)	23 (3.5%)	286 (43.9%)	223(34.2%)	120 (18.4%)	652 (100%)	7421
Mean no. inspections per vendor	2.03	1.88	2.37 ^{*b ***c}	1.93 ^{***d}	2.09	1.99 ^{***d}
Median no. inspections per vendor	2.00	2.00	3.00	2.00	2.00	2.00
Min-max no. inspections per vendor	1-5	1-5	1-5	1-5	1-5	1-15
Frequency of inspections – no. (%)						
1	14 (45.2%)	182 (47.5%)	82 (22.2%)	66 (40.7%)	344 (36.4%)	4507 (32.9%)
2	4 (12.9%)	77 (20.1%)	96 (26.0%)	52 (32.1%)	229 (24.2%)	5504 (44.6%)
3	12 (38.7%)	113 (29.5%)	164 (44.4%)	36 (22.2%)	325 (34.4%)	2032 (16.5%)
4	-----	10 (2.6%)	25 (6.8%)	6 (3.7%)	41 (4.3%)	533 (4.3%)
5	1 (3.2%)	1 (0.3%)	2 (0.5%)	2 (1.2%)	6 (0.6%)	130 (1.1%)
6+	-----	-----	-----	-----	-----	77 (0.6%)
During intervention						
Inspections – no.	8	93	498	457	1056	14449
Vendors	23	286	223	120	652	7421
Mean no. inspections per vendor	0.35 ^{***e}	0.33 ^{***e}	2.23 ^{***b,c}	3.81 ^{***b,c,d,e}	1.62 ^{***e}	1.95 ^{***b,c ***f}
Median no. inspections per vendor	0.00	0.00	2.00	4.00	2.00	2.00
Min-max no. inspections per vendor	0-2	0-3	0-4	0-6	0-6	0-10
Frequency of inspections – no. (%)						
0	16 (69.6%)	224 (78.3%)	3 (1.4%)	1 (0.8%)	244 (37.4%)	768 (10.4%)
1	6 (26.1%)	35 (12.2%)	8 (3.6%)	2 (1.7%)	51 (7.8%)	1448 (19.5%)
2	1 (4.4%)	23 (8.0%)	153 (68.6%)	17 (14.2%)	194 (29.8%)	3293 (44.4%)
3	-----	4 (1.4%)	52 (23.3%)	9 (7.5%)	65 (10.0%)	1364 (18.4%)
4	-----	-----	7 (3.1%)	65 (54.2%)	72 (11.0%)	447 (6.0%)
5	-----	-----	-----	22 (18.3%)	22 (3.4%)	79 (1.1%)
6+	-----	-----	-----	4 (3.3%)	4 (0.6%)	22 (0.3%)

Post- intervention						
Inspections – no.	49	676	574	277	1576	16528
Vendors	23	286	223	120	652	7421
Mean no. inspections per vendor	2.13	2.36***g	2.57*b,c ***g	2.31*d ***g	2.42***g	2.23*d ***g
Median no. inspections per vendor	2.00	2.00	2.00	2.00	2.00	2.00
Min-max no. inspections per vendor	1-4	1-5	1-5	1-5	1-5	1-9
Frequency of inspections – no. (%)						
1	1 (4.4%)	31 (10.8%)	20 (9.0%)	20 (16.7%)	72 (11.0%)	1486 (20.0%)
2	19 (82.6%)	170 (59.4%)	114 (51.1%)	67 (55.8%)	370 (56.8%)	3443 (46.4%)
3	2 (8.7%)	37 (12.9%)	31 (13.9%)	10 (8.3%)	80 (12.3%)	1925 (25.9%)
4	1 (4.4%)	46 (16.1%)	57 (25.6%)	22 (18.3%)	126 (19.3%)	475 (6.4%)
5	-----	2 (0.7%)	1 (0.5%)	1 (0.8%)	4 (0.6%)	76 (1.0%)
6+	-----	-----	-----	-----	-----	16 (0.2%)

* p<0.05; ** p< 0.01; *** p< 0.001.

^a Risk groups in the three pilot PHUs.

^b Comparing to the no-risk group in the same intervention period.

^c Comparing to the low-risk group in the same intervention period.

^d Comparing to the moderate-risk group in the same intervention period.

^e Comparing to both the pre- and post-intervention periods in the same risk group.

^f Comparing to the high-risk group in the same intervention period.

^g Comparing to the pre-intervention period and intervention period in the same risk group.

Compliance by Intervention

The compliance rate was calculated based on inspections conducted by sending a test shopper under 19 years of age into vendor establishments. In any given year (based on the intervention period), a vendor was defined as a non-compliant vendor if the sale of tobacco products was completed to the test shopper under 19 years of age at any inspections.

Compliance in PHU A

In the pre-intervention period, vendors in the low-risk group had the highest compliance rate with the youth access restriction (94%), compared to vendors in the no-risk (75%), moderate-risk (71%) and high-risk (66%) groups. The compliance rate was significantly higher in the low-risk group compared to the moderate and high-risk groups, and there was no difference in compliance among other risk groups. There was no difference in compliance during the intervention and in the post-intervention periods among different risk groups (Table 7).

The compliance rate significantly decreased from 94% in the pre-intervention period to 79% in the post-intervention period in the low-risk group, but significantly increased from 71% to 86% in the moderate-risk group, and from 66% to 94% in the high-risk group. The compliance rate for all risk groups combined increased significantly from 79% in the pre-intervention period to 85% in the post-intervention period in PHU A (Table 7).

