Report 2

Alcohol Warning Labels:

Evidence of impact on alcohol consumption amongst women of childbearing age.

Prepared by National Drug Research Institute (Curtin University of Technology), in collaboration with Drug and Alcohol Office (WA), National Drug and Alcohol Research Centre (University of New South Wales), Public Health Advocacy Institute. (Curtin University of Technology)

Authors: Celia Wilkinson, Steve Allsop, Denise Cail, Tanya Chikritzhs, Mike Daube, Gary Kirby and Richard Mattick.

Technical and other support: Maggie Halls, Richard Pascal and Vic Rechichi

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Preface

This report has been prepared for Food Standards Australia New Zealand (FSANZ) to assess the available evidence of the effectiveness of warning labels on packaged alcohol products with specific relevance to women of childbearing age and during pregnancy. The report was prepared by National Drug Research Institute (Curtin University of Technology), in collaboration with the Drug and Alcohol Office (WA), National Drug and Alcohol Research Centre (University of New South Wales) and the Public Health Advocacy Unit (Curtin University of Technology).

This report includes:

- Review of the harms associated with the use of alcohol during pregnancy;
- Discussion of the potential risks associated with alcohol use during breastfeeding;
- Review of government strategies and responses in relation alcohol use amongst women of childbearing age and during pregnancy;
- Discussion of a number of theoretical frameworks that underpin warning labels;
- Results of a scoping analysis to review and collate the warning labels of packaged alcohol that are available internationally;
- Critical review of the international research literature (published and grey literature) on the effectiveness of warning statements on labels of packaged alcohol;
- Review of lessons learnt from the use of warning labels in the tobacco field;
- Discussion of the optimum measures of effectiveness if warning labels were to be introduced; and,
- A detailed summary of the report and reviewed evidence, and reflection on a series of issues for consideration.

Executive summary

Background

This report has been prepared for Food Standards Australia New Zealand (FSANZ), with the central aim of assessing the available evidence regarding effectiveness of warning labels of packaged alcohol products. The report was prepared by the National Drug Research Institute (Curtin University of Technology) in collaboration with the Drug and Alcohol Office (WA), National Drug and Alcohol Research Centre (University of New South Wales) and the Public Health Advocacy Unit (Curtin University of Technology).

This report has two primary objectives. These are:

1. To provide a comprehensive and objective review of the available evidence regarding the effectiveness of warning labels on packaged alcohol products (with a particular focus research on the impact of warning labels on women of childbearing age, pregnant and breastfeeding women), drawing on domestic and international experience of alcoholic beverage labelling and comparable public health initiatives within the context of the Australian National Alcohol Strategy and New Zealand National Drug Policy.
2. To provide estimates of possible changes in outcomes which may be used to measure the effectiveness of labelling in Australia and New Zealand if warning labels on packaged alcohol were introduced, drawing on domestic and international experience of alcoholic beverage labelling and comparable public health initiatives, within the context of the Australian National Alcohol Strategy and New Zealand National Drug Policy.

The project involved a literature review, which was based on a systematic search for available and relevant literature on the effectiveness of alcohol warning labels (advisory statements). In addition, individuals who had published research in the area were contacted via email and asked to identify relevant publications and to recommend other suitable authors/organisations for the research team to contact. The literature was critiqued in relation to methodological rigour, reliability, validity and

generalisability. A reference group reviewed the methodology adopted for the project and the draft and final reports.

It was noted that despite the fact that over 20 countries have adopted mandatory alcohol warning labelling, and at least five countries have included labels that warn about the risk of alcohol use during pregnancy, there is only a relatively small research base that can inform evidence-based reviews of the effectiveness of this approach. Most publications have come from the U.S.

This report includes a brief discussion of alcohol consumption and the potential alcohol related harm that can occur in relation to Fetal Alcohol Spectrum Disorder (FASD) in both Australia and New Zealand; a discussion on the potential risks associated with alcohol consumption by women who are breastfeeding; an outline of models that inform responses to this harm; and, discussion of the range of factors that interact to influence the development and maintenance of harm. Most models of alcohol related harm in general, and responses to this harm, include a range of factors that interact to protect and/or increase the risk. This leads to a conclusion that isolated strategies are not likely to have impact, or will have limited impact – multifaceted approaches are required. While the evidence base about preventing and responding to problems arising from alcohol consumption during pregnancy and infancy (i.e. related to breastfeeding) is less well developed than other domains, multifaceted approaches are generally recommended.

In New Zealand and Australia combined approaches to alcohol problems have been adopted, typically broadly categorised as harm, demand, and supply control strategies. Governments in New Zealand and Australia have developed comprehensive alcohol policies and approaches that reflect the acknowledged complexity of alcohol use in society. New Zealand is finalising a National Alcohol Action Plan and Australia has developed the National Alcohol Strategy 2006-2009.

It is commonly acknowledged that strategies to reduce alcohol-related harms work best in combination – particularly when they complement each other. The complex nature of alcohol related problems, the range of initiatives which may occur across different sectors (e.g. police, health, policy), and design and measurement challenges

among research evaluations can all make it difficult for analysts to distinguish the specific effects of one intervention among a suite of activities. That is, it is generally not possible to disaggregate the effects of one strategy from other activities or events. The role of alcohol warning labels is considered in this context.

The role of warning labels

There have been recent calls to include warning labels on alcohol packaging in Australia and New Zealand, an approach adopted in some other countries. Warnings and consumer advice on packaging are common on diverse products, from pharmaceuticals to swimming pool equipment.

Various theoretical perspectives have been considered in understanding the influence of health communications, including warning labels. The Health Belief Model is one such perspective. Research into the Health Belief Model indicates that giving information about the risks of a particular behaviour may not be sufficient to result in behaviour change. Other theoretical approaches reach similar conclusions. They predict that a warning label, or other media, communicating messages about health risks may be noticed and understood in general, but might not be interpreted by an individual as having personal relevance. For example, self-serving optimism may increase the sense that the risks are only pertinent for other people. The various models indicate that health messages will need to be perceived as personally relevant before they are considered. Health information in a warning label may then be recognised by an individual, but other strategies, such as interpersonal discussion about risk and the individual having access to strategies that will assist them making any behavioural adjustment will be required. This suggests that health communications, such as warning labels, will not be sufficient to ensure behaviour change – other strategies will be required. Nonetheless, some researchers have concluded that a combination of narrowcasting, commercial and social marketing strategies (including health advisory messages) can potentially influence behaviour (Abroms and Maibach 2007; Grier and Bryant 2005). They may be particularly relevant for women of childbearing age and pregnant women as the times

immediately prior to conception and during pregnancy represent a critical window of opportunity or a "teachable moment" in which proximally timed interventions are more likely to prompt women to adopt risk reducing health behaviours (McBride, Emmons and Lipkus 2003). For example, there is evidence that a proportion of women who are about to become, or are pregnant, alter their diet (e.g. folic acid supplementation; reduce consumption of certain foods with a risk profile) cut down or cut out smoking (Floyd, Rimer, Giovino, Mullen and Sullivan 1993) and/or reduce their alcohol consumption (Bolumar, Rebagliato, Hernandez-Aguado and Florey 1994; Ockene, Ma, Zapka, Pbert, Valentine Goins and Stoddard 2002; Mitka 1998)

In recent reviews of the effectiveness of warning labels on a range of products, it was concluded that effectiveness can be measured in numerous ways. The criteria for assessing the effectiveness of warning labels have included:

1. Attention (the ability to attract the attention of the consumer);
2. Reading and comprehension;
3. Recall of the message;
4. Judgements of the product's risks and hazards; and,
5. Behavioural compliance with the message.

There are potential moderators of a warning label's effectiveness. These include:

1. *Vividness-enhancing characteristics*, such as font size, colour, spacing, level of specificity and symbols;
2. *Warning location*, such as whether the information is placed on or off the product (e.g. point of sale warning labels versus warning labels on the package), on the front or on the back of the package;
3. *Familiarity*, such as how familiar a consumer is with a product may also impact on whether or not a consumer notices a warning label;
4. *Age*, whereby cognitive abilities change with age and this may influence recall of label information; and,
5. *Product type,* (e.g. warning labels on product known to carry risks, such as pharmaceutical drugs versus products that have a more recent risk profile, such as sun beds).

There is some debate about legitimate expected outcomes regarding warning labels. This debate should be related to theoretical considerations, as indicated in the Health Belief Model and models that underpin our understanding of alcohol problems. Some will claim that if a warning label has not resulted in a change in behaviour, it is not effective. Others have commented that if a warning label successfully informs consumers of potential risk, even if they do not act on that information it can, at least in part, be judged effective. For example, two key researchers on this issue have noted that:

> "*Some warnings are designed to convey information about a product's potential risks, and as long as consumers understand the risk involved, the choice of behaviour is ultimately up to them. In addition, if consumers accurately recall the dangers associated with the consumption of a particular product but choose to ignore them, the warning label has still effectively served its purpose*." (Argo and Main 2004, p.205).

Outcome of the current review

Forty original research studies were located that specifically investigated the effectiveness of warning labels on alcoholic beverage containers. All but four of the papers were based solely on data from the U.S. Of the remainder, two studies were based on a comparison of U.S. and Canadian data, one was based on data from the U.S. and Australia, and another paper was from Israel. While thirty-five of the studies had some relevance for women of childbearing age, only five of these studies (conducted by Hankin and colleagues) specifically investigated the impact on alcohol warning labels with pregnant women. None focused on breastfeeding.

This review concluded, as have past reviews by others, that the majority of available research had significant limitations:

- Most studies did not include adequate control observations and thus, factors other than the alcohol warning labels may have influenced outcomes;
- Most studies originated from the U.S. raising questions about generalisability to other countries;

- Many studies had relatively small and/or non-representative samples (e.g. samples of marketing students, African-American pregnant women) reducing the generalisability of the results;
- Amongst those studies that have been well designed, most have relied on self-report with no confirmation of the reliability of these measures;
- The current research base does not allow a comparison between potential impacts of voluntary and mandated alcohol warning labels;
- The current research base does not extend to the function and effects of warning labels in licensed drinking settings (e.g. hotels, nightclubs, restaurants) where alcohol may be consumed from glassware and in the absence of its original packaging (e.g. tap beer, wine consumed by the glass);
- No research was identified which examined the potential effects that alcohol warning labels may have on beverage preferences and substitution effects with alternative substances;
- The studies do not allow assessment of unintended adverse outcomes of warning labels (e.g. unnecessary anxiety amongst pregnant women; unwarranted termination of a pregnancy; unwarranted and premature cessation of breastfeeding);

Using the measures of effectiveness described above, the research evidence indicated:

- A reasonable consensus that people are able to recall the presence of warning labels (even though it has been observed that U.S. labels are not particularly noticeable and do not stand out from their background);
- A substantial proportion of consumers, including younger consumers, who have reported that they had seen an alcohol warning label could recall the message;
- Only a small body of research indicated that warning labels have some impact on judgements about risks associated with alcohol consumption;
- There was insufficient assessment of whether consumers understood the information conveyed on warning labels;
- There is a very limited evidence base about the impact of alcohol warning labels on behaviour. Some research indicates that the introduction of alcohol

warning labels in the U.S. was associated with a self-reported increase in the likelihood of respondents having a conversation about the risks of alcohol. There is also some limited evidence that the warning labels reportedly prompted pregnant women to discuss the topic and the more types of warnings that respondents were exposed to (on advertisements, point of sale promotions etc.) the more likely they were to discuss alcohol associated risks. One study indicated that exposure to the warning message led to a reported reduction in alcohol consumption amongst pregnant women who were light drinkers, and pregnant for the first time.

There are a number of gaps in the evidence, including the following:

- There is a paucity of discussion about the models that underpin alcohol warning labels. Limited evidence, and sometimes conflicting findings, do not allow adequate testing of the models that have been considered;
- There is little evidence that can guide decisions, if they were to be adopted, about the nature and content of warning labels that are most effective (e.g. location, appearance, message); whether pictorial advice about not drinking during pregnancy is more or less effective than a written message;
- Evidence about behavioural impact is largely lacking;
- Strong conclusions about populations who are most responsive and least responsive to health communication strategies such as alcohol warning labels are not possible; but there is some evidence to suggest that younger age groups and heavier drinkers are more likely to recall warning labels;
- Conclusions about how best to link alcohol warning labels to other strategies are not informed by the evidence;
- Little attention has been paid to unintended and adverse outcomes (e.g. does the inclusion of a warning message lead to an increased risk of anxiety among otherwise well-women or perhaps an increase in terminations amongst women who have consumed alcohol during pregnancy; lead to a reduction in the proportions of women considering breastfeeding as an option; should particular approaches/messages be embraced/avoided); and,

- It is not possible to estimate cost, and in conjunction with other limitations identified above, cost-effectiveness/efficiency of the approach cannot be estimated.

The table below summarises the relevant research on the impact of warning labels on samples that include women of childbearing age, who are pregnant or breastfeeding. As noted, only a small number of studies specifically addressed alcohol use during pregnancy.

Finding	**Level of support from the available research**
Over time more people will become aware of the existence of warning labels	Moderate
Depending on the message and the characteristics of the individual, people who are aware of the presence of warning labels are able to recall the messages	Moderate
Some groups, such as young people (including women of childbearing age) and heavier drinkers, may be more aware of the warning labels	Moderate
Those people who see labels are more likely to have conversations about the risk of alcohol during pregnancy	Moderate
Exposure to more than one message source (e.g. warning label, poster, advertisement) has a greater impact on knowledge and behaviour and increased the likelihood of conversations on the topic	Weak-Moderate
Warning labels had no effect on behavioural intentions regarding future consumption	Weak-Moderate
Warning labels are associated with a reduction in consumption amongst women pregnant for the first time	Weak

The available evidence allows only tentative suggestions about the potential impact in New Zealand and Australia of adopting alcohol warning labels that specifically

target the risks associated with pregnancy. Based upon the available literature for a range of population groups, not specifically pregnant women:

- Within a two- to three-year period, the majority of women drinkers will have noticed the warnings;
- Younger women and heavier drinkers may be more likely to notice the warnings;
- Of those who notice the labels, approximately 50% will be able to recall the message (this will vary depending on the content of the message);
- There is likely to be an increase in the number of conversations that people will engage in on the risks of alcohol use during pregnancy message topics; and,
- It is less clear whether any behaviour change will occur. However, it is possible that:
    - If labels are complemented by point of sale, posters and other message sources, people ***may*** report a reduction in the consumption or their intentions to drink during pregnancy.

It is important to note that these possibilities are based on evidence of the effects of U.S. warning labels, which were small text based messages that were not clearly linked (in the research reports) to other strategies. As already indicated, it is not possible, from the research, to estimate the costs of adopting warning labels, nor to estimate unintended adverse outcomes. Nor was there any available evidence on the potential impact of alcohol warning labels on breastfeeding. Consequently, it is not possible to estimate cost-effectiveness/efficiency.

The conclusions drawn by this review should be considered in the following context:

- The majority of observed effects have been modest. This is perhaps not surprising given that follow-up in most research has been short-term (6 months or less). Such a brief period of time may not be sufficient for individuals to act on the information contained in the label;
- Warning label content has focussed primarily on a narrow band of messages, such as pregnancy/birth defects, drinking and driving, operating machinery,

information about alcohol content/standard drinks and less commonly chronic health effects;

- Most evidence indicates that alcohol warning labels have most impact on message recognition and there is some evidence about impact on conversations about risk. There is very little evidence about impact on behaviour. This is consistent with predictions that may be made under a Health Belief Model. Other strategies will be required to translate any impact of warning labels into changes in risk behaviour; and
- It has been commented that most alcohol warning labels currently in use are likely to have limited impact, given their location, nature and style. While a number of countries (e.g. France) have utilised pictorial based warnings on the risks associated with alcohol use during pregnancy, no research was available to compare the relative impact of such warnings as compared to the written warnings used in the U.S. The nature of alcohol warning labels compare unfavourably to tobacco warning labels, where there is a stronger body of evidence about effectiveness.

Tobacco warning labels

It is acknowledged that tobacco is not the same product as alcohol and that there are distinctions in how communities perceive and respond to problems associated with the two substances. However, there may be lessons to be learned from experiences with tobacco warning labels, which have been found to significantly influence smokers' understanding of the risks of tobacco use and on their reported consumption levels.

Evidence from New Zealand, Australia and elsewhere indicates that the content, style and presentation of tobacco warnings can markedly affect how noticeable and memorable warnings are, and also influence the extent to which consumers understand, believe and feel empowered to act upon the information they contain. Evidence indicates that tobacco warnings are most effective when they:

- Promote negative attitudes to smoking, while also promoting positive attitudes to quitting;
- Combine strong identification of risk with information about how risk can be avoided;
- Convey a sense of the negative social as well as negative health consequences;
- Focus on the relevant attitudes of the target groups;
- Increase perceived self-efficacy;
- Promote discussion about smoking among smokers friends and family; and,
- Confront self-exempting beliefs.

Based upon the body of tobacco research, it is evident that:

- Obscure text warnings appear to have minimal impact. Frequently alternated messages that depict health risks in a vivid and emotionally arousing manner and in clear simple language have the greatest impact;
- Pictures are more effective than text (even when text is clear and simple);
- The bigger the warning label the better. Smokers are more likely to recall larger warnings, with bigger warnings associated with greater appreciation and acceptance of risk; and,
- Warning labels on the front of tobacco packaging is more effective. Evidence indicates that smokers will have better recall of warning labels that appear on the front, rather than the side of packages.

In summary, research in the tobacco control area highlights that for warning labels to be most effective in increasing awareness and perceptions of risk, and prompting behaviour change, they need to be prominent, simple, and visually graphic. The relevance of these findings to alcohol has not been tested, and while some graphic labels warning women of the risks associated with alcohol use have been adopted, there use has not been evaluated.

Conclusion

To date, alcohol warning labels that have been adopted are relatively limited in nature (e.g. at least compared to tobacco warning labels) and have addressed only a small

range of alcohol related harms. The evidence base for alcohol warning labels is limited: there is reasonable consensus that alcohol warning labels are noticed and recalled but less evidence that they have impact on behaviour, particularly relating to pregnancy. There have only been a few rigorous long-term and extensive evaluations of the impact of warning labels on harms associated with alcohol use and there is only limited evidence related to risky or high-risk alcohol use in pregnancy and no research was located on alcohol warning labels and alcohol use while breastfeeding.

A number of commentators have noted that public health strategies should not just target those who are pregnant, but should be relevant for all women of childbearing age because a significant proportion of pregnancies in Australia and New Zealand are unplanned (and sometimes initially unnoticed). In addition, the focus has been on alcohol consumption in general, not just heavy drinking. This approach has been adopted even though there exists some contention concerning the teratogenic properties of alcohol use during pregnancy, particularly at low levels of alcohol consumption (e.g. Henderson et al., 2007). Despite this contention, given the lack of evidence that allows a determination of a safe level of alcohol consumption during pregnancy, the relevant positions in both Australia and New Zealand are that the safest option for pregnant women is not to drink, but it is also recognized that risk increases at increasing levels of consumption.

The alcohol warning label evidence currently available does not support bold unqualified conclusions. Taking this lack of certainty into account, this report has highlighted a number of important issues for consideration. The following discussion ***does not*** propose that alcohol warning labels should be adopted. The aim is to highlight issues that will be important to consider ***if*** warning labels were to be adopted.

1. Evidence from other domains, especially tobacco use, provides some useful information. This evidence indicates that to have impact warning labels should be prominent, graphic and should incorporate images as well as text. Evidence from the tobacco arena indicates that messages are most effective when mandatory and when

messages and images are frequently changed and alternated. Such approaches (at least in relation to prominence, use of images that are graphic) have not commonly been adopted in relation to alcohol warning labels and thus, of course, the impact of such approaches has not been evaluated. It is possible, given that both alcohol and tobacco are regulated, legal and psychoactive drugs; that experience from tobacco control may be generalisable to alcohol. Nonetheless, caution is indicated as there is currently no evidence to support such generalisation. In addition, there are important distinctions between tobacco and alcohol (e.g. no dose of tobacco is accepted as low risk, which is distinguished from perceptions of alcohol consumption). In the context of the above discussion, the apparently limited evidence about the impact of alcohol warning labels might be interpreted as "a paucity of opportunities for investigation and evaluation" as opposed to one of "no impact."

2. It can be difficult to differentiate between the specific effects of warning labels and other concurrent activities that aim to prevent and reduce alcohol related harm. Models about health communication and preventing and reducing alcohol related harm and related evidence suggest that interventions such as warning labels are likely to be most effective when part of a broader strategy. If alcohol warning labels were to be adopted, they should be consistent with, and where possible linked to, current alcohol policy and related strategies in Australia and those that are identified in the impending New Zealand policy. In relation to drinking among women of childbearing age, **if** warning labels were adopted they might focus on the risks of alcohol and unplanned pregnancies in addition to the risks associated with the ongoing consumption of alcohol during pregnancy and should complement other concurrent strategies and activities (e.g. strategies to avoid risk, alcoholic beverage price changes, advice by primary health care staff, increased screening of alcohol use during pregnancy, potential restrictions on alcohol promotions). Because of the tension between the benefits associated with breastfeeding and the risks associated with alcohol consumption whilst breastfeeding, it may be difficult to deliver such a complex message through an alcohol warning label. Subsequently, whether or not warning labels might specifically address alcohol and breastfeeding should be considered in the context of a broader approach.

This suggests the need for a coordinated approach. That is, if alcohol warning labels are adopted, it will be important to ensure communication among those tasked with oversight of the approach (e.g. FSANZ) with stakeholders (such as government agencies) who are responsible for implementing other alcohol public health strategies. Thus, for example, warning labels aimed at reducing the risk of Fetal Alcohol Spectrum Disorder among women of childbearing age should preferably be part of a broader and coordinated set of evidence-based strategies to reduce drinking risks among this target group (e.g. interventions by primary health care services and antenatal clinics; broad social marketing campaigns; supply control and demand reduction approaches).

3. Available evidence from the alcohol and tobacco research domains suggests that the content of any alcohol warning labels is likely to be influenced by the following:

(i) The evidence about alcohol related harms, focussing on the consequences that are more prevalent and costly, and amenable to intervention.

(ii) The capacity to effectively communicate information/advice about a specific issue in a warning label.

(iii) The relationship between the label content, government policy, strategic directions and broader strategies.

(iv) Characteristics of the consumers/target audience and target behaviours. The evidence indicates that there may be diverse needs and responsiveness of intended audiences.

(v) Drinking behaviour of the consumers/target audience. For example, if drinking largely occurs in licensed premises, consumers may not be exposed to warning labels attached to packaged liquor. Alternative/additional health communication approaches may be required.

4. Consideration of warning labels on the issues of pregnancy and breastfeeding may have implications for a wide range of stakeholders, including community members, governments, industry, public health experts, primary care physicians, midwives, child health nurses, obstetricians and paediatricians and so on, and a judicious planning phase would include substantial consultation with such groups. Sound choices regarding labelling content and design are most likely to arise in the context

of an evidence-based decision making process that includes health, behavioural science and social marketing expertise.

5. There is some evidence that pregnancy represents a "teachable moment" or a critical window of opportunity in which proximal interventions may be efficacious in encouraging a reduction in at risk behaviours. As such, interventions such as alcohol warning labels about alcohol and pregnancy, ***may*** be more likely to have impact with this target audience. However, this opportunity may not be evenly distributed among the target population. First, a significant proportion of women may be pregnant without realising it, at least in the early stages of pregnancy. Second, the evidence indicates that some women *may* be more responsive to health messages than others. For example, the research by Hankin and colleagues (1993, 1996) indicated that light drinkers and those women for whom this was their first pregnancy were more likely to moderate their drinking after exposure to alcohol warning labels compared to heavier drinkers and women who had previously been pregnant. This issue requires further investigation as does answering the questions: what impact do alcohol warning labels have on women in remote areas, women from diverse cultural backgrounds, Indigenous women, very young women, older women, women with multiple risk exposure (e.g. other drug use; tobacco use) and so on.

6. If adopted, alcohol warning labels should be coupled with adequate investment to effectively evaluate their impact. Drawing on evidence to date and taking current knowledge gaps into account, this should ideally include consideration of the following:

- Potential cost/benefit of the approach, to industry, the community and to government;
- Acceptability, credibility and believability of message content;
- Quality baseline data about target behaviours, including: a) knowledge about the risks associated with alcohol use during pregnancy; b) drinking behaviour prior to pregnancy; c) risk taking relevant to target behaviour (e.g. consumption during pregnancy); and d) public support for and understanding of aims of alcohol warning labels;

- Level of exposure of consumers and target audiences to alcohol warning labels;
- Impact of alcohol warning labels on: a) knowledge about risk/judgement of alcohol's risks and hazards (e.g. unplanned pregnancy, FASD; alcohol consumption during breastfeeding b) behavioural intention relating to drinking and associated risk taking relating to pregnancy; c) behavioural compliance or actual drinking behaviour and related risk taking; and d) adverse outcomes (e.g. increased anxiety amongst pregnant women, increased terminations, etc.).

Highest value would be obtained from evaluation which was, as far as possible, able to assess the impact of warning labels in isolation and as part of an overall strategy (e.g. acceptability and believability could be assessed in isolation, but behavioural impact might be assessed as part of an overall intervention).

Chapter 1: Introduction

1.1 Aims

This report has two primary aims. These are:

1. To provide a comprehensive and objective review of the available evidence regarding the effectiveness of warning labels on packaged alcohol products (with a particular focus research on the impact of warning labels on women of childbearing age, pregnant and breastfeeding women), drawing on domestic and international experience of alcoholic beverage labelling and comparable public health initiatives within the context of the Australian National Alcohol Strategy and New Zealand National Drug Policy; and,
2. To provide estimates of possible changes in outcomes which may be used to measure the effectiveness of labelling in Australia and New Zealand if warning labels on packaged alcohol were introduced, drawing on domestic and international experience of alcoholic beverage labelling and comparable public health initiatives, within the context of the Australian National Alcohol Strategy and New Zealand National Drug Policy.

1.2 Background

FSANZ is a statutory authority constituted by the Food Standards Australia New Zealand Act 1991. FSANZ's aim is to protect the health and safety of people in Australia and New Zealand through the development of effective food standards. FSANZ does this collaboratively with all Australian governments, the government of New Zealand and with industry, consumer and public health stakeholders.

FSANZ is responsible for developing and maintaining the Australia New Zealand Food Standards Code. This code has standards which regulate the labelling and composition of food including alcoholic beverages.

In February 2006, the Alcohol Advisory Council of New Zealand lodged an application (A576) with FSANZ seeking a variation to existing Standard 2.7.1 to

require a health advisory label on alcoholic beverage containers advising risk of consuming alcohol when planning to become pregnant and during pregnancy. FSANZ released a discussion paper for an eight- week period in December 2007. Ninety submissions were received and these have all now been evaluated by FSANZ (www.foodstandards.gov.au 21/01/09).

In May 2008, the Australia and New Zealand Food Regulation Ministerial Council asked FSANZ to consider mandatory health warnings on packaged alcohol. In response to the Ministerial Council request and the earlier ALAC application, the current review was commissioned.

Chapter 2: Methodology for preparing the report

This report does not represent a series of meta-analyses, but is a comprehensive review that is based on individual original research papers, meta-analyses and reviews.

The literature review involved a systematic search for available and relevant literature on the effectiveness of alcohol warning labels. As the 1988 Alcoholic Beverage Labeling Act (P.L. 100-690) in the U.S. did not require alcoholic beverages product manufacturers to include alcohol warning labels until November 1989, the initial search for relevant published material entailed scanning: 'Informit', 'Pubmed', 'PsychInfo', 'ScienceDirect', 'ProQuest' and 'Medline' databases for literature published in English from 1990 until October 2008. These databases covered drugs and alcohol, health, psychology and marketing. When searching for literature, key words included: 'alcohol labelling', 'warning labels', 'effectiveness of warning labels', 'tobacco and warning labels', 'effectiveness of alcohol and warning labels', 'pregnant women and warning labels', 'alcohol and warning labels', 'health warnings' and 'health warning labels'. Grey literature and unpublished information were identified using general internet search engines such as Google and Google Scholar and government/health websites e.g. National Drugs Sector Information Service (NDSIS- formerly ADCA). A second search of the literature using the same methodology as above was undertaken that covered 1989 till 1990. The only new paper that was identified during this search was a discussion paper by Engs (1989). Given that the first mandated alcohol warning labels occurred at the end of 1989, it is not anticipated that there are earlier studies of the impact of such approaches.

In addition, nine individuals who had published research in the area were contacted via e-mail and asked to identify other relevant publications and to recommend other suitable authors/organisations for the research team to contact. Based upon the recommendation from FSANZ, the Alcohol Advisory Council of New Zealand were also contacted and asked to provide any material that might be deemed of relevance to the investigation e.g. recent papers and publications on the topic of alcohol labelling. The original email sent to authors is included below:

"A small consortium with representation from the National Drug Research Institute, National Drug and Alcohol Research Centre, the Public Health Advocacy Institute (WA) and the Drug and Alcohol Office are reviewing the nature, provenance, impact etc of alcohol warning labels (i.e. on alcohol packages/bottles etc.) for Food Standards Australia and New Zealand. We are trying to identify relevant literature using the regular approach but also contacting colleagues and those of you who have already published in the area. Anything you can direct us to in relation to the topic would be fantastic. The only limit would be that publications need to be in English (at least the abstract). If you know of anyone else who may be able to provide information on the topic I would appreciate you forwarding to them a copy of this email or letting me know so that I can contact them directly.

Thank you very much."

In addition, based upon feedback from FSANZ on the first draft of the report the Directors of two government alcohol agencies in the United Kingdom were contacted to provide an update on legislative issues regarding alcohol warning labels and asked if they were aware of any new available research on the topic. This combination of a snowballing and targeted methodology resulted in eighteen individuals being identified who were potentially knowledgeable about the topic. However, as these individuals were not asked for permission to publish their names, it is not appropriate that they be identified in the report. The eighteen individuals contacted were from university (n=14), government (n=3) and industry based organisations (n=1). Six of the contacts were from Australia, three from New Zealand, three from Europe, four from the United States (U.S.) and two were from Canada.

Using the combined approach of a review of the literature, as discussed above, and seeking advice from the key individuals (discussed above) about literature that has specifically investigated the effectiveness of alcohol warning labels, forty original research studies were located (using the data bases accessible to the Drug and Alcohol Office and Curtin University of Technology) that specifically investigated the effectiveness of warning labels on alcoholic beverage containers. In addition over 40

general review/discussion papers were also located (See Appendix 4). The majority of available reviews reached similar conclusions, based on evidence available at the time. Four recent reviews, which include the more recent literature, were examined in some detail. It is relevant to note that, in general, research studies investigated impact on a range of behaviours, and very few reports focussed on the impact on specific areas of risk, such as pregnancy and none investigated breastfeeding.

Each research paper was critiqued with regard to the following criteria:

- Strength and appropriateness of methodological design (e.g. cross–sectional versus longitudinal data, use of matched pairs versus unmatched controls);
- Sound external validity (e.g. representative/random sample, generalisability of results, adequate sample size, consideration of confounding and historical factors, plausibility of assumptions); and,
- Sound internal validity (e.g. validity and reliability of measurement instruments, random allocation of subjects: consideration of maturation and selection effects).

