Investigating the Impact of the 2012 Canadian Graphic Health Warning Label Revisions: Findings from the ITC Canada Survey

by

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A thesis
presented to the University of Waterloo
in fulfillment of the
thesis requirement for the degree of
Doctor of Philosophy
in
Psychology

Waterloo, Ontario, Canada, 2017

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AUTHOR'S DECLARATION

I hereby declare that I am the sole author of this thesis. This is a true copy of the thesis, including any required final revisions, as accepted by my examiners.

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ABSTRACT

Background: Approximately 100 Canadians die every day from smoking-related illnesses. Health warnings labels (HWLs) on cigarette packages are a highly cost-effective strategy to inform the public on the health risks of smoking and to motivate smokers to quit. Warnings that display graphic images have been shown to be particularly effective in increasing quit intentions and cessation-related behaviours. Canada became the first country to implement graphic HWLs on cigarette packages in June 2001. The Canadian graphic HWLs were revised in 2012.

Objectives: This is the first longitudinal study to evaluate the impact of the 2012 Canadian graphic HWL revisions on: 1) Key indicators of warning label effectiveness (warning salience, and cognitive and behavioural HWL responses); 2) Affective reactions evoked by warnings; 3) Beliefs about smoking-related health statements displayed on warnings; 4) Rates of reading interior efficacy messages; 5) Levels of quit-efficacy and perceived difficulty to quit smoking; and 6) Quit intentions and cessation-related behaviours. Moderation of the impact by socioeconomic status (SES) was explored for each outcome. Mediation of the effect of HWLs on smokers' quit intentions and quit attempts through cognitive and affective reactions was also tested through a series of mediation models.

Methods: Data for this study were taken from Waves 1 to 9 (conducted between 2002 and 2014) of the ITC Canada Survey, a nationally representative longitudinal survey of smokers aged 18 years and older (n=5929). Using generalized estimating equations and segmented regression models, the overall secular trends of cognitive and behavioural outcomes were investigated to assess the impact of the 2012 graphic HWL revisions. Structural equation

modeling was used to test mediation of HWL impact on quit intentions through cognitive and affective reactions.

Results: Following the 2012 Canadian graphic HWL revisions, significantly more smokers reported to notice warnings "often" or "very often", think "a lot" about health risks of smoking and about quitting due to warnings, and avoid warnings. The HWL revisions also increased affective reactions evoked by warnings and warning believability (which were positively associated with quit intentions and quit attempts). Adding health messages to warnings significantly increased rates of correct beliefs about these health facts, and the removal of health information was shown to decrease positively trending rates in correct beliefs, and even reduce them. Although few smokers (15%) reported to read the interior efficacy messages in 2013, those who did had significantly higher levels of quit-efficacy, quit intentions, and were more likely to call the toll-free quit line. Quit-efficacy decreased and perceived difficulty to quit smoking increased following the 2012 HWL revisions, but these measures were not associated with quit attempts. Rates of calling the quit line more than doubled after the revisions (which included the addition of the toll-free quit line number on cigarette packages). Quit intentions and cessation-related behaviours did not significantly change, with the exception of rates of sustained smoking cessation, which significantly increased. Affective reactions evoked by the graphic HWLs significantly mediated the impact of HWLs on smokers' intentions to quit, but only after the warnings were revised in 2012. SES was not found to moderate the impact of the HWL revisions on any cognitive or behavioural outcome measures.

Conclusions: The 2012 HWL revisions were successful in reducing and even reversing the effects of wear-out, which were shown to be progressively diminishing the effectiveness of the Canadian graphic HWLs between 2002 and 2011. Affective reactions evoked by the graphic

HWLs were significantly and positively associated with increased cessation-related cognitions and behaviours, supporting the implementation of emotionally evocative warnings. The impact of the 2012 graphic HWL revisions was just as strong among smokers with a low income and education as it was among smokers with a high income and education.

ACKNOWLEDGEMENTS

This dissertation would not have been possible without the help and encouragement from numerous people. First, I would like to thank my supervisor, Dr. Geoffrey Fong. Geoff, I am so grateful to have worked with someone so knowledgeable and passionate about this field of work. Thank you for the time and effort you have dedicated towards my education, and for providing me with such incredible learning experiences all around the world. But most of all, thank you for being compassionate and understanding, inside and outside the realm of research. You have shown me great kindness and generosity, and for that I am very grateful.

I would also like to express my sincere appreciation to Dr. Edouard Tursan d'Espaignet. Edouard, thank you for your constant faith and confidence, and for seizing every opportunity to teach me. You always have my best interests at heart, personally and professionally. Thank you for your advice, your guidance, and your friendship.

I would like to thank my committee members, Dr. David Hammond and Dr. Richard Eibach, for their contributions throughout this research. Your feedback and advice has added considerable insight and value to this work.

To Rita Cherkewski, thank you for your help and support, administrative and otherwise. Your magical problem-solving powers never cease to amaze me.

This research would not have been possible without the financial assistance of the Canadian Institutes of Health Research Doctoral Award, as well as funding from Propel Centre for Population Health Impact.

I would like to extend a special thanks to my “ITC Family”. Pete and Gang, thank you for putting up with my never-ending statistics questions. I cannot thank you enough for your patience and your help, particularly over the past several months. To Lorraine, Janet, Mary and

Janine, thank you for always keeping a smile on my face with your friendship, humour, and most importantly, your Rice Krispies treats. To Dana, Gen, Anne, and Susan, thank you for all of your support and kindness over the past years.

I am very fortunate to have amazing friends all around the world. Seema, Amanda and Brandon, my time in Waterloo would have been much different without you. Thank you for pushing me to reach new heights, both on and off the climbing wall. To my incredible friends in Geneva (you know who you are!), thank you for *always* being there for me. Genuine friendship is a valuable thing, and I consider myself extremely lucky to have each of you in my life.

To Miguel, thank you for never letting me give up and for your unwavering encouragement. You came into my life at a period of transition and uncertainty, and after so many years moving around, I have found a home in you.

Finally, a very special thanks to my family: Bill, Annette, and Lars. Your unconditional love and support have meant the world to me. Lars, thank you for your kindness and for opening your home to me, no matter where you are in the world and at a moments notice. I feel safe in this world because of you. Mami, you have been my rock – no one understands me like you. Thank you for being a wonderful mother and an incredible friend. But most of all, I would like to thank Bill. Thank you for all of the sacrifices you have made for your family. You have always put us ahead of yourself. I cannot thank you enough for the endless encouragement, love, and support you have given me from all corners of the world.

DEDICATION

I dedicate this dissertation to my parents, to whom I attribute my passion for health and my love for traveling. These passions have navigated me to where I am today, and for that, I thank you from the bottom of my heart.

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1.0 INTRODUCTION

Tobacco use is the leading cause of preventable morbidity and mortality worldwide(1). More than 100 million people died in the 20th century due to tobacco-related diseases. This value is projected to reach 1 billion in the 21st century if current patterns of tobacco use continue(2).

The most common form of tobacco product worldwide is the cigarette. About 5.8 trillion cigarettes were smoked globally in 2014(2). This high number is concerning because tobacco smoke is extremely toxic, containing over 7000 chemicals of which at least 69 have been identified as carcinogens(3). Hundreds more have been shown to be detrimental to health and collectively affect almost all organ systems(4).

There is a substantial body of research on the health harms of tobacco smoke. Tobacco use and exposure to secondhand smoke (SHS) damages health in all stages of life, from in utero to old age. Children born to women who smoked during pregnancy are at higher risk of adverse birth outcomes, congenital disorders, cancer, respiratory disease, and sudden death(2,5). Direct smoking has been shown to cause multiple illnesses including cancer, ischemic heart disease, chronic obstructive pulmonary disease (COPD), and stroke. In fact, smoking increases risk of death from lung cancer and COPD by over 20 times(4). Smoking threatens the health of non-smokers as well; SHS exposure increases the risk of developing heart disease and lung cancer by 20-30%(6).

While the major health effects of tobacco use typically appear later in life, research has shown that smoking causes adverse effects in the short-term as well. Smoking has been linked to increased headaches, chronic coughing, asthma, anxiety, a weaker immune system, and poor mental health(4,7). Smoking also represents a substantial economic burden due to the high cost

of cigarettes and increased health care expenditures(8). Therefore, even if not immediately fatal, smoking forces individuals to live with a lower quality of life by deteriorating overall health and increasing economic stress.

Importantly, many of the health effects caused by smoking can be significantly reduced or even reversed after cessation(9). The positive health impacts of quitting range from almost immediate to long term. Life expectancy increases substantially after quitting as well. For example, a smoker who quits at about 30 years of age gains almost 10 years of life expectancy(10). Although the benefits are greater for smokers who quit earlier, there are substantial health benefits to cessation at any age(10,11). It is therefore crucial that smokers are informed that **it is never too late to quit smoking**.

Communicating the health risks of smoking (and the benefits of quitting) through evidence-based policies remains a priority in tobacco control worldwide(1). Health warning labels (HWLs) on cigarette packages represent a highly cost-effective strategy to inform the public on the health risks of smoking. Warnings that display graphic images have been shown to be particularly effective in motivating smokers to quit and discouraging non-smokers from initiating smoking. In fact, graphic HWLs have been associated with improved health knowledge and risk perception, higher motivation to quit smoking, and increased cessation behaviours(12).

International guidelines for HWLs on tobacco products have been established under Article 11 of the WHO Framework Convention on Tobacco Control (FCTC), the first international treaty devoted to public health. The FCTC calls for Parties to implement HWLs that cover at least 30% of the principal display areas(13). More detailed guidelines for the implementation of Article 11 recommend the implementation of large, clear, and periodically

rotating pictorial warnings that cover 50% or more (and no less than 30%) of the package principal display areas in the Parties' main language(s)(14).

In 2001, Canada became the first country to implement graphic HWLs on cigarette packages (accompanied by toxic emission statements and interior messages intended to increase smokers' efficacy). Studies investigating the effectiveness of Canada's graphic HWLs have found that compared to text-only warnings implemented in other countries, the Canadian warnings were associated with higher warning label salience and perceived effectiveness(15–18), increased knowledge of displayed health information(15,19), higher intentions to quit(15), and increased quit attempts and sustained quitting(20–22). However, after being in circulation for over a decade, the effectiveness of these warnings was shown to be gradually declining(23). This is consistent with basic principles of advertising and health communications, which claim that the salience of a message is greatest at initial exposure and gradually diminishes afterwards(12,24).

In 2012, the Canadian graphic warnings and the interior messages were revised to display new graphics and new health messages. This dissertation is the first longitudinal evaluation of the impact of the 2012 Canadian graphic HWL revisions on a multitude of cognitive and behavioural outcomes, including key indicators of HWL effectiveness, beliefs about smoking-related health statements displayed on cigarette packages, affective reactions evoked by warnings, quit-efficacy and perceived difficulty of quitting, and intentions to quit and cessation-related behaviours. Data for this research was drawn from nationally representative surveys conducted by the International Tobacco Control Policy Evaluation Project (ITC Project). Although data collected directly before and after the 2012 revisions were of particular interest, data from nine survey waves extending for over a decade (2002–2014) were used to take into

account the trend before implementation. This is important, because the consideration of pre-policy time trends increases internal validity when examining the impact of an intervention over time, and can reveal important information about its impact while taking into account the secular trend(25).

Two preliminary studies (commissioned by Health Canada) have examined the impact of the 2012 Canadian graphic HWLs. The Environics Research Group piloted a baseline evaluation of the graphic HWL messages, yet based its evaluation on telephone interviews conducted in March 2012, before the date that retailers were given to transition to the revised cigarette packages(26). Another preliminary study conducted by Harris/Decima assessed smoking-related behaviours at the time of the revisions (March–June 2012), and compared the results to those obtained one year after implementation (March 2013)(27). The current study is therefore the first to measure the impact of the Canadian graphic HWLs on cognitive and behavioural outcomes in its temporal context(25).

2.0 BACKGROUND

2.1 Prevalence and Patterns of Use in Canada

There have been substantial reductions in the prevalence of tobacco use in Canada over the past several decades. In the early 1980's, Canada had the highest rate of per capita cigarette consumption in the world(28). Levels of consumption dropped rapidly over the next decade, with the greatest declines seen among teens. In fact, government surveys revealed that smoking rates among youth (ages 15 to 19) almost halved between 1981 and 1991 (from 43% to 23%)(28).

Tobacco use rates by product

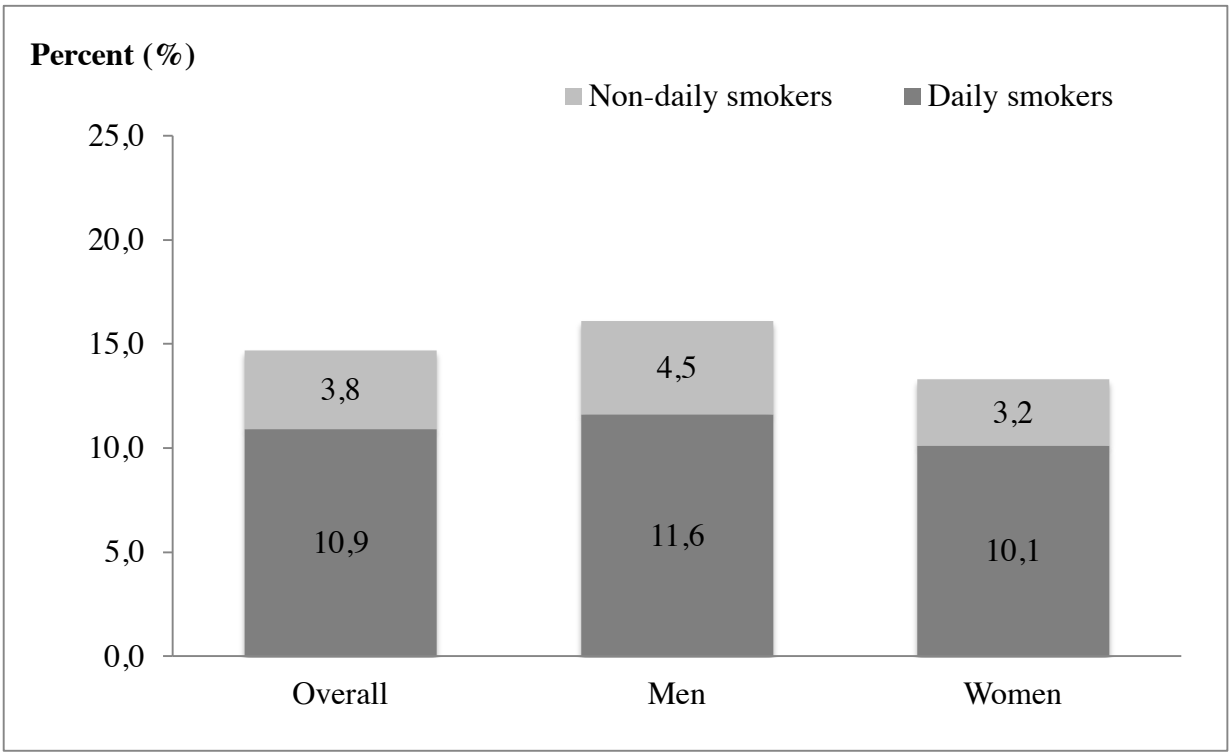
Cigarettes are by far the most popular tobacco product in Canada, with 14.6% of Canadians aged 15 years and older reporting to be current cigarette smokers in 2013 (equivalent to about 4.2 million people)(29). Among other tobacco products used by Canadians ("in the last 30 days"), 3% of smokers aged 15 years and older reported smoking any type of cigar, 2% reported smoking e-cigarettes, and less than 1% of reported smoking water-pipe or smokeless tobacco(29).

Smoking patterns by sex

Although the speed of decline has slowed in recent years, smoking rates have been steadily decreasing. In 2000, the overall smoking rate among Canadians aged 15 years and older was 24.4%(30). The prevalence decreased to 14.6% in 2013 (10.9% reported to be daily smokers and 3.8% non-daily)(29).

The prevalence of smoking among men was 16.0% in 2013 (11.6% daily and 4.5% non-daily). Among women, 13.3% reported to be smokers (10.1% daily and 3.2% non-daily)(29).

Figure 1. Smoking prevalence in Canada by sex, 2013



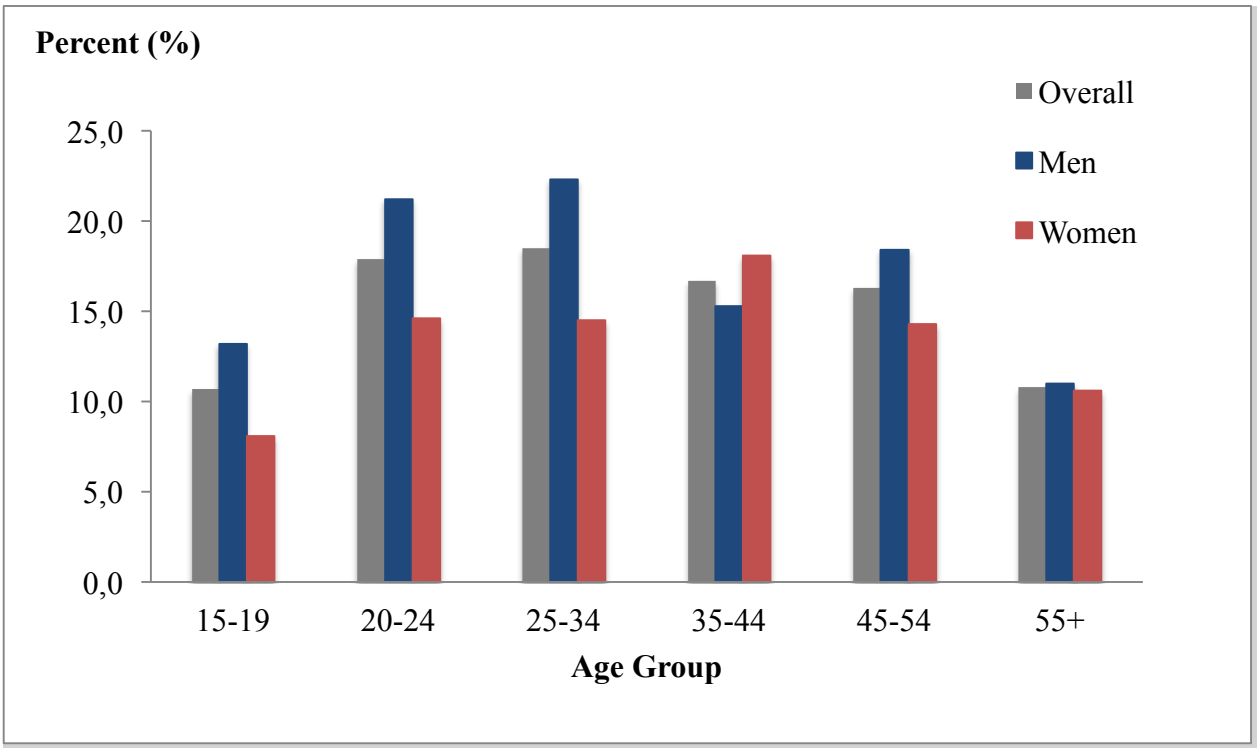
Source: Canadian Tobacco, Alcohol and Drugs Survey, 2013

Smoking patterns by age

In 2013, the overall prevalence of smoking was highest among adults aged 25 to 34 years (18.5%) and lowest among adults aged 15 to 19 years (10.7%) and 55 years and older (10.8%).

Among men, smoking rates were highest for those aged 25 to 34 years (22.3%). Among women, smoking rates were highest for those aged 35 to 44 years (18.4%)(29).

Figure 2. Smoking prevalence in Canada by age group and sex, 2013

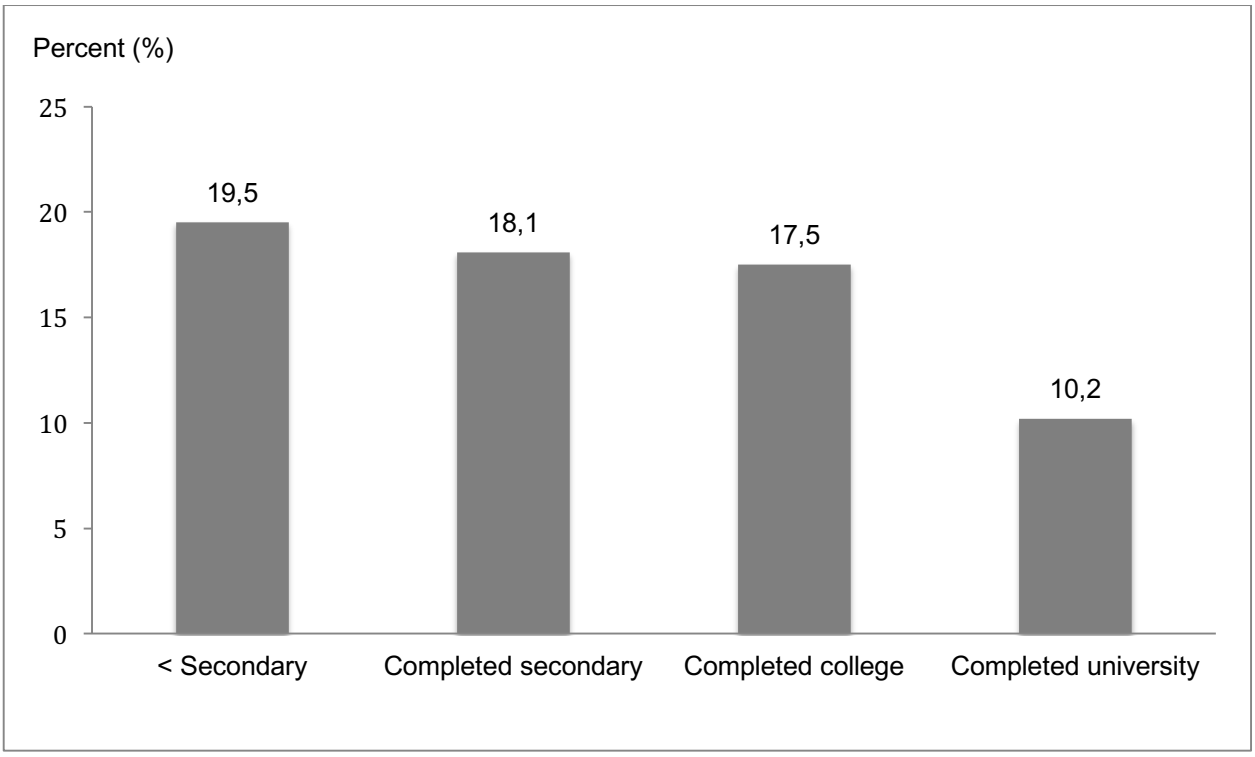


Source: Canadian Tobacco, Alcohol and Drugs Survey, 2013

Smoking by socioeconomic status

Smoking trends in Canada differ by socioeconomic status (SES). Historically, smoking was reserved for the wealthy and seen as a sign of prosperity and sophistication(31,32). In modern times, however, smoking is more common among those with lower levels of education and household income(32–34). As shown in Figure 3, national data from 2012 showed that smoking prevalence among the least educated was almost double than that of the most educated(35).

Figure 3. Smoking prevalence in Canada by education, 2012



Source: Canadian Tobacco Use Monitoring Survey, 2012

These differences in smoking rates by education have remained relatively stable over the past several years. A study that examined smoking rates across socio-economic groups between 1999 and 2006 showed that smoking prevalence was approximately double among the least educated compared to the most educated in each year studied(33). This is likely related to the fact that lower levels of education and income have been associated with lower awareness of smoking-related health risks(36). It has also been suggested that individuals with low SES experience greater levels of stress due to the nature of their environment and have limited resources to cope with these stressors compared to higher socioeconomic groups(37–39). These psychosocial factors are believed to play a critical role in the relationship between lower SES and smoking behaviour(40).

Canadians with a lower education and household income are not only more likely to smoke, but are also less likely to successfully quit(32–34). Data from the 2005 Canadian Community Health Survey showed that the quit ratio increased as household income increased (ranging from 0.9 and 1.0 for men and women earning less than $15,000 per year to 2.1 to 2.5 for men and women earning $80,000 per year, respectively)(32). Smokers with higher levels of education are also more likely to quit compared to smokers with lower levels of education, with highest rates of successful quitting among university graduates(33).

Importantly, these findings indicate that while recent tobacco control efforts in Canada have succeeded in reducing overall smoking prevalence, they have not impacted socio-economic groups equally(32–34). Tobacco control strategies that target socioeconomically disadvantaged smokers, who are disproportionately affected by the harms of tobacco use, may therefore be particularly effective in reducing overall smoking prevalence in Canada.

2.2 Impact of Smoking in Canada

2.2.1 Health Impact

Tobacco use is the leading preventable cause of premature death in Canada(41). More than 37,000 people die in Canada each year from tobacco use, representing about one of every six deaths(8). In fact, tobacco causes more deaths than alcohol and illicit drugs combined. In 2002, about 17% of deaths in Canada were due to smoking (20% among men and 12% among women)(8). Estimates generated by the World Health Organization based on 2004 data showed that among all deaths attributable to tobacco use, the most common were due to trachea, bronchus, and lung cancers (88%), chronic obstructive pulmonary disease (83%), and respiratory diseases (69%)(42). Although these estimates are based on deaths from the use of all tobacco products, the vast majority of these deaths can be attributed to smoking as cigarettes are by far the most popular form of tobacco product used in Canada(29).

While the majority of tobacco-related deaths occur late in life, research has shown that smoking also decreases quality of life due to increased health co-morbidities and mental illness(4,7,8,43). Smoking is associated with a host of short-term health problems such as headaches, anxiety, asthma, chronic coughing, and fatigue(4). A study conducted by Kirst, Mecredy, and Chaiton(44) that examined tobacco use and co-occurring mental health issues in Canada found that the odds of being diagnosed with a mood disorder or an anxiety disorder was more than double for smokers compared to non-smokers. Problematic alcohol dependence and illicit drug use was also significantly higher among smokers compared to non-smokers(44).

Importantly, smoking disproportionately impacts the health of individuals with low SES due to higher rates of cigarette consumption. Smokers with low SES generally suffer more from smoking-related diseases compared to smokers with higher SES(45). In fact, individuals in the

most socioeconomically deprived groups have been shown to have higher risk of lung cancer rates compared to those from higher socioeconomic groups(46).

2.2.2 Economic Impact

Cost studies investigating the economic impact of tobacco at the national or global level typically examine the impact of all tobacco products. In these studies, the economic impacts are usually categorized as direct costs (health care costs including acute care hospitalization, ambulatory care, physician fees, and prescription drugs) or indirect cost (lost productivity in the workplace place or at home resulting in part or in whole from the tobacco use)(8,47).

It has been estimated the global burden of tobacco use on health care costs and lost productivity in 2012 totaled $1.4 trillion USD(48). This is equivalent to 1.8% of the world's GDP. High-income countries in Europe and the Americas spent the greatest relative proportions on smoking-attributable illness(48).

In Canada, the total economic cost of tobacco-related illness was calculated to be more than $17 billion in 2002, of which about $4.4 was due to direct health care costs. Lost productivity due to illness and premature death (indirect costs) accounted for the largest economic cost of tobacco at $12.5 billion(8). A more recent cost study based on 2012 statistics estimated the total economic cost of tobacco use in Canada to be $18.7 billion (direct and indirect costs accounted for $6.4 billion and $12.3 billion, respectively)(47).

Smoking also has a substantial economic impact on the smoker at the individual level. A pack-a-day smoker in Canada will spend more than $4,000 on cigarettes per year (at the average price of $11 a pack)(49). Because smoking is more common among the poorest segments of the Canadian population(30,34), these groups (who are already under increased financial stress) will

spend a greater proportion of their household income on cigarettes leaving less money available for food, housing, or education(2,39).

2.3 Health Benefits of Smoking Cessation

It is critical that smokers are informed with an important health message: it is never too late to quit. Many of the health impacts caused by smoking can be significantly reduced or even reversed after cessation(4,9,11).

The positive health impacts of quitting range from almost immediate to long term(4). After 12 hours, blood carbon monoxide levels return to normal. Circulation and lung function improve after only two weeks. After 1 to 9 months, shortness of breath and coughing decrease. The excess risk of heart disease drops by 50% one year after quitting. After 5 to 15 years, the risk of stroke returns to that of a non-smoker. After 10 years, risk of lung cancer decreases by about half. After 15 years, the risk of coronary heart disease returns to that of a non-smoker(11).

Life extension is often presented as a tangible means of demonstrating the heath benefits associated with smoking cessation at various ages. Smokers who quit at about 30 years of age gain almost 10 years of life expectancy. Quitting by about 40 years of age extends one's lifespan by 9 years. Quitting by about age 50 and 60 adds about 6 and 3 years of life expectancy, respectively(10).

Overall, these findings illustrate that it is never too late and a smoker is never too old to quit smoking. The health benefits of quitting at any age are highly encouraging. It is therefore essential that evidence-based tobacco control policies be implemented to inform smokers about the health benefits of cessation to encourage smokers to quit.

Canada has already done this by providing information on the benefits of quitting in interior messages either on the slide or as inserts enclosed in cigarette packages. For example, one of eight new interior messages introduced in 2012 reads:

> *"Quitting smoking increases life expectancy and improves quality of life. People who quit smoking increase their chances of living longer. They improve their general health, leading to a better quality of life. It's never too late to quit. No matter how old you are, you'll start to feel major and immediate health benefits and have more energy to help you live life to the fullest."*(50)

Next, the rise of smoking in Canada and the evolution of Canadian HWL legislation are described to provide context for the study.

2.4 History of Smoking in Canada

It was not until World War I that cigarettes dominated the Canadian tobacco market. Before then, cigars were the most frequently used tobacco product and were promoted as a marker of sophistication and wealth. The First World War, however, made cigarette smoking commonplace in all social classes – and not only among men, but also among women who were previously strongly discouraged from smoking(51). In fact, the number of cigarettes consumed in Canada per year increased from 87 million in 1896 to 2.4 billion in the early 1920s – a 28-fold increase(52).

World War II continued to boost popularity of cigarettes for both men and women as tobacco companies emphasized their support in the war effort. Approximately three-quarters of men and half of women in their 20's and 30's were smokers during the Second World War. Canadian cigarette consumption increased approximately 10-fold between the 1920s and the late 1940's – reaching 28 billion cigarettes sold in 1949(52).

The rapid expansion of cigarette smoking began to slow in the 1950's when health researchers linked smoking to lung cancer. The results of a research study conducted by Canadian medical student Dr. Norman Delarue showing an increased likelihood of developing lung cancer among smokers was published in 1950(53) (along with another study published the same year by Doll and Hill(54)).

Although concern about the health risks of smoking started to spread in the in the 1950's, smoking rates in Canada remained very high. It was not until the early 1960's when official reports from the United Kingdom's Royal College of Physicians and the US Surgeon General linked smoking to cancer that the scientific evidence began to be taken seriously(31).

The next several decades consisted of a burgeoning tobacco control effort, vigorously and successfully fought by the tobacco industry. Due to the increasing number of tobacco control bills introduced to Parliament, the Canadian government created the "Standing Committee on Health, Welfare, and Social Affairs". This committee was chaired by Dr. Gaston Isabelle and soon adopted the name, the "Isabelle Commission". In 1969, the Isabelle Commission issued the *Isabelle Report*, which recommended that the Government implement tobacco control regulations including a complete ban on cigarette advertising and promotion and the requirement to display health warnings on all cigarette packages(31,51). Although a voluntary ban on

cigarette advertising in broadcast media was implemented in 1972, none of the other recommendations, including health warnings, were implemented until almost 20 years later(51).

2.5 Canadian Health Warning Legislation

Canada first implemented health warnings on cigarette packages in 1989 after the *Tobacco Products Control Act* (TPCA) came into force in December 1988(55). The TPCA (replaced by the *Tobacco Act* in 1997) presented the *Tobacco Products Control Regulations,* which required all cigarette packages to list toxic constituents and display one of the following four text-only warnings (in English and French)(56):

I. "Smoking reduces life expectancy"
II. "Smoking is the major cause of lung cancer"
III. "Smoking is a major cause of heart disease"
IV. "Smoking during pregnancy can harm the baby"

Although these warnings represented a significant achievement in tobacco control advocacy, tobacco companies tactfully displayed warnings to blend in with package colours, reducing their impact(57). In response, the Ministry of Health announced a policy reform in 1990, providing additional health messages and requiring warnings to be printed in black and white and occupy 35% (including borders) of the principal display surfaces. The reform, however, was almost immediately delayed due to the tobacco industry's constitutional challenge of the TCPA. Although the Quebec Superior Court initially ruled that the new legislation violated tobacco companies' freedom of expression, the Quebec Court of Appeal reversed this decision in 1993(55). The new warnings (and toxic emission messages) finally appeared on

cigarette packages in 1994, representing the largest health warnings in the world and setting global precedents for tobacco warning policy(57).

There was another setback in 1995 when the Supreme Court of Canada removed the legal basis for imposing health warnings in response to the tobacco industry's argument that companies should have the right to attribute the warnings to the Canadian Government. Until then, health warnings were printed unattributed. According to the tobacco industry, the unattributed nature of the health warnings resulted in the compelled expression imposed on tobacco companies(55). It was not until 1997 that the Canadian Government assumed the right to regulate the packaging of cigarette when the *Tobacco Act* was established(20).

In 2001, Canada became the first country to implement graphic warnings on cigarette packages as required by the *Tobacco Products Information Regulations* (TPIR), adopted under the authority of the *Tobacco Act*(58). These regulations mandated cigarette manufacturers to print one of 16 graphic warnings covering 50% of the front and back panel. These graphic warnings provided elaborative text explaining the reason for the health risk. For example, one warning stated "CIGARETTES CAUSE LUNG CANCER", and provided additional text explaining that "85% of lung cancers are caused by smoking" and that "80% of lung cancer victims die within 3 years"(50). The full set of warnings is presented in Appendix A.

In addition to health warnings, legislation required the inclusion of interior health messages either on the slide or as an insert enclosed in cigarette packages. The interior health messages were designed to motivate smokers to quit and to increase quit-efficacy by providing cessation tools and advice. Finally, the TPIR required toxic emission numbers for tar, nicotine, carbon monoxide, formaldehyde, hydrogen cyanide and benzene to appear on the side panels of cigarette packages(50).

Canada's three major tobacco manufacturers (Rothmans, Benson & Hedges; JTI-Macdonald; and Imperial Tobacco Limited) challenged the *Tobacco Act* in 2002, claiming that the financial burden of the graphic warnings would be substantial and that there was no serious evidence that warnings impact tobacco use. The Quebec Superior Court rejected these claims. The tobacco companies appealed this decision in 2005, arguing that the regulations violated their Constitutional rights. When the Quebec Court of Appeal also upheld the regulations for pictorial warnings, the tobacco companies brought their appeal to the Supreme Court of Canada. In 2007, the Supreme Court ruled that the *Tobacco Act* was a justifiable infringement of the Canadian Charter of Rights and Freedoms(59).

In 2011, the *Tobacco Products Labelling Regulations (Cigarettes and Little Cigars)* (TPLR-CLC*)* replaced the TPIR and outlined stronger labelling requirements. These requirements included a new set of 16 exterior warnings (covering 75% of the front and back panels), eight interior messages, and four toxic emission messages for the side panel. These revised labels also presented, for the first time, the number for a toll-free quit line. The display of these new warnings was enforced in March 2012(60,61). The revised graphic warnings, interior messages, and emission statements can also be found in Appendix A.

Table 1 presents the characteristics of the previous and current HWLs implemented in Canada.

