ARTICLE DETAILS

<table>
<thead>
<tr>
<th>TITLE (PROVISIONAL)</th>
<th>Perceptions and impact of plain packaging of tobacco products in low and middle income, middle to upper income countries and low income settings in high income countries: A systematic review of the literature.</th>
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</thead>
<tbody>
<tr>
<td>AUTHORS</td>
<td>Hughes, Nicole; Arora, Monika; Grills, Nathan</td>
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VERSION 1 - REVIEW

| REVIEWER | Alison O'Mara-Eves  
Evidence for Policy and Practice Information and Co-ordinating Centre, Social Science Research Unit, UCL Institute of Education, London, United Kingdom |
<table>
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<tr>
<td>REVIEW RETURNED</td>
<td>23-Nov-2015</td>
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GENERAL COMMENTS

I have been asked to comment specifically on the methods used and have generally limited my comments to those relating to methods.

I would recommend that the authors use the PRISMA statement to help them with presenting their methods: http://www.prisma-statement.org/

SEARCHING:

The authors did not include LMIC databases, as I would have expected given the review’s focus. It is therefore difficult to assess whether one of the main conclusions, that there is not enough evidence in LMIC settings, is due to lack of evidence or because the authors did not search broadly enough. There is evidence to suggest that LMIC literature not indexed in large databases such as Medline can be found in specialist LMIC databases (see Stansfield et al. 2013 doi:10.1093/pubmed/fdt09). There are various lists of LMIC research databases available; the Cochrane list available at http://epoc.cochrane.org/sites/epoc.cochrane.org/files/uploads/LMIC%20Databases%20August%202013.pdf is a good resource.

I would also expect to see a more sensitive search strategy (i.e., with more search terms), as used in the related systematic review by Stead et al. 2013 doi:10.1371/journal.pone.0075919.

In other words, I think it is likely that the search for studies might have missed relevant material. I believe the review missed at least one study in a HIC that reported results separately for low income participants: Hammond et al. 2011 in the USA (doi:10.1093/ntr/ntr045), which was included in the Stead et al. 2011 related systematic review. I would recommend that the authors carefully scan the studies in the Stead review for any other suitable studies.
### DATA EXTRACTION:
There are no details of what information was extracted from the studies.

### CRITICAL APPRAISAL:
The authors include a section in the results on “Study quality”, which focuses on sampling/generalisability. I would expect to see a thorough description of the critical appraisal undertaken in the methods section, and other features of the studies such as appropriateness of study design.

### SYNTHESIS METHODS:
There is no description of the synthesis methods used in the main body of text. The authors describe the synthesis as “qualitative” in the abstract, but this is uninformative. It appears that they conducted a thematic synthesis, but it would be useful for the researchers to specify and describe. For example, were the themes pre-specified, or were they generated based on the information as reported in the included studies? How, if at all, did study quality get taken into account in the synthesis? And what was the rationale for the synthesis method used?

### RESULTS:
Where appropriate, specify whether the results where for smokers only, non-smokers, or mixed groups.

### LIMITATIONS:
I would like to see more description of each study. It is very important to understanding the limitations of this evidence base to be clear that the studies are generally hypothetical—that is, they ask people about their perceptions and beliefs when shown images of tobacco packaging. This is potentially different to people’s behaviours in natural (“real-life”) settings, and is a potential limitation of this literature.

Related to the issue of heterogeneity raised by the authors, the different study designs and the knowledge claims that can be made based on them should be considered.

### CONCLUSIONS:
Overall, I found the strength of the conclusions to be too strong given the amount, quality, type, and heterogeneity of the evidence.

### REVIEWER
Alice Mannocci  
Sapienza University of Rome, Department of Public Health and Infectious diseases, Italy

### REVIEW RETURNED
26-Nov-2015

### GENERAL COMMENTS
The article could be necessary improved before the publication.

I think the topic chosen from the authors is an interesting point view of the packaging and labeling impact of tobacco product.

The bibliography and the strategy of search I think it’s exhaustive, but I strongly encourage the authors to resolve some methodological problems.
Firstly I suggest to the authors to follow PRISMA statement to perform their review. Secondly I have a list of points to review:

- Introduction
  1) line 10: include a recent publication in Italy: Public Health. 2015 Mannocci A et al. From directive to practice: are pictorial warnings and plain packaging effective to reduce the tobacco addiction?
  2) I think that line 12 it’s possible to include some articles to justify your sentence: Arora and Guillaumer articles (ref 42, 40) near the comment on plain packaging is less well understood is a possible solution.

- Table 4
  1) The last box lined up under the full text articles N=109 box and with a outgoing arrow to the right the full text articles n=105 box, see below:

- Methods
  1) Prima statement carefully check all points
  2) It’s important to explain if the selection and assessment of the studies were conducted by two or more independent reviewers (see PRIMSA statement)
  3) Describe in the method the Quality assessment methodology and in results findings (see results paragraph).
  4) Describe the list the data extracted according to Table 3.

- Table 3
  1) Check all the data in the table, for example the Arora in “measurements” contains the study design “cross-sectional”. See White et al. and Guillaumeir too.
  2) The “Type of comparison” contains rather the “types of packaging”
  3) I suggest to introduce a column that summarize the main results of each study and the quality, or if it hard to include another table.

**REVIEWER** Sara C. Hitchman
Kings College London

**REVIEW RETURNED** 26-Nov-2015

**GENERAL COMMENTS** I congratulate the authors on undertaking this review and searching for papers on LMICs and smoking, it is clear that more work is needed in this area. However, I think it is fair to say that because only 4 papers were considered, this is not a very substantial review,
and that conclusions about the consistency of the results of the 4 papers are not overly helpful, particularly due to different methods and contexts. The inclusion of only English language studies also seems to have potentially excluded some relevant papers and work? That said, a research letter might be helpful at his point to show the lack of studies.

It would also be useful for the authors to give further explanation why only studies from LMICs could be used to inform policies in LMICS on plain packaging, are not some of the basic principles the same? Additionally, 2 out of the 4 papers reviewed were from low SES groups in a HIC, Australia, and I am not sure that this makes them any more applicable to the context of LMICs than research on the general population in Australia or other HICs (if this is the assumption that is being made)?

Did the authors consider papers from HICs that tested for differences/interactions by SES? This would be useful to know. For example, in the paper by Swift et al., on support for plain packaging in Australia, the authors report that SES was not related to support for plain packaging. It does not appear that the authors considered whether the effects of plain packaging differ by SES in HIC? I think this would have been essential to consider before only including studies from low SES groups in HICs.

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**REVIEWER**

Emma Hock  
University of Sheffield, UK

**REVIEW RETURNED**

27-Nov-2015

**GENERAL COMMENTS**

The current study reviews the literature on perceptions and acceptability of plain packaging within low and middle income countries, middle to upper income countries and low income settings within high income countries. This is an interesting and highly topical area, and there is a good case for examining low income settings, in which the profile of smoking behaviour tends to differ from higher income contexts. There are some changes, however, that need to be made in my view for this review to be publishable.

A key change that needs to be made is to clarify the purpose/research question and how this relates to the methods and results, as at the moment it seems inconsistent. The title and aim mention the “effects” of plain packaging, the Abstract, Discussion and Strengths and Limitations talk about “effectiveness” and the results are focused around beliefs and perceptions. The inclusion criteria specify “Research investigating the impacts and effectiveness of plain packaging either by appeal, prominence, effectively of health warnings, response to plain packs, attitudes towards quitting, social effectives or likelihood of smoking.” (Table 2) Aside from a couple of typographical errors (“effectively” and “effectives”), this seems contradictory – the outcome variables specified seem to relate more to beliefs than effectiveness – effectiveness outcomes might include smoking behaviour (including perhaps smoking uptake or smoking cessation) for example. Therefore, you need to do one of two things: either (1) amend the title and research question/aim (and everywhere they are mentioned, e.g. the abstract) to focus on beliefs/attitudes/perceptions/views relating to plain packaging; or (2) broaden the aim (including in the Title, Abstract, Discussion etc.) out
to all research on plain packaging (effectiveness and beliefs/acceptability) and then say in the results that you didn’t find any evidence on the effectiveness of plain packaging and so the synthesis focuses on beliefs/views. This may be what was intended as the search terms are broad and just relate to tobacco and packaging, but this needs to be explicitly clear.

