

**SYSTEMATIC REVIEW OF THE EFFECTIVENESS OF AN INCREASE  
IN THE SIZE OF TOBACCO HEALTH WARNING LABELS ON  
CIGARETTE PACKS IN REDUCING SMOKING**

**FINAL REPORT**



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## **DECLARATION OF INTEREST**

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# Systematic Review of the evidence on the size of tobacco health warning labels on cigarette packs

## EXECUTIVE SUMMARY

The Framework Convention on Tobacco Control recommends that cigarette health warning labels (HWL) “should be 50% or more of the principal display areas but shall be no less than 30% of the principal display areas” (see Article 11.1(b)(iv)). The European Community requires HWLs of a minimum 30% of the “most visible surface” and 40% of the “other most visible surface”; larger sizes are mandated for countries with multiple official languages. The European Commission, Directorate General for Health and Consumers is considering increasing the size of the mandatory HWL. Against this backdrop the objective of this report is:

To conduct a systematic review to evaluate the effectiveness of an increase in tobacco package HWLs from 30% to at least 50% coverage (of the principal display areas) in reducing smoking prevalence and uptake, and increasing quit rates.

### Systematic review

Data sources: Medline and EMBASE were searched from beginning until present. Several other databases were also searched, as well as various web-sites and grey literature and hand searching was employed.

Study eligibility criteria for participants: Populations from a country with a policy of HWLs of at least 30% coverage of pack size were included.

Interventions: The interventions compared were HWL of at least 50% coverage versus between 30% and less than 50% of coverage.

Study appraisal and synthesis methods: An observational study design check list was used in quality assessment and, due to the heterogeneity of study design, synthesis was by narrative methods only.

Results: 1944 titles were screened and, from titles/abstracts, full papers were sought for 49. Of these, only two were found to fulfil all inclusion criteria. Two more involved a comparator of 29% HWL coverage and are also included. In other words, only four studies examined whether increasing HWL size actually resulted in reducing smoking prevalence or uptake or increasing quit rates. The first study, from Thailand, used a prospective cohort design and reported quit rates of 23.5% (HWL coverage of 33%) versus 21.8% (new HWL coverage of 50%). The second, using Canadian survey data, used a repeated cross-sectional design and reported a smoking prevalence of 25% (HWL coverage of 35%) versus 23.4% (HWL coverage of 50%). Further regression analysis found that the effect of HWL was not statistically significant. The third, using Australian survey data, employed an unusual study design where a cohort of participants was replenished over time to maintain sample size. They reported a quit rate of 25.90% (HWL coverage of 60%) after a year of policy change from 25.15% quit rate (HWL coverage of 29%). The final study was also based in Australia and used a repeat cross-sectional design. Over an eight year period (2000 – 2008) they reported a statistically significant decline in smoking prevalence from 20% (HWL coverage of 29%) to 17% (HWL coverage of 60%). Over the same time period the authors also

identified a statistically significant increase in the number of smokers making successful quit attempts of at least one month – from 18% (HWL coverage of 29%) to 24% (HWL coverage of 60%). There were problems with reporting for all four studies and only the Canadian study attempted to control for confounding factors, such as price.

Conclusions: There is a lack of good quality evidence on the effectiveness of increasing HWL size from 30% (or larger) to at least 50% on smoking uptake, prevalence and quitting. Three of the four studies found that larger HWLs make no difference to smoking uptake, prevalence or quitting. The fourth study did identify statistically significant reductions in smoking prevalence and increased quit attempts, however, six years elapsed from the time of the first survey in 2000 until the HWL size increase in 2006 and the study did not control for confounding factors, in particular price increases.

### **Implications of key findings**

Insufficient evidence exists to support a hypothesis that HWL size of 50% or greater are effective at reducing smoking uptake, prevalence or increasing quit rates. Current studies are of mixed quality and do not provide convincing evidence that HWLs of at least 50% reduce smoking prevalence or uptake or increase quitting more than HWLs of 30% do. Future research should ideally use an experimental study design, measure behavioural outcomes like quitting, and, if observational, employ statistical methods to control for confounding factors such as price changes.

## 1.0 BACKGROUND

The Framework Convention on Tobacco Control recommends that cigarette HWLs “should be 50% or more of the principal display areas but shall be no less than 30% of the principal display areas” (see Article 11.1(b)(iv)). In the European Union, the Tobacco Products Directive requires that “The general warning required pursuant to paragraph 2(a) ... shall cover not less than 30% of the external area of the corresponding surface of the unit packet of tobacco on which it is printed. That proportion shall be increased to 32% for Member States with two official languages and 35% for Member States with three official languages. The additional warning required pursuant to paragraph 2(b) shall cover not less than 40% of the external area of the corresponding surface of the unit packet of tobacco on which it is printed. That proportion shall be increased to 45% for Member States with two official languages and 50% for Member States with three official languages” (see Article 5 of Directive 2001/37/EC of 5 June 2001).

The European Commission Directorate-General for Health and Consumers commissioned research to review HWLs used on tobacco packages and recommend a set of future warnings. Sambrook Research International carried out this research and published a report entitled ‘A review of the science base to support the development of health warnings for tobacco packages’<sup>1</sup>. The report reviewed evidence on all health and tobacco package labelling as well as the health effects of tobacco and issued recommendations regarding labelling.

We conducted a critical appraisal of the Sambrook research concerning the size of tobacco package labelling. The appraisal revealed that the research, which was not described as a ‘systematic review’, but as a ‘systematic literature search’, was not well reported. Four studies were included in relation to HWL size (Createc 2008a; Createc 2008b; Environics Research 2008a; Environics Research Group 2008b)<sup>2-5</sup>. However, details about searches and other methods were missing; neither the method of data extraction nor the actual items extracted were reported. The results in relation to effectiveness were reported for only one study, which were in terms of opinion as to what survey respondents viewed as the “best option for warnings” (p. 43) rather than any measure of actual quitting or prevalence.

We therefore prepared a full systematic review to examine the effectiveness of tobacco HWL size at reducing smoking uptake and prevalence or increasing smoking cessation.

## 2.0 SYSTEMATIC REVIEW METHODOLOGY

### 2.1 Objective

Our objective was to evaluate whether increasing tobacco packaging HWL size from at least 30% to at least 50% is effective at reducing smoking prevalence and uptake, and increasing quit rates:

#### **Research question:**

Does increasing the size of tobacco packet health warning labels from at least 30% to at least 50% of the principal display areas reduce smoking uptake or prevalence or increase smoking cessation?

To answer this question and inform our evaluation, we have summarized the evidence presented in the studies that met the inclusion criteria, evaluated the methodological rigour of the included studies, and summarised the implications for future research.

## 2.2 Inclusion criteria

Inclusion criteria for considering studies for this review:

**Types of studies:** studies of any design that measure the effects of tobacco packet label size on smoking prevalence rates, uptake of smoking, or quit rates.

**Types of participants:** from countries that have tobacco pack health warnings of at least 30% of pack size (front and back of pack combined).

**Types of interventions:** tobacco packet warning labels of at least 50% of pack size (text and graphics, front and back of pack combined).

**Types of comparators:** tobacco packet warning labels at least 30% but less than 50% of packet size (text and graphics, front and back of pack combined).

**Types of outcome measures:** smoking prevalence rates, uptake of smoking, and cessation rates.

Papers were excluded from this systematic review if they:

1. Did not compare smaller HWLs (at least 30%<sup>a</sup>, but not more than 50%) to larger HWLs (at least 50% or more);
2. Reported affective or cognitive measures only (e.g. participants were asked to report on their feelings, beliefs, opinions or attitudes in response to various HWL options); and/or
3. Did not report primary research.

This systematic review followed the Centre for Reviews and Dissemination (2009) “Guidance for undertaking systematic reviews in health care” and the Cochrane Collaboration Handbook.<sup>6,7</sup>

## 2.3 Literature searches

The following databases were searched for relevant studies from inception to the present:

- MEDLINE (OvidSP)
- MEDLINE In-Process Citations (OvidSP)
- EMBASE (OvidSP)
- Cochrane Database of Systematic Reviews (CDSR) (Wiley)
- Cochrane Central Register of Controlled Trials (CENTRAL) (Wiley)
- Database of Abstracts of Reviews of Effects (DARE) (CRD website)
- NHS Economic Evaluation Database (NHS EED) (CRD website)
- Health Technology Assessment Database (HTA) (CRD website)
- PsycInfo (OvidSP)
- Social Science Citation Index (SSCI) (Web of Science)
- Science Citation Index (SCI) (Web of Science)
- Conference Proceeding Citation Index – Science (CPCI-S) (Web of Science)
- Biosis Citation Index (BCI) (Web of Science)

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<sup>a</sup> As only two studies were found to meet the minimum 30% HWL coverage inclusion criteria, two additional studies that involved a comparator of 29% were ultimately included as well.

- Sociological Abstracts (CSA Illumina)
- Health Management Information Consortium (HMIC) (OvidSP)
- OpenSIGLE (internet)

References in retrieved articles and relevant systematic reviews were checked. In addition, internet searches to identify grey literature<sup>b</sup> and statistics were undertaken on a range of resources, such as:

- Smoke-Free Canada: <http://www.smoke-free.ca/warnings/canada-warnings.htm>
- WHO Tobacco Free Initiative: <http://www.who.int/tobacco/en/>
- Tobacco Labelling Resource: <http://www.tobaccolabels.ca/>
- Campaign for Tobacco-Free Kids: <http://tobaccofreecenter.org>
- Tobacco Documents Online: <http://tobaccodocuments.org/about.php>

Identified references were downloaded in Endnote X4 software for further assessment and handling. We attempted to identify all relevant studies regardless of language or publication status (published, unpublished, in press, and in progress). The search strategies (keywords) were developed specifically for each database and detailed search strategies for each database are listed in Appendix 1.

## 2.4 Study selection

Two reviewers independently extracted data from the included studies, using a standardised form. Any disagreements were resolved by consensus. Studies were identified by the name of the first author and year in which the study was first published.

## 2.5 Quality assessment

Quality assessment is a standard step in systematic reviews<sup>7</sup> and is used to evaluate the rigour of individual studies. For quantitative research, assessing study quality is primarily concerned with identifying sources of potential bias: systematic errors in the way a study was conducted. This process is key to giving due weight to well conducted rigorous studies and identifying weaknesses and sources of bias in poorly executed research.

Quality assessment was carried out independently by two reviewers. Any disagreements were resolved by consensus. The results of the quality assessment were used for descriptive purposes to provide an evaluation of the overall quality of the included studies and to provide a transparent method of recommendation for design of any future studies.

Each of the included studies was observational and either used a cross-sectional or cohort design or some variation thereof. As such, for each of the four included studies we used the JBI Critical Appraisal Checklist for Descriptive/Case Series Studies as described in Table 7 in Appendix 2. Each study was awarded a '+', '-' or 'unclear/unknown' rating for each individual item in the checklist. Any additional clarifications or comments were also recorded.

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<sup>b</sup> Grey literature is a general term that refers to documents not published in an easily accessible form or listed in standard bibliographic databases. Examples include reports from all levels of government, conference proceedings, theses, internal documents or reports from scientific groups.

## **2.6 Methods of data synthesis**

Meta-analysis was considered unsuitable for the data identified (e.g. due to the heterogeneity of the studies) and therefore a narrative synthesis method was employed. Typically, narrative synthesis involves the use of narrative text and tables to summarise data in order to allow the reader to consider outcomes in the light of differences in study designs and potential sources of bias for each of the studies being reviewed. This involves organizing the studies by (as appropriate) intervention, population, or outcomes assessed, summarising the results of the studies, summarising the range and size of the associations these studies report, and describing the most important characteristics of the included studies. A detailed commentary on the major methodological problems or biases that affected the studies was also included, together with a description of how this has affected the individual study results.