Table 1. Characteristics of the previous and current Canadian graphic warnings

	Previous Warnings (January 2001 – March 2012)	**Current Warnings (March 2012 – present)**
Number of warnings	16 (rotating)	16 (rotating)
Language	English and French	English and French
Type	Text and graphics	Text and graphics
***Size**	50%	75%
Position	Top of front and back panels	Top of front and back panels
***Content**	**Health impacts** *Stroke, lung cancer, lung disease/emphysema, heart disease, mouth disease/oral cancer, impotence, preterm birth* **Harmful constituents** *- SHS contains carbon monoxide, ammonia, formaldehyde, benzo(a)pyrene, and nitrosamines* *- Tobacco smoke contains hydrogen cyanide* *- Tobacco smoke contains hydrogen cyanide, formaldehyde, benzene. SHS can cause death from lung cancer and other diseases* **SHS/impact on others** *- Children twice as likely to smoke if parents do* *- SHS contains more than 50 cancer-causing agents* *- Tobacco use during pregnancy increases risk of preterm birth. Babies born preterm are at an increased risk of infant death, illness, and disability* *- Tobacco use during pregnancy reduces growth of babies. Smaller babies may not catch up in growth after birth and risks of infant illness, disability and death are increased* **Addictive nature**	**Health impacts** *Stroke, heart disease, oral cancer, bladder cancer, blindness, premature death* **Harmful constituents** *- Over 70 cancer causing chemicals in tobacco smoke* **SHS/impact on others** *- Infants exposed to tobacco smoke are at greater risk of dying from SIDS* *- SHS contains many toxic chemicals that can harm an unborn baby* *SHS causes more frequent and severe asthmatic attacks in children* **Addictive nature**

***Style**	Factual	Factual Testimonial
***Emission statements**	Tar, nicotine, carbon monoxide, formaldehyde, hydrogen cyanide and benzene emission numbers on side panels	4 rotating qualitative statements about toxic constituents on side panels - *"Tobacco smoke contains fine particles that can damage the respiratory system"* - *"Tobacco smoke contains more than 70 chemicals that can cause cancer"* - *"Tobacco smoke contains hydrogen cyanide, a poisonous gas"* - *"Tobacco smoke contains benzene, a chemical that causes cancer"*
***Toll-free quit line number**	Not displayed on package exterior	Displayed on package exterior
***Interior Messages**	8 (rotating), text-only	8 (rotating), text with graphic image

*Changes occurred between 2001 and 2012 warnings
Source: Campaign for Tobacco Free Kids, 2016

Plain and standardized packaging is under formal consideration in Canada. On May 31, 2016, Health Canada launched a public consultation about the proposed plain packaging requirements for tobacco products(50). The measures under consideration include a single ordinary colour and the standardization of brand name displays on all cigarette packages. Importantly, the new requirements would not remove the current labeling requirements, including the obligation to display graphic and text warnings(41).

2.6 Health Warning Labels: A Review of the Literature

Well-designed warning labels on cigarette packages are an important strategy to inform the public about the harms associated with smoking, to help motivate smokers to quit, and to discourage initiation among non-smokers(12). This is particularly important because research has shown that while most people recognize that tobacco use is generally harmful, many underestimate the likelihood, magnitude, and severity of smoking-related health risks(19,62).

International guidelines for health warnings on tobacco products have been established under Article 11 of the WHO's Framework Convention on Tobacco Control (FCTC), the first international treaty devoted to public health(12). The FCTC calls for Parties to implement health warnings that cover at least 30% of the principal display areas(13). The Conference of Parties (COP) adopted more detailed guidelines for the implementation of Article 11 at its third session in 2008. These guidelines call for Parties to implement large, clear, and periodically rotating pictorial warnings that cover 50% or more (and no less than 30%) of the package principal display areas in the Parties' main language(s)(14).

There has been progress over the past decade in the implementation of HWLs on a global scale. In 2016, 105 countries had finalized graphic HWL requirements, covering about 58% of the world's population (up from 77 countries in 2014). Of these countries, 94 require warnings to cover at least 50% of the main display areas (up from 60 countries in 2014)(63).

2.6.1 Characteristics of effective health warning labels

Health warnings on cigarette packages are a highly cost-effective method of communicating the health risks of smoking. HWLs are unique among tobacco control policies in that they are present each time the product is used – up to 20 times per day and 7,300 times per

year for the pack-a-day smoker(64). With a high reach at the population level and a high frequency of exposure at the individual level, HWLs have a huge potential to influence populations if implemented in an optimal way(12).

Health warnings are highly visible to non-users as well. As a result, HWLs have the potential to discourage initiation among never-smokers and encourage continued abstinence among former smokers(14,65). Another important advantage of HWLs is their ability to reach disadvantaged groups that may receive little benefit from other tobacco control policies. This includes, for example, populations that live in remote or isolated areas, individuals with limited access to health services, those without radio/TV or other popular outlets of anti-smoking information, or low literacy-smokers and children(64,66).

When implemented in an optimal way, HWLs have the potential to result in a significant and positive population-level impact(12). The level of influence that warnings have on smokers' thoughts and behaviours, however, is influenced by several characteristics, described below.

Warning size

Article 11 of the FCTC specifies that HWLs should cover 50% or more (but no less than 30%) of the principal display areas(14). Research has shown that larger, more prominent warnings are more effective than smaller warnings(67–75). Larger warnings are more salient, are perceived to be more important, and are more likely to be remembered(76,77). Experimental research(75) conducted in Canada found that increasing the size of graphic warnings from 50% of the principal display area to 75%, 90%, and 100% enhanced their impact among Canadian adult smokers, youth smokers, and youth non-smokers. Larger warnings were also rated as more effective for communicating health risks, reducing smoking initiation, and helping smokers to quit(75).

Positioning

Warnings should be positioned in the upper sections of both the front and back panels of cigarette packages(14). Placing warnings on both panels ensures that they are visible regardless of which package face is displayed (and makes it more difficult for them to be hidden for point-of-sale marketing)(78). Moreover, warnings that appear on the front of packages are more noticeable and easier to remember compared to those that are displayed on the sides(64). For instance, a study that compared warnings on Canadian packages (at the time, text-only warnings printed on the front of packages) to warnings on packages in the US (text-only warnings printed on the side of packages) revealed that 83% of students in Canada were able to recall warning messages compared to only 7% of students in USA(79).

Colour

The FCTC Article 11 guidelines recommend that Parties require full colour warnings instead of only black and white(14). The use of colour can increase warning effectiveness by enhancing noticeability of pictorial elements and message content, and can make warnings more readable(12). The effectiveness of coloured warnings was demonstrated in a study conducted by O'Hegarty and colleagues(17) that asked US smokers and non-smokers to compare US text-only warnings to Canadian graphic HWLs. Results of this study revealed that the element of colour in the graphic warnings was associated with higher perceptions of warning effectiveness. However, it is important to select contrasting colours for the message and the background (such as dark-coloured lettering on a light coloured background) to optimize legibility of the text and increase comprehension(74).

Efficacy messages and quit line information

The FCTC Article 11 guidelines recommend that quitting advice and information on specific sources for cessation help, such as the national toll-free quit line number, is displayed on cigarette packages(14). These supportive messages aim to increase confidence and motivation to quit among smokers. This is particularly important because psychological theory and empirical research has shown that smokers are more likely to attempt to quit smoking if they believe they can succeed(80–82). In addition, the perceived difficulty of quitting has been shown to be negatively associated with short-term cessation behaviours(83). Examples of efficacy messages include general messages of support, information and tips on ways to quit smoking, or specific sources of help(64).

An important characteristic of efficacy messages is that they are *always* available and can capitalize on the times of intentions. This means that even if these informational messages are not initially as beneficial for smokers who do not intend to quit, they will be available to those smokers if they intend to quit at a later time.

Images

To increase the effectiveness of HWLs, Article 11 recommends including pictures or pictograms(13). Research has consistently shown that warning messages are more effective when they are accompanied by imagery(64,84,85). Warnings with images, such as symbols or pictorials, are more likely to capture attention and consequently result in greater information processing of message content(12,19,73,86). Picture-based warnings also compel viewers to imagine health consequences (to smokers themselves or to others via secondhand smoke (SHS)), which can aid individuals when making smoking-related judgments and/or decisions(64).

Pictorial HWLs have the added benefit of reaching low literacy smokers or those who cannot read the language in which the text warning is printed(1,87,88). Indeed, HWLs that display pictorials have been rated as more effective by smokers with lower levels of education(72,89,90), possibly because they must rely less on their literacy skills to process and interpret the information(91). This is particularly important because research has shown that in most countries, smoking is most common among those with low educational attainment(64,88).

Periodically rotating warnings

Article 11 of the FCTC specifies that health warnings should be periodically rotated(13). Rotating warnings decrease the chance of smokers becoming habituated to them due to overexposure, thereby reducing their effectiveness(12). This is consistent with basic principles of advertising and health communications, that imply the salience of a message is greatest at initial exposure and gradually diminishes afterwards(12,24). This phenomenon, known as "wear-out", has been found in several studies investigating the impact of health warnings over time(16,23,65,71,92–94).

2.6.2 Impact of graphic health warning labels

Pictorial warnings on cigarette packages often contain graphic images that evoke strong emotional/affective reactions (such as the warnings implemented in Canada). These graphic HWLs often present gruesome images of the health consequences of smoking (such as diseased organs), elements of human suffering, or provide information about the dangers of SHS on vulnerable populations (such as children or pregnant women). Extensive research, described

below, has shown that graphic warnings are particularly effective in positively impacting cessation-related cognitions and behaviours among smokers.

Perceived effectiveness of graphic HWLs

Several studies comparing the impact of text-only warnings to those displaying graphic images have shown that graphic warnings are perceived to be more effective in discouraging smoking(18,74,88,90,92,95,96). A study by Hammond and colleagues(88) exploring the effectiveness of HWL style among adult smokers in Mexico showed that graphic HWLs were rated as more effective compared to text-only warnings. Another study among non-smokers from Greece found that respondents perceived graphic warnings to be more effective in deterring them from smoking(95). Importantly, these studies suggest that graphic warnings are not only effective in discouraging smoking among current smokers, but also in dissuading initiation among non-smokers.

Incorporating testimonials (narratives describing personal experiences of the negative effects of smoking, usually written as a quote from a person in the image) can further increase warning effectiveness and credibility(88,97–101). A study by Davis and colleagues(100) that exposed smokers to warnings with four different themes (graphic images, testimonials, how to quit, and anti-tobacco industry) found that warnings exhibiting graphic images and testimonials were rated as the most effective. Hammond and colleagues(88) also showed that adding testimonial information to graphic HWLs significantly increased perceived effectiveness among smokers.

Impact on message recall and knowledge of health risks

A primary goal of HWLs is to communicate information on the health risks associated with smoking. Although smokers and non-smokers are generally aware that smoking is harmful to health, studies have indicated that there are gaps in smoking-related health knowledge(19,62).

Research has demonstrated that HWLs are successful at increasing smokers' understanding of smoking-related health risks(12,18,19,21,69,102–104). Canadian surveys conducted in the 1990s revealed that the majority of smokers considered warnings to be important source of health information, and reported a higher awareness of health risks(12). Additionally, an ITC study that evaluated the impact of warnings of the awareness of smokers in Canada, Australia, the UK and the US found that in each case where tobacco control policies differed between countries, smokers from countries that required HWLs reported greater health knowledge(19).

Graphic warnings in particular have been associated with enhanced recall and knowledge of smoking-related health risks(15,19,26,86,96,97,102). Graphic warnings are more likely to capture attention, resulting in greater information processing of content and improved memory of health risks over time(12,19,86). This was demonstrated in a study conducted by Swayampakala and colleagues(102) that explored levels of knowledge among smokers in Canada, Australia, and Mexico. Findings from this study revealed a greater awareness of smoking-related risks in those countries where graphic HWLs were revised or introduced for the first time(102).

Although informing smokers on smoking-related health risks is an important goal itself, knowledge of health risks also has a strong influence on smoking behaviour. Smokers who report greater knowledge of smoking-related risks are more likely to intend to stop smoking and to quit successfully(18,21,86,105–108). Given that most smokers tend to underestimate the health

consequences of smoking, it is crucial that governments implement graphic HWLs to better communicate the heath risks of smoking(19,62,109).

Impact on quit intentions

Psychological theory and empirical research emphasize that motivation to quit smoking is a critical factor for making quit attempts and for quit success(110–112). HWLs increase quit intentions by highlighting the consequences of smoking (to smokers themselves and to others via SHS), which in turn evoke health worries and concerns(12,105,113,114). These health concerns help to alter smoking behaviour; in fact, smokers who perceive greater or more serious health risk from smoking are more likely to intend to quit and to quit smoking successfully(19,107,115).

Several studies have demonstrated that graphic HWLs are particularly effective in increasing motivation to quit smoking(18,19,70,86,96,114,116–118). An ITC study that compared the effectiveness of Canada's graphic warnings to Mexico's text-only warnings found that Canadian smokers reported higher warning label salience, and warning label salience independently predicted intention to quit(15). Similarly, a study conducted by Bansal-Travers and colleagues(73) found that compared to text-only warnings, graphic warnings were more likely to attract attention, induce thoughts about smoking-related health risks, and motivate smoking cessation.

Graphic HWLs have also been associated with reduced urges to smoke. A study that explored the neurophysiological impact of HWLs showed that the affective reactions elicited by graphic warnings produced increased activation of the brain regions mediating emotional memory and were associated with greater reduction in the urge to smoke(119). Importantly, this

study proved that graphic warnings triggering strong negative emotions are important not only for motivating smokers to quit, but for their neurophysiological impact as well.

Impact on cessation-related behaviours

The ultimate goal of any tobacco control strategy is to reduce tobacco use in order to protect populations from the harmful effects of tobacco. Numerous studies have provided evidence illustrating that the enhanced salience of graphic HWLs induce greater health concerns among smokers, which in turn lead to cessation-related behaviours including reduced smoking, increased quit attempts, and sustained quitting(15,20–22,70,86,93,96,105,116,117,120–122).

For example, a longitudinal study conducted Azagba and Sharaf(20) investigating the effect of graphic cigarette warning labels on smoking behaviour found that graphic warnings had a statistically significant association with lower smoking prevalence and increased quit attempts. Similarly, an ITC study conducted by Huang, Chaloupka, and Fong(121) examining the effect of graphic HWLs on Canadian smoking rates (controlling for cigarette prices) also found a significant reduction in smoking prevalence after the adoption of graphic HWLs in Canada.

HWLs have also been shown to increase the use of cessation helplines. Studies from several countries including Canada, Netherlands, Australia, New Zealand, and Brazil demonstrated that HWLs accompanied by a national quit line number led to significant increases in call volumes(123–128).

For instance, a study by Miller and colleagues(125) found that calls to the toll-free quit line in Australia doubled after the quit line number was added to newly implemented graphic HWLs in 2006. Although the call volume gradually declined in 2007, it remained higher than before the appearance of the quit line number(125). Similarly, Baskerville and

colleagues(127,128) found that the display of the toll-free quit line number on the new 2012 Canadian graphic HWLs led to a relative increase of 160% in the average monthly call volume over 7 months post-introduction(127), and the vast majority (86%) of new callers reported seeing the quit line number on the warning labels(128).

Graphic HWLs and wear-out

Research suggests that larger, graphic-based warnings are more resilient to wear-out and retain their effectiveness longer(16,23,68,80). Hitchman and colleagues(23) investigated the changes in health warning effectiveness in Canadian graphic warnings and in US text-only warnings between 2002 and 2011. Results of the study showed that despite greater declines in warning effectiveness in Canada, the Canadian graphic warnings were significantly more effective than the US text-only warnings in each year studied(23). Similarly, another study comparing the impact of text- and graphic-based warnings implemented for various time lengths found that although some level of wear-out was evident with all warnings, graphics tended to sustain their effects for longer(68).

2.7 Fear Appeals and Efficacy Messages

There is a tendency to interpret fear as a "bad" emotion. However, fear has been critical within evolutionary history for quick and efficient decision-making necessary for avoiding health hazards(129). Fear is in fact an important source of information (via an Affect Heuristic), and influences human behaviour by motiving us to engage in pleasant and rewarding behaviours and to avoid those that are unpleasant and potentially dangerous(129).

2.7.1 Fear appeals

Research has shown that strong, fear-evoking graphic HWLs are more effective than those that cause weaker reactions (such as warnings that display symbols or 'mild' pictorial images)(22,70,88,92,97,100,101,114,117,119,130,131). Graphic depictions of smoking-related illnesses allow viewers to imagine these conditions more easily, which leads them to perceive the health threat as more likely to occur(132). A meta-analytic review of the literature on fear appeals by Witte and Allen(130) found that strong fear appeals are more effective in promoting behaviour change compared to weaker fear appeals by producing high levels of perceived severity and susceptibility of health risks. In fact, numerous studies on the use of fear appeals have shown that strong fear-evoking labels, both health and socially oriented, are rated as most effective by smokers and have the greatest impact on downstream behaviours(22,86,92,114).

For example, a study assessing the impact of the Canadian graphic HWLs implemented in 2001 found that smokers who reported greater levels of fear and disgust due to warnings were more likely to have quit smoking, made an attempt to quit, or reduced their smoking at follow up(22). Moreover, the study showed that smokers who reported avoiding the warnings (by covering the warnings or using a cigarette case) were no less likely to read and think about the warnings, nor less likely to engage in cessation behaviours at follow up(22).

A study by Evans and colleagues(117) that examined the psychological process set in motion due to the exposure to HWLs showed that compared to text-only warnings, fear-evoking graphic warnings had a greater effect on risk perceptions and quit intentions. Additionally, graphic warnings increased health message recall and increased smoking-related knowledge at follow up(117).

Finally, results from a study conducted by Kees and colleagues(86) investigating reactions to pictorial warnings varying in levels of graphic depiction also support the use of fear appeals. Their study demonstrated that graphic warnings had a strong positive effect on quit intentions, but the effect no longer existed when tests were controlled for fear. These findings indicate that fear fully mediated the effect of pictorial warnings on smokers' quit intentions.

2.7.2 The importance of efficacy messages

Importantly, caution must be taken when implementing overly threatening messages, because strong warnings may have a differential impact on motivation depending on smokers' pre-existing self-efficacy. Although strong fear-evoking warnings have been shown to be effective among smokers with high self-efficacy, these warnings may result in defensive reactions among low-efficacy smokers(80,130,133).

In their meta-analytic review of the literature on fear appeals, Witte and Allen(130) emphasize that although strong fear appeals are more effective in promoting smoking cessation compared to weaker fear appeals, overly threatening warnings can result in defensive reactions among low-efficacy smokers. However, strong fear appeals were shown to be highly effective among both high and low-efficacy smokers when paired with efficacy messages (providing encouragement and advice on how smokers can avoid the negative health consequences). This is consistent with psychological theory and empirical research asserting that smokers are more likely to attempt to quit smoking if they believe they can succeed(80–82).

In 2000, Canada became the first country to require cigarette manufactures to include efficacy messages either on the slide or as an insert (which were replaced by a new efficacy messages in 2012)(50,134). The effectiveness of these efficacy messages was investigated in a

series of studies conducted by Thrasher and colleagues(134,135). The results of these studies revealed that although not as many smokers reported reading interior messages compared to warning displaying on the exterior panels, smokers who read efficacy messages thought more frequently about health risks because of warning labels(135). Additionally, more frequent reading of interior messages was associated with higher quit intentions, quit attempts, and with stronger self-efficacy to quit at follow up(134).

Several other countries, such as Australia, Brazil and Singapore, have also implemented regulations that require graphic warnings to be paired with efficacy messages(64).

2.7.3 Message framing

Message framing has been an important focus in health communication research, including smoking prevention. The question of displaying 'gain-framed' warnings, those that focus on the positive aspects of smoking cessation, versus 'loss-framed' warnings, those that focus on the negative impacts of smoking, has been heavily debated and researched(80).

Previous literature has illustrated that effective application of gain- and loss-framed messaging is dependent on the health behaviour in question(136,137). A meta-analysis conducted by Gallagher and Updegraff(137) found that loss-framed messages are more effective when promoting illness detection (such as HIV testing or mammography utilization), whereas gain-framed messages are more effective when promoting prevention behaviours (such as smoking prevention).

Contrary to their conclusions, anti-smoking messages are typically loss-framed as warnings that evoke fear have been shown to be particularly effective in motivating smokers to quit, especially when coupled with efficacy message(130). Several studies have provided

evidence of the benefits of loss-framed anti-smoking messages, which are typically used for graphic HWLs(114,133,138–140). For example, Mead and colleagues(114) studied the motivational impact of both types of warnings by exposing smokers to warnings from four content categories: negative depictions of smoking-related health effects to smokers and others (loss-framed), and positive depictions of the benefits of cessation to smokers and others (gain-framed). Their results showed that the warnings depicting negative health effects to smokers were identified as most motivational (to quit), followed by labels depicting negative health effects to others. Smokers reported these warnings to be most effective because of the negative emotional reactions they triggered due to the perceived severity and susceptibility of effects(114).

Another study among Canadian adolescents showed that compared to gain-framed warnings, those displaying graphic depictions of disease (loss-framed) were rated as more effective and had a greater positive influence on adolescents' smoking-related beliefs and quit intentions(138).

Message framing has also been shown to impact smokers differently depending on their levels of self-efficacy. A study conducted by Mays and colleagues(133) found that while high-efficacy smokers reported loss-framed messages to be most motivational, gain-framed messages were perceived to be most motivational among low-efficacy smokers. This provides further support that graphic HWLs (which typically employ loss-framed messages) should be accompanied by efficacy messages to help increase confidence and efficacy beliefs.

2.7.4 Affective and cognitive reactions as mediators

Despite the growing evidence supporting the use of fear-evoking HWLs, less research has focused on the mechanisms that drive their effects(96). It has, however, been suggested that fear-evoking graphic HWLs alter smokers' thoughts and behaviours through indirect routes mediated by affective reactions and by cognitive reactions(86,116,117,141). Enhanced affective reactions due to graphic warnings encourage viewers to quit smoking by evoking concerns for their health. Cognitive reactions from processing the health information also play a critical role by influencing smoking-related judgments and risk perceptions(117,141,142). These cognitive reactions are important because research has shown that carefully thinking about information leads to longer lasting perceptions and is more influential on behaviour(143,144).

For example, a study by Emery and colleagues(116) among US youth showed that graphic warnings with additional text elaborating on the reason for the health risk (such as the Canadian warnings) positively influenced perceived risk and quit intentions through the indirect pathway of increasing concern about health risks of smoking (affect), and through the cognitive pathway by increasing believability of health information. Importantly, believability (through increased scrutiny of warnings) was especially important among smokers who reported being less concerned about their health. This research suggests that believability of graphic HWLs is critical in enhancing quitting beliefs and behaviours, particularly for smokers who are more resistant to altering their smoking habits(116).

2.7.5 Graphic warnings and potential adverse reactions

Some researchers have argued that fear-inducing graphic HWLs could also be associated with unintended adverse outcomes. For example, it has been suggested that strong warnings

could create defensive reactions among smokers that inhibit the desired behaviour change, such as message rejection or decreased likelihood of quitting(142,145,146).

However, there has been no evidence that graphic HWLs decrease warning effectiveness or reduce desired outcomes(64,68,86,122,147,148). Although strong fear appeals have been shown to result in message rejection among low-efficacy smokers, these behaviours can be avoided by accompanying threatening warnings with efficacy messages providing supportive messages and advice for quitting(80,130). It is also important to note that these studies have been based on experimental study designs that were conducted out of context(130,142,145,146,149). Experimental studies typically involve exposing smokers to graphic warnings and measuring the short-term impact. Logically, initial impressions to shocking images will be enhanced(12,24). Exposure to HWLs in the real world, however, tends to be more passive because individuals are exposed to HWLs multiple times over prolonged periods of time. Consequently, experimental studies are unable to replicate the conditions of the real world and are therefore unable to take into account the social context, reducing their external validity.

Another criticism of graphic HWLs is that they cause smokers to avoid warnings. However, studies have shown that smokers who attempt to avoid warnings are no less likely engage in cessation behaviours at follow up(22,93). In fact, a study exploring the pathways through which HWLs influence smokers' behaviour found that avoidance of warnings had a positive association with thoughts about health risks and with thoughts about quitting smoking(105). This suggests that avoidant behaviour may be more reasonably considered a measure of HWL effectiveness(64).

2.8 Theoretical Frameworks

Several psychological theories can be applied to HWLs to help explain the mechanisms through which they achieve their effectiveness.

2.8.1 Theory of Reasoned Action/Planned Behaviour

The Theory of Reasoned Action/Planned Behaviour(150) is a psychological model commonly applied to health promotion. According to this model, an individual's behaviour is determined by his/her attitudes, subjective norms, and perceived behavioural control(81,151). In the context of smoking, an individual's intention to quit will be based on his/her personal beliefs about quitting, the social norm (disapproval of smoking), and his/her efficacy and perceived control of the situation(82). Quit intentions represent a smoker's motivation to follow through with the behaviour change (cessation), and an individual with stronger intentions is more likely to exert more effort to achieve the goal(152).

This theory therefore supports the implementation of HWLs that are culturally relevant, both health and socially oriented, and enhance smokers' efficacy to engage in cessation behaviour.

2.8.2 Elaboration Likelihood Model

The Elaboration Likelihood Model(153) of persuasion helps explain the superiority of graphic warnings over text-only messages. According to this model, individuals are persuaded through two major routes: the central route and the peripheral route. The central route of persuasion involves thinking carefully about the content of a message and its arguments. It involves purposeful and analytic thought processing that aims to gather all of the information

relevant to the judgment at hand. The peripheral route of persuasion, on the other hand, is characterized by rapid and simpler judgments produced without much cognitive effort or thought. For example, the peripheral route involves forming associations with simple cues or characteristics that can quickly captivate attention and generate emotion (such as pictures or symbols)(80,92,147,153).

Applied to warnings labels, the Elaboration Likelihood Model suggests that individuals engage in the central route when reading messages describing smoking-related health risks, causing them to think about the implications of their own behaviour. In contrast, the peripheral route is activated when individuals look at graphic images and form rapid negative associations to smoking even without thinking deeply about the message content. In this way, the Elaboration Likelihood Model supports the implementation of graphic warnings over text-only warnings, as both the central and peripheral routes are stimulated.

2.8.3 The Protection Motivation Theory

Protection Motivation Theory(154) is a theoretical framework originally developed to help explain fear appeals. This theory claims that individuals protect themselves based on four factors: the perceived *severity* of a threatening event, the perceived probability of its occurrence (*vulnerability*), the perceived efficacy of the recommended preventive behaviour (*response efficacy*), and the level of confidence in the ability to achieve recommended preventative behaviour (*self efficacy*)(154).

According to this theory, an individual's protection motivation is the result of threat appraisal (severity and vulnerability) and the coping appraisal (response efficacy and self efficacy)(154). Therefore, the Protection Motivation Theory suggests that graphic HWLs must

create an optimal level of fear, because the degree to which smokers will be motivated to stop smoking depends on their judgment of the threat as well as their perceived ability to quit successfully.

2.8.4 Extended Parallel Process Model

The Extended Parallel Process Model (EPPM)(155) is likely the most predominant theory in the fear appeal literature(156). This model is based on Leventhal's danger/fear control framework(157) as well as Rogers' Protection Motivation Theory(154). The EPPM stipulates that fear can motivate people to change their behaviour if they believe it will reduce their risk of negative consequences (perceived response efficacy), and if they have high levels of self-efficacy(155).

Central to the EPPM is the argument that threatening information that increases fear will only result in the desired behaviour change, or "danger control" behaviours, when response-efficacy and self-efficacy are high. When perceived fear is higher than efficacy, individuals typically engage in defensive avoidance behaviours, also known as "fear control" behaviours(155,157).

This concept of fear control is comparable to the theory of cognitive dissonance(158), which refers to the rationalization of certain behaviours or lifestyle choices that individuals experience when confronted with information that is in direct opposition to those behaviours. In the context of smoking, the theory of cognitive dissonance suggests that smokers with a greater dependency to smoking, and possibly lower self-efficacy, may rationalize their behaviour to help overcome the dissonance they feel when exposed to messages about the health risks of smoking, which in turn reassures them to continue the behaviour.

Overall, the EPPM (and the theory of cognitive dissonance) supports the implementation of fear-evoking HWLs that increase perceived threat and severity of health risks, although importantly combined with efficacy messages to increase confidence and efficacy among smokers.

2.8.5 Narrative Transportation Theory

Narrative Transportation Theory(159) helps explain the mechanisms through which personal messages such as testimonials achieve their effectiveness. According to this theory, story receivers can get "transported" or "lost" in a narrative, causing their attitudes to change to reflect those in the story(159,160). Narrative transportation often involves emotional involvement and feelings of empathy for the story characters, and can be enhanced by implementing culturally grounded narratives or when viewers personally identify with narrative characters (perceiving them to be similar to themselves)(160,161).

Narrative Transportation Theory argues that this 'transportation' is one of the most important mediating factors through which narratives, such as testimonials on HWLs, influence behaviour(161).

2.8.6. Summary

In summary, these theoretical frameworks suggest that fear-arousing graphic HWLs that increase the perceived risk of severity of smoking-related health consequences are likely to be most effective. However, smokers (particularly those with low efficacy) may reject strong, fear-evoking messages if warnings are not accompanied by supportive messages that aim to increase smokers' confidence in their ability to quit. Testimonial messages can further increase the

effectiveness of warnings by increasing smokers' emotional involvement and instigating feelings of empathy for individual's displayed on warning labels.

3.0 STUDY RATIONALE AND HYPOTHESES

3.1 Study Rationale

Despite steadily decreasing smoking rates in Canada, tobacco use remains the leading preventable cause of premature death in Canada(41). Approximately 100 Canadians die every day from smoking-related illnesses(8). Importantly, research has shown that although most people recognize that smoking is generally harmful, many underestimate the likelihood, magnitude, and severity of the health risks(19,62). It is therefore crucial that individuals are adequately informed about the harms associated with smoking.

Well-designed graphic health warning labels (HWLs) on cigarette packages have been recognized as an important strategy to inform the public about the harms associated with smoking, to help motivate smokers to quit, and to discourage initiation among non-smokers(12–14). With a high reach at the population level and a high frequency of exposure at the individual level, graphic HWLs are a highly cost-effective health communication strategy(12). Graphic HWLs can also reach disadvantaged populations such as smokers living in isolated areas, those with limited access to health services, or low-literacy smokers(64,66). Finally, research has demonstrated that graphic HWLs are particularly effective among low socioeconomic groups, who are disproportionately affected by the harms of tobacco use(12,30,90). Graphic HWLs therefore have a huge potential to influence populations if implemented in an optimal way.

The level of impact that HWLs have on cessation-related thoughts and behaviours depends on effective HWL design, content, and implementation(12). Determining the ways in which these factors increase HWL effectiveness is critical to help inform policymakers in implementing optimal tobacco control strategies to prevent smoking and promote cessation.

As the first country to require graphics on warning labels in 2001, Canada has been a world leader in the development of HWLs. However, research has shown that the effectiveness of these warnings has consistently decreased since their introduction(23). To reduce this wear-out effect, the Canadian HWLs were revised in 2012 to display new and larger graphics, new health messages and different warning styles (factual and testimonial).

This study is the first longitudinal evaluation of the impact of the 2012 Canadian graphic HWL revisions on cognitive and behavioural outcomes including key indicators of HWL effectiveness, beliefs about smoking-related health statements displayed on cigarette packages, affective reactions evoked by warnings, quit-efficacy and perceived difficulty of quitting, and intentions to quit and cessation-related behaviours. This is also the first study to investigate if cognitive and affective reactions mediate the effect of the Canadian graphic HWLs on smokers' quit intentions and quit attempts, and if the 2012 revisions impact these mediational pathways. This is important, because few studies have tested mediation of the effects of HWLs on smoking behaviour. This lack of research was highlighted in a recent meta-analysis conducted by Noar and colleagues(96), which reviewed the literature examining the effectiveness and impact of graphic HWLs. This study can therefore strengthen the international evidence base for the impact of HWLs and enhance the understanding of the functional mechanisms of HWLS.

Data for this research were drawn from nationally representative surveys conducted by the International Tobacco Control Policy Evaluation Project (ITC Project). Although the data collected directly before and after the 2012 revisions were of particular interest, all available ITC Project data (2002–2014) was used to take into account the trend *before* implementation. This is important, as the consideration of pre-policy time trends increases internal validity when

examining the impact of an intervention over time, and can reveal important information about its impact while taking the secular trend into account(25).

Other preliminary studies (commissioned by Health Canada) have examined the impact of the 2012 Canadian graphic HWLs. The Environics Research Group piloted a baseline evaluation of the graphic HWL messages, yet based its evaluation on telephone interviews conducted from March 7-31, before the date that retailers were given to transition to the revised cigarette packages(26). Harris/Decima also reviewed the 2012 Canadian graphic HWLs by measuring smoking-related outcome variables at the time of the revisions (March 2012), and compared the results to those obtained one year after implementation (March 2013)(27). This study will therefore be the first to measure the impact of the Canadian graphic HWLs before and after the 2012 revisions.

Finally, the current study will also investigate whether socioeconomic status (SES) moderated the impact of the graphic HWL revisions. In Canada, as in most countries, smoking is more common among those with lower levels of education and household income(32–34). Because tobacco use is a major source of health disparities(4), it is important to assess whether tobacco control policies can reduce those health disparities by providing benefits for smokers from all socioeconomic groups. For example, if a particular policy leads to significant benefits but only among high-income groups, this would exacerbate existing health disparities. On the other hand, if the policy impact is as great or greater among low socioeconomic groups, then the policy would have the potential to reduce health disparities. Exploring the impact of graphic HWLs by SES is therefor a critical component to evaluating their effectiveness.

Several studies exploring the perceived effectiveness of HWLs among differing socioeconomic groups suggests that graphic HWLs are typically perceived as more effective

among lower SES groups(72,89,90). A study among Mexican smokers found that those with lower education rated graphic warnings as more effective compared to smokers with higher education(90). In the US, emotionally evocative smoking cessation ads and testimonials aired on television were shown to have a greater impact among smokers with low- and mid-SES compared to those with high SES(89).

Other studies, however, have found that warning label reactions do not differ between subgroups(66,162,163). For example, Cantrell and colleagues showed that while graphic HWLs were associated with increased perceived impact and intentions to quit (compared to text-only warnings), these results did not differ by education or income(66).

To my knowledge, the question of whether SES is a moderator of warning impact has not been addressed in Canada.

3.2 Study Hypotheses

Five primary hypotheses were proposed:

Hypothesis 1

It is hypothesized that key indicators of warning label effectiveness (salience, cognitive and behavioural reactions) will increase following the implementation of new graphic HWLs in 2012. This hypothesis is based on previous research indicating that smokers become habituated to warnings when they are not periodically changed, and that salience of a message is greatest at initial exposure(12,23,94). Additionally, testimonials were added to the 2012 warnings, and research has shown that incorporating testimonials into HWLs increase their effectiveness(88,97,98,100,101).

Further, the increase in key indicators of warning label effectiveness will be higher among smokers with lower SES. This hypothesis is based on the fact that some of the newly implemented warnings display highly graphic warnings and personal testimonials, and studies have demonstrated that graphic warnings evoking affective reactions have a greater impact among lower SES groups(72,89,90).

Hypothesis 2

It is hypothesized that the new 2012 graphic HWLs will increase affective reactions among smokers due to the display of new graphic images and testimonials, and affective reactions will be associated with increased cessation-related behaviours. This hypothesis is based on previous literature demonstrating that health warnings are particularly effective at motivating smokers to quit when they evoke emotions, as these emotions are important mediators to quit intentions and behaviour change(70,88,92,97,101,114,117,119,131).

Additionally, smokers with low SES will have greater increases in affective reactions. This hypothesis is based on previous research showing adults with lower SES rate warnings with graphic depictions of disease as significantly more effective than respondents with higher SES(72,89,90).

Hypothesis 3

It is hypothesized that the implementation of the 2012 graphic HWLs will be associated with increased levels of correct beliefs about smoking-related health statements added to cigarette packages, whereas levels of correct beliefs will remain the same or decrease after health statements are removed from packages. This hypothesis is based on the assumption that the

novelty of the warnings will capture more attention, resulting in greater information processing of content and subsequent knowledge acquisition(18,19,21,64,69,102–104).

Additionally, the increase in correct beliefs will be greater for smokers from higher SES categories. This is based on the idea that smokers with higher SES typically have higher baseline levels of knowledge on smoking-related risks and therefore may be more receptive to new messaging about the dangers of smoking(36,103,108).

Hypothesis 4

It is hypothesized that levels of quit-efficacy will increase and perceived difficulty of quitting (a construct of self-efficacy) will decrease after the 2012 graphic HWL revisions. This hypothesis is based on the fact that the 2012 revisions required the inclusion of new interior messages displaying supportive messages designed to increase smokers' efficacy. These interior messages also provide cessation advice to help smokers quit.

It is also hypothesized that the expected increases in quit-efficacy and decreases in perceived difficulty of quitting will be greater for smokers from higher SES categories. This is based on the idea that smokers with lower SES may experience greater levels of stress due to a more demanding lifestyle, which negatively affects self-efficacy to quit(37).

Hypothesis 5

It is hypothesized that the 2012 graphic HWL revisions will be associated with increased intentions to quit and increased cessation-related behaviours including use of the toll-free quit line, quit attempts, and sustained smoking cessation. This hypothesis is based on research showing a positive association between increased cognitive processing of new/revised warning

labels and smokers' intentions to quit and actual quitting behaviour(21,93,105) (and assumes that the previous hypothesis will be correct, in that salience will increase after the second set of graphic HWLs).