Another important clarification is that the type of packaging in the research question/aim and inclusion criteria needs to be explicitly stated. At the moment, both of these just state "plain packaging" and it is unclear whether this relates to all tobacco packaging or just cigarette packaging. Given the search terms, it looks like the former, however again this should be explicitly stated. The type of plain packaging also needs to be specified in the results, when describing and synthesising the research findings, in particular in Table 3.

In addition, a PRISMA checklist needs to be submitted.

Abstract
The Results section of the Abstract needs to be reworded to reflect the findings, as the current wording ("studies identified that plain packaging reduced appeal of tobacco products in low income settings"); p.4, lines 3-5) suggests a direction of effect that was only assessed in one study – the others are cross-sectional. Perhaps change the word “reduced” and/or rephrase to something like “plain packaging had lower/less appeal than branded packaging”.

Introduction
Data on smoking rates could be reworked slightly (p.5, lines 19-28). First, I don’t think the change in smoking rates in high income countries could necessarily be described as a “relentless decline” – in Australia the figures seem to have declined year on year, however recently smoking prevalence seems to have levelled off in recent years in the UK and USA, so perhaps this language could be tempered. Second, the data presented for India is not comparable as only data for males are presented – the WHO report gives data for males and females and overall, so the overall data need to be given instead, in order to make this comparable with the Australian figures. India is a complex example as fewer people there appear to smoke cigarettes (14% smoke tobacco; 5.7% smoke cigarettes according to the WHO report), whereas smokeless tobacco is more common in India (25.9% prevalence). You could also give examples of smoking prevalence among the lower income Eastern European countries, which tends to be higher than high income countries such as Australia, the UK and USA.

If there is scope to do so, it might be helpful to provide more detail on the recent systematic review on plain packaging by Stead et al., 2013 (p.6, lines 50-55), as this seems to be a key piece of literature in the field.

In the aims and objectives, it would be useful to clarify whether “all the published literature” includes quantitative, qualitative or both (p.7, lines 19-21). I think the inclusion of middle-upper income countries needs to be justified, as it is not clear currently why these countries would be more similar to low and middle income countries than they are to higher income countries and what the reasons are for grouping them with LMIC (p.7, lines 27-29).

For clarity, it would be useful if a research question (with all...
PICO/similar elements) could be presented at the end of the paragraph on aims (p.7).

Methods
Some detail on how the decision was made that evidence from LMIC was limited (p.8, paragraph 2, lines 16-24), especially given that only an additional two studies were included. Some quantification would be helpful to justify the decision.

In the search terms (Table 1), there is a missing bracket – there should be two close brackets after the first use of the word “homogenous”. It would also be helpful to have the search strategy used included in an appendix or online supplementary file, to aid replicability.

The inclusion criteria (Table 2) also need a bit of clarification (other than the addition of the type of plain packaging, as mentioned above). The income metric needs a reference and the exclusion criteria should specify that research conducted in HIC is only excluded where it has not been conducted in a low income or socioeconomically disadvantaged setting.

Finally, the methods section is missing subsections/paragraphs that talk about critical appraisal of included studies (e.g. how was study quality determined, what checklist was used and how was this process conducted?) and data extraction (which information was extracted, how extraction was conducted). These need to be added in to make the review transparent and clear.

Results
The comprehensive search strategy did not find four articles (p.11, line 7); it found 2757 records – of which four articles were included following study selection. This needs to be clarified. Also, the flow diagram represented in Table 4 (p.10) is actually a figure rather than a table and so it should be re-labelled as Figure 1.

A reference needs to be inserted for Arora et al. (p.11, lines 45).

When discussing studies in the synthesis (pp.11-14), it would be useful to mention the countries of the studies concerned by way of comparison, to save the reader from having to repeatedly refer to Table 3 to find out.

In the Study Quality subsection (p.14, lines 14-28), you need to say something about elements of study quality of the included studies in addition to the generalisability of the evidence. What was good overall? What was limited overall? What varied between studies? It would be useful to present more detail here.

Table 3 provides a handy summary of the included studies, however I think more detail is needed. It might make sense to in fact split this into two tables – one of study characteristics and another focused on the findings. In the characteristics table you will need to state the type of packaging (e.g. cigarette, tobacco overall, smokeless tobacco, etc.) for all studies (not just Arora et al. 2013) as mentioned above. It would also be useful to include that the sample in the Arora study was low and high socioeconomic status. References should also be added to the studies in the study column so that the reader can see instantly which papers these studies refer to. Some more detail on the measurements would also be helpful – for example,
what scales were people asked to respond to? In the findings table you will need to go into more detail on the findings. For the quantitative studies, results will need to be quantified, presenting numerical findings and statistical significance where relevant/available alongside each statement. For the qualitative studies it would be useful to include themes and/or illustrative quotations. If you present the findings in a table of their own there would be room to do this. Finally, should “luring” be “alluring” (outcomes column of Arora study)?

Discussion
The sentence “The studies were largely consistent with the evidence from HIC that suggest plain packaging is effective” (p.17, lines 22-24) needs a reference. Also, this sentence needs amending as your review did not look at effectiveness – as discussed above. Also, the final sentence in the same paragraph (“Further research on LMI settings would be required to determine if the magnitude of this effect was more or less than the effect in HICs”; p.17, lines 29-31) needs rewording slightly to clarify that you are referring to quantification of acceptability and beliefs about the effectiveness of plain packaging, since effectiveness was not assessed by the included studies.

Some findings are reported in the Discussion section that have not been mentioned in the Results (e.g. differences between low and higher socioeconomic status in the Arora study, p.17, lines 49-51; high proportion of participants (70%) supporting plain packaging in the Arora study, p.18, lines 14-16). All findings should be reported in the Results, with the Discussion used to place the findings in context. Therefore, all the findings reported in the Discussion need cross-checking against the Results and any not reported in the Results section and related table need to be added.

It would be useful to add in a few words to make it clear in the mind of the reader why the Swift et al. 2014 study stating 49.9% of Australians support plain packaging wasn’t included in the review (e.g. by adding “in high income smokers” or similar) (p.18, lines 21-26). Also, within the same sentence, I believe “implantation” needs changing to “implementation”.

I think that the fact that studies were restricted to English language could be mentioned as a limitation of the review, especially as studies examining LMIC may well publish in other languages – for example, South American countries may publish in Spanish or Portuguese. Of course you can then state the reasons you have for not believing this to be a problem for this particular review, for example your searches were not limited by language and no full texts were excluded on the basis of language (it is unclear if any abstracts were).

The passage “effective tobacco control interventions as a initial steps” doesn’t seem to make sense (p.18, lines 54-56) and needs to be amended.

While I agree with the sentiment, the statement “The tobacco industry has consistently leveraged its ability to create havoc” (p.19, lines 43-45) could be worded more diplomatically.
I have been asked to comment specifically on the methods used and have generally limited my comments to those relating to methods.

I would recommend that the authors use the PRISMA statement to help them with presenting their methods: http://www.prisma-statement.org/
- Yes, a prisma statement was completed at time of completing the review and this has been added to as a supplementary file.

SEARCHING:
The authors did not include LMIC databases, as I would have expected given the review's focus. It is therefore difficult to assess whether one of the main conclusions, that there is not enough evidence in LMIC settings, is due to lack of evidence or because the authors did not search broadly enough. There is evidence to suggest that LMIC literature not indexed in large databases such as Medline can be found in specialist LMIC databases (see Stansfield et al. 2013 doi:10.1093/pubmed/fdt09). There are various lists of LMIC research databases available; the Cochrane list available at http://epoc.cochrane.org/sites/epoc.cochrane.org/files/uploads/LMIC%20Databases%20August%202013.pdf is a good resource.
- Thank you for your comments on LMIC databases. We had sought advice from our head librarian at the University of Melbourne, and based on his advise we used the Global Health database. However, the above information was useful and we have re-run the search strategy in two of the global health databases that were most relevant for the topic we are researching. The search strategy now includes three databases specifically for LMIC literature – Global Health, British Library for Development Studies (BLDS) and Global Health Library.

