

Protocol for Plain Tobacco Packaging: A Systematic Review

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5th August 2011

Review Protocol

1. INTRODUCTION

The aim of this systematic review is to locate, assess and synthesise the published and grey literature relating to ‘plain’ tobacco packaging and the public health benefits that such a measure might have. Plain packaging will be the term used throughout the review to refer to the standardisation of pack colour and removal of all branding from packaging, with the exception of brand name which appears in a standardised font, typeface and position on the package. Some definitions of plain packaging are more explicit, and also cover the standardisation of pack shape, size and method of opening. In all definitions, however, relevant legal markings, such as health warnings and tax stamps, are retained. This review will consider the existing literature on plain packaging and assess in what ways, if any, this could benefit public health. This review will not consider the potential public health benefits of non-packaging related tobacco measures, nor will it consider the economic, legal or trade implications of plain packaging or any impact that plain packaging might have on the illicit trade of tobacco products.

2. BACKGROUND

2.1 The Marketing of Tobacco

Most governments now have at least some form of restrictions on how tobacco products are marketed. Indeed, as of 2009, 26 countries were considered to have complete bans on all forms of direct and indirect advertising and marketing (World Health Organisation: WHO, 2009). This has failed to prevent tobacco companies from marketing their products however, for two main reasons; 1) two-thirds (17) of the 26 countries with complete marketing bans fail to enforce these measures effectively, and 2) the complete marketing bans described do not include forms of marketing such as branded packaging and should therefore be more appropriately termed comprehensive, rather than complete, bans. Resultantly, the tobacco industry has been able to adapt to the loss of mainstream marketing channels by reallocating resource to packaging. Indeed, in countries with highly restricted marketing environments, or ‘dark markets’, tobacco packaging is now considered to be a key marketing driver (Freeman, Chapman & Rimmer, 2008). It appears, therefore, that packaging, one of the first marketing tools used to promote tobacco (Thibodeau & Martin, 2000), is now one of the last. As with other consumer products, packaging for tobacco products can be used to promote the product (via pack design, innovation, price-marking, and environmentally friendly or ‘green’

packaging), link to and reinforce other marketing activities, and influence consumer choice through pack colour and other design elements.

2.2 The Possible Use of Plain Packaging for Tobacco Products

Packaging was termed the ‘silent salesman’ fifty years ago to highlight that it has a marketing function at the point-of-sale (Pilditch, 1961). By the 1970s packaging was being increasingly recognised as an important and multifunctional marketing tool within the wider marketing literature. Within public health the importance of packaging for tobacco products was also beginning to be recognised, with the possible use of plain brown wrappers for tobacco products first suggested by Canadian doctors, in the mid-1980s, who argued that harmful products such as tobacco should not be allowed to be ‘dressed up’ (Lee, 1986). In terms of harm, the scientific evidence has established beyond any doubt that exposure to tobacco smoke causes death, disease and disability, with tobacco estimated to kill in excess of 5 million people a year globally, with 650,000 of these deaths in the European Union and approximately 80,000 in England (World Health Organisation, 2009; Aspect Consortium, 2004; HM Government, 2011).

2.3 Plain Packaging – The Policy Context

In 1989, the New Zealand Department of Health’s Toxic Substance Board recommended that cigarettes be sold in white packs with simple black and white text and no colours or logos. Following on from this, in 1992, the Australian Ministerial Council on Drug Strategy requested a report on plain packaging, and in 1994 the Canadian House of Commons Standing Committee on Health opened hearings on plain packaging. By the second half of the 1990s plain packaging was no longer on the policy agenda in these countries as policy attention instead turned to other elements of packaging, specifically health warnings and pack descriptors such as ‘Light’ and ‘Mild’.

