Systematic Review of the Effect of Pictorial Warnings on Cigarette Packages in Smoking Behavior

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We used a structured approach to assess whether active smokers presented with pictorial warnings on cigarette packages (PWCP) had a higher probability of quitting, reducing, and attempting to quit smoking than did unexposed smokers.

We identified 21 articles from among nearly 2500 published between 1993 and 2013, prioritizing coverage over relevance or quality because we expected to find only a few studies with behavioral outcomes. We found very large heterogeneity across studies, poor or very poor methodological quality, and generally null or conflicting findings for any explored outcome.

The evidence for or against the use of PWCP is insufficient, suggesting that any effect of PWCP on behavior would be modest. Determining the single impact of PWCP on behavior requires studies with strong methodological designs and longer follow-up periods. (*Am J Public Health*. 2014;104: e11–e30. doi:10.2105/AJPH. 2014.302129) SMOKING AND ITS ASSOCI-

ated health and mortality risks have been well established. Nearly one fifth of the world's population smoke, and close to 6 million die each year from tobacco use,¹ a figure estimated to reach 10 million by 2020.² In an attempt to curb this trajectory, governments have and continue to implement various tobacco control policies aimed at reducing smoking.

Common tobacco control policies include increased taxes, bans or restrictions on advertising, sponsorships, point-of-sale displays, smoking in public places,³ and, pertaining to this article, health warning labels on cigarette packages. Currently, most countries require warnings to be printed on cigarette packs, though format varies in terms of size, number, and how information is presented, ranging from vague text statements to graphic images alongside the text.⁴

Pictorial warnings on cigarette packages (PWCP) were first implemented in 2001.⁵ Since then, studies have assessed the perceptions and reactions elicited among smokers and nonsmokers and also the motivation or intention to quit or reduce smoking.^{6,7} However, research investigating whether PWCP bring about a change in smoking behavior has been limited.

HISTORICAL CONTEXT

Health warning labels on cigarette packages have evolved through 3 phases. The first began in 1965 when the United States first implemented a law requiring tobacco companies to print a small text warning on 1 side of the pack.^{5,8} Throughout the following 2 decades, this phase saw several other countries, such as the United Kingdom, Canada, and Australia, follow suit with similar warning-label arrangements.^{3,9} In the second phase, new legislative measures or modifications to existing laws were introduced in the 1980s-1990s; the small bland text messages were updated to appear with larger font on the front or back of the package and with greater variation in the types of warning messages.^{10,11} The third phase began in 2001 when Canada started using PWCP.⁵ By February 2012, more than 45 countries had implemented legislation that required the addition of a pictorial health warning alongside the text warning on cigarette packages.¹²

Globalization provided an avenue for widespread international cooperation to fight against the tobacco epidemic. The World Health Organization Framework Convention on Tobacco Control entered into force via the United Nations in 2005.¹³ With 168 signatory states, the treaty covered a wide array of tobacco control policies, including price and tax measures, exposure, education, advertising, and packaging and labeling of tobacco products.¹⁴

An important element in this global collaboration is the International Tobacco Control Policy Evaluation Project, a research program whose aim is to evaluate Framework Convention on

Tobacco Control policies by conducting homogeneous, population-level surveys to determine effective tobacco control policies.¹⁵ The Framework Convention on Tobacco Control treaty covers the recommendations for packaging and labeling of tobacco products.¹⁴ The fact that the inclusion of pictures is optional for participating states means that it is crucial for the research community to guide countries with appropriate recommendations and justifications for incorporating PWCP into their legislative tobacco control policies.

THE CIGARETTE PACKAGE AS A TOOL FOR COMMUNICATION

Both the tobacco industry and tobacco control advocates have agreed that the cigarette package serves as a crucial marketing tool and a means of communicating with the population.^{5,16,17} As a consequence of the increasing number of countries implementing marketing restrictions, the tobacco industry has reacted by improving their advertisement strategy,¹⁷ including the use of new cigarette pack designs that involve innovations in shape, color, size, and plastic wrapping.⁵

Besides providing a direct link to the consumer, the pack also becomes a portable advertisement device for the tobacco brand because the smoker puts it on display every time a cigarette is used.⁵ From the tobacco control perspective, the cigarette package can be an equally effective tool for

communicating the dangers of tobacco consumption to the public, especially among low-literacy smokers and children because the warnings will be put on display as often as the cigarette pack itself.⁵

EFFECTS OF PWCP ON BEHAVIOR

Although most smokers are aware of the harmful effects of tobacco, lack of knowledge and underestimation of the specific health risks associated with smoking constitute relevant factors that affect people's decision to quit or reduce smoking.^{9,18} It is therefore important to instigate tactics and policy enhancements that drive individuals toward more probable behavior change.

Even though many countries have incorporated PWCP into their legislation,¹² some are still hesitant or restrained because of insufficient evidence that PWCP can actually reduce smoking rates. In the United States, for example, the Food and Drug Administration was given the authority to regulate tobacco products in 2009 via the Family Smoking Prevention and Tobacco Control Act,¹⁶ which opened up the path to initiate the implementation of PWCP. However, the United States has not yet introduced PWCP because the overarching theme is still set in legal contentions.¹⁹ Thus, in countries with complex legal systems, substantial evidence to support PWCP is clearly needed.

So far, evidence has shown that PWCP are a cost-effective health communication, have high awareness and visibility among nonsmokers and youths, and are significantly more effective than text-only messages because they depict health risks vividly.^{5,6} Research has also shown that regularly updated, large, and prominent PWCP located on the top of packages are credible, have public support, and can increase health knowledge and motivation to quit.^{5,6} Frequent reminders about behavior change have generally been shown to be effective.²⁰ PWCP might have this effect.

However, evidence in terms of behavior change has not been systematically reviewed. Therefore, we conducted this review in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses recommendations to assess the evidence pertaining to the effect of PWCP on smoking behavior.²¹ We used a structured approach consisting of 5 criteria (type of population, intervention, comparator group, outcome, and study design) to frame our research question, namely, whether active smokers presented with PWCP had a higher probability of quitting, reducing, and attempting to quit smoking than smokers not presented with the PWCP.²¹ We purposely excluded outcomes not related to behavior change, such as those looking at perceptions, attitudes, reactions, knowledge, or even motivation and intention to quit.

METHODS

Because we expected the number of articles with original data investigating the effect of PWCP on behavior change to be small, we opted to ease the criteria for selecting studies to include all available evidence on the topic rather than identifying only methodologically rigorous studies.

Variables Examined

Participants had to be current, active smokers of manufactured or hand-rolled cigarettes and aged

10 years or older. Although the most common definition of "current smoker" refers to individuals who have smoked at least 100 cigarettes in their lifetime and who are currently smoking every day or some days,²² for the purpose of this review we used a much broader definition of any smoking at the time of the assessment. We examined the effect of any graphic, pictorial, photographic, or symbolic warning image of any size, color, content, and position, with or without text, printed or intended for printing on cigarette or hand-rolling tobacco packages.

Inclusion of a comparison group was a requisite and could have consisted of any of the following: smokers not exposed to PWCP or exposed to a variant of the PWCP intervention that could serve as comparison group, such as when pictorial warnings were used in combination with another exposure (e.g., plain packaging, media campaign, or self-affirmation); smokers exposed to textonly warnings such as in time periods or study settings in which PWCP had not yet been implemented; smokers with lower cognitive responses to PWCP (i.e., level of understanding) or who were unaware of the warnings.

The primary outcome was smoking cessation, following the definition of "not having smoked, not even a puff, in the 7 days before the follow-up measure."²³ The secondary outcomes included reduction, defined as "any self-reported as absolute or percentage decrease of the quantity of cigarettes smoked per day, with or without biochemical confirmation,"24 and attempt to quit, based on an affirmative response to questions about a "serious attempt to stop smoking for good that lasted for at least 24 hours"

in the recent past.²² However, to preserve a largely inclusive approach, we mostly used these definitions as a reference standard rather than as strict selection criteria.

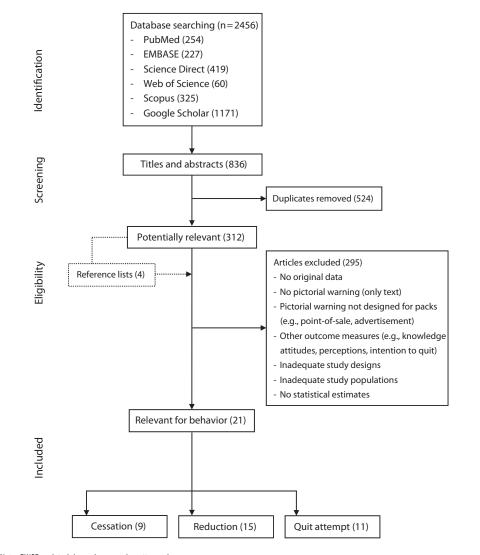
We considered experimental (e.g., randomized controlled trials [RCTs]) and quasi-experimental (e.g., time-series or pre-post design) studies and relevant observational studies with any type of follow-up period (e.g., prospective or retrospective cohorts), including repeated surveys in different time periods with different samples.

