**The impact of graphic warning labels on disparities in smoking analysis plan**

Bukola Usidame, James. F. Thrasher, Jidong Huang, Nancy L. Fleischer

**Research aim:**

To assess the differential impact of Canada’s graphic warning labels in 2000 and warning label size increase in 2012 on smoking outcomes by sex, income, and education.

**Datasets**

Canada

*National Population Health Survey (NPHS) (1994-1999):* The NPHS collects information related to the health of the Canadian population and related socio-demographic information. It is composed of three components: the Households, the Health Institutions, and the North components. The Household component started in 1994-1995 and is conducted every two years. The first three cycles (1994-1995, 1996-1997 and 1998-1999) were both cross-sectional and longitudinal.

*Canadian Tobacco Use Monitoring Survey (CTUMS) (1999-2002):* The Canadian Tobacco Use Monitoring Survey (CTUMS), conducted annually and designed to track changes in smoking status in Canada's at-risk populations, has collected information on tobacco use and related issues since 1999.

*Canadian Community Health Survey (CCHS) (2010-2018):* The CCHS is a cross-sectional survey that collects information related to health status, health care utilization and health determinants for the Canadian population. The CCHS uses a multistage stratified cluster design, where the dwelling is the final sampling unit.

USA

*National Health Interview Survey (NHIS) (1999-2002; 2010-2018):* The NHIS is a cross-sectional household interview survey. Sampling and interviewing are continuous throughout each year since 1957. The main objective of the NHIS is to monitor the health of the United States population through the collection and analysis of data on a broad range of health topics. The sampling plan follows an area probability design that permits the representative sampling of households and non-institutional group quarters (e.g., college dormitories).

The final dataset will combine the 1999-2002 CTUMS and 1999-2002 NHIS datasets for the first set of analyses, and the 2010-2018 CCHS and 2010-2018 NHIS datasets for the second set of analyses. Considering we have a single probability sample of ‘USA-Canada’, we will combine both data sets using their strata, PSUs, and weights. All models will account for clustering with robust standard errors, and adjust for age, age-squared, sex, marital status, annual household income in the past year, and education. More details on the survey sampling designs and variables are described in Table 1.

**Variables**

Outcome variables

The outcome variables were selected from the tobacco use questions that were consistent across the years and with previous studies1,2. Variables are focused on current smoking status, average number of cigarettes per day and quit attempts. Details on the outcome variables are included in Table 1.

* 1. Current smoking status: A current/former/never smoker variable will be constructed from the 100 lifetime cigarette question and whether participants currently smoke every day, some days, or not at all. We will consider further disaggregating current smoking into everyday and someday smokers.

Average number of cigarettes smoked per day among current smokers

* 1. Quit attempts among current smokers: In the past 12 months, did you stop smoking for at least 24 hours because you were trying to quit?

Exposure/ treatment variables

Indicator for the exposure group where Canada=1 and USA=0; Canada (treatment country) and USA (control country)

Third-difference variables

1. Sex: (Male/ Female)
2. Annual household income in the past 12 months: (<$50K, $50K-$100K, or $100K+)
3. Education: (<high school, high school diploma or GED, some college, and college or graduate degree )

Control variables

1. Age: Continuous age and Age squared (to address a possible non-linear relationship with the variable)
2. Sex: (Male/ Female)
3. Education: (<high school, high school diploma or GED, some college, and college or graduate degree )
4. Annual household income in the past 12 months: (<$50K, $50K-$100K, or $100K+)
5. Year: A time variable representing all the years included in this study

Pre and Post policy variables

Indicator variables for the period(s) following the policy implementation. Since there are two-time policy periods here, there will be two binary variables for each treatment year.

\*Pre 2000 policy implementation (NPHS&CTUMS/ NHIS): 1994-2000= 0 and 2001-2011= 1

*\*This variable will be used for sensitivity analyses*

Post-2000 policy implementation (CTUMS/NHIS): 1999-2000= 0 and 2001-2011= 1

Post-2012 policy implementation (CCHS/NHIS): 2000-2012= 0 and 2013-2018= 1

*Inclusion/exclusion criteria:*

Data will be focused on adults 25+ to allow for completion of education.

**Analyses:**

We will conduct a series of difference-in-difference (DD) regression models to assess the impact of the 2000 and 2012 regulations on smoking prevalence and cessation. The DD approach will be used to estimate changes in smoking prevalence in Canada relative to the US, controlling for time-invariant differences that may be related to smoking prevalence across both countries. Then, a difference-in-differences-in-differences (DDD) model will be used to estimate the variation in the effect of the policy implementation by sex, education, and income. We will conduct series of sensitivity analyses by including the NPHS/NHIS data to assess the robustness of the results.