The methodology for collecting literature, the design and structural plan and all drafts of the report had input from a reference group that included: Professor Steve Allsop (Director, National Drug Research Institute (NDRI), Curtin University of Technology), Associate Professor Tanya Chikritzhs (Senior Research Fellow, NDRI), Professor Richard Mattick (Director, National Drug and Alcohol Research Centre), Professor Mike Daube (Director, Public Health Advocacy Institute, Western Australia), and Mr Gary Kirby (Director, Prevention and Workforce Development, Drug and Alcohol Office, WA). The reference group received drafts of the report, made comment and recommendations and provided expert input on particular issues relevant to their expertise (for example, Professor Daube's expertise was instrumental in the development of the two chapters on tobacco health warnings; Professor Chikritzhs provided input on patterns of alcohol use and related harm, Mr Kirby's advice was sought on people's awareness of risks associated with alcohol consumption).

The current report has followed the principles of evidence-based medicine modified for the purposes of preparing a report on alcohol warning labels. The approach is

defined as "*the conscientious, explicit and judicious use of current best evidence in informing decisions about alcohol policy*" (Anderson 2007). In adopting such an approach the sentiments of Sir Muir Gray (1999) are noteworthy: "*The absence of excellent evidence does not make evidence-based decision making impossible; what is required is the best evidence available, not the best evidence possible*".

Although the report represents a comprehensive review of the evidence-based literature, it has been dependent on what is available. In light of the fact that over 20 countries have now adopted mandatory alcohol labelling, as will be indicated in the detailed review below, it is paradoxical that so little research is available to evaluate the behavioural effectiveness of this potentially important social marketing approach. As the overwhelming majority of available publications are from the U.S., it has not been possible to provide information that is necessarily generalisable to other countries, cultures and populations. Nor has it been possible to identify research that has investigated the impact of alcohol warning labels on burden of disease, disability adjusted life years (DALYs) or economic impact.

2.1 Structure of the report

The report commences with a discussion of alcohol use in both Australia and New Zealand, including reference to federal responses and alcohol strategies implemented in each country. This is followed by a brief discussion of theoretical frameworks underpinning generic and alcohol warning labels and exploration of definitions of effectiveness. The report then provides an overview of drinking guidelines in Australia and New Zealand, followed by a review of drinking patterns of women of childbearing age, patterns of drinking that are relevant to FASD, a review of alcohol consumption during pregnancy and examination of women's level of awareness and knowledge of the risks of consuming alcohol during pregnancy and breastfeeding..

Subsequently the report examines the history of alcohol warning labels, including a brief overview of the use of warning labels in all other English speaking OECD countries. This concludes with a synopsis of the current official position on alcohol warning labels of the European Union (EU). Specific examples of alcohol warning

labels are included and information provided on the specific wording used in labels from a number of countries.

Next the report concentrates on the available literature that has specifically investigated the effectiveness of alcohol warnings on recall/awareness, perception of risk and behaviour change. As tobacco health warnings have been commonplace in both Australia and New Zealand for more than thirty years (Smokefree Coalition 2008) and there exist a plethora of research on the effectiveness of such labels, this literature will be reviewed. It is acknowledged that there are differences between alcohol and tobacco, but there is a substantial literature regarding tobacco that may have relevance for alcohol.

The report then addresses the issue of possible changes in outcomes which may be used to measure the effectiveness of labelling in Australia and New Zealand following any potential introduction of warning labels on packaged alcohol, drawing on domestic and international experience of alcoholic beverage labelling and comparable public health initiatives, within the context of the Australian National Alcohol Strategy and New Zealand National Drug Policy.

The report concludes with a discussion that brings together the above elements and closes with identification of key issues that are important in any discussion about alcohol warning labels.

Chapter 3: Public health and the role of warning labels

3.1 Alcohol use in New Zealand and Australia

Apart from caffeine, alcohol is the most widely used psychoactive recreational drug in Australia and New Zealand (Australian Institute of Health and Welfare 1999; Australian Institute of Health and Welfare 2002; Australian Institute of Health and Welfare 2005; Australian Institute of Health and Welfare 2007; Ministry of Health 2007). Based upon national data from the 2004 Health Behaviours Survey, 83% of the New Zealand population aged 15 years and over and 74% of 15 to 17 year olds had consumed alcohol in the previous 12 months (Ministry of Health 2007). Among New Zealanders aged 12–65 years, who had consumed alcohol in the last 12 months, 14.7% consumed large amounts of alcohol at least once a week (for males this represented more than six standard drinks on one drinking occasion; for females this represented more than four standard drinks on one drinking occasion). Overall, an estimated 15.4% of New Zealand drinkers consumed alcohol seven or more times a week on average in the last 12 months and approximately one in six New Zealand drinkers (16.2%) consumed alcohol on average four to six times a week. Amongst 25-34 year old men and women, 12.2% reported drinking 7 times or more per week and 17.9% drank 4-6 times per week (no gender breakdowns were presented by age group) (Ministry of Health 2007). Data from large-scale New Zealand surveys indicate that while Māori are less likely to drink alcohol and drink less often, they drink more heavily on a typical drinking occasion when compared with non-Māori (Ministry of Health 2007).

In 2007, the average Australian aged 15 years or older consumed 9.88 litres of pure alcohol (Australian Bureau of Statistics 2008). In Australia the net government revenue from alcohol taxation increased from $3.6 billion in the period 1995-96 to $5.1 billion in 2004-05 (Australian Institute of Health and Welfare 2007). The 2007 National Drug Strategy Household Survey (NDSHS) estimated that 83% of the Australian population aged 14 years and over had consumed at least one full serve of alcohol in the past 12 months and 8% drank alcohol on a daily basis (Australian Institute of Health and Welfare 2008a).

For many people alcohol forms part of an enjoyable and healthy lifestyle (National Health and Medical Research Council 2001). Conversely between 1992 and 2001, over 31,000 Australians died from alcohol-caused injury and disease, and in the eight years between 1993/94 and 2000/01 over half a million hospitalisations in Australia were caused by alcohol (Chikritzhs, Catalano, Stockwell, Donath, Ngo, Young and Matthews 2003). According to Connor, Broad, Rehm, Vander Hoorn and Jackson (2005) alcohol consumption was estimated to contribute to 1,037 deaths in New Zealand in the year 2000. The majority of these alcohol-related deaths in New Zealand were due to injuries (51%), cancer (24%) and other chronic diseases (25%).

In 2004-05, Collins and Lapsley (2008) concluded that based upon crime, violence, treatment costs, loss of productivity and premature death, alcohol cost the Australian community $15.3 billion. In New Zealand, research by Easton (2002) indicated that the total social costs from alcohol were between $1 and $4 billion dollars per year. Later research by BERL suggested that in 2005/06 alcohol use cost New Zealand an estimated $4,794 million (Slack, 2009).

3.2 Responses to alcohol related harm

Alcohol consumption does not exist in isolation from other individual lifestyle behaviours (e.g. smoking, diet, exercise), cultural or environmental influences (Edwards et al. 1994). As such, governments have implemented a range of strategies for reducing alcohol related harms e.g. drink driving legislation, random breath testing, regulatory liquor licensing laws, hypothecated taxation, and thiamine supplementation. These strategies typically fall into one of three broad categories: harm, demand and supply reduction strategies. Included among a range of harm and demand reduction strategies are alcohol guidelines providing information on low risk drinking, school and community based education strategies, and warning labels on packaged alcohol. The implementation of a multifaceted approach by governments in Australia and New Zealand mirrors the complexity of alcohol use and encompasses many of the elements of the Public Health system model.

This model (see Figure 1) conceptualises the determinants of health and alcohol use on a continuum from macro to micro, acknowledging the range of prevention activities that can be adopted. These strategies range from international approaches to strategies that focus on the individual (Loxley et al. 2004).

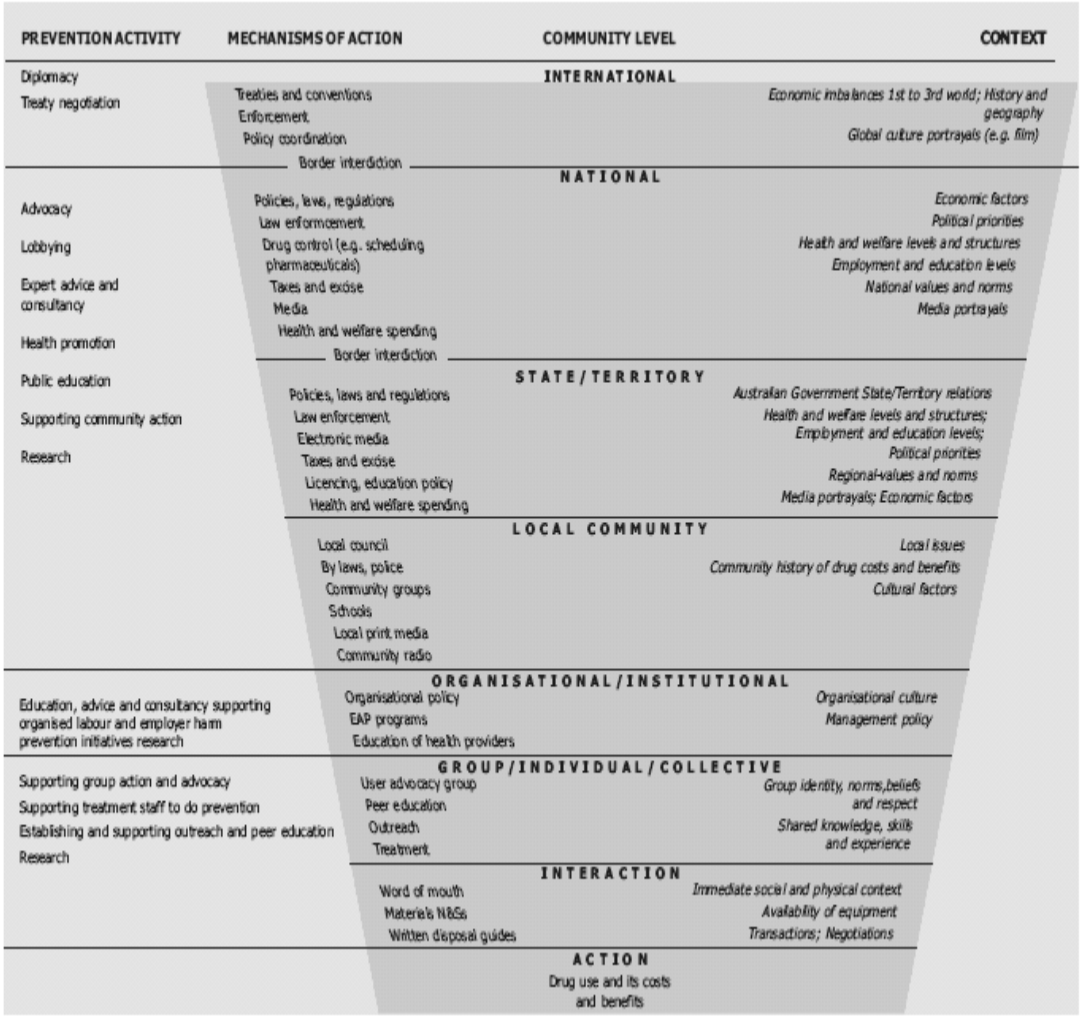

Figure 1: Systems approach to prevention as cited in Loxley et al. 2004.

Another useful framework for contextualising appropriate responses to alcohol use is the Risk and Protection model (Loxley et al. 2004, see Figure 2). This model acknowledges that alcohol risk and protective factors originate within both family and educational systems but are also influenced by community and cultural factors.

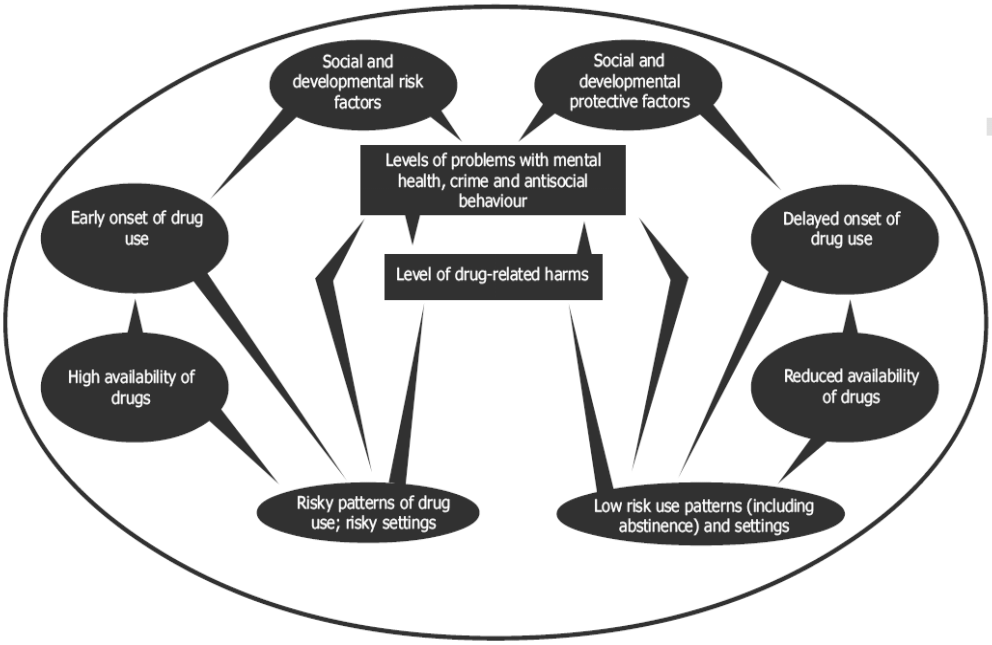

Figure 2: Risk and protection model as cited in Loxley et al. 2004.

Governments in New Zealand and Australia have developed comprehensive alcohol strategies that reflect the acknowledged complexity of alcohol use in society. New Zealand is finalising a National Alcohol Action Plan (Ministry of Health 2008), that has as its aim the reduction of alcohol-related social, economic, health and environmental harms. To achieve this aim, New Zealand has developed a framework for action (see Figure 3) including five primary goals which underpin the vision and aims of the plan and provide areas of focus. These goals relate the following areas:

1. Individuals, families and whanau;
2. Community and environment;
3. Workforce and skills;
4. National frameworks; and,
5. Information, research and communication.

These frameworks and strategies do include a focus on risky drinking by women, including women of childbearing age. Indeed, within these frameworks, there has been a recent specific focus on the issue of alcohol, pregnancy and Fetal Alcohol Spectrum Disorders (FASD).

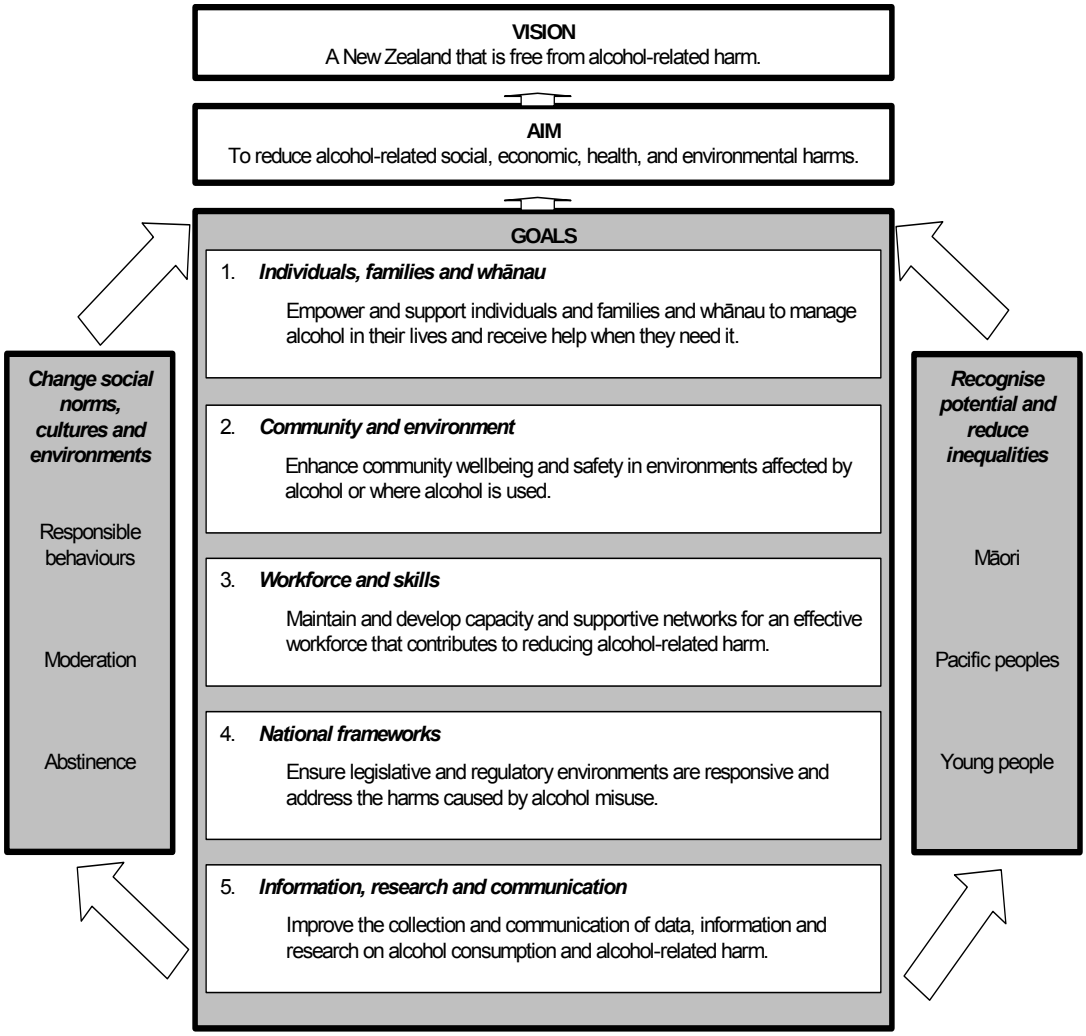

Figure 3: New Zealand Framework

For example, the National Drug Policy 2007-2012 includes recognition that alcohol related harm includes birth defects, including Fetal Alcohol Syndrome. In addition, the Interagency Committee for Drug Policy in New Zealand has agreed to develop a whole of government action plan to address FASD (see below for a description of FASD). As part of this plan, a Child and Maternal Health Action Plan is currently being developed and this will include FASD. It is anticipated that this Action plan will be completed by the end of 2009.

Similarly, Australia has developed the National Alcohol Strategy 2006-2009 (Commonwealth of Australia 2006). The goal of the National Alcohol Strategy is to prevent and minimise alcohol-related harm to individuals, families and communities in the context of developing safer and healthy drinking cultures in Australia. The

following four priority areas have been nominated as the focus of the National Alcohol Strategy 2006-2009:

1. Intoxication
2. Public Safety and Amenity
3. Health impacts
4. Cultural place and availability

An underlying premise of the Australian National Alcohol Strategy 2006-2009 is that cultural place and the availability of alcohol represent major determinants of behaviours that can lead to alcohol-related harm. The strategy also acknowledges that although many determinants, behaviours and outcomes of alcohol-related harm can be identified, many are inter-related and synergistic (Commonwealth of Australia 2006). The National Alcohol Strategy identifies Fetal Alcohol Syndrome (FAS) as a particular health concern and notes that better and more consistent data and evidence are required about the full range of alcohol-related birth defects, so that specific interventions can be developed to reduce its incidence, particularly in Aboriginal and Torres Strait Islander communities (Ministerial Council on Drug Strategy 2006). For a more detailed review of national responses in Australia and New Zealand to prevent the incidence of FAS and FASD see Chapter 4.

A recent review (Brand, Saisana, Rynn, Pennoni and Lowenfels 2007) of alcohol policies in 30 OECD countries ranked Australia as fifth and New Zealand as 11th overall. The study by Brand et al. (2007) rated the alcohol policies in each of the 30 countries using a composite score that was based upon the adoption of a range of policies and strategies such as the physical availability of alcohol, prices, drinking context, alcohol advertising and road safety. The study also found that as alcohol policies increased in strength (i.e. effectiveness) alcohol consumption decreased. In short, theory about and responses to alcohol problems usually embrace a diverse number of approaches working in combination.

Various researchers have identified those interventions that have been identified as effective. These have included:

1. Higher alcohol taxation
2. Partial or complete bans on the advertising and promotion of alcohol

3. Measures to reduce drink driving
4. Brief interventions by primary care physicians to reduce hazardous alcohol consumption (Commonwealth of Australia 2008, Chisholm, Doran, Shibuya and Rehm 2006; Collins and Lapsley 2008).

It is generally acknowledged that Babor and colleagues (2003) have provided one of the more authoritative reviews on effective approaches to prevent and respond to alcohol related problems. Below we provide a brief overview of their description of various strategies:

3.2.1 Tax/Price

Price is an important determinant of consumption and related harm. Alcohol taxation influences the price of alcohol over and above market forces (cost of production, supply etc.). Changes in taxation and other price changes (even small changes) have an effect on alcohol consumption. The evidence consistently indicates that higher priced alcohol is associated with per capita declines in consumption while lower priced alcohol is associated with increases in consumption. The evidence indicates that while there may be some variation in response to price changes across different groups' particular subgroups, such as young people and heavy drinkers, are sensitive to price changes.

3.2.2 Physical availability

The ease/difficulty of accessing alcohol can affect alcohol consumption. Of course, price can affect availability but there are other influences. Alcohol may be banned (e.g. through widespread/national prohibition or in a specific community/locale, as happens in some Indigenous communities in Australia). Controls may be placed on the type of alcohol available at certain times or events (e.g. at some sporting events there are controls on the types of alcohol available and alcohol content as well as limitations on how many drinks an individual can purchase at one time or bars may be only open for limited times). Limitations may be imposed on the days and hours of sale and, in some communities, there are restrictions on the nature of purchases (e.g. no bulk packaged liquor sales). Increases and decreases in the minimum purchase age

have been associated with corresponding changes in consumption and related problems.

3.2.3 Drinking context

Not all drinking contexts are associated with the same level of risk. For example, overcrowded, late night venues with poor crowd control techniques have higher risk of a range of adverse outcomes (e.g. violence) than venues with well-trained staff who comply with responsible server practices. It is not just a matter of training staff. Risk is reduced when training in responsible service of alcohol (e.g. not serving drunk people, not serving underage people, not engaging in promotions and other practices that encourage risky consumption, engaging skilled crowd controllers) is combined with enforcement strategies (e.g. through police and licensing authority activity).

3.2.4 Drink-driving

Random breath testing reduces drink driving, if there is a perceived high probability of detection. Certain individuals (such as those who record very high blood alcohol levels and who are alcohol dependent) who can be resistant to these strategies and additional approaches may be helpful (e.g., diversion to treatment, installation of devices that prevent car activation if a breath test is 'positive').

3.2.5 Alcohol promotions

Alcohol promotions have become diverse and more sophisticated as electronic and other communications have developed. Greater exposure to alcohol promotions has been associated with increased product recognition, more positive attitudes to alcohol and drinking and, in some studies, heavy drinking. Exposure to alcohol promotions may influence young people's knowledge, intentions and behaviour about drinking. Unlike alcohol availability, promotions have largely been subject to voluntary as opposed to statutory regulation. There are criticisms (based on evidence) that self-regulation has been ineffective. On the other hand, the evidence regarding statutory controls is inconsistent.

3.2.6 Education and persuasion

These include mass media communication, communicating guidelines on low-risk drinking and school- and college-based programs (e.g. information about the risks of alcohol; resistance skills). The acceptance of these programs appears high. While some well-resourced programs show modest effects, often these do not persist, particularly if the programs are conducted in isolation. Recent research in the U.S. has however, indicated some support for the use of community education campaigns (based upon the distribution of posters) targeting women about the risks associated with alcohol use during pregnancy (Glik, Prelip, Myerson and Eilers 2008).

3.2.7 Early intervention and treatment

A range of treatments for alcohol problems, including opportunistic and brief interventions for hazardous drinkers (e.g. in GP surgeries and hospitals or through self-help programs) or intensive treatments for people who are alcohol dependent, have been demonstrated to be effective. Widespread adoption of such approaches in primary health care settings remains elusive, despite the fact that routine screening of alcohol use amongst pregnant women is recommended (Morse and Hutchins 2000).

3.3 Prevention of FASD

Although not identified by Babor et al (2003) in the main categories of intervention, other work has specifically identified a range of responses that should focus on preventing and responding to FASD. For example, the Canadian Paediatric Society (1994) recommended a combination of primary, secondary and tertiary prevention efforts to reduce the incidence of FAS. These strategies included:

1. "Prevention efforts that target women before and during their childbearing years, as well as those who influence such women, including their partners, families, and the community.
2. Information should be provided to all health professionals regarding the risks of alcohol use during pregnancy to facilitate early recognition of at-risk drinking and early intervention.

3. Continuing education programs for health professionals designed to enhance counselling skills that motivate and support lifestyle change for at-risk drinkers, should be widely disseminated and evaluated.
4. Health professionals working with members and leaders of communities must provide consistent information to women and their partners that the prudent choice would be to not drink alcohol during pregnancy.
5. Health professionals play an essential role in identifying women who drink at levels that pose a risk to the fetus and themselves. Screening methods should be applied to identify women at high risk for heavy alcohol consumption before and during pregnancy. Similarly, health professionals have a responsibility to inform women at risk, and to initiate appropriate referrals and supportive interventions.
6. Alcohol and drug addiction treatment services should incorporate the needs of women, including transportation and daycare, into their program design. Pregnant women seeking help should be given high priority at alcohol and drug addiction treatment centres.
7. Health professionals should inform women who consumed small amounts of alcohol occasionally during pregnancy, that the risk to the fetus in most situations is likely minimal. They should also explain that the risk is relative to the amount of alcohol consumed, body type, nutritional health and other life-style characteristics specific to the expectant mother. If exposure has occurred, health professionals should inform mothers that stopping at anytime will have benefits for both fetus and mother.
8. Health professionals, including family physicians, paediatricians and others to whom children are referred, should increase their awareness of maternal alcohol use in pregnancy to identify the possible causes of birth defects and other developmental disorders and to identify and prevent adverse risks for subsequent pregnancies.
9. Communication between researchers and health-care providers must be an ongoing process to determine and evaluate the most effective means of primary, secondary, and tertiary prevention of FAS/FAE"(p.1).

It should be noted that the majority of interventions to prevent and respond to FASD are relatively recent and the evidence base is modest. The evidence regarding the

effectiveness of brief interventions by physicians is probably strongest. There is little specific focus on breastfeeding in this literature.

The models discussed above and the range of strategies discussed, indicate that approaches to respond to alcohol problems are often multifaceted. Generally, no single strategy is considered sufficient. This implies that strategies such as social marketing campaigns, school drug education, brief interventions and, in all likelihood, alcohol warning labels (if adopted) should be accompanied by other approaches. In short, integrated approaches that include a combination of strategies acting in synergy are more likely to be effective (Babor et al. 2003, Commonwealth of Australia 2008). For example, while the evidence suggests that initiatives such as school based alcohol education programmes, community action programmes and mass media education campaigns, have in isolation limited impact on behaviour, there is evidence that each has a positive contributory effect and is thus important (Edwards et al. 1994).

Research that highlights the complementary role of many public health initiatives indicates that a reductionist epistemology that focuses on the impact of single variables is important. However, it can preclude recognition that attributing causation to single variables assumes that individual strategies have incremental, additive effects, when in reality individual strategies are "*nurtured by the others, creating a synergism which produces"* a reduction in demand (Chapman 1993, p.432). Thus, the consensus is that alcohol use in general and specifically during pregnancy should be addressed through understanding and influencing the total and dynamic system, which comprises societal drinking and effective policies, and not addressed through an exclusive focus of picking off little pieces of the continuum (Edwards et al. 1994).

While it might be desirable, from one point of view, to disaggregate the effects of particular approaches from other approaches (e.g. the effects of social marketing campaigns from all other alcohol strategies) the integrative nature of current models suggests there will be limitations to such approaches. In addition, methodological challenges have limited the possibility of disaggregating the effects of one approach from others.

It is within a context of a comprehensive public health strategy, that we now review and analyse the available evidence on the efficacy of alcohol warning labels in the Australian and New Zealand context. As will be seen in this review, the overwhelming majority of studies are not able to isolate the effects of alcohol warning labels from other initiatives.

As part of this review three issues should be considered. These are:

1. What theoretical frameworks support the introduction of warning labels?
2. Against what criteria should the effectiveness of warning labels be assessed?
3. Can the effectiveness of warning labels be isolated from other influences?

3.4 Theoretical frameworks and warning labels

Warnings and consumer advice on packaging are common on diverse products, from pharmaceuticals to swimming pool equipment. For example, following a 1999 report from the National Highway Safety Administration in the U.S. highlighting that sports utility vehicles rolled over in side-impact tests, the U.S. Safety Administration mandated that manufacturers replace the 15-year-old text only label warning with a coloured label that showed a vehicle tilted to one side (Associated Press 1999- cited in Argo and Main 2004).

As indicated above, and according to Cox, Wogalter, Stokes and Tipton Murff (1997) warning labels have been developed because of manufacturers' concerns for user safety, fear of litigation, legal requirements and to meet industry standards. Warnings typically include information on the safe use of a product, handling and disposal, dosage, contraindications and emergency procedures (Chapman and Carter 2003). Providing such information to consumers about goods and services sold in the market place has been recognized as one of eight fundamental consumerist principles (Consumers International 2003). But what is the theoretical, and empirical, basis of support for warning labels?

One explanatory framework that has been directly applied to warning labels is the heuristic-systematic model (Chaiken 1980; 1987). This model proposes that two information processing modes may be responsible for explaining the relative

effectiveness of warning labels (Zuckerman and Chaiken 1998). The first of these modes is systematic processing whereby an individual accesses, analyses and integrates information to reach a judgment. In contrast, heuristic processing involves the use of learned knowledge structures in the form of simple decision rules, to make judgements. According to Zuckerman and Chaiken (1998) "*systematic processing will only occur when an individual possesses adequate levels of both cognitive capacity and motivation"* (p.622). Two components that are likely to serve as heuristic cues are the colour of the warning text and the signal word that introduces the text. According to Zuckerman and Chaiken (1998), research indicates that a warning in red text is perceived as implying a greater hazard than black text and use of the word **Danger** implies a great hazard than the word **Caution** (e.g. Braun, Sansing and Silver 1994; Wogalter, Magurno, Carter, Swindell, Vigilante and Daurity 1995).

A bias effect can occur when the warning label information is ambiguous and therefore open to interpretation (Zuckerman and Chaiken 1998). In addition, bias may also occur when one part of the warning, for example a pictograph influences the interpretation of another part of the warning (Frantz, Miller and Lehto 1991) or when a person is experienced with a product (Robinson 1991).

In relation to motivation, when a message is congruent with existing beliefs, the warning will be judged as more valid and accurate than incongruent material (Zuckerman and Chaiken 1998). The degree of this congruence will influence the effective of the warning material. In addition, the higher the degree of perceived invulnerability the more defence-motivated systematic processing is likely to occur i.e. disregard for information contained in the warning message (Zuckerman and Chaiken 1998). Zuckerman and Chaiken (1998) also contended that the heuristic-systematic model may also account for the influence that social context may have on compliance with product warnings (See Wogalter, Allison and McKenna 1989).

The context of pregnancy may present what has been referred to as a "teachable moment." According to McBride, Emmons and Lipkus (2003) the term

> *"teachable moment has been used to describe naturally occurring health events thought to motivate individuals to spontaneously adopt risk reducing health behaviours"(p.156).*

Thus, there are times when individuals may be more receptive to information and/or advice. For example, when an individual is admitted to hospital for a smoking related condition (Freund, DÁgostino, Belanger, Kannel and Stokes 1992) or receives a diagnosis of a chronic disease (Salive, Cornoni-Huntley, LaCroix, Ostfeld, Wallace and Hennekens 1992) they are more likely to cease smoking. The idea of "teachable moments" has been applied in a number of contexts. For example teachable moments have been suggested in connection to sexual behaviours and HIV prevention (Fabiano 1993), alcohol consumption (Mitka 1998), injury prevention (Helmkamp 2000) and lifestyle change (Nutting 1986).