It was not until the second half of the 2000s that plain packaging was seriously discussed again in a policy context. In 2007 the European Commission considered plain packaging as a possible policy option in the second report on the application of the current Tobacco Products Directive (2001/37/EC), stating that *‘in order to decrease the smoking initiation and to protect EU consumers on equal basis in all Member States the introduction of generic (black & white) standardised packaging for all tobacco products could be explored as a possibility to reduce the attractiveness’* (European Commission, 2007). In 2008, France placed plain packaging on the agenda at EU level during its Presidency of the EU, and the Department of Health in the UK alluded to plain packaging in a consultation on the future of tobacco control. The following year the Finnish Minister of Health and Social Services Paula Risikko recommended to then Commissioner for Health Androulla Vassiliou to introduce plain packaging at EU level, and in Australia Senator Fielding tabled a private Members bill that would involve the plain packaging of tobacco products. In 2010 the European Commission consulted on the possible revision of the current Tobacco Products Directive, including plain packaging, which was again mentioned in the UK with the Government’s ‘Comprehensive tobacco control strategy for England’ (HM Government, 2010), and the Australian Government announced its plan to introduce plain packaging from 2012 (Australian Government, 2010). Also in 2010, the report of the Māori Affairs Committee to the House of

Representatives in New Zealand recommended implementing plain packaging in 2012, at the same time as is planned in Australia (Report of the Māori Affairs Committee, 2010).

In 2011 policy interest in plain packaging has continued. For instance, MP Catherine Fonck tabled a bill in the Belgium House of Representatives in April that would amend existing legislation on the protection of consumer health with respect to food and other products, and see plain tobacco packaging introduced from January 2013. Most important to this review, however, is the Tobacco Control Plan set out by the UK Government in March 2011 (HM Government, 2011). The Tobacco Control Plan explains the need for a multi-faceted and comprehensive approach to tobacco control which includes, among other things, ‘stopping the promotion of tobacco’. To prevent tobacco products being promoted to both youth and adults the UK Government are to consider four main areas; 1) the promotion of smoking accessories, 2) the role of the internet in promoting tobacco, 3) the portrayal of smoking in entertainment media, and 4) the promotional impact of tobacco packaging. For the last, one of the key actions identified in the Tobacco Control Plan is a consultation, by the end of 2011, on possible options to reduce the promotional impact of packaging, including plain packaging. We will help inform this debate by systematically reviewing the available research on plain packaging.

2.4 Plain Packaging – The Literature

In the late 1980s, a market research study described by Trachtenberg (1987) is believed to have been the first study (in the public domain) to assess consumer perceptions of the plain packaging of a particular brand of cigarettes. In the 1990s academics began to take a greater interest in plain packaging, with numerous studies published during the first half of this decade. Interest in the topic appeared to wane thereafter, coinciding with plain packaging dropping off the policy agenda in countries such as Australia, New Zealand and Canada. A brief review of the plain packaging literature suggests that it was not until the second half of the 2000s that there was a renewed academic interest in plain packaging (Moodie, Hastings & Ford, 2009), although this review, like others (e.g. International Union Against Lung and Tuberculosis Disease, 2009; Devinney, 2010; Hammond, 2010; Padilla & Watson, 2010), failed to adopt a systematic approach. Systematic review is becoming an increasingly popular evidence based research method in public health and helps make the results from studies using a heterogeneity of methodological approaches more accessible and usable (Bambra, 2011). The systematic review attempts to systematically identify both published and unpublished research and evaluate it, critically, on grounds of relevancy and predetermined methodological inclusion criteria. Doing so provides the ‘best available evidence’ for the question under investigation (Higgins & Green, 2008).

2.5 Objectives

The guidelines for the implementation of Article 11 of the Framework Convention on Tobacco Control (FCTC), adopted at the third Conference of Parties to the FCTC, suggests there are three ways in which plain packaging might be expected to deliver public health benefits: 1) increasing the noticeability and effectiveness of health warnings and messages, 2) preventing the package from detracting attention from health warnings, and 3) addressing industry package design techniques that may suggest that some products are less harmful than others (WHO, 2008a). It is difficult to separate the first two of these proposed benefits as

increasing the noticeability of health warnings on the pack, a necessary precursor to effectiveness given that warnings that cannot be seen cannot be effective, is dependent upon preventing the ‘pack’, including branding and also structural design (e.g. shape, size and method of opening), from detracting attention from the health warnings in the first place, ie. making them less noticeable. The guidelines for the implementation of Article 13 of the FCTC also recommend plain packaging to eliminate the effect of advertising and promotion on packaging and also the product; ‘there should be no advertising or promotion inside or attached to the package or on individual cigarettes or other tobacco products’ (WHO, 2008b, p7).