Information Sources and Search Strategy

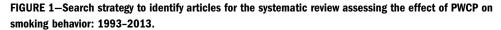
We identified articles published between 1993 and 2013 in PubMed, EMBASE, ScienceDirect, Web of Science, and Scopus using combinations of the keywords and MeSH terms (including plural forms): warning + (at least 1 of) graphic, image, visual, photo, picture, pictorial, design, label, pack + (at least 1 of) smoke, smoking, cigarette, tobacco (Figure 1).

We completed identification of relevant material using Google Scholar. Because of the limitations of this search engine, we had to screen document titles only. We used the following descriptors (including plural forms): warning + (at least 1 of) smoke, smoker, smoking, tobacco, cigarette, pack, package, graphic, image, visual, photo, picture, pictorial, and design.

We finalized the search by screening the reference lists of all relevant articles selected from the previous searches, including reviews related to the topic, to identify other potential documents. We limited the review to documents written in Chinese, Korean, Danish, Dutch, English, French, German, Italian, Norwegian, Portuguese,



Note. PWCP = pictorial warnings on cigarette packages.



Spanish, and Swedish because someone on the team or a close colleague was able to read these languages.

Study Selection and Data Extraction

First, we conducted a screening of titles and abstracts of all the hits obtained through the 7 search engines. Then, we excluded duplicate documents and expanded the list of those that were potentially relevant with articles recovered from reference lists. Finally, we performed a careful reading of hard copies to assess eligibility. Excluded documents were those containing no original data, looking at text warnings only or pictorial warnings not aimed for use on cigarette packs (e.g., point of sale and advertisements), or studying only cognitive effects of PWCP, such as people's knowledge, perceptions, reactions, attitudes, or intentions. We also excluded studies because of inadequate methodological designs (e.g., crosssectional studies, no comparison group) and study populations not fulfilling the inclusion criteria (e.g., nonsmokers) or because no statistical estimates were reported. The screening and assessment process was performed independently by 3 of us (B. L., F. G., and J. M.-E.), and disagreements were resolved by discussion.

We retrieved the following data from the selected articles: first author's last name, country and year of publication, journal of publication, study period, data source, relevant outcomes, study population, study design, sample size, outcome definition, exposure assessment, measurement instruments, statistical analyses and measures, control for potential confounders, and main results of interest. When the analyses were adjusted by confounding factors, we used the adjusted measures instead of the crude results. Two of us (B. L. and F. G.) extracted information separately for each of the outcomes, and differences were resolved after discussion with the first author (J. M.-E.).

Study Quality and Data Synthesis

Most of the selected studies did not primarily aim to assess the impact of PWCP on smoking behavior. In most cases, the results associated with the outcomes were secondary, and in few studies we had to specifically search for those potentially relevant to this review.

Articles were published in various types of journals, including the fields of psychology and marketing, which have a different approach than that of biomedical journals. This resulted in an extreme heterogeneity of designs, samples, definitions, exposure methods, study periods, and statistical analyses, precluding not only the possibility of metaanalyses, but even the use of a standard assessment with homogeneous criteria to determine the quality of the studies.

We therefore decided to use a simplified arbitrary quality assessment based on 4 basic criteria as judged independently by the 2 reviewers (J. M.-E. and B. J.): study design, outcome

TABLE 1—Quality Assessment of the Studies Included in the Systematic Review of the Effect of Pictorial Warnings on Cigarette Packages on Smoking Behavior for the 3 Outcomes Measured: 1993–2013

Author, Study Area, and Study Period	Outcome Assessed	Study Design ^a	Outcome Definition ^b	Exposure Definition ^c	Statistical Analyses ^d	Total Score	Overall Quality ^e
Hammond et al., ²⁵ southwest Ontario, CAN, 2001-2002 ^f	C + R + A	1	2	1	1	5	Fair
Christie and Etter, ²⁶ Switzerland, France, Belgium, 2001	С	0	0	1	1	2	Very poor
	R + A	0	2	1	1	4	Poor
Hammond et al., ²⁷ southwest Ontario, CAN, 2001-2002 ^f	C + R + A	1	1	1	1	4	Poor
Environics Research Group Ltd., 28 CAN, 2000-2004	Α	0	2	2	1	5	Fair
Hammond et al., ²⁹ AUS, UK, CAN, US, 2002-2005 ^g	R	1	1	2	2	6	Fair
Harris et al., ³⁰ University of Sheffield, UK, no period reported	R	2	2	0	1	5	Fair
Silpasuwan et al., ³¹ 5 regions, Thailand, 2005–2006	С	0	1	1	1	3	Poor
Borland et al., ³² AUS, UK, CAN, US, 2002-2006 ^g	С	1	2	1	1	5	Fair
	A	1	2	1	2	6	Fair
Borland et al., ³³ AUS, UK, CAN, US, 2002-2006 ^f	R	1	1	2	2	6	Fair
Shanahan and Elliott, ³⁴ AUS, 2000 and 2008	R	0	1	1	1	3	Poor
	A	0	2	1	1	4	Poor
Fathelrahman et al., ³⁵ Penang State, Malaysia, 2008	R	2	1	0	1	4	Poor
Heydari et al., ³⁶ Tehran, Iran, 2008-2009	R	0	1	1	1	3	Poor
Miller et al., ³⁷ South AUS, 2005-2006	С	0	0	0	1	1	Very poor
Moodie et al., ³⁸ Glasgow, Scotland, UK, 2010	R	1	1	1	1	4	Poor
Malouff et al., ³⁹ AUS, no period reported	C + A	2	0	1	1	4	Poor
	R	2	2	1	1	6	Fair
Thrasher et al., 40 2012, 7 cities, Mexico, 2010 and 2011 $^{\rm h}$	С	0	0	1	1	2	Very poor
	А	0	1	1	2	4	Poor
Zhao et al.,41 mid-Atlantic university, US, no period reported	R	2	2	2	1	7	Good
Azagba and Sharaf, ⁴² CAN, 1998–2008	A	1	1	2	2	6	Fair
Malouff et al.,43 cities in the United States, no period reported	С	0	0	1	1	2	Very poor
	R	0	2	1	1	4	Poor
	Α	0	1	1	1	3	Poor
Thrasher et al.,44 Mexico, 2010-2012 ^h	R + A	0	1	1	1	3	Poor
Yong et al., ⁴⁵ Thailand and Malaysia, 2005–2008	R	1	1	2	1	5	Fair

Note. A = attempt; AUS = Australia; C = cessation; CAN = Canada; PWCP = pictorial warnings on cigarette packages; R = reduction.

 a^{2} = randomized controlled trial; 1 = cohort study; 0 = other study designs.

^b2 = clear (explicit action) and complete (explicit time frame); 1 = unclear or incomplete; 0 = unclear and incomplete.

^c2 = appropriate PWCP; 1 = appropriate pictorial warning intended for printing in cigarette packages or inappropriate PWCP (e.g., very short exposure duration or lack of an unexposed control group); 0 = inappropriate warning (not a PWCP or intended for printing in cigarette packages).

^d2 = pertinent and adjusted; 1 = not pertinent or unadjusted; 0 = not pertinent and unadjusted.

e0-2 = very poor; 3-4 = poor; 5-6 = fair; 7-8 = good.

^fThese articles used similar or identical data for analyses.

^gThese articles used similar or identical data for analyses.

^hThese articles used similar or identical data for analyses.

definition, exposure definition, and statistical analyses. Agreement between raters was very high because the assessment instrument used was straightforward with clear definitions. There were minor disagreements in just a few studies or criteria, which were resolved by consensus between reviewers. Full details about the assessment can be found in Table 1.

We summarized the findings as positive when a statistically significant effect (P<.05) was reported, regardless of the strength of the

association; null when no significant effect was reported; mixed when either positive or null results were observed; and uncertain when the results available precluded a meaningful conclusion. In the text, the results were presented mostly in a narrative manner, trying to highlight the most relevant findings in context with the study limitations and strengths.