Similarly, pregnancy has been widely identified as teachable moment "because of mothers' strong motivation to protect the well being of the fetus" (McBride et al 2003, p.159). In relation to this, research has suggested that pregnancy represents a window of opportunity or a "teachable moment" where women are more likely to respond to health messages and events and reduce health compromising behaviours including smoking and alcohol use (Ershoff, Quinn, Boyd, Stern, Gregory and Wirtschafter 1999; Ockene et al 2002; O'Connor and Whaley 2006).

Social learning theory (Bandura 1986), the theory of reasoned action (Fishbein and Ajzen 1975), the Health Belief Model (Rosenstock 1974) and memory based models (Tolman 1932) have also been used to explain a number of health related behaviours. One element from these models that has been investigated, specifically in relation to alcohol warning labels, has been outcome expectancy. Stacy, Widaman and Marlatt (1990) have previously reported that general constructs of positive and negative expectancies toward alcohol use were empirically distinguishable from one another and from the construct of attitude towards drinking and those positive expectancies were a superior predictor compared to negative expectancies and attitudes of behaviour.

In follow up research, Stacy, MacKinnon and Pentz (1993) assessed the predictive strengths of different types of expectancy constructs in a sample of 12th grade high school students in the US in relation to the information included in warning labels on alcoholic beverages in the US. Stacy et al. (1993) reported that negative expectancies were generally predictive of alcohol-related behaviour, especially driving under the influence (DUI). The authors concluded that this result implied that it was **possible** that expectancies about the negative outcomes targeted by the warning label influence alcohol-related behaviour. The research also highlighted the importance of social acceptance expectancies as an important predictor of drinking behaviour.

Later research by Cable and Sacker (2007) in the United Kingdom indicated that positive alcohol expectancies predicted all types of adolescent alcohol use in young men and women. Negative alcohol expectancies did not predict any type of drinking behaviour. Research by Leigh and Stacy (2004) demonstrating that negative expectancies only produced reduced consumption after 35 years of age, may help explain why negative expectancies to protect young people from heavy episodic drinking often fail. One implication of this research is that warning labels may be less effective with younger populations as they are primarily based on increasing negative expectancies (at least the ones used to date). Cable and Sacker also reported that norms were the most important predictor of adolescent alcohol use, supporting the earlier U.S. research by Stacy et al. (1993). This suggests that the impact of communication strategies, such as warning labels, will be influenced by the social context in which the labels appear – other strategies may be important to influence this context.

The Health Belief Model has been important in the development and assessment of health communication. Evidence from research testing the principles of the Health Belief Model (Rosenstock 1974) has concluded that providing information or increasing knowledge about the risk of a particular behaviour is insufficient to affect a person's actions. According to the Health Belief Model, to change behaviour an individual must feel personally susceptible to a particular health problem; must feel that the problem can cause them serious harm; know what actions can be taken to avoid the harm and finally understand the cost or benefits of the actions (Engs 1989). If the costs of changing behaviour outweigh the benefits then action is unlikely to

occur (Engs 1989). Similarly, the Theory of Reasoned Action developed by Fishbein and Ajzen (1975) proposes that behaviour is a function of intention. Intention, in turn, is influenced by two components: attitude towards the behaviour (influenced by expectations) and social influences or norms.

The concept of conveying personal susceptibility and harm is particularly difficult with young people (Vinal 1986). In relation to the effectiveness of alcohol and drug education with university students, Goodstadt (1984) concluded that that while education increased knowledge, it resulted in minimal behaviour change. Similarly, after reviewing the effectiveness of over 100 alcohol and drug education programs across all school levels, Hanson (1982) reached a similar conclusion. Additionally, research by LaChausse (2008) indicated that while the Fetal Alcohol Spectrum Teaching and Research Awareness Campaign (a multimedia, peer-delivered educational intervention targeting high school students in the U.S.) increased participants knowledge regarding FAS, it had no significant effect on participants attitudes, beliefs about the dangers of FAS or intention to use alcohol during pregnancy. Other research by Olsen et al (as cited in Elliot, Coleman, Suebwongpat and Norris, 2007) indicated that a multi-faceted education campaign had no effect on the rates of alcohol consumption during pregnancy. Understandably, Rees (1986) concluded that other complex social and cultural factors, in addition to knowledge and beliefs are important in changing any behaviour.

Warning labels, of course, represent one example of a communication strategy. As such, research on communication and health beliefs indicates that the relationship between such strategies and beliefs and health related behaviors' is not necessarily direct. In an examination of the role of mass media in influencing beliefs and behaviour related to skin cancer, Morton and Duck (2001) cited McGuire (1986) noting that despite substantial faith and investment in mass media, the available evidence regarding the role of media in influencing either beliefs or behaviour is equivocal. Part of the problem is, of course, that individuals are not passive recipients of health information – a point discussed above in relation to other models and research. Many individuals appear to selectively attend to messages that are consistent with their beliefs and values. Morton and Duck noted that individuals are more likely

to attribute risk, identified in health messages, to others and to interpret information in relation to themselves in a manner that is self-serving and optimistic. That is, we might downplay or ignore personal risk and be overly optimistic about our own health. Health messages, such as those that might be included in alcohol warning labels, may have more impact raising concerns about risk to others or the broad community as opposed to raising concerns about risks to oneself. Thus, "I'm okay – I'm at low risk of skin cancer. Those other people (who are not quite like me) are the ones who are at risk."

As noted by Morton and Duck (2001):

> "*The theory holds that the effects of media will be most evident when media content provides individuals with unique information that is linked to personal goals …"* (p.605).

However, these authors have also observed that there is considerable variation in results across studies, limiting the ability to determine the relevant variables that influence outcomes. Some researchers (e.g. Flay and Burton 1990) have noted that media can raise awareness about health risks but interpersonal communication is also required for messages to be perceived to have personal meaning or relevance and for behaviour change to occur.

Other evidence indicates that impersonal information may become more relevant if attention were given to content and style of message delivery and messages will have more impact if the individual can identify with the source of communication. Some have argued that such factors helped increase the influence of media campaigns about HIV (e.g. Basil and Brown 1997). This point could possibly be generalized to alcohol warning labels. Thus, alcohol warning labels might increase awareness of risk to others or the broad community, but strategies also need to be in place to make messages personally relevant, to encourage interpersonal communication about messages, to challenge norms that support high risk use, and to consider message content, source and style that will most likely increase personal relevance. Using the elements of narrowcasting (i.e. where the subject matter is designed to appeal to a particular demographic), Glik and colleagues (2008) developed a series of posters warning women of the risks associated with the use of alcohol during pregnancy. The

six posters which were distributed in two low-income areas in California included images of an "idealized" Caucasian, African American and Latina Spanish woman and included the slogans: "Missed your period? Don't drink. Period", or "No wine, no beer no liquor, no way". While there were variations in messaging, distribution strategies and saturations levels amongst the target groups, the authors concluded that such low cost community campaigns are feasible.

Morton and Duck (2001), in their study, which examined the impact of media information about skin cancer, reported that the influence of media messages about risk was influenced by the degree to which an individual relied on the media for information that was perceived as personally useful for goal satisfaction. Consistent with other work they also found that interpersonal communication played a role in the impact of exposure to messages and perceptions of risk to oneself and broader perceptions of risk. That is, they noted that discussion of risk with others increased personal perceptions of risk, while exposure to media (e.g. newspaper articles) increased perceptions of risk to others.

Such reports have relevance for alcohol warning labels. First, the relationship between warning labels and beliefs and behaviors is not likely to be direct. Second, warning labels alone are unlikely to have significant impact. Third, influence of warning labels may vary among individuals. Individuals appear to differ to the extent to which they rely on media for information. Those who are more dependent on media for information may be more influenced by warning labels, whereas those who are more dependent on interpersonal communication may be less influenced by such media. Fourth, warning labels may increase knowledge of risk, but not necessarily change behaviour. Other complementary strategies may need to be adopted.

As noted, the research indicates that attention needs to be given to the style and content of health information, presumably including warning labels, along with the credibility of the source of information. This may also vary across individuals.

While there may not be strong evidence that health communication strategies, including warning labels, directly influence behavior, there is reason to believe that:

> "…*when delivered through channels that are perceived to be useful, they may become the starting point for further discussion of health issues, and, through this, increase the recognition of personal risk*." (Morton and Duck 2001, p.620).

In summary, the evidence about health risk communications through mass media is equivocal. While warning labels have not been directly considered in much of this research, similar processes, principles and conclusions probably apply. If we wish to affect perceptions of risk to others and the broad community, such strategies appear to have some influence. Beliefs about others may still have useful public health benefits:

> "*Beliefs about others may have little direct effect on individual health behavior. However, as part of the broader context in which health decisions are made, such beliefs may contribute to how audiences understand their own health and, through this, the relative importance attached to specific health issues and public health in general*." (Morton and Duck 2001, p.621).

If we wish to influence self-perception of risk, health communications may have greater impact if they are linked to other approaches that encourage discussion with other people, to facilitate positive interpersonal influences. Nevertheless, health communications may encourage changes in interactions around a particular (risk) behaviour that in turn may influence self-perception of risk. For example, recent research on alcohol warning labels by Tam and Greenfield (2008), that will be discussed later, lends some support to the possibility that warning messages may encourage a third party to attempt to intervene in another person's attempt at drink driving.

3.5 Defining effectiveness

Regulatory agencies have often encouraged, and in some cases mandated, that warning labels be included on products on the basis that a well–informed consumer will more safely interact with or use a product (Hadden 1991; Wogalter and Laughery 1996; Heaps and Henley 1999). Given that such beliefs exist and the potential harm

that could be caused should some warnings be ignored, it is important for public policy regulators to be aware of the effectiveness of warning labels. The majority of empirical research on the effectiveness of warning labels has focused on the types of information that will lead to consumers noticing or remembering information that has been included in labels and less frequently on the types of information that lead to behaviour modification (Heaps and Henley 1999).

In more recent reviews of the effectiveness of warning labels, Argo and Main (2004) and Hammond, Fong, Borland, Cummings, McNeill, and Driezen (2007) concluded that the effectiveness of warning labels can be measured in numerous ways, consistent with the processes postulated through models such as the Health Belief Model.

Using an information-processing framework (McGuire 1980; Wogalter and Sojourner 1999), Argo and Main (2004) developed the following criteria for assessing effectiveness:

1. Attention: Attention has been defined as the amount of cognitive effort and/or capacity that a person directs to a particular stimulus (Kahneman 1973). Warning labels need to cut through the visual information bombarding consumers (Lehto and Miller 1988, as cited in Argo and Main 2004) to attract attention.

2. Reading and comprehension: After a consumer notices a warning, it is important that they read and understand the content. According to Argo and Main (2004) consumer comprehension is a function of characteristics of the message: an opportunity to process the message: and characteristics of the message receiver.

3. Recall: Consumers must be able recall the potential risks conveyed in a warning and retrieve the information when necessary (McGuire 1980). According to Lehto and Miller (1988, as cited in Argo and Main 2004) limitations of memory and the context in which the information is presented will influence the likelihood that a consumer will store and retrieve warning messages.

4. Judgements: After a consumer has read and processed the information contained in a warning message, they form judgments of the products risks or

hazards (Argo and Main 2004). According to Mowen, (1995, as cited in Argo and Main 2004) these judgements represent an estimate of the likelihood that an outcome will happen and how favourable or problematic this outcome will be to the consumer.

5. Behavioural compliance: According to Argo and Main (2004) warning labels have two major objectives. These are to prevent consumers from engaging in behaviours that are unsafe and to promote appropriate behaviours when consumers use a product.

According to Argo and Main (2004) there are also several moderators that may influence warning label effectiveness. These moderators include:

- **Vividness-enhancing characteristics**. This variable relates to design features of a warning and may include font size, colour, spacing, level of specificity and symbols.
- **Warning location.** This refers to whether warning information is placed on or off the product.
- **Familiarity.** How familiar a consumer is with a product may also influence whether or not a consumer notices a warning label.
- **Age.** As cognitive abilities change with age (Law, Hawkins and Craik 1998), so too this may effect warning information recall.
- **Product type.** According to Argo and Main (2004) products fall under two categories: convenience goods and shopping goods. That is, goods that are frequently purchased with minimal comparative shopping and limited effort, those goods that are more expensive, less frequently purchased and involve more comparison shopping. This variable may also moderate warning label effectiveness.

After conducting a meta-analysis that included 44 articles (published between 1975 and 2001) investigating the impact of warning labels (alcohol, cigarettes, chemicals, pools etc) Argo and Main (2004) concluded that:

Attention: Warning labels moderately attract consumers attention (average r=0.22, n=8,915), the presence of vividness enhancing characteristics increased the likelihood that consumers noticed the warning (r=0.38, CI: 0.29 to 0.46; vs. r=0.2, CI: 0.18 to 0.23, in absence of vividness enhancing characteristics). Familiarity moderated attention (r=0.15, CI:0.12 to 0.19; vs r=0.24, CI:0.20 to 0.27 familiar vs not familiar with product). Product type did not produce any significant difference (convenience goods r=0.21, CI: 0.18 to 0.25; vs shopping goods r=0.27, CI: 0.19 to 0.35). Warning location also had an impact on attention (on product placement r=0.21, CI: 0.18 to 0.24; vs off product (e.g. poster, signs and/or advertisements r=0.35, CI: 0.27 to 0.42). This result indicates that warnings are more effective in attracting consumers attention when they are on posters/signs and/or advertisements (rather than on the product).

Reading and comprehension: only nine articles were available on this domain but Argo and Main (2004) concluded that when consumers are presented with warning information, they are more likely to read and understand the information than when a warning label is not present (average r=0.23, n=1,045).

Recall: consumers can moderately recall information presented in a warning (average r=0.32, n=1,538). The presence of vividness-enhancing characteristics (font size, colour, spacing etc) did not affect recall (presence: r=0.33, CI: 0.24 to 0.42; absence: r=0.28, CI: 0.20 to 0.35), nor did familiarity moderate recall (familiar: r=0.23, CI: 0.13 to 0.33; not familiar r=0.34, CI: 0.25 to 0.43).

Judgements: there was a weak relationship between warnings and consumers' judgements of product hazards and risks (average r=0.09, n=7,565). This was further exacerbated for convenience goods (alcohol, tobacco, household cleaners) (r=0.07, CI: 0.03 to 0.11), indicating that consumers have higher perceptions of risk with shopping goods (more expensive, less frequently purchased) (r=0.27, CI: 0.21 to 0.32).

Behavioural compliance: warnings moderately influence behavioural compliance (average r=0.19, n=3,877). Counter to assumptions, consumers were more likely to comply when they were familiar versus not familiar with a product (familiar r=0.39, CI: 0.35 to 0.44 versus non-familiar r=0.06, CI: -0.03 to 0.15).

These results indicated that warnings influence attention, consumers are likely to read and understand warning information, and although warnings are unlikely to influence a consumer's perception of risk, they can influence behaviour (Argo and Main 2004).

3.6 Isolating the impact of warning labels.

While historically and politically, behavioural change has represented the ultimate litmus test of warning label effectiveness, Argo and Main (2004) argued that other dimensions are of equal importance, depending on the aim of the warning label. They concluded that:

> "*Some warnings are designed to convey information about a product's potential risks, and as long as consumers understand the risk involved, the choice of behaviour is ultimately up to them. In addition, if consumers accurately recall the dangers associated with the consumption of a particular product but choose to ignore them, the warning label has still effectively served its purpose*." (Argo and Main 2004, p.205).

Finally, while measures of salience have been shown to be predictive of behaviour change, each outcome or domain will also be mediated by a range of other individual (e.g. socio-economic status) and environmental (other sources of health information and product promotion and marketing strategies) factors (Edwards et al. 1994). Subsequently, being able to isolate the single impact of one measure such as the presence of a warning label is as difficult as "*unravelling gossamer with boxing gloves*" (Chapman 1993, p.429).

In summary, warning labels that inform consumers of product risk have become increasingly commonplace and now appear on products as diverse as motor vehicles to sun tanning beds. The available theory suggests that health communication strategies may be more likely to inform (although they need to be personally relevant) than influence behaviour. Changing behaviour may require additional strategies, such as attention to interpersonal context, and assisting individuals to access relevant strategies to change when indicated. The available evidence does suggest that

consumers notice and are likely to read and understand warning information. Where the evidence is more equivocal is in relation to changing consumer's perception of risk, and influencing behaviour (Argo and Main 2004). On the other hand, increasing understanding of risk is, some argue, a legitimate goal.

In conclusion, it may be that warning labels can represent a useful public health strategy, when consistent with practices that have been described as influencing effectiveness. However, they are more likely to influence behaviour when included as one part of a comprehensive approach.

Chapter 4: The risks of alcohol consumption during pregnancy

As previously discussed, alcohol problems are manifest across all age groups. For that reason and to provide individuals with knowledge that would contribute to their ability to enjoy alcohol while minimising harmful consequences, alcohol guidelines have been developed in both Australia and New Zealand.

4.1 Australian Alcohol Guidelines

In Australia, the National Health and Medical Research Council (NHMRC) developed the *Australian Alcohol Guidelines: Health Risks and Benefits* with recommendations for low-risk drinking (National Health and Medical Research Council 2001). The NHMRC use the term standard drink when making recommendations about drinking limits. In Australia, one standard drink refers to a beverage containing 10 grams (equivalent to 12.5 millilitres) of alcohol (National Health and Medical Research Council 2001). In March 2009 the NHMRC released new Alcohol Guidelines in Australia (NHMRC 2009). The four Guidelines are as follows:

Guideline 1

Reducing the risk of alcohol-related harm over a lifetime

The lifetime risk of harm from drinking alcohol increases with the amount consumed. For healthy men and women, drinking no more than two standard drinks on any day reduces the lifetime risk of harm from alcohol-related disease or injury.

Guideline 2

Reducing the risk of injury on a single occasion of drinking

On a single occasion of drinking, the risk of alcohol-related injury increases with the amount consumed. For healthy men and women, drinking no more than four standard drinks on a single occasion reduces the risk of alcohol-related injury arising from that occasion. Each drinking occasion also contributes to the lifetime risk of alcohol-related harm.

Guideline 3

Children and young people under 18 years of age

For children and young people under-18 years of age, not drinking alcohol is the safest option.

Parents and carers should be advised that children under 15 years of age are at the greatest risk of harm from drinking and that for this age group, not drinking alcohol is especially important. For young people aged 15−17 years, the safest option is to delay the initiation of drinking for as long as possible.

Guideline 4

Pregnancy and breastfeeding

Maternal alcohol consumption can harm the developing fetus or breastfeeding baby. For women who are pregnant or planning a pregnancy, not drinking is the safest option. For women who are breastfeeding, not drinking is the safest option.

4.2 New Zealand Alcohol Guidelines

The New Zealand Ministry of Health Food and Nutrition Guidelines Statements for Healthy Adults include the recommendation: "If choosing to drink alcohol, limit your intake". The Alcohol Advisory Council of New Zealand also provide a set of guidelines for low risk drinking and recommend that men should consume no more than 21 standard drinks (equivalent to 10 grams of alcohol) in any one week and no more than six standard drinks on any one drinking occasion. For women, these levels are no more than 14 standard drinks per week and no more than four standard drinks on any one drinking occasion (ALAC 2008). In addition, the Alcohol Advisory Council advises that there is no level of drinking that is safe for all people all the time. They recommend that certain groups of people should drink less than these guideline amounts. These groups include:

- Thin people;
- Young people;
- Older people;
- People with a strong family history of alcoholism;
- People who are or who have been dependent on other drugs; and,
- People who have a poor diet, or are under-nourished.

On the basis that *"there is no known safe level for alcohol consumption at any stage during pregnancy"* (p.74), the Ministry of Health (2006) recommends that women who are pregnant or plan to become pregnant refrain from any alcohol during the entire pregnancy. Those women who have had some alcohol during pregnancy should be reassured while advised to refrain from any further alcohol use.

4.3 Basis for National Guidelines

The New Zealand and Australian guidelines and recommendations on alcohol use and pregnancy have been developed because of the concerns surrounding alcohol use during pregnancy and during infancy (when breastfeeding).

Although no threshold has been established at which prenatal exposure to alcohol results in harm, alcohol consumption during (and prior to confirmation of pregnancy) can affect the development of the fetal brain (Australian Government Preventative Health Taskforce 2008; O'Leary, Heuzenroeder, Elliott and Bower 2007); retard fetus growth and lead to delayed social and emotional development and deficits in mental and motor performance (Centers for Disease Control and Prevention 2004; NHMRC, 2009).

> *"The consequences of prenatal alcohol exposure fall along a continuum, ranging from subtle neurodevelopmental and behavioural manifestations to Fetal Alcohol Syndrome, the most serious outcome of prenatal exposure"* (Kyskan and Moore 2005, p.153)

This range of adverse outcomes has been collectively described by the terms Partial Fetal Alcohol Syndrome (PFAS) and Fetal Alcohol Spectrum Disorders (FASD) (Barr and Streissguth 2001).

Alcohol's small molecular size allows it to easily cross the placenta, resulting in similar concentrations of the drug in both the fetus and the mother. The teratogenic effect of alcohol is believed to occur through a reduction and malnutrition of cell populations in the fetus, by influencing maternal diet and disrupting the maternal-

fetal endocrine balance (Abel 1998; Michaelis and Michaelis 1994 as both cited in O'Leary 2002)

According to O'Leary (2002) exposure to alcohol during the first three weeks post conception can damage early development and neural tube elaboration increasing the risk of spontaneous abortion. Exposure to alcohol between weeks four and nine post conception can lead to malformations in the brain and the development of FASD (Zubrick et al. 2004). The effects of FASD may include physical, mental, behavioural and/or learning disabilities (Jones, Smith, Ulleland and Streissguth 1973; Centers for Disease Control and Prevention 2004)

Some investigators have found that the risk of associated defects is highest when women concentrate their weekly drinking by having five drinks or more in one day, while maintaining a weekly consumption of seven drinks (Streissguth, Sampson, Olson, Bookstein, Barr, Scott, Feldman and Mirsky 1994; Streissguth, Bookstein, Sampson and Barr 1995; Jacobson, Jacobson, Sokol and Ager 1998). Later research by Sood (2001) reported that children from six to seven years of age who had been exposed to as little as one drink per week during pregnancy were at increased risk of exhibiting externalized and aggressive behaviour. Other research suggests that drinking pattern, rather than average number of drinks per week, is likely to be the most significant factor that influences adverse pregnancy outcomes (Jacobson et al. 1998). In a report to the Department of Health in the United Kingdom (Gray and Henderson 2006) binge drinking was identified as a cause for concern in relation to poor neurodevelopment outcomes.

After considering the evidence, and gaps in the evidence base, about FAS and FASD, the NHRMC (2009) recently concluded that:

> *"While there is convincing evidence linking chronic or intermittent high level alcohol intake with harms, including adverse pregnancy outcomes and FASD, there remains uncertainty about the potential for harm to the fetus if a woman drinks low levels of alcohol during pregnancy. It is important that all women of child-bearing age are aware, before they consider pregnancy, of both this*

uncertainty and the potential risks of harm, so they can make informed decisions about drinking in pregnancy. Health professionals should highlight that:

- *the risk is higher with high alcohol intake, including episodic intoxication*
- *the risk appears to be low with low level intake*
- *it is impossible to determine how maternal and fetal factors will alter risk in the individual"*. (NHMRC 2009, p 77)

The NHMRC also noted that many fetuses will be inadvertently exposed to alcohol as many women may be unaware they are pregnant during the first trimester. According to the NHMRC, assessment of consumption during pregnancy and intervention should attempt to identify real risk (based on pattern and amount of alcohol consumed) while simultaneously, avoiding the creation of unnecessary anxiety in a pregnant woman.

As previously indicated, the Ministry of Health (2006) in New Zealand had previously adopted a similar position. On the basis that *"there is no known safe level for alcohol consumption at any stage during pregnancy"* (p.74) women who are pregnant or planning to become pregnant are advised to refrain from any alcohol during the entire pregnancy.

Evidence such as that discussed above has led the World Health Organization (1999) to identify FAS as the leading cause of environment-related birth defects and mental retardation in the western world. The worldwide prevalence of FAS is estimated at 0.97 cases per 1,000 live births (May and Gossage 2001). In the U.S., estimates of the incidence of FAS range from one to three per 1,000 live births (in epidemiological studies) to one per 10,000 live births (in birth defects registries) (Stratton, Howe and Battaglia 1996). While the extent of FASD in both New Zealand and Australia has not been accurately established, data from the New Zealand Ministry of Health estimates that there are approximately two to three per 1,000 live births for FASD and four to five per 1,000 live births for partial FASD (Alcohol Advisory Council of New Zealand 2005). This is higher than the rate for Cystic Fibrosis at one per 3,000 live births and Down Syndrome at one per 1,000 (Alcohol Advisory Council of New Zealand 2002; 2005). Using data from an econometric study in Canada, Alcohol

Healthwatch (2007) have estimated that using a prevalence rate of 3 per 1,000 live births, New Zealand might expect 173 children to be born affected by alcohol each year, at a cost to the tax payer of $3.46 million per annum. According to Elliot, Coleman, Suebwongpat and Norris (2008) the financial burden associated with FAS and FASD have never been fully assessed in New Zealand, but agreed that the primary and secondary disabilities associated with the disorder are likely to be significant.

Research in the Australian state of Victoria, indicated that the prevalence of FAS was 0.006 per 1,000 live births. This figure increased to 0.03 per 1,000 live births when possible cases of FAS were included (Allen, Riley, Goldfeld and Halliday 2007). In Western Australia, the overall prevalence of FAS was estimated at 0.18 per 1,000 live births between 1980 and 1997. FAS was reported over 100 times more frequently in Aboriginal children, with an incidence of 2.76 per 1,000 live births (Bower, Silva, Henderson, Ryan and Rudy 2000). In the Northern Territory, the estimated birth prevalence of FAS was 1.9 per 1000 Indigenous live births and of partial FAS plus partial FAS the incidence rose to 4.7 per 1000 Indigenous live births. The prevalence of FAS for the overall population was 0.68 per 1000 live births and the birth prevalence of FAS plus partial FAS for the overall population was 1.7 per 1000 live births (Harris and Bucens 2003). Based upon national data gathered between 2001 and 2004 by the Australian Paediatric Surveillance Unit (APSU), a total of 92 children with FAS were reported to APSU (Elliot, Payne, Morris, Haan, and Bower 2007).

It should be noted that the prevalence of FAS may be underestimated because of a limited knowledge of the criteria for diagnosis, limited health practitioner expertise and a possible reluctance to make a diagnosis that may carry some stigma for the child and the family (e.g see Payne et al. 2005; Elliot et al. 2006).

4.4 Alcohol consumption amongst Australian and New Zealand women of childbearing age

Based upon data from the 2007 NDSHS, amongst 20 to 29 year old Australian women, over 50% put themselves at risk or high risk of alcohol-related harm in the

short term on at least one drinking occasion during the previous 12 months and amongst 30-39 year olds this figure was approximately 40% (Australian Institute of Health and Welfare 2008b).

Findings from the Australian Longitudinal Study on Women's Health which included data from over 14,000 women aged 18-23 years of age indicated that in relation to drinking five or more drinks on once occasion:

- 18% did this at least once per week;
- 21% did this about once per month;
- 32% did this less than monthly; and,
- 29% never had five or more drinks on one occasion (Young and Powers 2006).

Based upon the socio-demographic characteristics of the women:

- The percentage of women drinking at risk was higher in rural and remote areas of Australia;
- Women who were currently pregnant were more likely to be non-drinkers (24.1%) compared to non-pregnant women (8.9%), although 3% of pregnant women reported drinking alcohol at risky levels; and,
- Women who had ever been pregnant were more likely to be non-drinkers (12.1%) than women who had not been pregnant (8.7%) (Young and Powers 2006).

In other Australia-wide research, that involved telephone interviews with women aged 14-24 (n=117), approximately 25% of the sample reported drinking between 5 to 8 standard drinks in a drinking session in the past month, and 5% reported drinking between 13 and thirty standard drinks in a single session in the past month (Roy Morgan Research 2004).

An examination of the Australian Longitudinal Study on Women's Health data by Clemens and colleagues (2007) led to similar conclusions. They noted that younger women were least likely to include abstainers and more likely to include women who drank at the highest levels – 60% of younger (18-23 years) women consumed three or

more drinks per drinking occasion. Whereas older women were less likely to consume at these levels, they drank more regularly. Some 71% of the younger women were drinking in a manner predictive of harm in the short term, compared to 33% of mid aged women (aged 45-50 years) (Clemens et al. 2007).

These data suggest that a significant proportion of women of childbearing age engage in risky drinking, at least occasionally. On the one hand this should not be interpreted as indicating that they drink whilst pregnant (women who were pregnant and/or who had been pregnant were more likely to be non- or lower risk drinkers). On the other hand, as noted earlier, there is an implied risk in that many may not be aware they are pregnant when they are drinking in a high-risk manner.

The 2004 Health Behaviours Survey- Alcohol Use, which aimed to assess alcohol consumption and drinking patterns in New Zealand, found that among women of childbearing age (18-44 years) approximately 80 to 85% had consumed some alcohol in the past 12 months (Ministry of Health 2007). Fewer Maori women consumed alcohol compared with non-Maori women except in the 18-24 year age group. Approximately, 30% of all women (18-44 years) consumed alcohol less than once per week, 40% one to three times a week, 15% four to six times a week and 10% seven or more times a week. Younger women (18-24 years) were more likely to consume large (more than four standard drinks) amounts of alcohol at least once per week compared to older women within the childbearing age group. In addition, Maori women were significantly more likely to consume large amounts of alcohol at least once per week compared with non-Maori women of childbearing age.

In 2005, Kypri et al (2009) collected data from a web- based survey that included 2,548 undergraduate University students in New Zealand's eight universities. Students ranged in age from 17 to 25 years and included Maori and non-Maori students. Amongst the women (n=1,542) in the study:

- 72.9% reported episodes of binge drinking (drinking in excess of 4 drinks in one session) in high school;
- 52.0% reported binge drinking on at least a monthly basis while in high school;

- 87.7% reported drinking alcohol in the past year;
- 81.0% reported the use of alcohol in the past 28 days;
- 58% had used alcohol in the past week;
- 23.1% reported engaging in one episode of binge drinking in the past seven days;
- 13.9% reported two or more episodes of binge drinking in the past seven days; and,
- 67.9% scored 4 or higher on the AUDIT-C (indicating hazardous drinking).

Amongst those women who had reported alcohol use in the past four weeks, 5.3% reported that they had engaged in unprotected sex, 3.1% had engaged in sex that they were unhappy about at the time and 1.3% had sex that they later regretted. These findings indicated that alcohol use was the norm rather than the exception, and that a number of the students were at risk of unplanned and alcohol exposed pregnancies.

Thus, there is a body of evidence that indicates that a significant proportion of women of childbearing age drink in a manner that may put them at risk, especially if they were pregnant.