I would also expect to see a more sensitive search strategy (i.e., with more search terms), as used in the related systematic review by Stead et al. 2013 doi:10.1371/journal.pone.0075919.
- The initial search strategy was discussed and devised in conjunction with our local expert on systematic literature reviews and we also utilised many of the key terms from the Stead et al study. However, we can see that incorporating the additional terms would be better and in response we have chosen to change the search terms for increased sensitivity and have included a more comprehensive search strategy. We ran the new search strategy in all databases and came up with a larger number of results, which has been recorded in the manuscript (search term table 1, flow diagram figure 1, and appendix added for full demonstration of search strategy). The more sensitive search strategy in combination with the two new databases provided a large number of new results, however, we were not able to find any further research or articles which met our inclusion and exclusion criteria.

In other words, I think it is likely that the search for studies might have missed relevant material. I believe the review missed at least one study in a HIC that reported results separately for low income participants: Hammond et al. 2011 in the USA (doi:10.1093/ntr/ntr045), which was included in the Stead et al. 2011 related systematic review. I would recommend that the authors carefully scan the studies in the Stead review for any other suitable studies.
- Thank you for noting this article, and we acknowledge that our strategy and method was not clearly explained. Because we are arguing the transferability from HIC low income settings to LMIC, we only accepted articles that had specifically and purposefully researched in hard to reach specific defined low resource settings, not articles which had included any sub analysis based on low SES or low
income status. The populations we were interested in are difficult to engage and find in HIC, and therefore the Hammond et al. 2011 did not meet our inclusion criteria. We have worked on the language to explain this within the inclusion criteria.

At the time of the initial search strategy we contacted a number of key experts in the area (including Dr Michelle Scollo, Professor Simon Chapman and Professor Mike Daube) to further attempt to find any research or articles that may have been conducted in LMIC or low income settings.

DATA EXTRACTION:
There are no details of what information was extracted from the studies
- We have now included data extraction information in the methods section and explained how and what data was extracted for the purpose of this review. Thematic analysis was conducted on the data extracted from the four studies.

CRITICAL APPRAISAL:
The authors include a section in the results on “Study quality”, which focuses on sampling/generalisability. I would expect to see a thorough description of the critical appraisal undertaken in the methods section, and other features of the studies such as appropriateness of study design.
- We used the strobe statement to base our study quality assessment. We have now provided improved information in the methods section of study quality assessment and also improve the study quality section of the results.

SYNTHESIS METHODS:
There is no description of the synthesis methods used in the main body of text. The authors describe the synthesis as “qualitative” in the abstract, but this is uninformative. It appears that they conducted a thematic synthesis, but it would be useful for the researchers to specify and describe. For example, were the themes pre-specified, or were they generated based on the information as reported in the included studies? How, if at all, did study quality get taken into account in the synthesis? And what was the rationale for the synthesis method used?
- Thank you for making us aware that this needs further explanation. The authors conducted a thematic analysis of the key results which we have now explained more clearly. We used themes that were determined a priori based from previous research, and then adapted these based on the results from the data from the four studies. Study quality was similar across the four studies and therefore no weighting occurred.

RESULTS:
Where appropriate, specify whether the results where for smokers only, non-smokers, or mixed groups.
- This has now been added into the results

LIMITATIONS:
I would like to see more description of each study. It is very important to understanding the limitations of this evidence base to be clear that the studies are generally hypothetical—that is, they ask people about their perceptions and beliefs when shown images of tobacco packaging. This is potentially different to people’s behaviours in natural (“real-life”) settings, and is a potential limitation of this literature.
- We agree with this very important distinction, which we have now included with increased clarity. This has been discussed in the study quality section of the results.

Related to the issue of heterogeneity raised by the authors, the different study designs and the knowledge claims that can be made based on them should be considered.
- We have provided increased discussion around the study quality section of the articles.
CONCLUSIONS:
Overall, I found the strength of the conclusions to be too strong given the amount, quality, type, and heterogeneity of the evidence.
- While we agree that with the reviewer that conclusions must be cautious from the limited and heterogeneity of the evidence, we believe that it provides a good grounding for concluding that more evidence is required and that early indications are that plain packaging is equally effective in LMICs. We have made the conclusion more nuanced.

Reviewer: 2
Reviewer Name: Alice Mannocci
Institution and Country: Sapienza University of Rome, Department of Public Health and Infectious diseases, Italy

Thank you for your reviews and comments. Suggestions 1 and 2 including references have been added to support both these points. Table four has been amended (now labelled figure 1). In regards to methods – a PRISMA statement has been attached to supplement information. The methods have been improved and more information provided, which answers your concerns regarding methods.

Table 3 has now been split into two tables, one for characteristics and the other for key results and findings to improve the clarity and also to allow for increased information. The data has been checked, and the errors that you highlighted have been amended.

Thank you again for your review.

Reviewer: 3
Reviewer Name: Sara C. Hitchman
Institution and Country: Kings College London, UK.

I congratulate the authors on undertaking this review and searching for papers on LMICs and smoking, it is clear that more work is needed in this area. However, I think it is fair to say that because only 4 papers were considered, this is not a very substantial review, and that conclusions about the consistency of the results of the 4 papers are not overly helpful, particularly due to different methods and contexts. The inclusion of only English language studies also seems to have potentially excluded some relevant papers and work? That said, a research letter might be helpful at his point to show the lack of studies.

- We believe that our review is helpful to report negative results even where there is a lack of studies on this issue. In addition to suggesting further research there are a number of important learnings from the 4 studies described in the synthesis, discussion and conclusions. This is where the thematic qualitative analysis has its strength even in the absence of quantitative evidence of effect. These qualitative data will inform future research methods and direction. This is a very topical area of research at the moment, and we therefore believe that it should be published as a full review.

It would also be useful for the authors to give further explanation why only studies from LMICs could be used to inform policies in LMICS on plain packaging, are not some of the basic principles the same? Additionally, 2 out of the 4 papers reviewed were from low SES groups in a HIC, Australia, and I am not sure that this makes them any more applicable to the context of LMICs than research on the general population in Australia or other HICs (if this is the assumption that is being made)?

- This is very relevant question and one that we sought expert feedback on when designing the
literature review. Ultimately, the context is very different in LMICs. The authors are actively involved in helping apply research on plain packaging undertaken in Australia to assist the Indian Government introduce plain packaging. However, the context is quite different and evidence from a HIC experience is of limited value and policy makers (from India at least) are asking for information relevant to them, for their particular context. In LMICs compared with HIC there are, in general, very different products with a preponderance of chewed and rolled forms and different usage patterns with men using at much higher levels. In high resource areas versus lower income setting there is typically better implement of laws; the sophistication of legal and political systems differs; forms of communications and media differ, and production of tobacco is concentrated in LMICS and MUIC (China, India, Indonesia). These factors mean that the context is quite different in LMICs and this justifies specific information on plain packaging in low resource settings.

Did the authors consider papers from HICs that tested for differences/interactions by SES? This would be useful to know. For example, in the paper by Swift et al., on support for plain packaging in Australia, the authors report that SES was not related to support for plain packaging. It does not appear that the authors considered whether the effects of plain packaging differ by SES in HIC? I think this would have been essential to consider before only including studies from low SES groups in HICs.

- The paper by Swift et al. reports that plain packaging effects did not differ based on SES of participants. We included hard to reach population settings within HIC based on the idea that particular populations of HIC, such as indigenous populations, very low SES populations were potentially comparable to LMIC settings. This meant that we only considered articles that had specifically and purposefully investigated these populations, as they are unlikely to be accessed through standard research methods unless purposefully investigated. There are a number of articles from HIC which breakdown their results based on SES and show similar results across SES based off standard recruiting methods. We did not feel that this analysis was either helpful or comparable to a LMIC setting, therefore excluding these articles.

Reviewer: 4
Reviewer Name: Emma Hock
Institution and Country: University of Sheffield, UK

The current study reviews the literature on perceptions and acceptability of plain packaging within low and middle income countries, middle to upper income countries and low income settings within high income countries. This is an interesting and highly topical area, and there is a good case for examining low income settings, in which the profile of smoking behaviour tends to differ from higher income contexts. There are some changes, however, that need to be made in my view for this review to be publishable.

