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Title	Impact of Canadian tobacco packaging on quitline utilization: an interrupted time series analysis of call volume and new callers
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Reviewer 1	Dr. Steve Kisely
Institution	Queensland Centre for Health Data Services, Brisbane, Australia
General comments and author response	<p>Comments to the Author</p> <p>The analyses are appropriate & they followed STROBE guidelines although in the checklist it would have been helpful if they had indicated where in the paper they had addressed the criteria rather than just ticking the box.</p> <p>Authors' response</p> <p>We have updated the STROBE table and have indicated where in our paper we have addressed each of the criteria where applicable.</p> <p>Comments to the Author</p> <p>The main limitation is that these data are nearly two years old and Figure 2 indicates that by December 2013, monthly call volumes were back down to pre-intervention levels - this is masked by presenting aggregate data over several months. In addition, the relationship between the two interventions (Driven to Quit & the warning labels) is unclear. In Figure 2, the January effect in 2012 is as strong as the increase in January 2013 which appears to coincide with the 'Driven to Quit' programme. It's thus unclear which contributed to the increase. In January 2013, the increase in calls is much smaller than in the previous two years.</p> <p>Another interpretation of these data to that proposed by the authors is therefore that:</p> <ol style="list-style-type: none"> It's impossible to tell whether the Driven to Quit programme increased calls as it coincided with the beginning of the year and the January effect The health warning labels were associated with a temporary increase in calls that had returned to pre-intervention levels by December 2013 as smokers became increasingly "immune" to their effect The health warning labels brought forward calls from people following the intervention who would have contacted the helpline anyway as a result of the January effect. <p>1 - The only way of establishing which explanation is correct is the addition of data from 2014 & 2015 that would indicate the size of subsequent January effects and whether the falls in call numbers from September to December 2013 were a blip or a harbinger of a return to pre-label quitline calls.</p> <p>Authors' response</p> <p>We have inserted the following sentence in the Interpretation " Future research should determine whether the increase in call volume is sustained over longer periods and ... " highlighting the need for future research to determine whether the increase is sustained over longer periods. Our analyses are based on a dataset with 48 months of observations (26 before and 22 after the intervention) and is more than adequate for ARIMA. Further, there was no Driven-to-quit intervention in 2013 so it is possible to separate out the effect of Driven-to-quit from the January effect as the methods describe and the time series shows.. Lastly, it is incorrect for the reviewer to state that " ... by December 2013, monthly call volumes were back down to pre-intervention levels ...". The raw data for call volume and new callers demonstrates that there are 26% more callers in Dec 2013 compared to Dec 2011 and 51% more callers receiving treatment.</p> <p>Call Volume New Callers</p> <p>Dec 2010 615 96</p> <p>Dec 2011 628 93</p> <p>Dec 2012 982 204</p> <p>Dec 2013 792 140</p> <p>2 - A second limitation that deserves more prominence is that quitline calls don't necessarily translate into successful smoking cessation.</p> <p>Authors' response</p>