The FCTC suggests, therefore, that there are three distinct ways in which plain packaging might be expected to deliver health benefits:

- 1) By making health warnings more prominent and therefore stronger
- 2) By preventing the use of pack colour and other elements of pack design that might mislead consumers and potential consumers about the dangers of smoking
- 3) By reducing the promotional power of the pack and the product

The aim of the study is to conduct a systematic review of the evidence of the impacts of plain tobacco packaging. The purpose is to help inform DH policy in this area.

2.6 Review Questions

The review questions are predicated upon the proposed benefits of plain packaging according to the FCTC. We propose that the study research questions will include:

1. What effect, if any, does plain packaging have on:
 - the salience and effectiveness of health warnings;
 - the appeal of packaging or product;
 - perceptions of product strength and harm?

We will also consider other potential benefits of plain packaging beyond those identified by the FCTC, and also any disbenefits of plain packaging. As such, a further research question will be:

2. Are there any other potential benefits of plain packaging not identified by the FCTC, or any disbenefits to plain packaging, and what are these?

Because a marked socio-economic differential exists in respect to smoking prevalence in the UK, and smoking prevalence has been declining at a slower rate for females than for males in the last five or so years (Office for National Statistics, 2011), a further research question will examine any differential effects of the above on different population sub-groups:

3. How do effects for all the above vary by gender, age, socio-economic status and ethnicity?

Finally, the review will also examine evidence about the factors which may assist, reduce or impede the impact of plain packaging. These may include aspects of the policy and economic environment; public, policymaker and stakeholder understanding of and attitudes towards

plain packaging as a policy measure; industry and retailer responses; and the presence or absence of related policies and interventions (for example, larger health warnings, legislation on point of sale display).

4. What are the facilitators and barriers to plain packaging having an impact?

3. METHODS

3.1 Criteria for Considering Studies for this Review

Types of literature

Published academic and grey literature (including theses and unpublished studies) in printed or electronic formats will be eligible for inclusion. Studies published since 1980 or later will be included. It is generally accepted that the first study relating to plain packaging was published in 1987 (Moodie et al., 2009; Hammond, 2010). This cut-off date will enable us to confirm this without retrieving too much irrelevant material from the search. The database searches will not be limited by language, although the search terms will all be in English. As a number of academic databases hold non-English language studies with English-translated titles and abstracts, consideration will be given to translating the full text of the study into English based on the (English language) information recorded in the bibliographic database.

Types of studies

The types of studies suitable for inclusion will be primary research, with human populations, exploring the plain packaging of tobacco products. For this review, ‘tobacco products’ include cigarettes, loose tobacco for hand-rolled cigarettes, cigars, cigarillos, pipe tobacco, kreteks, bidis (beedis), and also smokeless tobacco, which includes snuff and chewing tobacco; ‘packaging’ refers to the container (packet, pouch, tin) in which tobacco products are stored, but excludes the paper or leaves or other means of wrapping loose tobacco.

We do not currently propose to exclude studies based on the methods they employed (i.e. use a methodological filter), but will assess all relevant studies for their reliability and validity later in the review.

Types of participants

Human populations of all age groups will be eligible for inclusion.

Types of outcome measures

Relevant *outcomes* for the review questions concerned with the potential effects of plain packaging (research question 1) will include:

- Salience/prominence/seriousness/visibility/comprehension/understanding/believability of health warnings
- Attractiveness/appeal/desirability/value/judgements of packaging and the product
- Perceptions/understanding/awareness/judgements of product strength and harm
- Knowledge of tobacco harms, constituents, ingredients, brand knowledge
- Attitudes towards smoking
- Smoking-related intentions
- Product and packaging beliefs

- Brand attitudes and preferences
- Pack preferences

For research question 2 we have not suggested any relevant outcomes, but plan to include any benefits/disbenefits of plain packaging not addressed within the outcomes for research question 1. Relevant outcomes for review question 3 will be outcomes in all the above areas analysed by different population sub-groups. For review question 4, studies which explore the contextual factors that might impact on the effectiveness of plain packaging will be eligible for inclusion.