- Thank you for these comments, we agree that this is an interesting and topical area and appreciate your comments and suggested changes and have included them and further responses below.

A key change that needs to be made is to clarify the purpose/research question and how this relates to the methods and results, as at the moment it seems inconsistent. The title and aim mention the “effects” of plain packaging, the Abstract, Discussion and Strengths and Limitations talk about “effectiveness” and the results are focused around beliefs and perceptions. The inclusion criteria specify “Research investigating the impacts and effectiveness of plain packaging either by appeal, prominence, effectively of health warnings, response to plain packs, attitudes towards quitting, social effective or likelihood of smoking.” (Table 2) Aside from a couple of typographical errors (“effectively” and “effectives”), this seems contradictory – the outcome variables specified seem to relate more to beliefs than effectiveness – effectiveness outcomes might include smoking behaviour (including
perhaps smoking uptake or smoking cessation) for example. Therefore, you need to do one of two things: either (1) amend the title and research question/aim (and everywhere they are mentioned, e.g. the abstract) to focus on beliefs/attitudes/perceptions/views relating to plain packaging; or (2) broaden the aim (including in the Title, Abstract, Discussion etc.) out to all research on plain packaging (effectiveness and beliefs/acceptability) and then say in the results that you didn’t find any evidence on the effectiveness of plain packaging and so the synthesis focuses on beliefs/views. This may be what was intended as the search terms are broad and just relate to tobacco and packaging, but this needs to be explicitly clear.

- This is very helpful feedback and we have harmonised the references to effectiveness. It’s important to realise that the aim of plain packaging has been targeted to affect beliefs and perceptions, which in time and in combination with other interventions will affect prevalence of use. The measurable indicators of effectiveness of plain packaging are what are typical of interest in studies tracking the impact of plain packaging rather than prevalence which is slow and has multifactorial causes. This is reflected in the aims of PP in Australia, to:
  1. reduce the appeal of tobacco products to consumers;
  2. increase the effectiveness of health warnings on the retail packaging of tobacco products;
  3. reduce the ability of the retail packaging of tobacco products to mislead consumers about the harmful effects of smoking or using tobacco products.

In Australia most studies were more interested in capturing proximal indicators of use by looking at behaviour, perceptions and attitudes (or “determinants”). The prevalence of tobacco use at a population level is co-determined by multiple factors that are both internal and external to the individual. Given the complex and often lengthy process involved in reducing prevalence, it is important to study its determinants. This ensures that slower-than-hoped-for progress does not need lead to abandonment of policies/programs before auspicious changes in determinants have had time to take effect.

In summary we changed the expression to be focussing on evidence around the “effectiveness of plain packaging on the determinants of tobacco use”

Another important clarification is that the type of packaging in the research question/aim and inclusion criteria needs to be explicitly stated. At the moment, both of these just state “plain packaging” and it is unclear whether this relates to all tobacco packaging or just cigarette packaging. Given the search terms, it looks like the former, however again this should be explicitly stated. The type of plain packaging also needs to be specified in the results, when describing and synthesising the research findings, in particular in Table 3.

- Thank you, and yes our research relates to all tobacco packaging, not just cigarette packaging. We have amended the references to plain packaging to plain packaging of all tobacco products, and have made reference to what type of packaging (i.e. cigarette, beedis etc) in Table 3.

In addition, a PRISMA checklist needs to be submitted.
- Yes, a PRISMA checklist was completed at the time of conducting the review and this has been submitted.

Abstract
The Results section of the Abstract needs to be reworded to reflect the findings, as the current wording (“studies identified that plain packaging reduced appeal of tobacco products in low income settings”; p.4, lines 3-5) suggests a direction of effect that was only assessed in one study – the others are cross-sectional. Perhaps change the word “reduced” and/or rephrase to something like “plain packaging had lower/less appeal than branded packaging”. 
Introduction

Data on smoking rates could be reworked slightly (p.5, lines 19-28). First, I don’t think the change in smoking rates in high income countries could necessarily be described as a “relentless decline” – in Australia the figures seem to have declined year on year, however recently smoking prevalence seems to have levelled off in recent years in the UK and USA, so perhaps this language could be tempered. Second, the data presented for India is not comparable as only data for males are presented – the WHO report gives data for males and females and overall, so the overall data need to be given instead, in order to make this comparable with the Australian figures. India is a complex example as fewer people there appear to smoke cigarettes (14% smoke tobacco; 5.7% smoke cigarettes according to the WHO report), whereas smokeless tobacco is more common in India (25.9% prevalence). You could also give examples of smoking prevalence among the lower income Eastern European countries, which tends to be higher than high income countries such as Australia, the UK and USA.

- Thank you for these comments. We have changed the language around “relentless decline”, and have improved the comparability of the Australian and Indian figures. We have expanded the data to include the gender disparity that is one of the key differences in LMIC.

If there is scope to do so, it might be helpful to provide more detail on the recent systematic review on plain packaging by Stead et al., 2013 (p.6, lines 50-55), as this seems to be a key piece of literature in the field.

- Yes, we agree that the article by Stead et al is one of the key pieces of literature in the field. We have included numerous references to this review, and part of the rationale of undertaking this review is in response to recommendations outlined in the Stead article. We have included reference to the Stead article throughout.

In the aims and objectives, it would be useful to clarify whether “all the published literature” includes quantitative, qualitative or both (p.7, lines 19-21). I think the inclusion of middle-upper income countries needs to be justified, as it is not clear currently why these countries would be more similar to low and middle income countries than they are to higher income countries and what the reasons are for grouping them with LMIC (p.7, lines 27-29).

- We have changed this section of the introduction and have reworded it for improved clarity.

For clarity, it would be useful if a research question (with all PICO/similar elements) could be presented at the end of the paragraph on aims (p.7).

- This paragraph is now concluded with the research question.

Methods

Some detail on how the decision was made that evidence from LMIC was limited (p.8, paragraph 2, lines 16-24), especially given that only an additional two studies were included. Some quantification would be helpful to justify the decision.

- We have clarified this in the paper. From our preliminary pre review searches it become apparent that there were few articles relating specifically to LMICs. Therefore for the actual search strategy we included low resource settings not only in LMICs.

In the search terms (Table 1), there is a missing bracket – there should be two close brackets after the first use of the word “homogenous”. It would also be helpful to have the search strategy used included in an appendix or online supplementary file, to aid replicability.

- Search strategy has been amended based on other reviewer comments. Table 1 has been updated. An appendix has been added with a completed search strategy.
The inclusion criteria (Table 2) also need a bit of clarification (other than the addition of the type of plain packaging, as mentioned above). The income metric needs a reference and the exclusion criteria should specify that research conducted in HIC is only excluded where it has not been conducted in a low income or socioeconomically disadvantaged setting.

Table 2 has been amended with increased clarification for both inclusion and exclusion criteria.

Finally, the methods section is missing subsections/paragraphs that talk about critical appraisal of included studies (e.g. how was study quality determined, what checklist was used and how was this process conducted?) and data extraction (which information was extracted, how extraction was conducted). These need to be added in to make the review transparent and clear.

- This information has now been added to the methods section.

Results

The comprehensive search strategy did not find four articles (p.11, line 7); it found 2757 records – of which four articles were included following study selection. This needs to be clarified. Also, the flow diagram represented in Table 4 (p.10) is actually a figure rather than a table and so it should be relabelled as Figure 1.

- Table 4 has been changed to Figure 1, and p.11 line 7 the language has been changed.

A reference needs to be inserted for Arora et al. (p.11, lines 45).

- Reference has been added.

When discussing studies in the synthesis (pp.11-14), it would be useful to mention the countries of the studies concerned by way of comparison, to save the reader from having to repeatedly refer to Table 3 to find out.

- Within the synthesis country names have been included.

In the Study Quality subsection (p.14, lines 14-28), you need to say something about elements of study quality of the included studies in addition to the generalisability of the evidence. What was good overall? What was limited overall? What varied between studies? It would be useful to present more detail here.

- This section has been expanded in reference to study quality assessment, providing increased detail about the studies and increased information about their overall generalizability.