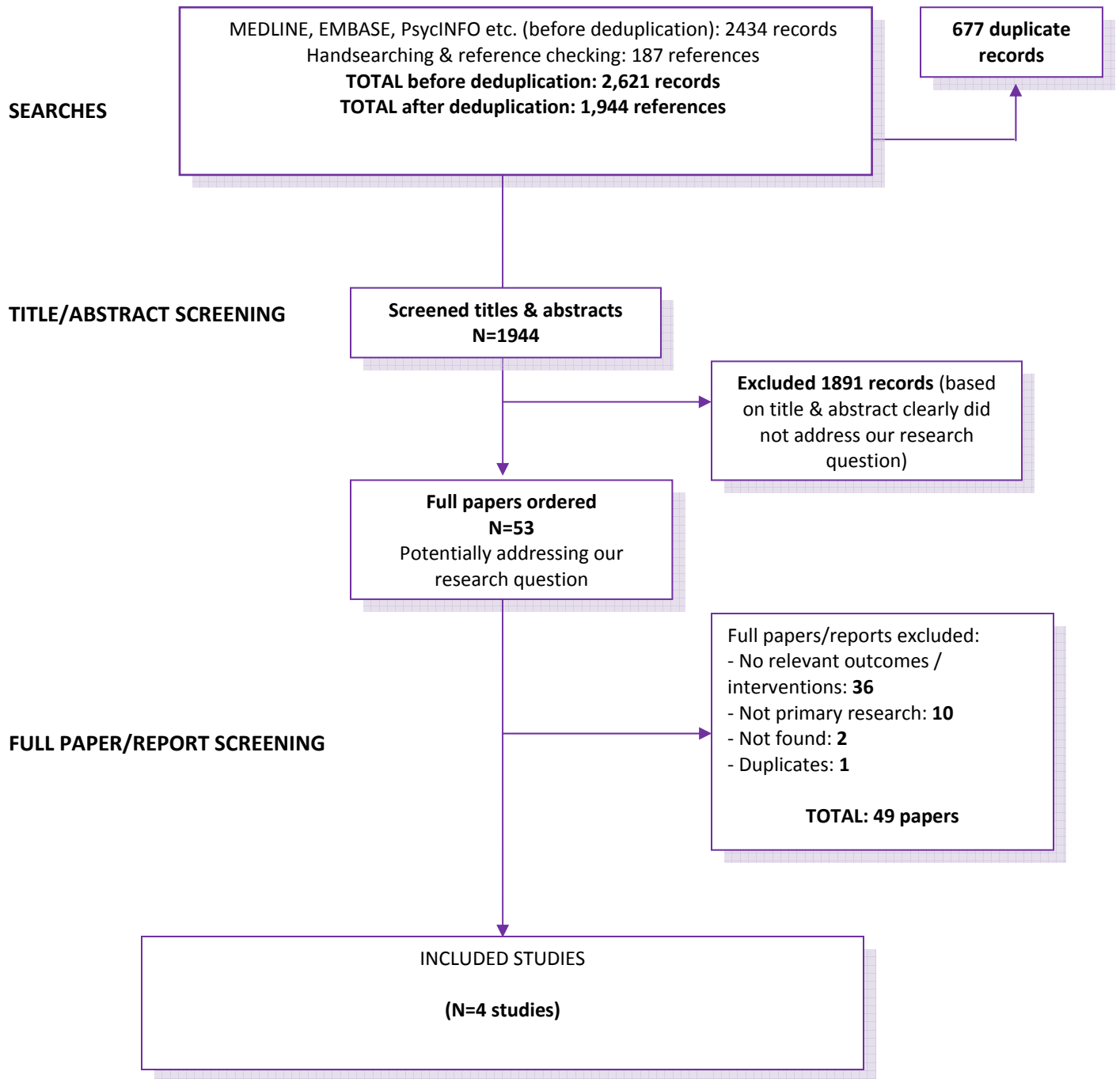
Full details on the methodology, population, comparator, intervention, outcome, results and conclusion for each of the included studies is set out in Appendix 3.

## **3.0 SYSTEMATIC REVIEW RESULTS**

### **3.1 Search results**

In total, 2434 titles were retrieved from the database searches. In addition 187 titles were found through supplementary searches, hand searches and contacts with researchers and organisations who have undertaken work in this area. After de-duplication the remaining 1944 titles and abstracts were screened for relevance. Figure 1 summarises the flow of studies through the search and screening process.

Figure 1: Flow of studies for inclusion in the review



A total of 1891 articles were excluded during the title and abstract screening stage and 53 full papers of potentially relevant studies were selected for further examination. Of these, 49 were ultimately excluded: 46 did not meet the inclusion criteria (36 did not report a relevant outcome and/or a relevant intervention and 10 were not primary research); two papers could not be found and one was a duplicate.

### 3.2 Characteristics of the excluded studies in the analysis of effectiveness

As stated above studies were excluded if they did not report primary research (e.g. editorials or review articles) or, when read against the predefined criteria for including studies – detailed above – they did not involve a relevant intervention or comparator (i.e. comparison of HWL size of minimum 30% and  $\geq 50\%$ ) and/or did not report relevant behavioural<sup>c</sup> outcomes (i.e. smoking prevalence, uptake, and/or cessation). For purposes of illustration, examples of excluded studies are provided below:

1. The BRC Marketing & Social Research study (2004) used “mini-group discussions” (p 4) to explore participants’ perceptions of “mock-up cigarette packets” (p 5) with regard to balance between text and graphics, size and colours of warnings. Hence, this study could not provide the review with relevant outcome measures as it did not measure smoking behaviour (uptake, prevalence or cessation) after exposure to larger tobacco HWLs.
2. Les Etude des Marche Createc (2008a; 2008b): These studies are cited to support the effectiveness of larger HWLs. However, the outcome measures in these studies relate to cognitive or opinion statements. The studies did not measure behavioural outcomes. Furthermore, the HWL sizes included in the research were 50%, 75%, 90% and 100% - the comparator of a HWL size minimum 30% but  $\geq 50\%$ , and a HWL size of at least 50% or greater was not included. For all of these reasons, these studies were excluded from the review.
3. The Environics Research Group (2008a; 2008b): The Environics Research Group’s work is also cited to support the claim that larger HWLs are more effective. Again, this study asked participants to give their opinion on which warning size was seen as the “best option”. Four HWL sizes were used in the research (50%, 75%, 90%, and 100%). These studies were excluded as they did not report behavioural outcomes, nor did they include the requisite comparator.
4. Fong (2009), Hammond et al (2008), Van der Kemp (2007): These papers are reviews and do not report primary research.

Of the 49 excluded articles, 36 did not report a relevant outcome and/or a relevant intervention and 10 were not primary research. Further details of these excluded papers and the reasons for exclusion can be found in Appendix 4. Four studies were included in the final review.

### 3.3 Characteristics of the included studies in the analysis of effectiveness

We found only four studies that measured prevalence and/or quit rates before and after the relevant change in HWL size. Two studies<sup>8, 9</sup> from Australia were included even though the size of the smaller HWL did not meet the 30% threshold – front display 25%, back display 33%, total HWL coverage 29%. A summary of study characteristics is reported in Table 1 below.

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<sup>c</sup>The terms ‘behaviour’ and ‘behavioural’ are used interchangeably to differentiate the behaviour of smokers (e.g. prevalence, uptake and quitting) from attitudes about HWLs, cognitive measures (e.g. intention to quit) and affective measures (e.g. emotional response to HWLs). Reduction in number of cigarettes smoked would also count as behaviour although this was not an outcome of interest in this review.

**Table 1: Main characteristics of included studies regarding gender differences**

	<b>Borland 2009</b>	<b>Gospodinov 2004</b>	<b>Shanahan 2009</b>	<b>Silpasuwan 2008</b>
<b>Comparison</b>	25% of front, 33% of back (29% average)	Warning label 35% (35,35)	25% of front, 33% of back (29% average)	33% (33,33)
<b>Intervention</b>	30% of front, 90% of back (60% average)	Warning label 50% (50,50)	30% of front, 90% of back (60% average)	Warning label 50% (50,50)
<b>Objective</b>	To examine prospectively the impact of health warnings on quitting activity.	This study uses micro data from two waves of Health Canada's Canadian Tobacco Use Monitoring Surveys (2000, 2001) to investigate if the introduction of the warnings had any significant impacts on smokers.	To determine and evaluate the effectiveness of the graphic health warnings on tobacco product packaging on consumers and to evaluate the impact of the content of the health warnings system in achieving its purpose.	Explore and investigate the perceptions and responses of employees regarding the effects of a Health Warning Label (HWL) on their decision to encourage quitting and stages of change in smoking behavior.
<b>Design</b>	Repeated cross-sectional design using a cohort which is topped in order to maintain original numbers.	Repeated cross-sectional	Repeated cross-sectional	Mixed method prospective cohort study.
<b>N</b>	Wave 1-2 (2002-2003): n = 1814 Wave 2-3 (2003-2004): n = 1419 Wave 3-4 (2004-2005): n = 1212 Wave 4-5 (2005-2006): n = 1030 (Australia only, calculated from percentage of 4 country total)	N =20,176	2000 N = 1204 (822 smokers) (nationwide stratified or quota random sample) 2008 N = 1304 (670) (nationwide disproportionate stratified random sample)	N = 609 (participants surveyed twice, before and after HWL changes)
<b>Mean age (range)</b>	Wave 1-2: 42.7, 14.2 Wave 2-3: 44.1, 14.0 Wave 3-4: 44.5, 13.5 Wave 4-5: 45.3, 13.6 only reported as mean of all 4 countries (mean, SD):	Not reported	Not reported	Not reported
<b>Country</b>	Australia	Canada	Australia	Thailand
<b>Follow-up</b>	only reported mean survey interval (days) for all 4 countries: Wave 1-2: 203 Wave 2-3: 388 Wave 3-4: 458 Wave 4-5: 361	2 periods: July-December 2000, February-June 2001. The authors noted that the second period might have been too soon after introduction of the larger labels to detect an effect on prevalence.	2 surveys: 2000 and 2008	10 months
<b>Outcomes</b>	Cessation rates defined as at least 1 month quit	Smoking prevalence for different groups, Probit model for various variables	Cessation rates defined as at least 1 month quit	Cessation rate (not defined)
<b>Quality</b>	-/+/-/-/unclear/unclear/+/-	-/+/+/-/unclear/NA/-/+/-	+/-/-/+/-/NA/NA/+/+	-/+/-/-/NA/+/-/+/-

Quality items: Sample selection / Inclusion criteria / Confounding factors / Objective outcome assessment / Group descriptors / Follow-up / Withdrawals / Reliable measurement / Statistical analysis

### 3.4 Results of the included studies in the analysis of effectiveness

No two studies had the same design, intervention and outcomes. Therefore the results from individual studies cannot be combined. Each study will be discussed separately, followed by a narrative synthesis by outcome.

#### Borland et al 2009

This study used data that had been collected as part of a larger project, the International Tobacco Control Policy Research Survey (ITC) Four Country study<sup>10-17</sup>, which surveyed annual cohorts from 2002, 2003, 2004, 2005 and 2006 from Australia, Canada, UK and US. Borland et al examined prospectively the impact of HWLs on what they describe as 'quitting activity'. The term quitting activity appears to include those who quit for at least one month as well as those who made a quit attempt. While the study reported results for all four countries, only the results for Australia are of interest in this review since Australia was the only country to implement a HWL size increase (from 29% (25, 33) to 60% (30, 90)) that meets our inclusion criteria.

Most of the methodological details of these surveys are provided in other publications including by Thompson et al 2006<sup>18</sup>. The study design appears to be a cohort study where participants are followed-up annually, but the drop-outs were replenished in order to maintain sample size. For each year (referred to as a 'wave') there was no attempt to maintain the characteristics of the original sample, but instead sampling was random. Sample size and percentage remaining/being added each year are presented, but reasons for dropping out are not given, although the Thompson paper does state that those who had quit were retained in the sample. Sample size data and data on baseline characteristics are presented as an aggregate for all four countries and not by individual country, in particular for Australia alone. The results are presented as 'Wave x-y' e.g. Wave 1-2 (2002-2003), Wave 2-3 (2003-2004), which is consistent with the percentage quitting as being those who were smoking in the previous year who had stopped in the next year. Other measures included 'salience' (how often HWLs had been noticed); cognitive reaction (how often the HWLs made subjects think about quitting) and behavioural (forgoing cigarettes or avoiding looking at the HWLs).

Results in terms of quitting for at least one month, for Australia, were:

- Waves 1-2 (2002-2003) 14.99% quit;
- Waves 2-3 (2003-2004) 22.93% quit;
- Waves 3-4 (2004-2005) 25.15% quit; and
- Waves 4-5 (2005-2006) 25.90% quit.<sup>d</sup>

The larger Australian HWLs were introduced in March 2006 so the waves of interest are 3-4 (2004-2005) and 4-5 (2005-2006).

There were some statistically significant relationships between some of the other measures (salience, cognitive reactions, forgoing and avoidance) and quit attempts however, the authors did not report statistical tests of difference in quit rates. The authors conclude that increases in the former (salience,

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<sup>d</sup> These percentages were calculated by the reviewers to yield the one month quit rates. It reflects the proportion of those who quit for at least one month from those who made any quit attempts.

cognitive reactions, forgoing and avoidance) predicted such attempts. However, except for cognitive reactions and only for Wave 3-4, this was not generally reflected for actual quitting. Indeed there was a statistically significant relationship between avoidance and quitting in Wave 3-4, but it was in the opposite direction, as was that between forgoing and quitting in Wave 4-5.