The average number of inspections per vendor per year during the intervention period was 0, 0, 1.9 and 2.0 in the no-risk, low-risk, moderate-risk and high-risk groups, respectively. The compliance rate from the pre- to the post-intervention period significantly decreased in the low-risk group, but increased in the moderate and high-risk groups. These findings suggest that at least one inspection in a year should be recommended even if vendors were classified in the low-risk group with compliance; close to 2 inspections per vendor per year might increase compliance in vendors in the moderate and high-risk groups.

Table 7: Compliance with Youth Access Restriction in PHU A, by Intervention and Risk^a

Intervention period	No-risk	Low-risk	Moderate-risk	High-risk	Total
	No./total no. vendors (%)				
Pre-intervention	3/4 (75.0)	87/93 (93.5)	87/122 (71.3)***^b	25/38 (65.8)***^b	202/257 (78.6)***^c
During the intervention	-----	3/3 (100.0)	55/64 (85.9)**^d	18/20 (90.0)**^d	76/87 (87.4) (NS)^c ***^d
Post-intervention	1/1 (100.0)	42/53 (79.2)**^d	51/59 (86.4)**^d	17/18 (94.4)***^d	111/131 (84.7) (NS)^c **^d

* p<0.05; ** p<0.01; ***p<0.001; NS, not significant.

^a Analysis for the compliance rate was restricted to inspections conducted by sending a test shopper under 19 years of age and vendors receiving inspections in both the pre- and post-intervention periods.

^b Comparing to the low-risk group in the same intervention period.

^c Comparison across all risk groups with valid data in the same intervention period.

^d Comparing to the pre-intervention in the same risk group.

Compliance in PHU B

In the pre-intervention period, vendors in the no- and low-risk groups had the highest compliance rate with the youth access restriction (100%); compliance rates were moderately high in the moderate-risk group (76%), and lowest in the high-risk (65%) group. The compliance rate in the high-risk group was significantly lower than that in the no-risk and low-risk groups, and the rate in the moderate-risk group was significantly lower than that in the low-risk group. There was no difference in compliance during the intervention and in the post-intervention periods among the four risk groups (Table 8).

There was no difference in compliance in all four risk groups, when comparing the compliance rate in the pre- to the post intervention period. The only significant difference was found in comparing the pre-intervention period to the intervention period in the high-risk group (increased from 65% to 92%). There was no change in compliance from pre- (84%) to post-intervention (85%) in all risk groups combined (Table 8).

The average number of inspections per vendor per year during the intervention periods was 1.2, 1.6, 2.7 and 4.9 in the no-risk, low-risk, moderate-risk and high-risk groups, respectively. Vendors in the no-risk, low-risk and moderate-risk groups received more inspections compared to the planned number of inspections (0, 1 and 2 inspections for the three risk groups, respectively), but a similar number of inspections were undertaken for vendors in the high risk group (5 planned inspections). The compliance rate did not change from the pre- to the post-

intervention period in all four risk groups. These findings suggest that the compliance rate for vendors in the no-risk and low-risk groups could be maintained if at least 1 inspection was conducted in a given year; close to 3 inspections for vendors in the moderate-risk group and close to 5 inspections for vendors in the high-risk group would not necessarily increase compliance.

Table 8: Compliance with Youth Access Restriction in PHU B, by Intervention and Risk^a

Intervention period	No-risk	Low-risk	Moderate-risk	High-risk	Total
No./total no. vendors (%)					
Pre-intervention	12/12 (100.0)	88/88 (100.0)	122/160 (76.3)**^b	17/26 (65.4)**^b *^c	239/286 (83.6)**^d
During the intervention ^c	5/6 (83.3)	42/47 (89.4)	64/81 (79.0)	12/13 (92.3)*^e	123/147 (83.7) (NS) ^d
Post-intervention	6/6 (100.0)	39/44 (88.6)	66/79 (83.5)	6/9 (66.7)	117/138 (84.8) (NS) ^d

* p<0.05; ** p<0.001; NS, not significant.

^a Analysis for the compliance rate was restricted to inspections conducted by sending a test shopper under 19 years of age and vendors receiving inspections in both the pre- and post-intervention periods.

^b Comparing to the low-risk group in the same intervention period.

^c Comparing to the no-risk group in the same intervention period.

^d Comparison across all risk groups in the same intervention period.

^e Comparing to the pre-intervention period in the same risk group.

Compliance in PHU C

In the pre-intervention period, vendors in the no-risk, low-risk and moderate-risk groups had similar high compliance rates (>90%), significantly higher than that in the high-risk group (76%). There was no difference in compliance during the intervention period and in the post-intervention period among the four risk groups (Table 9).

The compliance rate remained the same from the pre- to the post intervention period in the no-risk, low-risk and moderate-risk groups, but increased significantly from 76% to 95% in the high-risk group. The compliance rate increased significantly from 89% in the pre-intervention period to 95% in the post-intervention period in all risk groups combined in PHU C (Table 9).