4.5 Patterns of drinking among New Zealand and Australian women that has relevance for FASD

Research that has specifically focused on the consumption of alcohol during pregnancy indicated that in 1999, 10% of pregnant women in New Zealand, drank to intoxicating levels (Watson and McDonald 1999). Other data from a study of pregnant women in Wellington, surveyed in the same year (McLeod, Pullon, Cookson and Cornford 2002) indicated that at about 24 weeks gestation, 19.7% of Mäori and 26.2% of non-Mäori had drunk alcohol over the previous 7-days. In a report by Mathew, Kitson and Watson (2001), midwives estimated that 7% of the pregnant population were defined as regular drinkers, and about 13% were drinking more than a glass a day or were regular binge drinkers. In the 2004 ‘New Zealand Health Behaviours Survey,’ 17.6% of pregnant women reported consuming some alcohol during pregnancy and amongst drinkers who were planning a pregnancy although

79.2% had stopped all alcohol intake, 7.1% continued drinking (Ministry of Health 2007).

Based upon data gathered from New Zealand women aged 16-40 years in 2005, Parackal, Parackal, Ferguson and Harraway (2006), reported that amongst those women (n=552) who had given birth in the previous five years, or were currently pregnant, 53% had consumed some alcohol during pregnancy. However, 75% of these women reported having drunk some alcohol before they knew they were pregnant and stopped once they knew they were pregnant. The remaining 25% reported having consciously drunk some alcohol during pregnancy. Of those women who consumed any alcohol during pregnancy 37% reported to have binged at least once during the pregnancy. Most of these women reported that the binge drinking session occurred before they realized they were pregnant.

In relation to this research, the University of Otago issued the following press release:

> *"On examining the opinions of New Zealand women on alcohol consumption in pregnancy, only 40 per cent were of the opinion that women should abstain altogether from drinking during pregnancy. Half of the women surveyed were of the opinion that one drink or less was safe to be consumed on a typical drinking occasion in pregnancy.*
>
> *Alarmingly, the survey revealed that nearly 20 per cent of the women binged at some time during their pregnancy. Seventeen percent had done so before they realised they were pregnant."* (University of Otago 2006).

Some have suggested that we should not just focus on those who are currently pregnant. As indicated in the study by Parackal and colleagues (2006) most of the women who had "binged" during their pregnancy had done so before they realised they were pregnant. Also, research by Schader and Corvin (1999) has indicated that approximately 50% of pregnancies in New Zealand are unplanned, indicating the need to inform all women of childbearing age of the risks associated with the consumption of alcohol during pregnancy.

According to the NHMRC (2007) (as cited in the Australian National Preventative Taskforce Report, Commonwealth of Australia, 2008) 59% of Australian women drank alcohol at some time during their pregnancy. Of these, 14% reported drinking five or more drinks in a sitting in the three months prior to pregnancy - 58% during the first and second trimester and 54% in the third trimester. Wallace and colleagues (2007) reported that 47% of women in an Australian national survey reported they had consumed alcohol while pregnant.

Research by O'Callaghan, O'Callaghan, Najman, Williams and Bor (2003) found that, amongst those women who drank during pregnancy, the average alcohol consumption was less than two glasses per week in early pregnancy and approximately one glass per week in late pregnancy. "Binge drinking" in early pregnancy was reported by 20% of the women on at least one occasion.

In Western Australian research with non-Indigenous women, Colvin, Payne, Parsons, Kurinczuk and Bower (2007) reported that based upon information gathered during 1995 to 1997, 58.7% of pregnant women drank alcohol during at least one trimester, and 4.3% consumed 5 or more drinks on one occasion at some stage of their pregnancy. As with similar results from New Zealand, only 53.3% of the women had planned their pregnancy and 79.8% reported drinking alcohol in the three months prior to pregnancy (Colvin et al. 2007).

Some populations may be at particular risk. For example, in regional West Australian, the mothers of an estimated 23% of Aboriginal children reported that they had consumed alcohol at some point during their pregnancy and an estimated 17% had both smoked and consumed alcohol while pregnant (Australian Institute of Health and Welfare 2005). The Bibbulung Gnarneep Study of Aboriginal women in Perth reported that 44% of the women reported that they had consumed alcohol during their pregnancy and 23% had become intoxicated at least once during their pregnancy (Eades 2003). Other studies have also reported on higher FAS rates in some Indigenous communities (e.g. Bower et al. 2000; Harris and Bucens 2003; Elliot et al. 2008).

Considering that FASD "*has become recognized as the foremost preventable, non-genetic cause of intellectual impairment*" on the developing embryo (Giglia 2007, p.5), such results are of concern.

While a number of tools (e.g. 4-Digit Diagnostic Code (O'Leary 2002), are available to assist health professionals identify women at risk for an alcohol-exposed pregnancy (Ebrahim and Atrash 2006) health professionals must be willing to raise the issue of alcohol use with their pregnant patients (Morse and Hutchins 2000). Interventions during pregnancy can significantly reduce adverse outcomes as pregnancy can provide a "window of opportunity to intervene" for alcohol use issues (Morse and Hutchins 2000, p.225). However, as many women may be unaware that they are pregnant until the sixth week of gestation (Floyd, Decoufle and Hungerford 1999) population level strategies are required to reduce the incidence of alcohol-exposed pregnancies (Ebrahim and Atrash 2006).

4.6 Breastfeeding and alcohol consumption

Until relatively recently, the focus of preventive attention (including information on alcohol warning labels) has been on preventing and reducing risky drinking during pregnancy. More recently, for a variety of reasons, attention has also focused on breastfeeding, an aspect included in the Food and Nutrition Guidelines for Healthy Pregnant and Breastfeeding Women in New Zealand (Ministry of Health, 2006) and the recent Australian Alcohol Guidelines (NHMRC 2009).

While no information was available from the Ministry of Health (2006) on the proportion of breastfeeding mothers in New Zealand who consume alcohol, research from Australia indicates that although many breastfeeding mothers do not drink, or drink at low risk levels, a significant proportion (just under 20%) report drinking more than 7 drinks per week (Giglia and Binns 2008).

It is generally recommended that infants should be exclusively breastfed for the first six months of life and that breastfeeding is extended beyond this, with complementary

foods, into the second year of life (WHO 2003; NHMRC 2003). Alcohol readily enters breast milk and may persist for several hours after alcohol consumption (e.g. see Ho et al. 2001; Giglia and Binns 2006). The metabolism of alcohol varies, due to individual differences (e.g. weight and liver function) making it difficult to be prescriptive about the amount of time needed for the mother's blood alcohol to return to zero. According to the Institute of Medicine (1991 as cited in Ministry of Health, 2006), an excess of 0.5g of alcohol per kg of maternal body weight may be harmful to the infant because of a possible reduction in milk volume. While Giglia and Binns (2006) have cautioned that there is a lack of quality evidence, based on human studies, that allows the provision of definitive advice about alcohol consumption and breastfeeding they did note some risks of decreased lactational functioning, deficits in infant psychomotor development and impact on sleep patterns of infants at increasing levels of alcohol consumption.

Consistent with the lack of attention to this issue, some evidence indicates that breastfeeding mothers are not aware of the effects of alcohol on breastfeeding performance and infant development (see Giglia and Binns 2007). Interestingly, this research group noted that women who drank more than two standard drinks per day were almost twice as likely, compared to women who drank less than this, to discontinue breastfeeding before their infant was 6 months old (Giglia et al. 2008).

The limited evidence available led the Ministry of Health (2006) to recommend:

- *Alcohol should be avoided during breastfeeding, particularly in the first month, when it is important for sound breastfeeding patterns to be established;*
- *If it is not possible to abstain from alcohol, women should be advised to limit themselves to one or two standard drinks occasionally;*
- *Binges of alcohol should be avoided; and,*
- *Women who wish to drink alcohol could consider expressing milk in advance.* (p.77)

Similarly, in Australia the NHMRC (2009) recently advised:

- *Not drinking alcohol is the safest option;*

- *Women should avoid alcohol in the first month after delivery until breastfeeding is well established;*
- *After that:*
  - *alcohol intake should be limited to no more than two standard drinks a day*
  - *women should avoid drinking immediately before breastfeeding*
  - *women who wish to drink alcohol could consider expressing milk in advance.* (p. 81)

However, increasing the complexity of any response, the risks that arise from alcohol must be placed in the context of the advantages of breastfeeding over not breastfeeding (see also, Giglia and Binns 2007; Giglia, Binns, Alfonso, Scott and Oddy 2008). For example, Giglia (2007) concluded*: "Breastfeeding is the best way to feed infants and supporting mothers to breastfeed for longer will provide the greatest gains for the mother and infant" (p.6).* Therefore, while it is important to communicate the risks of drinking while breastfeeding, it is important that any strategy does not unnecessarily reduce breastfeeding.

4.7 Awareness of the health risks associated with alcohol in relation to pregnancy and breastfeeding

In Australia, in the most recent NDSHS (calculated on the basis of the 2001 Guidelines) 76.2 % of females aged 14 years or older who drank at low-risk levels for harm in the short term thought that an adult female could drink five or more standard drinks in a 6-hour period without putting her health at risk. Of females who drank at risky or high-risk levels for short-term harm 59.2% thought that an adult female could drink five or more standard drinks without putting her health at risk (Australian Institute of Health and Welfare, 2008b).

Of females aged 14 years or older who drank at low-risk levels for harm in the long term, 9.7% thought that an adult female could drink three or more standard drinks every day for many years without putting her health at risk. Of females who drank at risky or high-risk levels for long-term harm, 21.5% thought that an adult female could

drink three or more standard drinks every day for many years without putting her health at risk. According to the Australian Institute of Health and Welfare (2008b), although no data were available to investigate perceptions by different age groups, other data from the 2007 NDSHS indicated that amongst 14-19 year olds, 55% of males and 47.9% of females approved the regular use of alcohol. Amongst 20-29 year olds, 60.6% of males and 50.7% of females approved of the regular use of alcohol by an adult.

In relation to knowledge of the risks of alcohol consumption during pregnancy, research conducted by the Salvation Army, indicated that only 63% of Australian women aged 14 years and older agreed with the statement: "drinking during pregnancy is dangerous to a baby's health" (Roy Morgan Research 2005). In Western Australia research with women aged 18 to 45 years, over one third of women reported that they were not aware of the consequences to the fetus and child that could arise from drinking alcohol in pregnancy and a quarter of them indicated that they would continue to drink alcohol in future pregnancies (Peadon, Payne, Henley, D'Antoine, Bartu, Bower and Elliot 2007).

On the other hand, findings from a 2005 study, examining the opinions of women in New Zealand on alcohol consumption in pregnancy, indicated that 76% believed that stopping alcohol consumption during pregnancy increased the chance of a healthy baby (Parackal et al 2006). In addition, 40% of the women believed that during pregnancy women should abstain from drinking alcohol (Parackal et al. 2006).

Using the same data set, Parackal, Parackal, Harraway and Ferguson (2009) reported that when the women in the sample were asked the question: "Suppose a pregnant woman wants to drink some alcohol, in your opinion, how many drinks are safe for her to drink in any one day that she drinks?" only 10.2% reported that more than one standard drink was safe, whereas the remaining 90% were equally divided between 'no alcohol' (44.3%) and 'one standard drink or less' (45.5%). Moderate to heavy drinkers were 2.17 times more likely than abstainers, to be of the opinion that one standard drink or less was safe in pregnancy. This group of drinkers were also 3.53 times more likely than abstainers to be of the opinion that more than one standard drink is safe in pregnancy. A salient finding of the research was that:

> *"moderate/heavy drinkers who comprise 55% of the sample were more likely to be of the opinion that some alcohol consumption in pregnancy is safe*"(Parackal et al. 2009, p.139).

This is important as the authors noted that other studies (e.g. Floyd et al.) have found that drinking behaviour before pregnancy is highly predictive of drinking whilst pregnant. Thus:

> *"… moderate/heavy drinkers may have an increased risk of alcohol consumption in pregnancy*" (Parackal et al. 2009, p.139).

As indicated in the brief summary above, although the majority of women are aware of the potential risks of drinking alcohol during pregnancy, the incidence of FASD remains an ongoing concern, particularly as current drinking status appears to be associated with perceptions of safety and drinking behaviour during pregnancy. As the first few weeks after conception are probably the most crucial in relation to alcohol (a time when many women may be unaware they are pregnant), rather than just targeting pregnant women, there is a strong need for education about safe drinking for ***all*** women of childbearing age (Commonwealth of Australia 2006).

Although the majority of women agree that health professionals should ask women about alcohol consumption and advise them to abstain during pregnancy (Peadon et al. 2007) research by the Royal Australasian College of Physicians and the Royal Australia and New Zealand College of Psychiatrists (2005) suggested that less than half of health professionals routinely ask patients about alcohol use during pregnancy. In a West Australian study by Payne et al. (2005) of health care professionals, only 25% routinely provided information on the consequences of alcohol use in pregnancy, yet 96% agreed that education/information about the effect alcohol may have on the fetus should be readily available to women of childbearing age.

4.8 Responses in Australia and New Zealand to the prevention of FASD

As noted previously, governments in Australia and New Zealand are developing responses to reduce the incidence of FASD and to support both those individuals and families who live with the effects of FASD.

The prevention of FASD is complex and, as acknowledged by Poole (2008), involves more than the simple provision of information at one point in time through a single interaction with one health care provider. A holistic multi-sectoral approach that helps women to plan their pregnancies, obtain prenatal care, improve nutrition, reduce stress in pregnancy and respond to the causes of hazardous and harmful alcohol use is recommended (Poole 2008).

For example, the Public Health Agency of Canada recently developed a four-part framework for the prevention of FASD and improving the outcomes for those who are born with the condition. The four components of the framework include:

1. Broad awareness building and health promotion efforts;
2. Discussion of alcohol use and related risks with all women of childbearing age and their support networks;
3. Specialized, holistic support of pregnant women with alcohol and /other health social problems; and,
4. Postpartum support for new mothers assisting them to maintain/initiate changes in their health and social networks and to support the development of their children. (For more details on the Canadian government's response see http:www.phac-aspc.gc.ca/fasd-etcaf/index-eng.php).

Similarly, as noted by Kyskan and Moore (2005) and consistent with Stratton and colleagues (1996) the U.S. Institute of Medicine proposed three levels of prevention, including universal prevention, selective or targeted prevention and indicated prevention (i.e. to the broad population, such as all women of childbearing age, to communities with high levels of alcohol consumption and to women with a known risk).

Kyskan and Moore recommended that a range of approaches should be adopted. These included:

- Assessment of levels of community knowledge about FAS;
- Educating health care physicians and other relevant health care providers;
- Improved public health strategies that broadly target hazardous drinking across the community (e.g. price controls);
- Legislated use of alcohol warning labels; and
- Developing other effective social marketing strategies to reduce hazardous drinking especially during pregnancy.

However, they did not identify any evidence about the effectiveness of such approaches specifically relevant to FASD. Indeed, other reviews have noted a general lack of evidence about the different approaches in reducing hazardous alcohol use in pregnancy and reducing adverse outcomes such as FASD. For example, Loxley and colleagues noted that:

> *"Although maternal alcohol use is relatively common in Australia, there has been little research investigating universal strategies to reduce alcohol use in pregnancy."* (Loxley et al. 2004, p.97).

Most evidence of effective strategies has involved approaches that have targeted women who are already pregnant (e.g. Chabon, Lee-Wilkerson and Green 1992; Ettligner 2000) or worked with mothers during the child's infancy (e.g. Olds, Henderson, Kitzman, Eckenrode, Cole and Tatelbaum 1999).

Research from the U.S. has indicated that following a brief motivational intervention pregnant women with the lowest AUDIT scores were the most likely to reduce their risk of an alcohol-exposed pregnancy (i.e. those who might be considered at lower risk anyway), compared with those with medium and high scores (Sobell et al., 2003). Later research by O'Connor and Whaley (2006) indicated that there was no statistically significant difference in level of alcohol, consumption between pregnant women who received brief advice from a physician not to drink during pregnancy and those women who had not received any advice. Research by Chang, McNamara, Oray and Wilkins- Haug (2006) concluded that after a single session brief intervention with

a nurse, pregnant women who subsequently chose abstinence as their prenatal drinking goal were more likely to achieve their goal than those women who chose cutting down their alcohol consumption as a goal. Finally, research by Floyd et al. (2007) with pre-conceptional women found that four brief motivational interviewing sessions led to a significant reduction in the odds of the women experiencing an alcohol exposed pregnancy at the three, six and nine months follow up.

In a systematic review of the FASD prevention, diagnosis and management literature, conducted by Health Services Assessment Collaboration, and funded by the New Zealand Ministry of Health, Elliot and colleagues (2008) concluded that there was no strong evidence that any one primary prevention strategy was more effective in reducing alcohol consumption during pregnancy. The authors did, however, conclude that the research by Hankin (1993, 1996) on warning labels indicated a "modest reduction in alcohol consumption in light drinkers but not heavy drinkers and a significant correlation between label (sic) and reduced alcohol consumption in nulliparae but not multiparae women"(p.viii).

Of the secondary prevention studies identified, there was some evidence that pregnant women receiving an intervention had a significant reduction in alcohol use compared to a control group, but it was difficult for the authors to identify the factors that were critical to a successful outcome. Finally, in the review of tertiary prevention studies the authors concluded that only one study (Whiteside- Mansell, 1998 as cited in Elliot et al. 2008) reported that the intervention significantly reduced prenatal alcohol consumption relative to the control group. However, the authors also concluded that the quality of the available research precluded definitive conclusions.

In Australia, a number of organisations have been established in response to concerns about FASD. For example, in 1999, The National Organisation for Fetal Alcohol Syndrome and Related Disorders (NOFASARD) was established. In collaboration with the Rural Health Education Foundation, the Telethon Institute for Child Health Research and the Pilbara Population Health Alcohol and Pregnancy Project NOFASARD has been developing resources and conducting workshops to raise awareness of FASD amongst community and professional groups across Australia. The Drug Education Network, also represent a significant service, training and

resource provider on FASD issues across Australia. In 2007, the Drug Education Network established an online petition that all alcoholic beverages sold in Australia should carry warning labels to highlight that drinking alcohol while pregnant may cause birth defects.

Despite these efforts, as already noted, there is a significant lack of awareness in Australia of FAS amongst professionals and the public and according to Kyskan and Moore (2005) Australia's level of prevention, intervention and education initiatives were, at the time of their report, significantly lower than that of Canada and the U.S.

Since the publication of the report by Kyskan and Moore, the Australian Intergovernmental Committee on Drugs' Fetal Alcohol Spectrum Disorder (FASD) Working party was established at the request of the Ministerial Council on Drug Strategy. A draft monograph has recently been prepared by the FASD working party, and it is anticipated that the report may guide future national FASD prevention strategies in Australia.

In New Zealand, the Ministry of Health has developed a number of health related resources on drinking alcohol during pregnancy. For example

- The Alcohol and Drug Toolkit for District Health Boards (2001);
- The Food and Nutrition Guidelines for Healthy Pregnant and Breastfeeding Women (2006); and,
- The information pamphlet for women: Alcohol and Pregnancy: when you drink so does your baby.

As previously mentioned, the Health Services Assessment Collaboration in NZ have recently published a systematic review of the literature on the FASD (see Elliot et al, 2008). A copy of this report is available from: http//www.healthsac.net/downloads/publications/HSAC07_FASD_FINAL. In the report the authors (Elliot et al. 2008) concluded that the prevention of FASD should consist of primary (targeting the general population), secondary (aimed at pregnant women) and tertiary (targeted women considered to be at high risk) strategies.

Considering the rates of FAS in both Australia and New Zealand, particularly amongst high-risk populations (e.g. Indigenous women), and the continued high risk levels of consumption amongst a significant proportion of women of childbearing age, it is recognised that it is important that a range of public health strategies are developed to ensure that relevant groups are aware of the potential risks of the consumption of alcohol during pregnancy. Consideration of a comprehensive range of public health strategies:

> *"…. may have a two fold effect, addressing the risk associated with being of the opinion that some alcohol is safe in pregnancy and the risk associated with many women unintentionally drinking in early pregnancy, especially if the pregnancy is unplanned"* (Parackal et al. 2009, p.140)

However, as already noted, in developing a comprehensive public health strategy that reduces the incidence of alcohol consumption during pregnancy and breastfeeding strategies should not cause undue anxiety or produce other unnecessary adverse outcomes. For example, in the National Clinical Guidelines for the Management of Drug Use during Pregnancy, Birth and the Early Development Years of the New Born (Commonwealth of Australia, 2006a), an abstinence message was not recommended for women who were pregnant or might soon become pregnant, to avoid:

> *"anxiety among women with an unplanned pregnancy, many of whom consume some alcohol before they know they are pregnant, but usually without harmful consequences for the infant. Anxiety about alcohol consumption has sometimes resulted in precipitous decisions to terminate a pregnancy" (p.26)*

Indeed there is still some equivocation concerning the teratogenic properties of alcohol use during pregnancy, particularly at lower levels of consumption. For example, in a recent review by Henderson et al. (2007) of the effects of light to moderate prenatal alcohol consumption on fetal development there was no convincing evidence of adverse effects when up to 83g of alcohol were consumed per week. Despite this research and the contention, it is relevant to note that the relevant positions in both Australia and New Zealand have been determined precisely because

the evidence does not allow a determination of safe levels of alcohol consumption during pregnancy. Thus, the safest option is not to drink. The present position in both Australia and New Zealand, as expressed in national alcohol guidelines, is that it is preferable for women who are considering pregnancy to abstain from alcohol.

In summary, while the available research from both New Zealand and Australia indicates that a significant proportion of women are aware of the potential risks of drinking alcohol during pregnancy, a significant number drink in a manner that might be considered risky and the incidence of FASD remains an ongoing concern. As the first few weeks after conception are probably the most critical in relation to alcohol (a time when many women may be unaware that they are pregnant), there is an argument that there is a need for comprehensive prevention strategies to be developed for ***all*** women of childbearing age.

It is in such a context, that the adoption of warning labels on alcohol containers is considered and the next chapter will review the available evidence on the effectiveness of alcohol warning labels.

Chapter 5: International overview of alcohol warning labels

As already discussed in an earlier section, there has been significant investment by Governments in both New Zealand and Australia to prevent and reduce alcohol related problems, including those related to the consumption of alcohol during pregnancy. There is a body of evidence about what population level policies and strategies are effective, what hold promise and what is of doubtful value (e.g. Babor et al. 2003; Caswell and Maxwell 2005; Kypri et al. 2005; Loxley et al. 2004). Information and persuasion strategies fall into the category where there is less conclusive evidence, whether delivered through a public health strategy (e.g. information campaigns; school drug education) or through an alcohol industry marketing strategy (e.g. the influence of alcohol advertising). It is important to note, however, that in a developing body of knowledge, absence of evidence is not always indicative of "no effect." Methodological limitations have relevance to interpreting data. For example, econometric analyses of the effects of alcohol advertising, where consumer behaviour is aggregated, may not be the best assessment of the impact on segments of the population: advertising may have limited impact on saturated markets (e.g. middle-aged drinkers who have long established drinking preferences and behaviours) compared to less saturated and/or naive markets (e.g. younger people). Thus, using aggregated data may not be an appropriate method to assess the impact of such persuasion strategies. It is relevant to keep this point in mind when considering the evidence about alcohol warning labels.

5.1 History of warning labels

The United States was the first country to introduce health warnings on tobacco products in 1966 (Chapman and Carter 2003). Australia subsequently introduced warning labels on tobacco products in 1973 and New Zealand in 1974. Based on the extensive research investigating the efficacy of tobacco warnings Scollo and Winstanley (2008) have concluded that health warnings on tobacco packaging have been a highly cost-effective way:

- To inform consumers about the toxic constituents of tobacco smoke and the health effects of smoking; and
- To provide details of where to go for advice on quitting.

Similarly, it has been argued that alcohol warning labels allow consumers to make informed choices about what they drink and warn them of the potential dangers and health risks from the product (Wilkinson and Room 2008a; International Center for Alcohol Policies 2007). In providing such information, warning labels also deliver a clear message to consumers that alcohol is not an ordinary commodity (Deutsche Hauptstelle fur Suchtfragen e.V. (DHS) 2008).

Although alcohol health warnings are mandated in a number of countries (e.g. Argentina, Armenia, Benin, Brazil, Cape Verde, Colombia, Costa Rica, Ecuador, France, Guatemala, Honduras, Iceland, India (State of Assam), Indonesia, Mexico, Mongolia, Portugal, South Korea, Spain, Taiwan, Thailand, United States, Uruguay, Venezuela and Zimbabwe) (Stockwell 2006) and Colombia, France, South Africa, South Korea, United States and the United Kingdom (voluntary code) have introduced warnings that specifically refer to the risks of alcohol during pregnancy, there remains limited research that has specifically investigated their effectiveness. Conversely, research investigating the effectiveness of tobacco warning labels is extensive. Such research provides a useful context for analysing the available research that has examined the efficacy of alcohol warning labels.

5.2 An international overview of the history of alcohol warning labels

According to a report published by Stockwell in 2006, the following countries have all introduced mandatory alcohol warning labels: Argentina, Armenia, Brazil, Colombia, Costa Rica, Ecuador, Guatemala, Honduras, Iceland, India (State of Assam), Mexico, Portugal, South Korea, Taiwan, Thailand, Unites States, Venezuela and Zimbabwe. Other countries such as Japan, have introduced voluntary labelling, where local brewers include messages warning about drinking during pregnancy and in Canada, since 1992, the Yukon and the Northwest Territories have required liquor stores to provide warning labels on all bottles of wine and spirits as well as on packaged beer (Stockwell, 2006). In addition, the International Center for Alcohol

Policies (2007) reported that Benin, Cape Verde, Indonesia, Mongolia, Spain, and Uruguay have also now implemented health warning labels on alcohol containers.

In a later report by Anderson, for the German Centre for Addiction Issues (Deutsche Hauptstelle fur Suchtfragen e.V (DHS) 2008), it was noted that:

- Since October 2006, France had made it mandatory to include health warnings on alcohol about the risks of consumption during pregnancy;
- Germany has mandated for labelling to appear on "alcopops";
- The UK had included as part of a voluntary code the message "drink responsibly" and the web address for *drinkaware* on all alcoholic beverages; and,
- Denmark had instigated voluntary labelling.

Information from the Medical Research Council in Cape Town, also confirms that warning labels have recently been implemented in South Africa (personal communication).

Based upon unconfirmed information:

- Sweden displays one of the following messages on alcohol containers: "Under 18? Avoid alcohol", "Pregnant? Avoid alcohol", "Driving? Avoid alcohol" and "At work? Avoid Alcohol" (source: http://www.thelocal.se/7833/20070709/)
- In El Salvador the following message appears on alcohol containers : "Excessive consumption of this product is harmful to health, it is prohibited to be sold to people under 18" (Source: http://www.who.int/sybstance_abuse/publications/en/Alcohol%20Policy%20Report.pdf)

For examples of labels from the U.S., France and South Africa, see Figures 4 to 15. The figures from the U.S. highlight the variation that exists in relation to the placement of and background and font colours used for displaying the warnings. See Table 1 for examples of the different wording on alcohol warning labels that were included in the report by Stockwell (2006). It is acknowledged that in some cases the warning labels are not easy to identify. This issue is discussed in more detail later.

5.3 Examples of warning labels

Figure 4. Health warning label from a bottle of ale imported from Belgium - U.S.

Figure 5. Health warning label from an Alcoholic beverage produced in Spain and imported to the U.S.

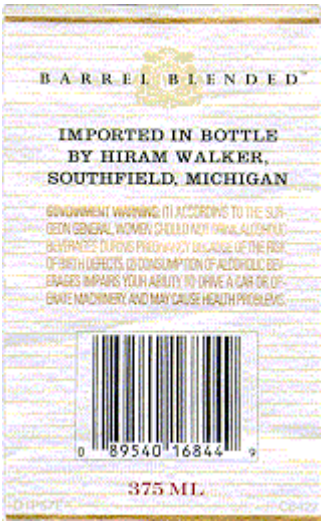

Figure 6. Health warning label on a bottle of Canadian Club Whiskey imported from Canada to U.S.

Figure 7. Health warning label on a bottle of Merlot produced in France – imported to U.S.

Figure 8. Health warning label on a Bacardi Breezer bottle – U.S.

Figure 9. Health warning label on a Budweiser bottle – U.S.

Figure 10. Health warning label on a Miller Lite beer bottle – U.S.

Figure 11. Health warning label on a Harp Lager bottle imported from Ireland – U.S.

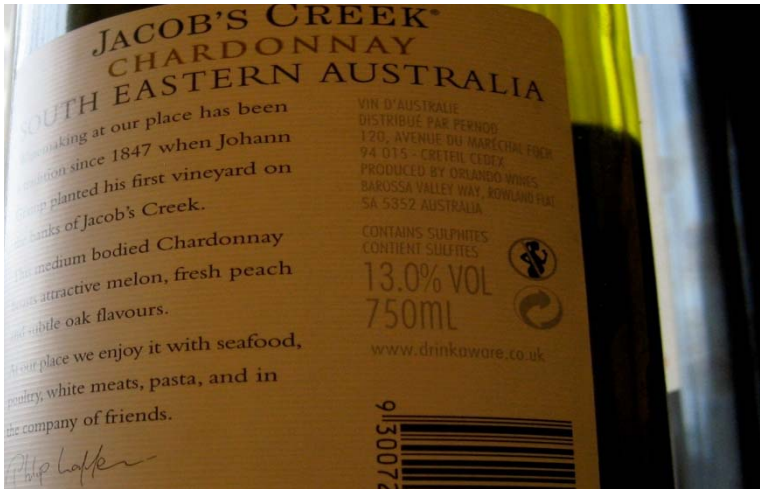

Figure 12: Health warning on bottle of Jacobs Creek Chardonnay depicting risks of drinking during pregnancy (France)

Figure 13: Bottles from France showing pregnancy warning labels

Figure 14: Bottles from South Africa depicting warnings about alcohol and health and drink driving

Figure 15: Bottle from South Africa depicting warning about pregnancy

Table 1 Text of alcohol warning labels from other countries

Country	**Text of warning**	
	General warnings	**Pregnancy related warnings**
Argentina	"Drink with Moderation" and "Prohibited for people under 18 years old"	
Brazil	"Avoid the risks of excessive alcohol consumption"	
Colombia	"The excessive use of alcohol is harmful to your health" "Prohibited for sale to minors"	"This product is harmful to the health of children and pregnant women"
Costa Rica	"Drinking liquor is harmful to health" or "The abuse of liquor is harmful to health"	
Ecuador	"Warning. The excessive consumption of alcohol restricts your capacity to drive and operate machinery, may cause damage to your health, and adversely affects	

	your family. Ministry of Public Health of Ecuador. Sale prohibited to minors under 18 years of age"	
France		"Consumption of alcoholic beverages during pregnancy even in small quantities, can have serious consequences on the health of the child" or Graphic below: 
Guatemala	"The excessive consumption of this product is harmful to the health of the consumer", or "The consumption of this product causes serious harm to your health"	
Honduaras	The law states that: "Preventative legends must be displayed on all alcoholic beverage packaging".	
India (State of Assam)	"Consumption of liquor is injurious to health"	
Mexico	"Excessive consumption of this product is hazardous to health"	
Portugal	"Drink alcohol in moderation"	
South Africa	"Alcohol abuse is dangerous to your health" or "Alcohol reduces driving ability, don't drink and drive"	**"**Drinking during pregnancy can be harmful to your unborn baby"
South Korea	One of the three following messages: "Warning: Excessive consumption of alcohol may cause liver cirrhosis or liver cancer and is especially detrimental to the mental and physical health of minors"	"Warning: Excessive consumption of alcohol may cause liver cirrhosis or liver cancer and, especially, women who drink while they are pregnant increase the risk of congenital

	or "Excessive consumption of alcohol may cause liver cirrhosis or liver cancer, and consumption of alcoholic beverages impairs your ability to drive a car or operate machinery, and may increase the likelihood of car accidents or accidents during work" *On spirits:* "Excessive drinking may cause cirrhosis of the liver or liver cancer and increase the probability of accidents while driving or working"	anomalies"
Taiwan	"Excessive consumption of alcohol is harmful to health" or "To be safe, don't drink and drive" "Excessive drinking is harmful to you and others" or "Please do not drink if you are a minor"	
Thailand	"Warning: Drinking Liquor Reduces Driving Ability" and "Forbidden to be sold to children under 18 years old"	
United States	"GOVERNMENT WARNING: (2) Consumption of alcohol impairs your ability to drive a car or operate machinery, and may cause health problems."	"GOVERNMENT WARNING: (1) According to the Surgeon General, women should not drink alcoholic beverages during pregnancy because of the risk of birth defects.
United Kingdom (voluntary agreement - the alcohol industry is not bound to include any information–Govt. preference is for text based rather than the pregnancy logo)	"UK Chief Medical Officers' recommend men do not regularly exceed 3-4 units daily and women, 2-3 units daily"; or "www.drinkaware.co.uk"; or "Know your limits" or "Enjoy Responsibly" or "Drink Responsibly"	"Avoid alcohol if pregnant or trying to conceive"; or graphic below: 

Venezuela	One of the following warning statements or something similar is required: "The abuse of alcohol beverages can damage the health" "Excessive consumption can be harmful to health"	
Zimbabwe	"(1) Alcohol may be hazardous to health if consumed to excess. (2) Operation of machinery or driving after the consumption of alcohol is not advisable"	

(Adapted from Stockwell, 2006)

It is worthwhile commenting on the nature and visibility of the alcohol warning labels included as Figures 4 to 15, in comparison with the tobacco examples that are later included in Figures 16 to 19. Even a cursory comparison indicates that the alcohol warning labels are less easily identifiable and prominent, represent a small proportion of the size of the overall label, use text and not images (with the exception of France and some labels in the U.K.) and are not particularly graphic. In addition, whereas research from the tobacco field has indicated that for warnings to be most effective they needed to be frequently upgraded (Elliot and Shanahan 2000), the warnings from the U.S. have not altered in over nineteen years. In short, the alcohol warning labels lack what has been considered, in the tobacco field, as essential elements for impact. Subsequently, any review of the effectiveness of alcohol warning labels and interpretation of the related evidence should take these factors into consideration.