Table 3 provides a handy summary of the included studies, however I think more detail is needed. It might make sense to in fact split this into two tables – one of study characteristics and another focused on the findings. In the characteristics table you will need to state the type of packaging (e.g. cigarette, tobacco overall, smokeless tobacco, etc.) for all studies (not just Arora et al. 2013) as mentioned above. It would also be useful to include that the sample in the Arora study was low and high socioeconomic status. References should also be added to the studies in the study column so that the reader can see instantly which papers these studies refer to. Some more detail on the measurements would also be helpful – for example, what scales were people asked to respond to? In the findings table you will need to go into more detail on the findings. For the quantitative studies, results will need to be quantified, presenting numerical findings and statistical significance where relevant/available alongside each statement. For the qualitative studies it would be useful to include themes and/or illustrative quotations. If you present the findings in a table of their own there would be room to do this. Finally, should “luring” be “alluring” (outcomes column of Arora study)?

- Table 3 has been split into two tables 3 and 4, and increased information, clarity, references and increased breath of results have been added.

Discussion

The sentence “The studies were largely consistent with the evidence from HIC that suggest plain
packaging is effective” (p.17, lines 22-24) needs a reference. Also, this sentence needs amending as your review did not look at effectiveness – as discussed above. Also, the final sentence in the same paragraph (“Further research on LMI settings would be required to determine if the magnitude of this effect was more or less than the effect in HICs”; p.17, lines 29-31) needs rewording slightly to clarify that you are referring to quantification of acceptability and beliefs about the effectiveness of plain packaging, since effectiveness was not assessed by the included studies.

- A reference has been added and the wording has been changed in both sentences to improve meaning and sentence quality.

Some findings are reported in the Discussion section that have not been mentioned in the Results (e.g. differences between low and higher socioeconomic status in the Arora study, p.17, lines 49-51; high proportion of participants (70%) supporting plain packaging in the Arora study, p.18, lines 14-16). All findings should be reported in the Results, with the Discussion used to place the findings in context. Therefore, all the findings reported in the Discussion need cross-checking against the Results and any not reported in the Results section and related table need to be added.

- Table 3 and 4 being split and reviewed has meant that more information has been provided in the results section. We have cross checked the results and discussion to ensure there are no other inconsistencies with new results been mentioned in the discussion section, and where this did occur (and the above mentioned comments) have been added to the results section.

It would be useful to add in a few words to make it clear in the mind of the reader why the Swift et al. 2014 study stating 49.9% of Australians support plain packaging wasn't included in the review (e.g. by adding “in high income smokers” or similar) (p.18, lines 21-26). Also, within the same sentence, I believe “implantation” needs changing to “implementation”.

- Thank you for this very useful inconsistency. This sentence has been amended to reflect the HIC status and the spelling error has been changed.

I think that the fact that studies were restricted to English language could be mentioned as a limitation of the review, especially as studies examining LMIC may well publish in other languages – for example, South American countries may publish in Spanish or Portuguese. Of course you can then state the reasons you have for not believing this to be a problem for this particular review, for example your searches were not limited by language and no full texts were excluded on the basis of language (it is unclear if any abstracts were).

- Yes we agree that this appears to be a limitation. We have now included a more lengthy limitations section, explaining our rationale why we feel that no studies were missed.

The passage “effective tobacco control interventions as a initial steps” doesn’t seem to make sense (p.18, lines 54-56) and needs to be amended.

- Thank you, language has been amended.

While I agree with the sentiment, the statement “The tobacco industry has consistently leveraged its ability to create havoc” (p.19, lines 43-45) could be worded more diplomatically.

- Thank you, language has been amended.

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**VERSION 2 – REVIEW**

<table>
<thead>
<tr>
<th>REVIEWER</th>
<th>Alice Mannocci</th>
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<tr>
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<td>Department of Public Health and Infectious disease,</td>
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<td>&quot;Sapienza&quot;</td>
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<td>University of Rome</td>
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<td>REVIEW RETURNED</td>
<td>25-Jan-2016</td>
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**GENERAL COMMENTS**

This manuscript has been greatly improved.

Title
- I suggest to the author to more effective the title. It’s not clear “low income settings”

Methods
- I’m very happy to see that the PRISMA statement was included, I suggest to cite with just one sentence at the beginning of the methods paragraph.
- The authors declare to use Strobe Statement for cross sectional studies to assess the quality, but I think that the STROBE statement is more suitable to write a manuscript than to evaluate the quality. I encourage the author to apply New Castel Ottawa scale (I think that the quality score are the same, but it is methodologically more correct).

Figure 1 it is not included in reviewed version (in the older version it’s ok).

In table 3 or 4 can you report the points of the quality of the studies.

REVIEWER
Emma Hock
University of Sheffield, United Kingdom

REVIEW RETURNED 19-Jan-2016

GENERAL COMMENTS
It is clear that much work has been done to improve the manuscript. I appreciate what a huge task it must have been to address the many comments and suggestions we have made. There are, however, still some changes that I feel need to be made. Also some of the amendments I suggested previously have not been addressed (either made or argued against).

Much has been done to clarify the whole issue of whether the review is examining effectiveness or perceptions and beliefs. I can understand the way that perceptions and beliefs can be regarded as determinants of behaviour, and can see the rationale for examining determinants, however I would still argue that this link is subject to some debate in the behaviour change literature and where the behaviour of people is concerned it is not a given that people will act on their beliefs (there is a whole literature on this). Therefore, it still seems a bit of a leap to be discussing the current evidence in terms of effectiveness. In my view, the things this review has looked at (appeal, salience of health warnings, perceived taste and enjoyment, and beliefs about tobacco use) are valuable, however they (or rather the way the studies have examined these things) do not tell us anything about effectiveness; one could not answer an “effectiveness” question with the kinds of research the current review identified. I still think that what has been done in the present review is to seek out research on effectiveness and acceptability/views and then report only the acceptability/views research, as that is what was found via extensive searches – which is fine, but this needs to be clearly and explicitly stated. Therefore, I think a few more subtle changes to the wording may be required, in most cases to add in “views” or “acceptability”, to make the distinction absolutely clear. For example:

• In the title, “Effect of plain packaging” could be changed to “Views on plain packaging”, “Acceptability of plain packaging” or “Appeal and perceptions of plain packaging” or similar.
• Abstract – objective – add in “views” or “acceptability” to “potential impact and effectiveness of plain packaging”, to make it more accurate (i.e., the review would have examined effectiveness, had
the evidence been there, however only views/beliefs/perceptions were reviewed).

- Abstract – study selection – again, add “views” or “acceptability” into “effectiveness and/or impact of plain packaging”, to make this clear.
- Strengths and limitations – first bullet (p.4, line 32) change “potential effectiveness” to “potential impact”.
- Introduction (p.7, line 28) – change “potential effectiveness and impact” to “potential effectiveness, impact and acceptability”.
- Introduction (p.7, lines 44-46) – change “the potential effectiveness of plain packaging” to “the potential effectiveness and acceptability of plain packaging”.
- Table 2, bullet 3 of inclusion criteria (p.10) – “impacts and/or effectiveness” needs to be changed to “Impacts, effectiveness and/or acceptability” or similar.
- Results (p.11, line 38) – change “actual or potential impact of plain packaging” to “views on plain packaging” or “acceptability of plain packaging” or similar, for clarity – also need to state that no evidence of effectiveness of plain packaging was identified after that first sentence, again for clarity.
- Results (p.12, lines 20-22) the term “potential effect of plain packaging” when discussing the findings of the Arora study also needs to be changed to mention “views” or “acceptability” or similar, as there is nothing in the Arora results as reported in the current review that suggests being able to examine the effect of plain packaging – the sort of data that might provide information on “effect” has not been reported for this study.
- Along a similar vein, the subheading “Tobacco usage behaviour” (p.14, line 20) needs changing to “perceptions of the impact on tobacco usage behaviour” or similar, as actual usage was not examined in any of the included studies.
- Discussion (p.19, lines 11-13) – change “potential impact of plain packaging” to “potential impact and acceptability of plain packaging” or similar.

The wording in the Abstract around plain packaging reducing appeal of tobacco products has been helpfully amended in the abstract. However, I have just noticed that the Conclusion mentions “plain packaging can potentially be effective at reducing the appeal of packs” (p.23, lines 30-32); “reducing” needs to be changed here too in a similar fashion. Also, the wording needs to be changed to remove “effective” as there is no evidence that examined the effectiveness of plain packaging on appeal of tobacco packs.