RESULTS

From the 2456 items identified, we considered 312 nonduplicate

documents plus another 4 extracted from reference lists as potentially relevant to the PWCP topic. From these, we excluded 295 for various reasons, leaving 21 studies with relevant behavioral outcomes (cessation, 9; reduction, 15; and attempt, 11).²⁵⁻⁴⁵

Two thirds (n = 14) of the selected studies had been published within the past 5 years. Canadian and Australian data were the most frequently analyzed with 7 and 6 articles, respectively, including 3 multicountry analyses with UK and US data used as the reference because these countries have not yet implemented PWCP. Nevertheless, each of these countries also contributed 2 other studies, mostly of an experimental nature. Data from developing countries were available for Mexico, Thailand, Malaysia, and Iran. Various articles were based on similar or identical data (i.e., multicountry studies, Mexican studies, and Canadian prospective cohorts).

On the basis of the quality assessment, we considered 57% of the reviewed studies (n = 12)to be of poor or very poor quality, and only 1 could be classified as being of good quality.⁴¹ Most studies compared data at different time periods, but 4 did not specify any study period (3 being experimental). Cohorts (prospective, retrospective, survey based, and panel) were the most frequent designs, used in 9 studies, followed by pre-post and RCT designs with 5 and 4 studies, respectively. Study population, sample selection, and data collection methods varied considerably across studies, making it difficult to summarize the results. Most studies focused on adult smokers aged 18 years or older, but 3 included adolescents (aged ≥ 15 years). Twelve articles examined only 1 outcome, 4 looked at 2, and

5 investigated all 3 behavioral outcomes.

Cessation

Of the 9 articles presenting any kind of smoking cessation results, 4 used variations of cohort designs,^{25,27,32,37} 4 were pre-post studies,^{26,31,40,43} and 1 was an RCT.³⁹ Sample sizes ranged from less than 100 smokers to nearly 1000.

Two studies did not report a cessation definition,^{26,37} 1 used an inappropriate definition (i.e., "quit smoking within 1 month"),31(p.554) 3 used stage of change toward cessation,39,43 2 used a cessation-related variable for which cessation was pooled together with reduction and attempt,^{25,27} and another used "reasons for having quit in ex-smokers" in the year preceding the survey.^{40(p.252)} Only 1 study defined cessation as smoking abstinence for 1 month or more before the repeated cohort measurement from those who attempted to quit.³² The exposure assessment showed large variability. Some studies used intermediary variables such as the depth of cognitive processing,^{25,32} avoidance and emotional reactions,²⁷ or salience with regard to the PWCP.³² Nearly all compared periods before and after implementation or use of PWCP in different ways, except for the RCT that directly compared pictorial with text only using computer screen warnings.³⁹ Statistical analyses relied mainly on logistic regression with adjusted odds ratios (ORs) as a measure of association^{25,27,32,40} or analysis of variance using mean score comparisons,^{37,39,43} but 2 articles presented only cessation proportions.^{26,31} Logistic models were adjusted for various sociodemographic (e.g., age, gender, income, and education) and smoking behavior (e.g., daily cigarettes and smoking years) variables.^{27,32} Other analyses were typically unadjusted.

Results were mixed and difficult to summarize because designs, exposure, outcome definitions, and statistical measures varied much. However, we can highlight the most relevant findings looking specifically at cessation (excluding stage of change toward cessation and cessation pooled with other behavioral outcomes). The prospective Canadian cohort found no effect of PWCP cognitive processing on cessation using unadjusted quartile analyses (fourth quartile score = 1.7, 95% confidence interval [CI] = 0.37, 5.3).²⁵ The Australian RCT showed no significant effect of pictorial warnings compared with text only at follow-up using computer screen messages once per week for 4 weeks (based on our own calculations from raw counts, 14% vs 8%; P = .65).³⁹ The Mexican prepost study reported an effect of PWCP compared with text only (before PWCP implementation) as a quitting reason in ex-smokers (adjusted OR = 2.44; 95% CI = 1.27, 4.72).40 Overall, the multicountry survey-based cohort study found no significant consistent adjusted effects for salience, avoiding or forgoing cigarettes, and cognitive response.³² Only 2 studies looking at cessation were of fair quality, and in both the results were null (OR = 1.74; 95%) CI = 0.37 - 5.3 for fourth quartile exposure to cognitive processing²⁵; no consistent statistically significant effect for PWCP's salience, cognitive response, and forgoing or avoiding cigarettes³²; Table 2.

Reduction

Studies on reduction included 6 different types of cohorts, 4

RCTs, and 3 pre-post studies. Experimental designs included 50 to 150 smokers, whereas the cohort studies surveyed as many as 2000. Nearly all studies used different definitions for reduction. Examples of relatively clear descriptions included decreased daily cigarette consumption of at least 1 per day,²⁵ mean daily cigarettes in the past week,39 and number of cigarettes smoked within the follow-up week.30 Other definitions related to the practice of forgoing cigarettes, such as whether the warnings stopped the smoker from having a cigarette when wanting to smoke 1 in the past month with categorical answers⁴⁵ or in the past 6 months with dichotomous responses.²⁹ Others were less specific and asked for the number of cigarettes smoked, coded as more, same, or less,³⁶ or smoking less around others, coded dichotomously,38 but even if studies used somewhat similar definitions, the time period or coding categories differed, precluding direct comparisons. For the statistical analyses, cohort studies used adjusted logistic regression models or generalized estimating equations.^{25,27,29,33,44,45} Experimental and pre-post studies tended to rely on analysis of variance,39,41 the McNemar test, 35,38 and the paired t test. 26 Two studies presented only proportions with³⁴ or without⁴³ a χ^2 test involved. In general, logistic models were adjusted for sociodemographic variables including gender, age, income, and education and for smoking-related factors.

Exposure assessment varied a lot and included the study of concomitant interventions expected to strengthen the warning's effect. For instance, 2 RCTs examined the impact of

Author, Study Area, and Study Period	Design and Sample	Outcome Definition	Exposure Assessment	Analyses	Measure and Adjustment	Main Results	Quality ^a and Finding: ^b Remarks
Hammond et al., ²⁵	Prospective cohort;	≥ 7 d abstinence	Depth of cognitive	Logistic regression	OR; no adjustment for	Q1 (Ref)	Fair, null
southwest Ontario, CAN,	n = 432 followed	(cessation-related	processing of PWCP, 9		cessation only (quartile	Q2: 0R = 1.4 (95%	Significant for cessation-
2001-2002 ^c		behavior including	items (5-point Likert		analyses), adjusted for	Cl = 0.37, 5.26)	related behavior
		cessation)	scale), quartile exposure		intention and attempts	Q3: OR = 3.0 (95%	(including cessation)
			(cessation only), and		to quit, gender,	Cl = 0.54, 7.65)	adjusted analyses.
			scale (used for		education, daily and	Q4: 0R = 1.7 (95%	
			cessation-related		years smoking for	Cl = 0.37, 5.3)	
			behavior, which		pooled outcome	Cessation-related	
			included cessation,			behavior (pooled	
			reduction, and attempt)			outcome); depth of	
			Assessment in 2002 (9 m			cognitive processing was	
			after full PWCP			adjusted; OR = 1.07	
			implementation)			(95% Cl = 1.03, 1.12)	
Christie and Etter, ²⁶	Pre-post; n = 393	No cessation definition	3 wk after baseline online	None for cessation	Cessation proportion at	Cessation rate 7% after	Very poor, uncertain
Switzerland, France,			survey, cig boxes with		follow-up; no	the follow-up, similar	No differences across box
Belgium, 2001			various messages were		adjustment	across box messages	messages
			sent to smokers who				
			used them for \sim 21 d; 1				
			mo after getting the				
			boxes, they filled in				
			another questionnaire				
Hammond et al., ²⁷	Prospective cohort;	Pooled variable:	Avoidance (no effort to	Logistic regression	OR; adjusted for daily	Avoidance: AOR = 0.86	Poor, mixed
southwest Ontario, CAN,	n = 432 followed	cessation-related	avoid vs covering,		cigarettes, smoking	(95% CI = 0.56, 1.32)	Pooled outcome
2001-2002 ^c		behavior (including	hiding, avoiding PWCP)		years, intention to quit,	Emotional reactions:	(cessation + reduction +
		cessation ≥ 7	and emotional reaction		prior quit attempts,	AOR = 1.37 (95%Cl =	attempt)
		d abstinence)	(5-point Likert scale) for		gender, age, education	1.15, 1.64)	
			extent of fear or disgust				
			at baseline; assessment				
			9 mo after full PWCP				
			implementation				

