



What has Happened to the Implementation of Pictorial Warning Labels on U. S. Cigarette Packages?

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Introduction

There is international consensus on inclusion of warning labels on tobacco products [1] (FCTC recommendations). The World Health Organization (WHO) has established guidelines in Article 11 of the Framework Convention on Tobacco Control (FCTC), including the size and location of the warnings [1]. In addition, WHO recommends that the warning include pictures [2-4]. As of June 2020, at least 125 countries have passed legislation to incorporate large pictorial health warnings on cigarette packages [4-7]. Since tobacco product packaging has been a channel for communication by the tobacco industry, it is logical that the package be used as a vehicle for communication about the risks of tobacco [4,6]. Warning labels need to be noticed; this can be accomplished through their color, design, content, size and location [8].

Pictorial Warning Labels (PWLs) incorporate a picture, graphic image, pictogram, or photograph (or a combination of these elements) that provide information on the health effects of smoking or ways to quit smoking. In 2001, Canada became the first country in the world to place graphic warning labels on cigarettes, with regulations on the size, location and language of the labels. In 2012, the original labels were replaced by larger labels with new graphics [9].

Warning labels have been added to other tobacco products such as to packaging of smokeless tobacco, bidis, e-cigarettes and waterpipes. A complete list of countries that now include labels can be found on the Campaign for Tobacco Free Kids website [5].



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The purpose of this special communication is to provide a summary of PWLs internationally, to describe some research findings that have attempted to quantify the potential impact of these labels and to document the legislation concerning warning labels in the US.

Warning labels on US cigarettes

In 1965, printed warning labels were added to one of the side panels on cigarette packages as mandated by the Federal Cigarette Labeling and Advertising Act of 1965 (Public Law 89-92). The label included the following "Caution: Cigarette Smoking May Be Hazardous to Your Health" and no additional text could be added by Federal, state or local governments. The label was modified in 1967, 1969 and additional labels added in 1981 [10]. Since the 1960s, the tobacco industry has been actively involved in manipulating the content of warning labels to protect the industry from litigation [11]. Cummings et al [11] present a detailed account of the events and activities from 1964 to the present that provides documentation of tobacco industry activities.

The Food and Drug Administration's (FDA) Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) passed the House of Representatives on April 2, 2009, the Senate on June 12, 2009 and was signed into law by President Barack Obama on June 22, 2009 [12,13]. The legislation provides the FDA authority to regulate tobacco products, to prohibit the use of specific flavors, to regulate advertising to youth and youth access to tobacco products and to implement a program of PWLs that was proposed to go into effect in 2012 [14]. The proposed set of new labels included both text and graphics designed to communicate health effects of smoking and secondhand smoke, to encourage smokers to quit and to prevent young people from starting [15]. In March of 2013, a federal appellate court affirmed a lower court ruling to strike down the proposed rule [16].

The tobacco companies challenged this legislation and eventually the case made it to the Supreme Court. On April 22, 2013, the U.S. Supreme Court announced it would not hear the tobacco industry's challenge to the 2009 Family Smoking Prevention and Tobacco Control Act's (Tobacco Control Act) provision to include graphic warning labels on cigarette package. This decision by the Supreme Court provided the basis for the FDA to mandate the use of graphic labels on cigarette packs [17]. Since that time, the FDA has conducted research into the use of the health warnings. In March of 2020, the US District Court for Massachusetts issued a final rule.

Currently, the FDA has recommended that graphic labels be put on cigarettes; 13 new pictorial labels have been approved for placement on cigarettes [18]. These proposed labels include information on lesser-known health risks of tobacco use. However, because of the COVID pandemic, this recommendation will not be implemented until October 2021, given the involvement of FDA personnel in fighting the pandemic [19].