In keeping with the results, the authors stated in the abstract that 'there were no consistent effects on quit success.' They also state: 'we conclude that the stronger the warnings the greater the reactions and thus the greater the quitting activity they evoke' (p. 6). The only evidence to substantiate this claim is a comparison of the percentage who quit, for Australia, between Waves 4 and 5 and other periods and, for the UK (which in 2003 had increased the size of its HWLs from 6% of the front / 6% of the back, to 30% of the front / 40% of the back), between Waves 1 and 2 and other periods. Yet, the increase for Australia was only 0.1%, which was in fact *lower* than between other periods and, for the UK, the percentage who quit in Wave 1-2 was the lowest of all periods. Moreover, the authors themselves acknowledged that in controlling for the effect of country on the predictions of quit attempts or actual quitting that '...no interactions with country were found...' (p. 3); they had tested for the effect of country in order to look for the effect of larger HWLs compared to smaller ones.

### Gospodinov 2004

In 2000 Canada became the first country in the world to make pictorial HWLs on tobacco products compulsory. These new HWLs comprised large-font text warnings in conjunction with gruesome images designed to draw smokers' attention to the health effects of smoking. The warning labels are required to take up 50% of the front and 50% of the back of the pack resulting in 50% of the total packet facing being appropriated to health warnings, compared to the previous 35% of package area. As Canada has two official languages (English and French), one side is in English and the other in French.

Gospodinov and Irvine's 2004 study investigates the impact of these new graphic HWL by looking at prevalence rates and weekly consumption per person before and after the introduction of the new labels. The data used for their analysis were derived from two waves (July-December 2000 and February June 2001) of the Statistics Canada/Health Canada Canadian Tobacco Use Monitoring Survey (CTUMS). The survey provides data on smoking status and intensity as well as a range of other social, economic and demographic variables. The CTUMS is a national telephone survey which uses random digit dialling (RDD) and is designed to provide Health Canada with a continuous supply of data on smoking prevalence rates against which changes in prevalence can be monitored.

Gospodinov and Irvine removed data where answers to key questions were missing, which reduced the sample size by 2.5%, rendering a sample of 20,176, with 15,062 non-smokers and 5,114 daily and occasional smokers. Data for the relevant outcome are displayed below in Table 2.

**Table 2: Average prevalence (%) by group**

	n	Year 2000	n	Year 2001	Difference between years
Whole sample	9729	25.0	10447	23.4	Δ -1.6
Male	4512	25.4	4824	25.0	Δ -0.6
Female	5217	24.7	5623	21.8	Δ -2.9
Language Eng	8024	24.7	8689	24.1	Δ -0.6
Language French	1186	28.3	1195	25.7	Δ -2.6
Eng & French	113	38.1	110	17.5	Δ -20.9
Language other	406	15.8	453	13.3	Δ -2.5
Educ < high school	3207	29.2	3611	27.3	Δ -1.9
Educ high school	4248	28.6	4421	25.9	Δ -2.7
Educ college	1052	25.8	1183	23.2	Δ -2.6
Educ university	1222	12.6	1232	13.6	Δ +1.0
Age 15-17	1613	19.8	1822	19.1	Δ -0.7
Age 18-19	1026	31.2	1053	30.5	Δ -0.7
Age 20-24	2183	32.0	2338	34.0	Δ +2.0
Age 25-34	982	29.0	1086	26.2	Δ -2.8
Age 35-44	1259	32.3	1337	26.0	Δ -6.3
Age 45-54	1008	23.8	1092	24.8	Δ -1.0
Age 55-64	707	18.0	727	17.7	Δ -0.3
Age > 64	951	11.9	992	12.2	Δ +0.3
Low income	1703	33.3	1831	30.0	Δ -3.3
Low-middle income	2257	32.0	2521	27.0	Δ -5.0
Middle income	1254	27.4	1384	20.4	Δ -7.0
Mid-high income	563	22.8	685	22.3	Δ -0.5
High income	453	15.6	607	21.9	Δ +6.3
Inc unrecorded	3517	18.0	3419	20.3	Δ +2.3

These results generally show a small decline in the prevalence rates – the large decline in prevalence for the English and French language group was based on a relatively small number of observations (113 for 2000 and 110 for 2001) and hence its accuracy is questionable. We calculated the 95% confidence interval for this difference as (-0.323, -0.095), which means the decrease could be as small as 9.5% to as large as 32%.

Gospodinov and Irvine also developed a Probit model to test the hypothesis that smoking declined between the two periods as a result of the new health warning labels. The authors stated, "we include a 'year/warnings' dummy variable, taking a value of zero in the first period and a value of one in the second. If smoking prevalence indeed declined we anticipate a negative sign for this variable" (p. 11). The new HWL (warnings dummy), whilst having a negative estimate on the log scale (indicating a

reduction in probability of smoking), was not found to be statistically significant. Table 4 below, replicates the author’s findings. The results show that there was no significant effect for the new larger HWLs on decreasing the probability of smoking, but the effect of price was statistically significant.

**Table 3: Probit estimator results**

	Mean Effect	Standard Error	95% CI
Warnings dummy	-0.0034	0.013	-0.029 to 0.021
Price	-0.0037	0.001	-0.006 to -0.002

### Shanahan 2009

Elliott and Shanahan Research prepared this report for the Australian Government Department of Health and Ageing. The research aimed to examine smoker and non-smoker reactions to the new graphic health warning labels applied to tobacco products sold in Australia during 2006 (30% front, 90% back). This research employed a similar methodological approach to a previous study, conducted by the same company in 2000 which evaluated smaller text-based HWLs.<sup>19</sup> As such, wherever possible the report makes comparisons between the 2000 and 2008 survey data.

The research was conducted using mixed methods: a quantitative nationwide telephone survey of 1304 adult participants, 17 full qualitative group discussions and seven mini group discussions, and 28 semi-structured interviews with stakeholders/experts. The sampling technique for the survey used random digit dialling and was representative in that it contained “the specific groups whose attitudes and behaviours were of interest” (p. 36). The resulting sample is described as a “disproportionate stratified random” (p. 36) and the authors say they weighted the results back to the population to provide views representative of the broader Australian population.

Many of the findings relate to participants’ attitudinal response to the new graphic HWLs. These are self-report measures and cover aspects such as noticeability, importance, believability, and understanding of HWLs. Nonetheless, there is a behavioural dimension to the findings with measures of smoking prevalence, frequency, type of tobacco smoked, and cessation. Table 4 and Table 5 below detail the relevant findings.

The authors conclude that the new Australian graphic health warning labels were effective on a number of fronts, including, raising concerns about smoking, helping smokers smoke less whilst increasing the intention to quit as well as actual quitting. They also note the avoidance behaviours of smokers and the disconcerting feelings the HWLs raise about smoking.

**Table 4 Smoking prevalence**

Smoking status	Total	
	2000 %	2008 %
I've never smoked	57	58
I use to smoke, but haven't smoked for years	19	19
I use to smoke, but haven't smoked for at least 12 months	2	3
I used to smoke, but gave it up in the last 12 months	3	3
I currently smoke	20*	17
<b>Total</b>	<b>1204</b>	<b>1304</b>

Reproduced from Shanahan 2009 p. 53.

\* This denotes a significant difference at the 95% confidence level across the two studies (i.e. the 2000 and 2008 surveys)

**Table 5 Recent attempts to quit**

Attempts to Quit	Smokers					
	Total		Male		Female	
	2000 %	2008 %	2000 %	2008 %	2000 %	2008 %
Tried to give up and been successful for at least 1 month	18	24*	17	24*	19	25*
Tried to give up and successful for less than one month	21	26*	22	25	20	28*
Never tried to give up	61*	50	61*	51	61*	47
<b>Total</b>	<b>822</b>	<b>670</b>	<b>378</b>	<b>366</b>	<b>444</b>	<b>304</b>

Reproduced from Shanahan 2009 p. 123.

\* This denotes a significant difference at the 95% confidence level across the two studies (i.e. the 2000 and 2008 surveys)

### Silpasuwan 2008

Silpasuwan et al set out to: "Explore and investigate the perceptions and responses of employees regarding the effects of a Health Warning Label (HWL) on their decision to encourage quitting and stages of change in smoking behaviour" (p. 551 ). Part of their study was qualitative and part quantitative including the measurement of rates of cessation before and after the introduction of a policy to replace text only HWLs with pictorial ones in 2005. There were conflicting reports about the exact size of the HWLs being investigated. The paper states: "The new health warning labels are six pictures displayed using a graphical design that covers 30% of the cigarette pack..." (p. 552). In contrast, other sources state that the new HWLs "are required to cover 50% of the front and 50% of the back of all cigarette packages" (<http://www.tobaccolabels.ca/healthwarningimages/country/thailand> and <http://www.tobaccolabels.ca/legislat/thailand>). The lead author was contacted about the size of the old HWLs and stated that they were "20% or less". This conflicts with a WHO report which states that since

1997 tobacco products in Thailand have been required to carry HWLs occupying “no less than one-third of the principal surfaces of the cigarette packages or cartons.”<sup>20</sup> (p. 6). We decided to include this paper as these external sources<sup>21</sup> indicated that during the timeframe of the study (two surveys: March 2005, January – February 2006) Thailand was moving from tobacco HWLs of 30% to 50% size.

The sampling was not reported to be random, but ‘systematic’ in order to be proportionate to region population size. The final sample size was reported to be 609, but more than half (691) were reported to have dropped out, mostly due to loss to follow-up. Moreover, in Table 2 (p. 554) a further 154 were reported as ‘missing’ with no explanation. They also did not report any participant characteristics, including whether the sample was mixed or single sex.

The results appeared to show the intervention to be effective, but they were reported unclearly in that in the abstract they stated that “3.8% stopped smoking after seeing the New-HWL” (p. 551), but elsewhere they stated “Of the employees who quit cigarette smoking after seeing the HWL, 2.3% of them quit in response to the Ex-HWL and 2.8% after seeing the New-HWL” (p. 554). If one assumes that the ‘3.8’ is a misprint of ‘2.8’ then one could infer that slightly more quit after the intervention. However, Table 2 appears to show that the percentage categorized as ‘quit smoking (within 1 month)’ decreased from 23.5% before the new HWL to 21.8% after the new HWL. Indeed this is acknowledged by the authors in the discussion: “It is possible that the quit smoking group decreased from 23.5% to be 21.8% because ‘cons’ of cigarette quitting is still high although ‘pros’ of cigarette use is also reduced...” (p. 556).

### **3.5 Quality assessment of included studies**

To a greater or lesser extent each of the included studies had problems with their methodological quality which exposes the studies to bias and jeopardises the rigour of the results. Overall, the methodological quality of the included studies was mixed. Detailed comments are included in Table 6 below.

One factor which is common to all studies is the use of self-reporting for prevalence and quitting data. A recent study<sup>22</sup> has reported that when compared to biochemical assessment, self-report prevalence surveys can underestimate tobacco smoking by as much as 4.4%. While it is important to note the general lack of biochemical assessment, it is striking that it is rarely discussed as an option for objectively measuring smoking behaviour. Of course, the effect of any reporting/recall bias on change in quit rates or prevalence might not be great if the bias operates both before and after HWL change, but when relying upon self-report outcomes we have no way of knowing the direction or size of the bias.