Further, it is hypothesized that smokers with higher SES will have greater increases in intentions to quit, quit attempts, and sustained quitting rates. This hypothesis is based on previous research showing that Canadians with higher levels of education are more likely to engage in cessation-behaviours and to successfully quit smoking(30,34). Therefore, the magnitude of impact on quit intentions will be higher among these groups as well.

Hypothesis 6

It is hypothesized that graphic HWLs impact quit intentions and quit attempts through indirect routes mediated cognitive reactions (thinking about the risks of smoking due to warnings, thinking about quitting due to warnings, and perceiving warnings to be believable) and affective reactions (perceiving warnings as alarming, worrisome, or unpleasant). Although this mediatory effect will be evident before the revisions, the strength will be stronger after the graphic HWL revisions in 2012.

This hypothesis is based on research indicating that that affective reactions encourage viewers to quit smoking by evoking concerns for their health, and cognitive reactions from processing the health information lead to perceptions of risk and judgments about engaging in smoking(86,117,141,142). Additionally, research has shown that higher levels of fear are associated with higher quit rates(22).

Final note

Although I expect to see an increase in the above-mentioned outcomes of interest, these changes will likely only be modest increases and will not return to the levels seen after the introduction of the first set of graphic HWLs in 2001. In 2001, warning labels were modified from text-only messages covering the top 35% of the front and back panels to contain graphic images covering the top 50% of the front and back panels. These revisions were more radical compared to those implemented in 2012 (newly implemented graphic images and an increase in size from 50% to 75%), so it cannot be assumed that the impact will be as significant.

Moreover, the Canadian population has been exposed to graphic warnings for over a decade, and although a revision of warnings and the increase in size will help to reduce the effect of wear-out, the strength of the initial impact or "shock" of the graphic warnings cannot be replicated. More dramatic changes will be necessary to illicit greater effects on smoking-related cognitions and behaviours (such as plain packaging, which is currently being considered for implementation by Health Canada).

4.0 METHODOLOGY

4.1 Study design

Data for this study were drawn from Waves 1 to 9 of the ITC Canada Survey. The ITC Canada Survey is part of the ITC Four Country (ITC-4) Survey, a prospective nationally representative cohort survey of adult smokers from Canada, Australia, the US, and the UK. ITC surveys are designed to evaluate the psychosocial and behavioural impact of key national-level tobacco control policies of the WHO Framework Convention on Tobacco Control (FCTC), including health warning labels (HWLs).

4.2 Sampling design

The nine waves of the ITC Canada Survey were administered between 2002 and 2014. Information about each survey wave is shown in Table 2.

Table 2. Summary of characteristics of ITC Canada Wave 1-9 Surveys

Wave	Survey mode	Survey Dates	Survey Firm
1	Telephone	October – December 2002	Environics Research Group
2	Telephone	May – September 2003	Environics Research Group
3	Telephone	June – December 2004	Roy Morgan Research
4	Telephone	October 2005 – Jan 2006	Roy Morgan Research
5	Telephone	October 2006 – February 2007	Roy Morgan Research
6	Telephone	September 2007 – February 2008	Roy Morgan Research
7	Telephone and web (pilot)	October 2008 – February 2009	Survey Research and Data Acquisition Resource (SRDAR)
8	Telephone and web	July 2010 – June 2011	SRDAR (telephone) and Survey Research Centre (SRC) at University of Waterloo (web)
9	Telephone and web	August 2013 – May 2014	SRDAR (telephone) and Survey Research Centre (SRC) at University of Waterloo (web)

Source: ITC Canada National Report

Data for Waves 1 to 6 were collected using computer assisted telephone interviews (CATI), following a random-digit dialing (RDD) sampling design to ensure random selection of households (with land lines) within strata defined by 14 geographical regions. Online web-based surveys were piloted in Wave 7 and made available for all respondents in Waves 8 and 9. Respondents who did not complete the web survey within a set timeframe were re-routed back into the telephone interview queue to complete the survey by CATI(164).

Survey administration time lengths varied significantly across waves. For example, Wave 1 surveys were conducted over the course of two months (October to December 2002), whereas Wave 9 surveys were administered over the course of 14 months (August 2013 to October 2014). Importantly, these differing survey periods left the possibility open for systematic differences in

responses to occur as a function of exposure time. In other words, lengthy administration periods are vulnerable to within-wave wear-out, in that respondents surveyed at the end of a wave would have been exposed to warnings much longer compared to respondents surveyed at the beginning of the wave. However, the possibility of within-wave wear-out was tested in the current study and found not to have significantly impacted smokers' responses (explained in detail in Appendix B).

4.3 Participants

Participants of the ITC Canada Surveys included smokers aged 18 years and older. Smokers were defined as having smoked more than 100 cigarettes in their lifetime and smoke at least monthly. Retention and response rates are displayed in Table 3.

Table 3. Number of respondents, retentions rates and response rates per wave

Wave	n	Response rate (%)	Retention rate (%)
1	2,214	N/A	-
2	2,196	N/A	75.8
3	2,108	N/A	71.2
4	2,029	18.4	71.6
5	2,022	35.7	70.4
6	2,015	11.8	72.2
7	1,846	29.7	75.7
8	1,581	29.4	74.4
9	1,592	13.8	71.8

Source: ITC Canada National Report

Once respondents are included in the ITC Survey, every effort is made to track and re-contact them at subsequent waves. However, as in any longitudinal survey, respondents are lost to attrition over time. As shown in Table 3, the retention rates ranged from 70.4% to 75.7%, and the corresponding attrition rates ranged from 11.8% to 35.7%(165). To maintain a sufficient sample size (between 1,500-2,000 respondents), new respondents were recruited at each wave. Each wave was thus made up of re-contacted respondents with previous experience with ITC surveys, and newly recruited respondents with no previous experience. These differences in experience are important because survey responses have been shown to systemically vary based on the number of times a respondent has completed the survey(166). These effects, known as "time-in-sample" effects, need to be controlled for when conducting analyses across multiple waves. To do this, time-in-sample was included as a covariate in regression models(166).

4.4 Survey administration, informed consent, and confidentiality

Each respondent completed two surveys: the Recruitment Survey and the Main Survey. The Recruitment Survey, which lasted an average of 9-13 minutes, was conducted at first contact to screen for eligibility and obtain informed consent. Respondents were told they would receive a small compensation (15$ CDN) to thank them for their cooperation and were assured that their responses would be kept strictly confidential. Additional information was provided on the details of the study, the research institutions and survey firm involved, and the contact information for the research team and the ethics committee. Respondents were contacted approximately six months later to complete the Main Survey, which lasted approximately 35-40 minutes(165).

4.5 Ethical approval

Research ethics approval was obtained from the University of Waterloo Human Research Ethics Committee.

4.6 Measures

Complete survey questionnaires for ITC Canada Waves 1 to 9 are publically available online(167).

4.6.1 Socio-demographic and smoking behaviour variables

Socio-demographic and smoking behaviour information was collected for all respondents to determine if the various trends explored in this study differed by these individual-level characteristics (and to include them as covariates in regression models).

Socio-demographics

The socio-demographic variables included in this study were:

Sex (male or female),

Age group (18-24 years, 25-39 years, 40-54 years, or 55 years and older),

Household income (low= less than $30,000; moderate= $30,000-$59,999, high= $60,000 or more; or not stated), and

Education (low= high school diploma or lower; moderate= technical, trade school, community college, or some university; or high= completed university or postgraduate)

Smoking behaviour variables

Smoking behaviour variables included smoking status and the Heaviness of Smoking Index (HSI).

Smoking status was defined as daily smoker, non-daily smoker (weekly or monthly smoker), or former smoker (re-contacted respondents who had quit smoking in a previous wave).

The HSI, which assesses smoking dependency, consists of two measures: time to the first cigarette of the day (TTF) and number of cigarettes smoked per day (CPD). Both variables measure dependency.

The first variable, TTF, is theoretically important because those who smoke early earliest after waking are considered most addicted to cigarettes (coded 0= 60 or more minutes after waking; 1= within 31–60 minutes; 2= within 6–30 minutes; or 3= less than 5 minutes)(168).

The second variable, CPD, also represents smoking dependency, and higher numbers of cigarettes smoked per day represents higher dependency (coded 0= 1–10 cigarettes per day; 1= 11–20 CPD; 2= 21–30 CPD; or 3= 31 or more CPD)(168,169).

When summed, they give a scale ranging from 0 to 6, with a higher number indicating greater smoking dependence(168). In the current study, HSI values 0 or 1 were coded as low HSI, values 2 or 3 were coded as moderate, and values 4, 5 and 6 were coded as high HSI due to low frequencies in some categories(170).

4.6.2 Key indicators of warning label effectiveness (HWL responses)

Warning label effectiveness was measured using three groups of indicators (HWL responses) – salience, cognitive reactions, and behavioural reactions – and the Labels Impact Index (LII), described below. These indicators have been used to evaluate the effectiveness of

HWLs in every ITC study across many countries(171) and are described in the section on evaluating HWLs in the 2008 Cancer Prevention Handbook of the International Agency of Research on Cancer on methods for evaluating the effectiveness of tobacco control policies, a compendium of best practices(25).

Salience

Salience was measured by two questions: 1) NOTICING: "In the last month, how often, if at all, have you noticed warnings on cigarette packages?" (Response options: 'never', 'rarely', 'sometimes', 'often', or 'very often') and 2) READING: "In the last month, how often, if at all, have you read or looked closely at the warning labels on cigarette packages?" (Response options: 'never', 'rarely', 'sometimes', 'often', or 'very often').

Cognitive reactions

Cognitive reactions were measured by two questions: 1) RISKS: "To what extent, if at all, do the warning labels make you think about the health risks of smoking?" (Response options: 'not at all', 'a little', 'somewhat', or 'a lot') and 2) QUITTING: "To what extent, if at all, do the warning labels on cigarette packs make you more likely to quit smoking?" (Response options: 'not at all', 'a little', 'somewhat', or 'a lot'). Both RISKS and QUITTING measures are only available from Waves 2 to 9.

Behavioural reactions

Behavioural reactions were measured by two questions: 1) FORGO: "In the last month, have the warning labels stopped you from having a cigarette when you were about to smoke

one?" (Response options: 'never', 'once', 'a few times', or 'many times') and 2) AVOID: "In the last month have you made any effort to avoid looking or thinking about the warning labels, such as covering them up, keeping them out of sight, using a cigarette case, avoiding certain warnings, or any other means?" (Response options: 'yes' or 'no'). The AVOID measure is only available from Waves 6 to 9.

Labels Impact Index

The LII is a composite measure that combines four key indictors of warning label effectiveness (NOTICING, RISKS, QUITTING, and FORGO). The LII was constructed by standardizing the original measures and then weighting and summing the standardized scores as follows:

LII = (NOTICING*1) + (RISKS*2) + (QUITTING*2) + (FORGO*3)

The measures were weighted according to their impact on quit attempts based on previous research(93). Some of these measures (RISKS and QUITTING) were not included in the Wave 1 survey, so the LII is only available for Waves 2 – 9 only. Higher LII scores indicate greater impact.

4.6.3 Affective reactions evoked by warnings and warning believability

An important aspect of the 2012 graphic HWL revisions was the addition of testimonials (brief narratives describing personal consequences of smoking, typically written as a quote from a person in the image). These testimonials may have caused viewers to experience greater levels of sadness or displeasure due to empathy. The revised warnings also displayed more gruesome and graphic images, potentially causing viewers to experience greater levels of alarm or worry.

These affective reactions (alarm, worry, and displeasure) were measured in the current study (at Wave 8 and Wave 9 only). Measuring the possible changes in affect is important because HWLs have been shown to be particularly effective at motivating smokers to quit when they evoke negative emotional reactions(12,88,92,100,101,130,172).

To measure these possible changes in affective reactions evoked by warnings, the following questions were asked:

Alarm

To assess if warning labels make smokers feel alarmed, they were asked, [ALARM:] "How do the warning labels make you feel? Do they make you…?" (Response options: 'very alarmed', 'somewhat alarmed', 'neither alarmed nor calm', 'somewhat calm', or 'very alarmed').

Worry

To assess if warning labels make smokers feel worried, they were asked, [WORRY:] "How to the warnings make you feel? Do they make you…?" (Response options: 'extremely worried', 'very worried', 'somewhat worried', 'a little worried', or 'not worried at all').

Displeasure

To assess if warning labels make smokers feel unpleasant, they were asked, [DISPLEASURE:] "How do the warnings make you feel? Are the feelings…?" (Response options: 'very unpleasant', 'somewhat unpleasant', 'neither unpleasant nor pleasant', 'somewhat pleasant', or 'very pleasant')

Believability

The persuasion theory of Fishbein and Ajzen(81) argues that messages must be believable in order to influence behaviour. If persuasive messages are to be effective, smokers must first accept or believe these messages displayed on cigarette packages(173).

To assess if smokers in this study find warnings believable, they were asked, "How believable do you think the health warnings are?" (Response options: 'not at all believable', 'a little believable', 'somewhat believable', 'very believable', or 'extremely believable'). This variable was also only measured in Wave 8 and Wave 9.

4.6.4 Beliefs about smoking-related health statements

Beliefs about the smoking-related information displayed on cigarette packages was examined to test the impact of adding health information to warnings and the impact of removing health information from warnings, both of which occurred as a result of the 2012 graphic HWL revisions. The belief about a health fact that was displayed both before and after the revisions was also tested (as a control measure).

The smoking-related information displaying on cigarette packages before and after the 2012 graphic HWL revisions is presented in Table 4.

Table 4. Health statements displayed on Canadian cigarette packages

Statements displayed before 2012 revisions	**Statements displayed after 2012 revisions**	**Survey waves that included measures**
Smoking causes stroke	Smoking causes stroke	Waves 1-8 (pre-2012), Wave 9 (post-2012)
Smoking causes impotence	-	Waves 1-8 (pre-2012), Wave 9 (post-2012)
-	Smoking causes bladder cancer	Wave 8 (pre-2012), Wave 9 (post-2012)
-	Smoking causes blindness	Waves 3-8 (pre-2012), Wave 9 (post-2012)
Cigarette smoke contains carbon monoxide	-	Waves 1-5, 8 (pre-2012), Wave 9 (post-2012)
-	Nicotine is the substance that causes addiction	Waves 6-8 (pre-2012), Wave 9 (post-2012)

Smokers were asked if they 'agree', 'disagree', or 'don't know' if smoking causes the following health outcomes: stroke, impotence, bladder cancer, and blindness. Smokers were also asked if they 'agree', 'disagree', or 'don't know' if cigarette smoke contains carbon monoxide and if nicotine is the main substance in cigarettes that makes people smoke (causes addiction) (Response options: 'true', or 'false').

4.6.5 Interior messages

In 2012, the interior messages previously implemented in 2001 were revised to provide new advice and coping information to promote self-efficacy to quit smoking. To determine how often smokers read these interior messages, smokers were asked, "Now thinking about printed material INSIDE of packs… how often, if at all, have you read the health warnings on the inside of cigarette packs?" (Response options: 'never', 'rarely', 'sometimes', 'often', or 'very often'). This variable was measured in Wave 9 only.

4.6.6 Quit-efficacy and perceived difficulty of quitting

The Extended Parallel Process Model (EPPM)(155) claims that HWLs are most effective when messages induce fear and if respondents have high levels of self-efficacy to quit. In fact, some researchers have argued that threatening warnings only have the desired effects among smokers with high efficacy, while smokers with low efficacy may instead engage in defensive reactions (such as avoidance or increased smoking)(142,146).

To measure quit-efficacy in the current study, smokers were asked, "If you decided to give up smoking completely in the next 6 months, how sure are you that you would succeed?" (Response options: 'not at all sure', 'slightly sure', 'moderately sure', 'very sure', or 'extremely sure').

To measure perceived difficulty of quitting (a construct of self-efficacy), smokers were asked, "How easy or hard would it be for you to quit smoking if you wanted to?" (Response options: 'very easy', 'somewhat easy', 'neither easy nor hard', 'somewhat hard', or 'very hard').

4.6.7 Quit intentions and cessation-related behaviours

To assess if the 2012 graphic HWL revisions impacted smokers' downstream quit intentions and cessation-related behaviours, variables measuring quit intentions, quit attempts, and rates of sustained quitting were included in this study. The telephone number for the national quit line was added to cigarette packages in 2012, so rates of quit line use were also analyzed.

To measure quit intentions, smokers were asked, "[When] are you planning to quit...?" (Response options: 'within the next month', 'within the next 6 months', 'sometime in the future, beyond 6 months', or 'not planning to quit').

To assess quit line use among smokers who reported having a quit attempt since the last survey date (LSD), respondents were asked, "Did you use telephone or quit line services?" (Response options: 'yes' or 'no'). This variable is available for Wave 8 and Wave 9 only.

To measure quit attempts among smokers and former smokers (who had quit smoking since the LSD), respondents were asked, "Have you made any attempts to stop smoking cigarettes since we last talked with you, that is, since [last survey date]?" (Response options: 'yes' or 'no').

To measure sustained smoking cessation, smokers and former smokers who reported making a quit attempt were asked, "Are you back to smoking or are you still stopped?" (Response options: 'back to smoking', or 'still stopped').

4.7 Analyses

4.7.1 General approach

All analyses were conducted using SAS version 9.4. To explore the wave-to-wave trends of the outcomes of interest, generalized estimating equation (GEE) regression models were conducted to compute the least squares means at each wave with data available. GEE models account for within-subject correlation arising when outcomes are measured on the same respondent more than once(174).

GEE analyses were conducted with a binomial distribution and the logit link for dichotomous variables. For continuous variables, GEEs were conducted with a normal distribution and identity link. All GEE analyses conducted in this study were adjusted for sex, age group, income, education, smoking status, HSI, wave, survey mode (web or telephone survey), and time-in-sample (the number of prior survey waves a respondent has previously

participated in).

Although the change from Wave 8 to Wave 9 was of particular interest (the 2012 revised warnings were implemented between these two waves) data from all nine waves were used to evaluate the impact of the HWL revisions to take into account the trend *before* implementation. This is important, because the consideration of pre-policy time trends increases internal validity when examining the impact of an intervention over time, and can reveal important information about its impact on the secular trend(25).

For example, if the GEE analyses show that there was no significant change in the means of a warning response variable between Wave 8 (pre-2012) and Wave 9 (post-2012), it does not necessarily mean that the 2012 HWL revisions had no effect on this warning response. This is because if the pre-policy data (Waves 1-8) show a significant decline of the warning response variable (wear-out), then the revisions in fact had an important impact in that it stopped the downward trend. Therefore, evaluating the impact of policies is best conducted when the data allow the evaluation to take place within the context of time trends(25).

Contrast estimates were conducted to produce comparisons (Wave 1 vs. Wave 8 for the trend prior to the 2012 graphic HWL revisions, and Wave 8 vs. Wave 9 for the trend after the HWL revisions). Because the time between survey waves varied, the median date of each wave was calculated and used to plot the secular trends of the variables.

In addition to comparing variable means at each wave with the GEE analyses, segmented regression models were conducted to explore possible changes in trends (slopes) before and after the 2012 graphic HWL revisions. Segmented regressions (also known as piece-wise regressions or bent-line regressions) consist of dividing a linear regression into separate intervals at a

specified "breakpoint", and a line segment is fit to each interval. When conducted appropriately[1], the difference at the "breakpoint" between the regression intervals can be taken as evidence of a treatment effect(175). Segmented regressions are implemented in cases where a single linear model does not accurately represent the data for different ranges of a variable of interest(176).

The advantage of using segmented regression analyses in the current study is that they are able to account for the secular trend in the data as well as for the differing time intervals between waves (time points as continuous variables rather than waves as categorical variables). Additionally, by assigning the segmented regression "breakpoint" to be the time of the 2012 graphic HWL revisions, comparing the slopes of both line segments can produce more time-precise interpretations of their impact.

Segmented regressions were conducted for all variables with data available in at least three waves. To construct the segmented regression in the current study, the median date of Wave 1 was set to T_1=0. The number of days between the median date of Wave 2 and T_1 was set as T_2. The number of days between the median date of Wave 3 and T_1 was set as T_3, and so on. The exact median dates used for each wave is presented in Appendix C.

Due to the large overall timespan of all nine waves, days were converted to years. The segmented regression "breakpoint" was set to the last possible date (June 19, 2012) that retailers were given to transition to packages displaying the new warnings(50). Contrast estimates determined if the slopes of the two line segments were statistically different ($p < 0.05$).

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[1] Segmented regression analyses often require the estimation of the "breakpoint" between the regression lines. Since the treatment effect is measured as the difference between the estimated regressions, an inaccurate estimation of the "breakpoint" can bias the treatment effect estimate(175). The current study, however, is unlike many other circumstances in that the "breakpoint" is already known (the date of the 2012 graphic HWL revisions), thereby eliminating the possibility of this bias.

In separate segmented regression analyses, two-way interactions between survey wave and level of education, survey wave and level of income, and survey wave and HSI was tested among all variables to explore possible moderators of the impact of the 2012 graphic HWL revisions. If significant moderation was found, separate segmented regression analyses were repeated for each level of the moderator to determine the effect (e.g. if HSI was found to moderate the increase of a particular outcome, separate segmented regression analyses were repeated for smokers with low, moderate, and high HSI).

All analyses, except for sample characteristics, were weighted to make the sample representative of the Canadian population. Weights used were either rescaled cross-sectional or longitudinal weights, depending on the nature of the analysis. Further information on how weights were constructed for the ITC-4 Surveys can be found in a paper by Thompson and colleagues(177).

For all analyses in this study, tests with associated p-values of $p < 0.05$ determined statistical significance.

4.7.2 Key indicators of warning label effectiveness (HWL responses)

To ensure comparability to other ITC studies(171), all warning label effectiveness variables were analyzed as a dichotomous measure except for the LII.

For the NOTICING and READING variables, response options were coded as 0: 'never', 'rarely', 'sometimes'; and 1: 'often', 'very often'. For the RISKS and QUITTING variables, response options were coded as 0: 'not at all', 'a little', 'somewhat'; and 1: 'a lot'. The FORGO variable was coded as 0: 'never'; and 1: 'once', 'a few times', 'many times'. The AVOID variable was already a dichotomous variable (Coded 0: 'no'; and 1: 'yes').

Wave-to-wave GEE analyses were conducted for all variables to plot trends. Segmented regression analyses were conducted to explore changes in slope before (Waves 1–8) and after (Waves 8–9) the 2012 graphic HWL revisions.

Cross-tabulation and correlation analyses were conducted between each warning response variable and affective reactions evoked by warnings, rates of reading interior messages, quit-efficacy and perceived difficulty to quit, and quit intentions and cessation-related behaviours.

4.7.3 Affective reactions evoked by warnings and warning believability

Variables assessing affective reactions (ALARM, WORRY, and DISPLEASURE) evoked by warnings and warning believability were left as continuous variables with a scale of 1 to 5. Reactions were coded so that high scores indicate greater levels of alarm, worry, displeasure, and believability.

Wave-to-wave GEE analyses were conducted to plot means in Wave 8 and Wave 9. Segmented regression analyses were not possible because these variables were only available in Wave 8 and Wave 9.

Cross-tabulation and correlation analyses were conducted between each affective reaction and HWL responses, rates of reading interior messages, quit-efficacy and perceived difficulty to quit, and quit intentions and cessation-related behaviours.

4.7.4 Beliefs about smoking-related health statements

Beliefs about smoking-related information were examined according to whether health information was <u>added</u> to warning labels after the revisions (smoking causes bladder cancer;

smoking causes blindness; and nicotine causes addiction), removed from warning labels after the revisions (smoking causes impotence; and cigarette smoke contains carbon monoxide), or whether information was continuously displayed during both HWL rotations (smoking causes stroke). For measures questioning respondents on health-impacts of smoking, responses were coded 0: 'no', 'don't know'; and 1: 'yes'. Responses were coded 0: 'false'; and 1: 'true' for the measure questioning respondents about whether nicotine is the substance that causes addiction.

Wave-to-wave GEE analyses were conducted to plot trends for data at each wave where available. Segmented regression analyses were conducted to explore changes in slope before and after the 2012 graphic HWL revisions (except for the bladder cancer variable that only had data available at Wave 8 and Wave 9).

4.7.5 Interior messages

The rate of reading interior messages at least "sometimes" was investigated by dichotomizing the measure (Coded 0: 'never', 'rarely'; and 1: 'sometimes', 'often', 'very often'). Regression analyses were conducted to explore socio-demographic predictors of reading interior messages. Cross-tabulation and correlation analyses were conducted between reading interior messages and quit-efficacy and perceived difficulty of quitting, and quit intentions and cessation-related behaviours (Wave 9 only).

To compare rates of reading interior warnings at least "sometimes" to reading exterior warnings at least "sometimes", the READING measure (of the exterior graphic HWL) was re-coded (Coded 0: 'never', 'rarely'; and 1: 'sometimes', 'often', 'very often').

4.7.6 Quit-efficacy and perceived difficulty of quitting

Variables measuring quit-efficacy and perceived difficulty of quitting (a construct of self-efficacy) were kept continuous (on a scale of 1 to 5). Higher scores indicate higher levels of quit-efficacy and perceived difficulty of quitting. Wave-to-wave GEE analyses were conducted to plot the trends for each measure. Segmented regression analyses were conducted to explore changes in slope before and after the 2012 graphic HWL revisions. Correlation analyses were conducted between both variables and with quit intentions and cessation-related behaviours.

4.7.7 Quit intentions and cessation-related behaviours

Quit intentions (original survey response options: 'within the next month', 'within the next 6 months', 'sometime in the future, beyond 6 months', or 'not planning to quit') were categorized three ways: 1) intending to quit sometime in the future (first three response options); 2) intending to quit within the next 6 months (first two response options); and 3) smokers who were not intending to quit (fourth response option only).

Variables measuring quit line use, quit attempts since the LSD, and sustained smoking cessation remained dichotomous.

Wave-to-wave GEE analyses were conducted to plot trends for each measure. Segmented regression analyses were conducted for quit intentions, quit attempts and sustained cessation.

4.7.8 Mediation Models

A series of mediation models were developed to explore the mechanisms through which the Canadian graphic HWLs influence smokers' quit intentions and quit attempts. In mediation,

the influence of intermediate variables (mediators) are explored to help explain how or why an independent variable (HWLs) influence an outcome (quit intentions or quit attempts)(178).

In the current study, it was hypothesized that there are two indirect routes through which HWLs could influence quit intentions and quit attempts: through cognitive reactions to warnings and through affective reactions to warnings.

Structural equation modeling (SEM) was used to test the proposed mediation models. Although regression-based models have often been used when studying the impact of HWLs, these analyses have limited the understanding of how and why HWLs work(105). SEM provides several important advantages and was used in the current study for the following reasons:

First, SEM allows for complex dependencies; that is, relationships between several dependent and independent variables. SEM can therefore perform simultaneous analyses of several variables in a model rather than running them separately(178,179). Because of this, SEM is better suited for more complex models.

Second, SEM has the ability to model key constructs using latent variables (unobserved variables), in contrast to regression analysis which only accommodate observed variables(105,178,179). In SEM, a measurement model defines theoretical constructs (often latent variables, e.g. HWL salience) that are inferred through indicator/manifest variables (e.g. reading warnings closely), and a structural model defines the causal and correlation links between theoretical constructs(180). By these means, biases and measurement errors of key variables can be accounted for, providing for a more precise examination of the relationships between latent variables. Modeling the relationships of latent variables is potentially a better method than modeling the relationships through the imperfect measurements of the indicators (observed variables) because those indicators include measurement error, which leads to lower

precision(179).

A third reason SEM is better suited for the current mediation analyses is that it is largely a confirmatory technique that can help to explain complex processes and relationships, such as those involved with how HWLs impact cessation-related behaviours. In contrast, regression models are more suited for prediction(181).

Model constructs and measures

First, the measurement model was outlined. The measurement model describes how observed/indicator variables are related to latent variables. Although the composition of latent variables was the same for each mediation model, Model 1 used indicator variables from 2010, Model 2 used indicator variables from 2013, and Models 3 and 4 used variables from both years (mediation model diagrams are explained in further detail below).

The *HWL Salience* construct was inferred using two (continuous) indicator variables: noticing warnings and reading warnings closely. Indicator variables were significantly ($p<0.001$) and positively correlated with each other in Wave 8 and Wave 9.

The first mediational construct, *Cognitive Reactions,* was inferred by three (continuous) indicator variables: thinking about risks due to warnings, thinking about quitting due to warnings, and forgoing a cigarette due to warnings. Indicator variables were significantly ($p<0.001$) and positively correlated with each other in Wave 8 and Wave 9.

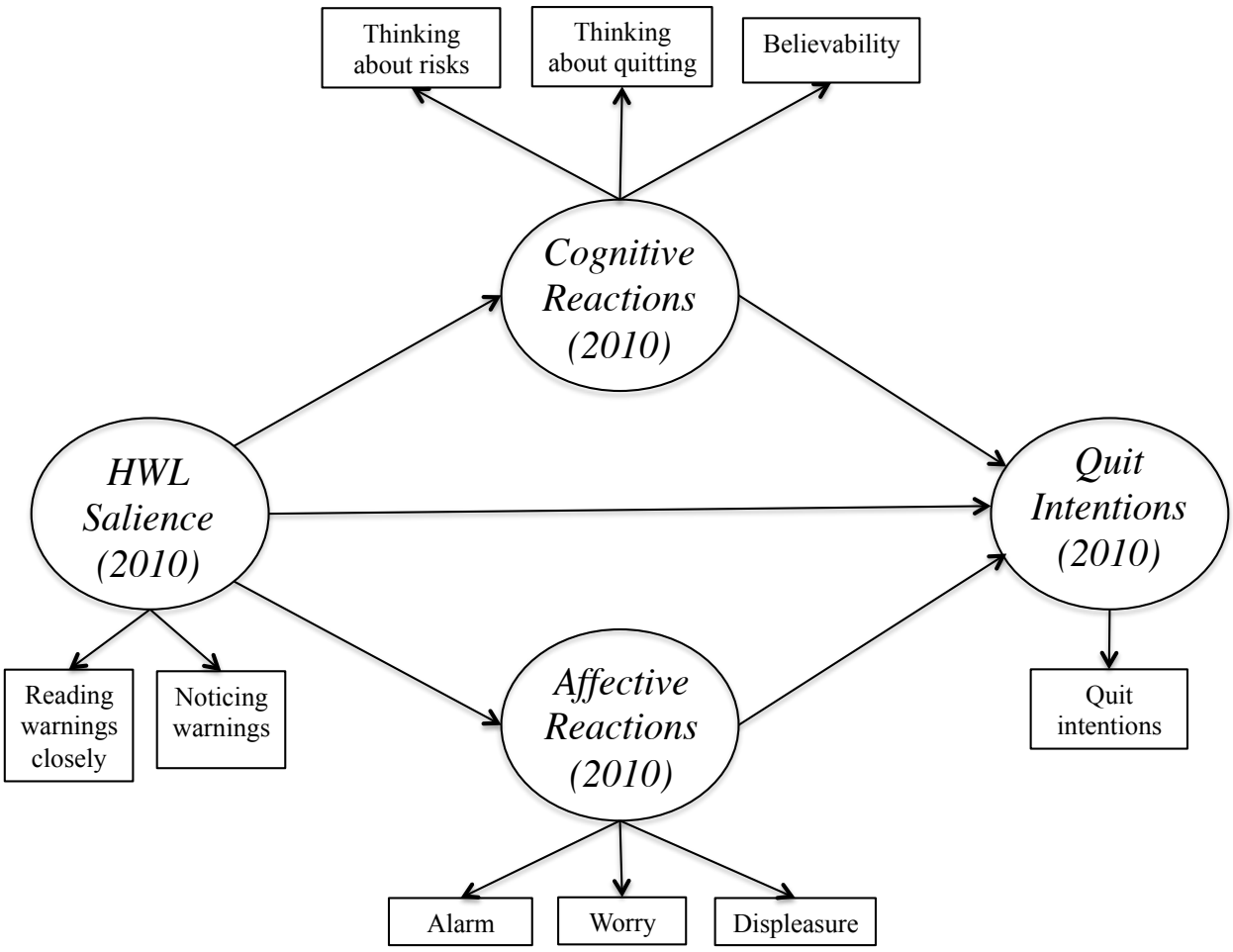
The second mediational construct, *Affective Reactions*, was inferred by three (continuous) indicator variables: warnings make smokers feel alarmed, warnings make smokers feel worried, warnings make smokers feel unpleasant. These variables were significantly ($p<0.001$) and positively correlated with each other in Wave 8 and Wave 9.

Finally, the two dependent variables, *Quit Intentions* and *Quit Attempts*, were each composed of a single indicator variable. Therefore, the latent variable was identical to the indicator variable (quit intentions was continuous and quit attempts was dichotomous).

Next, the structural model describing the functional relationships (links) between constructs was defined for each mediation model. By convention, ovals represented latent variables and rectangles represent indicator variables(178).

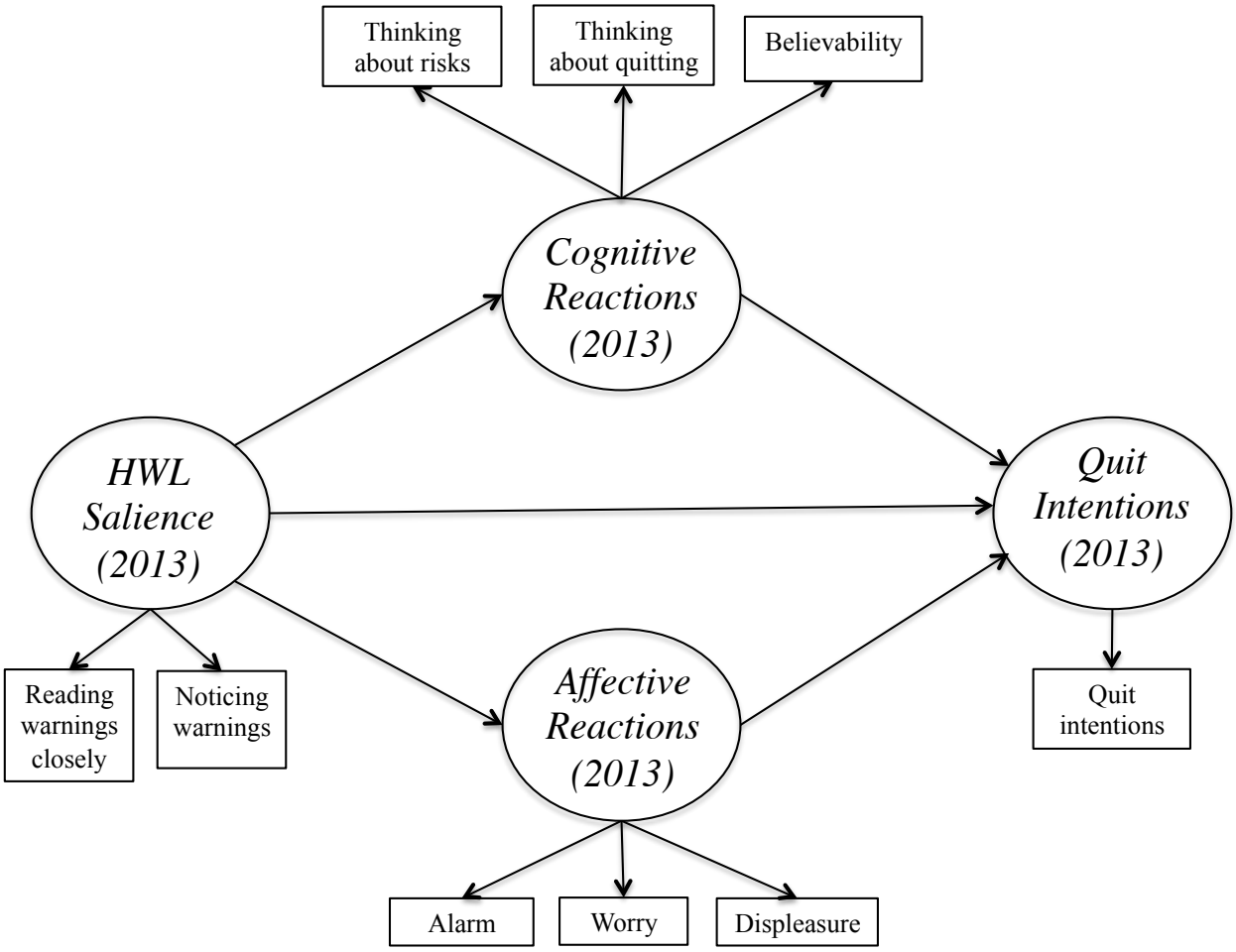
Model 1 (Figure 4) examines the impact of the Canadian graphic HWLs on quit intentions through the meditational pathways of cognitive reactions and affective reactions in 2010 (Wave 8), before the 2012 graphic HWL revisions.