It is useful that a reference to the World Bank has been added to the Methods in relation to MUIC. However, I think that two points remain unclear and in need of clarification, both in the Methods (p.8) and also in the aims and objectives paragraph on the preceding page:
- What the definition of MUIC actually is (in fact it would be useful to also define this for LMIC and HIC – if there is no room in the paper, this information could be presented in a supplementary document);
- Why MUIC have been included (i.e., why you would expect them to be more similar to LMIC than to HIC), as this still is not clear.

In response to my request for more detail on how the decision was made that evidence from LMIC was limited, you have helpfully specified that “there were few articles relating to LMICs”, however I cannot see where this is specified within the paper itself; could this be added please? It would also be useful to quantify this statement.
The inclusion criteria have been helpfully clarified. However, I still think that the exclusion criteria should specify that research conducted in HIC is only excluded where it has not been conducted in a low income or socioeconomically disadvantaged setting.

The splitting of Table 3 into two separate Tables detailing the study characteristics and findings has been helpful. I think a few details could be usefully added in.

- I think that for clarity the title of Table 4 should mention findings or results rather than outcomes (as the term “outcomes” does not imply that the findings/results will be reported there, just the outcomes).
- In Table 3, details on analysis could be reported (e.g., on the Likert scale and the pack selection task for the White study, on the opinion poll for the Arora study and on the 1-7 scale for the Guillaumier 2014 study). Details on recruitment in the Guillaumier studies could also be reported.
- In Table 4, numerical findings need to be added in where available (e.g., on the ratings in the White study, the finding on high SES participants being more attracted by branding compared with low SES participants, the reduced [also perhaps change that term to “lower” for consistency and clarity] positive cigarette brand image and smoker purchase intentions, decreased [lower?] taste ratings and ratings of pack characteristics for the Guillaumier 2014 study). If such information (e.g. numbers, percentages) is not available then this needs to be explicitly reported.

I previously suggested adding in a few words to clarify why the Swift et al. 2014 study stating 49.9% of Australians support plain packaging wasn’t included in the review (e.g. by adding “in high income smokers” or similar) (p.20, line 32). This has not been addressed, however I feel that the point still stands, to make this clear in the mind of the reader.

It is helpful that the language restriction has been added to the discussion of the limitations (p.23, lines 6-12) and useful to know that articles published in French and Italian were excluded. Further to this, it would be helpful to quantify the number of articles excluded on the basis of language.

In my mind, the first two sentences of the Conclusion (p.23, lines 20-28) are not strictly necessary. I think the Conclusion could be made more punchy by deleting them and starting this paragraph with the sentence beginning, “This review provides some early evidence…” – although I accept that this is a matter of opinion.

Finally, I have spotted a few grammatical inconsistencies and typos that have no doubt crept in during the extensive editing:

- Change “for LMIC it may take multiple years, and various supporting research” (p.21, line 14) to “for LMIC it may take many years, and much supporting research of various kinds” or similar.
- Change “difficulty in accessing with tobacco control interventions” (p.22, lines 26-28) to “difficulty in accessing tobacco control interventions”.

If I may, I could not help noticing that Reviewer 3’s suggestion regarding the Swift paper may have been misinterpreted (which, given the volume of corrections from the previous submission, is not totally surprising). I interpret that Reviewer 3 was asking for consideration of the effects of SES on plain packaging in the Introduction (i.e., “before only including studies from low SES groups
in HICs") rather than in the review itself, although I could be mistaken. Either way, I think this would be a useful point to include in the Introduction. The inclusion of MUIC needs to be better defined/justified, exclusion criteria around HIC need to be clarified, some specific detail (including numerical figures/quantities) needs to be added to Tables 3 and 4, the exclusion of the Swift study needs to be clarified and the number of articles excluded on the basis of language also need to be quantified.

VERSION 2 – AUTHOR RESPONSE

Reviewer Name: Alice Mannocci
Institution and Country: Department of Public Health and Infectious disease, "Sapienza" University of Rome
Please state any competing interests or state ‘None declared’: None declared

Please leave your comments for the authors below

This manuscript has been greatly improved.

title
- I suggest to the author to more effective the title. It's not clear "low income settings"

methods
- I’m very happy to see that the PRISMA statement was included, I suggest to cite with just one sentence at the begining of the methods paragraph.
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Figure 1 it is not included in reviewed version (in the older version it's ok).

In table 3 or 4 can you report the points of the quality of the studies.

***

Thank you for your very helpful comments, especially regarding the use of the strobe versus Newcastle Ottawa scale (NOS). Unfortunately because the studies included were not cohort or case studies NOS did not provide enough discussion points on quality. However, we have reassessed using all studies base on the QATSDD (an assessment designed for mixed methods approaches). We found similar methodological comments and these have been discussed in the study quality section of the manuscript.

We have included a reference to the PRISMA statement as suggested in the methods section (paragraph two).

Thank you for your comments on the title. We have re-worked the title a couple of times based on reviewer feedback. The title has been re-worded again, hopefully now reflecting a more appropriate title.

Figure 1 did not change any content between each version (the only change was in format, i.e. it has been changed from a table to a figure). Figure 1 has been attached in the supplementary section of the submission platform.
Table 3 has further details within it including some of the quality points (sample recruitment now listed in table 3). Further discussion outlining the quality and concerns of each study, based on our assessment, are in the section on study quality. We feel this provides an overview of each study quality in an accessible format, given there was only four studies reviewed.

We would like to thank you again for your reviews and comments to improve the quality of our manuscript, thank you.

Reviewer Name: Emma Hock
Institution and Country: University of Sheffield, United Kingdom
Please state any competing interests or state 'None declared': None declared

***

Thank you for your comprehensive work and review of this article. We thoroughly appreciate the considerable time and effort that you have put into reviewing our article. We wish to extend our appreciation of the time this has taken you to review this manuscript to enable us to create a better paper.

We have answered in response to your comments below:

Please leave your comments for the authors below

It is clear that much work has been done to improve the manuscript. I appreciate what a huge task it must have been to address the many comments and suggestions we have made. There are, however, still some changes that I feel need to be made. Also some of the amendments I suggested previously have not been addressed (either made or argued against).

Much has been done to clarify the whole issue of whether the review is examining effectiveness or perceptions and beliefs. I can understand the way that perceptions and beliefs can be regarded as determinants of behaviour, and can see the rationale for examining determinants, however I would still argue that this link is subject to some debate in the behaviour change literature and where the behaviour of people is concerned it is not a given that people will act on their beliefs (there is a whole literature on this). Therefore, it still seems a bit of a leap to be discussing the current evidence in terms of effectiveness. In my view, the things this review has looked at (appeal, salience of health warnings, perceived taste and enjoyment, and beliefs about tobacco use) are valuable, however they (or rather the way the studies have examined these things) do not tell us anything about effectiveness; one could not answer an “effectiveness” question with the kinds of research the current review identified. I still think that what has been done in the present review is to seek out research on effectiveness and acceptability/views and then report only the acceptability/views research, as that is what was found via extensive searches – which is fine, but this needs to be clearly and explicitly stated. Therefore, I think a few more subtle changes to the wording may be required, in most cases to add in “views” or “acceptability”, to make the distinction absolutely clear. For example:

***The key point that we have not perhaps made clear in the text is that the aim of the review is to determine the effectiveness of Plain packaging in achieving the stated aims of Plain Packaging as a policy. It is not the effectiveness of Plain packaging at decreasing prevalence and policy makers and researchers have been very careful to state that the a direct effect on prevalence is actually not the primary aim or measure. If they aimed for/measured change of prevalence, when the impact is multifactorial and overtime, it would leave them open to the tobacco companies claiming the policy had failed!
For example the Australian legislation has the following aims:
1) reduce the attractiveness and appeal of tobacco products to consumers, particularly young people;
2) increase the noticeability and effectiveness of mandated health warnings;
3) reduce the ability of the retail packaging of tobacco products to mislead consumers about the harms of smoking; and
4) through the achievement of these aims in the long term, as part of a comprehensive package of tobacco control measures, contribute to efforts to reduce smoking rates.