**Table 6: Critical appraisal checklist**

Domain	Decision	Comments
<b>Borland et al 2009</b>		
Sample selection	-	Subjects were randomly selected in 'Wave 1' in 2002. However, there were also an unreported number of drop-outs and new recruits between Waves 1-2 (2002-2003), 2-3 (2003-2004), 3-4 (2004-2005) and 4-5 (2005-2006).
Inclusion criteria	+	
Confounding factors	-	There was statistical analysis to adjust for confounding, but the effect of the HWL using country as a proxy was only treated as a confounder and no results for its effect were reported.
Objective outcome assessment	-	Self report only (rather than biochemically assessed).
Group descriptors	-	See Sample selection.
Follow-up	<b>unclear</b>	Follow-up varied between individuals and between intervention and control and length was not reported.
Withdrawals	<b>unclear</b>	Many dropouts but these are not reported, nor the reasons for withdrawal.
Reliable measurement	+	
Statistical analysis	-	Adjustments to make the sample representative of the population were reported to have been made, but no details were provided. Adjustment for confounding was reported to have been made, but the estimate of the adjusted effect was not reported.
<b>Gospodinov and Irvine 2004</b>		
Sample selection	-	Random sample generated with random digit dialling, however, 'This survey is particularly appropriate for our objective, since it over-samples heavily in the lower age groups. Typically, about 25% of each six-month survey wave of 10,000 individuals is for those aged 15-19 and an equal proportion for those aged 20-24.' (p. 6)
Inclusion criteria	+	
Confounding factors	+	Confounding factors that are noted include: increased tax on tobacco Spring 2001 (analysed in the results); secular decline in smoking from the 1980s (estimated at 3% p.a.) and seasonal variation (higher in summer/vacation months and decrease with workplace bans). Regression analysis used to control for price, age, gender and socioeconomic status.
Objective outcome assessment	-	Self report (rather than biochemically assessed).
Group descriptors	<b>unclear</b>	Surveys were conducted at two points in time, but it is not clear the extent to which subjects were repeatedly measured (single cohort) versus only measured once (repeated cross-sectional).
Follow-up	-	2 periods: July-December 2000, February-June 2001. The authors noted that the second period might have been too soon after introduction of the larger labels to detect an effect on prevalence.
Withdrawals	-	Not reported in this paper.
Reliable measurement	+	Not reported in this paper but detailed in CTUMS methodology.
Statistical analysis	<b>unclear</b>	Between measures correlation not mentioned, but the extent of repeated measurement was also not reported.
<b>Shanahan and Elliott 2009</b>		
Sample selection	+	The sampling approach was Random Digit Dialling (RDD) and used the RDD database that has been developed through the Association of Market and Social Research Organisations (AMSRO). Sampling occurred by the use of quotas i.e. targets to weight disproportionately (to the 15+ general population) by particular characteristics (age, sex, location and smoking status). The results were then re-adjusted by the use of census data for age, sex and location. Re-adjusted for smoking status using estimate from their own survey (3230 participants) of what they call 'incidence', although actually prevalence (see Technical report).
Inclusion criteria	+	
Confounding factors	-	Confounding factors such as mass media anti-smoking campaigns are noted but not discussed with reference to implications for the results. No statistical tests to control for confounders.
Objective outcome assessment	-	Self report (rather than biochemically assessed).
Group descriptors	+	No direct discussion but sampling technique appears to be the same between surveys.
Follow-up	<b>NA</b>	NA due to cross-sectional design
Withdrawals	<b>NA</b>	NA due to cross-sectional design
Reliable measurement	+	
Statistical analysis	+	
<b>Silpasuwan et al 2008</b>		
Sample selection	-	A systematic sampling frame was developed that ensured a proportional number of employees would be sampled from each region (North, Northeast, South, Central and Bangkok).
Inclusion criteria	+	
Confounding factors	-	New warnings were introduced during one of the survey years, but not discussed in the paper. Confounding factors were not adequately discussed.

Domain	Decision	Comments
Objective outcome assessment	-	Self report (rather than biochemically assessed) and interviewers and interpreters in some instances required to help participants provide answers.
Group descriptors	NA	NA single cohort
Follow-up	+	10 months (March 2005, January-February 2006)
Withdrawals	-	Large numbers of withdrawals (n=691), accounted for as lost to follow-up or incomplete questionnaires.
Reliable measurement	+	Interviewed by research assistants and translators also used, but training not mentioned
Statistical analysis	-	Some unclear analysis and at least 1 error in outcomes reported

+ denotes satisfactory

- denotes unsatisfactory

### 3.6 Narrative summary

Three out of the four included studies did not find that larger HWL (50% or greater) had statistically significant effects on prevalence or quit rates. Gospodinov and Irvine<sup>23</sup> report no effect for larger HWLs on prevalence rates, while Borland et al<sup>8</sup> and Silpasuwan et al<sup>24</sup> examined quitting and also did not report statistically significant effects. Shanahan and Elliott<sup>9</sup> did report a statistically significant decline in the numbers of current smokers between 2000 and 2008 as well as a statistically significant increase in the number of people who successfully attempted to quit smoking for at least one month, however the authors did not control for confounding factors and the long time gap between measurement periods jeopardizes the authors' ability to draw conclusions on the causal relation between larger HWL and their reported results.

Each of the studies suffers from incomplete reporting of the degree of exposure to larger HWLs, including the length of time after implementation that they were seen by participants. Gospodinov and Irvine address the issue of exposure by arguing that their failure to identify an effect might be partly explained by the short (6 month) follow-up after introduction of the new HWLs. Furthermore, even knowing the date of implementation of policy and date of survey does not guarantee knowledge of duration of exposure since full compliance and replacement of old stock will always take some time.

The time gap between surveys and implementation of larger HWLs is particularly problematic for the Shanahan and Elliott study as there is an 8 year gap between the surveys. As a result, there is a 6 year gap between the first measurement (2000) and the implementation of larger HWLs in 2006. It should be noted that, on its own, prevalence data is a poor means of investigating the effects of one particular policy – in this case larger HWLs – on smoking behaviour, because smoking behaviour is likely to be affected by a number of different factors. Research that seeks to assess policy effects by measuring smoking prevalence should therefore control for confounding factors such as the influence of co-interventions like mass media anti-smoking campaigns which, in Australia, also used the same images as those on tobacco health warning labels.<sup>9</sup> Larger HWLs may play a role in reducing smoking prevalence but we cannot isolate or quantify the size of that effect from prevalence data alone. While the Shanahan and Elliott study reported a significant increase in the number of people successfully quitting for at least one month between 2000 and 2008, over such a long time period and amidst numerous tobacco control interventions (restrictions on smoking in public places, mass media campaigns, price changes) it is unclear just what role, if any, larger HWLs played in helping smokers attempt quitting. Borland et al, Shanahan and Elliott and Silpasuwan et al did collect data on knowledge or salience of HWLs, but they did not control for these or the impact of other anti-smoking interventions in their estimates of quitting.

Finally, for Borland et al, it should be noted that the largest increase in the proportion who quit for at least one month was between Waves 1-2 and 2-3 – an increase in quit rates of 7.94%. This increase in quit rates occurred before the larger HWLs are introduced.

## 4.0 SYSTEMATIC REVIEW DISCUSSION

Overall, few studies were identified which matched the inclusion criteria and the quality of those studies that were included was mixed. Hence, any conclusions should be drawn with caution.

### 4.1 Interpretations of the evidence

There was a general lack of detail in the reporting of the size of HWLs for both intervention and comparator. Reporting of the comparator (previous smaller HWL) was particularly poor and the reviewers had to find these important details in other documents.

In terms of design, all studies were observational, but Silpasuwan et al suffered from a flaw in its use of a cohort design. Silpasuwan et al used a single cohort and thus suffered from ‘attrition bias’ in that those who were susceptible to quitting after introduction of the new HWL were only those who either had not quit or had relapsed prior to the implementation of the new HWL. It is possible that the result of this may have been to reduce the size of the effect since those most likely to quit would have already quit. While this may indicate an underestimate of the effect size, the authors do not mention this issue. The design of Borland et al, as outlined above, was unusual, but might have been analysed as two cohorts, one before and one after the HWL size change, which would prevent attrition bias. However, participants from the first cohort who had quit were also stated to have been retained and it was not clear that they were excluded from the analysis at the later time point. The cross-sectional design of Gospodinov and Irvine or Shanahan and Elliott cannot suffer from attrition bias. However, as surveys they cannot separate any effect on quitting from uptake, nor is the study type well suited to investigating causal links generally. Cross-sectional studies can be improved by controlling for key confounding factors. Gospodinov and Irvine did account for some confounding factors in their study, while Shanahan and Elliott did not.

It is important to note how few studies report behavioural outcomes – of the 1,944 studies identified only 4 matched the inclusion criteria (see also Appendix 4 for a list of excluded studies and reasons for exclusion). This is despite large quantities of empirical data from many international surveys of smoking<sup>25</sup> and the World Health Organization’s recommendation<sup>26</sup> to increase tobacco HWL size. Indeed, it is studies reporting non-behavioural outcomes that are cited in order to support these policies for example, Borland et al<sup>11</sup>, Environics Research Group<sup>4, 5, 27</sup>, Hammond et al.<sup>13</sup> Hence, the evidence base in terms of behavioural outcomes for HWLs on tobacco products covering at least 50% of the principal display areas is very thin and far from convincing.

We note there appears to be some disagreement as to whether behavioural outcomes or cognitive measures should be the appropriate outcome to measure. For example, Ruiter and Kok<sup>28</sup> argue against the conclusions of Hammond et al<sup>29</sup> that, on the basis of their study, HWLs with ‘vivid and striking features’ should be policy. The basis of Ruiter and Kok’s argument is that Hammond et al only measure intention to quit and not actual quitting. Hammond et al<sup>30</sup> responded by arguing that they know of no evidence that shows ‘graphic pictorial’ warnings to be ineffective or counter-productive. Finally, Ruiter and Kok respond<sup>31</sup> by recommending studies with an experimental design and behavioural measures. Another example of the ambivalence which surrounds the use of behavioural outcomes in this area is Hoek and Gendall’s 2005<sup>32</sup> report prepared for the New Zealand Ministry of Health. On the one hand they argue that cognitive measures cannot be assumed to offer insights into behaviour, while on the other hand they suggest that studies without behavioural measures can offer insights.

There are good reasons to conclude that behavioural outcomes are necessary to assess tobacco control interventions. As the above-mentioned debate highlights, there are two types of outcome measures. One group of outcomes are often described as clinical, true or patient-relevant outcomes. These outcomes measure real outcomes of a disease (e.g. death, stroke, mobility). The other set of outcomes are called surrogate outcomes and are an indirect measure of disease status. The problem with surrogate outcomes is that they can be misleading by over or underestimating the true outcome.<sup>33</sup> Opinions, beliefs and affective responses to HWLs and quitting are surrogate measures for quitting behaviour. As such they are an unreliable measure of actual quitting behaviour.

Another consideration to account for is whether increasing the size of HWLs may be counterproductive. Borland et al raise this point in their study: “Reactions to warnings could also be associated with reductions in desired outcomes as well as facilitating them. Some researchers have argued that strong warnings and various public health campaigns may inadvertently create psychological reactance that could potentially inhibit desirable behaviour change ... including quitting activity ... it is important to have population-based research to rule out reactance effects to cigarette packet health warnings, especially as the enhancement of pack warnings is a key provision of the World Health Organization’s Framework Convention on Tobacco Control.” (p. 670) Measuring behaviour change in terms of prevalence, quitting and uptake are essential for assessing the effectiveness of larger HWLs.

Finally, and significantly, Cochrane reviews<sup>34-37</sup> of tobacco control interventions also typically use smoking cessation as the primary outcome. It is imperative that research on anti-smoking interventions, including increased HWLs, report behavioural outcomes as these are participant-relevant outcomes and crucial for making sound causal links between interventions and desired behavioural change.

It is clear from the four studies included in this review that *it is possible to measure prevalence and cessation given some degree of exposure to a HWL*. While isolating the effect of a change in HWL size from other anti-smoking interventions is no doubt difficult, avoiding basic methodological and reporting errors would be a step in the right direction.

Based on the four included studies no convincing evidence was found for larger tobacco health warning labels having a significant effect on reducing smoking prevalence rates or increasing cessation rates. Given this finding, the dearth of research which examines behavioural outcomes and the mixed quality of the included studies, we conclude that there is insufficient evidence to support a policy to increase HWL size on the basis of an effect on smoking uptake, quitting or prevalence.

#### **4.2 Limitations of the review**

A potential limitation of this review is publication bias. Publication bias occurs when the publication of a study is influenced by its results, meaning studies reporting negative results may not be published and the published literature may over estimate the effect size of an intervention. We attempted to minimise publication bias by searching for grey literature and contacting authors. However, the lack of evidence and the heterogeneity of studies meant pooling was not possible which also meant we were unable to investigate publication bias (for example through funnel plots).

The review could also have included reduction in the number of cigarettes smoked as an outcome. However, none of the studies we excluded measured this outcome.

## 5.0 CONCLUSIONS

The systematic review of the effectiveness of HWL size of at least 30% to less than 50% of the principal display areas compared to 50% or greater found only four studies which measured the impact of the larger health warnings on smoking prevalence or cessation rates. No evidence was found regarding uptake. We excluded papers which were not primary research or which only measured attitudes, intentions or speculation. Most studies were excluded because they did not report relevant behavioural outcomes (prevalence, cessation, or uptake) or because the HWL comparator was not relevant. The four included studies suffered from a range of methodological problems including reporting problems (particularly of intervention and comparator and length of exposure to new HWLs); lack of control for confounding factors like price variation or simultaneous mass media anti-smoking campaigns; study timeframes which were too short or too long to fully investigate an effect; and reporting/recall bias from self-report measures of smoking and cessation rather than biochemical assessment of smoking.

Three of the four included studies did not find increased HWLs to have a statistically significant effect on prevalence or cessation rates. The Shanahan and Elliott study did report a statistically significant decline in smoking prevalence and a statistically significant increase in successful one month quit attempts, but these measures were taken over an eight year period and do not isolate or quantify the effect of larger HWLs on prevalence or cessation. Given the lack of effect from these studies and the small number of studies, there is insufficient evidence to say that increasing HWL size from 30-50% to 50% or greater is effective at reducing smoking rates or increasing cessation rates.

