Suboptimal industry adherence to the design specifications of the mandatory pregnancy warning label

Asad Yusoff,[1]* Bella Strȁuli,[1] Alexandra Jones,[1] Paula O'Brien,[2] Jacquie Bowden,[3] Michelle Jongenelis,[4] Aimee Brownbill,[5] Tim Stockwell,[6] Simone Pettigrew[1]

[1]The George Institute for Global Health, Australia
[2]Melbourne Law School, University of Melbourne, Australia
[3]National Centre for Education and Training on Addiction (NCETA), Flinders University, Australia
[4]Melbourne Centre for Behaviour Change, University of Melbourne, Australia
[5]Foundation for Alcohol Research and Education (FARE), Australia
[6]Department of Psychology, University of Victoria, Canada

Submitted: 5 November 2024; Revision requested: 19 February 2025; Accepted: 12 March 2025

Abstract

Objective: To assess whether products sold in the Australian alcohol market are displaying the mandatory pregnancy warning label as per the design requirements.

Methods: Between June and November 2023, data collectors photographed 5,964 unique alcoholic products from three Sydney alcohol retailers. A random sample of 20% of the 3,760 products displaying the mandatory pregnancy warning label was analysed to assess whether they met the design requirements outlined in the Food Standards Code.

Results: Across the sample, 11% of products displaying the mandatory pregnancy label did not do so correctly. Adherence was lowest for spirits (73%), then wine (90%), beer (94%) and premix (97%). In terms of package type, adherence was lowest for individual beverages in containers >800 ml in volume (74%).

Conclusions: The findings indicate that the application of the mandatory pregnancy warning label may be suboptimal in the Australian alcohol market. The lower adherence among spirits and wine products is concerning given their higher alcohol content.

Implications for Public Health: For the effectiveness of the mandatory pregnancy warning label to be optimised, it must be displayed as per specifications. There is a need for ongoing compliance monitoring to improve adherence.

Key words: alcohol labeling, pregnancy warning, alcohol policy, regulation

Introduction

Alcohol consumption during pregnancy is associated with numerous adverse outcomes for the foetus, including impaired growth, premature birth, foetal alcohol spectrum disorder (FASD), and death.[1] Despite increasing evidence of these risks, drinking during pregnancy remains high, with around one in ten women globally drinking at some point while pregnant.[2] Public health efforts to communicate these risks have included public education campaigns and general practitioner education programs.[3]

Over the last decade, public health organisations have advocated for the adoption of mandatory pregnancy warning labels to advise women who are pregnant or trying to conceive and the wider community about the risks of consuming alcohol while pregnant.[4] Currently, 31 countries have national requirements for the application of a pregnancy warning label on alcohol products.[5] Low and slow adoption worldwide has in part been due to industry resistance, such as claims about the negative impact on small businesses (e.g. label printing costs). This industry resistance has resulted in governments allowing long timelines for the implementation of pregnancy warning labels in various countries where the label has been mandated.[6–9]

Product labelling is one of the key recommendations of the World Health Organization's (WHO) global strategy to reduce harmful

*Correspondence to: Asad Yusoff, The George Institute for Global Health, Three International Towers, Level 18/300 Barangaroo Ave, Barangaroo NSW 2000, Australia; Tel.: 0432 439 053;
e-mail: ayusoff@georgeinstitute.org.au.

Aust NZ J Public Health. 2025; Online; https://doi.org/10.1016/j.anzjph.2025.100236

alcohol use.[10] To be effective, warning labels need to be visible and clearly state the risks involved with consumption.[11] Evidence on the efficacy of pregnancy warning labels is still emerging; while experimental studies have found they can reduce self-reported intention to drink and increase intention to seek further information among women of childbearing age, their effectiveness in real-world settings is unclear.[12–14] One reason for the lack of evidence of real-world effectiveness is likely to be due to low label salience. For example, in France it has been argued that the lacklustre effects are due to poor design and visibility of the label,[13,15] while in Australia, low awareness of voluntary pregnancy warning labels was attributed to poor design and low uptake of the industry-developed labels.[16]

The introduction of the mandatory pregnancy warning label in Australia was motivated by the low awareness of the impacts of drinking alcohol while pregnant among Australian women[4] and notably higher levels of alcohol consumption among pregnant women in Australia compared to global rates.[17] After more than two decades of public health advocacy, in July 2020 the Food Standards Code was amended to mandate that all alcohol products packaged and labelled on or after 1 August 2023 must carry a mandatory pregnancy warning label.[18] An exception was made for corrugated cardboard outer packaging, for which producers had until 1 February 2024 to comply with the regulation. The Australian state and territory governments are responsible for enforcement of the Food Standards Code, including the mandatory pregnancy warning label.[19]

