Author’s response to reviews

Title: Warning about drinking during pregnancy: lessons from the French experience

Authors:

Agnes Dumas (agnesdumas@free.fr)
Stephanie Toutain (stephanie.toutain@parisdescartes.fr)
Catherine Hill (catherine.hill@gustaveroussy.fr)
Laurence Simmat-Durand (laurence.simmat-durand@parisdescartes.fr)

Version: 1 Date: 22 Nov 2017

Author’s response to reviews:

Answers to reviewers

Reviewer reports:

Reviewer #1: Well written paper with a clear purpose. It needs to really focus on the problems associated with the tested warning.

The intro, discussion, limitations and conclusion need to include the following

1. The analyzed warning itself is problematic. "Zero alcohol during pregnancy." Does not warn the consumers about FASD. It simply instructs them to avoid warnings without providing a reason. It is also ambiguous. Further, the pictogram used is not graphic. A graphic warning, equivalent to one on a cigarette pack, will yield a stronger response. For example, an image of someone with FASD to depict the facial malformations associated with drinking during pregnancy. I suggest the authors visit Al-Hamdani, M. (2014). The case for stringent alcohol warning labels: Lessons from the tobacco control experience. Journal of Public Health Policy, 35(1), 65-74 and use this reference to explain how a stringent and clear warning such as "Drinking during pregnancy causes facial anomalies" along with an image to depict the consequence of drinking during pregnancy would have made a difference in how the participants perceived risks associated with beer and wine? Would they still think beer and wine are harmful? Visit Al-Hamdani and Smith (2015 and Wigg (2016) etc. to find the answer. Further, would 8.9% of the participants still think that beer is good for lactation if we showed them what alcohol really does?

We added sentences and references highlighting this point in the discussion.
“Furthermore, the pictogram does not warn the consumers about the nature of FASD. It simply instructs them to avoid warnings without explicating the reason. The use of a picture may yield a stronger fear about FASD than a simple pictogram, as it has been shown in studies on the risks associated with alcohol for the general population [28].”

What I am trying to say here is because the warning is problematic as described above, using a less problematic warning would yield different results that are more reliable.

The warning may be indeed problematic, but we do not have any possibility to change it or to make any comparison with any other message. The message is not a test but a national policy which has been displayed on every alcohol container in France since 2007. We cannot compare what has been done to a hypothetical situation.

You mention in your conclusion that "They (the warnings) should emphasize the risks associated with drinking during breastfeeding." You need to explain how?

This relates to the conclusion of the abstract which cannot be changed due to the restriction of the number of words. This point is explained more deeply in the discussion section and it has been changed to make it clearer. Indeed, the actual warning only states that “alcohol” is dangerous during pregnancy and breast feeding. Thus, we invite policy makers to warn about the harm related to beer and not to alcohol:

Thus, future prevention strategies could be targeted at educating women on the concept of standard drinks and their pure alcohol content. Information also needs to be regularly provided concerning beer and breastfeeding for instance by using the word “beer” and not “alcohol”.

The authors are incorrect to say that knowledge about SDLs is effective to increase risk perceptions. In fact SDLs alone have been shown to be mostly ineffective and sometimes detrimental (in case of price-sensitive youth). It is the use of stringent warnings that will increase risk perceptions, regardless of the type of alcohol involved. Adding SDLs in conjunction with stringent warnings may be useful.

There is a misunderstanding. We simply say that it might be more effective, but we cannot affirm it and we do not affirm it. The discussion about the use of more stringent warnings has already been added (see the answer to your first comment).

2. The very large sample size could have inflated significance. The authors need to comment on practical vs. statistical significance

Very large sample do inflate significance on small differences (e.g. 1 to 2% differences) but most of the time we found larger differences which cannot be related to the sample size.

Intro:
The authors need to justify at least some of the variables that they have used in their analyses. For instance, how/why would education be expected to result in differences in the outcomes measured.

Since we were addressing knowledge about a public health message we used education level because it is a well-known predictor of knowledge. See for instance:


Minor corrections The term "multivariable" is misleading, it implies multivariate analysis which the authors did not do. They seem to have used binary logistic regression with multiple variables. They need to say that they tested multiple variables.

You are right. The word multivariable has been replaced by multivariate.

Reviewer #2: This cross sectional survey of around 3,500 postpartum French women on their awareness of health warning labels on alcoholic products is topical for researchers in the field, as many countries are currently considering their introduction. Statistical analyses and interpretation are appropriate and I don't have any real methodological concerns, other than that the data may be somewhat outdated (the survey was done in 2012). However, the data is still valid if authors articulate that the results reflect women's awareness at 5 years post introduction.

You are right. The 1st sentence of the discussion already highlighted this point.

Five years after its implementation, the warning label on alcohol containers has been noticed by 77% of drinkers in the study.

Nevertheless, a sentence in the discussion has been added to further highlight this limitation:

Several limitations must be considered. Data were collected in 2012, five years after the implementation of the warning label policy and thus cannot provide an analysis of the impact of the warning label policy in a before-after design.

Specific comments:

Page 4 lines 6-12: There is now data from a 2017 meta analysis available and paragraph needs updating. Mamluk L, Edwards HB, Savović J, et al Low alcohol consumption and pregnancy and childhood outcomes: time to change guidelines indicating apparently 'safe' levels of alcohol

This reference has been added.