3.2 Search Strategy and Study Selection Procedure

Databases

The search strategy will include searches for studies in the academic and grey (unpublished) literature from generic and topic-specific electronic databases from the fields of health and addiction, public policy, business and marketing, social sciences and psychology.

Bibliographic databases:

- ABI INFORM
- ASSIA
- Business Source Premier
- Cochrane Library
- Conference Papers Index
- Conference Proceedings Citation Index- Social Science & Humanities
- EconLit
- EMBASE
- ERIC
- Health Promis
- HMIC
- Index to Theses (UK and Ireland)
- International Bibliography of the Social Sciences
- Pubmed
- Proquest Dissertation Abstracts
- PsycINFO
- Social Policy and Practice
- Social Policy Digest
- Sociological Abstracts
- TROPHI (Trials Register of Public Health Interventions)
- Social Science Citation Index
- Zetoc

Other catalogues and websites:

- Advertising education forum database
- British American Tobacco Documents Archive
- CDC Smoking and Health Resource Library
- Dart Europe (theses)
- ECDC: European Centre for Disease Prevention and Control

- Google Scholar
- Kings Fund Library
- Legacy Tobacco Documents Library
- OpenSIGLE (System for Information on Grey Literature in Europe)
- Social Science Research Network
- UK Tobacco Industry Advertising Documents Database
- tobaccopapers.com
- WHO: World Health Organisation
- World Advertising Research Center
- World Cat Library Catalogue
- A database of studies collected for a previous EPPI-Centre review on young people's access to tobacco

Google searches will also be run using selected search terms from the strategy.

The search strategy will be compiled with combinations of tobacco-related terms with packaging-related terms. We expect that this combination of 'tobacco' and 'plain packaging' terms will enable us to conduct a search that achieves good sensitivity without sacrificing so much specificity that the number of studies to screen becomes unmanageable. However, we will test different combinations of terms at the beginning of searching in order to optimise this strategy. The terms used in the search will be adapted in accordance with each database's search terminology. The terms will include (though will not be limited to) those listed in Appendix A.

The structure of the Boolean search will be critical to its efficient operation. All retrieved documents will be expected to contain 'tobacco' AND 'plain packaging' terms. In order to check the appropriateness and sensitivity of the above terms, a text mining analysis of a sample of documents that are identified as being relevant will be carried out using the National Centre for Text Mining's TerMine software. As is shown in Appendix B, this software is able to identify the key terms within a paper (or set of papers) and can suggest additional terms that might be included in the search strategy.

Tobacco industry document repositories are a challenging, but potentially useful source. They are challenging because they contain very large numbers of documents, sometimes in the millions, the vast majority of which are not research reports. We will therefore construct specific search strategies for these repositories, that enable us to identify relevant *research* documents from the vast number of documents which contain the correct topic terms, but do not report research findings.

Handsearching

The bibliographies from included studies will also be checked for further studies and citation trails, which check which papers have cited an included study, will be followed using Google Scholar, and the Web of Knowledge cited reference search.

Personal contact

Key individuals and organisations, identified through the search process above, will be contacted to identify further publications not retrieved in the searches. This will include, although not be limited to, persons who have previously conducted research on tobacco packaging, tobacco control experts, NGOs and non-academics who may have written on the topic, and those within the health and policy sectors in Australia (given plans to introduced

plain packaging in Australia in 2012). This will be done by the research team in Stirling, who will send a generic email to those identified by the EPPI-Centre from the review process and those known to have worked on tobacco packaging by the Stirling team.