What has been measured if PWLs are added to cigarette packages? What might be expected when text only labels are replaced with graphic ones? There are many possible measures specifically at the individual and population public health levels such as reductions in smoking related disease. At the individual level, there are three broad categories of variables as they relate to the potential impact of PWL: (1) knowledge of the labels and of the health risks of tobacco use, (2) attitudes toward the

labels and toward smoking and smokers and (3) behavior including quitting, changes in initiation, reductions in consumption, intentions to quit and behavior with regard to the packs (avoidance of the labels). There is also a fourth miscellaneous category that summarizes findings that do not clearly fit into the other categories. These specific categories have been taken from the research literature on warning labels. Within each major category, there are several subcategories that can be considered. In each section below, there are references that demonstrate the variable of interest. Included are citations that support the inclusion of PWLs. The citations are not meant to be inclusive, but are designed to illustrate the range of variables that have been studied.

KNOWLEDGE

Included under the broad category of knowledge are measures of the awareness and recall of labels as well as the knowledge of health effects of tobacco use.

Awareness of pictorial warnings/reading of pictorial warnings/depth of processing/notice of specific information/source of information on dangers of smoking/quitting

In general, awareness of the labels was higher among those exposed to pictorial labels as compared to text only labels [20]. Adult smokers report cigarette packages as a source of information on the dangers of smoking [21]. Of interest is the finding that noticing the labels was positively associated with health knowledge (ORs= 1.5-3.0 comparing knowledge among those who noticed the label to those who did not notice the label). Moodie et al., [22] found that smokers in the UK noticed the new graphic warnings and read them closely, when compared with the older labels.

Recall of pictorial warnings

Studies in Canada, Australia and the U.S. all found that recall both aided and unaided was higher among pictorial labels than text only labels [23-25].

Knowledge of health risks/think about health risks

Among Canadian adult smokers in southwestern Ontario, 51% reported that the pictorial warning made them think about the health risks of smoking [26]. In a comparison between adult smokers in Canada who were exposed to pictorial labels and those in Mexico with text only labels, the former group had higher levels of knowledge about health risks from smoking that were included on the Canadian but not Mexican labels [27]. Surveys in the Netherlands found that there was an increase in awareness of health risks following introduction of PWLs [28]. Moodie et al., [22] noted that smokers thought about the health risks and quitting following introduction of the new labels.

ATTITUDES

This category includes a range of attitudes those specifically related to the labels and those toward smoking and smokers.

Attitudes towards labels/packages/effect of labels on others smoking

In a small study of US college student smokers and US and Canadian women smokers aged 18-44 years, packages that included pictorial warnings decreased the perceived attractiveness of the package and had higher levels of negative affect [29]. Perceived credibility of measures of attention, concentration, thought, careful reading and argument strength were more fa-

avorable for pictorial warnings [25]. Some studies included questions on the potential impact of the labels on smoking among others. Using a web-based survey, O’Hegarty et al., [30] showed current and former smokers in the US pictorial labels from Canadian cigarette packages. These labels were rated as more effective for prevention, more effective in providing motivation for quitting and more informative than text-only labels.

Attitudes toward smoking

In an experimental study of exposure to text-only or pictorial warnings, a Canadian sample of youth exposed to the pictorial warnings were more likely to report negative smoking attitudes when seeing a movie scene with smoking than when no exposure to warnings occurred [31]. In two studies of teenagers in Canada and US, those who saw a pictorial warning had less positive attitudes towards brands and branded websites than those who did not see a warning or who saw a text-only warning [32,33]. Peters et al., [34] found that participants who viewed the 16 Canadian labels were more negative toward smoking than those who viewed the 4 US labels.

BEHAVIOR

This category includes a wide range of behavioral outcomes such as modifications to smoking behavior, cessation, prevention and avoidance of the labels.

Avoidance of warnings

Some studies reported attempts to cover up or avoid the label [35,36], while others did not. Australia changed to pictorial warnings in 2006; avoidance of warnings (as measured by responses indicating covering up the label, use of a cigarette case, keeping the label out of sight or avoiding particular labels) increased over the previous year and were higher than similar measures when the UK changed to larger text-based warnings [35].