The Food Standards Code provides for a set of pregnancy warning labels that apply to products of varying size: individual beverages ≤200 ml are only required to display a pictogram, while beverages >200 ml (and outer packaging for multi-packs) are required to display a warning mark that includes both a pictogram and the warning statement: "PREGNANCY WARNING: Alcohol can cause lifelong harm to your baby".[20] The warning mark comes in three size variations that correspond to different package types and sizes. The outer package of multipacks must show the largest label, followed by individual beverages over 800 ml, and then those between 200 ml and 800 ml (see Supplementary Table S1). The Food Standards Code also sets out requirements for text wording, text height, the size of individual elements (e.g. pictogram height), the colour of each element, and overall footprint.[20]

Recent research indicates that only around two-thirds of alcohol products are displaying the mandatory pregnancy warning,[21] and that when present, the warning is typically located on less visible parts of the product packaging.[21] However, there appears to be no evidence of the extent to which the alcohol industry is applying the warning label in accordance with the design requirements specified in the Food Standards Code. This issue is concerning given that the label was designed based on evidence of effective presentation formats,[14] and that adherence to the design specifications in the Food Standards Code is required to optimise warning outcomes. The aim of the present study was to assess whether products sold in the Australian alcohol market that display the mandatory pregnancy warning label adhere to the design requirements outlined in the Food Standards Code. Adherence was assessed overall, by product category and by product size.

Methods

Data were collected from three major Sydney alcohol stores between June and November 2023. Data collectors went into stores to capture high quality images of all available products. A purpose-built tripod with standardised lighting and a vertical ruler in a photographic compartment was used to position the products for image capture. Data coders then analysed the images and extracted on-pack information including product volume, product type, package type (single vs multi-pack), and presence and type of pregnancy warning label. Both the data collectors and data coders received training using protocols established for capturing and processing data on the labelling of packaged foods.[22] Quality management procedures were used to progressively check image quality and coding accuracy.

Alcohol products were classified into one of five categories (beer, wine, spirits, premix or cider), with versions of the same product in different configurations (e.g. single *vs.* multipack) treated as separate products to reflect the actual number and type of labels in the market. Products were also allocated to one of the four label groups based upon beverage volume and package type to accord with the requirements outlined in the Food Standards Code. These were: i) individual unit <200 ml, ii) individual unit 200-800 ml, iii) individual unit >800 ml and iv) outer packaging of multipacks or individual beverages >200 ml.

Only pregnancy warning labels visible on the outermost layer of packaging were captured (e.g. for a 4-pack of beer, only the warning label from the outer cardboard packaging was photographed and not the label on the internal cans or bottles). Of the 5,694 products included in data collection, 3,730 (66%) displayed the mandatory pregnancy warning label. Among these products, the Excel RAND function was used to randomly select 20% of products within each major product category (wine, beer, cider, spirits and premix), resulting in a sample of 743 products for analysis of adherence to the Food Standards Code pregnancy warning label size and style requirements.

Image processing software (ImageJ) was used to analyse the warning label data. ImageJ is commonly used for medical imaging and allows for precise measurements and analysis of images.[23] The "Set Scale" function was used to calibrate each image, with the ruler acting as the standardised measurement. The "Measure" function was then used to assess the sizing requirements. For the analysis, only vertical measurements were taken with the software, which were then used to extrapolate horizontal measurements and total label size. This was done to avoid measurement error caused by variations in bottle curvature. Style requirements (e.g. colour used, presence of border) were assessed manually. Labels that did not meet one or more of the requirements were considered to not adhere to the requirements outlined in the Food Standards Code.

Results

Across the assessed sample of 743 products, 89% displayed the mandatory pregnancy warning label correctly (Table 1). Adherence to the regulation was highest in the premix and cider categories (100% and 97%, respectively) and lowest for spirits (73%). By package type (Table 2), individual beverages <200 ml in size contained the highest proportion of products correctly displaying the label (97%), while individual beverages >800 ml contained the lowest (74%).

Table 1: Adherence by product type.

Product type	Number of sampled products[a]	Adherence with regulation (%)
Wine	419	90
Spirits	122	73
Beer	103	94
Premix	86	97
Cider	12	100
Total	743	89

[a]Sample comprised 20 % of products that were found to display the mandatory pregnancy warning label.

Table 2: Adherence with design specifications by product size.

