

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Impact of Australia's introduction of tobacco plain packs on adult smokers' pack-related perceptions and responses: Results from a continuous tracking survey
AUTHORS	Dunlop, Sally; Dobbins, Timothy; Young, Jane; Perez, Donna; Currow, David

VERSION 1 - REVIEW

REVIEWER	Dr Judith McCool University of Auckland, New Zealand.
REVIEW RETURNED	01-Jul-2014

GENERAL COMMENTS	<p>This paper is very well presented and as far as I can determine within the best.</p> <p>Overall the paper is offers a useful and timely contribution to the current debate on the value of introducing legislation to ensure all cigarettes and loose tobacco are sold in plain packets. Australia being the first country to take on the challenge presented by the tobacco industry is ideally placed to provide evidence on the impact of this transition. It is ideal also that the first study produced on the impact of this legislation is a large scale, prospective study with robust results. The paper was well presented with an appropriate level of detail from the rationale through to conclusion.</p> <p>Background – no changes suggested in this section. It is very coherent and provided a strong rationale for this research, stressing the distinctive offering from this research (as opposed to previous experimental studies) is the opportunity to use cross sectional data collected pre and post the introduction of plain packaging. The expectation that the introduction of the plain packaging will enhance the prominence and impact of the graphic warnings was noted. It was also important that the authors acknowledged previous work by Wakefield et al that identified a decline in the impact or salience of graphic warning labels over time.</p> <p>Methods</p> <p>The use of the CITTs is an exceptional opportunity to track changes over time in relation to legislative changes relevant to tobacco use. Again, evidently, it value has (and justification of cost?) has been justified as a unique opportunity to conduct the present study which will provide considerable support to justifying the benefits of plain packaging.</p> <p>The 40% response rate is, as acknowledged in the limitations section in the discussion, quite low. However, the overall sample size is compensatory. Overall, the methods are carefully described.</p> <p>Page 8, lines 12-18 long sentence.</p> <p>Page 9, lines 10-16 long sentence. Consider revising. Also, suggest re-state "pack perceptions".</p>
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	<p>Page 10, lines 3-5 – please clarify this statement.</p> <p>What are the authors thoughts on the impact of the plain packaging on younger smokers (below 18 years). Are there plans to monitor the impact on this age group? What might they expect to find?</p>
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REVIEWER	Angela Attwood University of Bristol, UK
REVIEW RETURNED	06-Aug-2014

GENERAL COMMENTS	<p>This is a cross-section survey of the effects of plain packaging (PP) legislation on smoker's responses to cigarette packs and health warnings. There are a number of strengths to this paper. First, it is timely given the debate regarding PP legislation around the world. The sample/sample size is OK (although subject to some biases that are acknowledged in paper), as is the statistical modelling of effects across time. There has been careful consideration of potential confounders such as advertising campaigns and good adjustment for these.</p> <p>Some points for consideration/response:</p> <p>The hypotheses are clearly defined and the methods adequate for testing. However, the questions themselves are limited in scope. It is relatively unsurprising for example that smokers find PP less attractive. Some indication of whether smoking behaviour/subjective experience had changed would have been better. This limits the impact of an otherwise well written and informative paper.</p> <p>The time series analysis indicates that PP "reversed a downward trend" in responsiveness to health warnings. However, it is not discussed whether a similar trend would be expected over time with PP, given the post-intervention timeframe that is assessed here is still relatively short.</p> <p>Due to the distributions, data were collapsed into binary variables - more information on distribution should be provided.</p> <p>Light smokers are defined as smoking less than 10 per day. Non-daily smokers (or "chippers") have been shown to be a different type of smoker on a number of outcomes and therefore should be considered as a separate group. Did the authors consider this and if so show any difference between non-daily and light daily smokers.</p> <p>The survey was restricted to smokers and therefore smokers who quit post-intervention would be lost in the latter assessments. This is also worthy of comment. It may actually strengthen the interpretation in that those who continue to smoke may be more resistant to the intervention, thereby providing more conservative estimates.</p> <p>The statistical plan and implementation of the analysis looks solid. However, I am not an expert in this type of analysis and therefore the Editor may want to consider specialist opinion on this.</p>
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REVIEWER	Jim Thrasher University of South Carolina, USA &
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	National Institute of Public Health, Mexico
REVIEW RETURNED	12-Aug-2014