Before examining the impact of alcohol warning labels, it is worthwhile briefly examining the history of the consideration of alcohol warning labels in a number of OECD countries where we have been able to access printed matter in English: U.S., Canada, UK, Ireland and in the European Union. A review of the Australian and New Zealand context follows this section. As will be seen, concern about the risks of drinking while pregnant was one key element influencing decisions.

United States

In 1967, Senator Strom Thurmond first introduced a bill to require health warning labels on alcoholic beverage containers (Scammon, Mayer and Smith 1991). In 1977, the Bureau of Alcohol, Tobacco and Firearms was urged to mandate label warnings of the risks of birth defects associated with the use of alcohol during pregnancy (Scammon et al. 1991). In 1979, the U.S. Senate passed and then dropped legislation that would have required warnings to appear on some alcoholic products (Scammon et al. 1991). In 1987, a U.S. court suggested that an alcohol beverage manufacturer might have a duty of care to provide consumers with a warning message about health risks (Andreas 1988). In 1988, three lawsuits were brought against seven alcohol companies by parents of children allegedly born with fetal alcohol syndrome, charging that there was not an adequate warning about the potential hazards of alcohol consumption during pregnancy (Moss 1988). In the same year, Congress enacted legislation (Public Law No. 100-690, 1988) mandating that from 18 November 1989, all domestic and imported alcoholic beverage containers for sale in the United States include the following warning message:

> *"Government Warning: (1) According to the Surgeon General, women should not drink alcoholic beverages during pregnancy because of the risk of birth defects. (2) Consumption of alcoholic beverages impairs your ability to drive a car or operate machinery, and may cause health problems."*

Alcohol warning labels remain mandatory in the U.S. All domestic and imported beverages continue to include the above warnings. For a more comprehensive review of the development of alcohol warning label policy in the U.S. see Kaskutas (1995).

Canada

In February 2005, a Private member's Bill C-206 received its second reading in the Canadian House of Commons. It had been brought forward by Paul Szabo (Liberal

Member of Parliament for Mississauga South) and proposed that the *Food and Drugs Act* be amended by adding after Section 5:

> *"5.1 No person shall sell a beverage containing more than half of one per cent alcohol by volume unless it bears a clearly printed and legible label, in the form and print size prescribed by the Governor in Council, that warns the consumer that alcoholic beverages impair the ability to operate vehicles and machinery, may affect the health of the consumer and may cause birth defects if consumed during pregnancy."*

In April 2005, the Health Committee prepared a report to the Canadian House of Commons and recommended that Bill C-206 not proceed. At the present time, Canada has no national alcohol warning legislation in place.

United Kingdom

From 1998, voluntary unit labelling on alcohol containers was introduced in the U.K. to support the government's "Sensible drinking" message and to make it easier for drinkers to associate those messages with the actual amount of alcohol they purchased (Alcohol Policy UK 2008). In May 2007, the Government secured a voluntary agreement with the alcohol industry to introduce, by the end of 2008, labels on alcoholic drink containers showing unit and other health information. In addition, the industry was also asked to include advice to women on the risks of alcohol during pregnancy (Campden & Chorleywood Food Research Association, 2008). In the final two weeks of March 2008, Campden and Chorleywood Food Research Association was commissioned by the Department of Health to undertake a large-scale independent market survey to assess compliance with the guideline. Campden and Chorleywood Food Research Association (2008) concluded that 43.4% of samples had included any slogan or statement, 57% had included any U.K. units information; 15.7% had included any sensible drinking message; 34.7% had included the drinkaware web site information; and 17.9% (2.2% included the wording: Avoid alcohol if pregnant or trying to conceive; 2.7% contained alternate statements that did not comply with the Chief Medical Officer's advice; and 13.1% contained the pregnancy logo) had included any pregnancy information. Campden and

Chorleywood Food Research Association (2008) also noted that the pregnancy logo was found most frequently on samples originating from Australia, followed by France and the U.K.

A report by the British Medical Association (BMA) included the recommendation to label all alcohol products with a common standard label indicating the number of alcohol units in the container, the recommended maximum daily alcohol intake and a message that exceeding the recommended alcohol guidelines could result in harm for the individual and to others (BMA Board of Science 2008).

In 2007, Lord Mitchell introduced a private members bill on alcohol labelling to the House of Lords in the U.K. The Bill would require all alcoholic beverage containers (containing alcohol above 0.5% alcohol/volume) to be labelled with the following warning message:

> *"GOVERNMENT WARNING: Avoid alcohol if pregnant or trying to conceive."* (House of Lords 2008)

The House of Lords agreed that the Alcohol Labelling Act (2008) become law no later than 1 January 2010 (House of Lords 2008). The Bill was passed by the House of Lords in July 2008 and was sent to the House of Commons, where it currently remains (House of Lords 2008).

Ireland

In 2007, following publication of the report entitled '*The Coombe Women's Hospital Study of Alcohol, Smoking and Illicit Drug Use, 1988-2005*' the Irish Minister for Health and Children asked the Chief Medical Officer (CMO) in the Department of Health and Children to consider the data presented in the study, particularly with respect to the finding that most pregnant women drank alcohol.

Later in 2007, the Department of Health and Children consulted with a number of stakeholders on the proposal to introduce a requirement that alcohol containers and

promotional materials carry a health warning statement about drinking alcohol during pregnancy.

However, as of 9 September 2008, Ireland did not have legislation requiring health warnings on alcoholic beverages (Govt urged to put pregnancy warning on alcohol, 2008).

European Union (EU)

According to information available from the European Centre for Monitoring Alcohol Marketing (EUCAM - established in 2007 by the National Foundation for Alcohol Prevention in the Netherlands) in February 2006, the Director General on Health and Consumer Protection of the European Commission concluded that health warnings could be an effective means to inform consumers of alcoholic beverages about risk associated with inappropriate consumption of alcohol. Despite this recommendation, in September 2007, the European Parliament rejected calls from its Health Committee to introduce standardized EU-wide health warnings on alcoholic drinks. Instead, members from the European Parliament asked the Commission to initiate a comparative study on the impact and effectiveness of various information and communication means and to publish the report by 2010 (EUCAM 2008).

In January 2008, the European Parliament decided to approve the proposal for mandatory warning labels to appear only on premixed alcoholic beverages and include nutritional information (energy, total fat, saturated fats, carbohydrates, sugars and salts) on the front of packages.

After the rejection by the European Parliament of standardized health warnings on **all** alcoholic beverages, a number of Member states took steps to introduce warning labels themselves. While initially planning to proceed with the introduction of mandatory warning labels(EUCAM (2008), the Finnish government withdrew plans to proceed with warning labels (Standing Committee on the Food Chain and Animal health Section on General Food Law, 2008).

The Australian and New Zealand context

Based upon information included in a review paper by Alcohol Healthwatch (2003), in 1990 the Joy McLaughlan Broadcast (Liquor Advertising) private members bill requested alcohol advertisements in New Zealand be accompanied by a prescribed health message. The Bill was rejected in favour of a review. The 1997 review rejected the proposal for inclusion of health and safety messages. In response, Labour Party member Dianne Yates tabled a supplementary order paper to the sale of Liquor Amendment Act. This was rejected by parliament. The 1999 supplementary order paper was drafted in to a private members Bill. The Bill was drawn from the ballot in 2000, but failed to reach a majority in parliament.

In 1997, the Tasmanian branch of the National Council of Women (application A306) applied to the Australia and New Zealand Food Authority (ANZFA) for the inclusion of alcohol warning labels about pregnancy. The application was rejected. A similar application (A359) presented by the Society Without Alcoholic Trauma (SWAT) in 1998 for labels on all alcohol containers to carry the message "This product contains Alcohol. Alcohol is a dangerous drug" was also rejected in 2000. ANZFA conducted a review of the evidence of the effectiveness of alcohol labelling and reached the following conclusion:

> *"Scientific evidence shows that warning statements are not effective in modifying at risk behaviour in relation to consuming excessive amounts of alcohol, and would therefore not provide any additional protection of public health and safety. Information to enable consumers to make an informed decision or prevent fraud and deception is already provided by existing labeling requirements and public health policies and campaigns."* (ANZFA 2000, p.3)

In addition, ANZFA suggested the costs of introducing alcohol labelling would outweigh the benefits:

> *"ANZFA has undertaken a regulation impact assessment process which also fulfils the requirement in New Zealand for an assessment of compliance costs. That process concluded that requiring the labeling of alcoholic beverages with a warning statement would offer no clear benefits to government, industry or*

*consumers but would introduce costs to government, industry and consumers."(*ANZFA 2000, p.3)

In the year 2000, the New Zealand House of Representatives received petitions requesting that the House legislate that all alcoholic beverages in New Zealand should carry health and safety messages, including the reference that drinking alcohol during pregnancy can cause birth defects. This petition was referred to the Health Select Committee who considered the literature provided and recommended that mandatory warning labels should be included on all types of alcohol to remind women of the risk of alcohol during pregnancy. The Health Select Committee also recommended that the labels should be supported by a range of health promotion and education initiatives and research (House of Representatives Health Committee, 2002 as cited in Food Standards Australia New Zealand, 2007)). In February 2003, the New Zealand Government agreed in-principle to ensure that labels should be on all alcoholic beverage containers advising of the potential dangers of drinking alcohol when planning a pregnancy and while pregnant.

In a submission to the NSW Alcohol Summit in 2003, SWAT called for warning labels to be carried on all alcoholic products, warning of the potential significant health risks to particular groups (SWAT 2003).

In February 2006, the Alcohol Advisory Council of New Zealand lodged an application (A576) with FSANZ seeking a variation to existing Standard 2.7.1 to require a health advisory label on alcoholic beverage containers advising risk of consuming alcohol when planning to become pregnant and during pregnancy. FSANZ released a discussion paper for an eight- week period in December 2007. Ninety submissions were received and these have all now been evaluated by FSANZ (www.foodstandards.gov.au 21/01/09).

In May 2008, the Australia New Zealand Food Regulation Ministerial Council asked FSANZ to consider mandatory health warnings on packaged alcohol in relation to high-risk drinking. As a result of these two projects the current review was commissioned.

Although neither Australia nor New Zealand have legislated to include health or safety warning labels on alcoholic beverages, it is a requirement under the ANZ Food Standards Code (Standard 2.7.1) for all alcoholic beverages to have their alcohol content expressed by declaration of alcohol by volume and in terms of numbers of "standard drinks", each equivalent to 10 grams of ethyl alcohol (Stockwell and Single 1997; New Zealand Food Safety Authority 2004).

According to Simpson Grierson (2003), the inclusion of standard drink information was for two main reasons: to bring the labelling of alcoholic beverages in line with other food labelling requirements and, to provide consumers with more accurate information about standard drinks that would be useful for the "*protection of health and safety of consumers*" (p.2)

Australian research suggests that the inclusion of standard drink labels on containers has a number of advantages (Stockwell and Single 1997). For example, it has been established that standard drink labelling substantially improves the extent to which drinkers can estimate the number of standard drinks in a container and accurately pour a standard drink. It has also been found that labelling is acceptable to consumers (Stockwell and Single 1997), but is more easily located when applied to the front than the back of alcohol containers (Chan, Chan, P'ng and Segarajasingam, 1997). Thus, standard drink labelling assists people in adhering to lower risk safe limits. As noted by Stockwell and Single:

> "*It is too early to evaluate the impact of standard unit labelling on the community at large as no evaluation of this initiative has been made publicly available. A number of experiments, focus group studies and community surveys have, however, examined drinkers' reactions and their abilities to utilise the information from such labelling. Collectively, the studies provide a strong rationale for the adoption of standard unit labelling and were, indeed, influential in the decision by the Australian government to adopt standard unit labelling in 1995*" (Stockwell and Single 1997, p.87).

However, recent exploratory research by Jones and Gregory (2009) with a sample of 44 young people aged between 18 and 22 years in New South Wales indicated the

need for some caution in relation to standard drink labels. After, interviewing participants about standard drink labelling the authors reported that some young drinkers may use standard drink labelling information to purchase alcohol based on a process which would ensure more "bang for your buck" (p.233). Jones and Gregory concluded that:

> "there is an important role for standard drink labelling as long as it is combined with other policies addressing the price, availability and marketing of alcohol"(p.234).

However, it is noted that how this evidence would translate to warnings about specific risks, such as drinking whilst pregnant or breastfeeding, is not clear.

As stated at the beginning of this section, concerns about the impact of alcohol on pregnancy have been one key factor in the adoption of alcohol warning labels. Little or no attention has been given to the related area of concern, namely the impact of alcohol consumption on breastfeeding.

Having provided a brief international overview of legislation on alcohol warning labels, the focus will now shift to examining briefly a range of other government and alcohol industry initiatives and then focus on the available literature on the effectiveness of alcohol warning labels.

5.4 Industry initiatives

Apart from the New Zealand and Australian government initiatives and policies developed to reduce alcohol related harm (including a focus on the risks of alcohol use during pregnancy) there have also been a range of industry sponsored initiatives aimed at the promotion of responsible drinking and reduction in FASD. For example, in Australia Lion Nathan have developed and are in the process of introducing www.BeDrinkAware.com.au on packaging and marketplace materials and in 2006 launched the www.drinkresponsibly.co.nz initiative to promote safe drinking behaviours in New Zealand.

Lion Nathan also contribute to DrinkWise Australia, and the "re-thinking Drinking: You're in control" school based education program in Australia**.** In New Zealand they contribute funds, through a levy, to the Alcohol Advisory Council of New Zealand (ALAC**)** and have supported the Students Against Drunk Driving (SADD) program and funding for national teacher development programme for the year 10-12 health education programme as developed and facilitated by the Christchurch College of Education. They have also provided funding for a programme launched by the Fetal Alcohol Support Trust to educate young people about the risks of drinking while pregnant. For more info see: www.lion-nathan.com.au

Similarly, DIAGEO promote responsible drinking through the DRINKIQ.com initiative. DIAGEO have also recently conducted "The choice is yours" responsible drinking campaign in Great Britain, Spain and Germany and the "Students know what's in it" campaign in Great Britain to provide information about the alcohol content in various alcoholic drinks. As part of their range of programmes and initiatives to support moderate and responsible drinking, in 2005 DIAGEO announced that the words "Drink Responsibly" (or relevant translation) would also appear on labels and secondary packaging, and alcohol content (ABV) information would be provided on labels and secondary packaging, the global website and consumer care-lines in markets where there was an agreed definition and recommended guidance on consumption from an authoritative source.

For more information on these and other industry initiatives see:

- www.bdrinkaware.com.au
- www.drinkresponsibly.co.nz
- www.tridentglaobl.com.au
- www.diageo.com
- www.drinkiq.com
- www.pernod-ricard.com

It is important to note that using the methodology that was previously described for accessing available literature on the effectiveness of alcohol warning labels, no peer reviewed publications on the effectiveness of industry labelling approaches was located. However, in research investigating brewer sponsored counter advertisements,

respondents have rated such advertisements as less informative, believable, on-target and effective than conventional public service announcements (Arkin et al. 1992 as cited in Agostinelli and Grube 2002).

Chapter 6: Studies on effectiveness of alcohol labelling

Forty original research studies were located that specifically investigated the effectiveness of warning labels on alcoholic beverage containers. All but four of the papers were based solely on data from the U.S. Of the remainder, two studies were based on a comparison of U.S. and Canadian data, one was based on data from the U.S. and Australia, and the last paper was from Israel. Six research teams (Andrews et al.; the Alcohol Research Group (e.g. Kaskutas, Greenfield, Graves et al.); Hankin et al.; MacKinnon et al.; Mazis et al.; Marin et al.) had produced a series of publications representing a substantial proportion of all such publications (n=30 papers), while the majority of other papers were stand-alone/isolated publications. Of the forty papers identified, five have been excluded from the current review. Three of these (Greenfield and Kaskutas 1993; Parker et al. 1994: Gorn et al. 1996) were excluded as they solely focused on warning labels and drink driving. The research by MacKinnon (1993) was excluded as it only focused on a comparison on the relative merits of the terms toxic versus poison in relation to cancer. Finally, the paper by Weiss (1997) was excluded as it was conducted in Israel as a prelude to the possible introduction of labelling and focused on knowledge concerning alcohol and the use of machinery, blood pressure and cancer. Of the remaining thirty-five papers, only five (Hankin and colleagues) specifically included pregnant women and investigated the impact of alcohol warning labels on knowledge, attitudes and behaviour. The remaining papers included a range of target groups (university students n=9; general population samples n=12; school students n=4; Hispanic adults n=2; Mormons n=1, homeless people n=1, Mexican women n=1) and focused on a range of issues. None of the papers investigated alcohol and breastfeeding. (All forty papers have been included in the summary table included in Appendix 3).

Each of the thirty five papers described above were critiqued with regard to:

- Strength and appropriateness of methodological design;
- Sound external; and,
- Sound internal validity.

As indicated above, it is important to note that the majority of available research was not directly concerned with alcohol use during pregnancy and had significant limitations. Both Babor, Caetano, Casswell, Edwards, Giesbrecht, Hill et al. (2003) and Stockwell (2006) have previously reached a similar conclusion. With very few exceptions (Alcohol Research Group; Creyer, Kozup and Burton 2002) most studies did not include control series (use of a matched comparison sample) and subsequently, even though many studies report significant results, these may have been influenced by a multitude of other factors. For example, evidence regarding the impact of consumption during pregnancy may have been influenced by other prevention countermeasures, advertising campaigns, antenatal information and posters. Thus, it is not possible to disaggregate the impact of warning labels from other initiatives. Many studies also had relatively small and/or non-representative samples (e.g. samples of marketing students, African-American pregnant women) and this reduced the overall generalisability of the results.

Bearing these limitations in mind, the following review will present a critique of those thirty five papers that have relevance for women of childbearing age and pregnant women. The findings from these critiqued papers have been summarised and included in Table 2. The major findings have been collapsed into three categories to represent whether or not the there is strong, moderate or only limited or weak evidence to support the claims.

Following the detailed critique of individual research, a brief synopsis of the major findings will be presented. The original research will then also be reviewed collectively using the effectiveness framework described by Argo and Main (2004).

The "level of support" classification system used in Table 2 was based upon the following criteria:

- Strong level of support meant that there was a body of evidence that was based upon research that had used appropriate methodological designs, included samples that were of sufficient size to allow for meaningful analysis to be conducted, had samples that were representative with no or very limited selection bias and where the research had sound internal and external validity;

- Moderate level of support was determined where conclusions were based on a small number of studies (sometimes only one study) and/or those studies that were available had a number of design/methodological limitations;
- Weak level of support was determined where conclusions were based on studies with significant design/methodological limitations.

Table 2 Summary of major findings relevant to women of childbearing age and pregnant women

Finding	**Level of support from the available research**
Over time more people will become aware of the existence of warning labels	Moderate
Depending on the message and the characteristics of the individual, people who are aware of the presence of warning labels are able to recall the messages	Moderate
Some groups, such as young people (including women of childbearing age) and heavier drinkers, may be more aware of the warning labels	Moderate
Those people who see labels are more likely to have conversations about the risk of alcohol during pregnancy	Moderate
Exposure to more than one message source (e.g. warning label, poster, advertisement) has a greater impact on knowledge and behaviour and increased the likelihood of conversations on the topic	Weak-Moderate
Warning labels had no effect on behavioural intentions regarding future consumption	Weak-Moderate
Warning labels are associated with a reduction in consumption amongst women pregnant for the first time	Weak

6.1 Critiques of original research

Papers from research groups

1. Andrews et al. studies – 1990 to 1993

Preceding the introduction of the mandated alcohol-warning legislation in the U.S., there had been some suggestions by policy makers and citizen groups that five warnings be included. These were:

> *1. GOVERNMENT WARNING: According to the Surgeon General, women should not drink alcoholic beverages during pregnancy because of the risk of birth defects.*
>
> *2. GOVERNMENT WARNING: Consumption of alcoholic beverages impairs your ability to drive a car or operate machinery, and may cause health problems*
>
> *3. GOVERNMENT WARNING: The consumption of this product, which contains alcohol, can increase the risk of developing hypertension, liver disease, and cancer.*
>
> *4. GOVERNMENT WARNING: This product contains alcohol and is particularly dangerous in combination with other drugs.*
>
> *5. GOVERNMENT WARNING: Alcohol is a drug and may be addictive.*

Prior to 18 November 1989 (when legislation came into effect in the U.S.), Andrews, Netemeyer and Durvasula (1990) conducted interviews with 273 undergraduate marketing students from two universities to determine the believability of and attitudes of the students toward alcohol warning information. The authors were also interested in investigating whether prior attitudes and beliefs toward drinking mediated the influence of the different labels. Students were each given one of the above five randomly assigned alcohol warning labels and were then required to answer questions regarding the believability of the label and attitudes toward information contained in the label.

Results indicated that the birth defects and driving impairment labels were perceived as significantly more believable than the other three labels. As Andrews et al. (1990)

indicated, it was not possible to determine if this result was due to the content of the message or the perceived credibility of the source i.e. the warning on birth defects was the only message that included reference to the Surgeon General.

Existing attitudes and beliefs toward drinking had a significant impact on believability. That is, the more favourable the respondent's attitudes towards drinking, the less they believed the birth effects, driving impairment and drug combination warning labels. The authors concluded that their research suggested a defensiveness on behalf of those who enjoy drinking and implied that alcohol warning labels fall on "blind eyes" and "deaf ears" of those who may need the warnings the most. This is consistent with health beliefs research discussed earlier – that there exists a "self-serving optimism." It is also consistent with a heuristic-systematic processing analysis, where individuals will judge a message as less valid or accurate when the message is incongruent with their personal beliefs and attitudes.

The research by Andrews et al. (1990) produced some interesting results but did have a number of limitations. Firstly, all students were marketing students and hence not representative of the general university population nor the broader population. Secondly, the labels were placed on bottles of low alcohol beer and wine coolers only. This was not controlled for as a variable. This methodology may have influenced the results, particularly the believability of the messages on the low alcohol beer. Finally, the authors did not include any information on how attitudes and beliefs were assessed making further analysis and comment difficult.

Andrews, Netemeyer and Durvasula (1991) produced another report using their data from 1989 with 273 undergraduate marketing students. In this study, the authors were interested in investigating believability of labels (see Andrews et al, 1990 for the five labels) in relation to a student's self-reported level of consumption.

A multivariate analysis of variance was used to examine the overall influence of consumption frequency (frequent versus occasional/non user) and warning label type on believability toward the label, attitude toward the label and attitude confidence. Label believability and attitude were not significantly different amongst the sample, but there was a significant effect on label attitude confidence ($F = 5.78$, $df = 1, 263$,

p<0.017) indicating that frequent alcohol users had a less positive attitude towards the warning labels than occasional or non users. No information was included in the on-line production of the paper that indicated how students were presented with the labels. Other limitations previously discussed- see Andrews et al. (1990) - also apply to this 1991 publication.

Andrews, Netemeyer and Durvasula (1993) produced a further report on their 1989 data, noting that of the 273 undergraduate students, 94 % were classified as frequent (greater than once per week) alcohol consumers. This component of their investigations explored cognitive responses (support for and against inclusion of particular labels) to determine persuasiveness of the labels (see Andrews et al 1990 for the five specific labels).

Of the five labels presented, alcohol and birth defects had more support than any other label. Further research by the same authors with the same sample indicated that the alcohol and birth defects message was also viewed as most believable compared to other labels.

However, as previously mentioned, the researchers used only light beer bottles and wine cooler bottles. The use of light beer as opposed to higher alcohol by volume beverages may have influenced the perceptions of the respondents and hence the internal validity of the data. Additionally, as discussed the sample was not representative of university students in general, nor of the general population and inadequate information was provided to enable a critique of the validity and reliability of measurements instruments used. Finally, one consideration is whether alcohol and birth defects may be more believable because it may have less personal relevance, at least for some respondents, such as males.

2. Alcohol Research Group – Kaskutas, Graves and Greenfield studies – 1991 to 1999

1991 – Public support for warning labels

To ascertain the level of public support for the introduction of alcohol warning labels Hilton and Kaskutas (1991) examined data from telephone interviews conducted in

1989, six months prior to the implementation of the alcohol labelling legislation with 2,006 adults randomly selected from across the country. The introduction of alcohol warning labels was supported by 87% of respondents, although this support was found to be higher among abstainers (97%) and low-level drinkers (90%) as compared to heavier drinkers (73%).

1992 – Awareness of warning labels pre and post legislation

Kaskutas and Greenfield (1992) used data collected from the earlier study (Hilton and Kaskutas 1991) and compared it with data collected from a second similar survey of 2,000 adults in 1990. At six months post the introduction of the health warning labels, greater proportions of key target groups, such as heavy (defined as consuming 5 or more alcoholic drinks at least once per week) drinkers (39%), young men at risk for drink driving (46%) and women of childbearing age who were heavy drinkers (39%) reported having seen the warnings. When analyses were conducted to assess the behavioural differences that might be associated with seeing the label, significantly more respondents who had probably seen the label reported having conversations about pregnancy (58% versus 45%).

1993 – Public attitudes towards alcohol policies after the introduction of mandated warning labels on alcohol containers

To assess changes in public attitudes after the introduction of alcohol warning labels Kaskutas (1993a) used data collected from the earlier study (Hilton and Kaskutas 1991) and compared it with data collected from a third similar survey of 2,017 adults in 1991. While the research did demonstrate a high level of support for the policy, the majority of respondents in both surveys indicated that ***in their opinion*** warning labels would have limited impact on heavy drinkers (87% of sample in 1991 and 89% of sample in 1989). In a similar study, Kaskutas (1993b) using the same data set of 2,017 adults who were interviewed in June, July and August 1991, aimed to investigate whether:

1. Respondents would see the warning label as less likely than taxes to affect people's drinking;
2. Heavier drinkers would perceive both policies as affecting their own drinking;

3. Heavier drinkers would be less likely to support either policy; and,
4. Those who supported either policy would be more likely to believe the policy would not affect their drinking.

One third of respondents indicated that in their opinion warning labels had affected moderate drinkers, while only 14% believed that warning labels affected heavy drinkers. Many more respondents (55%- no information was included as to whether or not this was statistically significantly higher) said that labels had affected their own drinking (respondents were not required to indicate in what way drinking had been affected). Heavier drinkers (defined as defined as consuming 5 or more alcoholic drinks at least once per week) were significantly less likely than moderate drinkers to believe that the label had affected their own drinking (chi square = 77.6, $p<0.00001$).

1994- Relationship between exposure to health messages and behaviour

Using telephone data from a nationally representative sample of adults, Kaskutas and Graves (1994) investigated exposure to the alcohol warning message on alcoholic beverage containers, warning posters in restaurants and bars and media advertisements. The outcomes assessed were:

- Knowledge of the alcohol-related risk of birth defects;
- Conversations about drinking during pregnancy; and,
- Self reported reduction of alcohol consumption due to health concerns.

Based upon data gathered in 1990 and 1991 (n= 4,017, adults over 18 years of age), over 80% of the sample reported exposure to at least one message source about drinking during pregnancy. Amongst women of childbearing age (defined as 40 years and under) 47%, 26% indicated that they had seen two message sources, and 8% said they had seen three message sources (no information was provided on which message source women were exposed to).

Twice the proportion of heavy drinkers compared to moderate drinkers reported seeing all three message types. No significant differences were found for income or ethnicity.

Multivariate logistic regression models were applied and those individuals who were exposed to one, two or three messages were significantly more likely (minimum odds ratio=1.85, $p<0.0001$) to be aware of the risk of birth defects associated with drinking than those who said they had not seen any of the warnings. Compared to those who said they had not seen any warning label, poster or advertisement about the risk of alcohol during pregnancy, those reporting a single exposure were twice as likely to report that they had a conversation about drinking during pregnancy (odds ratio=2.58, $p<0.0001$). Those reporting two exposures were more than three times as likely (odds ratio= 3.83, $p<0.001$) and those who said they had seen all three were four times as likely (odds ratio=4.11, $p<0.0001$) to report a conversation on the topic.

When considering whether respondents had limited their drinking in the past 12 months due to health concerns, there was no significant relationship between seeing a single message and reducing consumption. However those that were exposed to two message types were over one and a half times more likely (odds ratio=1.64, $p<0.01$) than those who had not seen any message. Those exposed to all three message sources were twice as likely to reduce their drinking due to health concerns (odds ratio= 2.03, $p<0.01$).

Among women of childbearing age, significant predictors for conversations about drinking during pregnancy included:

- Knowledge of the birth defect risk (odds ratio=1.90, $p<0.05$);
- Exposure to a single warning source (odds ratio=2.61, $p<0.00001$);
- Exposure to two warning sources (odds ratio=3.72, p<000.1);
- Exposure to all three warning types (odds ratio=3.96, $p<0.0001$); and,
- Having been pregnant in the last year (odds ratio=4.68).

Among this group of women, exposure to one or even two message sources did not predict having limited consumption of alcohol for health reasons. However, women who were exposed to all three message sources were over two and half times as likely than those not exposed to any message source to reduce consumption (odds ratio=2.83, $p<0.00001$). Thus, there is some evidence that exposure to multiple message sources was associated with increased awareness, increased discussion and changes in behaviour. Such findings relate to the Health Belief Model and emphasise

the importance of cues as potential precursors of behaviour change (McBride et al. 2003).