Figure 4. Mediation model (1) for the impact of HWLs on quit intentions (Wave 8, prior to the 2012 graphic HWL revisions)



Model 2 (Figure 5) is a replication of Model 1, but uses data from 2013 (Wave 9), after the 2012 graphic HWL revisions. Comparing the results of Models 1 and 2 provides insight on the stability of the hypothesized mediational model, and shows how the 2012 graphic HWL revision may have impacted the mediational pathways (by looking at the strengths of association between constructs).

Figure 5. Mediation model (2) for the impact of HWLs on quit intentions (Wave 9, after the 2012 graphic HWL revisions)



Model 3 (Figure 6) examines the *changes* in the relations among constructs due to the 2012 graphic HWL revisions. Specifically, this model tests if the *change* in HWL salience (expected to be an increase after the 2012 graphic HWL revisions) led to corresponding *changes* in the two mediators—cognitive reactions and affective reactions—and if those *changes* led to corresponding *changes* in quit intentions. In this model, each indicator was set as the difference between its 2010 (Wave 8) and 2013 (Wave 9) measure.

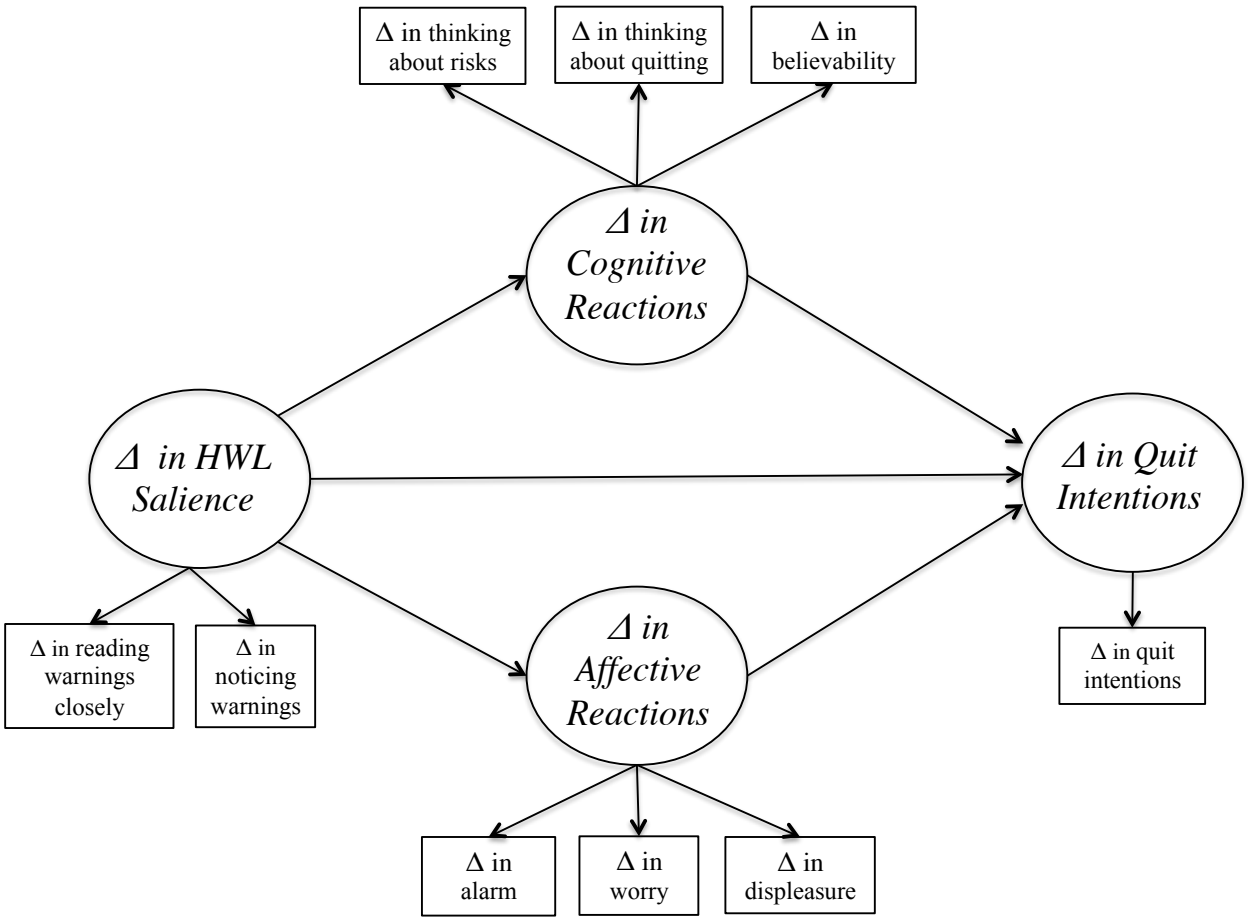
This mediation model is particularly important because it captures the possible causal mechanisms of the mediational pathways that changed during the transition from the previous warnings to the revised warnings. If the assumption that mediating variables are causally related to the outcome is correct, then an intervention that changes the mediating variables will change the dependent variable(182). Mediation analyses are becoming more popular in intervention studies for this reason(182,183).

Using longitudinal data to study whether an intervention led to changes in the mediator and subsequent changes in the outcome also incorporates the aspect of temporality(183). This is important because mediation models with accurate representations of the temporal order of change over time can lead to more meaningful conclusions about cause and effect(178).

Finally, it is important to note that this model only captures smokers who were not successful in quitting in the previous wave. This is because smokers who successfully quit are not asked about their quit intentions in the following survey wave, so were therefore not included in the sample. However, although the sample may be partially biased towards smokers who were not able to quit, the relationship between constructs is not biased because it is consistent in both years (Wave 8 and Wave 9). Therefore, this model still provides useful information about how

changes in HWL salience and in cognitive and affective mediators influence changes in smokers' quit intentions.

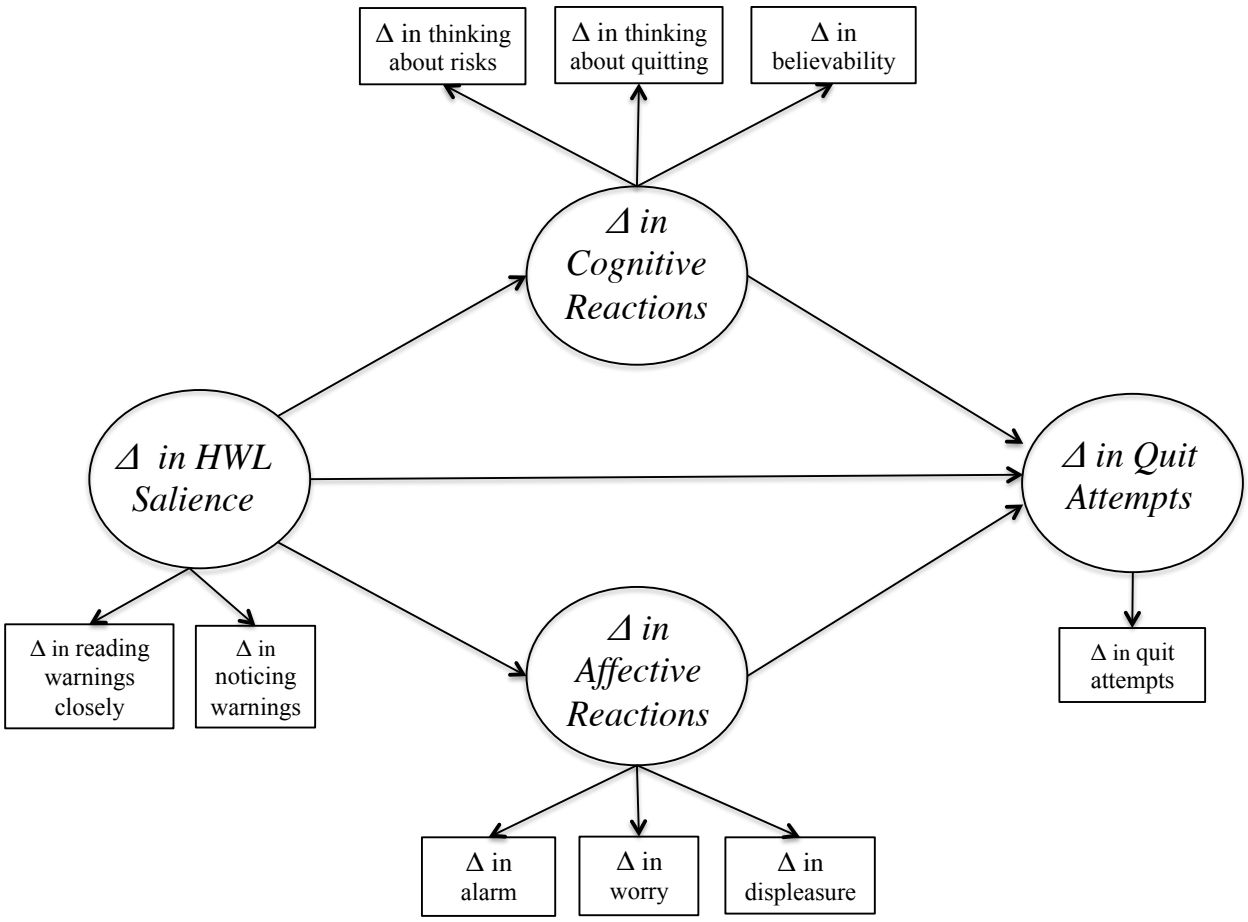
Figure 6. Mediation model (3) for the changes in impact of HWLs on quit intentions between 2010 and 2012 (Wave 8 and Wave 9)



Model 4 (Figure 7) investigates changes in mediational pathways that influence quit behaviour among smokers. Specifically, this model examines if changes in HWL salience and changes in cognitive/affective reactions to warnings between 2010 and 2013 led to changes in quit attempts. As in Model 3, measuring the changes in the mediator and outcome variables from before and after the graphic HWL revision can help to provide useful interpretations of the intervention impact. Unlike Model 3, the sample in Model 4 is unbiased because all respondents included in the survey (smokers and former smokers) were asked if they had any quit attempts since the LSD.

Importantly, it is not possible to include both quit intentions and quit attempts in one mediation model because of the discrepancies in the sample (only smokers are asked about their intentions to quit whereas all respondents are asked about their attempts to quit since the LSD). Additionally, including both quit intention and quit attempt variables would require another post-policy survey wave (Wave 10), because quit intentions and quit attempts cannot be measured from the same wave (quit attempts must follow quit intentions). Investigating the association of the changes in quit intentions and quit attempts between the same two surveys waves would therefore lead to temporal errors.

Figure 7. Mediation model (4) for the changes in impact of HWLs on quit attempts between 2010 and 2012 (Wave 8 and Wave 9)



Analytical procedure

SEM was conducted using the CALIS procedure in SAS. The EFFPART statement was used to partition the total effects of HWL salience on quit intentions and quit attempts into the direct effect (the association between HWL salience and quit intentions, controlling for cognitive and affective reactions) and the indirect effect (the association between HWL salience and quit intentions, via cognitive reactions and/or affective reactions)(184). The total effect of the association of HWL salience on quit intentions equals the sum of the direct and indirect effects.

All measures in the analyses were treated as continuous measures except for quit attempts, which was originally measured as a dichotomous variable (attempting to quit since the LSD, or did not attempt to quit since the LSD). Analyses were weighted and control for sex, age group, smoking status, income, education, survey mode, and HSI (by regressing these control variables on indicator variables).

The overall model fit was evaluated using the root mean square error of approximation (RMSEA), the standardized root square residual (SRMR), and Bentler's comparative fit index (CFI)(185,186). Acceptable model fit is indicated by a value of less than 0.05 for the MRSEA and SRMR, and greater than 0.9 for the CFI(184).

5.0 RESULTS

5.1 Sample characteristics

Table 5 presents the overall unweighted sample characteristics of respondents in Waves 1 to 9 of the ITC Canada Survey. Respondents were roughly equally distributed between men (47.0%) and women (53.0%). Almost half (47.9%) of respondents were from the low education category, whereas the distribution of respondents in low, moderate, and high categories was fairly equal (27.6%, 34.3%, and 29.5%, respectively). The majority (91.2%) reported being daily smokers.

Table 5. Unweighted sample characteristics, Waves 1-9 (n=5929)

	Frequency (n)	Percent (%)
Sex		
Male	2788	47.0
Female	3141	53.0
Age		
18-24	702	11.8
25-39	1732	29.2
40-54	2169	36.6
55+	1326	22.4
Education		
Low	2832	47.9
Moderate	2163	36.6
High	916	15.5
Missing	18	0.3
Income		
Low	1629	27.6
Moderate	2025	34.3
High	1740	29.5
Not stated	511	8.7
Missing	24	0.4
Status		
Daily smoker	5431	91.6
Non-daily smoker	402	6.8
Former smoker	96	1.6
Heaviness of Smoking Index		
Low	1324	22.3
Moderate	2650	44.7
High	1863	31.4
Missing	92	1.6
Wave of Recruitment		
Wave 1 recruits	2214	37.3
Wave 2 recruits	517	8.7
Wave 3 recruits	545	9.2
Wave 4 recruits	519	8.8
Wave 5 recruits	594	10.0
Wave 6 recruits	556	9.4
Wave 7 recruits	320	5.4
Wave 8 recruits	207	3.5
Wave 9 recruits	457	7.7

*Missing values were not included in analyses, but are listed in the descriptive statistics table to ensure accurate sample sizes.

5.2 Key indicators of warning label effectiveness (HWL responses)

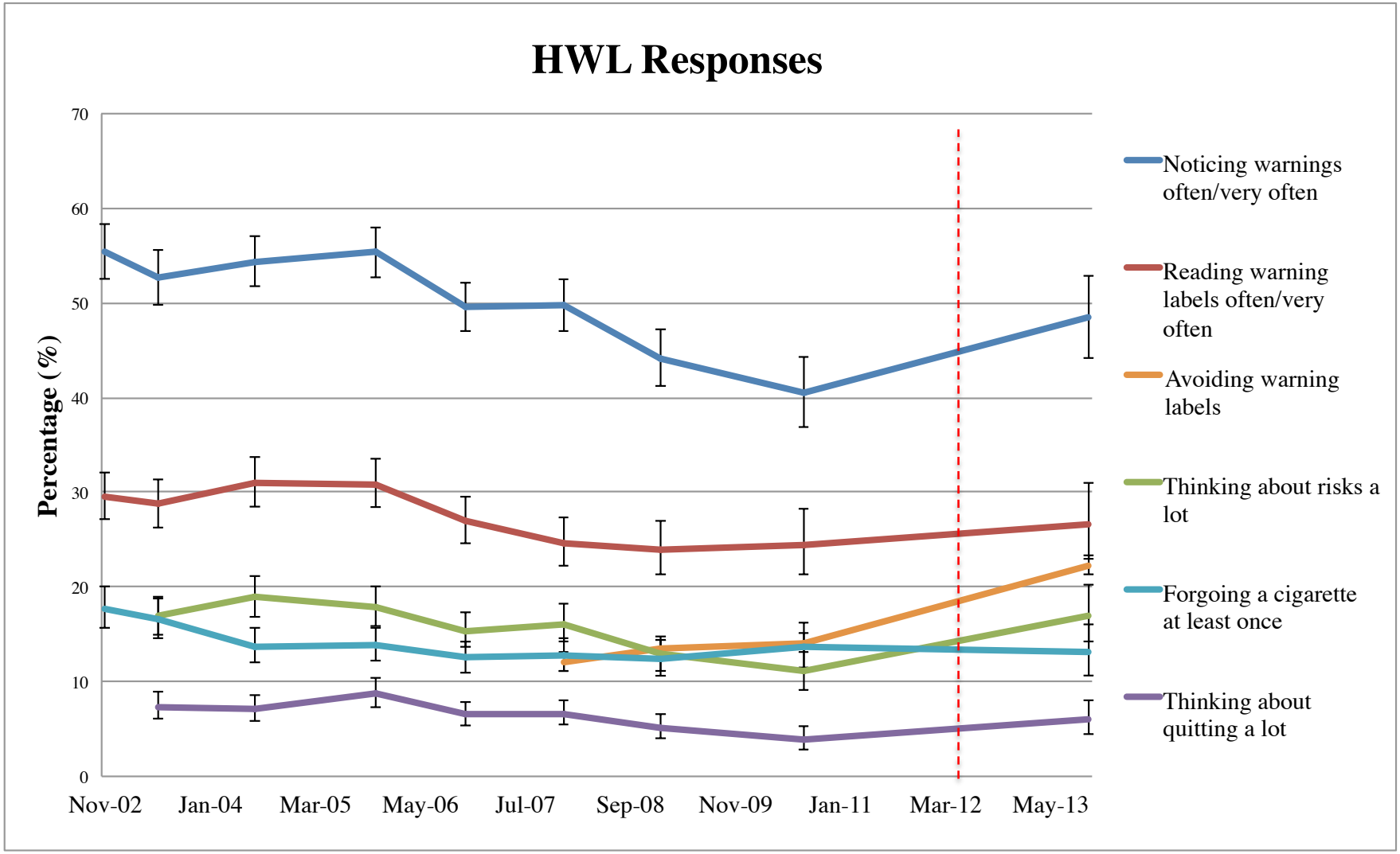
Table 6 displays the mean rates of each health warning label (HWL) response among Canadian smokers with 95% confidence intervals. The overall wave-to-wave trends are shown in Figure 8.

Table 6. Mean rates of HWL responses among Canadian smokers, 2002-2013

Median survey date (Wave #)	**Noticed labels "often" or "very often" (%)**	**Read labels closely "often" or "very often" (%)**	**Labels made smokers think about risks "a lot" (%)**	**Labels made smokers think about quitting "a lot" (%)**	**Labels made smokers forgo a cigarette at least once (%)**	**Avoided labels (%)**
Nov 2002 (Wave 1)	55.5 (52.5-58.3)	27.0 (24.6-29.6)	N/A	N/A	17.8 (15.6-20.1)	N/A
Jun 2003 (Wave 2)	52.7 (49.8-55.5)	26.1 (23.7-28.7)	16.9 (14.9-19.1)	7.4 (6.1-8.9)	16.5 (14.6-18.7)	N/A
Jul 2004 (Wave 3)	54.4 (51.7-57.1)	28.3 (25.8-31.0)	18.9 (16.9-21.2)	7.1 (5.9-8.6)	13.7 (12.0-15.6)	N/A
Nov 2005 (Wave 4)	55.3 (52.7-58.0)	28.2 (25.7-30.9)	17.9 (15.9-20.0)	8.7 (7.3-10.4)	13.9 (12.2-15.7)	N/A
Nov 2006 (Wave 5)	49.6 (49.0-52.1)	24.4 (21.9-27.0)	15.4 (13.6-17.3)	6.5 (5.4-7.8)	12.5 (10.9-14.3)	N/A
Dec 2007 (Wave 6)	49.8 (41.2-47.2)	22.0 (19.5-24.6)	16.1 (14.3-18.2)	6.6 (5.4-8.0)	12.8 (11.1-14.7)	12.1 (10.4-14.0)
Jan 2009 (Wave 7)	44.2 (36.9-44.2)	21.0 (18.3-23.9)	12.9 (11.1-14.9)	5.1 (4.0-6.6)	12.4 (10.6-14.4)	13.5 (11.6-15.6)
Aug 2010 (Wave 8)	40.5 (36.9-44.2)	20.8 (17.6-24.5)	11.1 (9.1-13.6)	3.9 (2.8-5.3)	13.7 (11.5-16.2)	14.1 (11.8-16.9)
Oct 2013 (Wave 9)	48.5*† (44.2-52.8)	22.5 (18.7-26.7)	17.0*† (14.3-20.2)	6.0*† (4.5-8.1)	13.1 (10.7-16.0)	22.3* (19.2-25.7)

Percentages are weighted
*Significant increase ($p<0.05$) from 2010 to 2013 (GEE contrast of the means)
†Significant difference ($p<0.05$) in slopes before and after 2012 graphic HWL revisions

Figure 8. Trends in HWL responses among Canadian smokers, 2002-2013



Salience

Noticing warnings "often" or "very often"

There was a significant decline in smokers' reports of noticing the warnings "often" or "very often" from 55.5% in 2002 to 40.5% 2010 ($p<0.001$). Following the 2012 HWL revisions, rates of noticing warnings "often" or "very often" significantly increased to 48.5% ($p<0.001$) in 2013. In fact, the odds of noticing warnings "often" or "very often" were 1.38 times greater after the Canadian warnings were revised.

Overall, smokers with a low education were significantly more likely to notice warnings "often" or 'very often" compared to moderately educated smokers (OR=1.14, $p=0.02$) and highly educated smokers (OR=1.20, $p=0.01$).

Smokers with a high Heaviness of Smoking Index (HSI; a measure of smoking dependency) had lower odds compared to those with a low HSI (OR=0.72, $p<0.001$), suggesting that smokers with a higher dependence on smoking were less likely to notice warnings "often" or "very often".

The segmented regression analysis showed that the trend in noticing warning labels "often" and "very often" changed significantly in a positive direction after the 2012 warning label revisions (pre-2012 segment $\beta=-0.067$, post-2012 segment $\beta=0.277$, $p<0.001$).

High HSI was found to significantly moderate the increase of noticing warnings after the 2012 graphic HWL revision. Separate segmented regression analyses showed that rates of noticing warnings "often" or "very often" only significantly increased among smokers with a high HSI ($\beta=0.366$, $p=0.004$) and a moderate HSI ($\beta=0.544$, $p<0.001$). Increases were not significant for smokers with a low HSI ($\beta=-0.167$, $p=0.35$). These results indicate that although smokers with a higher dependence on smoking were less likely to notice the previous warnings

compared to less dependent smokers, they were significantly more likely notice the revised warnings.

Reading warnings "often" or "very often"

There was a significant decline in smokers' reports of reading warnings closely "often" or "very often" from 27.0% in 2002 to 20.8% in 2010 ($p=0.01$). Rates increased to 22.5% in 2013, but it was not statistically significant ($p=0.48$).

Overall, rates of reading warnings decreased as HSI increased; smokers with a high HSI had lower odds of reading warnings closely "often" or "very often" compared to those with a low HSI ($OR=0.72$, $p<0.001$). This indicates that smokers with a higher dependence on smoking were less likely to read warnings closely "often" or "very often".

The segmented regression analysis showed that the pre-policy and post-policy slopes were not significantly different from each other, indicating that there was no significant change in the trend in reading warnings closely "often" or "very often" after the 2012 graphic HWL revisions (pre-2012 segment $\beta=-0.049$, post-2012 segment $\beta=0.138$, $p=0.08$).

Cognitive reactions

Thinking "a lot" about health risks of smoking due to warnings

There was a significant decline in smokers' reports of thinking "a lot" about health risks of smoking due to warnings from 16.9% in 2003 to 11.1% in 2010 ($p<0.001$). Following the 2012 warning label revisions, rates of thinking "a lot" about health risks significantly increased to 17.0% ($p<0.001$) in 2013. In fact, the odds of thinking "a lot" about health risks were 1.64 times greater in 2013 compared to 2010.

Overall, women were more likely than men to think "a lot" about risks of smoking (OR= 1.18, p=0.02).

Smokers with a low income had higher odds of thinking "a lot" about the risks of smoking compared to smokers with a high income (OR=1.35, p=0.001).

Rates of thinking 'a lot' about health risks due to warnings decreased as levels of smoking dependency increased; smokers with a high HSI had lower odds compared to those with a low HSI (OR=0.65, p<0.001).

The segmented regression analysis showed that the trend in warnings making smokers think "a lot" about health risks significantly changed in a positive direction after the 2012 graphic HWL revisions (pre-2012 segment β=-0.065, post-2012 segment β=0.378, p<0.001).

Thinking "a lot" about quitting smoking due to warnings

There was a significant decline in smokers' reports of thinking "a lot" about quitting smoking due to warnings from 7.4% in 2003 to 3.9% in 2010 (p<0.001). Following the 2012 warning label revisions, rates of thinking "a lot" about quitting significantly increased to 6.0% (p=0.03) in 2013. The odds of thinking "a lot" about quitting were 1.59 times greater in 2013 compared to 2010.

Overall, rates of thinking "a lot" about quitting due to warnings increased as age increased; smokers aged 55 years and older had twice the odds compared to those aged 18-24 years (OR=2.04, p=0.001).

Smokers with a low income were more likely to think "a lot" about quitting compared to smokers with a high income (OR=1.57, p<0.001).

Smokers with a low education were more likely to think "a lot" about quitting due to warnings compared to highly educated smokers (OR=1.37, p=0.04).

Smokers with a high HSI had lower odds compared to those with a low HSI (OR=0.55, p<0.001), indicating that rates of thinking "a lot" about quitting due to warnings decreased as smoking dependency increased.

The segmented regression analysis showed a significant and positive change in the trend in thinking 'a lot' about quitting smoking due to warnings after the HWLs were revised in 2012 (pre-2012 segment β=-0.072, post-2012 segment β=0.303, p=0.01).

Behavioural reactions

Forgoing a cigarette at least once due to warnings

There was a significant decline in smokers' reports of giving up a cigarette (forgoing) at least once due to warnings from 17.8% in 2002 to 13.7% in 2010 (p=0.02). Rates continued to decrease to 13.1% in 2013, but it was not statistically significant (p=0.70).

Overall, smokers with a low income were significantly more likely to give up a cigarette due to warnings compared to smokers with a high income (OR=1.56, p<0.001).

Low educated smokers had greatest odds of giving up a cigarette due to warnings compared to moderately educated smokers (OR=1.26, p=0.002) and highly educated smokers (OR=1.24, p=0.04).

Rates of giving up a cigarette due to warnings decreased as smoking dependency increased; smokers with a high HSI had lower odds compared to those with a low HSI (OR=0.49, p<0.001).

The segmented regression analysis showed that the pre-policy and post-policy slopes were not significantly different, indicating that the 2012 graphic HWL revisions did not change the trend in giving up a cigarette at least once due to warnings (pre-2012 segment β=-0.054, post-2012 segment β=0.125, p=0.11).

Avoiding warnings

Rates of smokers avoiding warnings increased from 12.1% in 2007 to 14.1% in 2010, but it was not statistically significant (p=0.17). After HWLs were revised in 2012, rates of avoiding warnings significantly increased to 22.3% (p<0.001) in 2013. In fact, the odds of avoiding warnings were 1.75 times greater in 2013 compared to 2010.

Overall, women were more likely than men to avoid warnings (OR= 1.28, p=0.01).

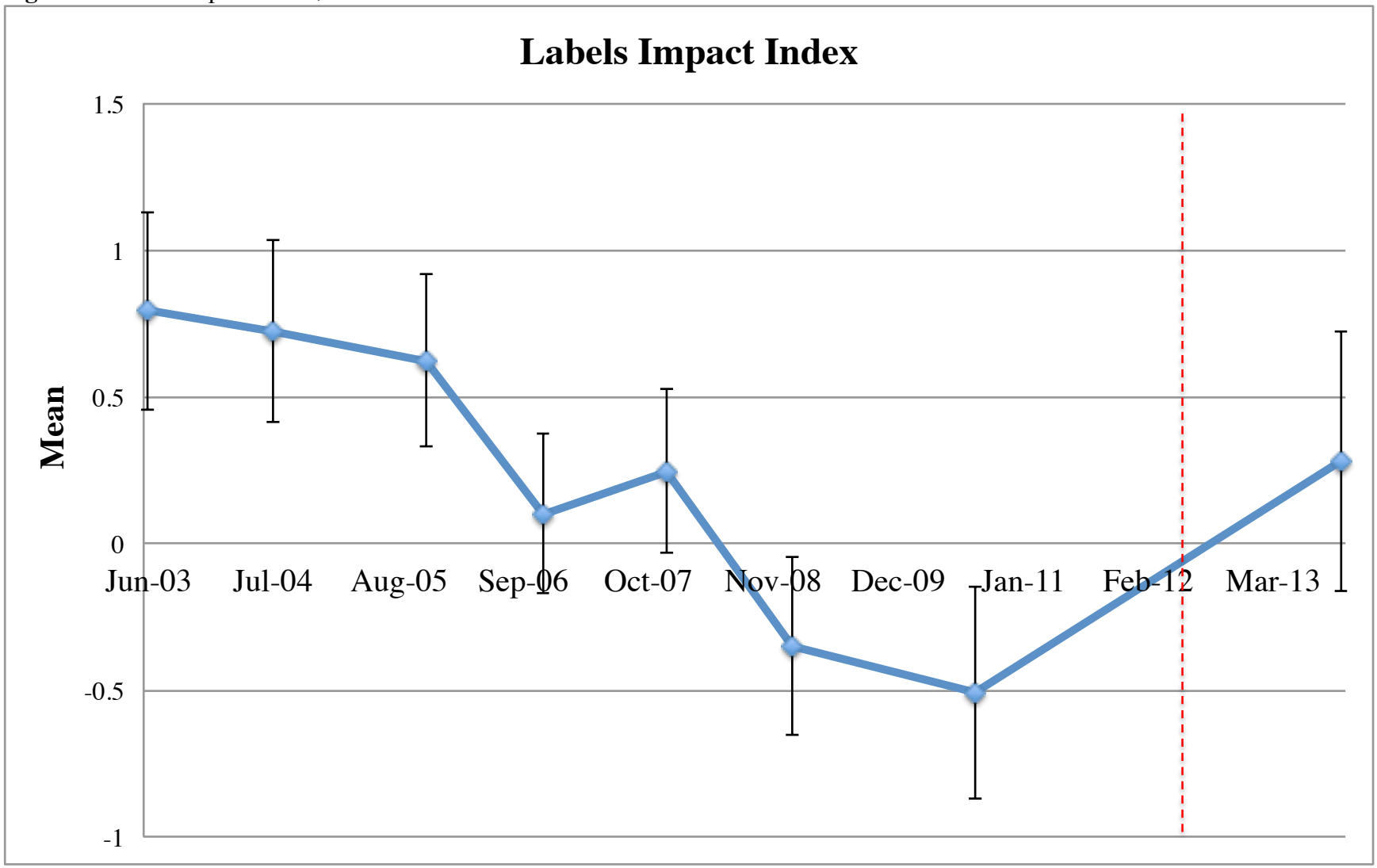
Smokers with a low income were more likely to avoid warnings compared to smokers with a high income (OR=1.76, p=0.001).

The segmented regression analysis showed that the slopes of both line intervals were not significantly different from each other, indicating that there was no significant change in the trend in avoiding warnings after HWLs were revised in 2012 (pre-2012 segment β=0.068, post-2012 segment β=0.310, p=0.16). This is likely due to the fact that the pre-policy trend was already in a positive direction (unlike the pre-policy trends of all other HWL responses, which were in a negative direction).

Labels Impact Index

Figure 9 displays the trend of the Labels Impact Index (LII) between 2002 and 2010.

Figure 9. Labels Impact Index, 2003-2013



There was a significant ($p<0.001$) decline in the LII between 2002 and 2010. After the HWLs were revised in 2012, the LII significantly increased ($p<0.001$) in 2013.

The segmented regression analysis showed a significant and positive change in LII scores after HWLs were revised in 2012 (pre-2012 segment $\beta=-0.189$, post-2012 segment $\beta=0.834$, $p<0.001$).

Associations with other outcome variables

Table 7 presents a Pearson correlation matrix between HWL responses and affective reactions evoked by warnings, rates of reading interior messages, quit-efficacy and perceived difficulty to quit, and quit intentions and cessation-related behaviours.

Table 7. Warning label responses Pearson correlation matrix

	Noticing warnings "often" or "very often"	Reading warnings closely "often" or "very often"	Thinking "a lot" about risks due to warnings	Thinking "a lot" about quitting due to warnings	Forgo a cigarette due to warnings	Avoiding warnings	Labels Impact Index
Warnings cause worry	0.235***	0.243***	0.404***	0.340***	0.312***	0.262***	0.603***
Warnings cause alarm	0.193***	0.213***	0.312***	0.255***	0.216***	0.184***	0.427***
Warnings are unpleasant	0.201***	0.180***	0.281***	0.224***	0.188***	0.260***	0.375***
Believability of warnings	0.158***	0.154***	0.229***	0.158***	0.102***	0.061**	0.305***
Read interior messages	0.226***	0.281***	0.149***	0.082**	0.241***	0.080**	0.272***
Quit-efficacy	0.049***	0.053***	0.067***	0.113***	0.056***	-0.030*	0.085***
Perceived difficulty of quitting	-0.021**	-0.028**	0.024**	-0.020*	-0.046***	-0.029*	-0.017
Quit intentions (in the future)	0.097***	0.080***	0.158***	0.124***	0.125***	0.067***	0.239***
Quit intentions (within 6 months)	0.089***	0.098***	0.174***	0.159***	0.130***	0.049***	0.219***
Quit line use	-0.006	0.030	0.014	0.045	0.071**	0.020	0.081**
Quit attempts	0.006	0.063***	0.146***	0.142***	0.123***	0.055***	0.209***

Associations are weighted
*<0.05, **<0.01, ***<0.001

Overall, HWL responses were significantly and positively associated with affective reactions evoked by warnings (ALARM, WORRY, DISPLEASURE) and with warning believability.

Each HWL response was significantly and positively associated with reading interior messages that aim to enhance smokers' efficacy.

Warning responses were significantly and positively associated with quit-efficacy (except for avoiding warnings). This indicates that HWL responses are associated with increased confidence in the ability to quit smoking.

With the exception of noticing warning labels "often" or "very often", HWL responses were significantly and negatively associated with perceived difficulty to quit smoking suggesting that HWL responses relieve smokers' judgments about the difficulty of quitting.

Warning responses were significantly and positively associated with intentions to quit (sometime in the future and within the next six months). Even avoiding warnings, a reaction that some researchers claim to be an adverse response due to highly graphic warnings or low efficacy(114), was associated with higher intentions to quit smoking (and quit attempts).

Forgoing a cigarette at least once due the warnings was significantly associated with calling the quit line.

With the exception of noticing warning labels "often" or "very often", HWL responses were significantly and positively associated with attempting to quit since the LSD.

5.3 Affective reactions evoked by warnings and warning believability

Table 8 presents the mean scores (on a scale of 1 to 5) of affective reactions evoked by warnings and warning believability before and after the 2012 revisions, with 95% confidence intervals.

Table 8. Mean scores of affective reactions evoked by warnings and warning believability among Canadian smokers, 2010-2013

Median survey date (Wave #)	Warnings cause alarm	Warnings cause worry	Warnings are unpleasant	Believability of warnings
Aug 2010 (Wave 8)	3.14 (3.08-3.20)	2.07 (2.07-2.14)	3.52 (3.48-3.57)	3.39 (3.32-3.46)
Oct 2013 (Wave 9)	3.18 (3.12-3.24)	2.14 (2.08-2.14)	3.62* (3.56-3.68)	3.51* (3.43-3.58)

Scores are weighted
*Significant increase ($p<0.05$) from 2010 to 2013 (GEE contrast of the means)

Alarm

Mean scores of alarm caused by warnings increased after the HWLs were revised in 2012, but it was non-significant (3.14 in 2010 to 3.18 in 2013, $p=0.32$).

Overall, smokers with a high education had 1.20 times greater odds of finding warning labels more alarming compared to smokers with a low education ($p=0.01$).

Smokers with a low HSI had 1.28 times greater odds of finding warnings alarming compared to smokers with a high HSI ($p<0.001$). This indicates that those who are less dependent on smoking are more likely to report feeling alarmed due to warnings.

Worry

Mean scores of worry caused by warnings increased after the HWLs were revised in 2012, but it was also non-significant (2.07 in 2010 to 2.14 in 2013, $p=0.10$).

Overall, highly educated smokers were more likely to report feeling worried due to warnings compared to smokers with a low education (OR=1.34, $p<0.001$).

Displeasure caused by warnings

Mean scores of displeasure caused by warnings significantly increased after the 2012 graphic HWL revisions (3.52 in 2010 to 3.62 in 2013, $p<0.01$).

Overall, women were more likely to find warnings unpleasant (OR=1.10, $p=0.02$).

Warning believability

Mean scores of warning believability significantly increased after the 2012 HWL revisions (3.39 in 2010 to 3.51 in 2013, $p<0.01$).

Overall, younger smokers were more likely to find warnings believable; smokers aged 18-24 years had 1.47 times the odds of smokers aged 55 years and older ($p=0.02$).

Highly educated smokers had 1.33 times greater odds of finding warning labels believable compared to low educated smokers ($p<0.001$).

Associations with other outcome variables

Table 9 presents a Pearson correlation matrix between affective reactions evoked by warnings and HWL responses, rates of reading interior messages, quit-efficacy and perceived difficulty to quit, and quit intentions and cessation-related behaviours.