GENERAL COMMENTS	<p>This is a well-written manuscript that evaluates the innovative policy of plain packaging to address important public health issue of smoking. Many researchers and government officials around the world await the evaluation of this policy, and this study provides important information regarding its effectiveness. I have only a few relatively minor questions and concerns that could be addressed to improve and already excellent manuscript.</p> <p>Methods: Page 11, line 47-56: For the logistic regression models, concerns about inflated SE are raised, with elimination of cigarette cost as the solution. In the limitations section of the discussion, can you revisit this issue? Can you reassure the reader that taxes were not implemented during the period of time when the policy was implemented (i.e., window of time analyzed in the regression models)?</p> <p>Page 12, line 3. Please clarify how the weights were constructed. Was the known population profile of smokers from NSW used to calculate weights that made the sample similar to this broader population? What characteristics were used to create the weights: age, sex, and region? What is meant by regional residents? Were these weights used in the ARIMA analyses? Or just the logistic regression analyses?</p> <p>Discussion: Page 17, lines 255-28: The authors allude to the issue of sustainability. They should probably point out that the 8 month post implementation assessment was their last data collection timepoint. Future research could address whether plain packaging inhibits wearout of warning label responses. Furthermore, the authors may consider the limitation of not assessing quit behavior, and public health impacts will require behavioral effects. They could refer to other research that has shown that responses to warnings, which are like those that they have assessed, translate into downstream cessation behaviors. Finally, the effects of this policy may be strongest when considering youth initiation, and policy effects may take longer to manifest this this population.</p> <p>Page 17, line 52 – page 18, line 12: The issue of the sampling frame (landline phones) is raised, pointing to recent research on the % of mobile only homes. What kind of bias might be introduced by leaving this population out of the sampling frame? Are they higher SES populations that are less likely to smoke anyway? Vice versa? Later in that paragraph, the authors mention that “both of these sampling issues were consistent across the study period.” Do they really mean that the % of mobile only homes was the same over this period of time? This seems unlikely. They may be referring to quit rates and response rates. If so this, should be clarified.</p> <p>More minor points: Introduction: Page 5, line 9. Is “quantity” equivalent to “number of cigarettes”?</p> <p>Methods: Page 9, line 3: is this “ever” tried to quit? Clarify. Also, it would be</p>
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	useful to include this in the sample description provided on Table 1.
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REVIEWER	Avinesh Pillai Department of Statistics University of Auckland New Zealand
REVIEW RETURNED	12-Sep-2014

GENERAL COMMENTS	A clearly written paper, with the analyses described and presented well. It is reassuring that a reference for the time series analyses and diagnostics was provided. Could a reference please be included for the logistics regression analyses and diagnostics?
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VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

1. Page 8, lines 12-18 long sentence.

- This sentence has been removed from the revised manuscript.

2. Page 9, lines 10-16 long sentence. Consider revising. Also, suggest re-state “pack perceptions”.

- We have changed this sentence to read: “Respondents’ pack perceptions and responses to health warnings might also possibly be influenced by the timing of their interview in terms of variations in anti-smoking advertising activity, changes in the costliness of cigarettes, or shifting social norms”. (p. 10)

3. Page 10, lines 3-5 – please clarify this statement.

- This sentence has been changed to “The influence of changing social norms was accounted for by statistically accounting for a time-based trend in the data, described below” in order to direct the reader to the Statistical Analysis section for more details. (p. 11)

4. What are the authors’ thoughts on the impact of the plain packaging on younger smokers (below 18 years)? Are there plans to monitor the impact on this age group? What might they expect to find?

- It is expected that plain packaging will have its greatest impact on youth, in that they will grow up in a world without tobacco branding, therefore contributing to the de-glamorising and de-normalisation of smoking. There are researchers in Australia monitoring this group, and we look forward to reading their research when it is published. We have added a sentence to the Discussion section (p. 21): “Future research should extend this study by... investigating whether the introductory effects identified in this study were apparent in youth smokers, and monitoring the impact of plain packaging on perceptions about smoking among non-smoking youth”.