Therefore, the studies in the plain packaging research space (and those we found in this literature review) generally assess the impact (or potential impact) by measuring the effect on a sub-set of indicators or associations with tobacco use. To simplify we have referred to these as “determinants of tobacco use”. This term “tobacco use determinants” was suggested by one of Australia’s leading tobacco control behavioral scientists, Prof David Hill. We had struggled to find an umbrella term to refer to these determinants and perhaps determinants is too deterministic (ie sounds like we are claiming it will lead to a change in tobacco prevalence). We do not claim in the paper that just because we detect an impact on these determinants that tobacco usage/prevalence will automatically be affected. However, there is a body of literature in the plain packaging space that suggests these determinants correlate, when combined with other tobacco control efforts, with tobacco use in the long term. But that is only an association with prevalence and this study does not rely on this. We focus on determining the impact of plain packaging on these determinants themselves. For example we do not claim that finding the pack less appealing will definitely affect tobacco prevalence. However, there is evidence, when this is combined with various other determinants of tobacco prevalence, that it may be one of many factors in changing decreasing tobacco use.

Based on the confusion around wording, we agree with that this needs to be clarified throughout the paper to ensure it will be clear to the general audience what the this article is investigating and discussion. We have incorporated all the changes suggested below, and added further limitations and points to ensure improved clarity of this article.

Added to introduction:
‘Such determinants (or associations) of tobacco use are typically the aim of plain packaging policies and the research to determine its impact. The direct effect of plain packaging on tobacco use prevalence is difficult to disaggregate and has not been the stated aim of plain packaging polices’.

Added to limitations:
‘In general, plain packaging research is often limited, as it does not aim to measure the direct effectiveness of plain packaging on tobacco use prevalence(13). Rather, as shown by the studies in this review, research on plain packaging generally measures the impact on a set of proxies or determinants and the assumption, based on other evidence, is that these may contribute in concert with other interventions to lowering tobacco use prevalence(69, 70).’

We have also tried to make this clearer in the text by changing the wording as suggested by the reviewer (see against each sentence below)***

• In the title, “Effect of plain packaging” could be changed to “Views on plain packaging”, “Acceptability of plain packaging” or “Appeal and perceptions of plain packaging” or similar.
**The title has been changed to ‘Perceptions and impact of plain packaging of tobacco products in low and middle income, middle to upper income countries and low income settings in high income countries: A systematic review of the literature’

• Abstract – objective – add in “views” or “acceptability” to “potential impact and effectiveness of plain
packaging”, to make it more accurate (i.e., the review would have examined effectiveness, had the evidence been there, however only views/beliefs/perceptions were reviewed).

**Thank you for highlighting this, we have now changed sentence to read ‘To review the current literature around the potential impact, effectiveness and perceptions of plain packaging in low income settings’

• Abstract – study selection – again, add “views” or “acceptability” into “effectiveness and/or impact of plain packaging”, to make this clear.

**Effectiveness has been removed, and sentence now reads ‘Studies investigating the impact of plain packaging on the determinants of tobacco use’

• Strengths and limitations – first bullet (p.4, line 32) change “potential effectiveness” to “potential impact”.

**Thank you. This has been changed to potential impact.

• Introduction (p.7, line 28) – change “potential effectiveness and impact” to “potential effectiveness, impact and acceptability”.

**We have changed this line to read ‘perceptions and potential impact and effectiveness of..’

• Introduction (p.7, lines 44-46) – change “the potential effectiveness of plain packaging” to “the potential effectiveness and acceptability of plain packaging”.

**This has been changed to read the ‘potential impact of plain packaging

• Table 2, bullet 3 of inclusion criteria (p.10) – “impacts and/or effectiveness” needs to be changed to “Impacts, effectiveness and/or acceptability” or similar.

**This is has been changed to read ‘the perceptions, impacts and/or effectiveness’

• Results (p.11, line 38) – change “actual or potential impact of plain packaging” to “views on plain packaging” or “acceptability of plain packaging” or similar, for clarity – also need to state that no evidence of effectiveness of plain packaging was identified after that first sentence, again for clarity.

**We have amended this sentence to refer to the impact on the behaviours, as we feel reflects our results. This sentence now reads to ‘actual or potential impact and perceptions of plain packaging on the determinants of tobacco use such…’

A second sentence has also been added to acknowledge study quality does not provide evidence for effectiveness: ‘No studies included in the review were able to investigate causality or demonstrate effectiveness’

• Results (p.12, lines 20-22) the term “potential effect of plain packaging” when discussing the findings of the Arora study also needs to be changed to mention “views” or “acceptability” or similar, as there is nothing in the Arora results as reported in the current review that suggests being able to examine the effect of plain packaging – the sort of data that might provide information on “effect” has not been reported for this study.

**This has been changed and now reads ‘Arora et al.(41) was the only study to review their results comparing the impact and perceptions of plain packaging between income groups’

• Along a similar vein, the subheading “Tobacco usage behaviour” (p.14, line 20) needs changing to “perceptions of the impact on tobacco usage behaviour” or similar, as actual usage was not examined in any of the included studies.

**The sub heading of Tobacco usage behavior has been changed (‘Perceptions of the impact on tobacco usage behavior’) and the references to the subheading throughout the rest of the manuscript have been changed to reflect this subheading change.
• Discussion (p.19, lines 11-13) – change “potential impact of plain packaging” to “potential impact and acceptability of plain packaging” or similar.

“This line has been changed to ‘This literature review found minimal research from Low to Middle Income (LMI) settings (i.e. including LMIC, MUIC and low income settings in HIC) investigating the potential impact or perceptions of plain packaging on the determinants of tobacco use’.

The wording in the Abstract around plain packaging reducing appeal of tobacco products has been helpfully amended in the abstract. However, I have just noticed that the Conclusion mentions “plain packaging can potentially be effective at reducing the appeal of packs” (p.23, lines 30-32); “reducing” needs to be changed here too in a similar fashion. Also, the wording needs to be changed to remove “effective” as there is no evidence that examined the effectiveness of plain packaging on appeal of tobacco packs.

“Thank you, this line in the conclusion has now been amended to instead reads ‘This review indicates plain packaging appears successful in reducing appeal of smoking and packets’

It is useful that a reference to the World Bank has been added to the Methods in relation to MUIC. However, I think that two points remain unclear and in need of clarification, both in the Methods (p.8) and also in the aims and objectives paragraph on the preceding page:

• What the definition of MUIC actually is (in fact it would be useful to also define this for LMIC and HIC – if there is no room in the paper, this information could be presented in a supplementary document);

**A supplementary document (Appendix) has been added which provides definition of MUIC, LMIC and HIC in an easy to understand format.

• Why MUIC have been included (i.e., why you would expect them to be more similar to LMIC than to HIC), as this still is not clear.

“We have included a section in the introduction outlining our rationale for inclusion ‘The rationale to include MUIC and purposefully researched low-income settings in HIC was that there are similarities between these settings, such as higher prevalence of disadvantage, poverty, illiteracy and marginalisation; price elasticity; vulnerability to marketing and image; difficulty in accessing tobacco control interventions and generally higher smoking rates compared to high income settings(65, 66).’

In response to my request for more detail on how the decision was made that evidence from LMIC was limited, you have helpfully specified that “there were few articles relating to LMICs”, however I cannot see where this is specified within the paper itself; could this be added please? It would also be useful to quantify this statement.

“This has been added (page 8, first sentence of second paragraph). There was only one paper found for low to middle income countries and therefore we made to the decision to broaden the study to include MUIC and low income settings in HIC.

The inclusion criteria have been helpfully clarified. However, I still think that the exclusion criteria should specify that research conducted in HIC is only excluded where it has not been conducted in a low income or socioeconomically disadvantaged setting.

“Thank you for this very useful pick up, as we agree it was missing and have now amended this. The inclusion and exclusion criteria have been clarified further, and in the exclusion of HIC it now explicitly states that research in HIC is only excluded where it has not been conducted in low income or socioeconomically disadvantaged setting.

The splitting of Table 3 into two separate Tables detailing the study characteristics and findings has been helpful. I think a few details could be usefully added in.