The average number of inspections per vendor per year during the intervention period was 0.1, 0.1, 2.0 and 4.1 in the no-risk, low-risk, moderate-risk and high-risk groups, respectively, which was very similar to the planned number of inspections. The compliance rate in the no-risk, low-

risk and moderate-risk groups remained high ($\geq 94\%$) in the post-intervention period, while the compliance rate in the high-risk group increased significantly from the pre- to the post-intervention period. These findings suggest that vendors in the no-risk and low-risk groups might maintain the same high compliance rate even if they did not receive any inspections during the intervention period; moderate-risk vendors receiving 2 inspections per year might maintain the same high compliance rate and high risk vendors receiving 4 inspections per year might increase their compliance rate.

Table 9: Compliance with Youth Access Restriction in PHU C, by Intervention and Risk^a

Intervention period	No-risk	Low-risk	Moderate-risk	High-risk	Total
No./total no. vendors (%)					
Pre-intervention	14/15 (93.3)	169/176 (96.0)	64/71 (90.1)	72/95 (75.8)***b *c	319/357 (89.4)***d
During the intervention ^c	1/1 (100.0)	11/12 (91.7)	68/71 (95.8)	81/86 (94.2)***e	161/170 (94.7) (NS)^d ***e
Post-intervention	15/15 (100.0)	168/178 (94.4)	67/71 (94.4)	83/87 (95.4)***e	333/351 (94.9) (NS)^d ***e

* $p < 0.05$; ** $p < 0.01$; *** $p < 0.001$; NS, not significant.

^a Analysis for the compliance rate was restricted to inspections conducted by sending a test shopper under 19 years of age and vendors receiving inspections in both the pre- and post-intervention periods.

^b Comparing to the low-risk group in the same intervention period.

^c Comparing to the moderate-risk group in the same intervention period.

^d Comparison across all risk groups in the same intervention period.

^e Comparing to the pre-intervention period in the same risk group.

Compliance: Three Pilot PHUs vs. Other 33 PHUs

The following section compares the findings on compliance in all three pilot PHUs against the other 33 PHUs. In the pre-intervention period, vendors in the no-risk (94%) and low-risk (96%) groups had significantly higher compliance rates, compared to vendors in the moderate (77%) and high-risk (72%) groups of the three pilot PHUs. Vendors in the other 33 PHUs had a lower compliance rate (87%) compared to vendors in the no- and low-risk groups, but a higher compliance rate compared to vendors in the moderate- and high-risk groups of the three pilot PHUs. The compliance in all risk groups in the three PHUs was lower than that in the other 33 PHUs in the pre-intervention period. In the post-intervention period, the compliance rate in all risk groups of the three pilot PHUs was higher than that in the other 33 PHUs, but there was no difference in compliance among individual risk groups (Table 10).

Compared to the pre-intervention period, the compliance rate in the post-intervention period did not change in the no-risk group (94% in the pre- and 100% in the post-intervention period), declined in the low-risk group (96% in the pre- and 91% in the post-intervention period), but increased in the moderate- (77% in the pre- and 88% in the post-intervention period) and high-risk (72% in the pre- and 93% in the post-intervention period) groups of the three pilot PHUs. In all risk groups of the three pilot PHUs, the compliance rate increased significantly from 84% in the pre-intervention period to 91% in the post-intervention period. In the other 33 PHUs, the compliance rate slightly increased from 86.8% in the pre-intervention period to 87.2% in the post-intervention period (Table 10).

During the intervention period, the average number of inspections per vendor per year was 0.4, 0.3, 2.2 and 3.8 in the no-risk, low-risk, moderate-risk and high-risk groups of the three pilot PHUs, respectively, while it was 1.95 in the other 33 PHUs. These findings suggest that vendors in the no-risk group might maintain their high compliance rate even if no inspections were conducted during the intervention period. However, vendors in the low-risk group did not maintain their high compliance rate in the post-intervention period if the majority of these vendors did not receive any inspections during the intervention period. Vendors in the moderate- and high-risk groups could increase their compliance rate if more inspections were conducted in a given year (2.2 for vendors in the moderate-risk and 3.8 for vendors in the high-risk groups). The compliance rate increased in the other 33 PHUs from the pre- to the post-intervention period. However, the magnitude of increase from the pre- to the post-intervention period was much larger among the three pilot PHUs [7.2%, i.e., $(90.5\% - 84.4\%) / 84.4\%$] than that of the other 33 PHUs [0.5%, i.e., $(87.2\% - 86.8\%) / 86.8\%$].

In summary, the risk-based enforcement model worked for vendors in the no-risk, moderate risk, and high-risk groups, but not in the low-risk group. The compliance rate in all risk groups of the three pilot PHUs increased from the pre-intervention period to the post-intervention period, despite the fact that the compliance rate declined in vendors in the low risk group. Although the compliance rate increased in the pilot PHUs and the other 33 PHUs, the magnitude of the increase was much larger in the three pilot PHUs compared to that in the other 33 PHUs.

Table 10: Compliance with Youth Access Restriction: Three Pilot PHUs vs Other 33 PHUs^a

	Pre-intervention	During the intervention	Post-intervention
PHU	No./total no. vendors (%)		
3 pilot PHUs			
No-risk	29/31 (93.5)	6/7 (85.7)	22/22 (100)
Low-risk	344/357 (96.4)	56/62 (90.3)	249/275 (90.5)***^b
Moderate-risk	273/353 (77.3)*^c ***^d	187/216 (86.6)	184/209 (88.0)**^b
High-risk	114/159 (71.7)*^c ***^d	111/119 (93.3)***^b	106/114 (93.0)***^b
All risk groups	760/900 (84.4)	360/404 (89.1)***^b	561/620 (90.5)**^b
Other 33 PHUs	10676/12302 (86.8)***^{d,e,f} *^g	5660/6648 (85.1)***^b *^f	6430/7376 (87.2)***^b *^g

* p<0.05; ** p<0.01; ***p<0.001; NS, not significant.