3.3 Data Collection and Analysis

Storage

Search results will be imported into reference management database and duplicates will be removed. A record of the total number of included studies at each stage of the systematic review will be completed throughout the process, and the results will be summarised as a flow chart in the final report. Throughout the search, EPPI-Reviewer 4 software (<http://eppi.ioe.ac.uk/cms/Default.aspx?tabid=2914>) will be used retrieval, assessment, appraisal and data extraction (Thomas et al., 2010).

Selection of studies

There will be three phases of study selection. In the first phase, one researcher (from the EPPI-Centre) will sift through the citations retrieved electronically and exclude obviously irrelevant material (e.g. studies that are not about tobacco, packaging and/or do not include human subjects). In the second stage of study selection, two researchers (one in the EPPI-Centre and one in Stirling) will independently screen the titles and abstracts of the studies stored in the EPPI-Reviewer database against the inclusion criteria to identify potentially relevant studies. Potentially relevant studies identified at this stage will be obtained in full text. A minimum of two researchers will then independently screen the full text studies for relevance and eliminate any that do not meet the inclusion criteria. Remaining studies after the second screening stage will be included in the review. Any discrepancies in studies selected for inclusion will be resolved by discussion between the reviewers.

To be included in the review the studies should be:

- a) from or after 1980
- b) about human populations
- c) about tobacco
- d) about packaging
- e) primary research

Assessing the relevance and quality of studies

As a range of study designs is eligible for inclusion in the review, a number of different tools will be needed to assess relevance and quality. Drawing on existing quality measures for different research types a range of appropriate tools will be developed or used ‘off the shelf’ (e.g. the QATSO or Newcastle-Ottawa quality assessment scales for observational studies for systematic review (Wong et al., 2008; Deeks et al., 2003), the EPPI-Centre tool for assessing the quality of qualitative research (Rees et al., 2009)). Pairs of reviewers will independently assess each study and then meet to agree both the quality of the study and its usefulness in helping to answer the review question. The results of such assessments may result in further exclusions from the review or a form of ‘sensitivity analysis’ to see if research findings differ according to quality.

Included studies will be subject to independent quality assessment by two reviewers with any disagreements resolved by third reviewer. Quality criteria will assess outcome measures used, the applicability of statistical methods employed, whether the results have been unduly

influenced by the study design, other risks of bias, the degree to which these have been controlled or adjusted for in the analysis, and thoroughness of reporting.

Assessments of the strengths and weaknesses of the studies captured in the systematic review give an indication of the strength of evidence the SLR provides. In respect to quality appraisal, appropriate tools will be selected for appraising each study according to study design and methodological rigour. Selection of the appropriate tool for each study will be determined by the methods employed in the study and the potential bias that its use might have in the context of the review. We anticipate that the quality of studies available may vary between review questions (and sub-questions). This being the case, the answers we give to some questions may be more provisional than others, depending on the quality and quantity of the research we have available.

Data extraction

Data from all studies identified as meeting the inclusion criteria will be extracted into a standardised data extraction form, which will be developed after the study selection process in response to the type and quality of studies identified for inclusion. Study data to be extracted will include (but are not restricted to): general information (author, publication year, publication type, funding source); study characteristics (aims, objectives, design); study participant characteristics; any theoretical basis; study setting; outcome measures and results; and the outcome of the quality assessment process.

The objective will be to ensure that the tool we use captures all relevant information. Data extraction will be carried out by one researcher, from the EPPI-Centre which will then be checked independently by a second researcher, from Stirling. Any disagreements will be resolved by discussion between the researchers. Records of any amendments or corrections to the data extraction forms will be kept for reference as part of the EPPI-Reviewer database.

Synthesis

The methods of synthesis in a review of this type are likely to be comparatively complex. An earlier review on this topic (Moodie et al., 2009), found considerable heterogeneity in terms of study design, context, participants, etc, and we expect that it will not be appropriate to combine study findings statistically in a meta-analysis (though meta-analysis may be appropriate to combine specific homogenous sub-groups of studies). Our methods for synthesis will embrace a conceptual framework which will be informed by an introductory chapter to the review explaining the multi-functional role of packaging. We therefore propose to use *framework synthesis* as the primary method for synthesising study findings (Carroll et al., 2011; Oliver et al., 2008). The review's conceptual framework will be mapped out in detail in a coding structure that enables us to associate particular issues with studies. The synthesis then involves matching the findings of studies to particular parts of the framework. This process entails refining the framework, and confirming or refuting parts of it, as well as extending the framework and specifying the particular populations those specific parts of the framework does, or does not apply to. For example:

- Part of the framework may discuss the possibility that imagery on plain rather than branded cigarette packs might increase attention to health warnings. This would be encapsulated in the area of the framework entitled: "Increases the salience and effectiveness of health warnings" and be summarised as "Imagery distracts from health warnings".