• I think that for clarity the title of Table 4 should mention findings or results rather than outcomes (as the term "outcomes" does not imply that the findings/results will be reported there, just the outcomes).
We agree the language could be improved and have changed the heading of the table to be the Summary of Findings which more accurately reflects what the table is aiming to do.

- In Table 3, details on analysis could be reported (e.g., on the Likert scale and the pack selection task for the White study, on the opinion poll for the Arora study and on the 1-7 scale for the Guillaumier 2014 study). Details on recruitment in the Guillaumier studies could also be reported. **Thank you for noting these details which were missing. Details on recruitment in both Guillaumier studies has been added (and others where missing), analysis methods for the White study have been added and analysis for Aurora study opinion poll has been added.**

- In Table 4, numerical findings need to be added in where available (e.g., on the ratings in the White study, the finding on high SES participants being more attracted by branding compared with low SES participants, the reduced [also perhaps change that term to “lower” for consistency and clarity] positive cigarette brand image and smoker purchase intentions, decreased [lower?] taste ratings and ratings of pack characteristics for the Guillaumier 2014 study). If such information (e.g. numbers, percentages) is not available then this needs to be explicitly reported. **Thank you for noting the missing details in Table 4. We have now added more details and numbers have been added to all ratings in the White Study have now been added, the Arora funding on SES has been giving numerical value, taste ratings and pack appeal ratings have been added for the Guillaumier study.**

I previously suggested adding in a few words to clarify why the Swift et al. 2014 study stating 49.9% of Australians support plain packaging wasn’t included in the review (e.g. by adding “in high income smokers” or similar) (p.20, line 32). This has not been addressed, however I feel that the point still stands, to make this clear in the mind of the reader. **Our apologies that this was not addressed when it was highlighted in the first review. This has now been amended with the sentence changed to explicitly highlight the high income setting. We have now written “This is similar to information coming out of HIC such as in the UK, where 62% support plain packaging(52) and up to 80% support it if plain packaging made packs less appealing to children and youth(53)), and Australia, where 49.9% of smokers support plain packaging(54)”.

It is helpful that the language restriction has been added to the discussion of the limitations (p.23, lines 6-12) and useful to know that articles published in French and Italian were excluded. Further to this, it would be helpful to quantify the number of articles excluded on the basis of language. **Articles were excluded based on language published at the abstract and title stage (as language was a exclusion criteria). At the abstract and title stage we did not collect reasons for exclusion, therefore are unable to publish the exact number of French and Italian articles excluded. We had discussed with leading experts in the area who were not aware of any of these articles having conducted research into low income settings, so it remains unlikely they would have met the criteria of the study.**

In my mind, the first two sentences of the Conclusion (p.23, lines 20-28) are not strictly necessary. I think the Conclusion could be made more punchy by deleting them and starting this paragraph with the sentence beginning, “This review provides some early evidence...” – although I accept that this is a matter of opinion. **Thank you for this suggestion, and we agree the conclusion could be punchier. The conclusion has been shortened slightly in line with your recommendations.**

Finally, I have spotted a few grammatical inconsistencies and typos that have no doubt crept in during the extensive editing:

- Change “for LMIC it may take multiple years, and various supporting research” (p.21, line 14) to “for LMIC it may take many years, and much supporting research of various kinds” or similar.
**Thank you for your very thorough read through of this paper, and keen eye for detail. This sentence has been amended.**

- Change “difficulty in accessing with tobacco control interventions” (p.22, lines 26-28) to “difficulty in accessing tobacco control interventions”.

**Thank you, the with has been removed.**

If I may, I could not help noticing that Reviewer 3’s suggestion regarding the Swift paper may have been misinterpreted (which, given the volume of corrections from the previous submission, is not totally surprising). I interpret that Reviewer 3 was asking for consideration of the effects of SES on plain packaging in the Introduction (i.e., “before only including studies from low SES groups in HICs”) rather than in the review itself, although I could be mistaken. Either way, I think this would be a useful point to include in the Introduction. The inclusion of MUIC needs to be better defined/justified, exclusion criteria around HIC need to be clarified, some specific detail (including numerical figures/quantities) needs to be added to Tables 3 and 4, the exclusion of the Swift study needs to be clarified and the number of articles excluded on the basis of language also need to be quantified.

**Thank you for the comments regarding reviewer’s 3 suggestions. We have now included a summary of the current literature for SES in the introduction. The exclusion criteria for HIC has been clarified, the rationale for inclusion of MUIC has been outlined in the introduction, table 3 and 4 have more details and numerical quantities, information of SES has been added into the introduction.**

**VERSION 3 - REVIEW**

<table>
<thead>
<tr>
<th>REVIEWER</th>
<th>Emma Hock</th>
<th>University of Sheffield</th>
<th>United Kingdom</th>
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<tbody>
<tr>
<td>REVIEW RETURNED</td>
<td>18-Feb-2016</td>
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</tbody>
</table>

**GENERAL COMMENTS**

I am satisfied that most of my comments have been addressed. There are just a couple of small things that require further clarity in my opinion.

First, in the introduction, the passage “including the effect of socio-economic status (SES) or ethnicity” (p.7, line 19) has been added, in relation to a previous review that has demonstrated impacts of plain packaging on attractiveness, appeal of smoking and salience of health warnings. It is unclear what the effects of socio-economic status are – please could this be clarified.

In Table 3, presumably the 5-point Likert scale in the White study (p.17, line 9) was a 1-6 scale? It would be useful to specify this, given that it would affect interpretation of the findings. Also, the table now states that the Arora study used purposive sampling (p.17, lines 22-23) – it would be helpful to say from where the sample were drawn.

In Table 4, the White study should say “branded pack” instead of “branded back” (p.18, line 21).

Lastly, I may have mentioned this before (or perhaps I forgot or overlooked it), but as with the Results section in the Abstract, ideally the Conclusion needs amending so that “reducing the appeal” (p.24, line 52) is changed to something that doesn’t suggest a temporal
VERSION 3 – AUTHOR RESPONSE

Thank you again for your review. Please see our comments under each point below.

I am satisfied that most of my comments have been addressed. There are just a couple of small things that require further clarity in my opinion.

**Thank you.

First, in the introduction, the passage “including the effect of socio-economic status (SES) or ethnicity” (p.7, line 19) has been added, in relation to a previous review that has demonstrated impacts of plain packaging on attractiveness, appeal of smoking and salience of health warnings. It is unclear what the effects of socio-economic status are – please could this be clarified.

**This has been clarified, and now reads ‘These findings, as listed above, were generally consistent regardless of sample and location, with no change in the effect of plain packaging found between different socio-economic status (SES), or between different ethnicities’

In Table 3, presumably the 5-point Likert scale in the White study (p.17, line 9) was a 1-6 scale? It would be useful to specify this, given that it would affect interpretation of the findings. Also, the table now states that the Arora study used purposive sampling (p.17, lines 22-23) – it would be helpful to say from where the sample were drawn.

**For the White study, this has been amended to include information on the likert scale, and this line now reads “…using a 5 point Likert Scale (e.g. 1 = ‘A lot more appealing’ to 5 = ‘A lot less appealing’)”. The details have been added for where the sample in the Arora study was drawn from, now reads ‘Sample recruited through purposive sampling methods from resident welfare associations and local communities of New Delhi’.

In Table 4, the White study should say “branded pack” instead of “branded back” (p.18, line 21).

**Thank you, this now reads ‘branded pack’ rather than ‘back’.

Lastly, I may have mentioned this before (or perhaps I forgot or overlooked it), but as with the Results section in the Abstract, ideally the Conclusion needs amending so that “reducing the appeal” (p.24, line 52) is changed to something that doesn’t suggest a temporal change, such as “tobacco products in plain packaging have less appeal”, as per the abstract (p.4, line 10).

**As you have suggested we have changed this sentence, which now reads ‘This review provides some early evidence that tobacco products in plain packaging have less appeal, increase the salience of health warnings and may reduce the initiation of smoking in LMICs.’
Perceptions and impact of plain packaging of tobacco products in low and middle income countries, middle to upper income countries and low-income settings in high-income countries: a systematic review of the literature
Nicole Hughes, Monika Arora and Nathan Grills

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