Page 4 line 20: RE Figure 2, I don't think you should be advertising a particular wine. Consider combining Fig 1 and 2 into one that simply shows the crossed out pregnant women and the 13.5% vol.

You are right, we should not advertise for a particular alcohol. We deleted the figure 2 because if we cannot show the whole picture this figure is useless (its aim was to show the size and colour of the pictogram with regard to the whole wine label).

Page 4 lines 13-25 and page 5 lines 1-9: I would restructure this section to alcohol and pregnancy, alcohol and breastfeeding, advice for alcohol in pregnancy, then advice on breastfeeding.

Done.

Page 5 lines 3-6: There is duplication of information on breastfeeding and deficits in lactation performance. Combine refs 6-8 into one sentence. Start para with 'Some studies report that'… and finish with …'while others have not".

Done:

"Regarding breastfeeding, some studies found a relationship between drinking alcohol during breastfeeding and deficits in lactation performance, sleep patterns of infants and infant development [6-8] while others have not [9, 10]."

Page 5 lines 12-13: Wrong spot to open with the study on breastfeeding, this should be after the explanation on alcohol in pregnancy.

You are right.

A reference that was published last month was added (Dossou et al. Eur J of Public Health) in the paragraph concerning alcohol in pregnancy.
Page 6 line 16: What's a 'doubloon' in this context?

It is a duplicate (the same woman could have been registered twice in the database). The word 'duplicate' was used instead of 'doubloon'.

Page 7: line 6: Please be consistent in how you refer to this. 'Booklet' or 'notebook'?

Thank you for your comment, this has been corrected (it is a notebook).

Also, after first mentioned on page 4 lines 22-23, you can leave out 'sent by the French Social Security Administration' at very mention after that.

Done.

Page 8: Lines 2-12: Why is there no multivariate analysis presented for 'perception of risks' as there is for 'knowledge of risks'?

We did not show regressions on perceptions of risks because multivariate analyses did not bring additional information as compared to bivariate analyses (alcohol abstainers and less educated women were more likely to think that daily drinking was not dangerous). Thus, in the article we only show bivariate analyses for the three outcomes and multivariate analyses focus on knowledge of risks and awareness of the warning.

Page 9 line 27: …daily alcohol consumption 'of alcohol' or binge drinking as harmful 'to the unborn child'…

Thank you, this has been corrected.

Page 10 line 1: noticed by 77% of drinkers 'in the study'.

Corrected.

Page 10 lines 3-4: I think this statement should be at the start of the discussion, it's a good impact statement.
We agree. This statement is already at the start of the discussion. The first sentence (before that) only resumes the major findings of the discussion but without discussing them.

Page 10 lines 6-7: the previous sentence does not actually state that women 'know about the official recommendation of abstinence'. Need amending/clarifying.

This sentence was made on a general basis. It was changed into: “However, knowing about a recommendation does not necessarily mean that one follows it.”

Page 11 line 11: healthcare professionals may need to be 'included in a' prevention strategy.

Corrected.

Page 11 lines 11-13. This is a bit of a red herring here, especially as the sentence begins with a 'however'. Consider separating from the previous statement and add in as a new topic with a bit more information or delete altogether.

You are right. We changed the sentence: However, an additional difficulty lies in the planning of pregnancy. “Additionally, early prevention strategies should be implemented but this is difficult to do since many women ignore that they are pregnant during the first months of the pregnancy, especially when it is unplanned.”

Page 11 lines 21-22: This is not a conclusion from your study. Delete or rephrase.

You are right. Both sentences/lines were deleted.

Page 11 Conclusion (overall): Language needs to be tightened up to read more like a conclusion. What can you actually conclude from your findings?

Some sentences from the conclusion were moved to the discussion section and a conclusive sentence was added.

Thus, the French warning label appears as ineffective in preventing about the harm of alcohol during pregnancy because of a lack of communication on the equivalence in pure alcohol content between alcoholic beverages.
Reviewer #3: This is a very clear article that provides information previously not known. It finds that pregnant and postpartum women think it is ok to have 2 drinks/day of wine during pregnancy, and that spirits is worse than other beverages in terms of risk. There are few issues with the methods or the writing. There are two places where a minor revision would be helpful.

The first is when the authors specify their response categories for drinking. It states that the variable is abstainer versus drinker or smoker. That led me to believe, until reading several paragraphs later, that being a drinker or being a smoker was a single combined variable, comparing that combined 'either drinker or smoker' variable to 'abstainer'. This should be rewritten to make it perfectly clear that there are two sets of comparisons, one comparing abstainers to drinkers and another comparing abstainers to smokers. In other words, make it clear that you aren't equating drinking with smoking when you are studying how abstainers differ from something else.

You are right. The term abstainer was changed to “non-drinker”.

The second minor revision similarly pertains to how categorical variables are described. In one of the findings, authors write about women age 35 or more versus women age 25 or more. These are overlapping variables and I must say, this type of error is surprising given the quality of the article. Perhaps therefore I have not read the paper quite carefully enough to understand how that statement actually is methodologically correct.

Thank you for noticing this error which was due to a lack of attention. This has been corrected:

"In multivariable analysis (Table 3), when drinking behaviour was controlled for, unawareness of the warning label was significantly higher in women aged 35 or over than in women aged 25 or above less (OR = 1.99; 95% CI = 1.52-2.61), in women with a low level of education (OR = 1.23; 95% CI = 1.02-1.47), and in single women (OR = 1.42; 95% CI = 1.01-1.98)."