Table 9. Affective reactions evoked by warnings and warning believability Pearson correlation matrix

	Warnings cause worry	Warnings cause alarm	Warnings are unpleasant	Believability of warnings
Noticing warnings "often" or "very often"	0.235***	0.193***	0.201***	0.158***
Reading warnings closely "often" or "very often"	0.243***	0.213***	0.180***	0.154***
Thinking "a lot" about risks due to warnings	0.404***	0.312***	0.281***	0.229***
Thinking "a lot" about quitting due to warnings	0.340***	0.255***	0.224***	0.158***
Forgo a cigarette due to warnings	0.312***	0.216***	0.188***	0.102***
Avoiding warnings	0.262***	0.184***	0.260***	0.061**
Labels Impact Index	0.603***	0.427***	0.375***	0.305***
Read interior messages	0.181***	0.114***	0.065**	0.079**
Quit-efficacy	0.006	-0.028	0.013	0.007
Perceived difficulty of quitting	0.117***	0.088***	0.093***	0.092***
Quit intention (in the future)	0.299***	0.215***	0.181***	0.163***
Quit intention (within 6 months)	0.223***	0.157***	0.154***	0.194***
Quit line use	0.064*	0.053*	-0.020	0.006
Quit attempts	0.127***	0.106***	0.112***	0.116***

Associations are weighted
*<0.05, **<0.01, ***<0.001

All affective reactions evoked by warnings, and warning believability, were significantly and positively associated with all HWL response variables and the LII. This indicates that the affective reactions evoked by warnings are associated with enhanced warning salience, increased cognitive reactions such as thinking about health risks and of quitting due to warnings, and increased behavioural reactions such as forgoing cigarettes due to warnings.

Affective reactions and warning believability were significantly and positively associated with reading interior messages.

None of the affective reactions evoked by warnings were significantly associated with quit-efficacy, indicating that the affective reactions evoked by the graphic warnings did not impact smokers' confidence in quitting (in a positive or negative way). However, all affective reactions were significantly and positively associated with perceived difficulty to quit.

Affective reactions and warning believability were significantly and positively associated with intentions to quit sometime in the future and within the next six months.

Alarm and worry caused by warnings were significantly and positively associated with calling the quit line.

Finally, all affective reactions evoked by warnings and warning believability were significantly and positively associated with quit attempts.

5.4 Beliefs about smoking-related health statements

Table 10 displays the mean levels of correct beliefs about smoking-related health statements with 95% confidence intervals. Statements are categorized as health messages that were added to cigarette packages in the 2012 warning label revision, those that were removed, and those that were continuously displayed.

Table 10. Rates of correct beliefs about smoking-related health statements among Canadian smokers, 2002-2013

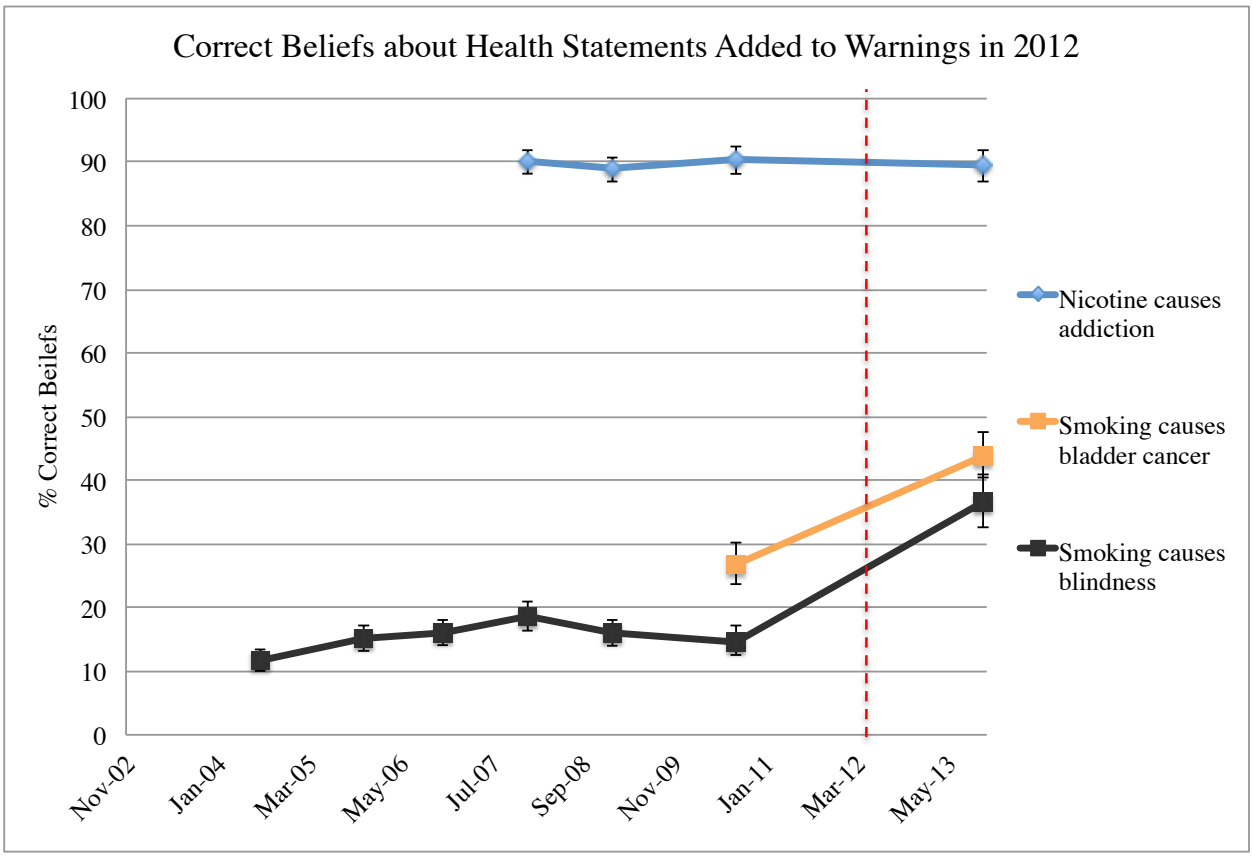
	Added			**Removed**		**Continuously displayed**
Median survey date (Wave #)	**Smoking causes bladder cancer (%)**	**Smoking causes blindness (%)**	**Nicotine causes addiction (%)**	**Smoking causes impotence (%)**	**Cigarette smoke contains carbon monoxide (%)**	**Smoking causes stroke (%)**
Nov 2002 (Wave 1)	N/A	N/A	N/A	60.7 (57.8-63.5)	90.9 (89.1-92.4)	84.6 (82.4-86.6)
Jun 2003 (Wave 2)	N/A	N/A	N/A	59.7 (56.8-62.4)	90.8 (89.1-92.2)	84.3 (82.0-86.3)
Jul 2004 (Wave 3)	N/A	11.7 (10.0-13.5)	N/A	61.3 (58.6-62.4)	92.8 (91.3-94.0)	86.6 (84.6-88.3)
Nov 2005 (Wave 4)	N/A	15.1 (13.2-17.2)	N/A	63.5 (61.0-66.0)	90.3 (88.6-91.7)	87.1 (85.2-88.8)
Nov 2006 (Wave 5)	N/A	16.0 (14.1-18.1)	N/A	65.7 (63.2-68.2)	91.2 (89.4-92.6)	86.9 (85.0-88.6)
Dec 2007 (Wave 6)	N/A	18.5 (16.4-20.8)	90.1 (88.2-91.7)	67.5 (65.0-69.9)	N/A	87.6 (85.6-89.3)
Jan 2009 (Wave 7)	N/A	15.9 (13.9-18.1)	89.0 (86.9-90.8)	66.2 (63.3-68.9)	N/A	87.3 (85.2-89.1)
Aug 2010 (Wave 8)	26.8 (23.7-30.1)	14.7 (12.5-17.1)	90.6 (88.2-92.5)	67.8 (64.3-71.1)	92.4 (90.1-94.2)	87.5 (84.7-89.8)
Oct 2013 (Wave 9)	44.0* (40.4-47.5)	36.7*† (32.6-40.9)	89.6 (86.9-91.8)	66.2† (62.3-69.9)	86.7*† (83.7-89.2)	88.7 (86.1-90.8)

Percentages are weighted
*Significant increase ($p<0.05$) from 2010 to 2013 (GEE contrast of the means)
†Significant difference ($p<0.05$) in slopes before and after 2012 graphic HWL revisions

Health messages added in 2012

Figure 10 displays the rates in correct beliefs about health statements that were added to the Canadian HWLs in 2012.

Figure 10. Trends in correct beliefs about health statements added to warnings among Canadian smokers, 2002-2013



Smoking causes bladder cancer

After the health message stating that smoking causes bladder cancer was added to cigarette packages in 2012, correct beliefs about this health fact significantly increased from 26.8% in 2010 to 44.0% in 2013 ($p<0.001$). In fact, smokers had more than double the odds of believing that smoking causes bladder cancer following the addition of this health message to cigarette packages (OR=2.14, $p<0.001$).

Overall, men were more likely to believe that smoking causes bladder cancer compared to women (OR=1.26, p=0.04).

Rates of correct beliefs increased as education level increased; compared to smokers with low education, smokers with a moderate education had 1.38 times the odds (p=0.01) and smokers with a high education had 1.57 times the odds (p<0.01) of believing that smoking causes bladder cancer.

Smoking causes blindness

Correct beliefs that smoking causes blindness significantly increased from 11.7% in 2004 to 14.7% in 2010 (p=0.04). Following the addition of this health statement to cigarette packages, rates increased 2.5 fold, to 36.7% in 2013 (p<0.001). In fact, the odds of believing that smoking causes blindness was 3.36 times greater following the addition of this health message to cigarette packages.

Overall, smokers with a low income had 1.33 times greater odds of believing that smoking causes blindness compared to smokers with a high income (p<0.01).

The segmented regression analysis showed a significant change in the positive direction in the trend in correct beliefs after the health statement was added to cigarette packages in 2012 (pre-2012 segment β=0.048, post-2012 segment β=0.719, p<0.001).

Nicotine is the substance that causes addiction

There were no significant changes in rates of correctly believing that nicotine is the substance that causes addiction before the 2012 revisions (from 90.1% in 2007 to 90.5% in 2010, p=0.76) or after (90.5% in 2010 to 89.6% in 2013, p=0.55). Over the course of six years (2007 to 2013), rates varied by less than two percentage points and stayed consistent at approximately 90%.

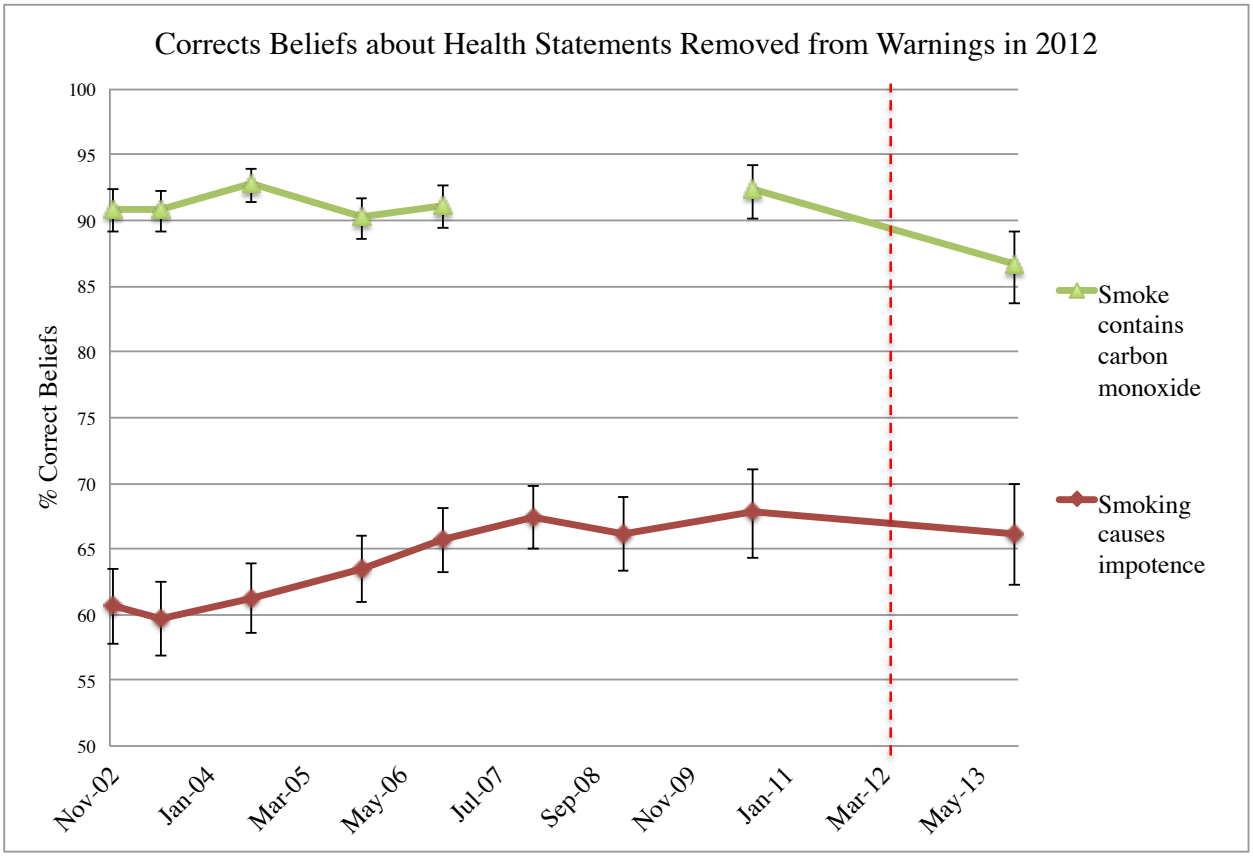
This lack of change following the addition of the health statement to cigarette packages may be explained by a ceiling effect. A ceiling effect occurs when levels of a dependent variable (levels of correct beliefs) are high and therefore are no longer affected the independent variable (HWL content)(102). Beliefs that nicotine causes addiction remained very high between 2007 and 2013, ranging from 89.0% to 90.6%. Therefore, adding this health fact to packages may have little effect on the already significant levels of awareness that nicotine causes addiction.

The segmented regression analysis showed that the trend in beliefs that nicotine causes addiction did not significantly change after this health statement was added to cigarette packages in 2012 (pre-2012 segment β=0.011, post-2012 segment β=-0.063, p=0.74).

Health messages removed in 2012

Figure 11 displays the trends in correct beliefs about smoking-related health statements that were removed from the Canadian HWLs in 2012.

Figure 11. Trends in correct beliefs about health statements removed from warnings among Canadian smokers, 2002-2013



Cigarette smoke contains carbon monoxide

Correct beliefs that cigarette smoke contains carbon monoxide remained stable at approximately 91-92% between 2002 and 2010 (p=0.28), during which health messages were displayed on cigarette packages. Following the removal of this health message in 2012, beliefs significantly decreased to 86.7% in 2013 (p<0.001).

Overall, men were more likely to believe that cigarette smoke contains carbon monoxide compared to women (OR=1.38, p<0.01).

Correct beliefs that cigarette smoke contains carbon monoxide decreased as age increased; smokers aged 18-24 years had almost three times the odds compared to smokers aged 55 years and older (OR=2.90, $p<0.01$).

Correct beliefs increase as levels of education increase; highly educated smokers had 1.91 times the odds ($p<0.001$) of believing that cigarette smoke contains carbon monoxide compared to low educated smokers, and moderately educated smokers had 1.42 times the odds ($p<0.001$).

The segmented regression analysis showed a significant and negative change in correct beliefs after the health message was removed from packages in 2012 (pre-2012 segment $\beta=0.014$, post-2012 segment $\beta=-0.446$, $p<0.001$).

Smoking causes impotence

Correct beliefs that smoking causes impotence significantly increased from 60.7% in 2002 to 67.8% in 2010 ($p<0.01$), during which health messages were displayed on cigarette packages. Following the removal of this health message from HWLs in 2012, beliefs fell to 66.2%, but this decrease was not statistically significant ($p=0.42$).

Overall, beliefs that smoking causes impotence decreased with older age; smokers aged 18-24 years had 3.81 times greater odds compared to smokers aged 55 years and older ($p<0.001$).

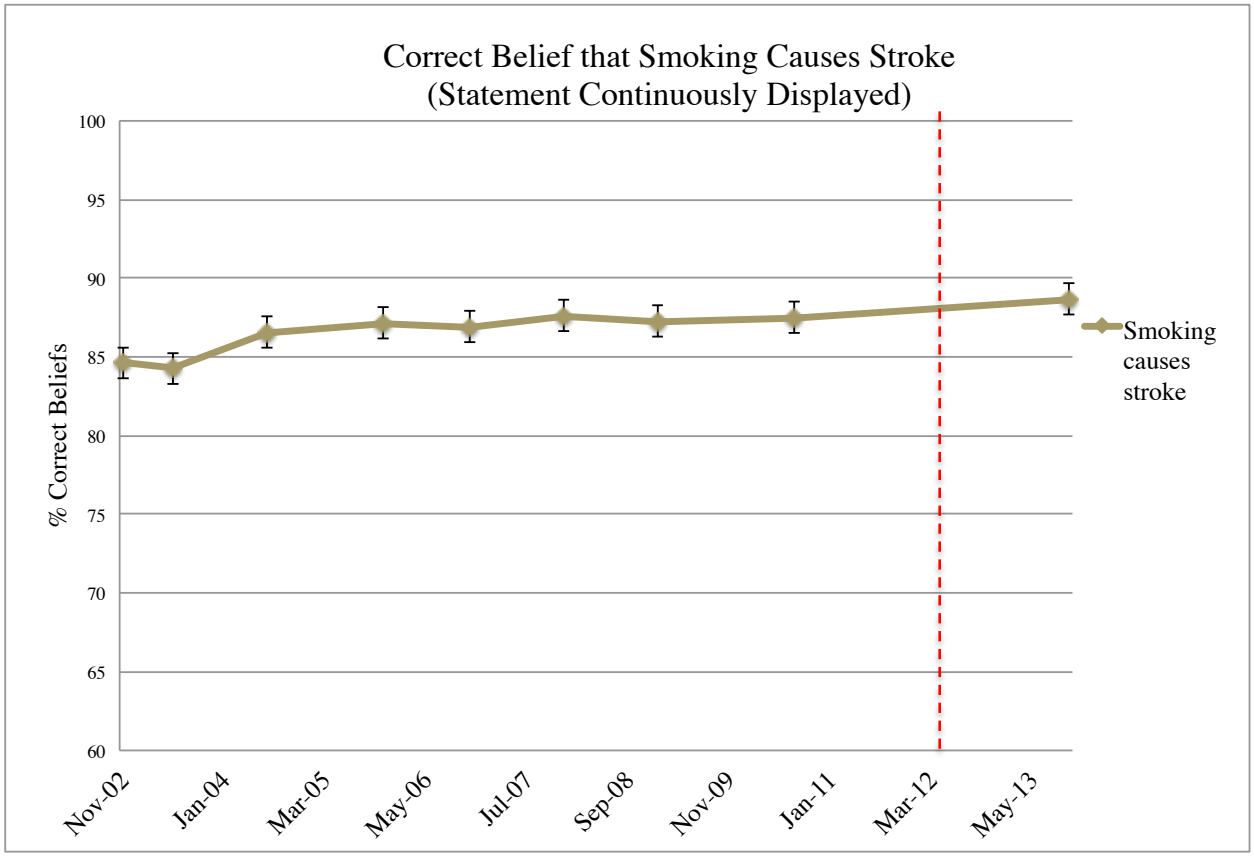
Highly educated smokers had 1.47 times the odds ($p<0.001$) of believing that smoking causes impotence compared to smokers with a low education, and moderately educated smokers had 1.30 times the odds ($p<0.001$)

Although the wave-to-wave GEE analysis found the 2010-2013 decrease not to be statistically significant, the segmented regression analysis showed the trend in beliefs that smoking causes impotence significantly changed in a negative direction after the health message was removed from cigarette packages in 2012 (pre-2012 segment $\beta=0.050$, post-2012 segment $\beta=-0.149$, $p<0.01$). This indicates that the positively trending rates of correct beliefs that occurred between 2002 and 2010 was broken off following the removal of this health message from cigarette packages.

Health messages continuously displayed

Figure 12 displays the trends in rates of correct beliefs that smoking causes stroke, a health statement that was continuously displayed on the Canadian HWLs (before and after the 2012 graphic HWL revisions).

Figure 12. Trends in the correct belief that smoking causes stroke (statement continuously displayed on warnings) among Canadian smokers, 2002-2013



Smoking causes stroke

Rates of believing that smoking causes stroke consistently increased from 84.6% in 2002 to 88.7% in 2013 (p=0.02). There was no significant change in beliefs between 2010 and 2013 (p=0.35).

Overall, the odds of believing that smoking causes stroke decrease as age increases. Smokers aged 18-24 years had more than double the odds compared to smokers aged 55 and older (OR=2.21, p<0.001).

Smokers with a high income had 1.38 times greater odds (p<0.001) of believing that smoking causes stroke compared to low-income smokers.

Highly educated smokers were more likely to believe this health fact compared to smokers with a low education (OR=1.29, p=0.02)

The segmented regression analysis showed no statistically significant changes in the trend in believing that smoking causes stroke (pre-2012 segment β=0.037, post-2012 segment β=0.003, p=0.73).

5.5 Interior messages

In 2013, 15.1% of smokers reported reading the interior messages containing efficacy messages (at least "sometimes"). This was substantially lower than the proportion of smokers who reported reading external warnings closely at least "sometimes" in 2013 (40.1%).

Women were more likely to read interior messages compared to men (OR=1.77, p<0.01).

Compared to smokers with a low HSI, those with a high HSI had lowest odds of reading interior messages (OR=0.36, p<0.001). This indicates that the most addicted smokers are the least likely to read the interior messages.

Associations and cross-tabulation analysis results

The cross-tabulation results between reading the revised interior messages and intentions to quit, quit-efficacy, and quit line use are presented in Table 11.

Table 11. Cross tabulation results of reading interior messages and quit-efficacy, quit intentions, and quit line use, 2013

	Smokers who read interior messages	**Smokers who did NOT read interior messages**
Quit-efficacy ("very" or "extremely" sure they can quit)	19.2% (11.9%-26.5%)	11.5% (9.1%-13.9%)
Intentions to quit in the future	86.3% (81.2%-91.4%)	76.2% (72.6%-79.8%)
Smokers called the quit line	9.0% (3.1%-14.9%)	3.0% (1.8%-4.3%)

Percentages are weighted and associations are statistically significant (ChiSq<0.05)

Reading interior messages was significantly and positively associated with quit-efficacy ($r=0.086$, $p<0.01$). In fact, among smokers who read interior messages, 19.2% were "very" or "extremely" sure they could quit smoking. Among smokers who did NOT read interior messages, only 11.5% were "very" or "extremely" sure they could quit smoking.

Reading interior messages was significantly and positively associated with quit intentions ($r=0.088$, $p<0.01$). Among smokers who read interior messages, 86.3% had intentions to quit in the future. In contrast, among smokers who did NOT read interior messages, 76.2% had quit intentions.

Reading interior messages was also significantly and positively associated with calling the quit line ($r=0.111$, $p<0.01$). Among smokers who read interior messages, 9.0% reported calling the quit line. In contrast, among smokers who did NOT read interior messages, only 3.0% called the quit line.

There were no significant associations between reading interior messages and perceived difficulty of quitting or quit attempts.

5.6 Quit-efficacy and perceived difficulty of quitting

Table 12 presents the mean scores (on a scale of 1 to 5) of quit-efficacy and perceived difficulty of quitting (a construct of self-efficacy). Higher scores indicate higher levels of quit-efficacy and perceived difficulty of quitting.

Table 12. Mean scores of quit-efficacy and perceived difficulty of quitting among Canadian smokers, 2002-2013

Median survey date (Wave #)	**Quit-efficacy**	**Perceived difficulty of quitting**
Nov 2002 (Wave 1)	2.68 (2.62-2.75)	4.07 (4.01-4.13)
Jun 2003 (Wave 2)	2.61 (2.54-2.67)	4.05 (3.99-4.11)
Jul 2004 (Wave 3)	2.63 (2.57-2.69)	4.06 (4.00-4.11)
Nov 2005 (Wave 4)	2.65 (2.59-2.71)	4.07 (4.02-4.13)
Nov 2006 (Wave 5)	2.62 (2.56-2.68)	4.12 (4.06-4.17)
Dec 2007 (Wave 6)	2.61 (2.55-2.68)	4.06 (4.00-4.11)
Jan 2009 (Wave 7)	2.62 (2.54-2.69)	4.13 (4.07-4.19)
Aug 2010 (Wave 8)	2.57 (2.49-2.66)	4.08 (4.01-4.16)
Oct 2013 (Wave 9)	2.37*† (2.28-2.46)	4.24*† (4.17-4.32)

Scores are weighted
*Significant increase ($p<0.05$) from 2010 to 2013 (GEE contrast of the means)
†Significant difference ($p<0.05$) in slopes before and after 2012 warning revision

Quit-efficacy

Quit-efficacy was trending in a downward direction between 2002 and 2010 ($p=0.05$). There was a significant decrease in mean scores of quit-efficacy to quit between 2010 and 2013 (2.57 to 2.37, $p<0.001$).

Overall, men were more likely to believe they could quit smoking compared to women (OR=1.12, $p<0.001$).

Quit-efficacy decreased as age increased. Compared to smokers aged 18-24 years, those aged 55 years and older had the lower odds of believing they could quit (OR=0.87, $p=0.01$).

Compared to smokers highly educated smokers, those with low education had lower odds of believing they could quit (OR=0.89, $p<0.01$).

Smokers with a high HSI had lowest odds of believing they could quit (OR=0.69, $p<0.001$).

The segmented regression analysis showed that the trend in quit-efficacy significantly changed in a downward direction after the 2012 graphic HWL revisions (pre-2012 segment $\beta=-0.008$, post-2012 segment $\beta=-0.039$, $p<0.001$).

Perceived difficulty to quit

Perceived difficulty to quit smoking did not significantly change between 2002 and 2010 ($p=0.83$). There was a significant decrease in mean scores of perceived difficulty to quit between 2010 and 2013 (4.08 to 4.24, $p<0.001$).

Overall, men had lower odds of believing smoking is difficult to quit (OR=0.91, $p<0.001$).

Perceived difficulty to quit smoking increased as age increased; compared to smokers aged 18-24 years, those aged 55 years and older had 1.26 times the odds of believing smoking is difficult to quit ($p<0.001$).

Compared to low-income smokers, high-income smokers had greater odds of believing smoking is difficult to quit (OR=1.12, $p<0.001$).

The segmented regression analysis showed that the trend of perceived difficulty to quit smoking significantly changed in a downward direction after the 2012 graphic HWL revisions (pre-2012 segment $\beta=0.006$, post-2012 segment $\beta=0.096$, $p<0.01$).

Associations with other outcome variables

Quit-efficacy and perceived difficulty to quit were significantly and inversely associated ($R=-0.38$, $p<0.001$).

Correlation analyses were conducted to explore the associations between efficacy/perceived difficulty to quit smoking and cessation-related intentions and behaviours. The results are presented in Table 13.

Table 13. Quit-efficacy and perceived difficulty to quit Pearson correlation matrix

	Quit-efficacy	**Perceived difficulty to quit**
Quit intention (in the future)	0.114***	0.027***
Quit intention (within 6 months)	0.186***	-0.022**
Quit line use	-0.008	0.016
Quit attempts	0.013	-0.007

Associations are weighted
*<0.05, **<0.01, ***<0.001

Quit-efficacy was significantly and positively associated with intentions to quit sometime in the future and intentions to quit within 6 months.

Perceived difficulty to quit smoking was significantly and positively associated with intentions to quit in the future, but negatively associated with intentions to quit within the next 6 months.

Both quit-efficacy and perceived difficulty to quit smoking were not associated with quit line use or quit attempts.

5.7 Quit intentions and cessation-related behaviours

Table 14 presents the rates of quit intentions, quit line use (among smokers and former smokers), quit attempts since the last survey date (LSD) (among smokers and former smokers), and sustained smoking cessation (smokers who quit smoking since the LSD and are still not smoking).

Intentions to quit were explored two ways: 1) smokers who intended to quit sometime in the future, and 2) smokers who intended to quit within the next six months. Intentions to quit were categorized this way to identify smokers who had more serious plans to quit (as intending to quit sometime in the future ambiguous and easy to idealize). This is evident from research showing that smokers who set a quit date are more likely to make quit attempts compared to those who don't(187).

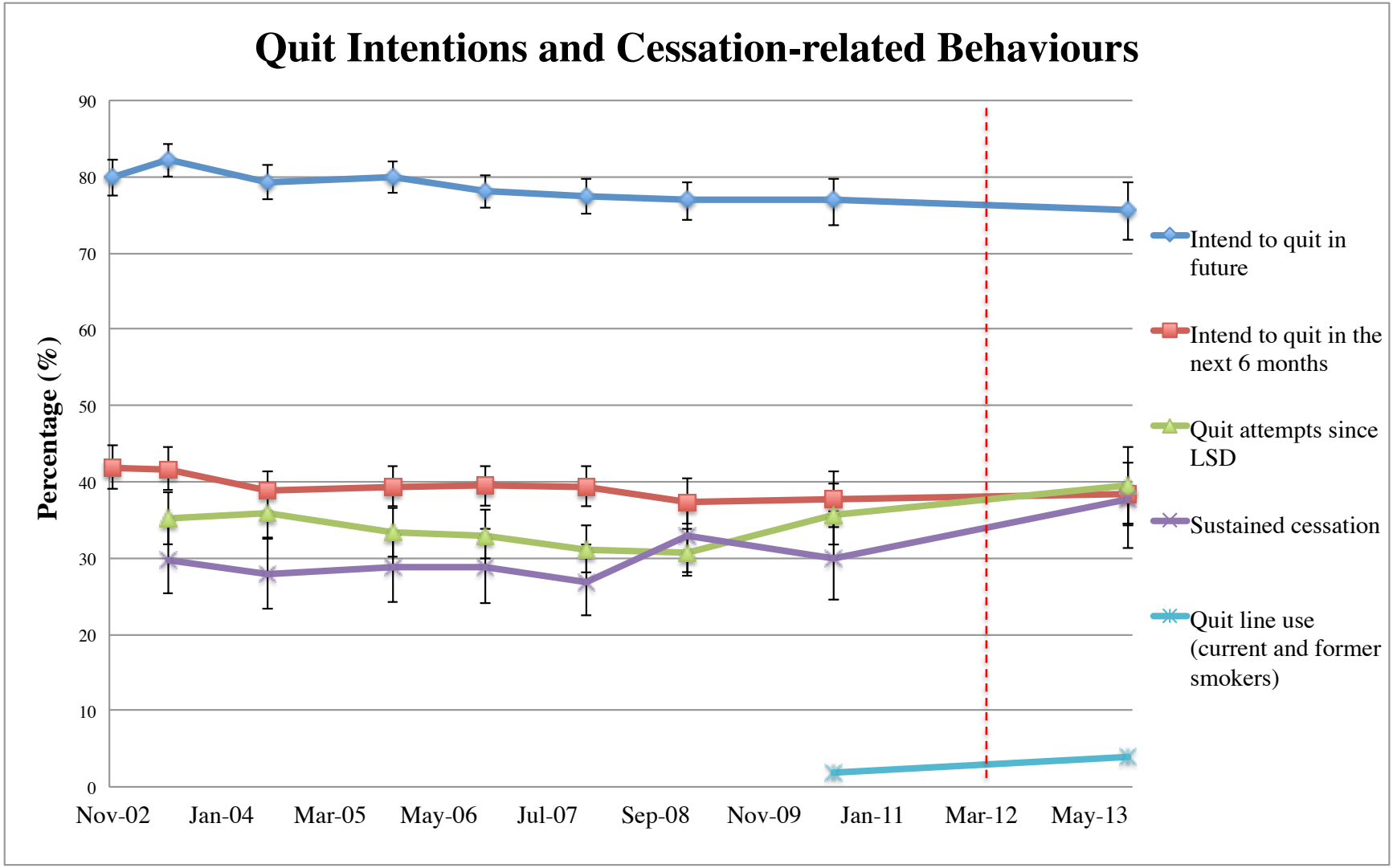
Figure 13 displays the trends in quit intentions and cessation-related behaviours.

Table 14. Mean rates of quit intentions and cessation-related behaviours among Canadian smokers, 2002-2013

Median survey date (Wave #)	**Intentions to quit in the future (%)**	**Intentions to quit within the next 6 months (%)**	**Quit line use (%)**	**Quit attempts since LSD (%)**	**Sustained smoking cessation (%)**
Nov 2002 (Wave 1)	80.0 (77.6-82.2)	41.9 (39.1-44.8)	N/A	N/A	N/A
Jun 2003 (Wave 2)	82.2 (80.0-84.3)	41.7 (38.9-44.5)	N/A	35.2 (31.8-38.7)	29.8 (25.4-34.6)
Jul 2004 (Wave 3)	79.4 (77.1-81.5)	38.8 (36.2-41.4)	N/A	35.8 (32.5-39.2)	27.8 (23.4-32.8)
Nov 2005 (Wave 4)	80.0 (77.8-81.9)	39.4 (36.8-42.0)	N/A	33.3 (30.1-36.6)	28.7 (24.2-33.7)
Nov 2006 (Wave 5)	78.2 (76.0-80.3)	39.4 (36.9-42.1)	N/A	33.0 (29.9-36.6)	28.7 (24.1-33.9)
Dec 2007 (Wave 6)	77.5 (75.1-79.7)	39.4 (36.7-42.1)	N/A	31.2 (28.1-34.4)	26.9 (22.5-31.7)
Jan 2009 (Wave 7)	76.9 (74.4-79.3)	37.4 (34.5-40.4)	N/A	30.7 (27.7-33.9)	32.9 (28.2-38.0)
Aug 2010 (Wave 8)	76.9 (73.7-79.9)	37.7 (34.0-41.4)	1.8 (2.73-2.67)	35.7 (31.7-39.8)	30.0 (24.6-36.2)
Oct 2013 (Wave 9)	75.7 (71.8-79.2)	38.4 (34.3-42.6)	3.9 (5.22-3.25)	39.5† (34.5-44.6)	37.8* (31.3-44.7)

Percentages are weighted
*Significant increase ($p<0.05$) from 2010 to 2013 (GEE contrast of the means)
†Significant difference ($p<0.05$) in slopes before and after 2012 warning revision

Figure 13. Trends in quit intentions and cessation-related behaviours among Canadian smokers, 2002-2013



Intentions to quit smoking in the future

The wave-to-wave GEE analysis showed no statistically significant changes in intending to quit smoking in the future before or after the 2012 warning label revisions.

Overall, intentions to quit sometime in the future decreased as age increased; compared to smokers aged 18-24 years, those aged 55 years and older had the lowest odds of intending to quit (OR=0.53, $p<0.001$).

Smokers with a high income had 1.32 times greater odds ($p<0.01$) of intending to quit smoking sometime in the future compared smokers with a low income.

Compared to low educated smokers, odds of intending to quit sometime in the future were greater among moderately educated smokers (OR=1.37, $p<0.001$) and highly educated smokers (OR=1.24, $p=0.02$).

Compared to those with a low HSI, smokers with a high HSI had lowest odds of intending to quit sometime in the future (OR=0.53, $p<0.001$).

The segmented regression analysis showed that the trend in intentions to quit smoking sometime in the future did not significantly change after the HWL revisions (pre-2012 segment $\beta=-0.037$, post-2012 segment $\beta=0.023$, $p=0.48$).

Intending to quit smoking in the future was significantly and positively associated with quit attempts ($r=0.280$, $p<0.001$).

Intentions to quit smoking within the next six months

Results from the wave-to-wave GEE analysis found no statistically significant changes in intending to quit smoking in the next six months before or after the 2012 HWL revisions.

Overall, high-income smokers had 1.27 times greater odds of planning to quit in the next six months compared to low-income smokers ($p<0.001$).

Moderately educated smokers had 1.14 times greater odds of planning to quit in the next six months compared to smokers with a low education ($p<0.002$).

Smokers with a high HSI had lowest odds of intending to quit sometime in the future (OR=0.58, $p<0.001$).

The segmented regression analysis showed that the trend in intentions to quit smoking within the next six months did not significantly change after the HWL revisions (pre-2012 segment $\beta=-0.023$, post-2012 segment $\beta=0.059$, $p=0.30$).

Intending to quit smoking within the next 6 months was significantly and positively associated with quit attempts ($r=0.395$, $p<0.001$).