Reviewer: 2

1. The hypotheses are clearly defined and the methods adequate for testing. However, the questions themselves are limited in scope. It is relatively unsurprising for example that smokers find PP less attractive. Some indication of whether smoking behaviour/subjective experience had changed would have been better. This limits the impact of an otherwise well written and informative paper.

- Firstly, we would also like to emphasise that the outcomes explored in this paper are closely linked to the objectives of the legislation, which should be the first step in evaluating this policy (as stated on p. 16: “This is an important first step in evaluating the policy as these outcomes relate closely to the intended purpose of the legislation”). The primary purpose of the plain packaging legislation was not to get adult smokers to quit, and we argue that the success of the intervention should not be judged on that criterion. The purpose of the policy was to make health warnings more salient and effective (in

order to educate smokers and non-smokers about the risks of smoking), to reduce promotional strategies that mislead consumers as to the relative risks of products, and to reduce the appeal of tobacco (with the aim to reduce smoking uptake among young people). The impact of these plain packaging effects on smoking rates are likely to be seen over a longer time-period than that of this study.

- Secondly, though this paper does not include any measures of quitting, we note in the Discussion section, how the outcomes included in this study are likely to relate to cessation (p. 17-18).
- We have also added a sentence to the Discussion section outlining some ideas for future research (p. 21): "Future research should extend this study by considering any relationships between smokers' responses to their plain packaging packs and changes in smoking behaviours, investigating whether the introductory effects identified in this study were apparent in youth smokers, and monitoring the impact of plain packaging on perceptions about smoking among non-smoking youth and adults."

2. The time series analysis indicates that PP "reversed a downward trend" in responsiveness to health warnings. However, it is not discussed whether a similar trend would be expected over time with PP, given the post-intervention timeframe that is assessed here is still relatively short.

- Though we are not able to explore this question with the current data, we feel that the downward trend is likely to re-emerge. It is likely that health warnings need to be refreshed often in order to maintain their impact. We have added a sentence to p. 17 urging future research to explore this question, "Future research should assess whether the downward trend in responses to health warnings resumes following the introductory period of plain packaging."

3. Due to the distributions, data were collapsed into binary variables - more information on distribution should be provided.

- We would like to thank the reviewer for this comment. In light of this point, we decided to include the full range of responses for each of the outcomes, and we present these responses over the time periods included in the regression analyses in two supplementary files (to be included online).
- As outlined in the introduction to this response, upon further inspection of the distributions, it was apparent that, for the items assessing responses to graphic health warnings, there were variations in the 'strongly agree', 'agree', 'disagree', and 'strongly disagree' responses over the plain packaging (PP) period. We therefore decided to include an analysis that assessed changes in overall sentiment for these responses, along with the original analysis which assessed changes in the proportion of smokers strongly agreeing with each statement. Rather than assessing changes in each response (strongly agree, agree, etc.) for every statement, and given that treating individual Likert-type items as continuous is inappropriate, we constructed an overall 'Graphic Health Warning impact' scale which was the average of responses to the four items (with strongly disagree=1, disagree=2, neither agree/disagree=3, agree=4, strongly agree=5). More details on the scale are included in the paper (p. 8-9): "Responses to these items were used in two ways. The first was collapsing responses to each into a binary variable indicating strong agreement vs. other. The second was averaging the responses to these items to create a scale indicating 'Graphic Health Warning Impact', with higher scores indicating greater overall impact (Cronbach's alpha =0.70)."
- In the same way, we also constructed a scale indicating 'Negative Pack Perceptions', (p. 9): "Responses to each item were dichotomised into strongly disagree vs. other, and they were also reverse scored and averaged to create a scale indicating 'Negative Pack Perceptions' (Cronbach's alpha=0.87), with higher scores indicating more negative perceptions." This scale replaces the 'negative pack perception index' in the original manuscript.
- For each of these scales, we used the same analysis strategy to assess changes in these outcomes as we did for the individual outcomes in the original paper. That is, we first provide an interrupted time-series analysis assessing changes in the mean score, with the same set of control variables as in the time-series analyses for the individual items. Then we provide multiple linear regression analyses assessing changes in the mean of the scales over the pp-period, as well as the comparison period in the prior year, using the same set of covariates included in the logistic regression models in

the original paper.