The DD analysis assumes that *“without treatment, outcomes would need to increase or decrease at the same rate in both groups”*3(pg 99). Gertler et al. (2011) suggest sampling at least two serial data years pre-intervention and at least two data years post-intervention as a validity check for trend equality. If the pre-intervention observations move in tandem, we can assume that they would have continued post-intervention. Hence, the analyses will use all the available years which are two or more years, pre and post-intervention, with an exception for CTUMS. CTUMS begins 1999, so there is only one data year pre-intervention for Canada.

Modeling and Results

Analyses include prevalence of selected characteristics of study sample and results for each outcome variable using the four models outlined below; results can be combined into one table.

*Study sample*: Selected characteristics of study sample using all the variables listed in the variable section

*Current smoking status* : Model **1-4**- Multinomial regression (current smoker/ former smoker/ never smoker)

: Model **1-4**- Multinomial regression (everyday smoker/ someday smoker/ non-current smoker) ‘*non-current includes former/never smokers’*

*Smoking frequency*: Model **1-4**- Linear regression (average number of cigarettes per day)

*Quit attempts*: Model **1-4**- Logistic regression (quit attempts)

*Model 1 (DD*)

Outcome (Change in smoking estimate) = βo + β1 Canada/USA (0/1) + β2 Post2000 (0/1) + β3 Canada/USA\* Post2000 + β4 Age + β5 Age^2 +β6 Sex + β7 Marital status + β8 Income + β9 Education + β10 ln (ExciseTax/PriceIndex) + β11 i.year + Ɛ

*Model 2 (Differential impact on sex-DDD)*

Outcome (Change in smoking estimate) = βo + β1 Canada/USA + β2 Post2000 + β3 Canada/USA\* Post2000 + β4 Sex + β5 Canada/USA\*Sex + β6 Post2000\*Sex + β6 Canada/USA\*Post2000\*Sex + β8 Age + β9 Age^2 + β10 Income + β11 Marital status + β12 Education + β13 ln (ExciseTax/PriceIndex) + β14 i.year + Ɛ

*Model 3 (Differential impact on Income-DDD)*

Outcome (Change in smoking estimate) = βo + β1 Canada/USA + β2 Post2000 + β3 Canada/USA\* Post2000 + β4 Income + β5 Canada/USA\*Income + β6 Post2000\*Income + β6 Canada/USA\*Post2000\*Income + β8 Age + β9 Age^2 +β10 Sex + β11 Marital status + β12 Education + β13 ln (ExciseTax/PriceIndex) + β14 i.year + Ɛ

*Model 4 (Differential impact on education-DDD)*

Outcome (Change in smoking estimate) = βo + β1 Canada/USA + β2 Post2000 + β3 Canada/USA\* Post2000 + β4 Education + β5 Canada/USA\*Education + β6 Post2000\*Education + β6 Canada/USA\*Post2000\*Education + β8 Age + β9 Age^2 + β10 Sex + β11 Marital status + β12 Income + β13 ln (ExciseTax/PriceIndex) + β14 i.year + Ɛ

All four models will be replicated for each outcome variable and the post-2012 policy implementation: current smoking status (current smokers/former smokers/never smokers; everyday/someday smokers as a subset of current smokers), average number of cigarettes per day and quit attempts.

Sensitivity analyses: We will run series of sensitivity analyses by including the NPHS/NHIS data\* (Post-2000 policy implementation [NPHS&CTUMS/ NHIS]: 1994-2000= 0 and 2001-2011= 1) to assess the robustness of the results. In addition, we will not construct the 100-lifetime cigarette question used to screen participants into every day and some day smoker using CTUMS and NHIS, as done in the main analyses. Excluding the 100-lifetime cigarette question will ensure consistency in the sensitivity analyses.