Package type	Required label	Sampled products (n)	Compliant (%)
Individual beverage <200 ml	Pregnancy warning pictogram: Label type 4	36	97
Individual beverage 200 ml-800 ml	Pregnancy warning mark: Label type 1	532	89
Individual beverage >800 ml	Pregnancy warning mark: Label type 2	19	74
Outer packaging[a]	Pregnancy warning mark: Label type 3	160	86

[a]Refers to outer packaging of either i) an individual unit >200 ml or ii) a beverage of any volume with more than one individual unit in the packaging.

As shown in Table 3, products were identified as being non-adherent for any of three reasons: i) the label having incorrect dimensions (e.g. the pictogram within the warning mark was too small), ii) the label displayed was intended for a smaller package size (e.g. a 1.5 L bottle using the <800 ml label), and/or iii) the label having some other formatting issue (e.g. the colour of the text was incorrect). The most common reason for incorrect application across the entire sample and for all product categories was the label having incorrect dimensions (65% of non-adherent products).

Analyses by package type (Table 4) found the most common reason for incorrect application of the label on individual beverages was the label having the wrong dimensions, while for products with outer packaging, non-compliance was most commonly due to use of the label intended for a smaller package size. In these cases, the label used was typically that required for the individual products inside the packaging rather than the label required for a multi-pack. For example, a 30 x 375 ml case of beer would display the label for 200-800 ml cans instead of the label required for the larger outer packaging.

Discussion

This appears to be the first study to assess whether the alcohol industry in Australia is applying the mandatory pregnancy warning label according to the specific design requirements set out in the Food Standards Code. While the majority of products displaying the mandatory pregnancy warning label did so correctly (89%), there was considerable variation across product categories. Adherence to the design requirements was lowest for spirits and wine product categories (73% and 90%, respectively), which is concerning given these products contain the highest Alcohol By Volume (ABV) on average and wine is the most common alcoholic beverage consumed by women.[24] These products may thus pose the greatest potential harm to women during pregnancy, making it critical that products in these categories are prioritised for ongoing compliance monitoring at the state and territory level.

Across package types, individual beverages >800 ml and those with outer packaging had the lowest rates of adherence to the Code (74% and 86%, respectively). The lack of adherence on high-volume and larger items is concerning, as using smaller labels on these large packages is likely to reduce visibility and therefore effectiveness of the label. As a result, ensuring proper compliance for larger products packaged after the transition period should also be a priority of monitoring by regulators.

Policy implications

At present, it appears that some products available for purchase in the period from June to November 2023 were not adhering to the mandatory pregnancy warning label design requirements, particularly in the spirits and wine categories. It is not possible in this study to determine whether these products were non-compliant with the mandatory pregnancy warning rules in the Food Standards Code because the label and its associated design requirements only became mandatory for products labelled on or after 1 August 2023, and there was no way in this study to determine the exact packaging date for each product (packaging dates are not required on alcohol products). A product packaged on 31 July 2023 without meeting the labelling requirements would be compliant with the law, whereas a product packaged the next day on 1 August 2023 without meeting the labelling requirements would be non-compliant. However, under the Code, producers had three years to prepare to implement the labelling change (1 August 2020 - 31 July 2023), and it was open to them to apply the mandatory pregnancy warning label to their products any time during this period.[18] For it to be as effective as possible, there is a need for dedicated compliance monitoring to

Table 3: Pregnancy warning label adherence issues by product type.

	Total (n=85)	Wine (n=43)	Spirits (n=29)	Beer (n=6)	Premix (n=3)	Cider (n=0)
Reason for non-compliance	%	%	%	%	%	%
Used mark intended for smaller package size[a]	24	21	24	50	0	0
Incorrect dimensions[b]	65	63	70	50	67	0
Formatting issue[c]	11	16	6	0	33	0

[a]The mark met all style requirements but was smaller than required.
[b]Label was considered to have incorrect dimensions if: i) height of the mark/pictogram was too small, ii) text was too small, and/or iii) pictogram presented within the mark was too small and did not match the exact label requirements for another package size.
[c]Formatting issue: Pictogram or mark size was correct, but the colour, border, and/or text were incorrect.

Table 4: Pregnancy warning label adherence issues by package type.

	Total (n=85)	Individual beverage			Outer packaging[a] (n=23)
		<200 ml (n=1)	200-800 ml (n=56)	>800 ml (n=5)	
Reason for non-compliance	%	%	%	%	%
Used mark intended for smaller package size[b]	24	0	5	20	70
Incorrect dimensions[c]	65	100	77	80	30
Formatting issue[d]	11	0	18	0	0

[a]Refers to outer packaging of either i) an individual unit >200 ml or ii) a beverage of any volume with more than one individual unit in the packaging.
[b]The mark met all style requirements but was smaller than required.
[c]Label was considered to have incorrect dimensions if: i) height of the mark/pictogram was too small, ii) text was too small, and/or iii) pictogram presented within the mark was too small and did not match the exact label requirements for another package size.
[d]Formatting issue: Pictogram or mark size was correct, but the colour, border, and/or text were incorrect.

ensure all products labelled from 1 August 2023 are applying the warning label and displaying it correctly to maximise salience.