- These changes are outlined in the Outcome Measures section (p.8-9), the Statistical Analysis Section (p. 12-13), and the Results Section (p. 15-16). Figure 3 and Table 3 present the results from these new analyses.
- We have removed the original logistic regression analyses (Table 3) from the manuscript, as we feel they are largely redundant with the new linear regression models.
- We note that while these additional analyses make the best use of all the available data, the results from these analyses do not change the implications or conclusions of the paper.

4. Light smokers are defined as smoking less than 10 per day. Non-daily smokers (or "chippers") have been shown to be a different type of smoker on a number of outcomes and therefore should be considered as a separate group. Did the authors consider this and if so show any difference between non-daily and light daily smokers.

- We thank the reviewer for this comment, and we have included smoking frequency (daily, weekly, less than weekly) as a covariate (p. 10). We note that, while we control for level of smoking and smoking frequency in the regression analyses, we did not do any subgroup analyses, and so all results are for the full sample of smokers.

5. The survey was restricted to smokers and therefore smokers who quit post-intervention would be lost in the latter assessments. This is also worthy of comment. It may actually strengthen the interpretation in that those who continue to smoke may be more resistant to the intervention, thereby providing more conservative estimates.

- Thank you for this suggestion, we have added the following to the Discussion section: "We note that the sample for this study consisted of current smokers only, and therefore any smokers who quit in the post-plain packaging period would not be included. This might have resulted in a sample of smokers somewhat resistant to this intervention, and as such, the estimates provided in this study might be more conservative than if we had also surveyed smokers who quit during this time." (p. 19)

Reviewer: 3

1. Page 11, line 47-56: For the logistic regression models, concerns about inflated SE are raised, with elimination of cigarette cost as the solution. In the limitations section of the discussion, can you revisit this issue? Can you reassure the reader that taxes were not implemented during the period of time when the policy was implemented (i.e., window of time analyzed in the regression models)?

- We have removed the logistic regression analyses, but this comment is now relevant to the multiple linear regression models.
- In light of this comment, we decided to include a variable indicating increase in cigarette costliness in the previous 12 weeks, as a percentage of current costliness (p 13). This overcame the issue with inflated SE, and we feel this creates a more complete model.

2. Page 12, line 3. Please clarify how the weights were constructed. Was the known population profile of smokers from NSW used to calculate weights that made the sample similar to this broader population? What characteristics were used to create the weights: age, sex, and region? What is meant by regional residents? Were these weights used in the ARIMA analyses? Or just the logistic regression analyses?

- Weights were used to make this sample similar to the broader population of NSW residents. The characteristics used to create the weights were age, sex, and region of residence. The weights were only used in the regression analyses. The description of weighting has been changed to: "Due to a slight over-representation in the CITTs sample of females, older respondents, and regional residents (living outside of the capital city) compared to the NSW population, weights were constructed using age, sex, and region of residence to make the sample more similar to the NSW population. Weights were applied in all regression analyses (using svy commands with 'p' weights)." (p. 13)

3. Page 17, lines 255-28: The authors allude to the issue of sustainability. They should probably point

out that the 8 month post implementation assessment was their last data collection time-point. Future research could address whether plain packaging inhibits wear-out of warning label responses.

- We have added a sentence urging future research to explore this question, “Future research should assess whether the downward trend in responses to health warnings resumes following the introductory period of plain packaging.” (p. 17)

4. Furthermore, the authors may consider the limitation of not assessing quit behavior, and public health impacts will require behavioral effects. They could refer to other research that has shown that responses to warnings, which are like those that they have assessed, translate into downstream cessation behaviors.