Quit line use

Rates of quit line use among smokers and former-smokers more than doubled from 1.8% in 2010 to 3.9% in 2013, but the change was not statistically significant at the 0.05 level ($p=0.06$).

Overall, there were no differences in rates if quit line use by sociodemographics.

Calling the quit line was not significantly associated with quit attempts.

Quit attempts

There were no significant changes in reported quit attempts since the LSD between 2003 and 2010 ($p=0.86$). Following the 2012 warning label revisions, quit attempt rates increased from 35.7% to 39.5%, but it was not statistically significant ($p=0.15$).

Smokers with a high HSI had lowest odds of reporting quit attempts ($OR=0.47$, $p<0.001$).

Although the wave-to-wave GEE analysis found the 2010-2013 increase not to be statistically significant, the segmented regression analysis showed that the trend in quit attempts significantly and positively changed after the 2012 graphic HWL revisions (pre-2012 segment $\beta=-0.004$, post-2012 segment $\beta=0.049$, $p<0.01$).

Sustained smoking cessation

There were no significant changes in rates of sustained smoking cessation between 2003 and 2010 ($p=0.94$). Following the 2012 warning label revisions, sustained smoking cessation increased significantly from 30.0% in 2010 to 37.8% in 2013 ($p=0.047$).

Overall, smokers aged 40-54 years had lowest odds of successful quitting ($OR=0.64$, $p=0.003$) compared to smokers aged 18-24 years.

Smokers with a high income had 1.61 times greater odds of successfully quitting smoking compared to smokers with a low income ($p<0.001$).

The segmented regression analysis showed that the trend in rates of successful quitting did not significantly change after the 2012 graphic HWL revisions (pre-2012 segment $\beta=0.077$, post-2012 segment $\beta=0.219$, $p=0.06$). This could be explained by the relatively stable yet slightly positive trend in rates of sustained cessation before the introduction of the revised warnings.

5.9 Mediation models

Using structural equation modeling (SEM), a series of mediation models were developed to test if the Canadian graphic HWLs influenced quit intentions and quit attempts through indirect routes mediated cognitive reactions and affective reactions.

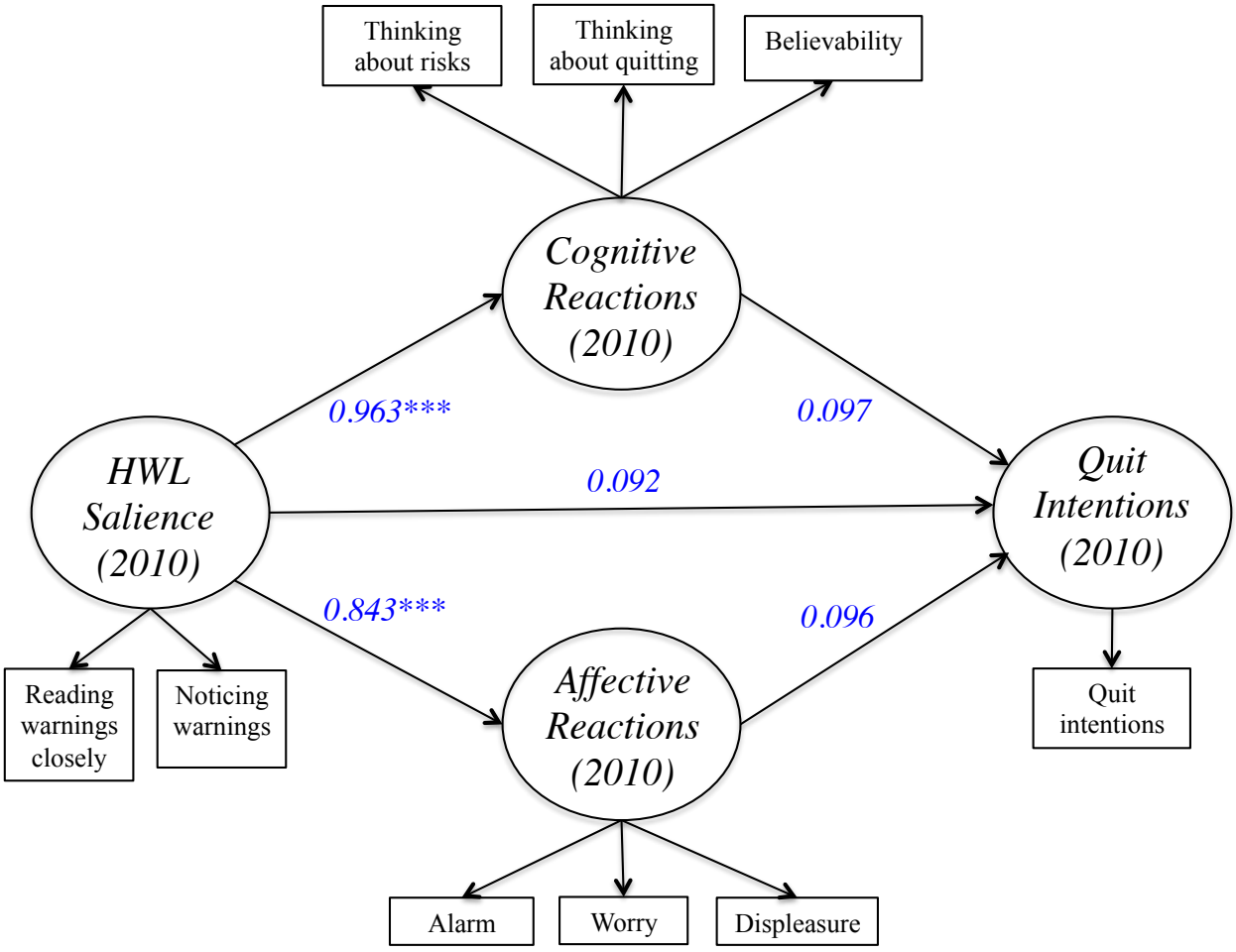
These mediation analyses provided results on both the direct effect (the association between HWL salience and quit intentions, controlling for cognitive and affective reactions) and the indirect effect (the association between HWL salience and quit intentions, via cognitive reactions and/or affective reactions). The total effect of the association of HWL salience on quit intentions equals the sum of the direct and indirect effects.

The overall model fit was evaluated using the root mean square error of approximation (RMSEA), the standardized root square residual (SRMR), and Bentler's comparative fit index (CFI)(181,185). Acceptable model fit is indicated by a value of less than 0.05 for the MRSEA and SRMR, and greater than 0.9 for the CFI(184).

Model 1

Model 1 examined the impact of the Canadian graphic HWLs on quit intentions through the meditational pathways of cognitive reactions and affective reactions in 2010, before the 2012 graphic HWL revisions. Results of Model 1 are shown in Figure 14.

Figure 14. Results of Mediation Model 1 with standardized regression coefficients



*<0.05, **<0.01, ***<0.001
Direct effect of HWL salience on quit intentions: β=0.092, p=0.86
Indirect effect of HWL salience on quit intentions: β=0.175, p=0.73

The results indicated that the model was a fairly good fit to the data (SRMR= 0.03; RMSEA=0.14; CFI=0.90).

In 2010, prior to the revision of the Canadian HWLs in 2012, HWL salience was significantly and positively associated with cognitive reactions (β=0.963, p<0.001).

HWL salience was also significantly and positively associated with affective reactions (β=0.843, p<0.001).

The association between cognitive reactions and quit intentions was not significant (β=0.097, p=0.83).

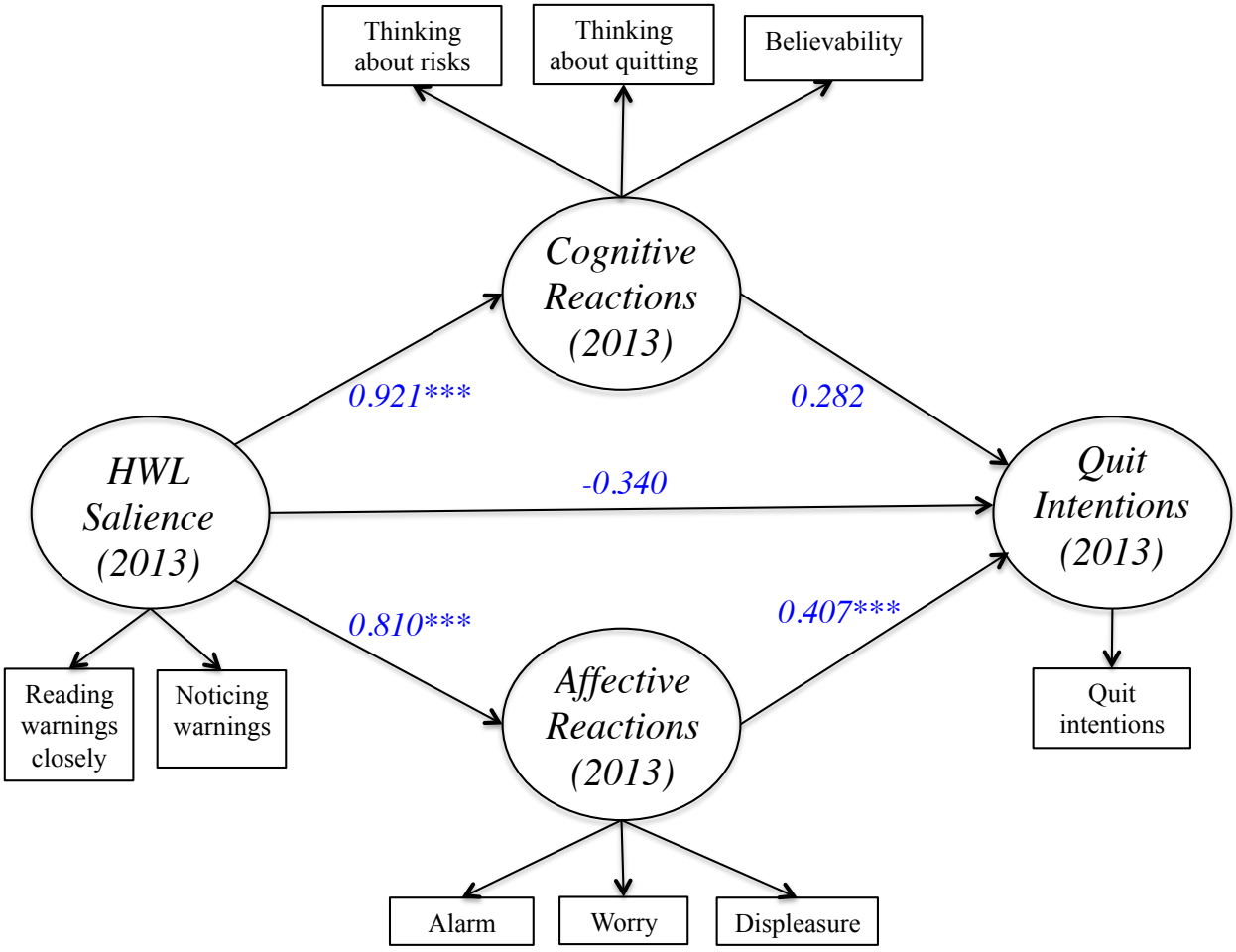
The association between affective reactions and quit intentions was also not significant (β=0.06, p=0.41).

Both the direct effect (β=0.092, p=0.86) and indirect effect (β=0.175, p=0.73) of HWL salience on quit intentions was not significant. This suggests that although HWLs were positively associated with both cognitive and affective reactions, these reactions did not mediate the impact on quit intentions in 2010.

Model 2

Model 2 examined the impact of the Canadian graphic HWLs on quit intentions through the meditational pathways of cognitive reactions and affective reactions in 2013, after the 2012 graphic HWL revisions. Comparing the results of Models 1 and 2 can provide insight on how the 2012 graphic HWL revision may have impacted the mediational pathways (by looking at the strengths of association between constructs). Results of Model 2 are presented in Figure 15.

Figure 15. Results of Mediation Model 2 with standardized regression coefficients



*<0.05, **<0.01, ***<0.001
Direct effect of HWL salience on quit intentions: β=-0.340, p=0.20
Indirect effect of HWL salience on quit intentions β=0.590, *p*=0.01

The model fit indices suggest that the model was a fairly good fit to the data (SRMR= 0.03; RMSEA=0.14; CFI=0.92).

In 2013, after Canadian HWLs revisions, HWL salience was significantly and positively associated with cognitive reactions (β=0.921, p<0.001).

HWL salience was also significantly and positively associated with affective reactions (β=0.810, p<0.001).

The association between cognitive reactions and quit intentions was not significant (β=0.282, p=0.19).

Unlike results from 2010, affective reactions were significantly and positively associated with quit intentions (β=0.407, p<0.001). This illustrates that the relationships between constructs changed following the 2012 graphic HWL revisions. Although affective reactions were not a significant mediator of the association between HWL salience and quit intentions in 2010 (Model 1), affective reactions became a significant mediator after the Canadian graphic HWLs were revised in 2012 (Model 2).

The direct effect of HWL salience on quit intentions was not significant (β=-0.340, p=0.20).

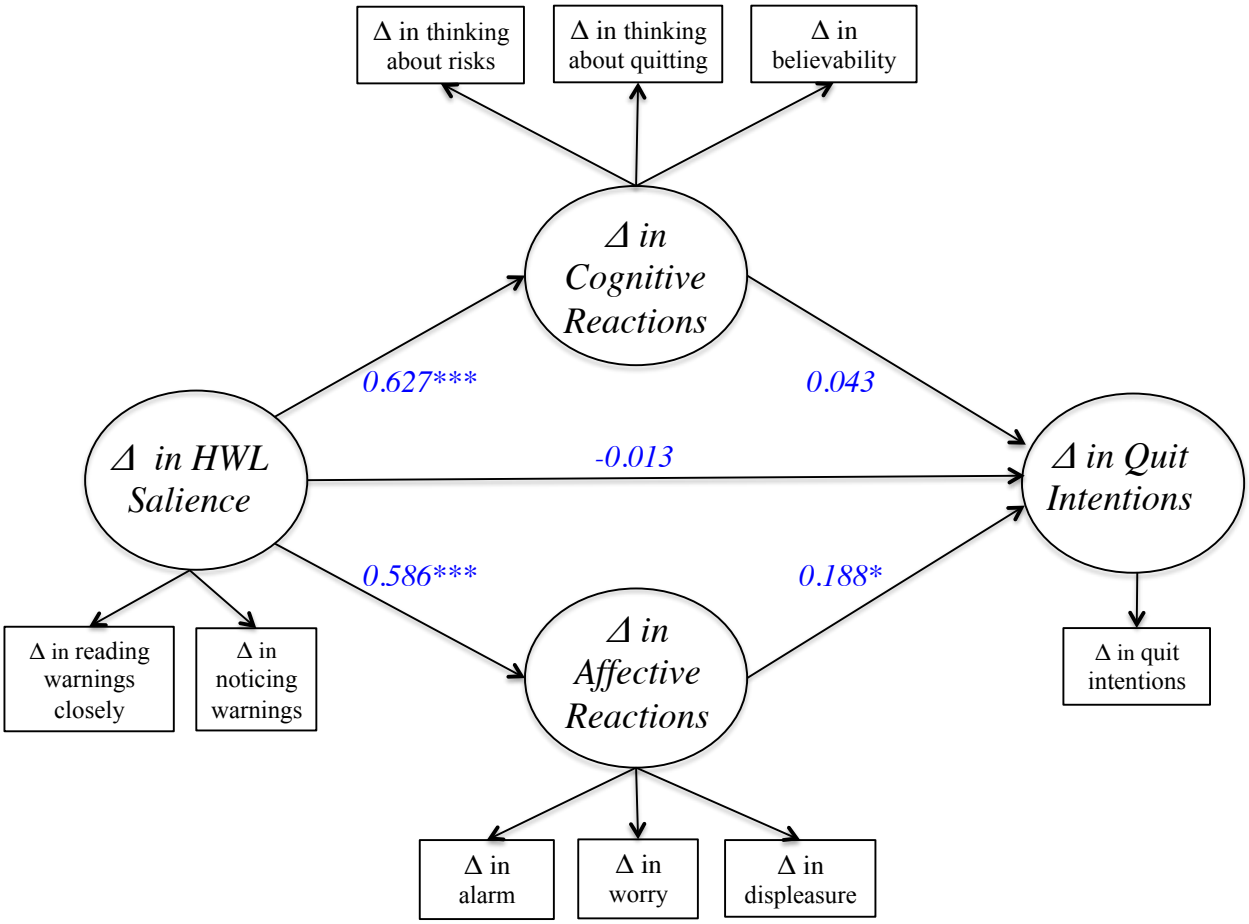
However, the indirect effect was significant (β=0.590, p=0.01) (attributable to the mediational pathway of affective reactions).

Model 3

Model 3 examined the changes in the relations between HWL salience, cognitive and affective mediators, and quit intentions due to the 2012 revisions to the graphic HWLs. Specifically, this model tested if the *change* in HWL salience (which was expected increase after the 2012 graphic HWL revisions) lead to corresponding *changes* in the two mediators—cognitive reactions and affective reactions—and if those *changes* lead 2013 measure to corresponding *changes* in quit intentions. In this model, each indicator was set as the difference between its 2010 (Wave 8) and 2013 (Wave 9) measure. As described earlier, this mediation model is particularly important it captures the possible causal mechanisms of the mediational pathways that changed during the transition from the previous warnings to the revised warnings.

Results of Model 3 are presented in Figure 16.

Figure 16. Results of Mediation Model 3 with standardized regression coefficients



*<0.05, **<0.01, ***<0.001
Direct effect of HWL salience on quit intentions: β=-0.013, p=0.92
Indirect effect of HWL salience on quit intentions β=0.137, *p*=0.12

The model fit indices suggest that the model was a fairly good fit to the data (SRMR= 0.04; RMSEA=0.13; CFI=0.86).

The change in HWL salience was significantly and positively associated with the change in cognitive reactions (β=0.627, p<0.001).

The change in HWL salience was also significantly and positively associated with the change in affective reactions (β=0.586, p<0.001).

The association between the change in cognitive reactions and the change in quit intentions was not significant (β=0.043, p=0.62).

However, the association between changes in affective reactions and changes in quit intentions was significant (β=0.188, p=0.050). This indicates that the change in HWL salience following the 2012 revisions was positively associated with the change in quit intentions, mediated by the change in affective reactions. The overall indirect effect, however, was not significant (β=0.137, p=0.12) because the change in affective reactions was combined with the non-significant effect of change in cognitive reactions.

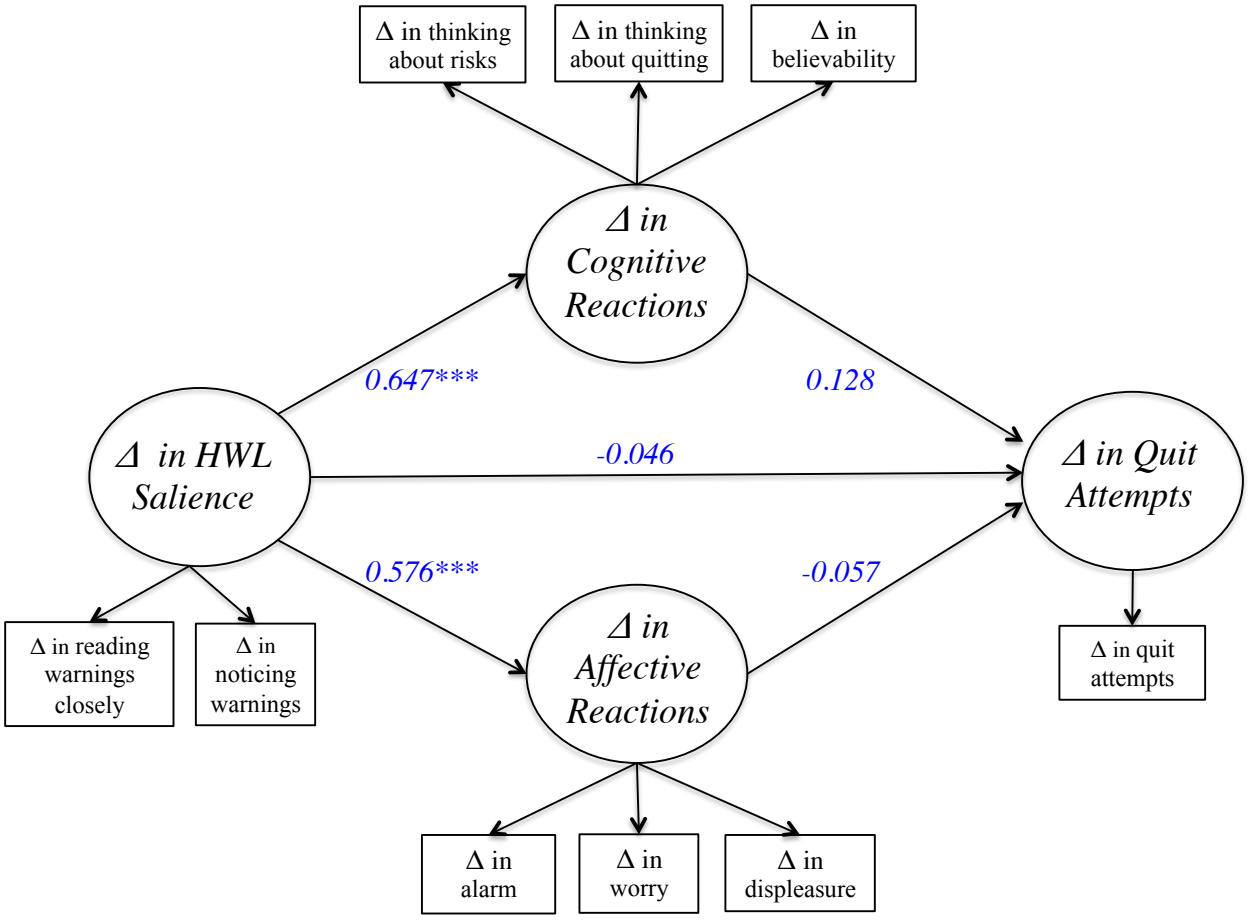
Finally, the direct effect of the change in HWL salience on the change in quit intentions was not significant (β=-0.013, p=0.92).

Model 4

Model 4 examined the changes in the relations between HWL salience, cognitive and affective mediators, and quit attempts due to the 2012 revisions to the graphic HWLs. Specifically, this model tested if the *change* in HWL salience (which was expected increase after the 2012 graphic HWL revisions) lead to corresponding *changes* in the two mediators—cognitive reactions and affective reactions—and if those *changes* lead 2013 measure to corresponding *changes* in quit attempts. In this model, each indicator was set as the difference between its 2010 (Wave 8) and 2013 (Wave 9) measure.

Figure 17 presents the results of Mediation Model 4.

Figure 17. Results of Mediation Model 4 with standardized regression coefficients



*<0.05, **<0.01, ***<0.001
Direct effect of HWL salience on quit attempts: β=-0.046, p=0.73
Indirect effect of HWL salience on quit attempts: β=0.050, p=0.58

The model fit indices suggest that the model was a fairly good fit to the data (SRMR= 0.04; RMSEA=0.14; CFI=0.82).

The change in HWL salience was significantly and positively associated with the change in cognitive reactions (β=0.647, p<0.001).

The change in HWL salience was also significantly and positively associated with the change in affective reactions (β=0.576, p<0.001).

The association between the change in cognitive reactions and the change in quit attempts was not significant (β=0.128, p=0.16).

The association between changes in affective reactions and changes in quit attempts was also not significant (β=-0.057, p<0.57).

The direct effect of HWL salience on quit attempts was not significant (β=-0.046, p=0.73), nor was the indirect effect (β=0.050, p=0.58). This indicates that despite significant affective and cognitive reactions due to warnings, these reactions did not mediate the impact on smokers' behaviours.

6.0 DISCUSSION

The discussion section of this dissertation outlines the research findings, implications of the research, strengths and limitations of the study, and future research.

6.1 Research Findings

This study is the first longitudinal evaluation of the impact of the 2012 Canadian graphic health warning label (HWL) revisions on a multitude of smoking-related outcomes, including key indicators of HWL effectiveness, beliefs about smoking-related health statements displayed on cigarette packages, affective evoked by warnings, quit-efficacy and perceived difficulty of quitting, and intentions to quit and cessation-related behaviours. This is also the first study to investigate if cognitive and affective reactions mediate the effect of the Canadian graphic HWLs on smokers' quit intentions and quit attempts, and if the 2012 revisions impact these mediational pathways.

Data for this research were drawn from nationally representative surveys conducted by the International Tobacco Control Policy Evaluation Project (ITC Project). ITC Survey data from 2002 to 2014 were included to account for the pre-policy trends of key smoking-related outcomes when investigating the impact the 2012 graphic HWL revisions.

The analytical procedure consisted of two principal approaches. First, generalized estimating equation (GEE) regression models (which account for within-subject correlation in cohort designs) were conducted to test for mean differences over time for all smoking-related outcomes included in the study. Second, segmented regression models with a "breakpoint" set to the 2012 HWL revision date compared the slopes of regression lines before and after the revisions – statistical differences between interval slopes can be taken as evidence of a treatment

effect(175). The segmented regression accounted for the differing time intervals between waves, and also produced more time-precise interpretations of the impact by taking into account the secular trends over a nine-year period (2002–2011) prior to the HWL revisions in 2012. Association and cross tabulations analyses were also conducted to provide further information about relationships between outcomes.

6.1.1 Key indicators of warning effectiveness (HWL responses)

Overall impact

The results of this study provide strong support for the first hypothesis that the key indicators of HWL effectiveness (HWL responses) and the Labels Impact Index (LII) would increase following the revision of the Canadian graphic HWLs in 2012. In fact, almost all HWL responses and the LII increased. It is important to note that these increases are likely to be underestimated because the post-policy survey (Wave 9) was administered 17-31 months after the introduction of the new warnings. This time delay may have diminished some of the initial impact of the revised warnings(23,94).

Results from the GEE analyses showed the increase in four HWL responses, and the LII, was statistically significant. These four HWL responses included: noticing warnings “often” and “very often”, thinking “a lot” about health risks due to warnings, thinking “a lot” about quitting due to warnings, and avoiding warnings.

The Elaboration Likelihood Model(153) can help to explain how the 2012 HWL revisions led to increases in warning effectiveness. Applied to HWLs, this model suggests that warnings can persuade smokers to change their behaviour through either the peripheral route of persuasion or the central route of persuasion. Making warnings more salient (or noticeable) by

adding cues or characteristics, such as graphic images, helps to capture the attention of smokers and activates the peripheral route of persuasion. This route involves the formation of associations between simple cues displayed on HWLs and quick and effortless judgments(153). In accordance with this theory, the proportion of smokers who reported noticing warning labels "often" and "very often" significantly increased from 40.5% to 48.5% ($p<0.001$) after warnings were revised to display new graphics and health messages, re-captivating the attention of smokers.

The Elaboration Likelihood Model also suggests that once smokers pay attention to warnings, they are able to engage in the central route of persuasion, which involves thinking carefully and analytically about the content of a message and its arguments(153). In line with this notion, the proportion of smokers who reported to think "a lot" about the health risks of smoking significantly increased from 11.1% in 2010 (pre-HWL revision) to 17.0% in 2013 (post-HWL revision)($p<0.001$). This suggests that the revised graphic HWLs resulted in increased information processing of the warning content (via the central route of persuasion). Further evidence supporting this theory is the fact that the proportion of smokers who reported thinking "a lot" about quitting due to warnings significantly increased from 3.9% to 6.0% ($p=0.03$).

This study also showed that the proportion of smokers who reported to avoid warning significantly increased from 14.1% to 22.3% ($p<0.001$) following the 2012 graphic HWL revisions. Although it has been suggested that avoidance of warnings is an adverse response which results in smokers' rejection of health messages ("fear control" behaviour), correlation analyses in the current study showed that avoiding warnings was significantly and positively associated with thinking "a lot" about health risks ($r=0.196$, $p<0.001$), thinking "a lot" about quitting ($r=0.156$, $p<0.001$), forgoing a cigarette due to warnings($r=0.202$, $p<0.001$), and

intending to quit in the future ($r=0.067$, $p<0.001$). This is consistent with previous studies that have found avoidance behaviour to be positively associated with measures of HWL effectiveness and increased motivation to quit (22,64,93).

Another finding of this study is that rates of forgoing cigarettes due to warnings did not significantly change after the 2012 graphic HWL revisions (13.7% in 2010 to 13.1% in 2013, $p=0.70$). The fact that there was no change in this behavioural reaction despite increases in other HWL responses may be explained by the theory of cognitive dissonance(158). According to this theory, there is a tendency for individuals to rationalize their behaviour and lifestyle choices when they are confronted with information that is in direct opposition to those behaviours. In the context of smoking, this theory suggests that smokers, particularly those with a greater dependency to smoking, may rationalize their behaviour to help overcome the discomfort (dissonance) they feel when exposed to messages about the health risks of smoking. As a result, this rationalization reassures them to continue smoking. In line with this concept, the results showed that smokers with a greater addiction to smoking (indicated by the Heaviness of Smoking Index (HSI), a measure of smoking dependency) were half as likely to report giving up a cigarette due to warnings compared to those with lower levels of addiction ($OR=0.49$, $p<0.001$).

Importantly, this study found that many HWL responses not only increased following the 2012 graphic HWL revisions, but these increases also reversed the previously decreasing trends in effectiveness (wear-out) that were evident between 2002 to 2010. This is demonstrated by the results of the segmented regression analyses comparing the slopes (and therefore trends) of the HWL responses before and after the warnings were revised in 2012.

However, the pre-policy trends of three HWL responses were not significantly impacted

by the revisions. First, the segmented regression analyses showed that the pre-policy trend in avoiding labels was not significantly impacted. This is likely due to the fact that although there was a significant increase in the means from Wave 8 to Wave 9 (14.1% to 22.3%, $p<0.001$; as demonstrated by the GEE analysis results), the pre-policy trend was already in a positive direction (unlike the pre-policy trends of all other HWL responses, which were in a negative direction).

Second, the trend in forgoing cigarettes due to warnings did not change significantly after the 2012 graphic HWL revisions. In fact, rates of forgoing cigarettes due to warnings have remained relatively stable since 2004, fluctuating only between 12.4% and 13.9%. As explained above, this lack of change may be explained by cognitive dissonance, which suggests that while smokers were more engaged with warnings after the 2012 revisions, many smokers were still resistant to changing their behaviours, particularly those with a greater dependence on smoking.

Third, the segmented regression analyses showed that the pre-policy trend in reading labels closely "often" or "very often" was also not significantly different from the trend after HWLs were revised. In fact, rates of reading labels closely "often" or "very often" appear to have somewhat plateaued since 2007, ranging between 21% and 22.5%. Therefore, the slight increase from 20.8% in 2010 to 22.5% in 2013 ($p=0.48$) did not significantly affect this trend.

It is interesting to note, however, that even though the increase in rates of reading labels closely after the revisions was not statistically significant, smokers still reported significant increases in thinking about health risks due to warnings, and thinking about quitting due to warnings. This suggests that even if smokers do not carefully inspect them, the Canadian graphic HWLs are still successful in evoking health concerns. Returning to the Elaboration Likelihood Model, this may have been because the graphic images activate the peripheral route of

persuasion, causing smokers to form negative associations to smoking even without thinking deeply about the message content(153).

Finally, higher smoking dependence (HSI) was found to positively moderate the increase in noticing warnings after the 2012 graphic HWL revision. This is interesting because the overall results from 2002 to 2013 showed that more dependent smokers were the least likely to notice the previous set of warnings. The finding that smokers with greater addiction were the most likely to notice the revised warnings could be explained by more frequent smoking and therefore more frequent exposure to warnings.

Impact by socioeconomic status

It was also hypothesized that smokers with lower socioeconomic status (SES) would have greater increases in HWL responses due to the revisions compared to smokers with higher SES. The results of the study did not support this hypothesis, as neither income nor education moderated the increase of any HWL response.

However, the overall results from 2002 to 2013 showed that smokers with low SES consistently reported greater HWL responses. In fact, no HWL response was found to be greater among smokers with a high education or income compared to their lower categorized counterparts. These results are consistent with previous research showing that graphic warnings evoking affective reactions have a greater impact among smokers from lower socioeconomic groups compared to those with higher SES (72,89,90). For example, a study by Thrasher and colleagues(90) showed that Mexican smokers with lower educational attainment rated pictorial warnings with evocative, graphic imagery as more effective compared to smokers with higher educational attainment.

This is a particularly important finding as smoking rates have been shown to be consistently higher among Canadians with lower levels of education and household income(32–34). The Canadian graphic HWLs therefore have the potential to not only decrease the prevalence of smoking in Canada, but also reduce the pre-existing smoking-related disparities between socio-economic groups.

Summary

This study is the first longitudinal evaluation of the impact of the 2012 revisions on the effectiveness of the Canadian graphic HWLs. Overall, the results showed that the revisions significantly enhanced the effectiveness of the Canadian graphic HWLs. Importantly, this impact is likely underestimated in the current study due to the delay (of 17-31 months) between the HWL revisions and the administration of the post-policy surveys.

The research findings also showed that the 2012 revisions were successful in reducing or even reversing wear-out on the Canadian HWLs found between 2002 and 2011(23). These results are consistent with previous studies showing that wear-out can be reduced by periodically modifying HWLs, and by displaying larger, graphic-based warnings shown to be more resilient to habituation from overexposure(16,68,80).

Finally, the findings of the current study also showed that lower socioeconomic groups were particularly (and positively) affected by the 2012 revisions. Importantly, this demonstrates that the revised graphic HWLs have the potential to positively impact the pre-existing socioeconomic inequalities of smoking in Canada.

6.1.2 Affective reactions evoked by warnings and warning believability

Overall impact

The second hypothesis posited that the new 2012 graphic HWLs would result in increased affective reactions due to the display of new graphic images and testimonial messages. Findings of the study partially supported the hypothesis; although affect (and believability) increased following the 2012 revisions, only the increases in displeasure caused by warnings and believability were statistically significant.

The lack of change in levels of alarm or worry caused by warnings could be explained by the fact that the post-policy (Wave 9) survey was administered 17-31 months after the introduction of the revised HWLs. It is therefore likely that the initial affective impact of the graphic HWLs had gradually diminished by the time these surveys were conducted, underestimating their effects. Additionally, graphic images have been displayed on Canadian warnings since 2002. Therefore, the "shocking" element of the HWLs was not new and may not have affected smokers as much as they did when they were first introduced in 2001.

Although levels of alarm and worry due to warnings were not significantly affected by the revisions, the HWL revisions were found to significantly increase feelings of displeasure and warning believability. This could be explained by the addition of testimonial messages, which describe personal stories of the consequences of smoking, typically written as a quote from a person displayed the image. According to the Narrative Transportation Theory(159), testimonial messages can enhance personal relevance of health warnings by providing context within a narrative or a story. Consequently, testimonials encourage emotional involvement among viewers and often result in feelings of empathy and sadness for characters displayed on HWLs(99,160,188). Additionally, testimonials have been shown to increase the credibility of

warnings because the health messages are presented as real life examples(64).

An important finding of this study is that each affective reaction was significantly and positively associated with all HWL responses and the LII. All affective reactions were positively associated with cognitions and behaviours indicative of "danger control" reactions (the desired behaviour change), such as thinking about quitting and forgoing a cigarette due to warnings. Affective reactions were also positively associated with quit intentions and quit attempts, further supporting the implementation of emotionally evocative warnings.

These results suggest that affective reactions evoked by the Canadian HWLs were not associated with "fear control" reactions, which would have been supported by critics of graphic warnings who claim that they lead to defensive avoidance behaviours(145). Importantly, these criticisms are based on experimental studies that measure the initial, short-term impact of graphic warnings(130,142,145,146,149). Logically, first-time impressions to shocking images will be strong(12,24). However, they do not mimic the nature of HWL exposure in the real world, which tends to be more passive because individuals are exposed to HWLs multiple times over prolonged periods of time. Consequently, these studies are conducted out of context, and are unable to replicate the conditions of the real world.

Finally, warning believability and all affective reactions were positively associated with the belief that smoking is difficult to quit. This finding emphasizes that graphic warnings must be accompanied by salient and noticeable efficacy messages that provide smokers with information on how to quit smoking. Although the Canadian regulations require these messages to be included inside packages, they are often overlooked by smokers (described in more detail below) and therefore cannot provide smokers with their intended benefits. However, affective reactions evoked by warnings were not associated with smokers' quit-efficacy.

Impact by SES

It was also hypothesized that smokers with low SES would have a greater increase in affective reactions compared to smokers with higher SES. This was not supported by the results, which found that highly educated smokers were significantly more likely to report greater levels of each affective reaction due to warnings (and rate warnings as more believable).