One way this could be achieved is through a pre-market approval system. Under such a scheme, companies would be required to submit their labels for pre-approval with the state or territory regulator where the products are produced or imported. This would enable labels to be checked prior to application in the manufacturing process rather than regulators needing to conduct post-market surveillance. Similar systems have been implemented in both non-food and food markets in Germany where the non-profit company RAL (National Commission for Delivery Deadlines and Quality Assurance) oversees the implementation of both the Blue Angel environmental label and the Nutri-Score food nutrition rating on food products.[25,26] Such a system could be more efficient for government, shifting the responsibility of compliance from government to industry, and save producers from paying reprinting costs in the event a label was incorrectly displayed. The alternative would be to introduce a comprehensive product monitoring and enforcement system to facilitate identification of non-compliant products and administration of penalties.

Strengths and limitations

This study appears to be the first analysis of pregnancy warning label design adherence. This topic is highly relevant to current policy discussions in Australia and internationally as more countries consider the introduction of pregnancy warning labels on alcohol products as supported by a growing evidence base.[4,20,27] The results provide evidence of potential use to governments in their efforts to stipulate and enforce effective pregnancy warning labels.

There were two main limitations of this study. First, while the majority of design requirements for the pregnancy warning label were assessed, three requirements could not be evaluated: i) the specific shade of red used, ii) the font used, and iii) the amount of white space around the label. Second, only a 20% sample of products collected from one major Australian city was used for the analysis. It is possible that compliance rates may differ across the total market, including in New Zealand where the label is also mandatory, but which was beyond the remit of the present study. These are areas that could be addressed in future research.

In conclusion, the findings of this study indicate that the implementation of the mandatory pregnancy warning label may be suboptimal, with around one in 10 sampled products that showed the label displaying it incorrectly. The identified level of non-adherence for spirits and wine is particularly concerning given their higher alcohol content. These results highlight the need for robust government monitoring system within the broader context of the continued slow uptake of the mandatory warning label. In the absence of such a system, it is possible that the effectiveness of the mandatory pregnancy warning label will be compromised.

Conflicts of interest

The authors declare they have no conflicts of interest.

Funding

This study was funded by National Health and Medical Research Council Ideas Grant #2021186.

Ethics

Ethical approval for this study was obtained from the University of New South Wales Human Research Ethics Committee, approval number iRECS4533.

Author ORCIDs

Asad Yusoff https://orcid.org/0009-0009-7640-2501
Bella Stŕauli https://orcid.org/0009-0008-2566-6972
Alexandra Jones https://orcid.org/0000-0001-5039-144X
Paula O'Brien https://orcid.org/0000-0002-6879-0489
Jacquie Bowden https://orcid.org/0000-0003-1983-8930
Tim Stockwell https://orcid.org/0000-0002-5696-6803
Simone Pettigrew https://orcid.org/0000-0003-3921-1174

References

1. Popova S, Lange S, Shield K, Mihic A, Chudley AE, Mukherjee RAS, et al. Co-morbidity of fetal alcohol spectrum disorder: a systematic review and meta-analysis. *Lancet* 2016;**387**(10022):978–87.
2. Tsang TW, Elliott EJ. High global prevalence of alcohol use during pregnancy and fetal alcohol syndrome indicates need for urgent action. *Lancet Global Health* 2017;**5**(3):e232–3.
3. *Foundation for alcohol research and education*. National FASD Program; 2021. Available from: https://fare.org.au/fasd-program/.
4. Heenan M, Shanthosh J, Cullerton K, Jan S. Influencing and implementing mandatory alcohol pregnancy warning labels in Australia and New Zealand. *Health Promot Int* 2023;**38**(3):daac022.
5. *Global status report on alcohol and health and treatment of substance use disorders*. Geneva: The World Health Organization; 2024.
6. Lim AWY, van Schalkwyk MCI, Maani Hessari N, Petticrew MP. Pregnancy, fertility, breastfeeding, and alcohol consumption: an analysis of framing and completeness of information disseminated by alcohol industry-funded organizations. *J Stud Alcohol Drugs* 2019;**80**(5):524–33.
7. Millot A, Serra M, Gallopel-Morvan K. How the alcohol industry fought against pregnancy warning labels in France. A press coverage analysis spanning 20 years. *Front Public Health* 2022;**10**:933164.