^a Analysis for the compliance rate was restricted to inspections conducted by sending a test shopper under 19 years of age and vendors receiving inspections in both the pre- and post-intervention periods.

^b Comparing to the pre-intervention period in the same risk group.

^c Comparing to the no-risk group in the same intervention period.

^d Comparing to the low-risk group in the same intervention period.

^e Comparing to the moderate-risk group in the same intervention period.

^f Comparing to the high risk group in the same intervention period.

^g Comparing to all risk groups in the three pilot PHUs in the same intervention period.

Logistic Regression Analysis of Compliance

Apart from risk categorization, other factors may affect compliance with the youth access restriction, such as type of vendor, test shoppers' age and gender, previous charges and warnings issued, and the secular trend. A logistic regression analysis taking into account repeated measures was applied to control for these other factors. In the following sections, adjusted logistic regression results are reported.

In PHU A, in the pre-intervention period, there was no difference in compliance in vendors in the no-risk group; the compliance was higher in vendors in the low-risk group, but lower in vendors in the moderate- and high-risk groups, compared to vendors in the other 33 PHUs. In the post-intervention period, there was no difference in compliance in vendors in the low-, moderate-, and high risk groups, compared to vendors in the other 33 PHUs, except that the compliance was much higher in vendors in the no-risk group of PHU A compared to vendors in the other 33 PHUs. There was no difference in compliance between PHU A (all risk groups combined) and the other 33 PHUs in the pre- and post-intervention periods. When comparing compliance in the post-intervention period to the pre-intervention period, there was no difference in compliance in

vendors in the moderate- and high risk groups, and all risk groups combined, but compliance was significantly lower in the low-risk group (adjusted OR=0.03, $p<0.0001$) of PHU A (Table 11).

In PHU B, in the pre-intervention period, there was no difference in compliance in vendors in the low-risk group, but the compliance was significantly lower in vendors in the no-, moderate- and high-risk groups, compared to vendors in the other 33 PHUs. In the post-intervention period, there was no difference in compliance in vendors in the low- and moderate- risk groups, but compliance was much higher in vendors in the no-risk group and lower in vendors in the high-risk group, compared to vendors in the other 33 PHUs. Compliance in the pre-intervention period was lower in all risk groups of PHU B compared to the other 33 PHUs, but there was no difference in compliance in the post-intervention period between all risk groups of PHU B and the other 33 PHUs. When comparing compliance in the post-intervention period to the pre-intervention period, there was no difference in compliance in vendors in the moderate- and high risk groups, but compliance decreased significantly in vendors in the low risk group of PHU B. There was no significant change in compliance from the pre- to the post-intervention period in all risk groups in PHU B (Table 11).

In PHU C, in the pre-intervention period, there was no difference in compliance in vendors in the no-risk, low-risk, and moderate-risk groups, but compliance was significantly lower in vendors in the high-risk group, compared to vendors in the other 33 PHUs. In the post-intervention period, compliance was significantly higher in vendors in the no-, low- and high-risk groups, compared to vendors in the other 33 PHUs; there was no difference in compliance in vendors in the moderate risk group of PHU C compared to the other 33 PHUs. There was no difference in compliance in all risk groups of PHU C in the pre-intervention period but higher in the post-intervention period, compared to the other 33 PHUs. When comparing compliance in the post-intervention period to the pre-intervention period, there was no difference in compliance in vendors in the low- and moderate-risk groups, but compliance increased significantly in vendors in the high risk group of PHU C. Compliance increased significantly from the pre- to the post-intervention period in all risk groups combined in PHU C (Table 11).

In all three pilot PHUs, in the pre-intervention period, compliance was lower in vendors in the no-, moderate-, and high-risk groups, but higher in vendors in the low-risk group, compared to vendors in the other 33 PHUs. In the post-intervention period, there was no difference in compliance for vendors in the low-, moderate, and high-risk groups in the three pilot PHUs, compared to the other 33 PHUs, except for vendors in the no-risk group (much higher).

Compliance in all risk groups in the three pilot PHUs was lower in the pre-intervention period but higher in the post-intervention period, compared to the other 33 PHUs. Compared to the pre-intervention period, compliance in vendors in the three pilot PHUs was higher (OR=2.83, $p<0.0001$) in the post-intervention period (Table 11).

In the other 33 PHUs, compliance increased in the post-intervention period compared to the pre-intervention period (OR=1.28, $p<0.0001$). The number of inspections during the corresponding intervention period was associated with compliance in the post-intervention period. Compared to vendors who did not receive inspections during the intervention period, those receiving 2 to 4 inspections increased their compliance (OR=1.28, 1.75, and 2.47, respectively, $p<0.05$), but those receiving only 1 or 5 or more inspections did not increase their compliance significantly in the post-intervention period. Compared to vendors who received 1 inspection during the intervention period, those receiving 2 to 5 inspections significantly increased their compliance (OR=1.48, 2.02, 2.85, and 1.77, respectively, $p<0.05$), while the highest compliance was found in vendors receiving 4 inspections. Compared to vendors receiving 2 inspections during the intervention period, those receiving 0-1 inspection had significantly lower compliance (OR=0.78 and 0.68, respectively, $p<0.05$), but those receiving 3 to 4 inspections had significantly higher compliance (OR=1.38 and 1.94, $p<0.01$), while those receiving 5 or more inspections did not have higher compliance (Table 11).