In conclusion, the systematic review has drawn attention to the dearth of research on tobacco HWLs that report participant-relevant behavioural outcomes. The review also emphasizes the need for further well designed studies to evaluate the effectiveness of larger tobacco HWLs.

### 5.1 Implications for future research

We offer the following suggestions for future research investigating the effectiveness of tobacco health warning labels:

- ❖ Accurate reporting – particularly of the research design, length of exposure to HWLs and the intervention(s) and comparator(s) being investigated;
- ❖ Cross-sectional designs should be avoided for their limited ability to demonstrate causality; if cross-sectional design is used, controlling for key confounding factors such as price and public information campaigns is essential;
- ❖ Avoid attrition bias through sound research design;
- ❖ Ensure an adequate length of follow-up to give the study every chance to identify an effect; and
- ❖ Use biochemical assessment of smoking status rather than self-report measures.

Given that changes in tobacco HWL are implemented and controlled by governments and that start dates are set-out well in advance, it seems a genuine missed opportunity for a well designed cohort study in Australia or Canada. Nonetheless, with numerous other countries planning to increase the size of tobacco HWLs future opportunities exist to rigorously investigate the effectiveness of larger HWLs compared with the smaller HWLs.

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## APPENDIX 1: Search strategies

### Medline (OvidSP): 1950-2010/08/wk 4 Searched 10.8.10

	Searches	No. of hits
1	Tobacco/	19,151
2	Smoking/	99,230
3	exp "Tobacco Use Cessation"/	15,490
4	"Tobacco Use Disorder"/	6,073
5	Nicotine/	18,605
6	smoking.ti,ab.	110,618
7	(smoker or smokers).ti,ab.	44,234
8	tobacco.ti,ab.	49,280
9	cigar\$.ti,ab.	39,958
10	nicotine.ti,ab.	22,936
11	or/1-10	206,511
12	Product Packaging/ or Product Labeling/ or HWL.ti,ab. or (product\$ adj2 (warning\$ or label\$)).ti,ab.	4,457
13	((warning\$ or caution\$) adj2 label\$).ti,ab.	328
14	((graphic\$ or pictorial or picture\$ or pack or packs or packag\$ or packet\$ or box or boxes or text) adj2 (warning\$ or label\$ or caution\$)).ti,ab.	675
15	(health warning\$ adj2 (pack or packs or packag\$ or packet\$ or box or boxes)).ti,ab.	6
16	(health caution\$ adj2 (pack or packs or packag\$ or packet\$ or box or boxes)).ti,ab.	0
17	or/12-16	5,265
18	11 and 17	319
19	((cigar\$ or tobacco) adj2 label\$).ti,ab.	95
20	18 or 19	372

### Medline In-Process Citations (OvidSP): up to 2010/08/09 Searched 10.8.10

	Searches	No. of hits
1	Tobacco/	1
2	Smoking/	1
3	exp "Tobacco Use Cessation"/	0
4	"Tobacco Use Disorder"/	0
5	Nicotine/	0
6	smoking.ti,ab.	3,785
7	(smoker or smokers).ti,ab.	1,434
8	tobacco.ti,ab.	3,113
9	cigar\$.ti,ab.	1,098
10	nicotine.ti,ab.	673
11	or/1-10	7,170
12	Product Packaging/ or Product Labeling/ or HWL.ti,ab. or (product\$ adj2 (warning\$ or label\$)).ti,ab.	135
13	((warning\$ or caution\$) adj2 label\$).ti,ab.	12
14	((graphic\$ or pictorial or picture\$ or pack or packs or packag\$ or packet\$ or box or boxes or text) adj2 (warning\$ or label\$ or caution\$)).ti,ab.	47
15	(health warning\$ adj2 (pack or packs or packag\$ or packet\$ or box or boxes)).ti,ab.	0
16	(health caution\$ adj2 (pack or packs or packag\$ or packet\$ or box or boxes)).ti,ab.	0
17	or/12-16	189
18	11 and 17	12
19	((cigar\$ or tobacco) adj2 label\$).ti,ab.	7
20	18 or 19	16

**Embase (OvidSP): 1980-2010/wk 31**  
**Searched 10.8.10**

	<b>Searches</b>	<b>No. of hits</b>
1	"smoking and smoking related phenomena"/ or cigarette smoke/ or smoking/ or tobacco smoke/	11,035
2	cigarette smoking/	39,773
3	smoking cessation/	26,161
4	tobacco/	22,389
5	tobacco dependence/	8,242
6	nicotine/	27,934
7	smoking.ti,ab.	126,031
8	(smoker or smokers).ti,ab.	49,910
9	nicotine.ti,ab.	25,680
10	tobacco.ti,ab.	54,314
11	cigar\$.ti,ab.	43,363
12	or/1-11	248,282
13	HWL.ti,ab. or packaging/ or (product\$ adj2 (warning\$ or label\$)).ti,ab.	6,066
14	((warning\$ or caution\$) adj2 label\$).ti,ab.	401
15	((graphic\$ or pictorial or picture\$ or pack or packs or packag\$ or packet\$ or box or boxes or text) adj2 (warning\$ or label\$ or caution\$)).ti,ab.	896
16	(health warning\$ adj2 (pack or packs or packag\$ or packet\$ or box or boxes)).ti,ab.	5
17	(health caution\$ adj2 (pack or packs or packag\$ or packet\$ or box or boxes)).ti,ab.	0
18	or/13-17	7,143
19	11 and 18	160
20	((cigar\$ or tobacco) adj2 label\$).ti,ab.	95
21	19 or 20	217

**Cochrane Database of Systematic Reviews (Cochrane Library Issue 8:2010)**  
**CENTRAL (Cochrane Library Issue 3:2010)**  
**Searched 10.8.10**

	<b>Searches</b>	<b>No. of hits</b>
1	MeSH descriptor Tobacco, this term only	104
2	MeSH descriptor Smoking, this term only	4,304
3	MeSH descriptor Tobacco Use Disorder, this term only	524
4	MeSH descriptor Tobacco Use Cessation explode all trees	2,261
5	MeSH descriptor Nicotine, this term only	1,263
6	smoking:ti,ab	9,353
7	(smoker or smokers):ti,ab	4,606
8	tobacco:ti,ab	1,720
9	cigar*:ti,ab	2,729
10	nicotine:ti,ab	2,338
11	(#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10)	12,494
12	MeSH descriptor Product Packaging, this term only	12
13	MeSH descriptor Product Labeling, this term only	19
14	hwl:ti,ab	0
15	(product* near (warning* or label*)):ti,ab	89
16	((warning* or caution*) near label*):ti,ab	22
17	((graphic* or pictorial or picture* or pack or packs or packag* or packet* or box or boxes or text) near (warning* or label* or caution*)):ti,ab	38
18	(health warning* near (pack or packs or packag* or packet* or box or boxes)):ti,ab	4
19	(health caution* near (pack or packs or packag* or packet* or box or boxes)):ti,ab	0

20	(#12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19)	161
21	(#11 AND #20)	10
22	((cigar* or tobacco) near label*):ti,ab	9
23	(#21 OR #22)	15

CDSR search retrieved 2 records.

Central search retrieved 12 records.

**Database of Abstracts of Reviews of Effects (DARE), Health Technology Assessment database (HTA) & NHS Economic Evaluation Database (NHS EED) (internet)**

<http://www.york.ac.uk/inst/crd/>

**Searched 10.8.10**

	<b>Searches</b>	<b>No. of hits</b>
1	Smoking OR smoker OR smokers OR tobacco OR cigar* OR nicotine	1,137
2	Hwl:ti	0
3	( Product* NEAR Packag* ) OR ( Product* NEAR Label* ) OR ( product* NEAR warning* )	38
4	( warning* NEAR caution* ) OR ( warning* NEAR label* )	4
5	( graphic* NEAR warning* ) OR ( pictorial NEAR warning* ) OR ( picture* NEAR warning* )	0
6	( pack NEAR warning* )	0
7	( packs NEAR warning* ) OR ( packag* NEAR warning* ) OR ( packet* NEAR warning* ) OR ( box NEAR warning* )	2
8	( boxes NEAR warning* ) OR ( text NEAR warning* )	0
9	( graphic* NEAR label* ) OR ( pictorial NEAR label* ) OR ( picture* NEAR label* ) OR ( pack NEAR label* )	3
10	( packs NEAR label* ) OR ( packag* NEAR label* ) OR ( packet* NEAR label* ) OR ( box NEAR label* )	6
11	( boxes NEAR label* ) OR ( text NEAR label* )	14
12	( graphic* NEAR caution* ) OR ( pictorial NEAR caution* ) OR ( picture* NEAR caution* )	20
13	( pack NEAR caution* ) OR ( packs NEAR caution* ) OR ( packag* NEAR caution* ) OR ( packet* NEAR caution* )	4
14	( box NEAR caution* ) OR ( boxes NEAR caution* ) OR ( text NEAR caution* )	81
15	2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14	168
16	1 and 15	7
17	( health AND warning* NEAR pack ) OR ( health AND warning* NEAR packs ) OR ( health AND warning* NEAR packag* )	0
18	( health AND warning* NEAR packet* ) OR ( health AND warning* NEAR box ) OR ( health AND warning* NEAR boxes )	3
19	( health AND caution* NEAR pack ) OR ( health AND caution* NEAR packs ) OR ( health AND caution* NEAR packag* )	54
20	( health AND caution* NEAR packet* ) OR ( health AND caution* NEAR box ) OR ( health AND caution* NEAR boxes )	212
21	16 or 17 or 18 or 19 or 20	271

DARE search retrieved 121 records.

HTA search retrieved 140 records.

NHS EED search retrieved 10 records.

**PsycINFO (OvidSP): 1806-2010/08/wk 1**

**Searched 10.8.10**

	<b>Searches</b>	<b>No. of hits</b>
1	exp tobacco smoking/	16,786
2	smokeless tobacco/	356
3	nicotine/	5,857

4	smoking cessation/	6,231
5	(smoking or smoker or smokers).ti,ab.	24,598
6	tobacco.ti,ab.	9,274
7	cigar\$.ti,ab.	9,739
8	nicotine.ti,ab.	8,062
9	or/1-8	33,808
10	warning labels/	124
11	(HWL or (product\$ adj2 (warning\$ or label\$))).ti,ab.	211
12	((warning\$ or caution\$) adj2 label\$).ti,ab.	161
13	((graphic\$ or pictorial or picture\$ or pack or packs or packag\$ or packet\$ or box or boxes or text) adj2 (warning\$ or label\$ or caution\$)).ti,ab.	357
14	(health warning\$ adj2 (pack or packs or packag\$ or packet\$ or box or boxes)).ti,ab.	3
15	(health caution\$ adj2 (pack or packs or packag\$ or packet\$ or box or boxes)).ti,ab.	0
16	or/10-15	710
17	9 and 16	75
18	((cigar\$ or tobacco) adj2 label\$).ti,ab.	33
19	17 or 18	82

**Social Science Citation Index (SSCI) (Web of Science): 1970-2010/08/07**  
**Searched 10.8.10**

	<b>Searches</b>	<b>No. of hits</b>
1	TS=(smoking or smoker or smokers or tobacco or nicotine or cigar*)	43,451
2	TI=HWL	0
3	TS=(product* SAME (warning* or label*))	791
4	TS=((warning* or caution*) SAME label*)	307
5	TS=((graphic* or pictorial or picture* or pack or packs or packag* or packet* or box or boxes or text) SAME (warning* or label* or caution*))	560
6	TS=(health warning* SAME (pack or packs or packag* or packet* or box or boxes))	74
7	TS=(health caution* SAME (pack or packs or packag* or packet* or box or boxes))	1
8	2 or 3 or 4 or 5 or 6 or 7	1,494
9	1 and 8	136
10	TS=((cigar* or tobacco) SAME label*)	91
11	9 or 10	163
12	TS=(cat or cats or dog or dogs or animal or animals or rat or rats or hamster or hamster or feline or ovine or canine or bovine or sheep)	68,756
13	11 not 12	162

**Science Citation Index (SCI) (Web of Science): 1970-2010/08/07**  
**Searched 10.8.10**

	<b>Searches</b>	<b>No. of hits</b>
1	TS=(smoking or smoker or smokers or tobacco or nicotine or cigar*)	>100,000
2	TI=HWL	1
3	TS=(product* SAME (warning* or label*))	10042
4	TS=((warning* or caution*) SAME label*)	592
5	TS=((graphic* or pictorial or picture* or pack or packs or packag* or packet* or box or boxes or text) SAME (warning* or label* or caution*))	1969
6	TS=(health warning* SAME (pack or packs or packag* or packet* or box or boxes))	104
7	TS=(health caution* SAME (pack or packs or packag* or packet* or box or boxes))	1
8	2 or 3 or 4 or 5 or 6 or 7	12192
9	1 and 8	228
10	TS=((cigar* or tobacco) SAME label*)	376
11	9 or 10	541
12	TS=(cat or cats or dog or dogs or animal or animals or rat or rats or hamster or hamster or feline or ovine or canine or bovine or sheep)	>100,000