Cessation proportion Quit within 1 mo: 23.5% Poor, null before and after follow- (pre) vs 21.8% (post) Smokers and ex-smokers up; no adjustment Of those who quit, 2.3% mixed did because of the text warning and 2.8% because of the PWCP.	OR: adjusted for age, gender, income,Point estimates: salience raves 1-2, 0.34;Fair, null only CAN and AUS had education, dailywaves 2-3, 0.94; waves education, dailywaves 2-3, 0.94; waves 3-4, 1.01; waves 4-5, 1.0; cognitive-waves 2-3, 1.02; waves 3-4, 1.17;* waves 4-5, 1.02; forging-waves 1-2, 0.99; waves 2-3, 1.04; waves 3-4, 1.02; waves 2-3, 0.98; waves 3-4, 0.77;* waves 4-5, 1.18	No measure; no Attitudes and beliefs sig. Very poor, uncertain adjustments relate to quit intention; Associations assessed intention to quit score Associations assessed intention; at baseline relates to marketing journal cessation at follow-up; marketing journal cessation at follow-up; 2.73 (80.5% still smoking) vs 3.53 (19.5% quitters; P = .01); small change in beliefs at follow-up, mostly nonsig.
eog	Logistic regression	Linear regression ANOVA paired samples
Questionnaire to assess stages of change in smoking cessation (never think to quit in 6 mo, quit smoking within 1 mo, smoking relapsing) for the old text vs new PWCP warnings with 8–12 mo in between	In relation to PWCP: salience, 2 items (noticed, read/looked last mol; cognitive response, 3 items (made think of health risk, more likely to quit, think about quitting in next 6 mol; forgoing cigarettes (ever-never); avoiding (yes-no), 4 items (covering, keep out of sight, using case, avoiding labels)	Reasoned action approach: If text-only warnings beliefs and attitudes correlate with quit intention at baseline (2005), and intention predicts cessation at follow-up (August 2006), then higher perception of PWCP (since March 2006) at follow-up should result in more
Unclear cessation definition ("quit smoking within 1 month")	≥ 1 mo abstinence since prior wave from those who attempted to quit; 5 waves	No cessation definition
Pre-post; n = 455 (including ex-smokers)	Survey-based cohort; waves 1–2, 1083/2371 (quit/attempt); waves 2–3, 1176/2138; waves 3–4, 1097/1823; waves 4–5, 918/1273	Cohortlike; n = 152
Silpasuwan et al., ^{3.} 5 regions, Thailand, 2005-2006	Borland et al. ³² AUS, UK, CAN, US, 2002-2006	2005-2006 2005-2006

TABLE 2–Continued							
Malouff et al., ³⁸ AUS, no period reported	RCT; n = 48 followed	Stage change toward cessation: 1 = no intention, 2 = intend 6 mo, 3 = plan 30 d, 4 = action to quit (stop or decrease)	27 exposed to text warnings only vs 29 exposed to text + PW; on computer screen once/wk for 4 wk Stage toward cessation assessed at baseline, end of trial (postexposure), 1 mo after (fillow_Lin)	Two-way ANOVA	Mean stage-of-change score difference; adjusted for preexposure	Stage change (including cessation in action-to- quit stage): postexposure 2.59 (text) vs 3.04 (PW), P = .04; follow-up 2.67 (text) vs 2.92 (PW), $P > .05$ Cessation: intervention, 3 of 21; control, 2 of 25 ($D = 657^{d}$	Poor, null Warnings on computer screen
Thrasher et al., ⁴⁰ 2012, 7 cities, Mexico, 2010 and 2011	Pte-post; quit last y: n = 106 (2010), n = 233 (2011)	Reasons for having quit among ex-smokers ("had quit in the year prior to the survey")	Comparison between 2010 (before PWCP) and 2011 (after); the 6 PWCP (influenced decision to quit a lot) were actually shown to participants (ITC	GEE, logistic regression	OR; age, income, gender, education, quit intention in next 6 mo, attempt to quit in past year	AOR = 2.44 (95% CI = 1.27, 4.72) for effect of PWCP vs text as quitting reason in ex-smokers between 2010 (13% text) and 2011 (26% PWCP)	Very poor, positive Measured warnings as reported reason for quitting
Malouff et al., ⁴³ cities in the US, no period reported	Pre-post; n = 77	Stage of change toward cessation	One different pictorial warning with text per week was e-mailed for 4 wk; a final questionnaire was sent 1 wk after the last warning	Pre-post ANOVA	Mean stage or score of change toward cessation; no adjustments	Stages or score of change toward cessation: higher scores at follow-up (<i>P</i> < .001)	Very poor, uncertain Warning in computer screen
Note: ANOVA = analysis of variance; AOR = adjusted cigarette packages; OR = odds ratio; Q = quaritie; R ^a Based on the total sum of points for study design (, 1 = appropriate warning intended for printing or inap as of very poor (0-2), poor (3-4), fair (5-6), and g ^b According to the most relevant finding. Positive: sta available precluded a meaningful conclusion. ^c Articles used similar or identical data for analyses. ^c Statistical test done by the reviewers.	Note. ANOVA = analysis of variance; AOR = adjusted odds ratio; Cl - cigarette packages; OR = adds ratio; Q = quartile; RCT = randomize Based on the total sum of points for study design (2 = RCT; 1 = co 1 = appropriate warning intended for printing or inappropriate PWCI as 0 very poor (0-2), poor (3-4), fair (5-6), and good (7-8) qua According to the most relevant finding. Positive: statistically signif available precluded a meaningful conclusion. "Articles used similar or identical data for analyses. "Statistical test done by the reviewers.	<i>Note.</i> ANOVA = analysis of variance; AOR = adjusted odds ratio; Cl = confidence interval; cig = cigarette(s); GEE = generalized estimating equations; ITC = International Tobacco Control; PW = pictorial warning; PWCP = pictorial warnings on cigarette packages; OR = odds ratio; Q = quartile; RCT = randomized clinical trial; sig = statistically significant. "Based on the total sum of points for study design (2 = RCT; 1 = contort; 0 = other designs), outcome definition (2 = clear and complete; 1 = unclear or incomplete; 0 = unclear and incomplete), exposure definition (2 = appropriate PWCP; 1 = appropriate PWCP; 0 = inappropriate PWCP; 0 = inappro	cig = cigarette(s); GEE = gener statistically significant. ns), outcome definition (2 = cl arming), and statistical analyse regardless of the association	alized estimating equations; aar and complete; 1 = undear is (2 = pertinent or adjusted, 3 strength; null = no significant	 confidence interval; cig = cigarette(s); GEE = generalized estimating equations; ITC = International Tobacco Control; PW = pictorial warning; PWCP = pictorial warnings on ed clinical trial; sig = statistically significant. abort; 0 = other designs, outcome definition (2 = clear and complete; 1 = unclear or incomplete; 0 = unclear and incomplete), exposure definition (2 = appropriate PWCP; 0 = inappropriate warning), and statistical analyses (2 = pertinent or adjusted, 1 = not pertinent or unadjusted, 0 = not pertinent and unadjusted); studies were classified PMCP; 0 = inappropriate warning), and statistical analyses (2 = pertinent or adjusted, 1 = not pertinent or unadjusted, 0 = not pertinent and unadjusted); studies were classified stift; 	trol: PW = pictorial warming: PV incomplete), exposure definit 0 = not pertinent and unadjust positive or null results observ	WCP = pictorial warnings on ion (2 = appropriate PWCP, ted); studies were classified ed; and uncertain = results