1997 – Health consciousness and attention to warning labels

Kaskutas and Greenfield (1997) suggested that the level of an individual's health consciousness may have an impact on the attention and exposure to health messages. In other words, the higher an individual's level of health consciousness[1], the more likely they will notice and pay attention to health messages regarding alcohol consumption. Using data collected from 1,026 participants in 1993, the researchers examined whether the health consciousness of an individual was more likely to draw their attention to health messages about alcohol.

Risks associated with alcohol consumption were reportedly seen in advertisements by 94% of respondents, 39% reported seeing the warning labels and 34% had seen a poster. Respondents aged 18 to 20 paid more attention to warning labels than any other age group. Health consciousness was not significantly associated with attention paid to warning labels or posters. Of those respondents who reported seeing the warning label, 86% recalled the message about health risks, 78% recalled the birth defects message, 44% recalled the drink driving messages, and 63% recalled the operating machinery message. The birth defects message was recalled by 89% of respondents aged 40 and younger (for whom such a message is more likely to be relevant) compared to older respondents.

1998 – Awareness of warning labels over time

Building on earlier studies, Greenfield and Kaskutas (1998) examined the longer-term impact of warning labels by comparing data gathered from interviews conducted in 1989 (n=2,006), 1990 (n=2,000), 1991 (n=2,017), 1993 (n=1,026) and 1994 (n=1,016). In 1990, 21% of participants recalled seeing the warning labels containing messages about alcohol and pregnancy and drinking and driving. In 1994, this figure increased to 51%. These results suggest an increase in awareness of warning labels on alcoholic beverages. Further analysis of data revealed that by 1994, 56% of female

[1] Health consciousness was assessed using a five item scale developed by the authors that included health related questions.

participants aged between 18 and 40 correctly recalled the pregnancy warning. However, there was some evidence to suggest that awareness of the warning labels and recall of its message appeared to plateau from four to five years after the labels introduction.

The authors did note that there was no effect seen between label exposure and alcohol consumption among women who were pregnant. However, they did caution that this conclusion was based on a small sample size (however no information was included in the report on the numbers of pregnant women included) and that consumption of alcohol amongst the sample was low overall with only 4% acknowledging drinking more than three drinks in a day. Because consumption of alcohol was low, detecting any reductions would be difficult.

1993 and 1999 – Comparison of U.S. and Canada

Between 1989 and 1991, Graves (1993) conducted four cross sectional surveys with a random sample of a 2,000 U.S. and 1,000 Canadian adults. As Canadian law did not require that alcohol beverage containers include health warnings, Canada was chosen as a research site to provide a control group. In 1991, 35% of U.S. participants reported seeing the warning labels in the last twelve months compared to 19% in Ontario. Viewing the label was also more likely to lead to discussions with others about pregnancy and alcohol consumption.

In 1994, in follow up research, more data from participants in both the U.S. and Canada were collected (Greenfield, Graves and Kaskutas 1999). Analysis of all data excluded any participants who reported never consuming alcohol over their lifetime. In 1990 in the U.S., 30% of the 1,700 participants reported seeing the warning labels on alcohol beverages and in 1991, this had increased to 39% of the 1,768 participants and up to 43% of 868 participants in 1993 and 43% of the 907 participants in 1994. In comparison, 16% of the 1,001 Canadian participants reported seeing warning labels on alcohol beverages in 1990; this increased to 19% of the 985 participants in 1991 and decreased to 15% of 985 participants in 1993 and down to 12% of the 973 participants in 1994. Further analysis of U.S. participants' data found that heavy drinkers (defined as those who consumed alcohol at least weekly and on occasion consumed five or more drinks) and participants who were aged between 18 and 29

were more likely to report seeing the health warning label. For the U.S., over the four years of the study, results were reasonably consistent each year, with approximately 80% of participants reporting the warning label mentioned birth defects. In comparison, about 42% of Canadian participants reported the warning label mentioned birth defects. Overall, the results suggested that awareness of labels may generate discussions of the risks associated with alcohol consumption but no direct causal link was identified.

2008- Impact of warnings on third parties

The following research on whether people may intervene to deter another person from drink driving was included in the review, even though it did not focus on issues related to pregnancy or breastfeeding, because it was the only research located that examined the impact of warnings on the behaviour of collaterals.

To test the hypothesis that those people who had seen and could recall the alcohol and drink driving warning message were more likely than others to intervene so as to deter another person from driving when intoxicated Tam and Greenfield (2008) analysed cross-sectional self-report data from 1,376 men and women that were gathered in 1993 and 1994. Label and message recall were assessed by the questions: "Now thinking about the last 12 months, have you seen any labels on bottles or cans of beer, wine or liquor? "and "Did the warning label say anything about drunk driving?". Average number of drinks per day was assessed and a dichotomous measure of three or more drinks per day was used to indicate higher consumption. Finally, container handling was also assessed. Interventions to deter drink driving were assessed by the following series of questions:

- Have you asked someone not to drive?
- Have you offered to drive someone home yourself?
- Have you asked someone to take a taxi, bus or subway?
- Have you tried to take someone's car key?
- Have you asked someone to stay at your home?

Response categories for each of the above questions were binary. Results indicated that usual consumption of three or more drinks on a drinking day (standardised B = 0.28), greater handling of alcoholic beverages (B=0.08) and recall of the drink driving message (B=0.08) all had significant positive effects on the intervention factor. While

men were more likely than women to usually consume three or more drinks (*B*=0.30), handle alcoholic beverages (*B*=0.13), and recall the drink driving message (*B*=0.09), they were less likely to intervene to deter others from drink driving (*B*=-0.0.11).

This research lends support to the possibility that warning messages may enhance a third party to attempt to intervene in another person's attempt at drink driving. Further longitudinal research on the impact of health warnings on social norms or collateral behaviour is warranted however, before any definitive causal conclusions can be drawn. This is consistent with some of the research on health beliefs, and the recommendations by Isaac (1995 as cited in Agostinelli & Grube 2002) which indicates that the influence of health messages, such as those delivered through warning labels or other media, may be mediated through interpersonal interactions. However, in relation to the current focus, it would be important to investigate the specific implications in relation to the risks of drinking during pregnancy and breastfeeding: the findings from drink driving may not, in this case, generalise to other domains such as pregnancy.

Summary

The work of the Alcohol Research Group indicated there was strong public support for the introduction and continued use of alcohol warning labels in the U.S. People who had reported seeing alcohol warning labels were more likely to report discussing the risks associated with alcohol consumption. Research indicated that among women of childbearing age who were heavy drinkers, 39% reported seeing warning labels (Kaskutas and Greenfield 1992) and amongst general population samples, of those people who recalled seeing a warning label, over 77% recalled the birth defects message (Kaskutas and Greenfield 1997).

The authors also concluded that within four years after the introduction of warning labels awareness appears to plateau. Greenfield and Kaskutas (1998) suggest that "*the meaning of this is not entirely clear, but the age results seen here, especially for those in the under-age group, serve to remind us that new cohorts of drinkers are coming on line, bombarded by youthful depictions in the cut loose vein"* (p.65). Research by Kaskutas and Graves (1994) is noteworthy for highlighting the potential cumulative impact of multiple message sources. The findings of Greenfield and colleagues are

particularly noteworthy as the research program by the Alcohol Research Group was methodologically rigorous. The cross sectional research was based on data from randomly sampled nationally representative adults and two research studies included the use of a matched control (i.e. Canada vs U.S.). Assessment of alcohol consumption was based on the use of previously validated measures and conclusions were restricted to the data analysis in each study. The research by the ARG has also previously been recognised by Stockwell as "*the strongest design of all the others that were conducted to evaluate the impact of any alcohol warning labels, and most weight should be placed on its findings*" (Stockwell 2006, p.5).

3. Hankin et al. Studies from 1993 to 1998

Hankin and colleagues have been involved in five studies to examine what impact alcohol warning labels have on the awareness and behaviour of pregnant women.

1993 – Awareness of alcohol warning labels and alcohol consumption

Between 1989 and 1991, 4,397 African-American pregnant women were interviewed in Detroit to ascertain their self-reported alcohol consumption and knowledge of the existence of warning labels on alcoholic beverage containers (Hankin, Firestone, Sloan, Ager, Goodman, Sokol, and Martier 1993). Women were questioned about the average amount of absolute alcohol consumed in the week of conception and the average amount of alcohol consumed during a two-week period at the time of their first prenatal visit. During the week of conception, 44% of women reported not drinking alcohol, 42% were assessed as consuming less than 0.5 ounces of absolute alcohol per day and 14% were identified as drinking 0.5 ounces of more of absolute alcohol per day. At the prenatal visit, 81% of pregnant women reported not consuming alcohol at all during pregnancy, 17% were classified as lighter drinkers and 2% were identified as high risk drinkers who consumed more than 0.5 ounces of absolute alcohol per day. Women were asked at the interview "Is there a warning label on alcoholic beverages (something that may affect your health)?" and responses were coded as "yes", "no" or "don't know".

Prior to the warning labels on alcohol beverage containers being introduced in November 1989, 35% of pregnant women interviewed between May and 18 November 1989 reported a false-positive (seeing the warning label when no warning

labels were actually yet on alcohol beverage containers). From 19 November 1989 to May 1990, 37% of pregnant women interviewed reported seeing the warning label and this increased to 56% of women interviewed between June 1990 and September 1991.

Self-reported alcohol consumption of pregnant women in the period prior to the introduction of warning labels and the period after the warning labels had been introduced, showed no significant changes. Prior to the introduction of warning labels on alcohol beverages, 80.4% of women reported abstaining from alcohol, 17.5% drank less than 0.5 ounces of absolute alcohol per day and 2.2% reported consuming more than 0.5 ounces of absolute alcohol per day. After the warning labels on alcohol beverages had been introduced, 81.7% of women reported abstaining from alcohol, 16.4% drank less than 0.5 ounces of absolute alcohol per day and 1.9% reported consuming more than 0.5 ounces of absolute alcohol per day. These results suggest that for this population of pregnant women, the introduction of warning labels on alcohol beverage containers did not significantly change their drinking behaviour.

After further analysis of the data, taking into account some demographic and consumption variables, Hankin et al. (1993) made a number of conclusions. These were: whilst the introduction of warning labels on alcohol beverage containers may be linked to a reduction in alcohol consumption by light or moderate drinkers (those that consume less than 0.5 ounces of absolute alcohol per day), it had no impact on the alcohol consumption of pregnant women who consumed more than 0.5 ounces of absolute alcohol per day. Secondly, although at-risk drinkers were exposed to the warning labels more often, this did not appear to have an impact on their alcohol consumption.

As Hankin et al. (1993) acknowledged, all participants in the research were inner city African-American pregnant women from the United States and 85% of this population were receiving welfare. As the sample was atypical, it limits the generalisability of the results to other populations. A further limitation was that women were questioned as to whether or not they had seen the warning labels on alcohol beverage containers, but were not actually required to identify or recall the content of the message. Consequently, whether the women actually saw the label, or

whether the message the warning label was trying to impart was recalled, was not identified. There were no study controls that would make it possible to ascertain what impact exposure to warning labels had independent of other variables (e.g. advice from health professionals, mass media campaigns).

1996 – Awareness of the alcohol warning label

A further study by Hankin, Sloan, Firestone, Ager, Sokol and Martier (1996a) expanded on the original dataset collected in the 1993 study, to monitor changes in awareness of the alcohol warning messages for 7,334 pregnant African-American women from 1989 to 1993. Results indicated that from 1989 to 1993, the level of awareness of alcohol warning labels increased from 29% to 78%. Over the four-year period, awareness of the warning label was reported by 57% of all women interviewed. At-risk drinkers reported the greatest awareness of labels (63%), followed by non-risk drinkers (59%) and non-drinkers (53%). These results suggest that increased exposure to the warning labels may result in increased awareness of warning labels. Analysis of all interviews conducted over the four years found that 84% of women who reported drinking at the time of conception (n=4,028) reported that they were also aware of the warning labels on alcoholic beverages. Interviews conducted in 1992 and 1993 found self-reported awareness of warning labels on alcoholic beverages had not changed substantially, indicating that about 80% of people in this population who consume alcohol will also report seeing the warning label. Older women were less likely to report being aware of the label and those who consumed more alcohol, and therefore categorised as 'at-risk' drinkers.

As with earlier research (Hankin et al. 1993) this study had significant limitations. Participants were not asked to recall the content of the message they had seen and therefore, although they may have reported seeing the label, this may not have been the case. In addition, the sample had low literacy levels and as research in the tobacco field has demonstrated, some text only health warnings may require college level education to comprehend (Malouff et al. 1992). The sample, although it included a group who may be considered one potentially high risk group, was also not representative of pregnant women and while this limits generalisability, the findings

are noteworthy because very little research has investigated the impact of warning labels on pregnant women.

1996 – Alcohol consumption for pregnant women who have previously given birth versus those pregnant for the first time.

The examination of alcohol consumption for expectant mothers was the basis of a further study by Hankin, Firestone, Sloan, Ager, Sokol and Martier (1996b). Data from 17,456 African-American inner-city women seen at a prenatal clinic between September 1986 and September 1993 was examined. Self-reports of alcohol consumption during pregnancy confirmed that 81% of pregnant women abstained from alcohol. Of the 19% that reported drinking alcohol, 42% had not previously given birth and 58% had. Analysis of these results found that at conception women for whom this was not their first pregnancy reported greater consumption of alcohol than the pregnant women for whom this was their first pregnancy (0.34 oz. vs 0.17 oz) and similar results were obtained for alcohol consumption at their first antenatal visit (0.06 oz vs 0.02 oz). After the introduction of warning labels on alcohol beverages, alcohol consumption for first time mothers decreased, whereas for mothers who had previously given birth, the warning labels on alcohol beverages appeared to have no impact on their alcohol consumption during pregnancy.

These results suggest that women who previously had given birth and consumed alcohol during pregnancy with no apparent alcohol-related birth complications, may not change their drinking behaviour after exposure to warning labels. On the other hand, women who are pregnant with their first child may actually change their drinking behaviour as a precaution to minimise any alcohol-related health risks with their pregnancy. However, changes in drinking behaviour could not be attributed wholly to the introduction of warning labels on alcohol beverages as women also receive information from other sources and as no controls or measures allowed analysis of such impacts, it is impossible to account for any such possibilities.

1998 - Awareness of alcohol warning labels and alcohol consumption

Awareness of alcohol warning labels and their impact on alcohol consumption was examined in a study Hankin, Sloan and Sokol (1998) that analysed interviews from

21,127 inner city African-American pregnant women presenting at an outpatient clinic in Detroit, Michigan from 1987 to 1994. Over this period of time the percentage of pregnant women abstaining from consuming alcohol at the time of conception decreased from 48.5% to 37.3%. In 1987 the average daily amount of absolute alcohol consumed was 0.213 ounces and by 1994 this had increased to 0.397 ounces. Overall results suggested that whilst 82% of pregnant women reported abstaining from alcohol during pregnancy, 18% continued to consume alcohol during their pregnancy. Of the women who consumed alcohol, the average amount of alcohol consumed was 1.5 ounces per week.

The limitations of this study were similar to those found in earlier studies by Hankin et al. (1993; 1996a; 1996b). All participants were inner-city African-American pregnant women who attended a University clinic for their pregnancy, therefore the ability to generalise the results from this study to all pregnant women is inadvisable although, of course, they are relevant for a potentially high-risk group. In addition, whether the women reported seeing or recalling an alcohol health label was not controlled for as an independent variable. Subsequently, it is impossible to determine what specific impact, if any, alcohol warning labels had on the results. Another limitation of the study was that women were interviewed at very different stages of their pregnancy (26% interviewed in their first trimester, 47% in the second trimester and 27% in their third trimester). This may also have impacted upon recall of drinking and affected the results as it was not adequately controlled for in the analysis.

1998 - Awareness of alcohol warning labels and alcohol consumption

To examine the awareness of alcohol warning labels among women and the impact of this on alcohol consumption, Hankin (1998) analysed data from 1,107 women who participated in a 1995 Detroit Metropolitan Area Public Policy Survey (DMAPPS). During the interview, women were asked: “Have you seen any warning labels on bottles or cans of beer, wine, liquor or wine coolers during the past 12 months?” Women reporting they had seen the label were then asked about the actual message itself and were requested to identify whether they had seen 3 correct messages (birth defects, drink driving, or operating machinery) and 2 incorrect messages (arthritis and cancer). In the previous 12 months, 39% of participants reported seeing the warning

label on alcohol beverages. However, when women who had not consumed alcohol in the last 12 months were eliminated, this increased from 39 to 52%. As the frequency of the amount of drinks consumed per week increased, so did the reported exposure of the warning label. Of the 405 women who reported seeing the warning label, 77% recalled the warning about birth defects, 51% recalled the operating machinery message and over a third reported seeing the drink driving warning. In addition, of all the women who reported seeing the warning labels only 24% could correctly identify the three messages that did actually appear on the warning labels and the two messages that did not appear. Similar to an earlier study by Hankin et al. (1996a) older women were less likely to see the label and if they did report seeing the label were more likely not to recall the actual message of the warning. Women who did not consume alcohol frequently were more likely not to be able to recall seeing a warning label and, if they did, were more likely not to recall the message. This supports the idea that more exposure to the warning label by more frequent drinkers can result in more women seeing and recalling the message on the warning label.

Despite the limitations of the research (i.e one metropolitan area; no control group or site) the research does indicate that six years after the introduction of alcohol warning labels, 52% of women who drink alcohol recall seeing a warning label.

Summary

In the studies conducted by Hankin and colleagues, the evidence indicated that awareness of the warning labels on alcohol beverages has increased over time. Hankin's research also indicated that amongst the African-American women who participated in the research, those who have conceived before were less likely than first time mothers to reduce their alcohol consumption as a result of exposure to the warnings on alcohol beverage containers. Such findings are important, but should be interpreted with caution, because of the identified design limitations.

4. MacKinnon studies – 1993 to 2001

MacKinnon, Pentz and Stacy (1993) surveyed 1,211, 12th grade students in September (n=934) and October (n=277) 1989 and 2006, 12 grade students during October (n=1,160), November (n=698), December 1990 (n=79) and February 1991 (n=69).

The purpose of the study was to determine awareness of the alcohol labelling law, beliefs about and memory for the risks on the labels. Results indicated that exposure to the warning label increased from 26% in 1989 to 41% in 1990.

MacKinnon and Fenaughty (1993) investigated whether higher reported alcohol consumption of 243 U.S. college participants was associated with an increased ability to recall the content of the warning messages. Results found a significant correlation between alcohol consumption and the ability to identify the warning message on a label when presented with the various options, suggesting more exposure to the warning label can have an impact on the ability to process and recall the content of the message.

Limitations of the study were that alcohol consumption was self-reported and may be unreliable (Johnston and O'Malley 1985), the participants were college students and results may not generalise to other groups within the population, although are of course to a potentially high risk group, including young women. Participants were also given the warning messages and asked to circle which ones they recalled seeing. Requesting participants to recall contents of the warning label messages, without prompting, may be a better indicator of the participants' ability to recall the content of the message.

MacKinnon and Lappin (1998) investigated whether providing a warning on an alcohol advertisement may be perceived as having more benefits when compared to a product with no warnings present. In two U.S. studies, the first of which involved 164 undergraduate university students and the second 268 undergraduate university students, non-drinkers perceived greater risks associated with alcohol than drinkers and were also more likely to indicate they would avoid alcohol in the future to minimise alcohol-related harm. The inclusion of warnings had no significant effect on intentions regarding future consumption. The results did not support the notion that inclusion of warning labels can be counterproductive (referred to as the boomerang effect such that drinkers perceive alcohol as having more benefits when the warning is present).

Nohre, MacKinnon, Stacy and Pentz (1999) analysed results from 6,391 12th grade students in the state of Indiana (U.S.). In 1989, prior to the appearance of alcohol warning labels, 1,211 participants were interviewed. After the warnings appeared, 2,006 and 3,174 students were interviewed in 1990/1991 and in 1991/1992 respectively. The study was designed to measure the effect of receiver characteristics on alcohol warning labels. Awareness of the warning label and the legislation of providing warning labels on alcoholic beverages were found to be higher among participants from lower SES, those who had lower grades, those who drank more alcohol and may have therefore been exposed to more alcohol warning messages. More exposure to the warning messages was also found among those participants who drank directly from the container (e.g. bottle or can) as opposed to those drinking from glasses. Students who drank from the container had more accurate memory for the risks on the warning than students who poured the beverage into a glass. However, drinking directly from the alcohol container was unrelated to awareness of the alcohol labelling law and beliefs about the risks on the label. Limitations of this study were that there was no control group, no validation of self-reported behaviour and the students represented a relatively homogenous sample, being from one county area, thus reducing the external validity of the results.

MacKinnon, Nohre, Pentz and Stacy (2000) conducted cross-sectional surveys of 16,661 grade 10 and 15,856 grade 12 students during each school year from 1989/90 to 1995/95 in Marion County, Indiana. Students were asked whether or not they had seen warning labels on alcohol beverage cans or bottles. For both grades, there was significant pre-post effect of the warning label on awareness. This research had a large sample size and involved most high schools in Marion County. However, as there was no control site, a number of extraneous variables may have influenced the results. While the results may be generalisable to Marion County, the reader was not informed as to how residents in this local area compare to other state or national populations, but the authors did indicate that 52% of the sample reported their father's job as executive, business owner, professional or high-end salesperson indicating a relatively high Socio-Economic-Status.

MacKinnon, Nohre, Cheong, Stacy and Pentz (2001) conducted longitudinal surveys with 649 Marion County students during the 1989/90, 1990/91 and 1991/92 school

years to investigate the occurrence of an exposure effect, a deterrent effect, and a harmful effect (a positive relationship between early exposure and subsequent consumption and both exposure and deterrent effects operating at the same time). Results indicated the presence of an exposure effect. Cross-lagged correlations between the constructs of alcohol use and warning exposure indicated that earlier exposure to the alcohol warning did not significantly reduce alcohol consumption, suggesting that the warning had no deterrent effect. Nor was there any evidence that exposure lead to an increase in consumption, indicating no harmful effect of the warning. The authors concluded that the results of their study support the conclusion that alcohol warning labels do not reduce alcohol-related risk behaviours, but that

> *"there is evidence that the warning is informing the public about the possible consequences of alcohol consumption". (p. 226).*

Summary

MacKinnon and colleagues found a significant correlation between alcohol consumption and the ability to identify the warning message on a label. The authors also reported that students who drank from the container had more accurate memory for the risks on the warning than students who poured the beverage into a glass. However, drinking directly from the alcohol container was unrelated to awareness of the alcohol labelling law and beliefs about the risks on the label. Finally, MacKinnon and colleagues reported that while exposure to an alcohol warning message did not reduce consumption, nor did it appear to lead to an increase in consumption. Over time awareness and accurate recall of the information included in warning labels increased. As the populations in the above research consisted of school and college students, the large majority of females would have been of childbearing age and hence these results have some relevance to the present focus. However, as previously discussed there are a number of limitations that reduce the generalisability of the research by MacKinnon and colleagues. The primary limitation was that the various samples were all from one county in continental U.S. As no information was provided to indicate how representative this sample was of other young people across the U.S., the interpretation and generalisability results are limited. There were also no matched

controls making it difficult to separate the impact of warning labels from other influences.

5. Mazis et al. – 1991 to1996

To measure the impact of the alcohol warning label on consumers in the U.S., Mazis, Morris and Swasy (1991) conducted independent cross sectional telephone interviews with a national sample of 1,008 adults in May 1989 and 1,020 adults in May 1990 (pre- and post-introduction of mandatory labelling). Participants were asked questions to measure perception of the risks associated with alcohol and awareness of the alcohol warning message. Those respondents who indicated that alcohol beverages were very or somewhat likely to contain warning labels were asked what information was contained in the label, and asked to identify what, if any, potential hazards they associated with drinking alcohol. Demographic data and information on participants' alcohol use were also collected.

Over the 12-month period between interviews, there was no statistically significant shift in respondents' perception of the risks associated with alcohol (49.8% rated alcohol as very harmful in 1989 and 54.1% rated alcohol as very harmful in 1990). However when results were analysed by age, younger respondents (18-29 years) showed a greater increase from 1989 (47.1%) to 1990 (55.5%) in the proportion rating alcohol as very harmful.

In May 1989, 23.3% of respondents indicated that it was likely or very likely that alcoholic beverage containers included warning labels. By May 1990 this figure had increased significantly to 35.1%. There was also a significant age by year interaction, with label awareness increasing from 21.4% (1989) to 43.1% (1990) amongst the youngest age group. Interestingly, heavier drinkers (defined as consuming five or more drinks per two-week period) showed a significantly greater change in reported label awareness than lighter drinkers and the proportion of them describing alcohol as very harmful increased from 21% (1989) to 30% (1990). One limitation of the research by Mazis et al. (1991) was that there was no control site for comparison. While more difficult, it would have been useful to employ longitudinal rather than cross sectional methods as this would have allowed better inference of cause and

effect. While it was beyond the scope of the paper, investigation of impact on behaviour change would have been beneficial considering the relatively large sample size.

Mazis et al.- 1996

In a follow up study Mazis, Morris and Swasy (1996) reported on the results of a 5-year study which involved cross sectional surveys conducted from May 1989 to 1993. In excess of 1,000 respondents were interviewed each year from across the continental United States using a proportionate stratified sampling design and random-digit dialing. There was a statistically significant change in reported awareness of the alcoholic beverage warning label over the five year period ($x2$ 271.65, df=4, $p<0.0001$). In 1990, 35 % of the sample indicated that it was likely that alcohol contained a warning label. This increased to 55.0% in 1993. Similarly, there was an increase in recall of the alcohol and pregnancy message over time, with 12.0% indicating recall of the message in 1990 and over 26% doing so in 1993.

One limitation of the research was there was no matched control site. A major weakness was the response rate, which was less than 50%, indicating the potential for selection bias.

6. Marin et al. – 1997

Marin and Gamba (1997) conducted a longitudinal telephone survey with 777 Hispanics and 234 non-Hispanic participants residing in San Francisco, in 1991 and 1992. Both groups of participants showed an increase in awareness of alcohol warning labels from 1991 to 1992 on beer and wine containers. Amongst Hispanic people, awareness of the health warnings on beer bottles increased significantly from 29.0% to 33.0%, while among non-Hispanic people awareness rose from 29.4% to 44.7%. However, as there were limited controls applied to the research, either in design or analysis, and because the messages had been used in other education campaigns, it is not possible to isolate the specific impact of the specific labels.

In a separate study, Marin (1997) conducted a cross-sectional telephone survey with 4,661 randomly selected Hispanics aged between 21 and 65 years between 1989 and 1992. By 1992, 96.4% of the sample indicated that they were aware of the alcohol and pregnancy message. According to Marin, this represented a statistically significant effect for year of survey.

The value of the study is limited by the fact that no detail was included in the paper on the response/consent rate or how representative the sample was of the general Hispanic community, and the four cohorts appeared to differ on a number of demographic variables (e.g. length of time in U.S.; mean annual income).

Papers from individual studies

As noted earlier, most of following studies were not specific to alcohol and pregnancy. Some of the studies assessed the impact of alcohol and pregnancy warning labels, among others, while others addressed alcohol warning labels broadly, but with populations that would include women of childbearing age. In none of the reports do the methodologies allow partialling out of effects with such key groups or message differentiation. With these limitations in mind, the following section will briefly review the research from individual studies.

1. Scammon et al. – 1991

In a study conducted in Utah, which has one of the lowest rates of alcohol consumption in the U.S. and a significant Mormon population, Scammon, Mayer and Smith (1991) analysed data collected from a total of 2,417 participants (no breakdown was provided of the specific numbers interviewed pre- and post- the implementation of warning labels). Participants were categorised as devout or non-Mormons. The study found that 34.9% of non-Mormons and 11.1% of devout Mormons[2] were aware of the alcohol labels in 1990. There was no evidence that consumers' perceptions of alcohol-related risks increased over time. On the contrary, amongst participants the percentage of birth defects attributable to alcohol declined between the study periods (from an average of 29.3% pre-warning to an average of 26.0% post-warning). As the

[2] Devout Mormons are unlikely to drink alcohol as the consumption of alcohol may violate Mormon doctrine as described in the Word of Wisdom (http://www.utlm.org)

research had no control intervention and the subjects were not representative of the adult U.S. population they cannot be generalised beyond Utah.

2. Snyder and Blood- 1992

To investigate whether or not subjects would perceive an alcohol product as less beneficial and of greater risk when it is presented with a warning, Snyder and Blood (1992) recruited 159 communication science undergraduate students from the University of Connecticut in 1990.

Subjects (approximately 40) were assigned to each of one of four conditions. They were told that they would be shown slides of products to evaluate and then viewed six slides of different alcohol products (two beers, two liqueurs, two spirits). In the first condition, the six slides each depicted a bottle against a neutral background. The second condition used slides against a neutral background that included a warning message at the bottom of each slide. The third condition depicted each bottle in a magazine advertisement. In the fourth condition, the warning was added to the bottom of the advertisement. After viewing each slide for 15 seconds, subjects evaluated the risk and benefits of each product using the same series of 7-point semantic differential items. Results indicated that the warnings had no effect on the students' ratings of product risk, and mixed effects on benefits. For non-drinkers, their estimates of the benefits were lower when they were exposed to the warnings, but this was not statistically significant. For drinkers, the warnings "boomeranged" (sic) causing drinkers to rate the alcohol product as more beneficial. In addition, the warnings caused the male drinkers to have greater dinking intentions ($F(1,61) = 4.99$, $p = 0.03$ $r2 = 0.07$).

This research does have a number of limitations. The sample size was small and non-representative reducing the generalisability of the results. In addition, subjects who reported that they did not see the warning, all those aged over 22 and male non-drinkers were excluded from the analysis. The resulting confounding between gender and drinking status precluded using gender as a variable in the analyses. In addition, the research was conducted in April and then again in October of the same year, again with university students from the same course. It was therefore possible that the

second wave of students were aware of the study design and purpose. This could potentially bias data. Finally, the authors did not include the means and the statistical test of the contrasts for the cited "boomerang effect."

3. Malouff et al. – 1993

Malouff, Schutte, Wiener, Brancazio and Fish (1993) used four small independent studies to analyse the noticeability of warning labels on alcohol beverage containers and investigated what design elements might increase the conspicuousness of the labels. In the first study, 43 college students (no information was included on how the subjects were recruited into the research) were each provided with one of 11 randomly selected beer cans or bottles. Subjects were then asked how prominent or conspicuous they felt the warning was. Thirty- three (77%) of subjects indicated that in their opinion the warning was not prominent.

In the second study, with 50 college students who rated how conspicuous vertical versus horizontal labels were, 66% (n=33) indicated that the horizontal labels were more conspicuous and noticeable. However, as the labels were only applied to beer bottles, the sample was small and comprised of mainly females (74%, n=37) the results cannot be generalised to other beverages or populations.

The results were supported by another small study where 21 college students were presented with beer containers that included a horizontal warning and 23 students were presented with beer containers that included a vertical warning. Results indicated that 38% (n=8) of students in the horizontal condition were aware of the warning, whereas only one of the other 23 students in the vertical condition were aware of the warning. It is also important to note that these were relatively small samples, limiting interpretation and generalisability of results.