- One included study might find that young people are more likely than others to take note of health warnings, and that plain packaging might affect this group more than others.
- This study would therefore be taken to confirm that part of the conceptual framework that suggests that imagery can distract from health warnings, but the framework would also be modified and extended to encapsulate the way in which young people are affected and the causal pathway that therefore applies in this case.

The close attention paid to the theory behind the causal pathways means that this synthesis has some commonalities with Realist Synthesis (Pawson, 2002). It will examine the context, mechanisms and outcomes of plain packaging, though without necessarily invoking a realist epistemology within the context of developing middle-range theory (Merton, 1968).

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Appendix A: Search Terms

Tobacco concept AND plain packaging, where:

<i>Tobacco</i>	
<i>Free text terms OR controlled terms where:</i>	
<i>Free text terms:</i>	<i>Controlled terms:</i>
cigar\$	(dependent on specific databases)
hand-roll\$	Tobacco products
HRT	Cigarettes
make-your-own	Tobacco industry
MYO	Smoking cessation
roll-your-own	Tobacco use
RYO	
smok\$	
Tobacco	
kretek	
bidis	
beedis	
Snuff	
chew\$	
gutk\$	
zarda	
pan mas\$	
paan	
Betel	
Beedi	
Bidi	
Rollie\$	
(nicotine)	

Plain Packaging		
(free text terms for packaging AND free text terms for plain) OR (controlled terms for plain packaging) where:		
	Free text terms:	Controlled terms:
Packaging	Pack\$ Container containers Carton Cartons Pouch Pouches Tin Tins Softpacks Hardpacks Hardpack Softpack Cans Canister canisters cardboard can plastic can	(dependent on specific databases) Brand names Brand Preferences Product packaging Product labelling Marketing (where a more specific term is absent)
Plain	dissuasive Generic Homogenous Plain standard, standardised, standardized Unbranded no-frills Neutral Plainer Plainest Unliveried Design Designs <i>Brand removal, terms (remove AND brand):</i> ((Remove OR removal OR absence OR restrict OR restricted OR restrictions OR outlaw OR outlawing OR ban OR bans OR prohibition OR prohibit) AND (descriptor OR descriptors OR trade mark OR trade marking OR trade marks OR trade marking OR graphic OR graphics OR graphical OR logo OR logos OR symbols OR symbol OR vignette OR vignettes OR brand OR brands branding OR liveried OR image OR images))	

Appendix B: TerMine Analysis

The following table contains the top 30 terms (as identified by TerMine¹) from Germain D, Wakefield MA, Durkin SJ (2010). Adolescents' Perceptions of Cigarette Brand Image: Does Plain Packaging Make a Difference? *Journal of Adolescent Health*;46:385-392.

Term	Score
plain pack	35
cigarette pack	19.6
positive pack characteristic	19.01955
health warning	19
pack condition	19
graphic health warning	14.264663
graphic health	10
plain packaging	9
tobacco industry	8.9
adolescent health	8
positive taste characteristic	7.924812
positive smoker	7
pack face	7
adult smoker	7
original pack	6
cigarette packaging	5
tob control	5
branded pack	5
plain cigarette pack	4.754888
pictorial health warning	4.754888
plainest pack	4
smoking experience	4
typical smoker	4
pack characteristic	4
health canada	4
nonsusceptible nonsmoker	4
cancer council victoria	3.754888
council victoria	3.714286
plain cigarette packaging	3.169925

¹ <http://www.nactem.ac.uk/software/termine/>