Table 11: Logistic Regression Analysis of Compliance, Comparison Between 3 Pilot PHUs and Other 33 PHUs^a

PHU	Group	Model	Pre-intervention ^b	Post-intervention ^b	Post- vs. pre-intervention ^c
			AOR (95% CI) ^d	AOR (95% CI) ^e	AOR (95% CI) ^f
PHU A	No-risk	1	0.80 (0.21-3.01)	Very large OR****	-----
	Low-risk		3.78 (1.70-8.41)**	0.65 (0.31-1.38)	0.03 (0.01-0.13)****
	Moderate-risk		0.67 (0.47-0.96)*	1.20 (0.51-2.80)	2.15 (0.48-9.74)
	High-risk		0.56 (0.36-0.88)*	3.00 (0.40-22.39)	0.35 (0.04-3.02)
	All risk groups	2	0.97 (0.71-1.33)	1.03 (0.52-2.01)	0.89 (0.33-2.37)
PHU B	No-risk	1	0.42 (0.35-0.50)****	Very large OR****	-----
	Low-risk		1.40 (0.90-2.19)	0.98 (0.42-2.28)	0.12 (0.05-0.34)****
	Moderate-risk		0.54 (0.43-0.69)****	0.67 (0.38-1.19)	0.81 (0.42-1.57)
	High-risk		0.34 (0.23-0.51)****	0.32 (0.11-0.98)*	0.94 (0.27-3.30)
	All risk groups	2	0.62 (0.51-0.75)****	0.72 (0.46-1.12)	0.71 (0.43-1.17)
PHU C	No-risk	1	1.41 (0.18-11.02)	Very large OR****	-----
	Low-risk		1.84 (0.83-4.06)	2.30 (1.24-4.27)**	1.32 (0.67-3.55)
	Moderate-risk		1.04 (0.48-2.24)	2.43 (0.93-6.39)	3.13 (0.96-10.23)
	High-risk		0.33 (0.21-0.50)****	2.90 (1.12-7.54)*	13.96 (4.93-39.50)****
	All risk groups	2	0.77 (0.55-1.78)	2.45 (1.56-3.84)****	3.90 (2.25-6.76)****

3 pilot PHUs	No-risk	1	0.57 (0.38-0.86)**	Very large OR****	-----
	Low-risk		2.04 (1.39-3.00)***	1.37 (0.92-2.04)	1.06 (0.64-1.75)
	Moderate-risk		0.61 (0.50-0.74)****	1.12 (0.73-1.73)	2.69 (1.75-4.13)****
	High-risk		0.38 (0.29-0.50)****	1.79 (0.88-3.65)	6.71 (3.18-14.16)****
	All risk groups	2	0.74 (0.63-0.87)***	1.37 (1.03-1.83)*	2.83 (2.13-3.75)****
Other 33 PHUs	All	1			1.28 (1.18-1.39)****
	# inspections during the intervention				
	0	2	-----	Referent	-----
	1		-----	0.86 (0.67-1.11)	-----
	2		-----	1.28 (1.01-1.62)*	-----
	3		-----	1.75 (1.34-2.30)****	-----
	4		-----	2.47 (1.70-3.59)****	-----
	5+		-----	1.36 (0.82-2.24)	-----
	1	3	-----	Referent	-----
	0			1.16 (0.90-1.48)	-----
	2			1.48 (1.26-1.73)****	-----
	3			2.02 (1.64-2.49)****	-----
	4			2.85 (2.05-3.96)****	-----
	5+			1.77 (1.02-3.06)*	-----
	2	4	-----	Referent	-----
	0		-----	0.78 (0.62-0.99)*	-----
	1		-----	0.68 (0.58-0.80)****	-----
	3		-----	1.38 (1.14-1.67)**	-----
	4		-----	1.94 (1.42-2.67)****	-----
	5+		-----	1.21 (0.70-2.09)	-----

* p<0.05; ** p<0.01; *** p<0.001; **** p<0.0001.

AOR: adjusted odds ratio.

CI: confidence interval.

^a Analysis for compliance rate was restricted to inspections conducted by sending a test shopper under 19 years of age and vendors receiving inspections in both the pre- and post-intervention periods.

^b In the pre- and post-intervention periods, the referent group was the other 33 PHUs, except for the analysis by the number of inspections during the intervention period.

^c When comparing the pre- to the post-intervention period, the referent group was the pre-intervention period for the same risk group or same PHU.

^d Adjusted for test shopper's age and gender, and vendor's type.

^e Adjusted for test shopper's age and gender, vendor's type, and previous charges and warnings.

^f Adjusted for test shopper's age and gender.

Discussion

A risk categorization model was applied to youth access to tobacco enforcement in three Ontario public health units over the course of a 12-month period. The purpose of the model was to maintain and/or to improve compliance with the youth access restriction, and to raise efficiency by reducing the number of inspections in vendors in the no-risk and low-risk groups, increasing the number of inspections in vendors in the high-risk group, and remaining the same number of inspections in vendors in the moderate-risk group.