Finally, in the fourth study, with 75 patrons in a bar, the authors attempted to investigate whether or not those patrons who recalled the message drank less. While the authors did make this conclusion, there were significant limitations. Firstly, the number of drinks was not determined by self-report but rather by the researchers obtaining copies of patron's bills from the bar staff. The fact that not all patrons may

have purchased their own beverages (i.e. they may have been involved in "rounds or shouts") may have reduced the validity of results. In addition, as the subjects were apparently not informed that they were part of a research project nor gave permission to the researchers to access their bar bills, there are some ethical concerns with the research.

4. Parsons et al. 1994

A cross-sectional study by Parsons, Johnson and Barrett (1994) analysed results from a random sample (n=481) of homeless persons interviewed in shelters, soup kitchens, drop-in centres and single room occupancy hotels in Illinois, U.S. during October and November 1990. Overall, 41% of the sample indicated that they were aware of the warning labels. Of these, 21% could not recall any of the labels messages, while 43% cited one of the two messages on the label. Those aged 18-29 and those who scored 2 or more on an adapted version of the Shortened Michigan Alcohol Screening Instrument (SMAST[3]) were significantly aware of warning labels appearing on alcoholic beverage containers. However, of those aware of the warning labels, there was no significant difference amongst the sample in relation to knowledge of the content of the warning label message.

Because of the sample used, these results have very limited generalisability and direct relevance for pregnancy and alcohol use is unclear. In addition, the authors do not explain in detail how the SMAST was adapted for the purpose of the research reducing the internal validity of the research, making it difficult to ascertain the significance of the scoring system used.

5. DeCarlo et al.- 1997

DeCarlo, Parrott, Rody and Winsor (1997) interviewed 111 undergraduate college students and 39 adults (over the age of 30 years) about their perception of the effectiveness of several alcohol warnings (no detail was provided on the precise number of warnings each subject was asked to assess). Fifty-nine percent of the

[3] Selzer, Vinokur and van Rooijen (1975). SMAST is a 13 item questionnaire in which each affirmative answer is given a score of 1.

respondents reported that they read warning labels on products before buying them and 59% reported that they were aware of the warning labels on alcohol containers. In addition, 56% reported that they find warning labels to be informative and 36% viewed warning labels as the best method of informing the general public about dangers associated with alcohol consumption. There was no statistically significant relationship between the amount of alcohol consumed and perceptions of alcohol warning effectiveness.

The research has a number of limitations. As no detail was provided on the courses that the students were studying or how representative they were of the student population, this reduces the generalisability of the results. This limitation was further compounded by the inclusion of the adult convenience sample recruited from a council meeting and via personal solicitation. The only gender information that was provided was for the entire sample, and not for each group; no information was provided as to whether all respondents drank alcohol or whether some were non-drinkers; and assessment of alcohol consumption was based upon self-reported average consumption per week rather than the use of a psychometrically valid assessment tool.

6. Creyer et al. – 2002

Creyer, Kozup and Burton (2002) examined responses from 168 U.S. university students and 106 Australian university students on how two different alcohol beverage health warnings placed on a fictitious brand of beer would influence alcohol-related perceptions. One warning was the current U.S. warning and the second warning stated:

> ***"GOVERNMENT WARNING**: THIS PRODUCT CONTAINS ALCOHOL. ALCOHOL IS A DRUG."*

Students were asked five questions to measure perceptions of the social benefits of drinking beer and three questions to measure perceptions of the health benefits of drinking beer. Next measures of perceived risk associated with drinking beer were assessed and finally, students were asked to rate several hypothetical drinking

behaviours. Results indicated that the warning type had no significant effect on perception of the social or health benefits of alcohol, but did affect perceptions of risk and drinking behaviours. For example, the ALCOHOL IS A DRUG warning led to greater perceptions of the risk of drinking when pregnant and risk of a driving under the influence legal charge, in both countries. In addition, for binge drinkers, use of the standard U.S. warning resulted in lower risk perception than the ALCOHOL IS A DRUG warning in both countries. Considering the risks associated with binge drinking and trauma, these results are interesting and significant. The study was one of the few evaluations in which a control site was included. However, as the sample size was relatively small, only focussed on consumption of beer and only included undergraduate university students (no information was provided on which disciplines students were studying) it is difficult to generalise results to a wider population.

7. Blume and Resor – 2007

Blume and Resor (2007) conducted face–to-face interviews with a convenience sample of 99 Mexican American women to investigate their awareness of warning labels on alcohol beverage containers and the risks of drinking during pregnancy. Not surprisingly, the authors conclude that English language skills significantly predicted participants' ability to remember health warnings on beverage containers. As the sample was small, little information was included on the demographic characteristics, and no indication was given of the response rate, caution is required in interpretation and it is difficult to generalise results. In addition, the authors reported that 23 of the women were born in Mexico, but no information was provided on how long these women had been resident in the U.S. It is therefore possible that not only language, but length of time spent exposed to alcohol warning labels, may have variously influenced results.

6.2 A brief examination of review papers on the effectiveness of alcohol labelling

Over the past fifteen years in excess of forty review papers have been published on the effectiveness of alcohol warning labels (see Appendix 4). Only the most recent of

these, (Stockwell 2006; Anderson (DHS) 2008; Wilkinson and Room 2008a; 2008b) have included the majority of available research**.**

Similar conclusions were reached by the majority of reviews, although of course variations occurred as new evidence emerged. The more recent reviews have reached similar conclusions to those reached in the current report: that the evidence regarding alcohol warning labels is limited and does not allow bold conclusions about impact. The recent reviews, (Anderson (DHS) 2008; Stockwell 2006; Wilkinson and Room 2008a; 2008b) concluded that there was little evidence that indicated that alcohol warning labels changed behaviour. Stockwell (2006) neither explicitly rejected nor argued strongly for the introduction of alcohol warning labels. Instead, he concluded that:

> "*It is likely, therefore, that a high proportion of the population may benefit from being reminded of the health and safety risks of alcohol consumption*." (p.8).

Wilkinson and Room (2008a; 2008b) and Anderson (DHS, 2008) separately agreed that as part of a multifaceted comprehensive strategy warning labels were warranted. For example, Wilkinson and Room concluded that:

> *"…adding warning labels to alcohol containers has a longer term social utility in helping to establish social understanding that alcohol is a special and hazardous commodity*." (Wilkinson and Room 2008a, p.19).

6.3 The role of warning labels in preventing and responding to alcohol related harms during pregnancy and breastfeeding – a summary

As noted earlier, many of the reviewed reports did not assess pregnancy related warning labels in isolation, and/or had an indirect relevance (e.g. assessed impact on young women). The following section aims to provide a brief summary of the

implications of the detailed review for the alcohol related risks during pregnancy and in relation to breastfeeding.

Research indicates that warnings about the risks of alcohol and potential birth defects are believable (Andrews, Netemeyer and Durvasula 1990). Research also indicates that people who recalled seeing a warning label were more likely (58 % versus 45 %) to report having a conversation about alcohol and pregnancy (Kaskutas and Greenfield, 1992). Of those people who did report seeing a warning label, the majority (up to 78%) recalled the birth defects message (Kaskutas and Greenfield 1997). Recall of this message was even higher (89%) amongst those who might be perceived to be a key target group, respondents 40 years and younger (Kaskutas and Greenfield 1997).

Over time, the proportions of samples who could recall seeing a warning label on the risk of alcohol and pregnancy increased. For example, Greenfield and Kaskutas (1998) reported that in 1990, 21% of participants recalled seeing the warning labels containing messages about alcohol and pregnancy. In 1994, this figure increased to 51%. Further analysis of data revealed that by 1994, 56% of female participants aged between 18 and 40 correctly recalled the pregnancy warning. Increased awareness of the warning labels over time was a common feature in the available research (e.g. Marin and Gamba 1997; Mazis, Morris and Swasy 1991) indicating that assessment of impact should include this “cumulative effect” of continued exposure.

The work of Hankin et al. (1993; 1996a; 1996b; 1998) which specifically investigated the impact of alcohol warning labels on the awareness and behaviour of pregnant women is particularly important. In all of the studies conducted by Hankin and colleagues, the evidence indicated that awareness of warning labels on alcohol beverages increased over time. It is also pertinent to note the impact on key target groups. For example, at-risk drinkers reported the greatest awareness of the labels and the majority of pregnant women who reported seeing a label could recall the warning about birth defects.

In relation to the impact on alcohol consumption, research by Greenfield and Kaskutas (1998) indicated that there was no effect observed between label exposure and consumption among women who were pregnant. However, the research by

Hankin et al, indicated that warning labels had a differential effect on at-risk drinkers (women consuming at least 0.5 ounces of absolute alcohol per day at conception) and lighter drinkers/abstainers (women consuming less than 0.5 ounces of absolute alcohol per day at conception): six months after the introduction of the warning label legislation, lighter drinkers decreased their drinking during pregnancy by a small but statistically significant amount. In contrast, pregnant at-risk drinkers did not significantly change their alcohol consumption.

The research by Hankin et al. also indicated that warning labels had a differential effect on nulliparae versus multiparae women. At conception, women for whom this was not their first pregnancy reported greater consumption of alcohol than the pregnant women for whom this was their first pregnancy. After the introduction of the warning labels, alcohol consumption for first time mothers decreased, whereas for mothers who had previously given birth the warning labels appeared to have no impact on their alcohol consumption during pregnancy.

These results suggest that women who previously had given birth and consumed alcohol during pregnancy, with no apparent alcohol-related birth complications, may not change their drinking behaviour as a result of health warnings on alcohol beverages. On the other hand, women who are pregnant with their first child may actually change their drinking behaviour as a precaution to minimise any alcohol-related health risks. This conclusion is supported by what we know about "teachable moments" (McBride et al. 2003). As discussed earlier, whether a cueing event (e.g. warning label) has an impact will depend, at least in part, on whether the event increases perception of personal risk and outcome expectancies, prompts strong responses and finally redefines an individual's concept of self. Prior experience of drinking during pregnancy without observed adverse outcomes may reduce the perception of risk that might otherwise be raised by a warning label.

The study designs do not allow us to determine to what extent the changes in drinking behaviour could be attributed to the introduction of warning labels on alcohol beverages, as women also receive information and advice about the risks of alcohol during pregnancy from other sources.

In summary, there is evidence to support the conclusion that warning labels that include information about the risks of alcohol and pregnancy are not only noticed by women, and in particular by women of childbearing age, but the information is also recalled by the majority of women who report seeing a label. Although some research (Hankin et al. 1993-1998) has suggested that some women, those who are light drinkers and first time mothers, may reduce their consumption following exposure to alcohol warning labels, the limitations inherent in the design of these research studies preclude conclusions and generalisations to the Australian and New Zealand context. As none of the identified research examined the impact of alcohol warning labels on breastfeeding, it is not possible to determine what impact alcohol warning labels may have on a woman's intentions or behaviour regarding alcohol and breastfeeding. There is a limited amount of evidence that supports the efficacy of warning labels to reduce alcohol consumption amongst pregnant women. As indicated earlier, it is relevant to note that pre-conception and pregnancy represent a window of opportunity or teachable moment in which interventions are more likely to prompt behaviour change (McBride et al. 2003). However, it has also been argued that most impact may occur if combined or multifaceted approaches are used to reduce risky alcohol use during pregnancy.

Chapter 7: Summary of literature on effectiveness of alcohol warning labels

This chapter will critique the body of available literature against those criteria described by Argo and Main (2004). These criteria for assessing the effectiveness of warning labels are:

1. **Attention** (whether or not a consumer is aware of the presence of the warning);
2. **Reading and comprehension** (after a consumer notices a warning do they read and understand its content);
3. **Recall** (whether or not a consumer can remember the information included in the warning);
4. **Judgements** (does the message impact on a consumer's beliefs); and
5. **Behavioural compliance** (whether or not a consumer will refrain from unsafe behaviour or engage in safe behaviour).

7.1 Effectiveness of alcohol warning labels

Attention

Despite concerns that the warning labels used in the U.S. are not very noticeable (Laughery, Young, Vaubel and Brelsford 1993), there is a reasonable body of evidence to suggest that people are able to recall their presence. For example, evidence from Kaskutas and Greenfield (1992) indicated that within six months of the introduction of warning labels in the U.S., over 20% of respondents reported having seen the label. When assessed across age categories, approximately one third of those aged 18-29 years of age had seen the label, about a quarter of those aged 30-39, a fifth of those aged 40-59 and approximately a tenth of those aged 60 years and older. With regard to drinking categories, 39% of heavy drinkers and about a quarter of other drinkers and a tenth of abstainers also reported seeing the warning message on alcohol beverage containers. By 1994, the proportion of respondents who indicated that they had seen a warning label had increased to over 51% (Greenfield

and Kaskutas 1998). Additionally, research indicated that continued exposure to alcohol warning labels increased awareness of the risks of alcohol use during pregnancy. For example, Greenfield and Kaskustas (1998) reported that while in 1990 only 21% of participants recalled seeing warning labels containing messages about alcohol and pregnancy, this figure increased to 51% in 1994. Further analysis of data revealed that by 1994, 56% of female participants aged between 18 and 40 correctly recalled the pregnancy warning.

In other research by Mazis et al. (1996) results from a 5 year study indicated there was an increase in recall of the alcohol and pregnancy message over time, with 12.0% indicating recall of the message in 1990 and over 26% doing so in 1993.

Reading and comprehension

None of the reviewed research papers on alcohol warning labels examined whether or not respondents were able to understand the information included in the warning message. However, research by Blume and Resor (2007) with a sample of Mexican-American women, did indicate that English language skills was a significant predictor of participants ability to remember the warning messages. In addition, research from the tobacco field suggests that no matter how clear and simple the written message is, pictorial messages are superior (Hammond et al. 2007). Research from the United States has found that written warnings on cigarette packaging may require college-level education to understand (Malouff et al. 1992). This significantly reduces their usefulness with young people, less educated people, and people with poorer reading skills. International evidence suggests that there exist fewer differences in health knowledge across educational levels in those countries with pictorial tobacco health warnings than those countries with text only (Siahpush et al. 2006). While research is required that assesses the reading level required to comprehend existing alcohol warnings, the experience from the tobacco field does suggest that this will be an important factor in explaining impact.

Recall

Research by Greenfield and Kaskutas (1998) indicated that 57.6% of 18-20 year olds who reported that they had seen an alcohol warning label could recall the drink driving message, this figure was 40.4% for 21-29 year olds, 32.4% for 30-40 year olds and 16.4% for those over 40 years of age. Similarly, of those who reported having seen a warning label, 70.4% of people aged 18-20 reported that they could recall the pregnancy message, this figure fell to 69.9% for those aged 21-29, and 63.6% for those aged 30-40 and 32.8% for those over 40 years of age. Research by a number of other authors (Graves 1993; Hankin et al. 1998) also indicated that a significant proportion of people who had seen a warning label could recall the warning message. This was particularly the case with the alcohol and pregnancy message. For example, in his research with women in Detroit, Hankin et al. (1998) reported that 77% of women who had seen a warning label knew that it mentioned birth defects. Additionally, when compared to those who said they had not seen any warning label, poster or advertisement about the risk of alcohol during pregnancy, those reporting a single exposure to any warning message/source were twice as likely to say they had a conversation about drinking during pregnancy.

Greenfield, Graves and Kaskutas (1999) described some evidence that supported the conclusion that warning labels were having a real impact on recall of messages. Comparing the U.S. (where there were mandated warning labels) with Canada (where there was no such mandate) indicated that in 1990, 30% of the U.S. respondents reported seeing warning labels on alcohol beverages, increasing to 43% of respondents in 1994. This compared to 16% of Canadian participants in 1990 decreasing to 12% in 1994.

Of course, one implicit threat to these studies is that demand characteristics may encourage respondents to affirm that they had seen messages, when in fact they had not. Greenfield and colleagues (1999) explored this possibility. Respondents were asked about exposure to five warning statements. Three of these were actually included in U.S. warning labels: birth defects; drinking and driving; operating machinery. Two were not included in the warning labels, which respectively focussed on cancer and arthritis. Respondents were asked to indicate which messages they

recalled seeing on the alcohol warning labels. For the U.S., over four years of study, results were fairly consistent each year with approximately 80% of participants reporting that the warning labels mentioned birth defects, about 46% mentioned drinking and driving and about 56% mentioned operating machinery. For the two incorrect messages, approximately 17% of U.S. participants incorrectly reported that the warning labels mentioned cancer and about 3 % reported that the labels mentioned arthritis. In comparison, about 42% of Canadian participants reported that the warning labels mentioned birth defects, 65% reported drinking and driving and 42% reported operating machinery. The results suggested that there is some confidence in the initial findings about recall, with a small proportion of "false positives."

Judgements

Research on the impact of warning messages on judgements is equivocal. For example, in research by Mazis et al. (1991), 50% of the 1,020 adults who were interviewed described alcoholic beverages as very harmful in 1989. This increased to 54% of the sample in 1990. Among heavy drinkers (those consuming more than 5 or more drinks per 2 week period) 21% described alcoholic beverages as "very harmful" in 1989, with the figure increasing to 30% in 1990.

Additionally, Kaskutas and Graves (1994) reported that individuals exposed to an alcohol warning label, poster or advertisement that included information about the risks of alcohol during pregnancy were more aware of the risks of birth defects associated with drinking than those who had not seen any of the aforementioned warnings.

Conversely, Creyer and colleagues (2002) examined responses from 168 U.S. university students and 106 Australian university students on how two different alcohol beverage health warnings placed on a fictitious brand of beer would influence perceptions of alcohol-related risk. Significantly less risk was associated with drink driving among those respondents who had been identified as engaging in heavy episodic drinking. In particular, although warning labels advising on the risks of drinking and driving have been on U.S. alcohol beverages for over a decade, U.S. heavy drinkers perceived less risk from such alcohol-related harm when compared to

Australian participants and those who were not identified as heavy episodic drinkers. Of course, interpretation of these findings is problematic, because there was no control of other factors. For example, drink driving countermeasures vary between the countries and these may have a significant bearing on the findings. A consistent problem with the available research has been the inability to disaggregate the effects of other strategies from warning label impact.

Behavioural compliance

It is on this criteria that the evidence base is very limited. There is some evidence that the introduction of alcohol warning labels:

- Lead to a reported increase in the likelihood of respondents having a conversation about the risks of alcohol (Kaskutas and Greenfield 1992);
- Prompted pregnant women to discuss the topic (Kaskutas et al. 1998); and;
- The greater number of warning types that respondents were exposed to the more likely they were to discuss alcohol associated risks (Kaskutas and Graves 1994).

However, there was very limited support for other behavioural change.

The research by Kaskutas and Graves (1994) is noteworthy as it highlighted the cumulative effect that multiple message sources may have on behaviour change. These data indicated that while exposure to one message source (no distinction was made between the efficacy of different sources) did not result in any significant behaviour change, exposure to two and three different message sources (warning label, poster, advertisement) did lead to a significant reduction in alcohol consumption due to health concerns. Amongst women aged 18 to 40 it was only amongst those seeing all three message types that a reduction in consumption was observed (odds ratio=2.8). That is, single message sources had no significant impact on behaviour, but exposure to two or more message sources was associated with a reduction in adult alcohol consumption.

Finally, based upon longitudinal research with 649 University students MacKinnon et al. (2001) concluded that while exposure to the alcohol warning did not significantly

reduce alcohol consumption, nor was there any evidence that exposure lead to an increase in consumption; therefore indicating no harmful effect of the warning.

Conversely, research by Hankin et al. (1993) did demonstrate behaviour change in which exposure to the warning message lead to a reduction in alcohol consumption amongst pregnant women who were light drinkers, and pregnant for the first time (Hankin et al. 1996).

Summary

In summary, the majority of research that has assessed the impact of alcohol warning labels indicates that the approach has had a limited impact on drinking and risk behaviour. That the majority of observed effects have been modest should however not be surprising considering that the follow up in most research has been short term (6 months or less). As argued by Kaskutas and Greenfield (1992) and Graves (1993) such a brief period of time may not be sufficient for individuals to act on the information contained in the label. Additionally, if the key criterion for success of warning labels is about shifting the cultural place of alcohol in a society, then short - term evaluations will inevitably be insufficient and disappoint (Wilkinson and Room 2008a). On the other hand, models of health communication suggest that we should expect that (well designed) health communication will be noticed and will inform individuals of risk – which is a legitimate goal in itself. The same models, and available research, indicate that we would less likely detect changes in behaviour, unless warning labels are coupled with other approaches. As many women may initially not be aware they are pregnant, and hence not notice or pay attention to pregnancy specific warnings, other, complementary, strategies may also be necessary to reduce the incidence of fetal alcohol exposure.

A major problem in advancing theory, and in reaching definitive conclusions about impact, is as indicated throughout the discussion, that there are limitations in the existing research, and research gaps, and it is to these we now turn.

7.2 Limitations and gaps in the existing research

As previously mentioned, despite the fact that over twenty countries have now implemented legislation that requires that all imported and domestically produced alcohol is to include a warning label, limited research has assessed the impact of this strategy. Of the research that has been conducted, researchers from the U.S. have dominated outputs. Apart from a few well designed and controlled studies, much of the effort has been constrained by relatively small samples with non-representative populations. Amongst those studies that have been well designed, most have relied on self-report with no confirmation of the reliability and validity of these measures.

These limitations have significant implications on the internal and external validity of the research and restrict the generalisability of findings. More international research is required to determine how the U.S. studies are applicable to other nations. More research that includes adequate control, in design and analysis, is also required so that the impact of warning labels can be assessed with some confidence, independent of other potentially confounding extraneous variables. In those countries that may be considering the introduction of alcohol warning labels, comprehensive baseline and post intervention data are required. As research to date has relied on self-report, it is also important that future research includes reliable and valid measures of alcohol consumption and alcohol sales data and data on alcohol related risk behaviours. Such research would also require the sophistication to adequately control for or account for the impact of other factors such as price fluctuations, advertising and other promotion controls, policy changes and other preventive activity.

At present it is not possible to compare the impact of voluntary and mandated alcohol warning labels, but most countries that have adopted warning labels have mandated such developments, an approach consistent with public health responses to tobacco. The lesson from the tobacco field is that there was significant tension between public health advocates, government and industry surrounding the introduction of tobacco warnings (see Scollo and Winstanley 2008; Chapman and Carter 2003). It is likely that such tensions will emerge in any consideration of alcohol warning labels, especially in the light of the current status of the evidence base.

Unfortunately, no research was identified that examined what potential effects alcohol warning labels may have on beverage preferences and substitution effects with other drugs; nor how alcohol warning labels may have impact in hotels, nightclubs and other licensed premises where bottled alcohol might not be served, or does not form a significant part of sales. The only identified relevant research was by Nohre et al. (1999) who reported that whether students regularly drank from an alcohol container (hence more exposure to the warning) as opposed to those who poured the beverage into a glass, was unrelated to awareness of the alcohol labelling law and beliefs about the risk on the label. Students who did drink from the alcohol container had more accurate memory for the risks on the warning. This research highlights the need for further investigation of how method of consumption may mediate the influence and impact of warning labels. There has been research from the tobacco field that indicates that avoidance of warnings may not necessarily be a negative outcome but may be predictive of making an attempt to quit (Borland et al. as cited by Scollo 2008).

While research by Snyder and Blood (1992) indicated the possibility that warning labels may have some negative consequences, later research by MacKinnon and Lapin (1998) and MacKinnon et al. (2001) did not find any evidence of a potential "boomerang" or harmful effect after exposure to an alcohol warning label. Nonetheless, the issue of unintended adverse outcomes has not been well investigated, particularly in relation to pregnancy and breastfeeding. Recent American research (Bui, Burton, Howlett and Kozup 2008) with a sample of 230 university students indicated that including serving facts information (calorie, nutrient and alcohol content) on alcohol beverage containers significantly decreased calorie and carbohydrate evaluations of wine and increased consumption intentions and for distilled spirits, it reduced perceived fat and carbohydrate levels and also increased future consumption intentions. Results of this study are indicative of the need for further consideration of the issue of potential unintended consequences.

There are also some limitations of the pregnancy and alcohol warning label research (these should be seen in the context of the overall limited available evidence on the effectiveness of most strategies to reduce FASD) and how to deal with the complex

issue of alcohol use and breastfeeding. This suggests the need for caution, particularly because of the lack of knowledge about unintended outcomes of any strategy, including warning labels.

7.3 Conclusion

Current policy discussion and initiatives in both New Zealand and Australia are focussing on the risks associated with alcohol during pregnancy. Both countries have recently moved to more conservative recommendations regarding alcohol and pregnancy. In the U.S. the risks associated with alcohol and pregnancy are recognised as a priority and form the basis for the first of two warning messages that appear on all domestic and imported alcohol. There is some evidence that suggests that such warning labels result in increases in recall of the messages about risks associated with alcohol use in pregnancy, an increase in conversations on the topic and that more frequent drinkers are more exposed to alcohol warning labels. However, there remains no substantial body of evidence that supports a bold conclusion that alcohol warning labels have an impact on consumption levels and/or on the incidence of alcohol exposure in utero, or on the prevalence of FAS or FASD.

In addition, there was no research located that investigated whether exposure to the alcohol warning labels lead to any adverse outcome amongst pregnant women. For example, did exposure to a warning label on the risks of alcohol during pregnancy lead to an increase in anxiety or an increase in terminations amongst those pregnant women who had consumed alcohol.

Research from other countries, particularly those that may/have introduced pictorial messages warnings of the risk of alcohol during pregnancy, (e.g. France) would be of use to compare to results from the US (where warnings are text only). We speculate that this may be valuable given the research by Blume and Resor (2007) that indicated that English skills may be associated with awareness of the warning labels and research from the tobacco area that has indicated that pictorial images have a greater impact than text based warnings.

As no literature was identified that addressed the impact of warning labels on breastfeeding, it is not possible to identify the merits of the approach in this domain. However, as we have noted, this is likely to be a challenging area in which to rely on alcohol warning labels because of the tensions between encouraging women to breast-feed and the potential risks to a breastfed infant when a mother has been drinking.

In short, consistent with other reviews, we conclude that the existing evidence does not allow bold conclusions about the value of warning labels, in particular with reference to the impact on behaviour. In frustration, some public health advocates will point to the evidence about the importance and impact of tobacco warning labels and be perplexed by the lack of supporting evidence from research investigating the impact of alcohol warnings. It is relevant to note that in design, impact, prominence, and integration with broader based substantial campaigns, alcohol warning labels are more modest than tobacco warnings and this ***may*** be a factor in the lack of supporting evidence. It is also relevant to note that some have argued that even in the absence of strong evidence about impact, consumers have a right to be able to access quality information about risks, and providing that information in close proximity to consumption is reasonable.

It is observed that investigation of potential unintended adverse outcomes of alcohol warning labels was not a feature of many evaluations. In particular, any adverse impact such an increase in anxiety amongst pregnant women who have consumed alcohol, an increase in precipitous decisions to terminate a pregnancy (Commonwealth of Australia, 2006a) and ceasing breastfeeding prematurely have not been examined. Similarly, the costs, to governments, community and the alcohol industry that would be associated with the implementation of alcohol warning labels have not been clearly addressed in evaluations. These are important omissions, and future endeavour should address these shortcomings.

Finally, while not identified in any detail in the relevant literature, it is important to recognise that warning labels will not always result in message exposure to all those at risk. For example, people who regularly drink in clubs, bars, restaurants and hotels may not be highly exposed to information on an alcohol container, indicating the

possible need to include other strategies if alcohol warning labels are embraced as a strategy or a component of a broader harm reduction approach.

7.4 Estimates of possible changes in outcomes

One of the objectives of the review was:

> To provide estimates of possible changes in outcomes which may be used to measure the effectiveness of labelling in Australia and New Zealand if warning labels on packaged alcohol were introduced, drawing on domestic and international experience of alcoholic beverage labelling and comparable public health initiatives, within the context of the Australian National Alcohol Strategy and New Zealand National Drug Policy.

As indicated, the paucity and quality of the research limits the ability to which such estimates can be made. The tobacco experience indicates that warning labels, at least for this product, can have impact, when part of a broader strategy. This latter research also indicates that particular types of warning labels are more effective than others. However, we should be cautious in assuming that this experience can simply be generalised to alcohol. There is not sufficient evidence to make such an assumption.

Nevertheless, the available evidence does allow us to make some tentative estimates. These estimates are drawn from the literature review, being based on the higher quality and more consistent research findings regarding alcohol warning labels.

The available evidence allows only tentative suggestions about the potential impact in New Zealand and Australia of adopting alcohol warning labels that specifically target the risks associated with pregnancy. Based upon the available literature for a range of population groups, much of which has been conducted in the US, not Australia or New Zealand, and not specifically with pregnant women:

- Within a two- to three-year period, the majority of women drinkers will have noticed the warnings;

- Younger women and heavier drinkers may be more likely to notice the warnings;
- Of those people who notice the labels, approximately 50% will be able to recall the message (this will vary depending on the content of the message);
- There is likely to be an increase in the number of conversations that people will engage in on the message topics;
- It is less clear whether any behaviour change will occur. However, it is possible that:
    - If labels are complemented by point of sale, posters and other message sources, people ***may*** report a reduction in the consumption or their intentions to drink during pregnancy;

It is unclear what unintended adverse outcomes may arise. It is not possible to estimate costs or the cost-effectiveness/efficiency of the approach because such information was not provided in the research reviewed. It is important to note that these suggestions are based on evidence of the effects of U.S. warning labels, which were small text based messages that were not clearly linked (in the research reports) to other strategies.

Chapter 8: Tobacco warning labels - lessons for alcohol?

Before concluding the review of alcohol warning label research, it is worthwhile considering the impact of tobacco warning labels. It is noted that alcohol and tobacco differ in a number of respects. For example, no level of tobacco consumption is considered low risk, and the aim of public health strategies is to encourage people not to commence smoking at all or to quit if they do. This is distinguished from messages of moderation included in most countries' alcohol policies and the policies and strategies adopted in New Zealand and Australia. In the following discussion, we do not aim to equate alcohol with tobacco, nor intend to suggest it necessarily demands the same public health strategies. On the other hand, responses to tobacco have involved multifaceted public health approaches, including a substantial focus on product labels, probably more than most other products, and we explore tobacco warning labels to examine if there are any lessons worth considering in relation to alcohol.

In 1973, Australian legislation enabling a health warning to appear on cigarette packages was introduced (Australian Government Attorney Generals Department 2008). One year later, similar legislation was passed in New Zealand (Smokefree Coalition 2008). Initial tobacco labelling in Australia involved just one health message: 'Warning—Smoking is a health hazard'. In 1985, the number of health warnings increased to four and warnings also began appearing on print advertisements and billboards (Scollo and Winstanley 2008). In 1987, in New Zealand new, varied and stronger health warnings linking smoking to heart and lung disease began to appear on the front and back of cigarette packets.

In 1995, the number of health warnings in Australia increased to six (Scollo and Winstanley 2008). Legislation required that the warning label had to be printed in black on a white background, within a black border. On each pack of cigarettes, the warning message had to cover at least 25% of the area of the face on which it was printed and the explanatory message at least 33.3% (Scollo and Winstanley 2008). Warnings had to be positioned at the top edge of the pack faces (Scollo and Winstanley 2008). Research indicated that these new warnings were effective in

improving knowledge and understanding and in eliciting responses that were predictive of quitting (Borland 1997; Borland and Hill 1997).

Research commissioned by the Commonwealth Department of Health and Ageing in 2000, indicated that consumers agreed that warning labels needed to be upgraded more frequently, should be more specific and should be more prominent on packaging (Elliot and Shanahan Research 2000).