8. Barlow P, Gleeson D, O'Brien P, Labonte R. Industry influence over global alcohol policies via the World Trade Organization: a qualitative analysis of discussions on alcohol health warning labelling, 2010–19. *Lancet Global Health* 2022;**10**(3): e429–37.
9. Mathews R, Thorn M, Giorgi C. Vested interests in addiction research and policy. Is the alcohol industry delaying government action on alcohol health warning labels in Australia? *Addict Abingdon Engl* 2013;**108**(11):1889–96.
10. *Global strategy to reduce the harmful use of alcohol*. The World Health Organization; 2010. Available from: https://www.who.int/publications/i/item/9789241599931.
11. Kokole D, Anderson P, Jané-Llopis E. Nature and potential impact of alcohol health warning labels: a scoping review. *Nutrients* 2021;**13**(9):3065.
12. Rout Jocelyn, Hannan Tim. *Consumer awareness and understanding of alcohol pregnancy warning labels*. Health New Zealand; 2016. Report, https://doi.org/10.60967/healthnz.27977127.v1.
13. Lacoste-Badie S, Droulers O, Dossou G, Gallopel-Morvan K. Improving the effectiveness of pregnancy warning labels displayed on alcohol containers: a French eye-tracking study. *Public Health* 2022;**212**:22–7.
14. Food Standards Australia New Zealand. *Pregnancy warning labels on packaged alcohol: a review of recent literature*. Available from: https://apo.org.au/node/263901; 2019.
15. Dumas A, Toutain S, Hill C, Simmat-Durand L. Warning about drinking during pregnancy: lessons from the French experience. *Reprod Health* 2018 Feb 2; **15**(1):20.
16. Coomber K, Martino F, Barbour IR, Mayshak R, Miller PG. Do consumers 'Get the facts'? A survey of alcohol warning label recognition in Australia. *BMC Public Health* 2015;**15**(1):816.
17. Popova S, Lange S, Probst C, Gmel G, Rehm J. Estimation of national, regional, and global prevalence of alcohol use during pregnancy and fetal alcohol syndrome: a systematic review and meta-analysis. *Lancet Global Health* 2017; **5**(3):e290–9.
18. Food Standards Australia New Zealand. *Pregnancy warning labels on alcoholic beverages*. Available from;, https://www.foodstandards.gov.au/business/labelling/pregnancy-warning-labels; 2024.
19. Australian Government. *Australia New Zealand Food Standards Code – standard 2.7.1 – labelling of alcoholic beverages and food containing alcohol*. Australian Government; 2023.
20. *Pregnancy warning labels – design elements and downloadable labels*. New Zealand: Food Standards Australia; 2024. Available from: https://www.foodstandards.gov.au/business/labelling/pregnancy-warning-labels/pregnancy-warning-labels-downloadable-files.
21. Davies T, O'Brien P, Bowden J, Stŕauli B, Yusoff A, Jongenelis M, et al. Suboptimal uptake and placement of a mandatory alcohol pregnancy warning label in Australia. International Journal of Drug Policy. 2025 Jan 1;135:104661.
22. Dunford E, Trevena H, Goodsell C, Ng KH, Webster J, Millis A, et al. FoodSwitch: a mobile phone app to enable consumers to make healthier food choices and crowdsourcing of national food composition data. *JMIR MHealth UHealth* 2014 Aug 21;**2**(3):e37.
23. Schroeder AB, Dobson ETA, Rueden CT, Tomancak P, Jug F, Eliceiri KW. The ImageJ ecosystem: open-source software for image visualization, processing, and analysis. *Protein Sci Publ Protein Soc*. 2021;**30**(1):234–49.
24. *Do Australian men and women drink different types of alcohol beverages?: the National Alcohol and Drug Knowledgebase*. National Centre for Education and Training on Addiction; 2019.
25. Nutri-Score. *RAL logo lizenz*. Available from: https://www.ral-logolizenz.de/nutri-score/; 2023.
26. Blue Angel. *RAL gGmbH – the awarding body for the Blue Angel ecolabel*. Available from: https://www.blauer-engel.de/en/blue-angel/actors/ral; 2021.
27. The World Health Organization. *Health warning labels on alcoholic beverages in the WHO European Region in 2024*. Regional Office for Europe: World Health Organization; 2024. Available from: https://www.drugsandalcohol.ie/41438/.

Appendix A Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.anzjph.2025.100236.