Overall, the risk categorization model worked on average in the three pilot PHUs. The average number of inspections per vendor per year was 2.09 in the pre-intervention period, 1.62 during the intervention period, and 2.42 in the post-intervention period among all risk groups in the three pilot PHUs. During the intervention period, the average number of inspections was 0.35, 0.33, 2.23 and 3.81 for vendors in the no-, low-, moderate-, and high-risk groups of the three pilot PHUs, respectively, which was close to the planned number of inspections (0, 0-1, 2, and 4-5 for the four risk groups, respectively). In the other 33 PHUs, the average number of inspections was 1.99, 1.95, and 2.23 in the pre-intervention, intervention, and post-intervention periods, respectively. The average number of inspections during the intervention period in the three pilot PHUs was smaller compared to the pre- and post-intervention period in the three pilot PHUs, and also was smaller compared to that of the intervention period in the other 33 PHUs. The compliance rate did not change in vendors in the no- and low-risk groups, but increased significantly in vendors in the moderate- (OR=2.69, $p<0.0001$) and high-risk (OR=6.71, $p<0.0001$) groups from the pre- to the post-intervention period in the three pilot PHUs. Compared to the other 33 PHUs, compliance was lower in the pre-intervention period (OR=0.74, $p<0.001$), but higher in the post-intervention period (OR=1.37, $p<0.05$) in all risk groups in the three pilot PHUs. Compliance from the pre- to the post-intervention period increased in the other 33 PHUs (OR=1.28, $p<0.0001$), but the increase was much larger in the three pilot PHUs (OR=2.83, $p<0.0001$). These findings indicate that the risk categorization model was working, with overall compliance (i.e., in all risk groups) increased from 84% in the pre-intervention period to 91% in the post-intervention period, while controlling for other potential confounding factors and taking into account the secular trend.

Because the three pilot PHUs were not randomly selected from all PHUs, they may not be the representative sample of all PHUs. There were some important variations among the three pilot PHUs. If other PHUs were more similar to PHUs A and B, we should be able to save some

resources in inspections (205 and 39 fewer inspections per year in the two PHUs were saved during the intervention period, compared to the pre-intervention period). However, the compliance rate significantly decreased from the pre- to the post-intervention period in the low-risk group of the two PHUs (from 94% to 79% in PHU A and from 100% to 89% in PHU B). Vendors in the low-risk group received no intervention visits in PHU A, but 1.66 intervention visits in PHU B, indicating that no intervention visits (inspections) in PHU A and close to 2 intervention visits (inspections) in PHU B were not sufficient to maintain the compliance rate in vendors in the low risk group in these two PHUs. In PHU B, vendors in the moderate- and high-risk groups received 2.71 and 4.85 inspections on average during the intervention period, respectively, but the compliance rate did not increase significantly from the pre- to the post-intervention period (from 76% to 84% in the moderate-risk group and from 65% to 67% in the high-risk group). Compared to the pre-intervention period, all risk groups together in PHUs A and B did not increase their compliance in the post-intervention period, while the other 33 PHUs significantly increased their compliance from the pre- to the post-intervention period. Thus, broad implementation of the risk-based enforcement should be accompanied by continued study.

Strong support for risk-based enforcement came mainly from findings in PHU C. During the intervention period, the number of inspections was 0, 0, 2 and 4 for the four risk groups, same as the planned number of inspections in PHU C. For vendors in the no- and low-risk groups in PHU C, not having intervention visits during the intervention period did not decrease their compliance rate in the post-intervention period. For vendors in the moderate-risk group, 2 inspections per vendor per year maintained the compliance rate. For vendors in the high-risk group, 4 inspections per vendor per year significantly increased the compliance rate (from 76% in the pre- to 95% in the post-intervention period). When all risk groups were considered together in PHU C, the overall compliance rate increased significantly from 89% in the pre-intervention period to 95% in the post-intervention period. Findings in PHU C indicate that the risk categorization model worked. However, more inspections would be needed during the intervention period compared to the pre-intervention period (81 more inspections in PHU C).

Given that only a small proportion of vendors were classified in the no-risk group, and the planned number of inspections in the no- and low-risk groups in PHUs A and C was the same (zero inspection), we suggest that vendors should be classified into three groups: low-, moderate- and high-risk, i.e., get rid of the no-risk group.