Interestingly, this is not consistent with previous studies that have typically found smokers from low socioeconomic groups to be more effected by fear-evoking HWLs(72,89,90). For example, a study conducted by Durkin and colleagues(89) showed that emotionally evocative anti-smoking ads and testimonials that aired on television in the US had a greater emotional impact among smokers from low- and mid-socioeconomic groups compared to those with a high SES.

A possible explanation for the finding that higher educated smokers reported greater affective reactions is that these groups typically have greater baseline knowledge of smoking-related risks(36), and may therefore be more receptive and influenced by health messages. Smokers who are skeptical of health messages may be more resistant to changing their smoking habits and likely less concerned about the health consequences of smoking(108,116).

This idea would be supported by the Protection Motivation Theory(154), which asserts that smokers' motivation to engage in protective behaviour (smoking cessation) depends on their perceived severity of the event (severity of the health effects displayed on warning labels), and their perceived probability of its occurrence (perceived vulnerability of suffering these health consequences). If smokers do not believe that the health consequences described on cigarette packages are tangible or realistic threats, then they will not fully accept these messages nor be concerned by them(103). Finally, this idea is further supported by the fact that higher educated

smokers were significantly more likely to perceive warnings as believable compared to lower educated smokers (OR=1.33, $p<0.001$).

Summary

This study is the first to explore the impact of the 2012 revisions on the capacity of the Canadian graphic HWLs to evoke affective reactions among smokers. Overall, the results showed that the revisions led to increases in the proportion of smokers who found the warnings to be unpleasant and believable (possibly due to the addition of testimonial messages). However, the proportion of smokers who found warnings to be alarming or worrisome did not significantly increase following the 2012 graphic HWL revisions, likely due to the fact that "shocking" graphic warnings have been displayed on Canadian cigarette packages since 2001.

This study also found that smokers with higher educational attainment were significantly more likely to report greater levels of each affective reaction due to warnings, as well as higher levels of warning believability. Although these results are not consistent with previous research showing that fear-evoking HWLs have greater impact among low SES groups, this finding is supported by psychological theories emphasizing the importance of credibility for message acceptance and subsequent behaviour change.

6.1.3 Beliefs about smoking-related health statements

Overall impact

The findings of this study provided strong support for the third hypothesis that correct beliefs would increase for health statements added to warnings, whereas correct beliefs would remain the same or decrease for statements removed from warnings. After health facts were

added to Canadian HWLs in 2012, significant increases were found in rates of believing that smoking causes bladder cancer (26.8% in 2010 to 44.0% in 2013, <0.001) and that smoking causes blindness (from 11.7% in 2010 to 14.7% in 2013, p=0.04). In fact, the odds of believing that smoking causes bladder cancer and smoking causes blindness was 2-fold and 3.4-fold greater, respectively.

Although the health message explaining that nicotine causes addiction was also added to the revised warnings, there was no significant change in beliefs of this fact. However, this is likely to have occurred because a very similar statement was displayed on the first set of warnings: "*Cigarettes are highly addictive*". Though not explicitly attributing addiction to nicotine, this detail may be common knowledge among smokers. This could therefore explain why rates of correct beliefs were high both before and after the 2012 graphic HWL revisions.

Another possible explanation of why rates in beliefs that nicotine causes addiction did not increase after this fact was added to warnings is a ceiling effect. A ceiling effect occurs when levels of a dependent variable (health knowledge) are high and therefore no longer affected the independent variable (HWL content)(102). Correct beliefs that nicotine causes addiction remained very high between 2007 and 2013, ranging from 89.0% to 90.6%. Therefore, adding this health fact to packages may have had little effect on the already significant levels of correct beliefs that nicotine causes addiction.

The findings of the current study are consistent with previous research illustrating that graphic HWL content is associated with greater awareness of smoking-related health risks. For example, an ITC study including smokers from Canada, Australia, and Mexico found higher levels of smoking-related knowledge in countries where graphic HWLs were revised or introduced for the first time(102). These results, as well as the findings from the current study,

support the implementation of graphic HWLs as an effective health communication strategy to inform the public about the health risks associated with smoking.

Importantly, this study also showed that removing health facts from graphic HWLs led to reductions in correct beliefs about smoking-related health facts. After the health message explaining that cigarette smoke contains carbon monoxide was removed from warnings in 2012, rates of correct beliefs about this statement significantly decreased from 92.4% in 2010 to 86.7% in 2013 ($p<0.001$).

Another health fact removed from the revised warnings was the statement explaining that smoking causes impotence. Although the GEE analysis of the means found that the removal of this health fact did not significantly impact subsequent beliefs about this health fact, the segmented regression analysis showed that it did negatively impact the trend. Between 2002 and 2010 (during which the health message was displayed on HWLs) correct beliefs that smoking causes impotence increased significantly from 60.7% to 67.8% ($p<0.01$). However, the positively trending rate in beliefs was broken off following the removal of this health message (rates decreased slightly from to 66.2% in 2013). Accordingly, the results of the segmented regression analyses found that the trend in believing that smoking causes impotence significantly changed ($p<0.01$) in a negative direction after the health message was removed from cigarette packages. This proves that HWLs are indeed an important source of health information for smokers, and that removing health facts from HWLs can curtail the benefits in awareness that arise from their display.

Finally, the health message stating that smoking causes stroke was displayed on HWLs both before and after the 2012 revisions. The results showed that rates of believing this fact increased consistently during the 11 years that it was displayed on Canadian HWLs (84.6% in

2002 to 88.7% in 2013, p=0.02), and no change occurred between 2010 and 2013. This provides further evidence of the important link between health knowledge and HWL message content.

Overall, the finding that the addition *and* removal of health warning information led to significant increases and decreases (respectively) in smokers' awareness of these risks has important implications on policy development and implementation. Policymakers must take careful consideration when deciding which health messages should appear on HWLs in order to optimize knowledge gains among smokers. Furthermore, this study showed that well-known health facts are less likely to be affected by HWL messages. This is consistent with research findings from a study conducted by Swayampakala and colleagues(102), which also found a ceiling effect for knowledge about well-known smoking-related health risks.

Impact by SES

It was also hypothesized that the magnitude of changes in correct beliefs would be greater for smokers from with higher SES. Although no moderation by income or education was found for the changes following the 2012 graphic HWL revisions, the overall results showed that smokers with higher SES were generally more likely to correctly believe most smoking-related health statements.

The finding that smokers with lower levels of education and income generally had lower levels of correct beliefs about smoking-related health facts is consistent with previous research. For example, an ITC study investigating socioeconomic differences in knowledge among smokers in Canada, Australia, the US and the UK found that for nearly all knowledge measures, higher education and income levels were associated with higher awareness(36).

These findings emphasize that there is a critical need to improve knowledge of the

dangers of smoking among disadvantaged groups, who are disproportionately affected by the harms of tobacco use(45). This is particularly important because enhanced awareness on the health risks of smoking has been shown to be an important predictor of motivation to quit and sustained cessation(18,21,86,105–108).

Summary

This study is the first longitudinal evaluation of the impact of the 2012 graphic HWL revisions on beliefs about smoking-related health statements displayed on cigarette packages. Consistent with previous research, this study showed that significant gaps exist in smokers' awareness about the health impacts of smoking. Adding health messages to warnings significantly increased rates of correct beliefs about this information, and the removal of health warnings was shown to reduce correct beliefs. This emphasizes that policymakers must take careful consideration when determining which health messages are to appear on HWLs in order to optimize knowledge gains among smokers.

Finally, the results of this study found that smokers with higher SES were generally more likely to correctly believe most smoking-related health statements. Given that smoking is more common among the disadvantaged, it is important to improve smoking-related knowledge among these groups – not only because improved knowledge is an important goal itself, but also because enhanced knowledge has shown to be an important predictor of motivation to quit and sustained cessation (18,21,86,105–108).

6.1.4 Interior messages

In 2012, the interior messages previously introduced in 2001 were revised to display new messages designed to promote motivation and self-efficacy to quit smoking. Findings of this study showed that in 2013, 15.1% of smokers reported reading the interior messages. Compared to smokers with a low dependence on smoking (HSI), highly dependent smokers had lowest odds of reading interior messages (OR=0.36, $p<0.001$). Rates of reading interior messages did not differ by income or education.

These results are concerning for several reasons. First, the finding that most smokers neglected to read the interior warnings is problematic because these messages play a critical role in reducing "fear-control" behaviours among smokers, particularly among smokers with low self-efficacy(80,130,133). As predicted by the Extended Parallel Process Model(155), graphic HWLs that evoke fear will be effective in eliciting "danger control" behaviours when response efficacy (the belief that the change in behaviour will reduce the risk of negative consequences) and self-efficacy (the belief that they can achieve the behaviour change) are high. It is therefore more likely that a smoker will engage in defensive avoidance ("fear control") behaviours if they are exposed to graphic warnings but ignore the efficacy messages inside cigarette packages (155,157).

Second, the results showed that individuals with the greatest dependence on smoking were significantly less likely to read interior messages. However, highly addicted smokers would benefit the most from reading these messages because they are designed to increase confidence and motivation to quit. This concept is supported by the Theory of Reasoned Action/Planned Behaviour(150), which claims that a smoker's intention to quit and subsequent cessation behaviour is based on his/her personal beliefs about quitting, the social norm (disapproval of

smoking), and his/her efficacy to achieve the goal(82). Interior messages can positively influence each of these factors by emphasizing the social and health benefits of quitting, describing the negative effect that smoking has on the smoker and on others (via secondhand smoke), and providing cessation-related support and advice. Interior messages are therefore particularly important for increasing intentions to quit and subsequent cessation behaviours, especially for smokers with a greater dependence to smoking who may be more resistant to quitting.

This study also had some encouraging results in regards to the interior messages. The findings showed that reading interior messages was significantly and positively associated with enhanced quit-efficacy. In fact, 19.2% of smokers who read interior messages were "very" or "extremely" sure they could quit smoking, compared to only 11.5% of smokers who did not read interior messages. This is an important and positive finding, given that a primary objective of the interior messages is to enhance quit-efficacy among smokers.

Another objective of interior messages is to provide cessation-related guidance to help smokers overcome the mental and physiological barriers of quitting (such as increased motivation, information on helpful resources, or advice on how to cope with cravings and withdrawals)(14). The results, however, showed that reading interior messages was not significantly associated with perceived difficulty to quit smoking in 2013. Because quit-efficacy and perceived difficulty are logically inversely related, these findings indicate that the magnitude of impact that interior messages had on quit-efficacy could have been even greater if the interior messages were more successful in providing encouraging messages about the prospect of achieving cessation. Enhancing guidance-related messages is likely to also impact quit attempts, which were found not to be significantly associated with reading interior messages in 2013.

Finally, the findings showed that reading interior messages was positively associated with calling the quit line and with intending to quit. Among smokers who read interior messages, 86.3% had intentions to quit in the future. In contrast, among smokers who did not read interior messages, 76.2% had intentions to quit. This is another important and positive finding, because psychological theory and empirical research emphasize that quit intention is a significant predictor for making quit attempts and for quit success(110–112).

It is important to note that the causal direction of the relationship between reading interior messages and quit intentions could be bidirectional: reading interior messages could lead to increased quit intentions, and/or higher quit intentions may cause smokers to read interior messages. The possibility of the latter relationship highlights an important benefit of HWLs in that they are always available and can capitalize on the times of intentions. This means that even if these informational and efficacy enhancing messages are not initially as beneficial for smokers who do not intend to quit, they will be available to those smokers if they intend to quit at a later time.

Few studies have investigated the impact of efficacy messages enclosed in cigarette packages on smokers' quit-efficacy. However, consistent with the present findings, the limited research has shown that more frequent reading of interior messages is associated with increased cessation-related thoughts and behaviours(134,135). For example, a study by Thrasher and colleagues(134) that explored the impact of the revised Canadian inserts found that reading interior messages was associated with higher quit intentions, quit attempts, and with stronger self-efficacy to quit at follow up.

Summary

In 2013, reading interior messages was positively associated with quit-efficacy, quit intentions, and calling the quit line. However, very few smokers (15%) reported to read the interior messages. This is problematic because these messages play a critical role in reducing "fear-control" behaviours among smokers, particularly among smokers with low quit-efficacy.

This study also found no association between reading interior messages and perceived difficulty to quit smoking or quit attempts. This may indicate that the interior messages are not effectively delivering cessation-related guidance to ease smokers' apprehensions to quit.

6.1.5 Quit-efficacy and perceived difficulty of quitting

Overall impact

The results of the study did not support the fourth hypothesis that the 2012 graphic HWL revisions would increase levels of quit-efficacy and decrease perceived difficulty of quitting. After the HWLs and interior messages were revised in 2012, quit-efficacy significantly decreased (2.57 to 2.37, $p<0.001$) and perceived difficulty to quit significantly increased (4.08 to 4.24, $p<0.001$). The fact that these variables changed in opposing directions is unsurprising because quit-efficacy and perceived difficulty to quit are logically inversely related: if a smoker believes that cessation is difficult to achieve, his or her self-efficacy for that task would be low(189). The results of this study confirmed this inverse association ($r=-0.380$, $p<0.001$).

A possible explanation for these findings could be that smokers with highest levels of efficacy were successful at quitting between Wave 8 (2010) and Wave 9 (2013), and were therefore no longer included in the analysis at Wave 9 (only current smokers are asked about quit-efficacy and perceived difficulty to during the survey process). Drop out due to quitting

would therefore leave smokers in the cohort who had lower efficacy, thus reducing the mean level of quit-efficacy.

The finding that a significant increase in rates of successful quitting coincided with the decrease in levels of quit-efficacy (and the increase in perceived difficulty of quitting) supports this idea. In fact, rates of all three measures (quit-efficacy, perceived difficulty to quit, and successful smoking cessation) did not significantly change between 2002 and 2010, prior to the HWL revisions, but changed simultaneously between 2010 and 2013, after the HWL revisions. This could indicate that the HWLs did in fact have a positive impact on smokers' quit efficacies, which subsequently led to increased rates of successful quitting.

Several theories support this idea by emphasizing the importance of high quit-efficacy in quitting smoking. For example, the Theory of Reasoned Action/Planned Behaviour(150) states that quit intentions and subsequent cessation behaviour is based on a smoker's personal beliefs about quitting, the social norm, and his/her efficacy to quit(82). Similarly, the Protection Motivation Theory(154) claims that an individual's motivation to engage in self-protective behaviour (smoking cessation) is based on the balance between threat appraisal (their perceived vulnerability of severity of health effects) and coping appraisal (response efficacy and self efficacy). Studies have provided evidence of the important link between self-efficacy and cessation-related cognitions and behaviours, thus supporting these theories(80,115,130,134,135,142).

However, it is important to note that the decrease in quit-efficacy found between 2010 and 2013 did not prevent smokers from attempting to quit smoking. Although quit-efficacy was positively associated with quit intentions, no direct association was found between quit-efficacy

and quit attempts. Additionally, the results did not show a corresponding decrease in quit attempts between 2010 and 2013 (discussed in the next section).

These findings are consistent with previous literature. For example, a study conducted by Thrasher and colleagues(122) among Canadian and Australian smokers found that strong self-efficacy predicted future cessation behaviour, but efficacy beliefs did not moderate the effects of HWL responses on cessation attempts. Similarly, a study by Riet and colleagues(140) among smokers in the Netherlands found that HWLs increased quit intentions among smokers with high efficacy, but there was no association between smokers' self-efficacy and number of quit attempts. Therefore, while the results of these studies (and of the current findings) did not find any evidence that graphic HWLs are counterproductive, they did indicate that low-efficacy smokers are not benefiting from the HWLs the same way that high-efficacy smokers do.

Impact by SES

It was also hypothesized that the expected increases in quit-efficacy and decreases in perceived difficulty of quitting would be lower among lower SES smokers. The results of the study did not support this hypothesis as no moderation by income or education was found. Overall socioeconomic differences in quit-efficacy and perceived difficulty to quit smoking between 2002 and 2013 were also inconsistent.

With respect to quit-efficacy, low educated smokers were found to have lower odds of believing they could quit (OR=0.89, $p<0.01$). These low levels of quit-efficacy are likely an important contributing factor to the typically higher rates of smoking among lower educated groups (again supported by the multiple theoretical frameworks described above). Studies exploring educational differences in cessation-related cognitions and behaviours in other

countries, such as the Netherlands and China, have also found lower levels of efficacy among low educated smokers(190,191).

For perceived difficulty of quitting (a construct of self-efficacy), the results showed that smokers with a high income had greater odds of believing smoking is difficult to quit than low-income smokers (OR=1.12, $p<0.001$). Interestingly, a corresponding decrease in quit-efficacy was not found for high-income smokers. This may indicate that although high-income smokers believed that smoking cessation is a difficult task, they personally believed that they would be able to quit if they tried. A possible explanation for this is the nature of their environment. It has been suggested that compared to individuals with low SES, those with higher SES experience lower levels of routine stress, enhanced social and community support, and have greater access to information and resources to promote health (such as cessation aids)(37–39). This lifestyle may help to increase their self-confidence in achieving their goals.

Summary

This study is the first longitudinal evaluation of the impact of the 2012 Canadian graphic HWL revisions on the smokers' quit-efficacy and perceived difficulty to quit smoking. The results showed that quit efficacy decreased and perceived difficulty to quit smoking increased following the 2012 graphic HWL revisions. This, however, could be due to drop out of former smokers who successful quit smoking. Additionally, these findings do not indicate that graphic HWL revisions inhibited low-efficacy smokers from quitting. Although quit-efficacy was positively associated with quit intentions, no association was found between quit-efficacy and quit attempts.

Socioeconomic differences in quit-efficacy and perceived difficulty to quit smoking were

inconsistent. However, results from the current study and from past research indicate that lower socioeconomic groups typically have lower quit-efficacy beliefs (often attributed to a more stressful lifestyle with lower access to resources to promote health)(37,38).

6.1.6 Quit intentions and cessation-related behaviours

Quit intentions

The results of the study did not support the fifth hypothesis that intentions to quit would increase after the 2012 graphic HWL revisions. Levels of intentions to quit smoking sometime in the future remained relatively stable between 2002 and 2013, ranging from 76% to 82%. Levels of intentions to quit within the next six months also remained stable during this time period, ranging between 37.4% and 41.9%.

The finding that quit intentions didn't significantly change between 2010 and 2013 could again be explained by successful quitting among smokers with highest levels of quit intentions. Drop out due to quitting would remove these smokers from this analysis, as quitters are not questioned about their quit intentions at follow up. The significant increase in rates of successful quitting smoking between 2010 and 2013 supports this concept. This may indicate that the HWLs did in fact have a positive impact on smokers' quit intentions, which subsequently led to increased rates of successful quitting.

Another possible explanation for the unchanging rates of quit intentions after the 2012 HWL revisions is cognitive dissonance(158). To reiterate, cognitive dissonance refers to the rationalization of certain behaviours or lifestyle choices that individuals experience when confronted with information that is in direct opposition to those behaviours. In the context of smoking, this theory suggests that smokers, particularly the most addicted, rationalize their

behaviour to help overcome the discomfort (dissonance) they feel when exposed to messages about the health risks of smoking. Smokers who rationalize their smoking will therefore be less motivated to quit.

This idea is supported by the finding that smokers with a greater dependence (HSI) on smoking were the least likely to hold quit intentions. In fact, highly dependent smokers were about half as likely to report intentions to quit smoking sometime in the future (OR=0.53, $p<0.001$) or within the next six months (OR=0.58, $p<0.001$) compared to those with a low dependence on smoking. Although this finding is unsurprising, it illustrates that tobacco control strategies must target smokers with greater dependencies because they are the most resistant to changing their behaviours.

Importantly, quit intentions were found to be significantly and positively associated with quit attempts. Although the association was significant for both quit intention measures, the strength of association was stronger for quit intentions within the next 6 months. This is consistent with the principles of behaviour change theories, of which most prominent is the Transtheoretical Model (TTM)(192). Central to the TTM is the idea that behaviour change involves the progression through a series of stages (*pre-contemplation, contemplation, preparation, action, maintenance*), with the possibility of relapse (regressing to an earlier stage).

In context of smoking, an individual who intends to quit sometime in the future would be in the *contemplation* stage, whereas a smoker who has set a quit date would be in the *preparation* stage. Because the *preparation* stage precedes the action stage (in which an individual executes the desired behaviour change), smokers in this stage would be farther along the progress of behaviour change compared to those in the *contemplation* stage (who have not set a quit date). These principles have also been supported by previous research showing that smokers who

prepare themselves to engage in cessation behaviours (such as setting a quit date or looking into cessation programs) are more likely to engage in subsequent quit attempts(187). The dissemination of cessation-advice that encourages smokers to take small steps towards quitting is therefore particularly important in effective tobacco control strategies.

Although the TTM is frequently applied to health promotion interventions (including tobacco control policies), it has been heavily criticized(193,194). For example, West(193) claims that the TTM defines stages with arbitrary boundaries simply to categorize individuals, giving them little meaning (e.g. smokers who intend to quit in 30 days are in a different category than those who intend to quit in 31 days). The TTM has also been criticized for its lack of consideration regarding the roles of reward and punishment, addiction, and unplanned or spontaneous behaviour changes(193).

Impact on quit intentions by SES

It was also hypothesized that smokers with higher SES would have greater increases in quit intentions following the 2012 graphic HWL revisions. The results did not support this hypothesis as no moderation in intentions to quit by income or education was found. However, the overall results from 2002 to 2013 showed that compared to smokers with low SES, smokers with higher SES reported greater intentions to quit sometime in the future and within the next six months.

Previous studies examining SES and intention to quit have been inconsistent. For example, a study that examined smoking-related cognitions and behaviours among Canadian smokers between 1999 and 2006 found scarce educational differences in intentions to quit(33). Other studies, however, have found that smokers from higher socioeconomic groups have significantly greater intentions to quit compared to smokers from low socioeconomic groups

(195–197). It has been suggested that this could be due to lower levels of awareness of the negative health effects of smoking generally found among low SES groups, which in turn leads to decreased health concerns (shown to be important predictors of quit intentions)(36,103).

Quit line use

The 2012 Canadian graphic HWLs present, for the first time, the toll-free quit line number. It was therefore hypothesized that rates of calling the quit line would significantly increase following the graphic HWL revisions. The results of the study supported this hypothesis: although found not to be statistically significant at the 0.05 level (p=0.06), rates of calling the quit line more than doubled after the revisions (from 1.8% in 2010 to 3.9% in 2013), indicating a substantial relative increase.

The fact that this increase was found not to be statistically significant is likely due to the relatively small sample size available for detecting a low-probability behaviour (reducing the statistical power of this analysis). The results of this study are in fact similar to those found in studies by Baskerville and colleagues(127,128), which also investigated the impact of the newly displayed toll-free quit line number on Canadian cigarette packages. These studies, however, used data drawn directly from participating Canadian quit line providers and therefore had much greater sample sizes. The results of these study showed a relative increase of 160% in the average monthly call volume over 7 months post-revision(127), and the vast majority (86%) of new callers reporting seeing the quit line number on the warning labels(128). These results, as well as the findings from the current study, illustrate that displaying the quit line number on Canadian cigarette packages led to significant relative increases in quit line use.

Nevertheless, use of the quit line remains very low despite the increase shown between

2010 and 2013. Importantly, these low rates represent a significant lost opportunity for smokers to seek cessation-related guidance. In 2013, more than three-quarters of smokers (76%) reported intending to quit in the future, and 38% of smokers intended to quit in the next six months. It is critical that interventions effectively encourage smokers to act on these intentions and take the next steps in the quitting process. Enhancing perceptions of the quit line as an easily accessible and free cessation tool could help to increase call volume and subsequently bridge the gap between smokers' quitting-related intentions and actions. Strategies encouraging smokers to call the quit line should also target lower socioeconomic smokers who may otherwise have less access to cessation resources compared to higher socioeconomic status(37,38).

Quit attempts

The results of the study partially supported the hypothesis that rates of quit attempts since the last survey date (LSD) would significantly increase following the 2012 graphic HWLs revisions. Although rates increased from 35.7% in 2010 to 39.5% in 2013, the increase was not statistically significant (p=0.15). The potential impact of drop out due to quitting is not a threat in this analysis because both current and former smokers were included in the sample.

The fact that rates of quit attempts did not increase by a greater magnitude could again by explained by the theory of cognitive dissonance(158). This theory suggests that smokers, particularly the most addicted, rationalize their behaviour to overcome the discomfort (dissonance) they feel when their actions clash with beliefs or information about the negative effects of smoking. Smokers who rationalize their smoking will therefore be less inclined to engage in cessation behaviours. This notion is supported by the finding that smokers with a greater dependence (HSI) on smoking were the least likely to attempt to quit. In fact, highly

dependent smokers were less than half as likely to attempt to quit (OR=0.47, $p<0.001$) compared to those with a low dependence on smoking.

Importantly, the finding that the increase in quit attempts was not statistically significant does not mean that the revised graphic HWLs did not significantly impact smokers' quitting behaviours. In fact, the segmented regression analysis showed that the trend in quit attempts significantly and positively changed after the 2012 graphic HWL revisions (although the upward trend appears to have begun in 2009 for reasons that remain unclear).

It is also important to consider that smoking cessation is achieved either abruptly (setting a date to quit smoking completely) or gradually (regularly reducing cigarette consumption until one stops smoking). Although the abrupt method of attempting to quit is generally more common, research has shown that smokers with high levels of income and education are more likely to utilize this method(198). Therefore, low socioeconomic smokers (who are indeed the majority of smokers in Canada) could be engaging in gradual quit attempt behaviours. Future research could investigate this possibility by studying rates of cigarette consumption in Canada over time.

Impact on quit attempts by SES

The results did not support the hypothesis that the predicted increase in quit attempts would be greater among smokers from higher socioeconomic groups. No moderation by income or education was found. Additionally, no differences by SES were found in the overall rates of quit attempts between 2003 and 2013, indicating greater socioeconomic equity for this measure. This is consistent with a study by Reid, Hammond, and Driezen(33), which also found no socioeconomic differences in quit attempts among Canadian smokers between 1999 and 2006.

Other studies, however, have found quit attempt rates to be higher among smokers from high socioeconomic groups (4,39,45). For example, statistics from the US in 2012 showed that almost half (49%) of smokers with a college degree reported quit attempts over the past year compared to only 39% of smokers with a high school degree or less(4). It has been suggested that smokers with higher SES are more likely to attempt to quit due to higher awareness of the health impacts of smoking and greater access to information and resources to promote health (such as cessation aids)(37,38).

Sustained smoking cessation

Finally, the fifth hypothesis posited an increase in rates of sustained smoking cessation following the 2012 graphic HWL revisions. The results supported this hypothesis as rates of successful quitting significantly increased from 30.0% in 2010 to 37.5% in 2013 (p=0.047).

Although several factors play an important role in sustained smoking cessation (e.g. social support, avoiding triggers or stressful environments, and managing cravings(37,199)), warning labels have been shown to reduce the risk of relapse by reminding former smokers of their reasons for quitting(65,200). Additionally, ex-smokers who relapse are exposed to HWLs not only at the time of smoking, but also at the point of purchase. Health warnings are therefore present at critical decision-making times and can help to prevent relapse by presenting ex-smokers with convincing reasons to resist temptation(64,200).

Impact on sustained smoking cessation by SES

It was also hypothesized that smokers with higher SES would have greater increases in rates of sustained quitting. The results did not support this hypothesis, as no moderation by income or education was found.

However, the overall results between 2003 and 2013 showed that smokers with a high income had 1.61 times greater odds of successfully quitting smoking compared to smokers with a low income ($p<0.001$). This is consistent with previous research showing that individuals with higher levels of income and education are typically more likely to successfully quit smoking compared to those with lower income and education(32–34,37,39,196,201–203). For example, a study using data from ITC Surveys and the Global Adult Tobacco Surveys (GATS) examining the socio-economic patterns in smoking cessation among smokers from eight countries found that smokers with a high income were 43% more likely to quit than smokers with a low income(39).

Higher relapse rates among lower socioeconomic groups could be attributable to several factors. As previously described, smokers from lower SES categories typically experience higher levels of stress from a more demanding lifestyle(37–39). In fact, research has shown that increased stress is a significant predictor of smoking relapse, particularly among smokers with low SES(204,205). Lower SES smokers are also typically less knowledgeable on the negative health effects of smoking, and lower health literacy has been shown to be associated with smoking relapse(205).

Summary

This study is the first longitudinal evaluation of the impact of the 2012 Canadian graphic HWL revisions on the smokers' quit intentions and cessation-related behaviours. The results of the study showed that there were no significant changes in intentions to quit. This, however, could be due to the drop out of former smokers who had high quit-efficacy and where therefore

more successful in quitting. Cognitive dissonance could also explain the lack of change in intentions, as smokers who rationalize their behaviour will be less motivated to quit.

Rates of calling the toll-free quit line more than doubled (from 1.8% in 2010 to 3.9% in 2013) following the 2012 graphic HWL revisions. Nevertheless, quit line use remains very low. Given that 38% of smokers reported intending to quit in the next six months, this low use of the quit line represents a significant lost opportunity for smokers to seek cessation-related guidance. It is critical that interventions effectively encourage smokers to act on these intentions and take the next steps in the quitting process.

This study did not find a statistically significant increase in quit attempts following the introduction of the revised graphic HWLs. However, the segmented regression analysis showed that the trend in quit attempts significantly and positively changed after the 2012 graphic HWL revisions. Future research should continue to investigate changes in quit attempts and cigarette consumption in Canada over time.

Finally, rates of successful quitting significantly increased between from 30.0% in 2010 to 37.5% in 2013. Although several factors play an important role in sustained smoking cessation, HWLs have been shown to reduce the risk of relapse by reminding former smokers of their reasons for quitting during their moments of weakness.

6.1.7 Mediation models

A series of four mediation models were developed to help understand the mechanisms through which the Canadian graphic HWLs influence smokers' quit intentions and quit attempts. It was hypothesized that the Canadian graphic HWLs impact quit intentions and quit attempts through indirect routes mediated by cognitive reactions and affective reactions. Although it was

expected that cognitive and affective reactions would mediate the effect of the warnings before the 2012 revisions as well, it was hypothesized that the strength of associations between mediational constructs and latent variables would be stronger following the introduction of new graphics and testimonials messages.

Using longitudinal data for the mediation analyses allowed for the examination of cross-sectional relations between constructs in the waves directly prior to and following the 2012 graphic HWL revisions, in addition to the examination of the change between the two waves. Inferences about causality were made possible by testing to see if changes in mediator variables were associated with changes in outcome variables. If the assumption that mediating variables re causally related to the outcome is correct, then an intervention that changes the mediating variables would change the dependent variable as well(182).

The results showed that in 2010, prior to the HWL revisions, neither cognitive reactions nor affective reactions mediated the association between HWL salience and quit intentions. Although HWLs were positively associated with both cognitive and affective reactions, these reactions did not mediate the impact on quit intentions.

After the Canadian graphic HWLs were revised, affective reactions due to warnings were found to mediate the association between HWL salience and quit intentions such that noticing and reading warnings elicited greater affective reactions, which in turn increased quit intentions. This illustrates that while both the old and new Canadian HWLs elicited cognitive and affective reactions among smokers, only the new warnings were successful in influencing quit intentions (mediated by affective reactions).

To extend this finding, Model 3 examined how the 2012 graphic HWL revisions changed the impact of the mediating variables on smokers' quit intentions in a single analysis. This type

of mediation analyses is not uncommon in intervention research, and is based on determining how an intervention causes changes in the outcome variables via changes in the mediators(182). The results of Model 3 further confirmed that the change in affective reactions after the HWL revisions mediated the change in quit intentions. In other words, the increase in rates of reading and noticing the new warnings was positively associated with changes in affective reactions, and these changes were in turn positively associated with quit intentions.

The finding that the revised graphic HWLs increased smokers' quit intentions via increased affective reactions could be explained by the addition of testimonial messages. Testimonials describing personal consequences of smoking (usually written as a quote from a person in the image) have been found to increase levels of credibility and elicit stronger emotions among smokers(12,64,88). These emotions, which involve rapid judgments produced without much cognitive effort, are essential to evoking health concerns among smokers, which motivates smokers to quit(117,141,142).

Finally, the results of Model 4 showed that changes in cognitive and affective reactions due to the HWL revisions were not associated with changes in quit attempts. This indicates that despite significant affective and cognitive reactions due to warnings, these reactions were not sufficient to successfully influence smokers' behaviours. Applying the concepts of the TTM can help to explain this finding: smokers must be in the *preparation* stage (ready to change their behaviour) before progressing to the *action* stage (engaging in cessation-related behaviours). Therefore, although the graphic HWLs may have been successful in helping smokers progress into the *contemplation* stage (recognizing that smoking is harmful), they may not have provided smokers with the necessary resources to progress into/past the *preparation* stage(192).

The few studies investigating the influence of HWLs on quit intentions mediated by cognitive and affective reactions have found similar results. An experimental study by Evans and colleagues(117) found that compared to text-only warnings, graphic warnings elicited more affective reactions, which indirectly influenced risk perceptions and quit intentions. Similarly, a study by Emery and colleagues(116) found that the effects of the graphic HWLs on smokers' cessation-related beliefs were mediated by cognitive and affective reactions rather than direct.

Unlike these studies, however, the current research did not find that cognitive reactions mediated smokers' quit intentions. This could be due to the differing study designs. The current study had a naturalistic observation study design, in that behaviours were measured in the natural environment without forced exposure to HWLs. In contrast, previous research has been based on experimental study designs. Although these studies allow for greater control over the study parameters, it is not possible to mimic the effects of the real world where individuals are exposed to HWLs multiple times over prolonged periods of time. Instead, these experimental studies involved forced and initial, short-term exposure to graphic HWLs, which may have led to stronger reactions.

Summary

This is the first population study investigating whether cognitive or affective reactions mediated the impact of the Canadian graphic HWLs on cessation-related intentions and behaviours. The results showed that in 2010, HWLs did not significantly influence smokers' quit intentions through pathways mediated by cognitive or affective reactions. However, after the warnings were revised in 2012, affective reactions evoked by the warnings significantly mediated the impact of HWLs on quit intentions. This implies that the addition of emotionally

evocative messages such as the testimonial messages led to significant increases in smokers' quit intentions.

The study also found that neither affective reactions nor cognitive reactions mediated the impact of HWLs on smokers' quitting attempts. This suggests that although the HWLs were successful in instigating affective and cognitive reactions among smokers, these reactions were not enough to successfully impact smokers' behaviours.

6.2 Implications

This study found that the 2012 HWL revisions were successful in reducing and even reversing the effects of wear-out, which were shown to be progressively diminishing the effectiveness of the Canadian graphic HWLs between 2002 and 2011. Following the introduction of new graphics and new health messages in 2012, salience of the exterior warnings increased and significantly more smokers reported to think about health risks due to warnings and of quitting smoking due to warnings. The new graphic warnings were also associated with increased levels of displeasure and believability, likely due to the addition of testimonial messages.

This study also showed that adding health statements to HWLs increased correct beliefs about this information, whereas removing health messages from HWLs resulted in the reversal of positively trending knowledge gains, and even reduced levels of correct beliefs. This emphasizes that policymakers must take careful consideration when determining which health messages are to appear on HWLs in order to optimize knowledge gains among smokers.

The study findings showed that smokers' quit intentions and cessation behaviours were not significantly impacted despite increased cognitive and behavioural HWL responses (although

this could be due to drop out of successful quitters). This demonstrates that it may be possible to further enhance the Canadian warnings to increase their impact on smokers' downstream behaviours. The remainder of this section describes some possible strategies to improve the Canadian graphic HWL regulations, with a particular focus on enhancing the impact of the currently underutilized interior efficacy messages.

First, significant increases in efficacy and subsequent cessation-related intentions and behaviours may be achieved by enhancing the salience of the interior messages. These interior messages are designed to increase smokers' confidence in their ability to quit by providing helpful cessation-related information and support. Individuals who ignore these interior messages (which consist more than three-quarters of current smokers) are therefore unable to obtain these benefits.

A potential strategy to increase the salience and subsequent impact of the efficacy messages could be to display them on the outside of cigarette packages where they are more likely to be seen. The salience of the exterior warnings was shown to be far superior to the salience of the interior warnings (40.1% of smokers read exterior warnings at least "sometimes" vs. 15.1% read interior messages at least "sometimes"). Therefore, placing efficacy messages on one of the external panels of cigarette packages (a graphic warning on one side and the efficacy message on the other) would likely substantially enhance salience.

The concept of placing efficacy messages on the outside of cigarette packages is not unlike the concept of gain-framed warnings(80). To reiterate, gain-framed warnings are those that focus on the positive aspects of smoking cessation, whereas loss-framed warnings focus on the negative impacts of smoking. However, an important difference that distinguishes efficacy messages from gain-framed warnings is that the first should also incorporate cessation support

and advice, thereby increasing a smokers' quit-efficacy and their perceived control over their cessation goals.