	<p>It is true that not everyone who calls a quitline successfully quits smoking. We have indicated in the paper that quitlines are an effective population health intervention for quitting smoking based upon the latest Cochrane review. Further, the U.S. Department of Health and Human Services Clinical Practice Guidelines support the effectiveness of quitlines for quitting smoking and we have added a reference to these guidelines. The randomized trials that are a part of these reviews have large sample sizes as compared to the research literature, for example, on Nicotine Replacement Therapy. Further, NRT studies are predominantly efficacy trials set in ideal conditions whereas the trials on quitlines are effectiveness studies delivered under typically real-world quitline conditions to large numbers of smokers. Quitlines, as a population-based intervention, have larger reach than other quit smoking interventions. The systematic reviews of quitline interventions demonstrate comparable results to Nicotine Replacement Therapy and we inserted an additional reference that summarizes the success of quitlines and smoking cessation.</p>
Reviewer 2	Mr. David Boisclair
Institution	UQAM, Chaire de recherche Industrielle Alliance sur les enjeux économiques des changements démographiques, Montréal, Que.
General comments and author response	<p>General comments</p> <ol style="list-style-type: none"> 1. The article generally complies with scientific standards and with applicable guidelines. 2. The article adds to the literature on quitlines, an important tool for tobacco use cessation. 3. The paper is carefully written and generally reads very well. <p>Authors' response</p> <p>We thank the reviewer for the positive comment and have addressed remaining concerns below.</p> <p>Comments to the Author</p> <ol style="list-style-type: none"> 4. To the uninformed reader, it is not clear throughout the paper whether it is the Ontario SHL's number that appeared on the new packaging or another quitline number. This must be made very clear, probably in the introduction. <ol style="list-style-type: none"> a. If it is not the SHL's number appearing, authors should explain why they are not using data from the quitline whose number appears on the packs. b. If it is the SHL's number appearing, authors should A) explain how it is possible to have a province-wide only phone number appearing on country-wide packaging; and B) why they do not carry out their analysis by comparing quitline outcomes in Ontario with those of other provinces. <p>Authors' response</p> <p>The number on the new tobacco packages is a pan-Canadian toll-free number and once called the caller is automatically sent to the quitline service of their respective province. We have revised the second sentence of the second paragraph of the introduction to read "A new set of pictorial health warning labels were introduced by Health Canada in 2012 and included, for the first time, a pan-Canadian quitline toll-free number that once called automatically sends the caller to the quitline service of their respective province." Ontario is Canada's largest province, representing 40% of the population of the country. There is considerable variation across provinces with regard to such things as tobacco cessation campaigns and taxation, both of which contribute to quitline utilization. Therefore, conducting an ARIMA analysis for all provinces combined that controlled for various confounders was not advisable given the very different provincial contexts. We have addressed this issue in second last sentence of the Interpretation which states "Future research should ... investigate the impact of the policy on other provinces given the differences that exist across Canada with regard to promotion and tobacco taxation."</p> <ol style="list-style-type: none"> 5. Since the new HWLs were in fact phased in between March (manufacturing) and June, 2012 (retail), it would seem appropriate to carry out a formal sensitivity analysis by at least placing the beginning of the intervention in June, instead of March. In fact, using March as the beginning of the intervention could make little sense if manufacturers waited until the very last minute, i.e. 75% into the month, to stop producing packs with the old HWLs. A rationale should be provided if this keeps being overlooked.

Authors' response

The time series demonstrated that tobacco manufacturers had distributed products with the new health warning labels before the June 18th deadline prohibiting the sale of cigarettes with the old health warning labels. Call volumes peaked in June 2012 and the packages with the new health warning labels were phased in during the months prior. Therefore, the time-series analysis was conducted with March 2012 as the start of the intervention as manufactures were prohibited from producing cigarette packages without the new health warning labels from this date. The sentence in the Methods section has been edited to read "Since health warning labels were on cigarette packages from 21 March 2012", we considered March 2012 the start of the intervention".

Specific comments

1. Introduction (p.3): it is unclear to me that the experiment described in the paper is an "ideal setting" for a natural experiment (evaluating the effect of the new labels). A "more ideal" setting would have involved the availability of a comparison, or control, group - which is obviously not the case here as all of Canada was subject to the intervention at the same time. Accordingly, the results obtained should probably be interpreted with slightly less enthusiasm. The analysis method used is perhaps one of the least compelling - albeit the best one available given the experiment being analyzed.

Authors' response

We have removed the word "ideal" from the last sentence of the Introduction. The sentence now reads "Implementation of the new health warning labels and pan-Canadian quitline number on tobacco packaging is an example of a natural experiment - i.e. a rapidly unfolding policy that is not under the control of the intervention team."

2. More could be said (Methods, p.3) about why only the number of new callers "receiving treatment" is tracked, e.g. citing evidence that those who receive the "treatment" as described have an increased probability of quitting.

Authors' response

We have inserted a reference supporting the effectiveness of telephone counselling treatment for smoking and inserted the following sentence "Treatment was defined as receiving at least one proactive telephone counselling session as those who receive treatment have an increased probability of quitting."

3. I would like to be reassured further, in the Methods / Measures section, that no other tobacco-related promotion or policy change has taken place over the study period.