**References**

1. Huang J, Chaloupka FJ, Fong GT. Cigarette graphic warning labels and smoking prevalence in Canada: a critical examination and reformulation of the FDA regulatory impact analysis. *Tobacco Control*2014;**23:**i7-i12.
2. Hammond D, Fong GT, McDonald PW*, et al.* Impact of the graphic Canadian warning labels on adult smoking behaviour. *Tobacco Control*2003;**12:**391-395
3. Gertler, P, Martinez S, Premand, P, et al., 2011. Impact evaluation in practice. Washington, DC: World Bank

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| Table 1. Comparison of CTUMS (1999-2012), CCHS (2010-2018), and NHIS (1999-2018) Surveys | | | | |  |
| **Outcome variables** | | | | |  |
|  | Canadian Tobacco Use Monitoring Survey (CTUMS): 1999-2012 | | Canadian Community Health Survey (CCHS):2010-2018 | National Health Interview Survey (NHIS): 1999-2018 | National Population Health Survey (NPHS): 1994-1999 |
| Survey type | Cross-sectional | | Cross-sectional | Cross-sectional |  |
| Target population | All persons 15 years of age and over living in Canada with the following two exceptions:  1) residents of the Yukon, Northwest Territories and Nunavut, and 2) full-time residents of institutions. | | 12 years and older who are living in private dwellings in the ten provinces and three territories. It covers approximately 98% of the Canadian population aged 12 and older. | The NHIS covers the civilian noninstitutionalized population residing in the United States at the time of the interview. Examples of persons excluded are patients in long-term care facilities; persons on active duty with the Armed Forces (though their dependents are included); persons incarcerated in the prison system; and U.S. nationals living in foreign countries | The Household component includes household residents aged 12 and older in the ten Canadian provinces excluding persons living on Indian Reserves and Crown Lands, residents of health institutions, full-time members of the Canadian Forces Bases and some remote areas in Ontario and Quebec |
| Response rate (formula) | Person Response Rate was calculated as the proportion of records of selected persons with corresponding complete roster and valid household data whose records had valid person data. | | Person Response Rate was calculated as the proportion of responses obtained for individuals from the total number of selected units that were in-scope for the survey. | Conditional response rate for the Sample Adult component was calculated by dividing the number of completed Sample Adult interviews by the total number of eligible sample adults; Unconditional or final response rate for the Sample Adult component was calculated by multiplying the conditional rate of by the final family response rate | 1994/95- 83.6% 1996/97- 92.8% 1998/99- 88.2% |
| Sampling frame | National two-stage sampling design of civilian, noninstitutionalized US population | | National three-stage sampling frames to select the sample of households: area frame, telephone numbers and a Random Digit Dialling (RDD) sampling frame. | National multistage stratified clustered sampling design of civilian, noninstitutionalized US population; Oversampled Black, Hispanic, and Asian persons | The NPHS employed a stratified two-stage sample design (clusters, dwellings) based on the Labour Force Survey (LFS) in all provinces except Québec, where another design was used. |
| Data collection method | Computer Assisted Telephone Interviewing (CATI) or Computer Assisted Personal Interviewing (CAPI) | | Computer Assisted Telephone Interviewing (CATI) or Computer Assisted Personal Interviewing (CAPI) | Computer Assisted Personal Interviewing (CAPI) | Data collection is performed using a computer-assisted interview (CAI) system. |
| **Outcome variables** | | | | |  |
| Current smoking status | Current smoker | | | |  |
| Have you smoked at least 100 cigarettes in your life **(Yes)-** *All respondents*; At the present time, do you smoke cigarettes every day, occasionally or not at all? **Every day/Occasionally -** *All respondents* | | | Have you smoked at least 100 cigarettes in your life **(Yes)-** *Sample adults 18+*; Do you NOW smoke cigarettes every day, some days or not at all? **Every day, some days-** *Sample adults 18+ who ever smoked 100 cigarettes* | At the present time do/does ... smoke cigarettes daily, occasionally or not at all? (Daily)-  *Respondents 12+* |
| Former smoker | | | |  |  |
| Have you smoked at least 100 cigarettes in your life **(Yes)-** *Sample adults 18+*; At the present time, do you smoke cigarettes every day, occasionally or not at all? **Not at all -** *Sample adults 18+ who ever smoked 100 cigarettes* | | | Have you smoked at least 100 cigarettes in your life **(Yes)-** *Sample adults 18+*; Do you NOW smoke cigarettes every day, some days or not at all? **Not at all-** *Sample adults 18+ who ever smoked 100 cigarettes* | At the present time do/does ... smoke cigarettes daily, occasionally or not at all? (Not at all) **AND** Have/has you/he/she ever smoked cigarettes at all (Yes)? -  *Respondents 12+* |
| Never smoker | | | |  |  |