Inconsistent findings were found for the number of inspections and compliance. For vendors in the low-risk group, no inspections were conducted in PHU A during the intervention period, and the compliance rate declined from 94% in the pre-intervention period to 79% in the post-intervention period; in PHU B, close to 2 (1.66) inspections were conducted in low-risk vendors during the intervention period, but the compliance rate declined significantly from 100% in the pre-intervention period to 89% in the post-intervention period; in PHU C, no inspection was conducted for vendors in the low-risk group and the compliance rate stayed the same in the pre- (96%) and the post-intervention (94%) periods. Thus, no inspections might or might not maintain the compliance rate for vendors in the low-risk group. As a caution, we would suggest that at least one inspection should be conducted in vendors in the low-risk group. For vendors in the moderate-risk group, the compliance rate increased significantly from 71% in the pre-intervention period to 86% in the post-intervention period in PHU A (receiving 1.87 inspections during the intervention period), but the increase was not significant in the adjusted analysis (likely due to small sample size, $n=59$ vendors). The compliance rate was 76% in the pre-intervention period and 84% in the post-intervention period for moderate-risk vendors in PHU B (receiving 2.71 intervention visits during the intervention period), but the increase was not significant in both the crude and adjusted analyses. Vendors in the moderate risk group in PHU C received 2.04 inspections during the intervention period and their compliance rate did not change significantly (90% in the pre-intervention period and 94% in the post-intervention period). Vendors in the moderate-risk group in all three pilot PHUs received 1.9-2.7 inspections during the intervention period and the compliance rate increased significantly from 77% in the pre-intervention period to 88% in the post-intervention period, indicating that 2-3 inspections may be needed to maintain or increase the compliance rate for vendors in the moderate-risk group. For vendors in the high risk group, receiving 2.0 inspections per vendor per year in PHU A increased the compliance rate from 66% in the pre-intervention period to 94% in the post-intervention period; receiving 4.9 inspections in PHU B did not increase the compliance rate (65% in the pre-intervention period and 67% in the post-intervention period); and receiving 4.1 inspections in PHU C increased the compliance rate from 76% in the pre-intervention period to 95% in the post-intervention period. Findings for vendors in the high-risk group indicate that 4-5 inspections may be needed to improve compliance.

Findings about the association between the number of inspections during the intervention period and compliance in the post-intervention period in the other 33 PHUs indicate that 0-1 inspection was significantly associated with lower compliance compared to 2 inspections; 3-4 inspections was associated with higher compliance compared to 2 inspections. If risk

categorization information is not available, 2 inspections per vendor per year should be conducted. To increase compliance, 3-4 inspections per vendor per year would be needed.

During the process of data cleaning, it was found that vendors kept the same vendor IDs when the ownership was changed. There might be some mismatched data due to this practice. Since vendor compliance behaviors may change with a new owner, we suggest that a new vendor ID should be assigned to the new owner.

In the analysis, the compliance rate was calculated based on no violation of the youth access restriction in a given year rather than being based on the last inspection in a given year. The last inspection approach may result in biased findings if a PHU keeps inspecting until the vendor complies with the law (purposely increase the compliance rate).

The three pilot PHUs were not randomly selected from all PHUs in Ontario. They may not be a representative sample of all PHUs. Adherence to the protocol was imperfect. For example, vendors in the high risk group in PHU A received 2 fewer intervention visits than planned 4 intervention visits. Sample sizes in PHUs A and B were small, making detection of significant changes challenging.

In conclusion, the risk categorization model may save resources in inspections and improve compliance levels in all PHUs in Ontario. However, broad implementation of risk-based enforcement should be accompanied by continued study.

Appendix

Youth Access Enforcement Prior to the Pilot Project

Although there is a standard protocol for youth access enforcement across the province, there are differences in how each of the three participating public health units conducted enforcement activities prior to the pilot project. Table A-12 summarizes these enforcement practices to provide context for the findings.

Table A-12: Public Health Unit Enforcement Practices Prior to the Pilot Project

	PHU A	PHU B	PHU C
Number of annual youth access compliance checks or enforcement checks per tobacco vendor	1	2	1
Number of routine inspections to assess signage, display and promotion compliance, and to provide education	1-2	1	1
Test shopper provides photo ID when asked by clerk	Yes	Yes	No
Number of 'Who is 25?' compliance checks	2	1	N/A
Other	<ul style="list-style-type: none"> Quarterly tobacco vendor newsletters Written notice regarding non-compliance during enforcement and 'Who is 25?' checks Violations listed in local newspaper for enforcement and 'Who is 25?' checks 		
	Letter to all tobacco vendors to inform that a round of compliance checks/enforcement checks has been completed and includes the overall compliance rate.		

Overview of the Risk Categorization Model for Youth Access to Tobacco Pilot Project

A Risk Categorization Model is a management tool that enables consistent inspection planning and efficient resource allocation by identifying premises that are at higher risk for non-compliance. A risk assessment questionnaire is used to score premises by a list of risk factors. The resulting total risk score is used to group premises into risk categories. This is the enforcement model that is currently applied to food inspections conducted in Ontario.²

Risk Assessment Questionnaire

A questionnaire was developed for the purpose of categorizing tobacco vendors according to non-compliance with the youth access restriction in the *Smoke-Free Ontario Act*. Questions were drafted using information gathered through a literature review, a public health unit risk assessment web-survey, and a risk-factor analysis and feedback from the participating public health units. Consideration was also given to the information contained in the Ontario Ministry of Health and Long-Term Care's *Tobacco Inspection System* (TIS) when drafting questions to minimize the need for manual scoring of tobacco vendors.

Seven core questions were applied to tobacco vendor in all three participating public health units and included the following risk factors: enforcement history (four questions), tobacco vendor density, corporate versus independent ownership, and proximity to schools. Up to three questions could be added by each participating public health unit to meet their local risk assessment needs. The elective questions selected by the participating public health units included the following risk factors: history of complaints (PHU A, PHU C), history of failing to properly calculate age during a 'Who is 25?' compliance check (PHU A), seasonal operation (PHU B), and tobacco vendors barring entry to persons less than 19 years of age (PHU B). Table A-13 resents the risk assessment questionnaire and the response values. Once the questionnaire was finalized, each of the participating public health units manually completed the questionnaire for every tobacco vendor in their region using Excel. The scoring could not be automated in TIS since the TIS Risk Module was not fully developed at that time.