Authors' response

We conducted a scan of all Ontario promotion and policy changes during the time period under study and are confident that no other campaign promoting quitline services had taken place. The first sentence of the second paragraph under Measures now reads "We conducted an environmental scan of Ontario Quitline promotion campaigns for the period under study and identified Driven-to-quit as the only province-wide quitline promotion campaign. Other variables that could increase the volume of calls ..."

4. The reference provided as the source of the tobacco prices (reference #24 from Statistics Canada, cited on p.4) does not in fact provide absolute prices, only relative ones: the Consumer Price Index and its components. An accurate and complete reference should be provided for the source of cigarette prices used.

Authors' response

We have revised the last sentence of paragraph 2 under measures to provide an accurate description and sources for cigarette prices. The sentence now reads "Ontario tobacco prices (\$ for 200 cigarette pack) were included to adjust for the effect of price on desire to quit smoking. Cigarette prices starting in 2010 were provided by the Non-Smokers' Rights Association and were adjusted for inflation (2002=100) for each month using the Consumer Price Index provided by Statistics Canada."

5. The first complete sentence on p.6 seems to over-reach and should be re-phrased. I don't see any "time to peak" measure in the analysis, while the "duration of the initial effect" is not measured either - only the "initial effect" itself is. The analysis doesn't use duration models.

Authors' response

We agree with the reviewer's comment and have removed this sentence from the Methods section.

6. The first paragraph of the Results section (p.6), which describes changes in caller characteristics, seems somewhat peripheral to the research question. This aspect should be dropped from the article unless it is better substantiated, both earlier and later in the paper.

Authors' response

The last paragraph of the introduction states as one of the objectives of the paper the investigation of changes in the characteristics of new callers. The methods section describes the analysis plan for determining changes in caller characteristics between the pre and post label periods. The fact that the characteristics of the callers significantly changed post-label period is an important finding, particularly given that callers post-label were more likely to be younger, male, lower educational status and representing different ethnicities. This speaks to how the health warning label policy with a pan-Canadian toll free quitline number has reduced inequity, particularly for those who bear an undue burden from tobacco.

7. First paragraph of p.7 asserts that the number of callers stabilizes at higher volumes post-intervention. This is apparently true for the fitted values, but not so for the "actual" values shown in the graph, which seem to decline starting in July, 2013. This statement should thus be nuanced and/or moved to the following paragraph, which describes the model's predicted call volumes.

Authors' response

We have revised the statement in second paragraph of the Results section and have removed the phrase "before stabilizing at higher values than pre-policy".

8. The first sentence of the Interpretation section should be re-phrased. It is unclear and incorrect in several respects (the paper "was" not a natural experiment; it doesn't look at the impact of the implementation of a new quitline number; etc.).

Authors' response

We have revised the first sentence to read "This paper investigated the impact of the new toll-free quitline number as part of Canadian tobacco packaging warning label policy on changes in Smokers' Helpline call volumes and number of new callers receiving treatment."

9. Reference #8, on p.12, is incomplete.

Authors' response

We have provided a complete reference.

10. In Table 3, the number of observations should be reported.

Authors' response

We have added 48 months to the title of the table to indicate the number of observations being reported.

11. The notes to table 3 could be clarified by dropping the confusing note 1; omitting the last parts of notes 3 and 4 (starting with "adjusting..."); and adding notes to the "Driven-to-quit" and the "January effect" variables explaining their meaning/construction (i.e. that the former is equal to 1 for February 2010-11-12-13 and 0 otherwise, and the latter is equal to 1 in January and 0 otherwise). Alternatively, the latter could be explained in the text, but at the moment it isn't.

Authors' response

We have revised the footnotes to the table as suggested. Note that the Driven-to-quit campaign was not conducted in February 2013.

12. In Figure 2, the scale for tobacco prices, on the right axis, could be changed so as to be more relevant (e.g. not start at zero - the \$0-70 interval is not used at all in the graph).

Authors' response

We have kept the y axis for tobacco prices at zero so as not to exaggerate the scale of the graph and distort the data. Given that there is no substantive change overtime in Ontario tobacco pricing, it does not impact our overall results.