Studies exploring the impact of message framing on smokers' quit intentions have shown that although high-efficacy smokers reported loss-framed messages to be most motivational, gain-framed messages were perceived to be most motivational among low-efficacy smokers(114,133,140). Displaying both types of messages could therefore benefit both high-efficacy smokers *and* low-efficacy smokers. This is important because highly addicted smokers (with generally lower levels of efficacy) were found to be the least likely to read interior efficacy messages.

Modifying the content of the interior messages could potentially further enhance smokers' efficacy and downstream behaviours. An important objective of interior messages is to provide cessation-related guidance to help smokers overcome the mental and physiological barriers of quitting (such as increased motivation, information on helpful resources, or advice on how to cope with cravings and withdrawals)(14). The results, however, showed that reading interior messages was not significantly associated with perceived difficulty to quit smoking in 2013. This suggests that the warnings were not successful in providing smokers with cessation guidance to ease their apprehensions about the difficulties in quitting. Altering the content to provide more direct cessation-related information could be more effective. Enhancing guidance-related messages is likely to also impact quit attempts, which were found not to be significantly associated with reading interior messages in 2013.

Reviewing the content of the revised Canadian interior messages (shown in Appendix A) helps to illustrate this point. Although the current interior messages explain the benefits of quitting (e.g. healthy pregnancy, increases in life expectancy and quality of life, health benefits),

they are not as comprehensive with providing quitting advice and information on specific sources for cessation help. For example, three warnings present cessation-related advice or support: one provides quit line information, a second explains that cravings typically last only a few minutes, and a third highlights that most smokers try to quit several times before they succeed (which could potentially encourage first-time quitters to relapse). Implementing additional messages that provide more direct cessation-advice and alternative sources for help (in addition to the quit line) may help to reduce smokers' perceived difficulty to quit smoking, and also further enhance self-efficacy to quit.

Finally, another strategy to encourage cessation behaviours among smokers could be to enhancing the value and credibility of the quit line. The results showed that less than 4% of smokers called the quit line in 2013, despite 38% of smokers reporting to intend to quit in the next six months. A potential way to enhance the credibility or reputation of the quit line could involve the display of testimonials from former quitters who benefited from using the quit line (similar to a 'gain-framed' HWL). At present, the only elaborative texts about the quit line (beyond displaying the contact number) are in the form of interior messages that list some resources that the helpline provides and a small quote from a smoker mentioning that she called the quit line (however, it is buried in other text and not a clear testimonial). However, as this study demonstrated, very few smokers read these interior messages. Displaying larger, more salient testimonial messages on the exterior of cigarette packages could potentially increase inspiration among smokers to call the quit line. This would also be in line with the previous recommendation of displaying a graphic warning on one side of the cigarette package and an efficacy message on the other.

Although this study showed that the Canadian graphic HWLs positively impacted smoking-related cognitions and behaviours, it is important to note that there are limits to what these warnings can achieve when implemented in isolation. Incorporating HWLs into a broader tobacco control strategy can enhance their effectiveness as well as increase the overall impact of anti-smoking campaigns(80). For instance, health messages on warning labels are limited to brief statements due to space restrictions. However, social marketing and mass media campaigns can disseminate longer and more elaborated health messages to compliment those displayed on HWLs. Indeed, evidence from Australia has demonstrated that mass media campaigns and graphic HWLs operate in a complementary manner to positively impact smoking-related knowledge and motivation to quit(206). Graphic HWLs should therefore be viewed as one component of a multi-pronged, comprehensive tobacco control strategy.

6.3 Strengths and Limitations

6.3.1 Strengths

This study is the first longitudinal evaluation of the impact of the 2012 graphic HWL revisions on a range of downstream outcomes including key indicators of HWL effectiveness, beliefs on smoking-related health statements displayed on cigarette packages, affective reactions evoked by warnings, quit-efficacy and perceived difficulty of quitting, and intentions to quit and cessation-related behaviours.

A key strength of this study is that it is based on naturalistic observation. Naturalistic observation studies refer to those that observe or measure behaviours in the natural environment where they would ordinarily occur. These studies explore genuine behaviours without the impact of forced experimental conditions, thus increasing ecological validity(207). In contrast, most of

the studies exploring the impact of HWLs have been conducted using experimental designs. The benefit of implementing experimental studies is increased control over study parameters. However, these studies may produce misleading results because they are based on forced, short-term exposure to graphic HWLs, and are therefore unable to replicate the conditions of the real world by not taking the social context into account (individuals are exposed to HWLs multiple times over prolonged periods of time). Ideally, inferences should be based on both observational and experimental studies, as these study designs are complimentary and each type provides important advantages that the other does not.

An additional strength of this study is its use of data from nationally representative longitudinal cohort surveys conducted over nine waves that extended for over a decade (2002–2014). Although the change in smoking-related cognitions and behaviours between Wave 8 (201) and Wave 9 (2013) were of particular interest (these waves were conducted directly before and after the 2012 revisions), including all of the data in the analyses allowed pre-policy and post-policy trends to be examined over time.

A third strength is the extensive set of cognitive and behavioural outcomes included in the analyses. The ITC Surveys are designed to evaluate the psychosocial and behavioural impact of various key tobacco control policies on smokers, including HWLs. They are therefore comprehensive assessments that include over 150 measures over a wide range of policy domains, allowing for thorough and in-depth analyses.

Finally, the comprehensive methodological approach increased the internal validity of the study, thereby strengthening the interpretations drawn from the research findings. In this study, the impact of the 2012 graphic HWL revisions was explored two ways. First, generalized estimating equation (GEE) regression models were conducted to compute the least squares

means of outcome variables at each wave. The GEE analyses produced the values for the graphs depicting the secular trends in various cognitive and behavioural outcomes and determined if increases between Wave 8 and Wave 9 were statistically significant. Second, segmented regression models with a "breakpoint" set to the 2012 revised HWL introduction date compared the slopes of the pre-policy and post-policy regression lines (statistical differences between interval slopes were taken as evidence of a treatment effect(175)). The segmented regression analyses accounted for the differing time intervals between waves and produced more time-precise interpretations of their impact on secular trends. Therefore, using both analytical methods resulted in thorough analyses that were also time-precise that took into account the secular trend and the differing time intervals between waves.

6.3.2. Limitations

A limitation of the current study lies in the sampling methods of the ITC Surveys. From Waves 1 to 9, respondents were surveyed through computer assisted telephone interviews using a random-digit dialing sampling design (online web-based surveys were also used starting in Wave 8). Only households with landline telephones were eligible. Because more Canadians are now using mobile phones (sometimes exclusively) compared to landlines(208), a portion of the Canadian population may have been excluded due to the sampling design.

However, this is unlikely to have led to a significant sampling bias. The longitudinal nature of the study required the inclusion of as many original (or returning) respondents as possible, and landline telephones were far more common when the study commenced in 2002 (and in following years). This is illustrated in a report from the Canadian Radio-television and Telecommunications Commission(208) that presented the percentages of Canadians with

landline telephones and cellphones between 2002 and 2013. The report showed that 97% of Canadians had landline telephones in 2002 compared to 79% in 2013. Because retention rates of the current study were high (between 70-75% over nine waves), the majority of respondents were carried through from previous years when landlines were more popular. Nevertheless, this changing norm (and the replacement of respondents lost to attrition) emphasizes that current and future studies should implement procedures to ensure a nationally representative sample (e.g. in this study, online surveys were added to the sampling design in Wave 8).

Another minor limitation of this study is that smoking-related health beliefs were based on a measure of agreement (yes/no responses). It is possible that lower levels of correct beliefs may have been observed if they had been measured by unprompted recall (e.g. because agreement questions may lead to answers based on deduction, or because agreement questions are more vulnerable to social desirability bias compared to recall questions). However, even if rates of correct beliefs were lower than those reported in this study, it is likely that the nature of the trend would be the same. This is expected based on previous research showing that unprompted message recall and smoking-related knowledge increased following the introduction of new content on health warnings in Australia, with levels of knowledge measured by open-ended questions(69).

Another limitation of the study is in regards to the naturalistic observational study design. Although measuring behaviours in their natural environment increases the likelihood that they are genuine and unaffected by experimental conditions, the lack of control over the observational setting increases the possibility that extraneous variables (such as simultaneous anti-smoking campaigns) impacted the outcomes of interest(207). Because the cognitive, behavioural and affective reaction measures in this study were worded in direct relation to the HWLs, it can be

confidently concluded that the results reported in this study are direct outcomes of the warnings. However, measures assessing knowledge, efficacy, and cessation-related behaviours were not explicitly linked to warnings, and therefore could have been influenced by extraneous variables (additionally, the more downstream response variables are from explanatory variables, the more possible it is that other factors may have impacted those outcomes).

To ensure the internal validity of this study, this possibility was investigated. Being a nationally representative study, any external variables strong enough to significantly influence the study outcomes would have had to be nation-wide and also coincide with the 2012 graphic HWL revisions. National level anti-smoking or health awareness campaigns launched by Health Canada or other public health affiliations were identified and explored (described in detail in Appendix D). Due to discrepancies in timelines and specific target groups (e.g. school children and youth), it was found to be highly unlikely that the outcomes of this study were biased by simultaneous extraneous variables.

Finally, the present study also has limitations common to survey research, including the possibility of social desirability bias. Social desirability bias refers to the tendency of individuals to inaccurately report on sensitive topics to present themselves favorably and in accordance with societal and cultural norms(209). For example, it has been suggested that smokers (particularly the most addicted) may underreport cigarette consumption or express intentions to quit simply as a learned response to deflect criticism(210). These criticisms are not unlike those that criticize the use to self-reports when studying smoking behaviours.

However, it is unlikely that social desirability bias significantly affected the results and conclusions of this study for several reasons. First, interviews were conducted over the phone and via web-based surveys, reducing the pressure for socially desirable responding (compared to,

for example, in-person interviews which can cause high pressure for socially desirable responding)(211).

Second, the threat of social desirability bias in studies assessing smoking behaviours has been shown to higher among certain vulnerable populations, such as pregnant women or underage youth (both of which were not included in the study)(211).

Third, social desirability has been shown to vary significantly according to cultural orientation. Individuals from societies with collectivist orientations (such as those found in many Eastern Asian countries) typically value the preservation of good relationships with group members and put group interests ahead of their own. These individuals are therefore more likely to strive to align themselves within the values of their culture, and if smoking is taboo, more likely to report anti-smoking or pro-quit cognitions and behaviours(212). In contrast, those from individualistic cultures (such as those typically found in 'Western' countries including Canada) emphasize the importance of autonomy and value freedom of opinion. Individuals from these cultures tend to be less affected by societal norms, and have been shown to accurately report smoking-related cognitions and behaviours(211–213).

6.4 Future Research

This study investigated the cognitive and behavioural impact of the graphic HWL revisions on smokers in Canada. This research, however, only focused on adult smokers aged 18 years and older. Future studies could explore the impact of the Canadian HWL revisions on initiation and smoking behaviours of youth and non-smokers as well. Given that 90% of all adult smokers begin smoking before the age of 18, significant improvements in public health could be achieved by effectively discouraging the initiation of smoking among adolescents(4). For

example, cognitions that predict the initiation of experimental or regular smoking among adolescents have been identified (such as curiosity, influence from social circles, or weakening of intention not to smoke) (214,215). Determining if the revised Canadian warnings impact these cognitions can provide insight on ways to reduce initiation among youth and ultimately reduce the prevalence of smoking in Canada.

Future research should also explore ways of increasing smokers' efficacy through HWLs and through other population-level policies. The results of this study showed that although the Canadian regulations require cigarette manufacturers to include efficacy messages inside packages, smokers, especially those most dependent on smoking, the majority of smokers overlook these messages. Because efficacy is particularly important for encouraging the desired 'danger-control' behaviours instead of 'fear-control' behaviours, future research should explore other aspects of the policy environment that can enhance quit-efficacy.

An important finding of the current study was that quit intentions did not significantly increase after the 2012 graphic HWL revisions, despite significant increases in rates of smokers thinking about health risks of smoking and thinking about quitting due to warnings. Future studies could explore ways to reduce cognitive dissonance among smokers, which is likely to have been a contributing factor to these paradoxical findings. For example, it is believed that dissonance can be reduced by providing new information that outweighs dissonant beliefs (e.g. persuasive health facts that smokers cannot ignore) or by reducing the value of cognitions (e.g. the short term benefits of smoking are not worth the long-term health consequences)(216). Future studies could explore ways to effectively implement these strategies to ultimately help smokers quit.

Finally, future research should also continue to monitor the cognitive and behavioural trends outlined in this research. The analytical approach of this study involved exploring the impact of the HWL revisions in their temporal context by considering the pre- and post-policy trends. Because this research was based on eight waves of pre-policy data and one wave of post-policy data, it is important that future studies continue to examine the cognitive and behavioural impact to pick up any longer-term impacts. Continued monitoring of these outcomes would also shed light on how resilient the new warnings are to the inevitable effects of wear-out.

7.0 CONCLUSIONS

This dissertation showed that the revised Canadian graphic health warning labels (HWLs) were successful in reducing and even reversing the diminishing effects of wear-out on many important smoking-related cognitive and behavioural outcomes. Additionally, the impact of the 2012 graphic HWL revisions was just as strong among smokers with a low income and education as it was among smokers with a high income and education. This is a particularly important finding because smoking disproportionately impacts the health of individuals with low socioeconomic status due to higher rates of cigarette consumption. It is therefore critical to implement tobacco control policies can reduce those health disparities by providing benefits for smokers from all socioeconomic groups.

A significant finding of this study is that the negative affective evoked by the Canadian graphic HWLs were significantly and positively associated with increased cessation-related cognitions and behaviours. This shows that the affective evoked by the graphic warnings were not associated with "fear control" reactions (such as defensive behaviours). Instead, these affective reactions were positively associated with thoughts and behaviours indicative of "danger control" reactions (the desired behaviour change), such as thinking about the health risks of smoking, increased intentions to quit, and future quit attempts. Further supporting the implementation of graphic warnings was the finding that affective reactions significantly mediated the impact of the revised HWLs on smokers' quit intentions. Altogether, these illustrate that negative affect is a crucial ingredient in successful graphic HWLs.

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APPENDICES

Appendix A: Previous and Current Canadian Graphic HWLs

Previous Canadian Graphic HWLs (16), January 2001 – March 2012

CIGARETTES CAUSE STROKES: tobacco smoke can cause the arteries in your brain to clog. This can block the blood vessels and cause a stroke. A stroke can cause disability and death.

CIGARETTES ARE HIGHLY ADDICTIVE: Studies have shown that tobacco can be harder to quit than heroin or cocaine.

CIGARETTES SEE CHILDREN DO: Your children are twice as likely to smoke if you do. Half of all premature deaths among life-long smokers result from tobacco use.

DON'T POISON US: Second-hand smoke contains carbon monoxide, ammonia, formaldehyde, benzo(a)pyrene and nitrosamines. These can harm your children.

CIGARETTES HURT BABIES: Tobacco use during pregnancy reduces the growth of babies during pregnancy. These smaller babies may not catch up in growth after birth and the risks of infant illness, disability and death are increased.

TOBACCO USE CAN MAKE YOU IMPOTENT: Cigarettes may cause sexual impotence due to decreased blood flow to the penis. This can prevent you from having an erection.

WHERE THERE'S SMOKE THERE'S HYDROGEN CYANIDE: Tobacco smoke contains hydrogen cyanide. It can cause headaches, dizziness, weakness, nausea, vertigo and stomach aches in smokers and non-smokers.

YOU'RE NOT THE ONLY ONE SMOKING THIS CIGARETTE: The smoke from a cigarette is not just inhaled by the smoker. It becomes second-hand smoke, which contains more than 50 cancer-causing agents.

CIGARETTES CAUSE LUNG CANCER: 85% of lung cancers are caused by smoking. 80% of lung cancer victims die within 3 years.

IDLE BUT DEADLY: Smoke from a lit cigarette contains toxic substances like hydrogen cyanide, formaldehyde and benzene. Second-hand smoke can cause death from lung cancer and other diseases.

CIGARETTES ARE A HEARTBREAKER: Tobacco use can result in the clogging of arties in your heart. Clogged arteries cause heart attacks and can cause death.

CIGARETTES CAUSE LUNG CANCER: Every cigarette you smoke increases your chance of getting lung cancer.

CIGARETTES LEAVE YOU BREATHLESS: Tobacco use causes crippling, often fatal lung diseases such as emphysema.

TOBACCO SMOKE HURTS BABIES: Tobacco use during pregnancy increases the risk of preterm birth. Babies born preterm are at an increased risk of infant death, illness, and disability.

CIGARETTES CAUSE MOUTH DISEASES: Cigarette smoke causes oral cancer, gum diseases and tooth loss.

Each year, the equivalent of a small city dies from tobacco use.

Current Canadian graphic HWLs (16), March 2012 – present

"Look at the power of the cigarette… Remember this face and that smoking killed me": Barb Tarbox died at 42 of lung cancer caused by cigarettes.

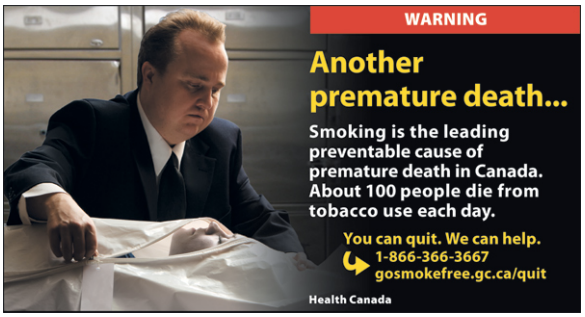
Cigarette addiction affects generations: Mother and daughter are both addicted to tobacco. Nicotine is the drug in tobacco that causes addiction.

Tobacco smoke hurts everyone: Infants who are exposed to tobacco smoke are at greater risk of dying from Sudden Infant Death Syndrome (SIDS).

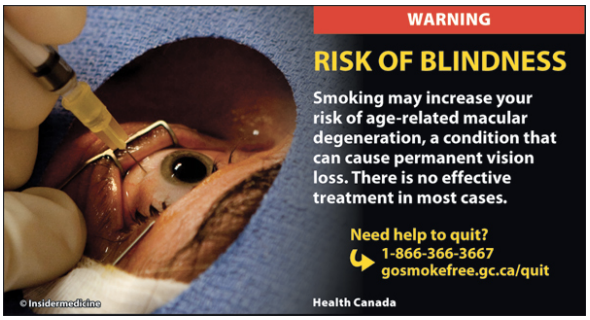
Tobacco Smoke: no thanks: Second-hand smoke contains many toxic chemicals that can harm an unborn baby.

Your kids are sick of your smoking: second-hand smoke causes more frequent and severe asthmatic attacks in children.

Smoking in the car hurts more than just you: Having the windows open does not protect passengers from the over 70 cancer causing chemicals in tobacco smoke.



Another premature death… Smoking is the leading preventable cause of premature death in Canada. About 100 people die from tobacco use each day.



RISK OF BLINDNESS: smoking may increase your risk of age-related macular degeneration, a condition that can cause permanent vision loss. There is no effective treatment in most cases.

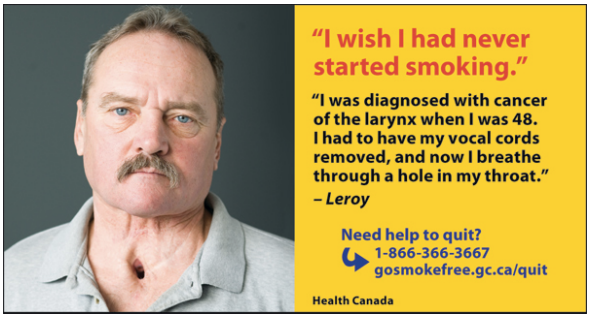
Cigarettes are a major cause of heart disease: Smokers are up to 4 times more likely to develop heart disease than non-smokers.

"Just breathing is torture"
"Smoking caused by lungs to collapse four times before I was diagnosed with emphysema at 42. Without my oxygen tank, it feels like I'm breathing through a straw." – Lena

This is what dying of lung cancer looks like. Barb Tarbox died at 42 of lung cancer caused by cigarettes.

ORAL CANCER: These white spots are a form of oral cancer caused primarily by smoking. Even if you survive, you may lose part or all of your tongue.

Cigarettes cause bladder cancer: Toxic chemicals in tobacco smoke damage the lining of the bladder causing cancer. The most common sign is blood in the urine.

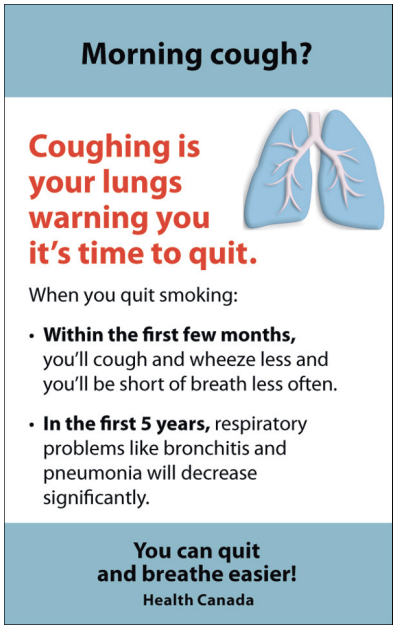


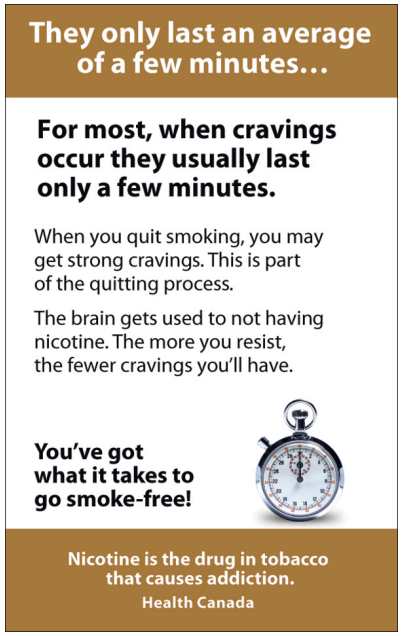
"I wish I had never started smoking."
"I was diagnosed with cancer of the larynx when I was 48. I had to have my vocal cords removed, and now I breathe through a hole in my throat." – Leroy

When you smoke it shows: Cigarettes are addictive and harmful

A single stroke can leave you helpless: Cigarettes are a major cause of stroke.

Current Interior messages (8), March 2012 – present





"I had enough of feeling guilty…"

"Quitting is hard and it takes a lot of will power.

"I had enough of feeling guilty. I was ashamed of being a smoker.

"When I was ready to quit, I called a quitline and, with their support, I made it through the first few days of cravings.

"As the days went by, I was more and more proud of myself and my will to keep going got stronger."

– Susan

1-866-366-3667

Tobacco products are highly addictive.
Health Canada

Never quit trying to quit.

Most smokers try to quit several times before they succeed.

Think of every attempt as a learning experience, not a failure.
Never quit trying to quit.

Pick a quit date, write it down or tell someone about it.

_____/_____/_____

Nicotine is the drug in tobacco that causes addiction.
Health Canada

How can the quitline help me?

WHEN YOU CALL THE TOLL-FREE QUITLINE 1-866-366-3667

You'll speak one-on-one with a quit specialist who will help you:

- Create a quit plan that works for you.
- Access information and tools to become smoke-free.
- Cope with cravings and withdrawal symptoms.
- Find services and resources in your community.

There are many reasons to quit. What's yours?

Tobacco is the single most preventable cause of premature death and disease.
Health Canada

It's never too late…

Quitting smoking increases life expectancy and improves quality of life.

People who quit smoking increase their chances of living longer. They improve their general health, leading to a better quality of life.

It's never too late to quit. No matter how old you are, you'll start to feel major and immediate health benefits and have more energy to help you live life to the fullest.

Talk to a health care provider.
Health Canada

Thinking of having a baby?

Quitting smoking before pregnancy will increase your chances of having a healthy baby.

You'll lower your risk of:

- Miscarriage
- Stillbirth
- Having a baby with serious health problems.

Although quitting is most beneficial before conception, there are some benefits to quitting at any time during your pregnancy.

Talk to a health care provider.
Health Canada

Current Toxic emission statements (4) on side panels, March 2012 – present

Tobacco smoke contains fine particles that can damage the respiratory system.
Health Canada

La fumée du tabac contient des particules fines qui peuvent endommager le système respiratoire.
Santé Canada

Tobacco smoke contains hydrogen cyanide, a poisonous gas.
Health Canada

La fumée du tabac contient du cyanure d'hydrogène, un gaz toxique.
Santé Canada

Tobacco smoke contains more than 70 chemicals that can cause cancer.
Health Canada

La fumée du tabac contient plus de 70 substances chimiques qui peuvent causer le cancer.
Santé Canada

Tobacco smoke contains benzene, a chemical that causes cancer.
Health Canada

La fumée du tabac contient du benzène, un produit chimique qui donne le cancer.
Santé Canada

Images retrieved from:

Tobacco Labelling Resource Centre. Canada [Internet]. 2016. Available from: http://www.tobaccolabels.ca/countries/canada/

Appendix B: Testing for within-wave wear-out

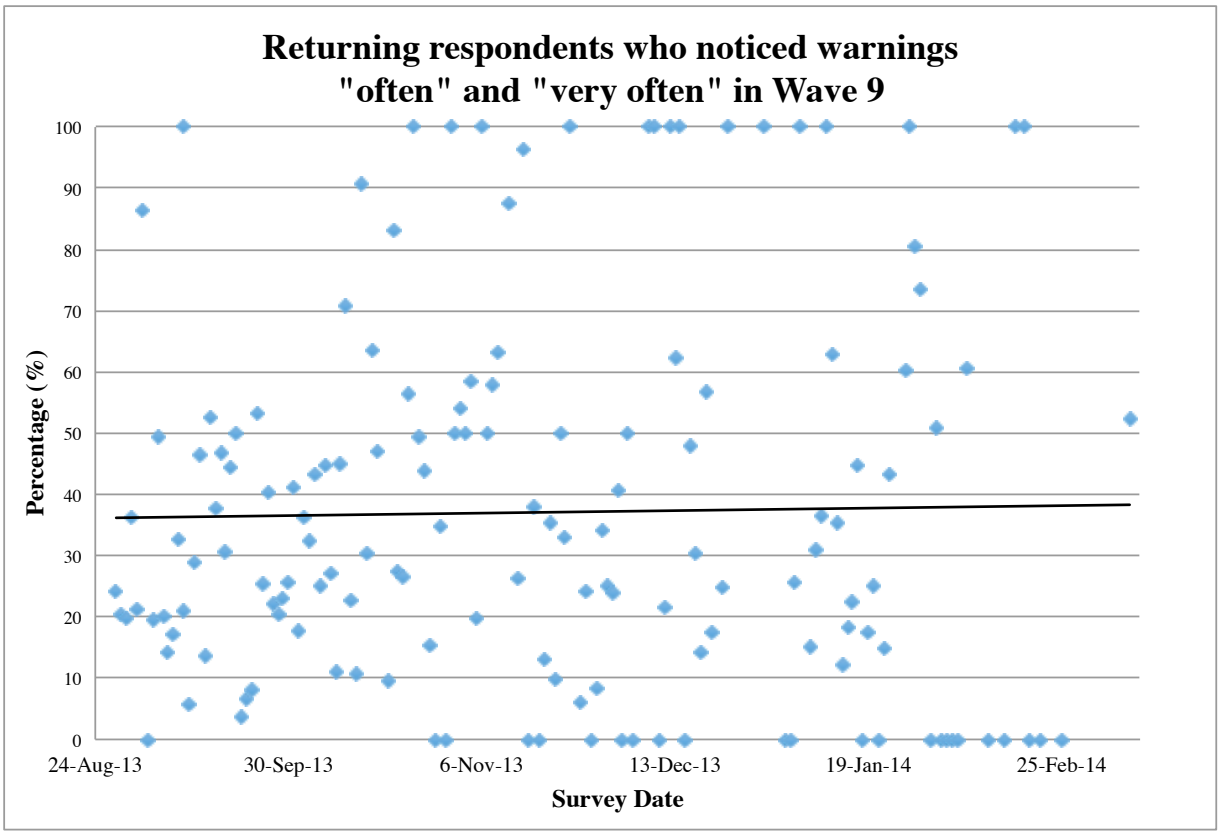
Survey administration time lengths varied significantly across waves. Importantly, these differing survey periods left the possibility open for systematic differences in responses to occur as a function of exposure time.

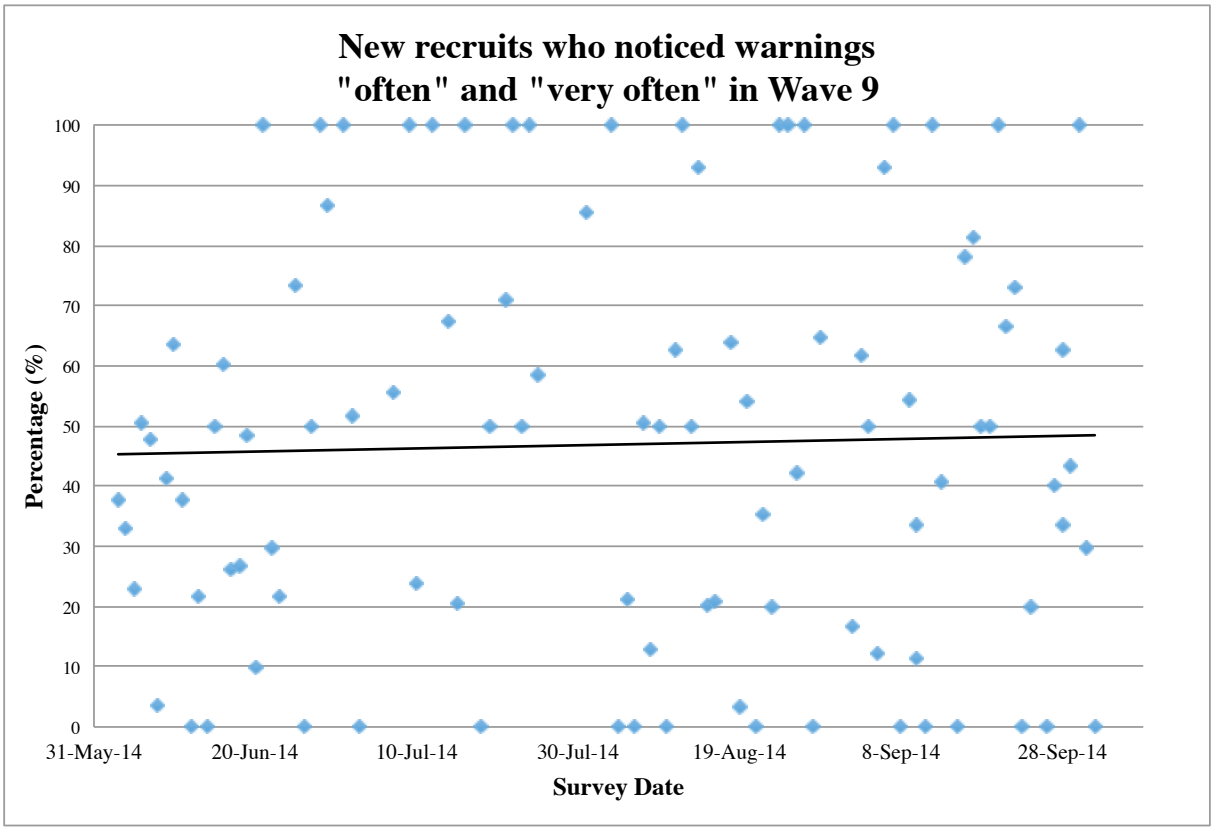
For example, Wave 9 surveys were administered over the course of 14 months (August 2013 – October 2014), 17-31 months after the graphic health warning label (HWL) revisions (in March 2012). This means that respondents in the same wave who were surveyed at the end of the Wave 9 were exposed to warnings for more than a year longer than respondents who were surveyed at the beginning of the wave. Because the impact of the warnings may have diminished over time, cognitive and behavioural responses may have varied as a function of exposure time (within-wave wear-out). In contrast, Wave 1 surveys were administered over the course of only two months (October – December 2002; 16-18 months after the introduction of the first set of graphic HWLs). This short administration period is therefore unlikely to have resulted in within-wave systematic differences in responses.

To test if exposure time caused within-wave systematic differences in responses, the rates of smokers in Wave 9 who reported noticing warnings "often" and "very often" were plotted. Wave 9 was selected because the survey period was longest of all waves (making it most susceptible for within-wave wear-out), and because it was the first wave conducted after the 2012 graphic HWL revisions. Because warning salience is greatest upon initial exposure(12), systematic differences would be most apparent in this wave. Rates of noticing HWLs was selected as the measure for this test because between the two variables measuring HWL salience (noticing and reading warnings, which are likely to have been effected the most by overexposure), rates of noticing warnings increased the most following the 2012 revisions.

In Wave 9, returning respondents were surveyed first (from August 13, 2013 to March 10, 2014) and new recruits were surveyed second (from June 3, 2014 to October 2, 2014). Because responses have been shown to systematically differ depending on how many times a respondent has participated in a survey (time-in-sample effects), wear-out was explored separately in these two groups.

The rates of returning respondents and new recruits who reported to notice warnings "often" and "very often", with trend lines, are presented below.





As both figures illustrate, no indication of within-wave wear-out was found for both returning respondents and new recruits were. This indicates that the possibility that within-wave wear impacted the results of the study is very unlikely.

Appendix C: Exact median dates for Waves 1-9 of the ITC Canada Survey

Survey wave	Median date
1	November 14, 2002
2	June 13, 2003
3	July 25, 2004
4	November 27, 2005
5	November 25, 2006
6	December 7, 2007
7	January 17, 2009
8	August 16, 2010
9	October 25, 2013

Appendix D: Investigating the possibility that simultaneous extraneous variables influenced the study outcomes

Although measuring behaviours in their natural environment increases the likelihood that they are genuine and unaffected by experimental conditions, the lack of control over the observational setting increases the possibility that extraneous variables (such as simultaneous anti-smoking campaigns) impacted the outcomes of interest(207). Because the cognitive, behavioural and affective reaction measures in this study were worded in direct relation to the health warning labels (HWLs), it can be confidently concluded that the results reported in this research are direct outcomes of the warnings. However, measures assessing knowledge, efficacy, and cessation-related behaviours were not explicitly linked to warnings, and therefore could have been influenced by extraneous variables.

This possibility was investigated to ensure the internal validity of this study. Being a nationally representative study, any external variables strong enough to significantly influence the study outcomes would have had to be nation-wide as well as coincide with the 2012 graphic HWL revisions. National level anti-smoking or health awareness campaigns launched by Health Canada or other public health affiliations were explored.

As part of the 2001-2011 *Federal Tobacco Control Strategy* (FTCS)(217), Health Canada launched three major national mass media campaigns. All three campaigns (which consisted of televisions ads describing the dangers of secondhand smoke, tobacco use in the workplace, and direct and passive smoking inside the home) were launched before the removal of mass media as an FTCS strategy in 2007(217).

The FTCS was renewed in 2012(218) and in January 2014, the Government of Canada and the Canadian Cancer Society launched a joint tobacco awareness and cessation campaign

called *Break It Off*(219). This campaign provides a number of online resources to help smokers quit and targets young adult smokers aged 20 to 24 years.

Health Canada has also developed cessation guidebooks to help smokers quit. For example, *Quit4Life*(220) was developed in 1993 and provides youth who seek to quit smoking with a handbook to help guide them through the cessation process. Health Canada also developed the *On the Road to Quitting* guides(221) in 2003. These guides also provide smokers who seek to help to quit smoking with cessation-related information.

Overall, these programs represent useful tools to help guide smokers through the cessation process. However, it is highly unlikely that these anti-smoking programs influenced the results of this study, which explored the impact of the 2012 graphic HWL revisions on cognitive and behavioural outcomes among Canadian smokers. This conclusion is based on several factors.

First, these national level programs did not coincide with the 2012 graphic HWL revisions. Although the *Break It Off* campaign came close, it is a web-based campaign with significantly less exposure compared to the graphic HWLs (which are exposed to smokers each time they smoke). Additionally, the *Break It Off* campaign specifically targets young adult smokers (aged 20 to 24 years old), and the results of this study showed that smoking-related knowledge, quit intentions and quit attempts did not differ in this age groups compared to the rest of the Canadian population.

Second, the majority of these tools are intended for smokers who are already planning to quit smoking and need guidance to do so. Therefore, they are not as influential on smokers who do not currently hold quit intentions because they will not seek out this information.