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Author, Study Area, and Study Period	Design and Sample	Outcome Definition	Exposure Assessment	Analyses	Measure and Adjustment	Main Results	Quality ^a and Finding: ^b Remarks
Hammond et al. ²⁵ southwest Ontario, CAN, 2001-2002 ⁶	Prospective cohort; n = 432 followed	Decreased daily cig consumption of $\geq 1/d$	Depth of cognitive processing of PWCP, 9 items (5-point Likert), quartile exposure (reduction only)	Logistic regression	OR; no adjustment for reduction only (Q analyses)	Q1 (ref); Q2, OR = 1.52 (95% Cl = 0.67, 3.45); Q3, OR = 1.80 (95% Cl = 0.82, 3.98); Q4, OR = 2.68 (95% Cl = 1.21, 5.93); 24.3% reduction at follow-up	Fair, positive Reduction in Q4 only (increasing trend Q2-Q4)
Christie and Etter, ²⁶ Switzerland, France, Belgium, 2001	Pre-post; n = 365	No. cig smoked period) d (unspecified period)	3 wk after BL, online survey; 4 cig boxes (addiction, passive smoking, health risks, smell) were sent to smokers who used them for 21 d 1 mo after getting the boxes, smokers filled out a questionnaire	Paired 7 test	Mean difference; no adjustments	Still smoking at follow-up (all boxes): mean cig/ d 19.4 before vs 18.1 after, $P < .01$ Pre-post mean diff. in cig/d across boxes: addiction, 0; passive smoking, -2.3^* ; bad breath, -1.6^* ; health risk, -3^*	Poor, positive 3 of 4 boxes showed reductions, short-term effect
Hammond et al., ²⁷ southwest Ontario, CAN, 2001-2002 ^c	Prospective cohort; 432 followed	Cessation-related behavior (including daily reduction in cigs)	Avoidance (no vs covering, hiding, avoiding PWCP) and emotional reaction (5- point Likert scale) for extent of fear and disgust at baseline; assessment 9 mo after full PWCP implementation	Logistic regression	OR; adjusted for daily cigarettes, smoking years, intention to quit, prior quit attempts, gender, age, education	Avoidance: AOR = 0.86 (95% CI = 0.56, 1.32) Emotional reactions: AOR = 1.37 (95% CI = 1.15, 1.64)	Pooled outcome

Hammond et al., ²⁹ AUS,	Survey-based cohort; >	Warning stopped smoker	CAN PWCP in January	GEE	Proportion, OR; adjusted	Very similar results	Fair, positive
UK, CAN, US, 2002-	2000 per country and	from having a cig when	2001-PWCP in Canada		for gender, age, income,	(patterns in figures) as	Same as Borland et al. ³³
2005	wave	about to smoke 1 in	(2001, ITC standard)		education, minority	in Borland et al. ³³	but with 1 fewer wave
		past 6 mo (ever vs	and AUS (2006, slightly		status, heaviness of		
		never)	below ITC), US-UK text		smoking index, attempt		
			only (well below ITC)		to quit in past year;		
			Waves: wave 1, 2002;		accounted for design		
			wave 2, 2003; wave 3,		effect and nonresponse.		
			2004; wave 4, 2005;				
			warnings noted 2002-				
			2005 often or very often				
			in last mo (%): CAN,				
			60%; AUS, 52%; UK,				
			44%; US 30%				
Harris et al., ³⁰ University	Experiment (RCT); BL,	No. cig smoked in last	Randomized for the SA vs	Linear regression	No. cigs/d or wk at	Cig/d, SA: 0.03, model 1;	Fair, null
of Sheffield, UK, no	n = 44 SA, n = 43 C;	d of follow-up wk and in	C groups; 4 pictorial		follow-up predicted by	-0.01, model 2	The effect of affirmation
period reported	follow-up, n = 21 SA,	a typical d of follow-up	warnings with text shown		SA; adjusted by model 1	Cig/wk, SA: 0.10 (model	was tested rather than
	n = 14 C	wk (combined variable);	to groups		BLrisk and model 2	1); -0.15 (model 2); all	PWCP.
		total cigs smoked in	No. cigs/d right after PWs		interaction (BLrisk $ imes$ SA)	coefficients nonsignificant	
		follow-up wk	were shown considered			(<i>P</i> > .05)	
			BLrisk				
Borland et al., ³³ AUS, UK,	Survey-based cohort; >	Forgoing cig (ever vs	PWCP in CAN (2001) and	GEE	Proportions; weighted by	Before and after PWCP	Fair, positive
CAN, US, 2002-2006 ^c	2000 per country and	never) because of the	AUS (2006), US and UK		age and gender,	(waves 4-5): 10%-17%	Sig. forgoing increase
	wave	warnings (2 countries	text only; wave 1, 2002;		accounted for design	(<i>P</i> < .001); also sig.	after PWCP in AUS,
		only had text) at each	wave 2, 2003; wave 3,		effect and nonresponse	between wave 5 and	similar increase for
		wave	2004; wave 4, 2005;			among waves 1, 2,	recent warning change
			wave 5, 2006			and 3	between AUS (text to
			Before and after PWCP in			Warning change: AUS	PWCP) and UK (small to
			AUS			(waves 4-5) vs UK	large text); lower PWCP
			Warning change: AUS			(waves 2-3): increase of	wear-out effect (CAN)
			(change from text to			7% in both countries	compared with text (UK)
			PWCP) vs UK (change to			(P = .98)	
			larger text)			Wear-out: more sustained	
			Wear-out effect: UK (3.5 y			response to PWCP in	
			after larger text) vs CAN			CAN compared with	
			(2.5 y after PWCP)			larger text in UK,	
						controlling for difference	
						in implementation time	

Shanahan and Elliott, ³⁴	Repeated surveys;	Reduction in amount of	Implementation of PWCP	χ^2 test	Proportions; no	Reduction 27% in 2000	Poor, uncertain
AUS, 2000 and 2008	n = 822 in 2000,	tobacco smoked per	in 2006	:	adjustments	vs 33% in 2008	Cross-sectional surveys
	n = 670 in 2008	d past 12 mo				(reported sig., no P presented)	compared
Fathelrahman et al., ³⁵	RCT; n = 140	To what extent warning	BL assessment; after 1 wk	McNemar's test	Proportions; no	Text, 31.4 before vs	Poor, uncertain
Penang State, Malaysia,		labels cause you to stop	random allocation to 5-		adjustments	31.4% after; PWCP, 24.6	Potential future reduction
2008		from having a cig? (0 =	min inspection of PWCP			before vs 58% after	rather than reduction
		never, $1 = $ once, few	vs text only; final			(P < .001)	was assessed
		times, many times)	assessment of smoking			No P for difference	
			reduction right after			between groups	
:						reported.	
Heydari et al., ³⁶ Tehran,	Pre-post; n = 1590	No. of cig and	Participants surveyed in	Wilcoxon (smoking rate);	Proportions, mean	"No sig. decrease in rate	Poor, null
Iran, 2008-2009		consumption coded as	2008 (before PWCP),	χ^2 test	difference; stratified by	of smoking" (mean	Negative results reported
		"more, same, less"	follow-up 9 mo after		gender, age, and time of	difference = 0.179;	
			PWCP implementation		first cigarette in the	P = .86); 7.6% smoked	
					morning	less, 12% smoked more	
						after PWCP compared	
						with 2008	
Moodie et al., ³⁸ Glasgow,	Quasi- experimental;	Forgoing cig: smoking less	Half of the participants	McNemar's test	Proportions; no	Measure, plain vs	Poor, positive
Scotland, UK, 2010	n = 48	around others (yes-no	used plain packs (with		adjustments	branded: forgoing-l,	The effect of plain
		responses)	PWCP) for 2 wk and then			15% vs 4%; II, 20% vs	package was tested
			branded packs (with			0.6%; III, 19% vs 6%;*	rather than PWCP
			PWCP) for other 2 wk;			IV, 30% vs 9%.* Smoke	
			the other half vice versa			less around others-l,	
			Four measurements (2			33% vs 11%;* II, 37% vs	
			per wk): I, II, III, IV			10%; III, 46% vs 13%;*	
						IV, 44% vs 7%*	
Malouff et al., ³⁹ AUS, no	RCT; 48 followed	Cigs smoked yesterday	27 exposed to text only vs	Two-way ANOVA	No. cigarettes smoked	Cigs smoked yesterday:	Fair, null
period reported		(mean daily cig in	29 exposed to text and		yesterday; adjusted for	post exposure, 5.86	Narrow definition for
		past wk)	PW; on computer screen		preexposure	(text) vs 6.60 (PW)	reduction
			once per week for 4 wk;			P > .05; follow-up, 5.29	
			stage toward cessation			(text) vs 5.22 (PW),	
			at baseline, end of trial			P > .05 (similar results	
			(post exposure), 1 mo			for mean daily cigs in	
			after (follow-up)			past wk)	