Foregoing cigarettes and changes in consumption

After Australia changed to pictorial warnings, reports of foregoing a cigarette as a result of the warning increased over the previous year [35], with the amount of change being similar to that which resulted from the UK change to larger text-only warnings [35]. Two and a half years after changes to the labels, Canadian smokers (pictorial labels) were more likely than UK smokers (larger text labels) to report foregoing cigarettes as the result of the warning [37]. The potential result of forgoing cigarettes is overall reductions in consumption and the findings are consistent, although the amount of reduction tends to be small.

Confidence in quitting/thinking about quitting

Pictorial warnings can provide information to improve a smoker’s self-efficacy (their confidence in being able to achieve abstinence). After Australia changed to pictorial warnings, reports of the warnings leading the person more likely to quit increased over the previous year [35], with levels being higher than levels in the UK, which changed to larger text-only warnings [35]. Among Canadian adult smokers in southwestern Ontario, 33% reported that the pictorial warning increased their likelihood of quitting and 24.8% reported that the warnings increased their confidence in quitting [26]. Moodie et al., [22] noted that smokers were more likely to think about quitting fol-

lowing introduction of the new labels.

Intentions to quit/intentions to reduce consumption

One objective of placing pictorial warnings on cigarette packs is to increase smokers’ intentions to quit smoking, actually considering taking action, which would be the next step after thinking about quitting. Among Canadian adult smokers in southwestern Ontario, those who reported reading and thinking about the pictorial warnings had greater intentions to quit [23]. In a study of current smokers at the University of Sheffield, England, those who reported feeling a threat from the pictorial warnings reported greater intentions to reduce consumption [38].

Quit attempts

Thinking about quitting and intention to quit can lead to actual quit attempts. After pictorial warnings were released in Australia, quit attempts increased from the previous year; in contrast, no such increase in quit attempts was noted when the UK increased the size of their text-only warnings [39]. Among Canadian adult smokers in southwestern Ontario, those who read, thought about and discussed the pictorial warnings in greater depth were more likely to make a quit attempt (any attempt in past 3 months of at least 24 hours) at follow-up [23].

Demand for cessation services

Calls to the Australian quitline and the quitline number on packs doubled during 2006, after introduction of graphic warnings; the proportion of first time callers in South Australia -the one area that measured this- did not change during this time period suggesting messages were reaching both new attempters and prior attempters [24]. Almost 5.0% of smokers listed warning labels as a source of cessation information but this was not an increase over pre implementation levels when demographic and smoking status variables were controlled [26].

Quitting

Awareness of warnings and avoidance of warnings (Australia, Canada, United Kingdom and United States) were not related to short-term cessation [35]. However, in Thailand, 3.8% of 699 employees who smoked and participated in a cohort study reported that they had stopped smoking after seeing the new pictorial labels [40]. Among Canadian adult smokers in southwestern Ontario, those who read, thought about and discussed the pictorial warnings in greater depth were more likely to have quit (quit attempt with abstinence at follow-up) [23]. In addition, 26.5% of former smokers indicated that the warning labels had helped them to remain abstinent [41].

Prevalence

Godspodinove & Irvine found that Canada’s change to pictorial warnings did not result in change in prevalence between two-to-six months after the change took effect [42], while Azagba & Sharaf [34] found the odds of being a smoker decreased after the PWLs were implemented. Levy and his colleagues [4,45] reported on changes in prevalence following simulations of the implementation of a number of tobacco control measures including PWL, taxation and restrictions on smoking in public places. The models predicted that there would be a small reduction in smoking prevalence that could be attributed to the introduction of strong health warnings 1.3% to 3.8% of the overall decrease in prevalence would be attributed to the

introduction of the labels).

Prevention/intentions to smoke

Along with increasing smoking cessation among established smokers, preventing smoking initiation among youth and young adults will contribute to a reduction in overall smoking prevalence. Canadian teenage nonsmokers were exposed to a tobacco branded website using a factorial design. They reported lower levels of intention to smoke when exposed to pictorial warnings than text only or no warning. In contrast, the pictorial warnings were least effective for Americans nonsmokers [33].