- In the Discussion section, we have noted how the outcomes included in this study are likely to relate to cessation or smoking behaviour: “Importantly, the impact of graphic health warnings on smoking behaviours appears to be a function of the depth of smokers’ cognitive processing of and responses to the warnings (such as those monitored in the current study),³⁴⁻³⁶ suggesting that if plain packaging can intensify smokers’ responses to warnings, flow-on effects on consumption and quitting are likely.” (p. 17) And: “Notably, changes in the way smokers perceive their pack have the potential to augment smokers’ subjective experience of smoking, leading to a more negative perception of the taste of their cigarettes and less enjoyment in the act of smoking... The likely impact of changes in the perceived experience of smoking is an avenue for future studies, but research identifying enjoyment of smoking as a barrier to quitting suggests that smokers who find smoking their less enjoyable might be more likely to try and quit.⁴⁴”(p. 18).

- Further, as noted above (in response to Reviewer 2), we also emphasise that the outcomes explored in this paper are closely linked to the objectives of the legislation, which should be the first step in evaluating this policy. The impact of plain packaging effects on smoking rates are likely to be seen over a longer-time period than that of this study.

5. Finally, the effects of this policy may be strongest when considering youth initiation, and policy effects may take longer to manifest in this population.

- We also agree that the effects of this policy are likely to be strongest in youth, as noted above in response to Reviewer 2, and included in our final sentence of the Discussion section (p. 21).

6. Page 17, line 52 – page 18, line 12: The issue of the sampling frame (landline phones) is raised, pointing to recent research on the % of mobile only homes. What kind of bias might be introduced by leaving this population out of the sampling frame? Are they higher SES populations that are less likely to smoke anyway? Vice versa? Later in that paragraph, the authors mention that “both of these sampling issues were consistent across the study period.” Do they really mean that the % of mobile only homes was the same over this period of time? This seems unlikely. They may be referring to quit rates and response rates. If so this, should be clarified.

- We have made some substantial changes to this paragraph, which now reads (p. 20):

“The rate of mobile-only households in Australia, recently estimated at 19%, increased over the years of this study.⁴⁶ Recent dual-frame surveys have shown that samples recruited via mobile-phone are more likely to include younger respondents and males than landline samples.⁴⁷ The impact of these demographic differences are likely to be reduced in the current study due to the inclusion of age and gender as covariates, the use of data weighted for these variables where appropriate, and the inclusion of smoking-related covariates that might be related to these demographic characteristics. The response rate of CITTs is similar to that of other population telephone surveys on tobacco use in Australia,⁴⁸ and was consistent across the study period, limiting its influence on the observed pattern of results.”

- We note that we have not found any evidence that Australian mobile-phone only households are higher or lower SES.

7. Page 5, line 9. Is “quantity” equivalent to “number of cigarettes”?

- Yes, this refers to the number of cigarettes in the pack, changed in the text (p. 6).

8. Page 9, line 3: is this “ever” tried to quit? Clarify. Also, it would be useful to include this in the sample description provided on Table 1.

- We have clarified this in the paper as ‘1=tried to quit in the last 12 months; 0=did not’ (p. 9). And we have added this to Table 1.

Reviewer: 4

1. Could a reference please be included for the logistics regression analyses and diagnostics?

- We have now removed the logistic regression analyses, using multiple linear regression models instead to assess changes in the mean score of the GHW impact and negative pack perception scales. We have included a reference for these analyses (p. 12).

We thank you once again for the thorough reviews of this manuscript and would be happy to respond to any further queries you have.

VERSION 2 – REVIEW

REVIEWER	Judith McCool University of Auckland, New Zealand.
REVIEW RETURNED	21-Nov-2014

GENERAL COMMENTS	A thoroughly well presented paper that will add value to the current debate on the impacts associated with implementing mandatory plain packaging. An interrupted, time-series data-set such as that presented in this paper adds new weight to the experimental, naturalistic and theoretical and qualitative smaller-scale work. This version has been sufficiently revised according to recommendations.
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REVIEWER	Angela Attwood University of Bristol United Kingdom
REVIEW RETURNED	17-Nov-2014

GENERAL COMMENTS	The authors have responded well to the comments.
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