13	11 not 12	489
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**Conference Proceedings Citation Index – Science (CPCI-S) (Web of Science): 1990-2010/08/07**

**Searched 10.8.10**

	<b>Searches</b>	<b>No. of hits</b>
1	TS=(smoking or smoker or smokers or tobacco or nicotine or cigar*)	16,173
2	TI=HWL	0
3	TS=(product* SAME (warning* or label*))	1,175
4	TS=((warning* or caution*) SAME label*)	78
5	TS=((graphic* or pictorial or picture* or pack or packs or packag* or packet* or box or boxes or text) SAME (warning* or label* or caution*))	1,079
6	TS=(health warning* SAME (pack or packs or packag* or packet* or box or boxes))	6
7	TS=(health caution* SAME (pack or packs or packag* or packet* or box or boxes))	0
8	2 or 3 or 4 or 5 or 6 or 7	2,267
9	1 and 8	19
10	TS=((cigar* or tobacco) SAME label*)	16
11	9 or 10	34
12	TS=(cat or cats or dog or dogs or animal or animals or rat or rats or hamster or hamster or feline or ovine or canine or bovine or sheep)	>100,000
13	11 not 12	32

**BIOSIS Citation Index (BCI) (Web of Science): 1969-2010/07/27**

**Searched 10.8.10**

	<b>Searches</b>	<b>No. of hits</b>
1	TS=(smoking or smoker or smokers or tobacco or nicotine or cigar*)	321,078
2	TI=HWL	1
3	TS=(product* SAME (warning* or label*))	53,102
4	TS=((warning* or caution*) SAME label*)	957
5	TS=((graphic* or pictorial or picture* or pack or packs or packag* or packet* or box or boxes or text) SAME (warning* or label* or caution*))	7,406
6	TS=(health warning* SAME (pack or packs or packag* or packet* or box or boxes))	120
7	TS=(health caution* SAME (pack or packs or packag* or packet* or box or boxes))	29
8	2 or 3 or 4 or 5 or 6 or 7	60,166
9	1 and 8	733
10	TS=((cigar* or tobacco) SAME label*)	2,209
11	9 or 10	2,519
12	11 AND Taxa Notes=(Humans)	689

**Sociological Abstracts (CSA Illumina): 1952-2010/08/24**

**Searched 24.8.10**

Searched using Advanced search (all fields), Thesaurus and command search options.  
Broad strategy exploded thesaurus terms.

	<b>Searches</b>	<b>No. of hits</b>
1	DE="smoking"	1,409
2	smoking or smoker or smokers or tobacco or cigar* or nicotine	5,590
3	(DE="smoking") or(smoking or smoker or smokers or tobacco or cigar* or nicotine)	5,590
4	TI=HWL	1
5	AB=HWL	1
6	(product* within 2 (warning* or label*))	50
7	(warning* or caution*) within 2 label*))	34
8	(graphic* or pictorial or picture* or pack or packs or packag* or packet* or box or boxes	24

	or text) within 2 (warning* or label* or caution*))	
9	(health warning* within 2 (pack or packs or packag* or packet* or box or boxes))	0
10	(health warning* within 2 (pack or packs or packag* or packet* or box or boxes))	0
11	(health caution* within 2 (pack or packs or packag* or packet* or box or boxes))	0
12	(AB=HWL) or(product* within 2 (warning* or label*)) or((warning* or caution*) within 2 label*) or(health warning* within 2 (pack or packs or packag* or packet* or box or boxes)) or(health warning* within 2 (pack or packs or packag* or packet* or box or boxes)) or(health caution* within 2 (pack or packs or packag* or packet* or box or boxes))	83
13	((DE="smoking") or(smoking or smoker or smokers or tobacco or cigar* or nicotine)) and((AB=HWL) or(product* within 2 (warning* or label*)) or((warning* or caution*) within 2 label*) or(health warning* within 2 (pack or packs or packag* or packet* or box or boxes)) or(health warning* within 2 (pack or packs or packag* or packet* or box or boxes)) or(health caution* within 2 (pack or packs or packag* or packet* or box or boxes)))	15
14	((cigar* or tobacco) within 2 label*)	7
15	((DE="smoking") or(smoking or smoker or smokers or tobacco or cigar* or nicotine)) and((AB=HWL) or(product* within 2 (warning* or label*)) or((warning* or caution*) within 2 label*) or(health warning* within 2 (pack or packs or packag* or packet* or box or boxes)) or(health warning* within 2 (pack or packs or packag* or packet* or box or boxes)) or(health caution* within 2 (pack or packs or packag* or packet* or box or boxes))) or((cigar* or tobacco) within 2 label*)	19

**Health Management Information Consortium (HMIC) (OvidSP): 1983-2010/05  
Searched 10.8.10**

	Searches	No. of hits
1	exp tobacco/	434
2	nicotine/	91
3	exp smoking/	2,670
4	tobacco consumption/	108
5	exp tobacco products/	304
6	smoking cessation/	1,268
7	smoking control/	351
8	(smoking or smoker or smokers).ti,ab.	4,567
9	tobacco.ti,ab.	1,365
10	cigar\$.ti,ab.	858
11	nicotine.ti,ab.	282
12	or/1-11	5,954
13	product design/	44
14	product labelling/	127
15	safety labelling/	17
16	(HWL or (product\$ adj2 (warning\$ or label\$))).ti,ab.	23
17	((warning\$ or caution\$) adj2 label\$).ti,ab.	13
18	((graphic\$ or pictorial or picture\$ or pack or packs or packag\$ or packet\$ or box or boxes or text) adj2 (warning\$ or label\$ or caution\$)).ti,ab.	67
19	(health warning\$ adj2 (pack or packs or packag\$ or packet\$ or box or boxes)).ti,ab.	3
20	(health caution\$ adj2 (pack or packs or packag\$ or packet\$ or box or boxes)).ti,ab.	0
21	or/13-20	242
22	12 and 21	42
23	((cigar\$ or tobacco) adj2 label\$).ti,ab.	13
24	22 or 23	43

**OpenSIGLE (Internet)  
<http://opensigle.inist.fr/>  
Searched 24.8.10**

	<b>Searches</b>	<b>No. of hits</b>
1	(label or labels or labelling or labelled or labeled or labeling or warning or warnings or caution or cautions) AND (tobacco or smoke or smoking or cigarette or cigarettes or cigar or cigars or smoker or smokers or nicotine)	10
2	(cigar or cigars or cigarette or cigarettes or tobacco) AND (label or labels or labelling or labelled or labeled or labeling)	4

## APPENDIX 2: Quality Assessment

Table 7: JBI Critical Appraisal Checklist for Descriptive/Case Series Studies<sup>38</sup>

Domain	Item	Description
Sample selection	Was the study based on a random or pseudo-random sample?	Studies may report random allocation from a population, and the methods section should report how allocation was performed.
Inclusion criteria	Were the criteria for inclusion in the sample clearly defined?	How was the sample recruited? Give consideration to whether responders have potential to differ in some significant way to non-responders. Was inclusion based on clearly defined characteristics or subjective values and opinions such as personal interest of the participants in the topic?
Confounding factors	Were confounding factors identified and strategies to deal with them stated?	Any confounding factors should be identified, and methods reported for measuring their potential impact on the study results.
Objective outcome assessment	Were outcomes assessed using objective criteria?	Were any measurement tools used validated instruments or was observer/self reporting used?
Group descriptors	If comparisons are being made, was there sufficient description of the groups?	Have the authors made some attempt to identify and measure the similarities between included groups?
Sufficient follow-up	Was follow up carried out over a sufficient time period?	The opinions of experts in clinical practice or clinical research may assist in determining an appropriate duration of follow-up.
Withdrawals	Were the outcomes of people who withdrew described and included in the analysis?	Commonly, intention to treat analysis is utilised where losses to follow-up are included in the analysis. Intention to treat (ITT) analysis may reduce bias due to changes in the characteristics between control and treatment groups that can occur if people either drop out, or if there is a significant level of mortality in one particular group.
Reliable outcome measurement	Were outcomes measured in a reliable way?	Were all those involved in collecting data trained in the use of the instrument/s?
Statistical analysis	Was appropriate statistical analysis used?	Could more appropriate alternative forms of analysis have been used? Also, did the authors report baseline data, or change values in addition to endpoint data?

### APPENDIX 3: Data extraction for effectiveness studies

Borland 2009			
Study details and conclusions	Population	Characteristics of Intervention and Control/Comparator	Outcomes and results
<p><b>Study group:</b> International Tobacco Control Four-Country Survey.</p> <p><b>Country:</b> Australia, Canada, UK, US although only Australia measured relevant outcome (at least one month quit) before and after policy to increase HWL from 30% to greater than 50% of pack.</p> <p><b>Funding:</b> none declared.</p> <p><b>Design:</b> Other Repeated cross-sectional design using a cohort which is topped in order to maintain original numbers.</p> <p><b>Objective:</b> To examine prospectively the impact of health warnings on quitting activity.</p> <p><b>Definition of smoking used:</b> 18 years or older who have smoked more than 100 cigarettes in their lifetimes and who have smoked at least once in the past 30 days.</p> <p><b>Definition of cessation used:</b> at least one month quit.</p> <p><b>Authors' conclusions:</b> This study adds</p>	<p><b>Total number of participants (by warning size/control; allocated and analysed):</b> (Australia only, calculated from percentage of 4 country total) Wave 1-2 (2002-2003): 1814 Wave 2-3 (2003-2004): 1419 Wave 3-4 (2004-2005): 1212 Wave 4-5 (2005-2006): 1030</p> <p><b>Total withdrawals (n/N):</b> Not reported.</p> <p><b>Mean age:</b> only reported as mean of all 4 countries (mean, SD): Wave 1-2: 42.7, 14.2 Wave 2-3: 44.1, 14.0 Wave 3-4: 44.5, 13.5 Wave 4-5: 45.3, 13.6</p> <p><b>Gender (% female): only reported for all 4 countries:</b> Wave 1-2: 55.8 Wave 2-3: 56.2 Wave 3-4: 57.9 Wave 4-5: 58.1</p> <p><b>Legal smoking age (years):</b> N/A</p> <p><b>Legal tobacco purchasing age (years):</b> N/A</p>	<p><b>Characteristics of the intervention(s):</b> Australia: 30% of front, 90% of back (60% average)</p> <p><b>Characteristics of the control(s):</b> 25% of front, 35% of back (30% average)</p> <p><b>Co-intervention details:</b> None stated.</p> <p><b>Additional comments:</b></p>	<p><b>Length of follow-up:</b> only reported mean survey interval (days) for all 4 countries: Wave 1-2: 203 Wave 2-3: 388 Wave 3-4: 458 Wave 4-5: 361</p> <p><b>Outcome assessment:</b> Respondent</p> <p><b>Type of analysis used (ITT versus per protocol or mixture):</b> N/A</p> <p><b>Relevant outcomes</b> <b>Smoking prevalence rates:</b> N/A <b>Uptake of smoking:</b> N/A <b>Cessation rates:</b> at least 1 month quit, <b>Australia:</b> Wave 1-2: 14.99% Wave 2-3: 22.93% Wave 3-4: 25.15% Wave 4-5: 25.90%</p>

<p>to the evidence that forgoing cigarettes as a result of noticing warnings and quit-related cognitive reactions to warnings are consistent prospective predictors of making quit attempts. This work strengthens the evidence base for governments to go beyond the Framework Convention on Tobacco Control to mandate health warnings on tobacco products that stimulate the highest possible levels of these reactions.</p> <p><b>Record number: 1421</b></p>		<p><b>Additional comments:</b></p>		
<b>Domain</b>	<b>Decision</b>	<b>Comments</b>		
<b>Sample selection</b>	-	Subjects were randomly selected in 'Wave 1' in 2002. However, there were also an unreported number of drop-outs and new recruits between waves 1-2 (2002-2003), 2-3 (2003-2004), 3-4 (2004-2005) and 4-5 (2005-2006)		
<b>Inclusion criteria</b>	+			
<b>Confounding factors</b>	-	A statistical analysis to adjust for confounding was conducted but the effect of the HWL using country as a proxy was only treated as a confounder and no results for its effect were reported.		
<b>Objective outcome assessment</b>	-	Self report only.		
<b>Group descriptors</b>	-	See sample selection, above.		
<b>Follow-up</b>	<b>unclear</b>	Follow-up varied between individuals and between intervention and control and length was not reported.		
<b>Withdrawals</b>	<b>unclear</b>	Many dropouts but these are not reported, nor the reasons for withdrawal.		
<b>Reliable measurement</b>	+			
<b>Statistical analysis</b>	-	Adjustments to make the sample representative of the population were reported to have been made, but no details were provided. Adjustment for confounding was reported to have been made, but the estimate of the adjusted effect was not reported.		