Zhao et al., ⁴¹ mid-Atlantic	RCT; n = 91	Daily cigs smoked in 7	3 groups: 1, no PWCP, no	ANOVA	Mean difference;	Similar mean smoking	Good, null
university, US, no period		d after intervention	affirmation; 2, PWCP		stratified by daily vs	index across the 3	No difference between
reported		using diary (data	only; 3, affirmation		occasional smokers	groups $(P = .56)$	daily vs occasional
		changed into smoking	(protecting an image of			Mean smoking index	smokers
		behavior index by	integrity, morality,			between daily vs	
		tallying the total no. of	adequacy), followed by			occasional smokers	
		cig during the 7 d)	PWCP			similar in 3 groups	
			BL data on daily vs			(P = .96)	
			occasional smoking				
Malouff et al., ⁴³ cities in	Pre-post; n = 78	No. cig smoked in	Different PW warning and	Pre-post ANOVA,	Mean difference, r	Mean pre vs post: cig/d,	Poor, positive
the US, no period		previous 24 h and wk	text/wk e-mailed for 4	correlation	between warning	11.5 vs 8.9, P < .05;	Warning in computer
reported			wk; assessment 1 wk		distress and usefulness	cig/wk, 77.4 vs 58.2,	screen
			after last warning;		score and cigs (prior 24	<i>P</i> < .05	
			perceived distress and		h or wk); no adjustments	cig/wk: distress $r =25$	
			usefulness of warning as			(P < .05); usefulness	
			mediator factors			<i>r</i> =34, (<i>P</i> > .05); cig/d:	
						nonsig	
Thrasher et al., ⁴⁴ Mexico,	Retrospective-like cohort;	Health warnings (text and	Exposure (recall of	Logistic regression	OR; adjusted for age,	AOR (95% Cl; refrained	Poor, positive
2010-2012	1765	pictorial) "make	having seen): PWCP		gender, income, civil	%): None as Ref (11%),	Similar to media, and
		smokers stop when	(September 25, 2010),		status, education,	PWCP, 2.55 (1.43, 4.57;	PWCP and media;
		about to smoke"	media campaign (only		smoking intensity, quit	23%); media, 2.13	variable duration of
		(refraining yes-no)	October 2010), PWCP		intention, exposure to	(1.23, 3.69; 22%);	exposure, based on
		during the previous mo	and media (none);		PWCP and media	PWCP + media, 2.51	cross-sectional data
			warnings were actually			(1.46, 4.31; 24%)	
			shown to assess recall				
			Data collected from				
			October 17, 2010-				
			November 30, 2012				

Warnings stopped smoker	Wave 1: 2005, before	Logistic regression, GEE	OR; adjusted for age,	Change in forgoing cig	Fair, positive
from having a cig when	PWCP in T and M		gender, education,	over time between T and	62%-73% noticed PWCP
wanting to smoke 1 in	Wave 2: July-September		cohort, urban vs rural,	M (Ref): waves 2-1,	in T vs 57%-54% text in
past m (forgoing never,	2006, 14-18 m after		income, ethnicity, daily	2.59 (P < .001); waves	M; low retention,
once, few times, many	PWCP in T; August		vs nondaily smoking,	3-2, 1.49 (<i>P</i> < .05);	replenishment needed
times)	2006-March 2007 in M		number cigs/d,	waves 3-1, 3.86 (P	
	(only text; control		cigarette type	<.001)	
	country)				
	Wave 3: 2008 in T and M				
ji ji ji ji	tting to smoke 1 in et m (forgoing never, ee, few times, many es)	ug to smoke 1 in π (forgoing never, few times, many	ug to smoke 1 in π (forgoing never, few times, many	Ig to smoke 1 in Wave 2: July-September n (forgoing never, 2006, 14-18 m after few times, many PWCP in T; August in 2006-March 2007 in M (only text; control country)	It is smoke 1 in Wave 2: July-September cohort, urban vs rural, n (forgoing never, 2006, 14–18 m after income, ethnicity, daily few times, many PWCP in T; August vs nondaily smoking, number cigs/d, (only text; control cigarette type country)

ccording to the most relevant finding. Positive: statistically significant effect (P < .05) regardless of the association strength; null = no significantly positive effect; mixed = either positive or null results observed; and uncertain = results

Articles used similar or identical data for analyses

'Significant on the basis of 95% Cl or P < 0.05. available precluded a meaningful conclusion.

affirmation on the effect of warnings on daily and weekly cigarette consumption,30,41 1 retrospective-like cohort study compared the effect of PWCP with and without an antismoking media campaign,44 and a quasiexperimental study compared PWCP printed on plain or branded packs.38

As with smoking cessation, findings for reduction were mixed. Cognitive processing score in the fourth quartile only was associated with reduction (crude OR = 2.68; 95% CI = 1.21, 5.9).²⁵ Similar reductions in the mean number of cigarettes smoked were observed between text and pictorial warning messages shown on a computer in a RCT after 4 weeks.³⁹ The multicountry cohort showed a significant proportion forgoing after PWCP implementation in Australia. It also showed a similar increase in those forgoing after changing from text to PWCP in Australia compared with small to large text in the United Kingdom and a lower wear-out effect of PWCP in Canada compared with text only in the United Kingdom.^{29,33} Although neither of the 2 RCTs comparing the combined effect of affirmation and pictorial warnings led to positive findings,^{30,41} the experiment assessing the exposure to pictorial warnings printed on plain packages showed significant reductions for both forgoing and smoking less around others compared with warnings printed on branded packs.38 The combined effect of PWCP and media campaigns showed a significant impact, but one similar to PWCP and media alone.44 Concerning smoking reduction, 4 studies of fair quality showed positive findings,^{25,29,33,45} and 3 (2 of fair quality and 1 of good quality) revealed null findings (Table 3).^{30,39,41}

Attempt

Of the 11 articles looking at attempt, 9 also investigated reduction, cessation, or both. The articles included 5 cohort studies, 3 pre-post studies, 2 repeated surveys, and 1 RCT. Sample sizes ranged from 48 smokers in the RCT³⁹ to more than 2000 in a multicountry cohort.³² Various definitions were used, such as any attempt to guit that lasted 24 hours or more within the past month²⁶ or past 3 months^{25,27} or within the period before the cohort wave under study 32,40 ; an attempt to quit in the past 6^{42} or $12 \text{ months}^{28,40,44}$; or a quitting period of at least 1 month during the past year.³⁴

Adjusted regression modeling was the more frequent method of statistical analysis, though 2 studies used a simple χ^2 test to compare proportions,^{26,34} and 1 displayed only the proportion of smokers who attempted to quit at different survey periods without statistical comparisons.28

The Canadian cohort panel was the most relevant study, focusing only on quit attempt and showing that significantly higher proportions attempted to quit compared with those not exposed among all smokers and among daily smokers using various time-dependent definitions.42

Attempt to quit results were mixed. Although cognitive processing of PWCP had no effect on the basis of quartile exposure²⁵ or when compared with text-only warnings,40 significant associations of cognitive response to PWCP were reported in a cohort.32 Recall of having seen PWCP significantly increased the likelihood of a quit attempt, but not when it occurred in addition to a media campaign.⁴⁴ Exposure to various types of PWCP for 3

Author, Study Area, and Study Period	Design and Sample	Outcome Definition	Exposure Assessment	Analyses	Measure and Adjustment	Main Results	Quality, ^a Finding, ^b and Remarks
Hammond et al., ²⁵	Prospective cohort;	Any attempt to quit	Depth of cognitive	Logistic regression	OR; no adjustment for	23.1% attempted at	Fair, null
southwest Ontario, CAN,	n = 432	smoking that lasted \geq	processing of PWCP, 9		attempt only (Q	follow-up	Increasing trend from Q2-
2001–2002 ^c		24 h in 3 mo follow-up	items (5-point Likert		analyses)	Q1, Ref; Q2, OR = 1.21	Q4 of PWCP cognitive
			scale), Q exposure			(95% CI = 0.44, 3.36);	processing on attempt
			(reduction only)			Q3, 1.28 (0.46, 3.50);	in nonadjusted quartile
						Q4, 1.37 (0.50, 3.70)	analyses
Christie and Etter, ²⁶	Pre-post; n = 365	≥ 1 quit attempt lasting	3 wk after online survey 4	χ^2 test	Proportions; no	Pre-post change, quit	Poor, null
Switzerland, France,		≥ 24 h in prior 4 wk	cig boxes (addiction,		adjustments	attempt proportion,	Addiction even decreased
Belgium, 2001		(yes-no)	passive smoking, health			27% vs 22%, P> .05;	attempt proportion sig.
			risks, smell) were sent to			pre-post difference	after exposure
			smokers who used them			across boxes: passive	
			\sim 21 d; evaluation 1			smoking, -1%; health	
			mo after getting the			risk, -7%; bad breath,	
			boxes			+2%; addiction, -15%*	
Hammond et al., ²⁷	Prospective cohort;	Cessation-related	Avoidance (no vs	Logistic regression	OR; adjusted for daily	Avoidance: AOR = 0.86	Poor, mixed
southwest Ontario, CAN,	n = 432 followed	behavior (including	covering, hiding,		cigarettes, smoking	(95% Cl = 0.56, 1.32)	Pooled outcome
2001-2002 ^c		attempt lasting ≥ 24 h	avoiding PWCP) and		years, intention to quit,	Emotional reactions:	
		in past 3 mo)	emotional reaction		prior quit attempts,	AOR = 1.37 (95%	
			(Likert scale) for extent		gender, age, education	Cl = 1.15, 1.64)	
			of fear and disgust at				
			BL; assessment 9 mo				
			after full PWCP				
			implementation				
Environics Research	Repeated survey;	Times stopped smoking	Implementation of PWCP	None	Proportion; no	2000 (before PWCP),	Fair, uncertain-report
Group Ltd., ²⁸ CAN,	n = 1002 smokers	≥ 24h in past y	in January 2001; all		adjustments	60%; 2001 (1 y after),	
2000-2004			brands in June 2001			60%; 2002, 67%; 2003,	
						67%; 2004, 65%	