Weights were assigned to each question in the risk assessment questionnaire to calculate the risk score for each tobacco vendor. The magnitude of each question weight was determined individually by the participating public health units, yet the sum of the question weights for each public health unit equalled 100. This flexible approach to risk categorization allowed each public health unit to customize how risk for non-compliance with the youth access restriction was defined at the local level in order to account for contextual differences between public health units. Question weighting for each public health unit is summarized in Table A-14.

Table A-13: Risk Assessment Questionnaire and Response Values

Label	Question	Response Values
Core	Has this tobacco vendor ever sold tobacco to someone under the age of 19 years in the past 5 years (regardless of asking for proper ID)?	0 = No 1 = Yes
Core	Has this tobacco vendor ever neglected to ask someone who appears under the age of 25 years (i.e., test shopper or Who is 25? Shopper) for ID in the past 5 years?	0 = No 1 = Yes
Core	What action has been taken at this tobacco vendor as a result of non-compliance with the youth access restriction in the past 5 years?	0 = None 1 = Warning(s) 2 = 1 charge 3 = 2 charges 4 = 3+ charges 5 = Automatic Prohibition
Core	What action has been taken at this tobacco vendor as a result of non-compliance with other SFOA-related restrictions in the past 5 years?	0 = None 1 = Warning(s) 2 = 1 charge 3 = 2 charges 4 = 3+ charges
Core	Is this tobacco vendor located in an area densely populated with other tobacco vendors?	0 = 0 vendors/block 1 = 1-2 vendors/block 2 = 3-4 vendors/block 3 = 5-6 vendors/block 4 = 7-8 vendors/block 5 = 9+ vendors/block
Core	Is this tobacco vendor independently owned (e.g. Mom & Pop shop)?	0 = No 1 = Yes
Core	Is this tobacco vendor located within a 1 km radius of a school?	0 = No 1 = Yes
Elective	Has any complaint been received?	0 = No 1 = Yes
Elective	Does this tobacco vendor prohibit entry to persons less than 19 years?	0 = No 1 = Yes
Elective	Has this tobacco vendor failed to correctly calculate the age of the purchaser during a 'Who is 25?' compliance check in the past 5 years?	0 = No 1 = Yes
Elective	Is this tobacco vendor operated seasonally?	0 = No 1 = Yes

Table A-14: Risk Assessment Questionnaire and Question Weighting, by Public Health Unit Site

Label	Question	PHU A	PHUB	PHU C
Core	Has this tobacco vendor ever sold tobacco to someone under the age of 19 years in the past 5 years (regardless of asking for proper ID)?	25	30	25
Core	Has this tobacco vendor ever neglected to ask someone who appears under the age of 25 years (i.e., test shopper or Who is 25? Shopper) for ID in the past 5 years?	15	10	20
Core	What action has been taken at this tobacco vendor as a result of non-compliance with the youth access restriction in the past 5 years?	15	15	15
Core	What action has been taken at this tobacco vendor as a result of non-compliance with other SFOA-related restrictions in the past 5 years?	15	11	5
Core	Is this tobacco vendor located in an area densely populated with other tobacco vendors?	5	8	5
Core	Is this tobacco vendor independently owned (e.g. Mom & Pop shop)?	5	13	5
Core	Is this tobacco vendor located within a 1 km radius of a school?	5	6	10
Elective	Has any complaint been received?	5	-	15
Elective	Does this tobacco vendor prohibit entry to persons less than 19 years?	-	4	-
Elective	Has this tobacco vendor failed to correctly calculate the age of the purchaser during a 'Who is 25?' compliance check in the past 5 years?	10	-	-
Elective	Is this tobacco vendor operated seasonally?	-	3	-
Sum of weights		100	100	100

References

- ¹ Dubray J, Kirst M, Yates E, Schwartz R. *Evaluation of the Risk-Based Enforcement Pilot: A Risk Categorization Model for Youth Access to Tobacco, Interim Report*. Toronto: Ontario Tobacco Research Unit (Released as an OTRU Special Report: June 2013). (http://otru.org/wp-content/uploads/2013/06/special_enforcement.pdf; accessed October 20, 2013).
- ² Federal/Provincial/Territorial Committee on Food Safety Policy. *Risk Categorization Model for Food Retail/Food Service Establishments* - 2nd Edition, 2007 (http://www.hc-sc.gc.ca/ahc-asc/alt_formats/hpfb-dgpsa/pdf/pubs/risk_categorization-categorisation_risques-revised_revisee-eng.pdf; accessed October 20, 2013).
- ³ Ontario Ministry of Health Promotion. *Protocol for Determination of Tobacco Vendor Compliance*. 2006.
- ⁴ Program Training and Consultation Centre. Overview of enhancements made to Ontario's tobacco Inspection System (TIS) for 2012/2013. Toronto, Ontario (<https://www.ptcc-cfc.on.ca/cms/One.aspx?portalId=97833&pageId=290531>; accessed December 10, 2013).
- ⁵ Fagerland MW, Lydersen S, Laake P. The McNemar test for binary matched-pairs data: mid-p and asymptotic are better than exact conditional. *BMC Med Res Methodol* 2013;doi: 10.1186/471-2288-13-91.
- ⁶ Williamson DS, Bangdiwala SI, Marshall SW, Waller AE. Repeated measures analysis of binary outcomes: applications to injury research. *Accid Anal Prev* 1996;28:571-9.