| Have you smoked at least 100 cigarettes in your life **(No)-** *Sample adults 18+*; At the present time, do you smoke cigarettes every day, occasionally or not at all? **Not at all -** *Sample adults 18+ who ever smoked 100 cigarettes* | | | Have you smoked at least 100 cigarettes in your life **(No)-** *Sample adults 18+*; Do you NOW smoke cigarettes every day, some days or not at all? **Not at all-** *Sample adults 18+ who ever smoked 100 cigarettes* | At the present time do/does ... smoke cigarettes daily, occasionally or not at all? (Not at all)-  **AND** Have/has you/he/she ever smoked cigarettes at all (No)? *Respondents 12+* |
| Every day smoker | | | |  |  |
| Have you smoked at least 100 cigarettes in your life **(Yes)-** *All respondents*; At the present time, do you smoke cigarettes every day, occasionally or not at all? **Every day -** *All respondents* | | | Do you NOW smoke cigarettes every day, some days or not at all? **Every day-** *Sample adults 18+ who ever smoked 100 cigarettes* | At the present time do/does ... smoke cigarettes daily, occasionally or not at all? (Daily)-  *Respondents 12+* |
| Some day smoker | | | |  |  |
| Have you smoked at least 100 cigarettes in your life **(Yes)-** *All respondents*; At the present time, do you smoke cigarettes every day, occasionally or not at all? **Occasionally -** *All respondents* | | | Do you NOW smoke cigarettes every day, some days or not at all? **Some days-** *Sample adults 18+ who ever smoked 100 cigarettes* | At the present time do/does ... smoke cigarettes daily, occasionally or not at all? (Occasionally)-  *Respondents 12+* |
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| Average number of cigarettes per day | Thinking back over the past seven days, starting with yesterday, how many cigarettes did you smoke (Min: 0 Max: 90)?- *Current smokers* | | | On the average, how many cigarettes do you now smoke a day?- *Every day smokers*   OR   On the average, when you smoked during the PAST 30 DAYS, about how many cigarettes did you smoke a day? - *Some day smokers* | How many cigarettes do/does you/he/she smoke each day now?  *Respondents 12+ who smoke daily now* |
| Quit attempts | In the last year, how many times did you stop smoking for at least 24 hours because you were trying to quit (Min: 0 Max: 94)?- *Current smokers*  (This can be recoded into a binary variable matching NHIS and CCHS question) | In the past 12 months, did you stop smoking for at least 24 hours because you were trying to quit?- *Current smokers* | | During the past 12 months, have you stopped smoking for more than one day because you were trying to quit smoking?- *Current smokers* | At the present time do/does ... smoke cigarettes daily, occasionally or not at all? (Not at all)-  *Respondents 12+* **AND** Have/has you/he/she ever smoked cigarettes daily (Yes)? |
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| **Third-difference/ Control variables** | | | |  |  |  |  |
| Total Household Income |  |  |  |  |
| 1994-2002 | What is your best estimate of your total household income for the last 12 months before taxes and deductions? Please include income from all household members and from all sources.  Was it ... (Less than $15,000 to $120,000 or more) - *All respondents*. |  | What is your best estimate of [fill2: your total income/the total income of all family members] from all sources, before taxes, in [fill3: last calendar year? ($0-$999,995+) – *All respondents.*  Follow up questions break the income categories down. There is also a recoded variable under the Socio-demographic (FSD) section of the Family Core. | Thinking about your total household income, from which of the following sources did your  household receive any income in the past 12 months? |
| 2010-2014 |  | Can you estimate in which of the following groups your household income falls? Was the total household income in the past 12 months...? (Less than $50,000 including income loss AND $50,000 and more)- *All respondents*.  Follow up questions break the income categories down (interviewer reads to respondents- less than $5,000 to $150,000 or more) |  |
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| Education | "What is the highest grade or level of education you have ever attained?” <high school: No schooling, some elementary, completed elementary, some secondary  high school diploma or GED: Completed secondary Some college: Some community college, technical college, CEGEP or nurse’s training, completed community college, technical college, CEGEP or nurse’s training, some university or teacher’s college  College or graduate degree: completed university or teacher’s college (10) other education or training – *All respondents* | “What is the highest certificate, diploma or degree that you have completed?” <high school: Less than high school diploma or its equivalent  high school diploma or GED: High school diploma or a high school equivalency certificate, Trade Certificate or Diploma  Some college: College, cegep or other non-university certificate or diploma (other than trades certificates or diplomas, University certificate or diploma below the bachelor’s level  College or graduate degree: Bachelor’s degree (eg. B.A., B.Sc., LL.B.), University certificate, diploma or degree above the bachelor’s level – *All respondents* | What is the highest grade or level of education you have ever attained? <high school, high school diploma or GED, some college, and college or graduate degree – *All respondents* | Have/has ... graduated from high school (Yes?No)?  What is the highest level of education that ... have/has attained?  high school diploma or GED; Some college;  College or graduate degree. |