<b>Gospodinov 2004</b>			
<b>Study details and conclusions</b>	<b>Population</b>	<b>Characteristics of Intervention and Control/Comparator</b>	<b>Outcomes and results</b>
<p><b>Study group:</b> Concordia University, Montreal</p> <p><b>Country:</b> Canada</p> <p><b>Funding:</b> Social Sciences and Humanities Research Council of Canada</p> <p><b>Design:</b> Cross-sectional</p> <p><b>Objective:</b> This study uses micro data from two waves of Health Canada's Canadian Tobacco Use Monitoring Surveys bordering the legislation to investigate if the introduction of the warnings had any significant impacts on smokers.</p> <p><b>Definition of smoking used:</b> Not reported</p> <p><b>Definition of cessation used:</b> Not reported</p> <p><b>Authors' conclusions:</b> Our findings indicate that the warnings have not had a discernible impact on smoking prevalence. The evidence of their impact on quantity smoked is positive, though only at a relatively low level of confidence.</p> <p><b>Record numbers:</b> 13</p>	<p><b>Total number of participants (by warning size/control; allocated and analysed):</b> N = 20,176</p> <p><b>Total withdrawals (n/N):</b> n = 504 (generated from proportion of incomplete data cited in paper)</p> <p><b>Mean age:</b> Not reported</p> <p><b>Gender (% female):</b> 53.73%</p> <p><b>Legal smoking age (years):</b> Not reported</p> <p><b>Legal tobacco purchasing age (years):</b> Not reported</p> <p><b>Additional comments:</b></p>	<p><b>Characteristics of the intervention(s):</b> Warning label 50-60%</p> <p><b>Characteristics of the control(s):</b> Warning label 30-40%</p> <p><b>Co-intervention details:</b> Increased tax on tobacco Spring 2001 (analysed in the results). Secular decline in smoking from the 1980s (estimated at 3% p.a.). Seasonal variation (higher in summer/vacation months and decrease with workplace bans).</p> <p><b>Additional comments:</b></p>	<p><b>Length of follow-up:</b> n/a (cross sectional) 6 months between surveys</p> <p><b>Outcome assessment:</b> Respondent</p> <p><b>Type of analysis used (ITT versus per protocol or mixture):</b> NA</p> <p><b>Relevant outcomes</b> <b>Smoking prevalence rates:</b> Whole sample: 25.0% (2000) / 23.4% (2001) <math>\Delta</math> -1.6 Male: 25.4% (2000) / 25.0% (2001) <math>\Delta</math> -0.6% Female: 24.7% (2000) / 21.8% (2001) <math>\Delta</math> -2.9% Language Eng: 24.7% (2000) / 24.1% (2001) <math>\Delta</math> -0.6% Language Fr: 28.3% (2000) / 25.7% (2001) <math>\Delta</math> -2.6% Eng &amp; Fr: 38.1% (2000) / 17.2% (2001) <math>\Delta</math> -20.9% Lang other: 15.8% (2000) / 13.3% (2001) <math>\Delta</math> -2.5% Educ &lt; h school: 29.2% (2000) / 27.3% (2001) <math>\Delta</math> -1.9% Educ h school: 28.6% (2000) / 25.9% (2001) <math>\Delta</math> -2.7% Educ college: 25.8% (2000) / 23.2% (2001) <math>\Delta</math> -2.6% Educ university: 12.6% (2000) / 13.6% (2001) <math>\Delta</math> +1.0% Age 15-17: 19.8% (2000) / 19.1% (2001)</p>

			<p> <math>\Delta</math> -0.7%  Age 18-19: 31.2% (2000) / 30.5% (2001)  <math>\Delta</math> -0.7%  Age 20-24: 32% (2000) / 34% (2001)  <math>\Delta</math> +2.0%  Age 25-34: 29.0% (2000) / 26.2% (2001)  <math>\Delta</math> -2.8%  Age 34-44: 32.3% (2000) / 26.0% (2001)  <math>\Delta</math> -6.3%  Age 45-54: 23.8% (2000) / 24.8% (2001)  <math>\Delta</math> -1.0%  Age 55-64: 18.0% (2000) / 17.7% (2001)  <math>\Delta</math> -0.3%  Age &gt;64: 11.9% (2000) / 12.2% (2001)  <math>\Delta</math> +0.3%  Low income: 33.3% (2000) / 30.0% (2001)  <math>\Delta</math> -3.3%  Middle income: 27.4% (2000) / 20.4% (2001) <math>\Delta</math> -7.0%  Mid-high income: 22.8% (2000) / 22.3% (2001) <math>\Delta</math> - 0.5%  High income: 15.6% (2000) / 21.9% (2001)  <math>\Delta</math> + 6.3%  Unrecorded income: 18.0% (2000) / 20.3% (2001) <math>\Delta</math> +2.3% </p> <p> Probit model results:  Warnings dummy variable: Mean Effect = -0.0034, SE = 0.013, 95% CI = -0.029 – 0.021  Low inc: Mean Effect = 0.0613, SE = 0.026, 95% CI = 0.009 – 0.109  Low-mid inc: Mean Effect = 0.0585, SE = 0.024, 95% CI = 0.010 – 0.105  Price: Mean Effect = -0.0037, SE = 0.001, 95% CI = -0.006 - -0.002 </p> <p> <b>Uptake of smoking:</b> Not reported </p>
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			<b>Cessation rates:</b> Not reported
<b>Domain</b>	<b>Decision</b>	<b>Comments</b>	
<b>Sample selection</b>	-	Random sample generated with random digit dialling, however, 'This survey is particularly appropriate for our objective, since it over-samples heavily in the lower age groups. Typically, about 25% of each six-month survey wave of 10,000 individuals is for those aged 15-19 and an equal proportion for those aged 20-24.' (p. 6)	
<b>Inclusion criteria</b>	+		
<b>Confounding factors</b>	+	Confounding factors that are noted include: increased tax on tobacco Spring 2001 (analysed in the results); secular decline in smoking from the 1980s (estimated at 3% p.a.) and seasonal variation (higher in summer/vacation months and decrease with workplace bans). Regression analysis used to control for price, age, gender and socioeconomic status.	
<b>Objective outcome assessment</b>	-	Self report.	
<b>Group descriptors</b>	<b>unclear</b>	Surveys were conducted at two points in time, but it is not clear the extent to which subjects were repeatedly measured (single cohort) versus only measured once (repeated cross-sectional).	
<b>Follow-up</b>	-	2 periods: July-December 2000, February-June 2001. The authors noted that the second period might have been too soon after introduction of the larger labels to detect an effect on prevalence.	
<b>Withdrawals</b>	-	Not reported in this paper.	
<b>Reliable measurement</b>	+	Not reported in this paper but detailed in CTUMS methodology.	
<b>Statistical analysis</b>	<b>unclear</b>	Between measures correlation not mentioned, but the extent of repeated measurement was also not reported.	

Shanahan 2009			
Study details and conclusions	Population	Characteristics of Intervention and Control/Comparator	Outcomes and results
<p><b>Study group:</b> Elliott and Shanahan Research.</p> <p><b>Country:</b> Australia</p> <p><b>Funding:</b> Australian Government Department of Health and Ageing.</p> <p><b>Design:</b> Cross-sectional (telephone survey) &amp; group discussions</p> <p><b>Objective:</b> to determine and evaluate the effectiveness of the graphic health warnings on tobacco product packaging on consumers and to evaluate the impact of the content of the health warnings system in achieving its purpose.</p> <p><b>Definition of smoking used:</b> Current smoker (not defined).</p> <p><b>Definition of cessation used:</b> Quit for at least 1 month and less than 1 month</p> <p><b>Authors' conclusions:</b> the graphic health warnings on tobacco product packaging have had a positive effect on the behaviour of smokers, recent quitters, and non-smokers; for example: encouraged people to smoke less, to think about quitting, to give up smoking and stay quit.</p>	<p><b>Total number of participants (by warning size/control; allocated and analysed):</b> 2000 N = 1204 (822 smokers) (nationwide stratified or quota random sample) 2008 N = 1304 (670) (nationwide disproportionate stratified random sample)</p> <p><b>Total withdrawals (n/N):</b> N/A</p> <p><b>Mean age:</b> Not reported</p> <p><b>Gender (% female):</b> 2008: 47% (45% of smokers) 2000: not reported (54% of smokers)</p> <p><b>Legal smoking age (years):</b> <b>Not reported</b></p> <p><b>Legal tobacco purchasing age (years):</b> <b>Not reported</b></p> <p><b>Additional comments:</b></p>	<p><b>Characteristics of the intervention(s):</b> Australia: 30% of front, 90% of back (60% average)</p> <p><b>Characteristics of the control(s):</b> 25% of front, 35% of back (30% average)</p> <p><b>Co-intervention details:</b> Anti-smoking mass-media campaigns and further restrictions on smoking in licensed venues and public places.</p> <p><b>Additional comments:</b> “The results were weighted back to the population and incidence of smoking within the community. This provided us with an immediate “snap shot” of smoking in the community and the statistics reported are representative of the views of the overall Australian population. It should be noted that post weighting of sample data is very common practice in social and market research. It takes advantage of the fact that stratified designs are more cost effective than general random samples, and allows more detailed analysis of small but important segments in the population” (see p. 36)</p>	<p><b>Length of follow-up:</b> n/a (cross sectional) <b>8 years between surveys</b></p> <p><b>Outcome assessment:</b> Respondent</p> <p><b>Type of analysis used (ITT versus per protocol or mixture):</b> NA</p> <p><b>Relevant outcomes</b> <b>Smoking prevalence rates:</b> <u>‘I currently smoke’:</u> 2000 – 20% (N = 1204) 2008 – 17% (N = 1304) “Significant difference at the 95% confidence level”, but no further details given (p. 53).</p> <p><b>Uptake of smoking:</b> Not reported</p> <p><b>Cessation rates:</b> (at least 1 month) <u>Total:</u> 2000 – 18% (n = 822) 2008 – 24% (n = 670)</p> <p><u>Male:</u> 2000 – 17% (n = 378) 2008 – 24% (n = 366)</p> <p><u>Female:</u> 2000 – 19% (n = 444) 2008 – 25% (n = 304)</p> <p>Each comparison significant at the 5%</p>

<b>Record numbers: 337</b>			level but no further details reported (p.123).
<b>Domain</b>	<b>Decision</b>	<b>Comments</b>	
<b>Sample selection</b>	+	The sampling approach was Random Digit Dialling (RDD) and used the RDD database that has been developed through the Association of Market and Social Research Organisations (AMSRO). Sampling occurred by the use of quotas i.e. targets to weight disproportionately (to the 15+ general population) by particular characteristics (age, sex, location and smoking status). The results were then re-adjusted by the use of census data for age, sex and location. Re-adjusted for smoking status using estimate from their own survey (3230 participants) of what they call 'incidence', although actually prevalence (see Technical report).	
<b>Inclusion criteria</b>	+		
<b>Confounding factors</b>	-	Confounding factors such as mass media anti-smoking campaigns are noted but not discussed with reference to implications for the results. No statistical tests to control for confounders.	
<b>Objective outcome assessment</b>	-	Self report only (rather than biochemically assessed).	
<b>Group descriptors</b>	+	No direct discussion but sampling technique appears to be the same.	
<b>Follow-up</b>	NA	NA due to cross-sectional design.	
<b>Withdrawals</b>	NA	NA due to cross-sectional design.	
<b>Reliable measurement</b>	+		
<b>Statistical analysis</b>	+		