The Technical Advisory Group assisting the Australian Commonwealth recommended that new warnings should cover 50% of both front and rear pack faces. This proposal went to public comment, and was subsequently modified to cover only 30% of the front and 90% of the back. New regulations were passed in 2004 (Trade practices (Consumer product information standards)(tobacco) Regulations 2004) and applied to all tobacco products imported into or manufactured in Australia after 1 March 2006 (Scollo and Winstanley 2008). As part of these regulations, graphic images had to be shown with each warning message (Trade practices (Consumer product information standards) (tobacco) Regulations 2004, Part 3, Regulation 17).

In 2008, New Zealand also legislated for the introduction of picture-based warnings on tobacco (Ministry of Health 2008a). Prior to the introduction of graphic warnings, New Zealand had six different text warnings that featured on tobacco packages. These were: smoking causes lung cancer, smoking is addictive, smoking kills, smoking causes heart disease, smoking when pregnant harms your baby and your smoking can harm others.

In November 2006, the New Zealand government announced that by February 27 2008, all cigarettes sold in that country must have one of 14 warnings covering 90% of the back of the package and 30% of the front. Legislation dictated that the warnings must appear in both English and Maori languages. The graphic health warnings were also required on cigars. From 28 February 2008, seven graphic warnings appeared on cigarette packets in both English and te reo Māori and from March 2009 a further seven warnings will be introduced, which will then be rotated each year thereafter (Ministry of Health 2008a).

Cigarette packets in New Zealand will also display the Quitline free phone number and other information about quitting smoking. The government also revised its toxic constituent labelling for the side panel of cigarette packages (Ministry of Health 2008a).

For examples of the warning labels used in Australia and New Zealand, see Figures 16 to 19 below (Electronic access details for each figure can be found in Appendix 2).

Figure 16. Initial warning label on tobacco in Australia, 1973

Figure 17. Warning labels on Australian cigarette packages from 1994 to 2005

Figure 18. Examples of warning labels on cigarette packaging in Australia from 2006

Figure 19. Three examples of health warning labels (front and back) from New Zealand cigarette packets as at February 2008

Chapter 9: Evidence on the effectiveness of tobacco health warnings

Warning labels on tobacco products have an effect on smokers' understanding of the risks of tobacco use and on their reported consumption levels (Hammond, Fong, Borland, Cummings, McNeill and Driezen 2007). Canadian and Australian research has found that tobacco warning labels represent an important source of health information (Tandemar Research Inc 1996; Borland 1997). Research by Hammond, Fong, McNeill, Borland and Cummings 2006 using nationally representative samples of adult smokers from the U.S., the U.K., Canada and Australia indicated that cigarette packages were a prominent source of health information. For example, 84% of Canadian, 69.3% of Australian, 56.1% of UK, and 46.7% of US respondents agreed that cigarette packages were of a source of health information. Smokers have also reported that warning labels have prompted them to reduce their consumption levels, increase their likelihood of quitting, increase their motivation to quit and increase the likelihood of remaining abstinent following an attempt to quit (Hammond, McDonald, Fong and Cameron 2004a; Hammond, Fong, McDonald, Brown and Cameron 2004b; Hammond et al. 2006; Hammond et al. 2007; O'Hegarty, Pederson, Yenokyan, Nelson and Wortley 2007; Willemsen 2005; Hill 1988).

In the Netherlands, placement of the national Quitline number on tobacco packs with text-based warnings led to a 3.5 fold increase in the number of calls, (Willemsen, Simons and Zeeman 2002) and calls to the Quitline in Australia also increased after the introduction of improved consumer product information in 2006 (Cancer Council of Victoria 2007). As in Australia and New Zealand, laws requiring picture-based warnings on cigarette packages have now been finalised in Belgium, Brazil, Canada, Chile, India, Jordan, Singapore, Thailand, Uruguay and Venezuela (Australian Government Preventative Health Taskforce 2008). The EU directive for tobacco warning labels mandates that the general warning must cover at least 30 % of the external area of the surface of the packets (Hammond et al. 2007).

9.1 Elements of effective tobacco labels

Evidence from both New Zealand, Australia and elsewhere indicates that the content, style and presentation of tobacco warnings can markedly affect how noticeable and

memorable warnings are, and also influence the extent to which consumers understand, believe and feel empowered to act upon the information they contain (Scollo and Winstanley 2008). Evidence drawn from social psychology (Strahan, White, Fong, Fabrigar, Zanna and Cameron 2002) indicates that tobacco warnings are most effective when they:

- Promote negative attitudes to smoking, while also promoting positive attitudes to quitting;
- Combine strong fear appeals with information about how risk can be avoided;
- Convey a sense of the negative social as well as negative health consequences;
- Focus on the relevant attitudes of the target groups;
- Increase perceived self-efficacy;
- Promote discussion about smoking among smokers friends and family; and,
- Confront self-exempting beliefs (Scollo and Winstanley 2008).

There is also now a considerable body of research that indicates what form and style of tobacco warning labels is the most effective. Based upon this research it is evident that:

- **Obscure text warnings appear to have little impact**. The evidence indicates that messages that depict health risks in a vivid and emotionally arousing manner, in clear simple language (Createc and Market Studies 2003) and are frequently rotated have the greatest impact (Strahan et al. 2002; Witte and Allen 2000). Australian research shows that the peak levels of response to warnings is in the period immediately after their introduction (Borland and Hill 1997);
- **Pictures are more effective than text.** There is a growing body of evidence that suggest that no matter how clear and simple the written message is, pictorial messages are superior (Hammond et al. 2007). Analysis of warnings on cigarette packaging in the United States indicates that comprehending the messages requires college-level education (Malouff, Gabrilowitz and Schutte 1992). This significantly reduces their usefulness with young people, less educated people, and people with poorer reading skills. International evidence suggests that there exist fewer differences in health knowledge across

educational levels in those countries with pictorial tobacco health warnings than those countries with text only (Siahpush, McNeill, Hammond and Fong 2006). In addition, picture based warnings have been rated as more effective than text only warnings as a deterrent for new smokers and as a means of increasing cessation among existing smokers (Liefeld 1999; O'Hegarty, Pederson, Nelson, Mowery, Gable and Wortley 2006);

- **The bigger the warning label the better**. Smokers are more likely to recall larger warnings, with bigger warnings associated with greater appreciation and acceptance of risk (Centre for Behavioural Research in Cancer 1992; Environics Research Group Ltd. 2005; Cragg and Dawson Ltd. 1990; Strahan et al. 2002; Createc 2008). Evidence also indicates that warnings in boxed sections are more effective (AGB Spectrum Research Ltd. 1987). Research recently undertaken for the Canadian Government found that health warnings occupying 75% of the pack were more effective than warnings occupying 50% of the pack in conveying information about the health risks of smoking (Createc 2008). Research (Health Canada 2005; AGB Spectrum Research Ltd. 1987; Strahan et al. 2002) has also demonstrated that not only are smokers are more likely to recall larger warnings, they also equate the size of the warning with the level of risk. Research from Canada indicated that smokers judged those warnings that covered 80% of the package as most effective (Environics Research Group Ltd 1999); and,
- **Put warning labels on the front of tobacco packaging.** Evidence indicates that smokers will have better recall of warning labels that appear on the front, rather than the side of packages (Centre for Behavioural Research in Cancer 1992; Cragg and Dawson Ltd. 1990; AGB Spectrum Research Ltd. 1987; Linthwaite 1985; Environics Research Group Ltd. 1999). Illustrative of this finding was 1995 comparative research undertaken in Canada, where warnings appeared on the front of tobacco packages and the U.S. where labels appeared on the side. Results indicated that 83% of Canadian students recalled health warnings compared to 7% of U.S. students (Northrup and Pollard 1995). Additionally, research indicated that the top of the front is likely to have greater impact than the bottom of the front (Centre for Behavioural Research in Cancer 1992). Research also shows that the warnings should be on plain

backgrounds (e.g. white for black text), so they do not blend in with other information on the packaging (Borland and Hill 1997; University of Toronto 1993; Rootman and Flay 1995; Goldberg, Liefeld, Madil and Vredenburg 1999; Beede and Lawson 1992).

In summary, research in the tobacco control area highlights that for warning labels to be most effective in increasing awareness and perceptions of risk, and prompting behaviour change they need to be prominent, simple, and visually graphic. There is little doubt that the comprehensive suite of tobacco control measures in both Australia and New Zealand have been very successful in reducing the prevalence of smoking and related morbidity and mortality in both countries. For example, based upon data from the 2004 National Drug Strategy Household Survey 17.4% of people aged 14 years or older reported they smoked daily which decreased to 16.6% in 2007 (Australian Institute of Health and Welfare 2008). Similarly, the prevalence of daily smoking amongst New Zealanders aged 15 years and older has decreased from 23.4% in 2002/03 to 18.7% in 2006/07 (Ministry of Health 2008b).

The advances in warning messages on tobacco products have been significant, and research demonstrates that such warnings represent an effective health strategy. However, it is also important, as noted above, to acknowledge that the reductions in smoking rates in both Australia and New Zealand have been the result of a combination of initiatives that have included:

- Raising the retail price of cigarettes;
- Boosting mass-reach campaigns;
- Banning displays of tobacco products at point of sale;
- Increasing penalties and enforcement of laws banning sales to minors;
- Subsidising nicotine replacement therapy for low-income smokers;
- Encouraging people to quit in every interaction with the health care system; and,
- Comprehensive health warnings on tobacco products (Chapman 2008).

Again, while acknowledging that tobacco and alcohol represent different psychoactive drugs and are responsible for different types of harm, the public health initiatives and

results from the tobacco field represent an important evidence base in which to consider other public health initiatives.

9.2 Lessons learnt from tobacco

While it is acknowledged that the tobacco experience cannot simply be replicated and generalised to the alcohol field, the results from research into the impact of tobacco labels do provide a pointed and sharp contrast (Wilkinson and Room 2008a). Evidence from the tobacco field categorically identifies that for warnings to be effective the warning message must:

- Depict health risks in a vivid and emotionally arousing manner, in clear simple language (Createc and Market Studies 2003);
- Be frequently updated and rotated (Strahan et al. 2002; Witte and Allen 2000);
- Should include pictures rather than rely solely on text (Hammond et al. 2007; Liefeld 1999; O'Hegarty et al. 2006);
- Must be large and prominent (Centre for Behavioural Research in Cancer 1992; Environics Research Group Ltd. 2005; Cragg and Dawson Ltd. 1990; Strahan et al. 2002; Createc 2008); and,
- Should be put on the front of packaging (Centre for Behavioural Research in Cancer 1992; Cragg and Dawson Ltd. 1990; AGB Spectrum Research Ltd. 1987; Linthwaite 1985; Environics Research Group Ltd. 1999).

In contrast, despite legislation in the U.S. stipulating that alcohol warnings "shall be located in a conspicuous and prominent place on the container" (Alcohol Beverage Labelling Act of 1988, 27 USC. Sec 215), in reality, it has been claimed that the warnings are *"almost impossible to read and illegible,"* (Senator Albert Gore, Democrat of Tennessee, as quoted in the New York Times on November 15, 1989). They also represent a small proportion of the size of the overall label; most commonly use text and not images and are not particularly graphic. In addition, the warnings from the U.S. have not altered in over nineteen years. In short, the alcohol labels lack what has been considered, in tobacco warnings, as essential elements for impact.

Research in other areas

Research from domains such as the effectiveness of warnings, disclaimers and product experience on consumers' perceptions about dietary supplement mirror many of the general findings from investigation with alcohol. For example, Mason, Scammon and Fang (2007) reported that the use of a disclaimer did not impact on consumers' beliefs about the efficacy or the safety of dietary supplements, but heavy product users were responsive to specific warning messages, consistent with some of the alcohol warning label research. The authors concluded that prior beliefs about a product are difficult to change and these beliefs act as a filter through which the warning message/disclaimer is interpreted. This is consistent with Health Belief research, discussed earlier, indicating that information is most likely to have impact if it is concordant with personal goals.

Research investigating the effectiveness of product placement information in relation to soy protein claims, indicated combining short health claims on the front of the package with full health claims on the back of the package leads to consumers more fully processing and believing the stated information (Wansink 2003).

Australian research conducted by the Cancer Council of Victoria (Makin, Dobbinson and Strong 2007), on awareness, understanding and use of the SunSmart Ultraviolet (UV) Alert which provides information on forecast variations in UV radiation levels during the day indicated that nearly half of all respondents recalled having seen the Alert. Of those who reported having seen the UV Alert on the day of the survey or in the newspaper during summer 65% reported that seeing the warning helped to remind them that they might need to use sun protection when they went outdoors. However, no conclusions could be drawn regarding the effectiveness of the Alert in prompting the use of sun protection.

The above information lends support to findings from the investigation of alcohol warning labels. That is, people have a relatively high degree of awareness of the existence of labels, but it is difficult to conclude what impact labels have on behaviour change. Such evidence also highlights the complexity of behaviour change and the difficulty that single strategies face in altering an individual's actions.

Chapter 10: Discussion

There is some contention about alcohol warning labels, despite their adoption in many countries. Various models that have been used to predict the impact of health communication in general and warning labels in particular have indicated that warning labels are likely to be noticed. They are also likely to inform (when certain conditions are met) and to be perceived favourably, particularly when they are congruent with an individual's personal beliefs. Any influence they may have on behaviour is limited and only likely to occur when other factors such as interpersonal context, providing a means to change and altering social norms and expectations have also been addressed. While behaviour change may be viewed by some stakeholders as the ultimate or only aim of warning labels, others may argue that the simple act of increasing awareness and providing information to consumers is an equally valid and successful outcome.

According to MacKinnon et al. (2001) the lack of evidence to support any deterrent effect from warning labels, does not necessary imply that warning labels are ineffective. MacKinnon and colleagues argued that consistent with research by Gerbner Gross, Morgan and Signorielli (1986) on effects of the media and in light of the Health Belief model and the impact of social norms (Stacy et al. 1993; Cable and Sacker 2008), as more people are exposed to warning labels this may encourage community discussion and slightly adjust beliefs. Thus, societal norms may slowly begin to change, followed by changes in the behaviour of individuals. MacKinnon et al. (2001) concluded that:

> *"Behavioural effects of the alcohol warning may not be expected until those born after the warning appeared are adults (i.e. around the year 2009)". (p. 226).*

However, evidence supporting such a conclusion is yet to emerge.

The available research evidence about the impact of warning labels is limited. However, there is some evidence indicating some impact on respondents' recall and knowledge of the messages about alcohol-related risk. Very little research has assessed behaviour change and in this domain the results have been mixed. There is

also little evidence about potential and actual adverse outcomes of warning labels, such as exposure to warning labels leading to an increase in consumption (MacKinnon and Lappin 1998, MacKinnon et al. 2001).

But should warning label effects be considered in isolation? Models of health communication and behaviour change and models of alcohol related problems suggest not. The research by Kaskutas and Graves (1994) is illustrative as it demonstrated that when individuals were exposed to only one message source (i.e. warning label, poster, advertisement) there was no significant reduction in alcohol consumption. However, when the number of message sources increased so too did the likelihood that a reported reduction in alcohol use would occur.

For some analysts, interpretation of available research evidence may lead to the conclusion that "warning labels do not work". However, such a conclusion may also be premature. There is some contention about what impact should be expected from warning labels. If the aim is to inform consumers, there is reasonable evidence that they do in fact inform consumers of risks. If the aim is to assist consumers to moderate risk, the evidence is less compelling. But, models of health communication point to the former as a more reasonable expectation and the latter only where additional strategies accompany warning labels.

Much of the research is relatively weak in a methodological sense, disallowing firm conclusions about causation and precluding bold statements as to whether warning labels do or do not "work." The range of message content that has been evaluated has also been limited, and the visibility and style of warning labels are qualitatively dissimilar to warning labels on other products where there has been more evidence of warning label impact (e.g. tobacco products).

Finally, there is a dearth of research that will allow assessment of the cost-effectiveness/efficiency of alcohol warning labels. The lack of evidence around this issue is a challenge for government and policy makers who are required to make balanced decisions on policies in terms of safety to consumers and legitimate commercial activities.

Chapter 11: Conclusion and issues for consideration

To date, alcohol warning labels that have been adopted are relatively limited in nature (e.g. at least compared to tobacco warning labels) and have addressed only a small range of alcohol related harms. The evidence base for alcohol warning labels is limited: there is reasonable consensus that alcohol warning labels are noticed and recalled but less evidence that they have impact on behaviour. There have been few rigorous long-term and extensive evaluations of the impact of warning labels on harms associated with alcohol use and there is little evidence about their impact on behavioural intentions and behaviours specifically related to risky or high risk alcohol use.

The alcohol warning label evidence currently available does not support bold unqualified conclusions. Taking this lack of certainty into account, this report has highlighted a number of important issues for consideration. The following discussion ***does not*** propose that alcohol warning labels should be adopted. The aim is to highlight issues that will be important to consider ***if*** warning labels were to be adopted.

1. Evidence from other domains, especially tobacco use, provides some useful information. This evidence indicates that to have impact warning labels should be prominent, graphic and should incorporate images as well as text. Evidence from the tobacco arena indicates that messages are most effective when mandatory and when messages and images are frequently changed and alternated. Such approaches (at least in relation to prominence, use of images that are graphic) have not commonly been adopted in relation to alcohol warning labels and thus, of course, the impact of such approaches has not been evaluated. It is possible, given that both alcohol and tobacco are regulated, legal and psychoactive drugs; that experience from tobacco control may be generalisable to alcohol. Nonetheless, caution is indicated as there is currently no evidence to support such generalisation. In addition, there are important distinctions between tobacco and alcohol (e.g. no dose of tobacco is accepted as low risk, which is distinguished from perceptions of alcohol consumption). In the context of the above discussion, the apparently limited evidence about the impact of alcohol warning labels

might be interpreted as “a paucity of opportunities for investigation and evaluation” as opposed to one of “no impact.”

2. It can be difficult to differentiate between the specific effects of warning labels and other concurrent activities that aim to prevent and reduce alcohol related harm. Models about health communication and preventing and reducing alcohol related harm and related evidence suggest that interventions such as warning labels are likely to be most effective when part of a broader strategy. If alcohol warning labels were to be adopted, they should be consistent with, and where possible linked to, current alcohol policy and related strategies in Australia and those that are identified in the impending New Zealand policy. In relation to drinking among women of childbearing age, **if** warning labels were adopted they might focus on the risks of alcohol and unplanned pregnancies in addition to the risks associated with the ongoing consumption of alcohol during pregnancy and should complement other concurrent strategies and activities (e.g. strategies to avoid risk, alcoholic beverage price changes, increased screening of alcohol use during pregnancy, potential restrictions on alcohol promotions). Because of the benefits associated with breastfeeding as opposed to the risks associated with alcohol consumption whilst breastfeeding, it may be difficult to deliver such a complex message through an alcohol warning label. Subsequently, whether or not warning labels might specifically address alcohol and breastfeeding should probably be considered in the context of a broader approach.

This suggests the need for a coordinated approach. That is, if alcohol warning labels are adopted, it will be important to ensure communication among those tasked with oversight of the approach (e.g. FSANZ) with stakeholders (such as government agencies) who are responsible for implementing other alcohol public health strategies. Thus, for example, warning labels aimed at reducing the risk of Fetal Alcohol Spectrum Disorder among women of childbearing age should preferably be part of a broader and coordinated set of evidence-based strategies to reduce drinking risks among this target group (e.g. interventions by primary health care services and antenatal clinics; broad social marketing campaigns; supply control and demand reduction approaches.

3. Available evidence from the alcohol and tobacco research domains suggests that the content of any alcohol warning labels is likely to be influenced by the following:

(vi) The evidence about alcohol related harms, focussing on the consequences that are more prevalent and costly, and amenable to intervention.

(vii) The capacity to effectively communicate information/advice about a specific issue in a warning label.

(viii) The relationship between the label content, government policy, strategic directions and broader strategies.

(ix) Characteristics of the consumers/target audience and target behaviours. The evidence indicates that there may be diverse needs and responsiveness of intended audiences.

(x) Drinking behaviour of the consumers/target audience. For example, if drinking largely occurs in licensed premises, consumers may not be exposed to warning labels attached to packaged liquor. Alternative/additional health communication approaches may be required.

4. Consideration of warning labels on the issues of pregnancy and breastfeeding may have implications for a wide range of stakeholders, including community members, governments, industry, public health experts, primary care physicians, midwives, child health nurses, obstetricians and paediatricians and so on, and a judicious planning phase would include substantial consultation with such groups. Sound choices regarding labelling content and design are most likely to arise in the context of an evidence-based decision making process that includes health, behavioural science and social marketing expertise.

5. There is some evidence that pregnancy represents a "teachable moment" or a critical window of opportunity in which proximal interventions may be efficacious in encouraging a reduction in at risk behaviours. As such, interventions such as alcohol warning labels about alcohol and pregnancy, ***may*** be more likely to have impact with this target audience. However, this opportunity may not be evenly distributed among the target population. First, a significant proportion of women may be pregnant without realising it, at least in the early stages of pregnancy. Second, the evidence indicates that some women *may* be more responsive to health messages than others.

For example, the research by Hankin and colleagues (1993, 1996) indicated that light drinkers and those women for whom this was their first pregnancy were more likely to moderate their drinking after exposure to alcohol warning labels compared to heavier drinkers and women who had previously been pregnant. This issue requires further investigation as does answering the questions: what impact do alcohol warning labels have on women in remote areas, women from diverse cultural backgrounds, Indigenous women, very young women, older women, women with multiple risk exposure (e.g. other drug use; tobacco use) and so on.

6. If adopted, alcohol warning labels should be coupled with adequate investment to effectively evaluate their impact. Drawing on evidence to date and taking current knowledge gaps into account, this should ideally include consideration of the following:

- Potential cost/benefit of the approach, to industry, the community and to government;
- Acceptability, credibility and believability of message content;
- Quality baseline data about target behaviours, including: a) knowledge about the risks associated with alcohol use during pregnancy; b) drinking behaviour prior to pregnancy; c) risk taking relevant to target behaviour (e.g. consumption during pregnancy); and d) public support for and understanding of aims of alcohol warning labels;
- Level of exposure of consumers and target audiences to alcohol warning labels;
- Impact of alcohol warning labels on: a) knowledge about risk/judgement of alcohol's risks and hazards (e.g. unplanned pregnancy, FASD; alcohol consumption during breastfeeding b) behavioural intention relating to drinking and associated risk taking relating to pregnancy; c) behavioural compliance or actual drinking behaviour and related risk taking; and d) adverse outcomes (e.g. increased anxiety amongst pregnant women, increased terminations, etc.).

Highest value would be obtained from evaluation which was, as far as possible, able to assess the impact of warning labels in isolation and as part of an overall strategy (e.g. acceptability and believability could be assessed in isolation, but behavioural impact might be assessed as part of an overall intervention).

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Appendix 1: Examples of alcohol warning labels

Figure 4. Health warning label from a bottle of ale imported from Belgium - US
Available from:
http://www.google.com.au/imgres?imgurl=http://www.whitebeertravels.co.uk/images/sixtus_label_us.jpg&imgrefurl=http://www.whitebeertravels.co.uk/sixtus.html&h=354&w=450&sz=76&tbnid=gByu36iRTKMJ::&tbnh=100&tbnw=127&prev=/images%3Fq%3Dalcohol%2Blabels%2BUS%2Bimages&hl=en&usg=__X8prTs4socc5p0M3Bmz8DSL7pEM=&sa=X&oi=image_result&resnum=4&ct=image&cd=1
Figure 5. Health warning label from an Alcoholic beverage produced in Spain and imported to the US
Available from:
http://www.google.com.au/imgres?imgurl=http://bp2.blogger.com/_Za9dUl3jzA0/RtNOSxOS8QI/AAAAAAAAARc/pTPpf7YPuI8/s400/022.JPG&imgrefurl=http://passionatefoodie.blogspot.com/2007_08_01_archive.html&h=400&w=300&sz=18&tbnid=eS-eGStLtK0J::
Figure 6. Health warning label on a bottle of Canadian Club Whiskey imported from Canada to US
Figure 7. Health warning label on a bottle of Merlot produced in France – imported to US
Figure 8. Health warning label on a Bacardi Breezer bottle – US
Figure 9. Health warning label on a Budweiser bottle – US
Figure 10. Health warning label on a Miller Lite beer bottle – USA
Figure 11. Health warning label on a Harp Lager bottle imported from Ireland – USA
Available from:
http://alcoholism.about.com/gi/dynamic/offsite.htm?site=http://www.cspinet.org/booze/iss%5Fwarn.htm
Figure 12. Health warning label on bottle of Jacobs Creek Chardonnay depicting risks of drinking during pregnancy (France)
Available from: Celia Wilkinson
Figure 13. Bottles from France showing pregnancy warning labels
Available from: Celia Wilkinson
Figure 14: Bottles from South Africa- available from Celia Wilkinson (received via personal communication from Medical Research Council, Cape Town, SA)
Figure 15: Bottle from South Africa- available from Celia Wilkinson (received via personal communication from Medical Research Council, Cape Town, SA)

Appendix 2: Tobacco warning labels

Figure 16. Initial health warning on cigarette packets in Australia, 1973
Figure 17. Health warnings on Australian cigarette packages from 1994 to 2005
Figure 18. Health warnings on Australia cigarette packaging from 2006
Available from:
http://www.tobaccoinaustralia.org.au/chapter-12-tobacco-products/attachment-12-1-health-warnings
Figure 19. Examples from 14 health warning labels (front and back) on New Zealand cigarette packets from February 2008
Available from:
http://www.moh.govt.nz/moh.nsf/indexmh/tobacco-warnings-new

Appendix 3: Review of research investigating the effectiveness of alcohol warning labels.

Author(s)	Subjects	Summary of Major findings	Summary of Major Limitations
Andrews et al. 1990 - 1993	Undergraduate marketing students (n=273)	• Warnings on birth defects and driving impairment were believable • The more favourable the attitude to drinking and the greater amount of alcohol consumed the less believable the warning labels	• Cannot disaggregate relative impact of content of message from credibility of source • Labels were on low alcohol beer and wine coolers • Sample not representative • Questions surrounding validity and reliability of measurement instruments used
Alcohol Research Group 1991- 2008	Primarily: cross sectional random sample of nationally representative adults in U.S.	• In 1991- 87% support for alcohol warning labels- but 89% indicated that warnings would have limited effect • 6 months after introduction of warnings-39% of heavy drinkers, 46% of young men and 39% of women of childbearing age who were heavy drinkers reported seeing the labels • From 1989 to 1990 there was a 3% increase in the number of respondents reporting that they had used machinery after drinking. • In 1990 those who had seen the labels were more likely to: o Drive when they knew they would have been in trouble if stopped by police o Limit their drinking because of driving	• Difficulty disaggregating impact of warning message from other influences • Alcohol consumption based upon self report • No longitudinal data

		○ Had conversations about drink driving and pregnancy • From 1989 to 1991 there was a decrease in the impact of the label on perception of risk • In 1991- 55% of sample reported that labels had affected their own drinking • In 1991 drinkers, who saw the label were more likely to report limiting their drinking when driving compared to those who had not seen the label • People who were exposed to two message sources were 1.6 times more likely to limit their drinking • Respondents 18 to 20years of age paid more attention to warning labels than any other age group • Of those who saw the labels- the pregnancy warning was recalled by 89% of respondents 40 years and younger • From 1989 to 1994- awareness of warning labels increased over first four years then plateaued • There was no effect from exposure to warnings and alcohol consumption amongst pregnant women • Those who could recall seeing the drink driving message were more likely to intervene to deter another person from drink driving	

Hankin et al. 1993-1998	African American pregnant women from Detroit	• Introduction of warning labels linked to a reduction in consumption amongst light to moderate, but not heavy drinkers • From 1989 to 1993 awareness of warning labels increased from 29% to 78% • Following introduction of warning labels consumption amongst first time mothers decreased	• No matched controls • Non representative sample • Recall of the content of the warning labels was not assessed or controlled for as a variable
MacKinnon et al. 1993 - 2001	12th grade school students and college students from Marion County U.S.	• Amongst school students exposure to warning labels increased from 26% in 1989 to 41% in 1990 • Amongst college students alcohol consumption was correlated with ability to identify warning message • Warning labels had no effect on intentions regarding future consumption of alcohol • Warning labels did not lead to a reduction in alcohol use, nor an increase in use	• Non representative sample

Mazis et al. 1991-1996	Cross sectional telephone surveys with national sample of adults	• From May 1989 till May 1990 no increase in respondents perception of the risks associated with alcohol- except amongst 18-29 year olds where there was an 8.4% increase in proportion rating alcohol as very harmful • From 1989 till 1990- heavier drinkers reported greater change in reported awareness of labels than lighter drinkers • From 1990 till 1993- increase from 35% to 55% in awareness of labels	• Short follow up in first study • No control site • Potential for selection bias
Scammon et al. 1991	Adults in Utah- Mormons versus non- mormons (n=2417)	• In 1990- 35% of non-Mormons and 11% of Mormons were aware of the labels	• No matched control site • Population not representative
Snyder and Blood1992	Communication undergraduate students (n=159)	• Warnings had no effect on students rating of product risk • For drinkers exposure to the warnings lead to an increase in rating of alcohol as beneficial and increase in drinking intentions	• Sample non-representative • Those over 22 years of age and male non-drinkers excluded from analysis • Potential that second wave of students were aware of the study and hence potential for bias in data- demand characteristics • Limited results presented
Malouff et al. 1993	4 studies primarily with college students	• Horizontal labels more conspicuous than vertical	• Small sample sizes • Sample not representative • Labels only placed on beer bottles

Parsons et al. 1994	Homeless persons Illinois (n=481)	• In 1994- 41% of sample were aware of labels	• Very limited generalisability
Parker et al. 1994	Random sample survey of adults in California (n>1,000)	• Those at risk of drink driving were more likely to see and recall labels • No evidence of behaviour change	• Difficult to determine how representative sample was of general population • Some pre-test interviews were conducted after labels introduced- potential for confounding data
Gorn et al. 1996	Canadian university students (n=55)	• Current warning labels not rated as optimum	• Small sample and non representative
Weiss 1997	Adolescents in Israel (n=3,065)	• 89% of respondents supported introduction of warning labels	• Intended as baseline data but no follow up results located
Marin and Gamba 1997	Telephone survey- (n> 2,000) adults (Hispanic and non-Hispanic). San Francisco	• From 1991 to 1992 there was an increase in awareness of labels on beer and wine containers	• Unclear how representative sample was • Potential confound of other educational campaigns
Marin 1997	Telephone survey- (n=4,661) Hispanic (ages 21+) San Francisco	• By 1992- 96% were aware of alcohol and pregnancy message and 81% aware of alcohol and driving message	• No information on consent rate- hence potential for selection bias • Across the four years the groups differed on a number of demographic variables

DeCarlo et al. 1997	Interviews with 111 undergraduate students and 39 adults	• 59% read the warning labels on product before buying them • 59% were aware of such labels • 56% found the info on labels informative	• No information on consent rate- hence potential for bias • Sample was disparate and recruitment through personal solicitation • No information on whether sample included non-drinkers • No gender information provided in results

Creyer et al. 2002	US versus Australia university students (n=274)	• Type of warning had no significant effect on perception of social or health benefits of alcohol but did effect perception of risk of drinking behaviours	• Sample size relatively small- questions of generalisability and limited to consumption of beer
Blume and Resor 2007	Convenience sample Mexican women (n=99)	• English language skills predict ability to remember health warnings on beverage containers	• Small sample • Length of time in country and hence exposure to labels not controlled for

Appendix 4: List of the review papers identified

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