MISCELLANEOUS ISSUES

There are some additional measures that have been considered in relation to PWLs. These include reduction in sales and demand for cigarettes following implementation of the labels. In addition, judgment as to the attractiveness of the packages and reactions to the labels such as fear or disgust could be measured. One study by Thrasher et al., [46] estimated the reduction in demand for cigarettes associated with implementing pictorial warning labels. Using the experimental auction method with 89 smokers in Mexico, they found that cigarette packs with graphic images had a mean attributed value that was 17% lower than text-only packs. The authors concluded that the consistently lower value associated with the pictorial label packs would likely reduce demand for cigarettes. This finding is consistent with one by Qin et al., [47] that found that packs with PWLs were less likely to be given as gifts in China. Individuals in France reported that the packs were less attractive [48] and that the attractiveness of the packs was reduced with PWLs [49,50]. Several studies reported reactions such as fear or disgust (e.g., [26,52,44]), but the findings were inconsistent.

What can be expected from the addition of PWLs on US cigarettes?

Hammond [52] discusses the potential adverse outcomes from fear arousal as well as the positive outcomes associated with warning labels such as changes in knowledge, attitudes and call to a Quitline. He provides summaries of research on the content, location and size of the labels and concludes that health warning on packages provide an effective way of communicating health risks to smokers. He concludes that large pictorial labels are more effective than smaller text only labels. Additionally, a computer simulation model was developed to examine the potential impact on public health if graphic warning labels were implemented in the US [44,45]. The *SimSmoke* model projected that smoking prevalence would be reduced in the short term by 5% if PWLs were added to tobacco products.

It is not necessarily simple to draw conclusions about the direct impact on cigarette smoking that could result from the addition of PWLs to the cigarette packs. In a systematic review of 21 articles from 1993-2013, Monarrez-Espino et al., [53] concluded that there was no direct effect of labels on cessation, reduction in consumption and quit attempts. However, it does appear that the pictorial labels will be noticed and may provide motivation to reduce tobacco use overall. The addition of PWLs would be consistent with tobacco use restrictions in the US that have been adopted in recent years. Smoking is only permitted in specific areas. It is no longer permitted in many restaurants, office buildings, large indoor and outdoor public gatherings and even in vehicles with children present (Canada).

In addition, the PWLs provide a source of information about

health effects from smoking (cancer, cardiovascular disease and secondhand smoke exposure, as well as beneficial effects from quitting (improved health, reduced costs). The labels can direct smokers to a myriad smoking cessation aids, such as nicotine replacements (patches, gum and inhalers) and prescriptions such as Champix and Zyban, as well as counseling programs and quitlines [54]. While it may not be possible to attribute specific population level effects such as prevalence or prevention directly to the labels, the fact that the labels are consistent with many other policies about tobacco use can cumulatively reduce prevalence and incidence of smoking and ultimately result in a decrease of smoking related diseases such as cancer and heart disease. For example, in a review article of *SimSmoke* studies, Levy et al., [44,45] reported that the introduction of large graphic warnings may reduce smoking prevalence and increase cessation rates by 2.0%. While the size of the decrease in smoking prevalence that was attributed to PWLs was small in every study, all of the findings were in the same positive direction. It should be noted that if these declines in prevalence are considered at the population level, the actual number of people who are not smoking can be substantial.

It is important that the labels that ultimately are placed on cigarette and other tobacco packaging are informative and address issues of relevance to a broad range of population subgroups, defined by age, gender, race and socio-economic status. Adoption of these types of labels in the US is long overdue. It is unclear why the implementation is being delayed apparently because of COVID-19. Currently there are no peer reviewed publications about the relationship of smoking and COVID-19 [55]. However, the specific act of smoking may increase the risk of contracting COVID-19 and there may be increased risk of lung disease from continued smoking and contracting COVID-19. Awareness that the tobacco industry and its lawyers may continue to pursue restrictions on these labels should not be forgotten or dismissed, given that the proposed implementation will not occur until October 2021.

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