Silpasuwan 2008			
Study details and conclusions	Population	Characteristics of Intervention and Control/Comparator	Outcomes and results
<p><b>Study group:</b> (lead author) Department of Public Health Nursing, Faculty of Public Health, Mahidol University, Bangkok</p> <p><b>Country: Other</b> Thailand</p> <p><b>Funding:</b> Thailand Health Promotion Institution (Thai Health)</p> <p><b>Design: Other</b> Mixed method prospective cohort study.</p> <p><b>Objective:</b> Explore and investigate the perceptions and responses of employees regarding the effects of a Health Warning Label (HWL) on their decision to encourage quitting and stages of change in smoking behaviour.</p> <p><b>Definition of smoking used:</b> Not reported</p> <p><b>Definition of cessation used:</b> Not reported</p> <p><b>Authors' conclusions:</b> New-HWL significantly increased attitudes about smoking cessation.</p> <p><b>Record numbers: 18</b></p>	<p><b>Total number of participants (by warning size/control; allocated and analysed):</b> N = 609 participants surveyed twice, before and after HWL changes</p> <p><b>Total withdrawals (n/N):</b> n = 691 (80% loss to follow-up, 20% incomplete questionnaire)</p> <p><b>Mean age:</b> Not reported</p> <p><b>Gender (% female):</b> Not reported</p> <p><b>Legal smoking age (years):</b> Not reported</p> <p><b>Legal tobacco purchasing age (years):</b> Not reported</p> <p><b>Additional comments:</b> Unclear if only male or mixed sample.</p>	<p><b>Characteristics of the intervention(s):</b> Warning label 50-60%</p> <p><b>Characteristics of the control(s):</b> Warning label 30-40%</p> <p><b>Co-intervention details:</b> In 2006, a new set of 9 warnings were put in place. Unclear if this was during the survey period. No other co-interventions reported.</p> <p><b>Additional comments:</b> The author states that due to participants' low educational levels interviewers and interpreters had to help answer questions. No table summary of participant characteristics. No discussion of potential confounding factors. Cessation not defined.</p>	<p><b>Length of follow-up:</b> 6-12 months</p> <p><b>Outcome assessment:</b> Respondent</p> <p><b>Type of analysis used (ITT versus per protocol or mixture):</b> NA</p> <p><b>Relevant outcomes</b> <b>Smoking prevalence rates:</b> NA</p> <p><b>Uptake of smoking:</b> NA</p> <p><b>Cessation rates:</b> <b>Before new HWLs: 23.5%</b> <b>After new HWLs: 21.8%</b> '3.8% stopped smoking after seeing the New-HWL'. (p. 551) 'Of the employees who quit cigarette smoking after seeing the HWL, 2.3% of them quit in response to the Ex-HWL and 2.8% after seeing the New-HWL.' (p.554)</p>

<b>Domain</b>	<b>Decision</b>	<b>Comments</b>
<b>Sample selection</b>	-	A systematic sampling frame was developed that ensured a proportional number of employees would be sampled from each region (North, Northeast, South, Central and Bangkok).
<b>Inclusion criteria</b>	+	
<b>Confounding factors</b>	-	New warnings were introduced during one of the survey years, but not discussed in the paper. Confounding factors were not adequately discussed.
<b>Objective outcome assessment</b>	-	Self report (rather than biochemically assessed) and interviewers and interpreters in some instances required to help participants provide answers.
<b>Group descriptors</b>	NA	NA single cohort
<b>Follow-up</b>	+	10 months
<b>Withdrawals</b>	-	Large numbers of withdrawals (n=691), accounted for as lost to follow-up or incomplete questionnaires.
<b>Reliable measurement</b>	+	Interviewed by research assistants and translators also used, but training not mentioned.
<b>Statistical analysis</b>	-	Some unclear analysis and at least 1 error in outcomes reported.

## APPENDIX 4: Excluded studies

Table 8: Excluded studies (full references are given below)

Study	No relevant intervention	No relevant outcomes	Not primary research	Notes
AGB Spectrum research Ltd 1987		X		Opinion only
Borland et al 1997	X	X		HWL <30%; opinion only
Borland et al 2004				Not found
Borland et al 2009		X		Saliency and cognitive only
BRC Marketing & Social Research 2004		X		Opinion only
Cavana et al 2005	X	X		HWL size not varied; opinion only
Cotter et al 2008		X		Opinion only
Crane and MacLean 1996	X	X		HWL <30%; cognitive only
Cunningham 2009			X	Think-piece
Decima Research 2007	X	X		Warnings not on packets; opinion only
Environics Research Group 1999		X		Opinion only
Environics Research Group 2001		X		Consumption reduction, opinion and saliency only
Environics Research Group 2005a		X		Saliency and opinion only
Environics Research Group 2005b		X		Saliency and opinion only
Environics Research Group 2008a	X	X		No <50% alternative; cognitive, affective and opinion
Environics Research Group 2008b	X	X		No <50% alternative; cognitive, affective and opinion
Fayter et al 2008			X	Systematic review
Fong 2009			X	Review
Fong et al 2009a			X	Review
Fong et al 2009b				Not found
Fonseca Cardoso et al 2006	X			HWL only one type
Fonseca Cardoso et al 2006				Duplicate of above
Hammond 2008			X	Review
Hammond et al 2007		X		Saliency and cognitive only
Hammond et al 2006			X	Letter to editor
Hammond et al 2004a	X			HWL only one type (> 50%)
Hammond et al 2004b		X		Saliency, affective and consumption reduction only
Hammond et al 2003	X			HWL only one type (> 50%)
Hassan et al 2008	X	X		No ≥50% alternative; saliency, cognitive and consumption reduction only
Kalafatis et al 2004	X	X		HWL size not varied; opinion only
Kees et al 2006	X	X		No ≥50% alternative; affective and opinion only
Les Etudes des Marche Createc 2008a	X	X		No <50% alternative; cognitive, affective and opinion
Les Etudes des Marche Createc 2008b	X	X		No <50% alternative; cognitive, affective and opinion
Les Etudes des Marche Createc 2008c	X	X		No <50% alternative; cognitive, affective and opinion
Liefield 1999		X		Conjoint analysis only
Liefield 2000		X		Conjoint analysis only
Mahood 1995			X	Think piece
Mahood 1999			X	Think piece
Murphy 1980	X			HWL <30%
Nilsson 1999		X		Legibility and opinion only
O'Hegarty et al 2006		X		Opinion only
O'Hegarty et al 2007	X	X		HWL size not varied; opinion only
Ozkaya et al 2009	X			HWL size not varied
Portillo and Antonanzas 2002	X			HWL size not varied; opinion only
Senior 2000			X	Think piece
Thrasher et al 2007		X		Quit intention only
Van der Kemp 2007			X	Review
Willemson 2005	X	X		HWL only one type
Zatonski 1999	X			HWL only one type

## APPENDIX 5: List of excluded studies with full citation

AGB Spectrum Research Ltd. *Testing the positions of health warnings on cigarette packs; prepared for Health Promotion Programme, Department of Health, New Zealand [Internet]*. Auckland, New Zealand: AGB Spectrum Research Ltd, 1987 [cited 9.9.10]. 6p. Available from: <http://legacy.library.ucsf.edu/tid/lel70g00/pdf>

EXCLUDE: No relevant outcomes

Borland R. Tobacco health warnings and smoking-related cognitions and behaviours. *Addiction* 1997;11:1427-1435.

EXCLUDE: No relevant outcomes/interventions

Borland R, Lal A. Position of cigarette packs. Melbourne, Victoria, Australia: VicHealth Centre for Tobacco Control, 2004 Unpublished Report.

NOT FOUND

Borland R, Wilson N, Fong G, Hammond D, Cummings K, Yong H, et al. Impact of graphic and text warnings on cigarette packs: findings from four countries over five years. *Tob Control* 2009;18(5):358-364.

EXCLUDE: No relevant outcomes

BRC Marketing & Social Research. *Smoking health warnings study: optimising smoking health warnings. Stage 2: text, graphics, size and colour testing [Internet]*. Wellington, New Zealand: Ministry of Health, 2004 [cited 9.9.10]. Report No: BRC 2946 Available from:

[http://www.maorihealth.govt.nz/moh.nsf/pagescm/907/\\$File/smokinghealthwarnings2aug2004.pdf](http://www.maorihealth.govt.nz/moh.nsf/pagescm/907/$File/smokinghealthwarnings2aug2004.pdf)

EXCLUDE: No relevant outcomes

Cavana E, Fryer M, McMillen P, BRC Marketing & Social Research. *Smoking health warnings study. Stage 3: concept testing the impact of pictorial health warnings in helping people consider their smoking-related behaviour [Internet]*. Wellington, New Zealand: Ministry of Health, 2005 [cited 9.9.10]. Report No: BRC 3003 Available from:

[http://www.ndp.govt.nz/moh.nsf/pagescm/906/\\$File/smokinghealthwarnings3may2006.pdf](http://www.ndp.govt.nz/moh.nsf/pagescm/906/$File/smokinghealthwarnings3may2006.pdf)

EXCLUDE: No relevant outcomes/interventions

Cotter T, Perez D, Dessaix A, Crawford J, Denney J, Murphy M, et al. *NSW smokers' attitudes and beliefs: changes over three years [Internet]*. Sydney: Cancer Institute NSW, 2008 [cited 9.9.10]. 94p.

Available from: [http://www.cancerinstitute.org.au/cancer\\_inst/publications/pdfs/pm-2008-01\\_smoking-attitudes-and-beliefs.pdf](http://www.cancerinstitute.org.au/cancer_inst/publications/pdfs/pm-2008-01_smoking-attitudes-and-beliefs.pdf)

EXCLUDE: No relevant outcomes

Crane FG, MacLean VA. A consumer evaluation of health warning labels on cigarette packages in Canada. *Health Mark Q* 1996;13(3):47-57.

EXCLUDE: No relevant outcomes/interventions

Cunningham R. Gruesome photos on cigarette packages reduce tobacco use. *Bull World Health Organ* 2009;87(8):569.

EXCLUDE: Not primary research

Decima Research. *Testing bilingual health warning notices for Tobacco industry print advertising. Final report [Internet]*. Toronto: Health Canada, 2007 [cited 15.7.10]. 101p. Available from:

<http://www.tobaccolabels.ca/health/canada2007>

EXCLUDE: No relevant outcomes/interventions

Environics Research Group. *Canadian adult and youth opinions on the sizing of health warning messages; prepared for Health Canada [Internet]*. Toronto: Environics Research Group., 1999 [cited 9.9.10]. Report No: HC-003-155-9925 (Contract Number: H4097-9-0017/001/CB) Available from: <http://dsp-psd.pwgsc.gc.ca/Collection/H49-134-1999E.pdf>

EXCLUDE: No relevant outcomes

Environics Research Group. *Evaluation of new warnings on cigarette packages. Focus Canada 2001-3*. Toronto: Environics Research Group, 2001. 66p.

EXCLUDE: No relevant outcomes

Environics Research Group. *The health effects of tobacco and health warning messages on cigarette packages: survey of adults and adult smokers: Wave 9 surveys; prepared for Health Canada [Internet]*. Toronto: Environics Research Group, 2005 [cited 9.9.10]. Report No: HC-POR-04-19 (Contract Number: H4133-4-0536). 94p. Available from:

<http://www.tobaccolabels.ca/health/canad~8>

EXCLUDE: No relevant outcomes

Environics Research Group. *The health effects of tobacco and health warning messages on cigarette packages: survey of youth: Wave 9 surveys; prepared for Health Canada [Internet]*. Toronto: Environics Research Group, 2005 [cited 9.9.10]. Report No: HC-POR-04-19 (Contract Number: H4133-4-0536). 97p. Available from: <http://www.tobaccolabels.ca/health/canad~10>

EXCLUDE: No relevant outcomes

Environics Research Group. *Consumer research on the size of health warning messages - quantitative study of canadian adult smokers; prepared for Health Canada [Internet]*. Toronto: Environics Research Group, 2008 [cited 15.7.10]. Report No: HC-POR-07-46 (Contract Number: H4133-071119/001/CY). 1-147p. Available from: <http://epe.lac-bac.gc.ca/100/200/301/pwgsc-tpsgc/por-ef/health/2008/245-07-a-e/report.pdf>

EXCLUDE: No relevant intervention

Environics Research Group. *Consumer research on the size of health warning messages - quantitative study of canadian youth [Internet]*. Toronto: Health Canada, 2008 [cited 15.7.10]. Report No: HC-POR-07-46 (Contract Number: HC4133-071119/001/CY). 160p. Available from:

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EXCLUDE: No relevant intervention

## APPENDIX 6: Contacts with Researchers

### Respondents who supplied information or material

Supplied by	Material	Comment
Pimpan Silpasuwan	Replied to email query placed 31/8/2010 about the size of the old HWLs in their study. The author stated that the old HWLs were 20% or less of principal display areas.	<b>INCLUDE:</b> We decided to include this paper as several other sources indicated that during the timeframe of the study Thailand was moving from tobacco HWLs of 30% to 50% size.
Ben Toombs, Cragg Ross & Dawson	# 2279. Cragg, Ross & Dawson Ltd. <i>Health Warnings on Cigarette and tobacco packs: Report on research to inform European standardisation</i> . London: Hamilton House and Department of Health, 1990	<b>EXCLUDE: No relevant outcomes/intervention</b>
Witold Zatoński	# 2252. Zatoński W, Prezwoźniak K, Porebski M. The impact of enlarged pack health warnings on smoking behaviour and attitudes in Poland. In: <i>Proceedings of the Second European Conference on Tobacco or Health; 24-26 February 1999; Las Palmas, Spain Las Palmas. Uitgever, 1999.</i>	<b>EXCLUDE: No relevant outcomes/interventions</b>