	1-2 2371/6525	since prior wave since	in relation to pwcp; salience. 2 items	LUGISUU TEGIESSIUI	uk; adjusted tor age, øender income, country.	Point estimates in 4 waves:	Fair, mixed Only CAN and ALIS had
0001 1001 (
	(attempt/total), wk z-3	previous wave out of the	(noticea, read, or		equcation, daliy cig,	salience-waves 1-2,	PWCP
	2138/5257, wk 3-4	total	looked past month);		baseline quit intention	1.02; waves 2-3, 0.96;	
	1823/4439, wk 4-5		cognitive response, 3			waves 3-4, 0.97; waves	
	1273/3993		items (made think of			4-5, 0.97; cognitive-	
			health risk, more likely			waves 2-3, 1.28;*	
			to quit, think about			waves 3-4, 1.14;*	
			quitting in next 6 mo);			waves 4-5, 1.16;	
			forgoing cigs (ever-			forgoing-waves 1-2,	
			never); avoiding (yes-			1.38;* waves 2-3, 1.23;	
			no); 4 items (covering,			* waves 3-4, 1.42;*	
			keep of sight, using			waves 4-5, 1.30;*	
			case, avoid labels)			avoidance-waves 1-2,	
						1.17*; waves 2-3, 1.09;	
						waves 3-4, 1.03;*	
						waves 4-5, 1.03	
Shanahan and Elliott, ³⁴ R	Repeated survey; n = 822	Tried to give up and have	Implementation of PWCP	χ^2 test	Proportions; no	For ≥ 1 mo: 18% in 2000	Poor, positive
AUS, 2000 and 2008	in 2000, n = 670 in	been successful for ≥ 1	in 2006		adjustments	vs 24% in 2008 (sig)	Cross-sectional surveys
	2008; smokers	mo or <1 mo in past y				For <1 mo: 21% in 2000	compared
						vs 26% in 2008 (sig)	
Malouff et al., ³⁹ AUS, no R	RCT; n = 48 followed	Stage change toward	27 exposed to text-only vs	Two-way ANOVA	Mean stage-of-change	Stage change (including	Poor, mixed
period reported		cessation (includes	29 exposed to text +		score difference;	action-to- quit stage):	Unclear whether attempt
		"action to quit such as	PW; on computer screen		adjusted for	postexposure, 2.59	was included in "action
		stopping or decreasing	once per week for 4 wk;		preexposure	(text) vs 3.04 (PW),	to quit"
		use")	stage toward cessation			P = .04; follow-up, 2.67	
			at baseline, end of trial			(text) vs 2.92 (PW),	
			(post exposure), 1 mo			P > .05	
			after (follow-up)				

 GEE (population-averaged Proportion, OR; adjusted marginal effects of for gender, age, marginal effects of for gender, age, marginal effects of marital and immigration status, job, residence, smoking bans, price, a nicotine dependence nicotine dependence for age, income, civil status, education, gender, quit intention, smoking intensity, PWCP or media exposure 	TABLE 4–Continued	P						
Retrospective-like cohort; Attempt to quit in Exposure (recall of having Logistic regression Proportion, OR; adjusted O n = 1765 previous year, but after seen): PWCP (introduced for age, income, civil PWCP was implemented September 25, 2010), media (only October status, education, Retrospective-like NCP was implemented September 25, 2010), status, education, Retrospective-like Contober status, education, gender, quit intention, Retrospective-like 2010), PWCP + media status, education, gender, quit intention, Retrospective-like 2010, PWCP + media contexter status, education, Retrospective-like Retrospective-like or media exposure Rotob	Azagba and Sharaf, ¹² CAN,1998-2008	Cohort panel; n = 1459 (6269 person-yaars)	Smokers tried to quit in past 6 mo (yes-no)	3 exposure definitions: positive to PWCP (started January 2001) if (1) \geq July 2001, (2) \geq December 2001, (3) January-December 2001 Scale 0-1 (January-June = 0, July = 0.1, August = 0, July = 0.1, August = 0.3, September = 0.5, October = 0.7, November = 0.9, December = 1.0)	GEE (population-averaged marginal effects of PCMC)	Proportion, OR, adjusted for gender, age, education, income, marital and immigration status, job, residence, smoking bans, price, nicotine dependence	Attempt: 1998, 30.1%; 2000, 34.6%; 2002, 40.2%; 2004, 33.1%; 2006, 34.6%; 2008, 29.6% All, ≥ July 2001, 0R = 1.32 (95% Cl 1.18, 1.49); January- December 2001, 0R = 1.33 (95% Cl 1.17, 1.49) Daily smokers: ≥ December 2001, 0R = 1.33 (95% Cl 1.17, 1.50); January- December 2001, 0R = 1.33 (95% Cl 1.17,	Fair, positive Population average effect rather than individual
November 30, 2012)	Thrasher et al., ⁴⁴ Mexico 2010-2012		Attempt to quit in previous year, but after PWCP was implemented	Exposure (recall of having seen): PWCP (introduced September 25, 2010), media (only October 2010), PWCP + media (none); warnings were shown to assess recall (data collected from October 17, 2010- November 30, 2012)	Logistic regression	Proportion, OR, adjusted for age, income, civil status, education, gender, quit intention, smoking intensity, PWCP or media exposure	 1.50) OR (95% Cl; % attempt during study period): no recall of exposure. Ref (6%); PWCP, 4.23 (2.05, 8.69; 17%); media. 1.85 (0.81, 4.21; 9%), PWCP and media, 1.63 (0.75, 3.54; 9%) 	Poor, positive No effect of media, or PWCP and media; variable duration of exposure, based on cross-sectional data

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weeks resulted in no increase in quit attempt proportions after 1 month, regardless of the warning message involved.²⁶ The 4 studies with fair quality looking at attempt to quit showed positive, mixed, null, or uncertain results, respectively (Table 4).

DISCUSSION

The results of this systematic review showed that evidence concerning the effect of PWCP on smoking behavior is inconclusive, in contrast with previous reviews reporting a significant impact on smokers' intention to quit.^{7,10,46,47} These results are in line with the notion that turning the intention to quit smoking into actual and sustained behavioral change is an outcome more difficult to attain and demonstrate with formal tests of effectiveness in evaluation research.

In fact, during this review we also identified articles looking at intention to quit and found nearly 20 studies approaching this issue in different ways,^{7,10,25,26,28,30,31,33-} ^{35,37,39,41,43,46-49} 11 of which reported positive findings.^{7,10,25,26,} ^{34,35,40,41,43,46,47} The fact that two thirds of the studies dealing with behavioral outcomes were published within the past 5 years indicates the growing interest in examining the effects of PWCP on smokers.

Among the few countries that conducted studies on behavioral outcomes, Canada provided the largest number of studies. This country not only pioneered using PWCP in 2001, but it was also the only 1 fully complying with International Tobacco Control standards.⁵ Canada has been collecting data systematically to assess the short- and long-term trends in smoking rates, resulting in one third of the selected articles included in this review.^{25,27–29,32,33,42}

Australia has also produced relevant results on the topic.^{37,39} Limited evidence from developing countries came from studies conducted in Mexico,^{40,44} Thailand,^{31,45} Malaysia,³⁵ and Iran.³⁶

The methodological heterogeneity of the studies was so large that two articles could seldom be compared with one another. This heterogeneity concerned first and foremost the definition of the outcomes. For example, reduction was defined in terms of cigarette consumption (daily, weekly, past 24 hours, past week), as forgoing cigarettes (yes or no; never, once, few times, many times) in various time periods (past month, 6 months, 12 months), or by using different categorical definitions (smoking more, same, or less; smoking less around others as dichotomous variable). The variability in terms of exposure measurement, study design and population, and statistical analysis and adjustments was also very large.

Being a smoker was an eligibility criterion. However, 1 study overtly combined ex-smokers,³¹ and another seemed to include ex-smokers in the analysis.⁴⁰ This finding was particularly difficult to interpret because the study outcomes could only occur among a smoking population.

Study quality was generally low. For instance, in 3 articles relevant to cessation no definition was given^{26,37} or it was unclear.³¹ Some studies also did not provide an association measure.^{26,28,31,43} Thus, the results should be contextualized with the poor methodological quality of the studies, adding to the limitations in their interpretation.

Some studies assessed PWCP exposure using intermediary indicators. For instance, authors used the understanding of PWCP (i.e., cognitive process- $(ing)^{25,32,37,40}$ or the emotional reaction (i.e., fear, disgust) and avoidance behavior²⁷ as measures of exposure. Although 2 of these studies were of fair methodological quality, the lack of an actual comparison with a nonexposed group and the fact that they mainly assessed the short-term effect of PWCP makes questionable the value of the findings observed, which were null in these studies for the cessation outcome.

In 4 studies, it was not possible to disentangle the effects of PWCP on specific behavioral indicators because the outcomes were combined.^{25,27,39,43} For instance, 2 studies used scales to measure the stage of change toward smoking cessation,^{39,43} including the precontemplation, contemplation, action, and maintenance phases, rather than using the behavioral outcomes separately. These were included in the action phase, making it impossible to discriminate the effect on the specific outcomes under study. Similarly, 2 other studies pooled attempt, reduction, and cessation into 1 outcome, precluding separate analyses.^{25,27}

Some studies looked at the combined effect of PWCP along with another intervention. Although these studies aimed to examine the effect of this other intervention rather than the sole effect of PWCP, we decided to include them because they compared a combined PWCP with a PWCP-only intervention. For instance, 2 studies tested the notion that an intervention to protect the person's image of integrity, morality, and adequacy (i.e., selfaffirmation) along with the exposure to PWCP would enhance the warning's impact on behavior (i.e., more favorable message

response).^{30,41} Yet, the results of these fairly well-conducted studies showed similar effects of PWCP on reduction and attempt to quit smoking regardless of the selfaffirmation intervention.

Another study examined the combined effects of recalling PWCP and a media campaign (TV or radio),⁴⁴ showing positive effects on smoking reduction—though similar to a media campaign alone or combined with PWCP—and attempt to quit; we classified this study as being of poor quality.

Tobacco industry representatives have expressed doubts concerning the added value of pictorial warnings to inform consumers about the risks of smoking and their effect on behavior.¹⁹ The argument is that text-only warnings might have a similar effect without having to "harass" smokers. In this regard, we identified various studies comparing text only and PWCP, using different approaches. Results differed depending on the outcome assessed.

Three studies indirectly assessed the difference between warnings for cessation: a Mexican pre-post study found a positive effect of PWCP over text as reason for quitting,40 an Australian RCT using computer-based messages only allowed a comparison of the proportions of those quitting smoking with no significant differences after 1 month followup,³⁹ and a study from Thailand showed similar effects before (text only) and after the implementation of PWCP.³¹ We classified all 3 studies as being of poor or very poor quality.

For reduction, data that compared Canada, Australia, the United Kingdom, and the United States showed higher forgoing of cigarettes with PWCP,³³ which

also had a lesser wear-out effect. Similar results were seen for a study comparing Thailand (PWCP) with Malaysia (text only).⁴⁵ Conversely, 2 studies showed no differences in cigarettes smoked before (text only) and after implementation of PWCP.^{34,36} Mixed results were also reported for attempt with a Mexican pre– post study showing no effect,⁴⁴ contrasting with Australian surveys showing a higher proportion after PWCP implementation.³⁴

Although studies looking at plain tobacco packs have suggested that removing the branding from the pack can reduce the demand for smoking, 50-52 so far the evidence concerning behavior change has been very limited. In this review, we identified only 1 study comparing the effect of PWCP printed on a plain cigarette package with that of standard branded packages, with PWCP leading to significant forgoing of cigarettes; however, the study was relatively small, and individuals could receive more than £40 for their participation over 4 weeks, leading to potential bias.³⁸

Nearly all studies examined the combined effect of different pictorial warnings, but 2 tried to discriminate between those producing higher and lower impact on behavior.^{26,40} The Mexican study found no effect on attempt across the 6 PWCP examined,⁴⁰ but the Swiss study found that cigarette boxes depicting passive smoking, bad breath, and health risks were related to reduced smoking, as those showing addiction messages were with attempt to quit smoking.²⁶

That warning messages need to rotate and be updated periodically as the effect of the messages wears away with time has been discussed.⁵ In this review, we identified only 1 study assessing the wear-out effect (about 3 years after implementation) on behavior.³³ This study showed a higher impact on forgoing cigarettes for the PWCP implemented in Canada than for the larger text warnings introduced in the United Kingdom, after controlling for differences in implementation times.

Not all studies used actual cigarette packages displaying the pictorial warnings; some used alternative means such as computer screenshots presented in a laboratory setting⁴¹ or sent through e-mail^{39,43} and photographs already used^{40,44} or for possible use on cigarette packs.44 Although these types of warnings differed from the real branded cigarette packs with pictorial warnings printed on their surface, we believe that these substitutes mimicked well the logic of the PWCP. In most cases, the reason for not using the actual PWCP was logistical because it was difficult to contact individuals periodically to deliver the exposure.

Effect on Smoking Rates

The evidence concerning the impact of PWCP on smoking rates at the population level was beyond the scope of this review. However, for the sake of completeness, we include a perusal of 8 studies included in this review and presenting results on this issue. Three studies presented similar data from Canada, 28,42,53 1 was a report from Australia comparing the prevalence of current smokers before and after the implementation of PWCP,34 and 2 were simulation studies of tobacco control policies, including PWCP, to forecast effects on smoking prevalence up to 2040.54,55 The simulation exercises were conducted in Finland and the Netherlands, 2 countries that to date have not implemented PWCP. The remaining 2 studies compared surveys

from 2^{45} or 3^{56} countries with and without PWCP implementation in different years. However, only the Canadian and to some extent the Australian data were useful in assessing population trends in smoking prevalence. The decreasing trends observed in Canada (from 26.8% in 2000, 1 year before PWCP, to 21.4% in 2008) and in Australia (from 20%) in 2000, 6 years before PWCP, to 17% in 2008) could be attributed to the implementation of various policies, such as regulations concerning advertising and packaging, higher taxes, and bans on smoking in public places, besides PWCP.

Delayed Smoking Initiation

A possible added value of PWCP has been purported with regard to preventing or delaying smoking initiation among adolescents and young adults. In our broad literature search, we did not find any publication specifically looking at this issue. However, 2 experimental studies with adolescents reported decreased intention to smoke after exposure to PWCP compared with no warning⁵⁷ or text warning.58 However, an undergraduate thesis reported that the way in which the pictorial warnings messages are framed (i.e., gain vs loss) had no effect on the intention to smoke among high school students.48

Conclusions

Until now, studies assessing the effect of PWCP on cessation, reduction, and attempt to quit smoking have been very limited in amount and quality and therefore have provided no clear evidence regarding the question of effectiveness of pictorial warning on smoking behavior. Of the 21 articles that were included in this review, very few would have been selected had we used more strict criteria such as are used in systematic reviews assessing the effect of an intervention.²¹

Irrespective of study quality, the reported findings were generally null or conflicting for any explored outcome. In fact, the proportions of studies showing null results for cessation, reduction, and attempt to quit smoking were 44.4%, 26.6%, and 27.2%, respectively. The corresponding proportions of positive results were 11.1%, 53.3%, and 27.2%, respectively; the remaining studies presented mixed or uncertain results.

Although the evidence for or against the use of these warnings is insufficient, evidence so far suggests that if PWCP have an effect on behavior, it would be modest compared with other tobacco control policies. It should be borne in mind that tobacco control efforts do not usually rely on a single intervention but on a comprehensive strategy of which PWCP would be just a part. Determining the single impact of PWCP on behavior would require studies based on strong methodological designs, preferably with longer follow-up periods.

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Contributors

All authors participated in the study design and in the interpretation and

discussion of the results. J. Monárrez-Espino, B. Liu, and F. Greiner conducted the literature search and extracted data for the analyses. J. Monárrez-Espino and B. Liu assessed the methodological quality of and classified the selected studies. J. Monárrez-Espino wrote the first draft of the article, and B. Liu, F. Greiner, S. Bremberg, and R. Galanti provided critical comments on the final version.

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Human Participant Protection

No protocol approval was necessary because data were obtained from secondary sources.

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